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APPLICATION NO.	ISSUE DATE	PATENT NO.
17/865,315	09-MAY-23	11642209

PERKINS COIE LLP - SEA General PATENT-SEA

P.O. BOX 1247

SEATTLE, WA 98111-1247

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/865,315	05/09/2023	11642209	111552-8018.US03	7298

25096 7590 04/19/2023
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ISSUE NOTIFICATION

The projected patent number and issue date are specified above. The patent will issue electronically. The electronically issued patent is the official patent grant pursuant to 35 U.S.C. § 153. The patent may be accessed on or after the issue date through Patent Center at <https://patentcenter.uspto.gov/>. The patent will be available in both the public and the private sides of Patent Center. Further assistance in electronically accessing the patent, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-888-217-9197.

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Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional inventors):

Ben Merritt, San Clemente, CA;
Jacqueline Macias, Fullerton, CA;
Brian Michael Strauss, San Clemente, CA;
Thomas Tu, Louisville, KY;

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Inari Medical, Inc., Irvine, CA;

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Doc code: IDS

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2012. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17/865,315 - Conf# 7298
	Filing Date	July 14, 2022
	First Named Inventor	Ben Merritt
	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552-8018.US03

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	228.	20160228134	08-11-2016	Martin et al.	
	229.	20160262790	09-15-2016	Rosenbluth et al.	
	230.	20160287276	10-06-2016	Cox et al.	
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 Change(s) applied
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 4/6/2023

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	195.	20150059908	03-05-2015	Mollen	
	196.	20150088190	03-26-2015	Jensen	
	197.	20150127035	05-07-2015	Trapp et al.	
	198.	20150133990	05-14-2015	Davidson	
	199.	20150150672	03-07-2017	Ma ^{06/2015}	
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	202.	20150190155	07-09-2015	Ulm III	
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	204.	20150196380	07-16-2015	Berrada et al.	
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	211.	20150305756	10-29-2015	Rosenbluth	
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	Examiner Name	Not Yet Assigned
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	162.	20130345739	12-26-2013	Brady et al.	
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	Attorney Docket Number	111552-8018.US03

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Change(s) applied
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	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552-8018.US03

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132.	7938809	05-10-2011	Lampropoulos et al.	
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141.	8066757	11-29-2011	Ferrera et al.	
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150.	8197493	06-12-2012	Ferrera et al.	
151.	8246641	08-21-2012	Osborne et al.	
152.	8261648	09-11-2012	Marchand et al.	
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155.	8317748	11-27-2012	Fiorella et al.	
156.	8337450	12-25-2012	Fotjik	
157.	8357178	01-22-2013	Grandfield et al.	
158.	8361104	01-29-2013	Jones et al.	
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160.	8486105	07-16-2013	Demond et al.	
161.	8491539	07-23-2013	Fotjik	
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Change(s) applied
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17/865,315	07/14/2022	Ben Merritt	111552-8018.US03	7298
25096	7590	04/06/2023	EXAMINER	
PERKINS COIE LLP - SEA General			RASSAVONG, ERIC	
PATENT-SEA			ART UNIT	
P.O. BOX 1247			PAPER NUMBER	
SEATTLE, WA 98111-1247			3781	
			NOTIFICATION DATE	DELIVERY MODE
			04/06/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentprocurement@perkinscoie.com

Supplemental Notice of Allowability	Application No. 17/865,315	Applicant(s) Merritt et al.	
	Examiner ERIC RASSAVONG	Art Unit 3781	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 03/28/2023.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 2-9 and 11-20. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)	5. ☐ Examiner's Amendment/Comment
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date ____	6. ☐ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material ____	7. ☐ Other ____
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date ____	

/E.R./ Examiner, Art Unit 3781	/SUSAN S SU/ Primary Examiner, Art Unit 3781
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	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US03

U.S. PATENTS AND PUBLICATIONS						
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/E.R./		6564828		05-20-2003	Ishida	
/E.R./		5197485		03-30-1993	Grooters	
/E.R./		20130035628		02-07-2013	Garrison et al.	
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/E.R./		20210022843		01-28-2021	Hauser	
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/E.R./		20220347455		11-03-2022	Merritt et al.	
/E.R./		20220346800		11-03-2022	Merritt et al.	
/E.R./		20220346813		11-03-2022	Quick	
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/E.R./		3675657		07-11-1972	Gauthier	
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/E.R./		9980813		05-29-2018	Eller	
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/E.R./		20110034986		02-10-2011	Chou et al.	
/E.R./		20190336142		11-07-2019	Torrie et al.	
/E.R./		20190239910		08-08-2019	Brady et al.	
/E.R./		20060217664		09-28-2006	Hattler et al.	
/E.R./		20170252057		09-07-2017	Bonnette et al.	
/E.R./		20170340867		11-30-2017	Accisano, II	
/E.R./		11457936		10-04-2022	Buck et al.	
/E.R./		11259821		03-01-2022	Buck et al.	
/E.R./		11439799		09-13-2022	Buck et al.	
/E.R./		20210315598		10-14-2021	Buck et al.	
/E.R./		11529158		12-20-2022	Hauser	

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

Based on PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17/865,315, Conf. No. 7298
	Filing Date	2022-07-14
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US03

/E.R./		20220362512		11-17-2022	Quick et al.	

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵

EXAMINER SIGNATURE

Examiner Signature /ERIC RASSAVONG/	{01/26/2023}	Date Considered	01/26/2023
-------------------------------------	--------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

Based on PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17/865,315, Conf. No. 7298
	Filing Date	2022-07-14
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US03

- ☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

- ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

- ☐ See attached certification statement.

- ☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

- ☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2022-12-22
Name/Print	Matthew S. Williams	Registration Number	77,516

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Benjamin Edward Merritt et al.

Application No.: 17/865,315

Confirmation No.: 7298

Filed: July 14, 2022

Art Unit: 3783

For: SYSTEM FOR TREATING EMBOLISM AND
ASSOCIATED DEVICES AND METHODS

Examiner: Eric Rassavong

COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

In the Notice of Allowability mailed March 23, 2023, the Examiner allowed claims 2–9 and 11–20. The Applicant acknowledges Examiner's statements of Reasons for Allowance of the above-referenced patent application and agrees that the claimed subject matter is patentable. However, the Applicant takes no position regarding the Reasons for Allowance presented by the Examiner other than the positions the Applicant may have previously taken during prosecution. Therefore, the Examiner's Reasons for Allowance should not be attributed to the Applicant as an indication of the basis for the Applicant's belief that the claims are patentable. Furthermore, the Applicant respectfully asserts that there may also be additional reasons for patentability of the claimed subject matter not explicitly stated in this record and the Applicant does not waive its rights to such arguments by not further addressing such reasons herein.

Dated: March 30, 2023

Respectfully submitted,

By /Matthew S. Williams/
Matthew S. Williams
Registration No.: 77,516

Perkins Coie LLP
P.O. Box 1247
Seattle, WA 98111-1247
Phone: (206) 359-3343
Fax: (206) 359-7198

Attorneys for Applicant



UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC PAYMENT RECEIPT

APPLICATION #
17/865,315

RECEIPT DATE / TIME
03/30/2023 03:43:24 PM ET

ATTORNEY DOCKET #
111552-8018.US03

Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 7298

FILED BY JiYoung Anderson

PATENT CENTER # 61842709

AUTHORIZED BY Matthew Williams

CUSTOMER # 25096

FILING DATE 07/14/2022

CORRESPONDENCE
ADDRESS -

FIRST NAMED
INVENTOR Ben Merritt

Payment Information

PAYMENT METHOD
CARD / 3369

PAYMENT TRANSACTION ID
E20233TF44425052

PAYMENT AUTHORIZED BY
JiYoung Anderson

FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
1501	UTILITY ISSUE FEE	1200.00	1	1200.00
TOTAL AMOUNT:				\$1,200.00

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage

submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PART B -- FEE(S) TRANSMITTAL

Complete and send this form, together with the applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By fax, send to: (571) 273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

25096
Perkins Coie LLP
P.O. Box 1247
PATENT - SEA
Seattle, WA, 98111-1247
US

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

JiYoung Anderson	(Typed or printed name)
/JiYoung Anderson/	(Signature)
2023-03-30	(Date)

APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
17/865,315	Jul 14, 2022	Benjamin Edward Merritt	111552.8018.US03	7298

TITLE OF INVENTION: SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
UTILITY	LARGE	1200	0	0	1200	2023-06-23

EXAMINER	ART UNIT	CLASS-SUBCLASS
Eric Rassavong	3783	-

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363)

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47, Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
- (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1. Perkins Coie LLP

2.

3.

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE or COUNTRY)

Inari Medical, Inc.

Irvine, CA

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. Fees Submitted: ☒ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment (Please first reapply any previously paid fee shown above):

- ☒ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)
- ☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 50-0665

5. Change of Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29.
- ☐ Applicant asserting small entity status. See 37 CFR 1.27.
- ☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid Certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken as a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken as a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Matthew S. Williams/

Date 2023-03-30

Typed or printed name Matthew S. Williams

Registration No. 77,516

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.** Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
17/865,315

RECEIPT DATE / TIME
03/30/2023 03:43:24 PM ET

ATTORNEY DOCKET #
111552-8018.US03

Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 7298

FILED BY JiYoung Anderson

PATENT CENTER # 61842709

FILING DATE 07/14/2022

CUSTOMER # 25096

FIRST NAMED
INVENTOR Ben Merritt

CORRESPONDENCE
ADDRESS -

AUTHORIZED BY Matthew Williams

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-3-30 Issue Fee - 111552-8018US3.PDF	2	Issue Fee Payment (PTO-85B)	251 KB
2023-3-30 Comments - 111552-8018US3.PDF	2	Miscellaneous Incoming Letter	89 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-3-30 Issue Fee - 111552- 8018US3.PDF	E8C83426C8A81795732D7F02E954DDB04B2215E13DA9B3F6F DE6CD6882170020924C558D9733B6B1E273AD919CA0F146E3

161CDC96B2D723FFBB14D697063847

2023-3-30 Comments - 111552-
8018US3.PDF32C16DD14186058BFFFF7B61DC1BBD021263812EE555FB39E
AB1B253C51292ED6416476145D0BD4F4FFB52C014C3ADF093
15F9D37C9D5E9C2F8D399074403121

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

25096 7590 03/23/2023
PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

EXAMINER	
RASSAVONG, ERIC	
ART UNIT	PAPER NUMBER
3781	

DATE MAILED: 03/23/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/865,315	07/14/2022	Ben Merritt	111552-8018.US03	7298

TITLE OF INVENTION: SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	06/23/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

25096 7590 03/23/2023
PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

	(Typed or printed name)
	(Signature)
	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/865,315	07/14/2022	Ben Merritt	111552-8018.US03	7298

TITLE OF INVENTION: SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	06/23/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
RASSAVONG, ERIC	3781	604-006090

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/865,315	07/14/2022	Ben Merritt	111552-8018.US03	7298
25096	7590	03/23/2023	EXAMINER	
PERKINS COIE LLP - SEA General			RASSAVONG, ERIC	
PATENT-SEA				
P.O. BOX 1247			ART UNIT	
SEATTLE, WA 98111-1247			PAPER NUMBER	
			3781	

DATE MAILED: 03/23/2023

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 17/865,315	Applicant(s) Merritt et al.	
	Examiner ERIC RASSAVONG	Art Unit 3781	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 03/07/2023.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 2-9 and 11-20. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892) 2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ 3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____ 4. ☒ Interview Summary (PTO-413), Paper No./Mail Date. _____	5. ☒ Examiner's Amendment/Comment 6. ☒ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____
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/E.R./ Examiner, Art Unit 3781	/SUSAN S SU/ Primary Examiner, Art Unit 3781
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EXAMINER'S AMENDMENT/REASONS FOR ALLOWANCE

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Status of Claims

2. **Claims 2-9 and 11-20** are currently pending. **Claims 2-6, 8-9, and 11-20** are currently amended. **Claims 1 and 10** have been cancelled. No new subject matter is added.

Examiner's Amendment

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
4. Authorization for this examiner's amendment was given in an interview with Matthew S. Williams on 3/15/2023.
5. The application has been amended as follows:

Claim 2:

In line 5 --- comprises a plunger of the first syringe slidably received in the first barrel;
an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;

a second chamber in between the aspiration pump and the aspiration catheter, ---

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In the last clause --- wherein upon actuation to opening of the valve ~~with and~~ the negative pressure having been generated in the first and second chambers, fluid is rapidly aspirated from the aspiration catheter into the second chamber ~~fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.~~ ---

Claims 3 and 4:

In lines 2-5 --- the valve comprises a user-actuatable stopcock valve, ~~wherein upon user actuation to open the stopcock valve with the negative pressure having been generated in the first and second chambers, the fluid flow at least partially from the second chamber into the first chamber causes the rapid aspiration into the second chamber; and~~ ---

Claim 9:

In line 4 --- negative pressure in the first chamber contributes to a rapid pressure drip in the aspiration catheter. ---

Claim 14:

In line 8 --- a second chamber in between the aspiration pump and the aspiration catheter, ---

In the last clause --- wherein upon actuation to opening of the valve ~~with and~~ the negative pressure having been generated in the first and second chambers, fluid is rapidly aspirated from the aspiration catheter into the second chamber ~~fluid flow at least partially from the second chamber into the first chamber causes rapid decrease in pressure in the aspiration catheter.~~ ---

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Claim 19:

In line 8 --- a second chamber in between the aspiration pump and the aspiration catheter, ---

In the last clause --- wherein upon actuation to opening of the valve ~~with and the~~ negative pressure having been generated in the first and second chambers, fluid is rapidly aspirated from the aspiration catheter into the second chamber ~~fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.~~ ---

Allowable Claims

6. **Claims 2-9 and 11-20** are allowed.

Allowable Subject Matter

7. The following is an examiner's statement of reasons for allowance:

Claims 2, 14, and 19 are allowable for reciting, *inter alia*, "the first chamber comprises a first barrel of a syringe; the pump comprises a plunger of the first syringe slidably received in the first barrel; and the second chamber comprises a second barrel".

As previously discussed in the Final Rejection filed 02/10/2023, Heaton fails to teach the first chamber comprising a first barrel of a syringe; the pump comprises a plunger of the first syringe slidably received in the first barrel; and the second chamber comprises a second barrel. The chambers of Heaton are fixed volume with a bellows pump and do not mention any syringes. There is no prior art that discloses two syringes connected together as described in the claim language. Therefore, the combination of limitations of claims 2, 14, and 19 are considered allowable. **Claims 3-9 and 11-13** are allowable for depending from claim 2. **Claims**

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15-18 are allowable for depending from claim 14. **Claim 20** is allowable for depending from claim 19.

8. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC RASSAVONG whose telephone number is (408)918-7549. The examiner can normally be reached Monday - Friday 9:00am-5:30pm PT.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas J. Weiss can be reached on (571)270-1775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for

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information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E.R./ (3/17/2023)

Examiner, Art Unit 3781

/SUSAN S SU/

Primary Examiner, Art Unit 3781

17 March 2023

<i>Examiner-Initiated Interview Summary</i>	Application No. 17/865,315	Applicant(s) Merritt, Ben		
	Examiner ERIC RASSAVONG	Art Unit 3781	AIA (First Inventor to File) Status Yes	Page 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
ERIC RASSAVONG	Examiner	Telephonic
Matthew Williams	Attorney	

Date of Interview: 14 March 2023

Issues Discussed:

Proposed Amendment(s)

Examiner and Attorney agreed upon amending claims to include allowable subject matter.

☒ Attachment

/ERIC RASSAVONG/ Examiner, Art Unit 3781	/SUSAN S SU/ Primary Examiner, Art Unit 3781
<p>Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04</p> <p>Please further see: MPEP 713.04 Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b) 37 CFR § 1.2 Business to be transacted in writing</p>	

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

<i>Search Notes</i> 	Application/Control No. 17/865,315	Applicant(s)/Patent Under Reexamination Merritt et al.
	Examiner ERIC RASSAVONG	Art Unit 3781

CPC - Searched*		
Symbol	Date	Examiner
A61B17/12109, 17/221, 2017/22034, 2017/22079, 17/005	09/10/2022	/E.R./
A61F2/01	09/10/2022	/E.R./
A61M1/84,25/10	09/10/2022	/E.R./
A61B17/12109, 17/221, 2017/22034, 2017/22079, 17/005	02/05/2023	/E.R./
A61F2/01	02/05/2023	/E.R./
A61M1/84,25/10	02/05/2023	/E.R./
A61B17/12109, 17/221, 2017/22034, 2017/22079, 17/005	03/14/2023	/E.R./
A61F2/01	03/14/2023	/E.R./
A61M1/84,25/10	03/14/2023	/E.R./

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

/E.R./ Examiner, Art Unit 3781	
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<i>Search Notes</i> 	Application/Control No. 17/865,315	Applicant(s)/Patent Under Reexamination Merritt et al.
	Examiner ERIC RASSAVONG	Art Unit 3781

Search Notes		
Search Notes	Date	Examiner
CPC and Text Searching Completed	09/10/2022	/E.R./
Inventor Name Search in PALM	09/10/2022	/E.R./
Consulted Primary Examiner Susan Su on Prior art	09/13/2022	/E.R./
Consulted Primary Examiner Susan Su on Prior art	02/02/2023	/E.R./
Updated Search	02/05/2023	/E.R./
Consulted Primary Examiner Susan Su on Prior art	03/14/2023	/E.R./
Updated Search	03/14/2023	/E.R./

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	Keyword Search in USPAT	03/14/2023	/E.R./

/E.R./ Examiner, Art Unit 3781	
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Issue Classification 	Application/Control No. 17/865,315	Applicant(s)/Patent Under Reexamination Merritt et al.	
	Examiner ERIC RASSAVONG	Art Unit 3781	

CPC						
Symbol					Type	Version
A61F	/	2	/	01	F	2013-01-01
A61B	/	17	/	12109	I	2013-01-01
A61M	/	1	/	84	I	2021-05-01
A61M	/	1	/	815	I	2021-05-01
A61B	/	2017	/	22034	A	2013-01-01
A61B	/	17	/	221	A	2013-01-01
A61B	/	2017	/	22079	A	2013-01-01
A61B	/	2217	/	005	A	2013-01-01
A61M	/	25	/	10	A	2013-01-01
A61M	/	1	/	79	A	2021-05-01

CPC Combination Sets					
Symbol				Type	Set

/ERIC RASSAVONG/ Examiner, Art Unit 3781 (Assistant Examiner)	15 March 2023 (Date)	Total Claims Allowed: 18	
/SUSAN S SU/ Primary Examiner, Art Unit 3781 (Primary Examiner)	17 March 2023 (Date)	O.G. Print Claim(s) 2	O.G. Print Figure 20C

Issue Classification 	Application/Control No. 17/865,315	Applicant(s)/Patent Under Reexamination Merritt et al.	
	Examiner ERIC RASSAVONG	Art Unit 3781	

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61F2/01	/	2	/	01	
A61B17/12	/	17	/	12	
A61M1/00	/	1	/	00	
A61B17/22	/	17	/	22	
A61B17/221	/	17	/	221	
A61M25/10	/	25	/	10	
NON-CLAIMED					
	/		/		

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

/ERIC RASSAVONG/ Examiner, Art Unit 3781 (Assistant Examiner)	15 March 2023 (Date)	Total Claims Allowed: 18	
/SUSAN S SU/ Primary Examiner, Art Unit 3781 (Primary Examiner)	17 March 2023 (Date)	O.G. Print Claim(s) 2	O.G. Print Figure 20C

<i>Issue Classification</i> 	Application/Control No. 17/865,315	Applicant(s)/Patent Under Reexamination Merritt et al.
	Examiner ERIC RASSAVONG	Art Unit 3781

☐ Claims renumbered in the same order as presented by applicant
 ☐ CPA
 ☐ T.D.
 ☐ R.1.47

CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
-	1	-	10	17	19										
1	2	9	11	18	20										
2	3	10	12												
3	4	11	13												
4	5	12	14												
5	6	13	15												
6	7	14	16												
7	8	15	17												
8	9	16	18												

/ERIC RASSAVONG/ Examiner, Art Unit 3781 (Assistant Examiner)	15 March 2023 (Date)	Total Claims Allowed: 18	
/SUSAN S SU/ Primary Examiner, Art Unit 3781 (Primary Examiner)	17 March 2023 (Date)	O.G. Print Claim(s) 2	O.G. Print Figure 20C

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L111	591	A61B2017/22079.cpc. AND A61M1/84.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:20 PM
L112	206	A61B2017/22034.cpc. AND A61M1/84.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:20 PM
L113	388	A61B17/221.cpc. AND A61M1/84.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:20 PM
L114	388	A61B17/221.cpc. AND A61M1/84.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:20 PM
L115	117	A61M25/10.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:20 PM
L116	97	A61B2217/005.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:20 PM
L117	97	A61B2017/22079.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD,	OR	ON	ON	2023/03/14 09:20 PM

L118	97	A61B2017/22079.cpc. AND A61F2/01.cpc.	DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:20 PM
L119	214	A61B2017/22034.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:20 PM
L120	709	A61B17/221.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:20 PM
L121	709	A61B17/221.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:20 PM
L122	155	A61M1/84.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:21 PM
L123	445	A61B2217/005.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:21 PM
L124	405	A61B2017/22079.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD,	OR	ON	ON	2023/03/14 09:21 PM

L125	523	A61B2017/22034.cpc. AND A61B17/12109.cpc.	DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:21 PM
L126	1047	A61B17/221.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:21 PM
L127	155	A61M1/84.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:21 PM
L128	117	A61F2/01.cpc. AND A61M25/10.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:21 PM
L129	44	A61M1/79.cpc. AND stopcock AND container	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:21 PM
L130	249	A61M1/79.cpc. AND container AND ((negative reduce) NEAR pressure) AND pores AND small	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:21 PM
L131	1188	rapid AND aspiration AND catheter AND (syringe NEAR (dual	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD,	OR	ON	ON	2023/03/14 09:22 PM

L132	53	two multiple)) rapid AND aspiration AND catheter AND (syringe NEAR (series serial))	DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/14 09:22 PM
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PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N1	0	(rapid quick fast accelerated speedy).clm. AND (aspiration suction).clm. AND (catheter).clm. AND (syringe).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/14 09:24 PM
N2	28	(rapid quick fast accelerated speedy).clm. AND (aspiration suction).clm. AND (catheter).clm. AND (syringe).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/14 09:25 PM
N3	5	(rapid quick fast accelerated speedy).clm. AND (aspiration suction).clm. AND (catheter).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/14 09:25 PM
N4	2	(rapid quick fast accelerated speedy).clm. AND (aspiration suction).clm. AND (syringe).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/14 09:25 PM
N5	1	(rapid quick fast accelerated speedy).clm. AND (catheter).clm. AND (syringe).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/14 09:25 PM
N6	6	(aspiration suction).clm. AND (catheter).clm. AND (syringe).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/14 09:25 PM
N7	205	(rapid quick fast accelerated	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/14 09:25 PM

N8	77	speedy).clm. AND (aspiration suction).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/14 09:26 PM
N9	63	(aspiration suction).clm. AND (syringe).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/14 09:26 PM
N10	29	(rapid quick fast accelerated speedy).clm. AND (aspiration suction).clm. AND (syringe).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/14 09:26 PM
N11	29	(rapid quick fast accelerated speedy).clm. AND (syringe).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/14 09:26 PM
N12	113	(rapid quick fast accelerated speedy).clm. AND (syringe).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/14 09:26 PM

Bibliographic Data

Application No: 17/865,315

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☒ No ☐ Met After Allowance

Verified and Acknowledged: /ERIC RASSAVONG/

Examiner's Signature

Initials

Title:

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED
DEVICES AND METHODS

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
07/14/2022	604	3781	111552-8018.US03
RULE			

APPLICANTS

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Thomas Tu, Louisville, KY, UNITED STATES

CONTINUING DATA

This application is a CON of 16536185 08/08/2019 PAT 11559382

16536185 has PRO of 62718248 08/13/2018

16536185 has PRO of 62718269 08/13/2018

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

07/25/2022

STATE OR COUNTRY

UNITED STATES

ADDRESS

PERKINS COIE LLP - SEA General

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SEATTLE, WA 98111-1247

UNITED STATES

FILING FEE RECEIVED

\$6,160

PATENT**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF: BEN MERRITT ET AL.
 APPLICATION NO.: 17/865,315
 FILED: JULY 14, 2022
 FOR: SYSTEM FOR TREATING EMBOLISM AND
 ASSOCIATED DEVICES AND METHODS

EXAMINER: ERIC RASSAVONG
 ART UNIT: 3781
 CONF. NO: 7298

Proposed Claim Amendments for Entry via Examiner's Amendment

2. (Proposed Amendment) An aspiration system with accelerated response, comprising:

an aspiration pump in communication with a first chamber, wherein the first chamber comprises a first barrel of a first syringe, and wherein the aspiration pump comprises a plunger of the first syringe slidably received in the first barrel;

an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;

a second chamber in between the aspiration pump and the aspiration catheter, wherein the second chamber comprises a second barrel of a second syringe; and

a valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers; and

wherein upon actuation to open the valve and the negative pressure having been generated in the first and second chambers, fluid is rapidly aspirated from the aspiration catheter into the second chamber.

3. (Proposed Amendment) The aspiration system of claim 2 wherein:
 the valve comprises a user-actuatable stopcock valve; and

the aspiration tube comprises a first tubing section coupled to the second chamber and one side of the stopcock valve and a second tubing section coupled to the other side of the stopcock valve.

4. (Proposed Amendment) The aspiration system of claim 2 wherein:

the valve comprises a user-actuatable stopcock valve;

the aspiration tube comprises a first tubing section coupled to the second chamber and one side of the stopcock valve and a second tubing section coupled to the other side of the stopcock valve; and

the second syringe further comprises a second plunger slidably received in the second barrel.

14. (Proposed Amendment) An aspiration system with accelerated response, comprising:

an aspiration pump in communication with a first chamber, wherein the first chamber comprises a first barrel of a syringe, and wherein the pump comprises a plunger of the first syringe slidably received in the first barrel;

an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;

a second chamber in between the aspiration pump and the aspiration catheter, wherein the second chamber comprises a second barrel; and

a valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;

wherein upon actuation to open the valve and the negative pressure having been generated in the first and second chambers, fluid is rapidly aspirated from the aspiration catheter into the second chamber.

19. (Proposed Amendment) An aspiration system with accelerated response, comprising:

an aspiration pump in communication with a first chamber, wherein the first chamber comprises a first barrel of a syringe, and wherein the pump comprises a plunger of the first syringe slidably received in the first barrel;

an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;

a second chamber in between the aspiration pump and the aspiration catheter, wherein the second chamber comprises a second barrel, wherein the second chamber is configured to sealingly receive the first barrel; and

a valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;

wherein upon actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid is rapidly aspirated from the aspiration catheter into the second chamber.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Ben Merritt et al.

Application No.: 17/865,315

Filed: July 14, 2022

For: **SYSTEM FOR TREATING EMBOLISM
AND ASSOCIATED DEVICES AND
METHODS**

Conf. No.: 7298

Art Unit: 3781

Examiner: Eric Rassavong

Customer No. 25096

AMENDMENT AND REPLY TO FINAL OFFICE ACTION
UNDER 37 C.F.R. § 1.111

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

In response to the Office Action mailed on February 10, 2023, please amend and consider the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims beginning on page 2.

Remarks begin on page 7 of this paper.

AMENDMENTS TO THE CLAIMS

Please amend claims 2–6, 8, 9, and 11–20, and cancel claims 1 and 10. Following is a complete listing of the claims pending in the application, as amended:

1. (Canceled)

2. (Currently Amended) ~~The~~ An aspiration system with accelerated response, comprising: of claim 1 wherein:

an aspiration pump in communication with a first chamber, wherein the first chamber comprises a first barrel of a first syringe, and wherein; the aspiration pump comprises a plunger of the first syringe slidably received in the first barrel; and
a second chamber in between the aspiration pump and the catheter, wherein the second chamber comprises a second barrel of a second syringe; and
a valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers; and
wherein upon opening of the valve with the negative pressure in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.

3. (Currently Amended) The aspiration system of claim ~~1~~2 wherein:

the valve comprises a user-actuatable stopcock valve, wherein upon user actuation to open the stopcock valve with the negative pressure having been generated in the first and second chambers, the fluid flow at least partially from the second chamber into the first chamber causes the rapid aspiration into the second chamber; and

the aspiration tube comprises a first tubing section coupled to the second chamber and one side of the stopcock valve and a second tubing section coupled to the other side of the stopcock valve.

4. (Currently Amended) The aspiration system of claim ~~1~~2 wherein:
the valve comprises a user-actuatable stopcock valve, wherein upon user actuation to open the stopcock valve with the negative pressure having been generated in the first and second chambers, the fluid flow at least partially from the second chamber into the first chamber causes the rapid aspiration into the second chamber;
the aspiration tube comprises a first tubing section coupled to the second chamber and one side of the stopcock valve and a second tubing section coupled to the other side of the stopcock valve; and
~~the first chamber comprises a first barrel of a first syringe;~~
~~the pump comprises a plunger of the first syringe slidably received in the first barrel; and~~
~~the second chamber comprises a second barrel of a second syringe, and wherein the second syringe further comprises a second plunger slidably received in the second barrel.~~

5. (Currently Amended) The aspiration system of claim ~~1~~2, further comprising a one-way valve separate from the valve between the first chamber and the second chamber configured to block flow from the first chamber to the second chamber and allow flow from the second to the first chamber.

6. (Currently Amended) The aspiration system of claim ~~4~~2, wherein the first syringe comprises a secondary pressure source and the second syringe comprises a primary pressure source.

7. (Original) The aspiration system of claim 6 wherein the first plunger is rotationally received in the first barrel and the second plunger is rotatably received in the second barrel.

8. (Currently Amended) The aspiration system of claim ~~1~~2 wherein a negative pressure in the first chamber causes fluid flow from the second chamber to the first chamber when the valve is opened.

9. (Currently Amended) The aspiration system of claim 1-2 wherein the first chamber and the second chamber are configured such that both the first chamber and the second chamber can both be at a negative pressure at the same time, and wherein upon opening the valve the negative pressure in the first chamber contributes to a rapid pressure drop in the catheter.

10. (Canceled)

11. (Currently Amended) The aspiration system of claim 1-2, further comprising a filter in the second chamber.

12. (Currently Amended) The ~~vacuum~~-aspiration system of claim 11 wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.

13. (Currently Amended) The ~~vacuum~~-aspiration system of claim 1-2 wherein the first chamber is fluidically coupled in serial to the second chamber.

14. (Currently Amended) ~~The~~ An aspiration system with accelerated response, comprising: ~~vacuum aspiration system of claim 1 wherein:~~
an aspiration pump in communication with a first chamber, wherein the first chamber comprises a first barrel of a syringe; and wherein the pump comprises a plunger of the first syringe slidably received in the first barrel; ~~and~~
an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;
a second chamber in between the aspiration pump and the catheter, wherein the second chamber comprises a second barrel; and
a valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;

wherein upon opening of the valve with negative pressure in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid decrease in pressure in the aspiration catheter.

15. (Currently Amended) The ~~vacuum~~-aspiration system of claim 14 wherein the second chamber is configured to sealingly receive the first barrel.

16. (Currently Amended) The ~~vacuum~~-aspiration system of claim 14, further comprising a filter in the second barrel.

17. (Currently Amended) The aspiration system of claim ~~10~~14, further comprising a filter in the second chamber, wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.

18. (Currently Amended) The ~~vacuum~~-aspiration system of claim ~~10~~14 wherein the first chamber is fluidically coupled in serial to the second chamber.

19. (Currently Amended) ~~The vacuum~~ An aspiration system with accelerated response, comprising: ~~of claim 10 wherein:~~

an aspiration pump in communication with a first chamber, wherein the first chamber comprises a first barrel of a syringe; and wherein the pump comprises a plunger of the first syringe slidably received in the first barrel; ~~and~~

an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;

a second chamber in between the aspiration pump and the catheter, wherein the second chamber comprises a second barrel, wherein the second chamber is configured to sealingly receive the first barrel; and

a valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second

chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;
wherein upon opening of the valve with the negative pressure in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.

20. (Currently Amended) The ~~vacuum~~—aspiration system of claim 19, further comprising a filter in the second barrel.

REMARKS

Claims 1–20 were pending when the present Office Action was mailed on February 10, 2023. In this response, claims 2, 14, and 19 have been rewritten in independent form to put these claims in condition for allowance. Claims 3–6, 8, 9, 11–13, 15–18, and 20 have been amended herein to change the dependencies of these claims and/or to further clarify certain features of these claims to expedite prosecution of this application. Claims 1 and 10 have been canceled. The foregoing amendments and cancelations are made without commenting on or conceding the merits of the rejections of these claims and without prejudice to or disclaimer of pursuing the subject matter of these claims in a continuation or other related application. No new claims have been added. Accordingly, claims 2–9 and 11–20 are currently pending.

The status of the application in light of the February 10, 2023 Office Action is as follows:

(A) Claims 1–10 were rejected under 35 U.S.C. § 112(a);

(B) Claims 1, 8–11, 13, and 18 were rejected under 35 U.S.C. § 102(a)(1) over U.S. Patent No. 8,535,283 to Heaton et al. (“Heaton”); and claims 12 and 17 were rejected under 35 U.S.C. § 103 over a combination of Heaton and U.S. Patent Application Publication No. 2005/0054995 to Barzell et al. (“Barzell”); and

(C) Claims 2, 14–16, 19, and 20 were indicated to be allowable if rewritten in independent, and claims 4, 6, and 7 and were indicated to be allowable if rewritten in independent and the Section 112(a) rejections were overcome.

A. Response to the Section 112(a) Rejection of Claims 1–10

Claims 1–10 were rejected under 35 U.S.C. § 112(a). Without commenting on or conceding the merits of this rejection, claims 1 and 10 have been canceled and allowable claim 2 has been rewritten in independent form. Accordingly, the Section 112(a) rejection of claims 1 and 10 is now moot, and the Section 112(a) rejection of claim 2 (and claims 3–9 depending therefrom) should be withdrawn.

B. Response to the Section 102/103 Rejection of Claims 1, 8–13, 17, and 18

Claims 1, 8–11, 13, and 18 were rejected under 35 U.S.C. § 102(a)(1) over Heaton. Claims 12 and 17 were rejected under 35 U.S.C. § 103 over the combination of Heaton and Barzell. Without commenting on or conceding the merits of the rejection of these claims, allowable claims 2 and 14 have been rewritten in independent form and independent claims 1 and 10 have been canceled.

Accordingly, for at least the foregoing reasons, the Applicant respectfully submits that the Section 103 rejection of independent claims 1 and 10 is now moot, and claims 2 and 14 (and claims 8–13, 17, and 18 depending from one of allowable claims 2 or 14) are in condition for allowance. Thus, the Section 102/103 rejections of claims 8–11, 12, 13, 17, and 18 should be withdrawn.

C. Indication of Allowable Subject Matter

Claims 2, 14–16, 19, and 20 were indicated to be allowable if rewritten in independent, and claims 4, 6, and 7 and were indicated to be allowable if rewritten in independent and the Section 112(a) rejections were overcome. As noted previously, claims 2, 14, and 19 have been rewritten in independent form and are therefore in condition for allowance. The Applicant thanks the Examiner for indicating that claims 2, 4, 6, 7, 14–16, 19, and 20 are allowable. Although the undersigned attorney agrees with the Examiner's conclusion that claims 2, 4, 6, 7, 14–16, 19, and 20 are allowable, the undersigned attorney notes that these claims may be allowable for reasons other than those identified by the Examiner and does not concede that the Examiner's characterization of the terms of these claims and the art of record are correct.

Conclusion

In view of the foregoing, the pending claims comply with 35 U.S.C. § 112 and are patentable over the applied art. The Applicant accordingly requests reconsideration of the application and respectfully submits that the application is in condition for allowance. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to contact Matthew S. Williams at (206) 359-3343.

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicant is not conceding that previously pending claims are not patentable over the cited references; instead, any alteration or characterizations are being made to facilitate expeditious prosecution of this application.

The Applicant reserves the right to later pursue any previously pending or other broader or narrow claims that capture any subject matter supported by the present disclosure, including subject matter that might be found disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present

Please charge any underpayment or credit any overpayment to Deposit Account No. 50-0665, under Order No. 111552-8018.US03 from which the undersigned is authorized to draw.

Respectfully submitted,

Dated: March 7, 2023

By: /Matthew S. Williams/

Matthew S. Williams
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Attorney for Applicant



ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
17/865,315

RECEIPT DATE / TIME
03/07/2023 06:44:39 PM ET

ATTORNEY DOCKET #
111552-8018.US03

Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 7298

FILED BY JiYoung Anderson

PATENT CENTER # 61704227

FILING DATE 07/14/2022

CUSTOMER # 25096

FIRST NAMED
INVENTOR Ben Merritt

CORRESPONDENCE
ADDRESS -

AUTHORIZED BY Matthew Williams

Documents

TOTAL DOCUMENTS: 3

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-3-7 Response to FOA - 111552-8018US3.PDF	9	-	65 KB
2023-3-7 Response to FOA (1-1) - 111552-8018US3- A.NE.pdf	1	Response After Final Action	16 KB
2023-3-7 Response to FOA (2-6) - 111552-8018US3- IACS.pdf	5	Amendment Copy Claims/Response to Suggested Claims	31 KB
2023-3-7 Response to FOA (7-9) - 111552-8018US3-REM.pdf	3	Applicant Arguments/Remarks Made in an Amendment	41 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-3-7 Response to FOA - 111552-8018US3.PDF	B046996684D9D3D314EEF8FAAD2D65556724B41973ACA4593 162E4463189E656DF787D98C9827E29C2364767CD6E497F3DE E0F5F8DB385CBC114CBB362CED099
2023-3-7 Response to FOA - 111552-8018US3-A.NE.pdf	746F03631F6218195D31FC79910A1A31683CE70AABA1D6B374 71900E41AEDC2D6E36F582759F1B20CD363CA5433F20F215C 7189CC1CDED3676D660018EC5D581
2023-3-7 Response to FOA - 111552-8018US3-IACS.pdf	6DFC730320671C1141D351CC64DCC72079C2EE4F13C075AB4 18295AB82CACAA892CBA57D2D93C4CF9937D0C937A6CAF08 6F33C6FF8E4FC07C702CD38FE5DB8C0
2023-3-7 Response to FOA - 111552-8018US3-REM.pdf	7A714535BE33778FD1B3E5418857EF1898BFA318D489FD3138 52FBCBC61ECA335927DD4C05ACF1647CBEB2443022AC987B B644AF6C4C0A36DA2DADEB4F6ACE84

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 17/865,315		Filing Date 07/14/2022		☐ To be Mailed			
ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO											
APPLICATION AS FILED - PART I											
		(Column 1)		(Column 2)							
FOR		NUMBER FILED		NUMBER EXTRA		RATE (\$)		FEE (\$)			
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))		N/A		N/A		N/A					
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))		N/A		N/A		N/A					
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))		N/A		N/A		N/A					
TOTAL CLAIMS (37 CFR 1.16(i))		minus 20 = *				x \$100 =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 = *				x \$480 =					
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))											
* If the difference in column 1 is less than zero, enter "0" in column 2.						TOTAL					
APPLICATION AS AMENDED - PART II											
		(Column 1)		(Column 2)		(Column 3)					
AMENDMENT	03/07/2023	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 18	Minus	** 20	= 0			x \$100 =		0	
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0			x \$480 =		0	
	☐ Application Size Fee (37 CFR 1.16(s))										
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
								TOTAL ADD'L FEE		0	
		(Column 1)		(Column 2)		(Column 3)					
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=			x \$0 =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=			x \$0 =			
	☐ Application Size Fee (37 CFR 1.16(s))										
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
								TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.								LIE			
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".								/DANTE SMITH/			
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".											
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.											

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/865,315	07/14/2022	Ben Merritt	111552-8018.US03	7298
25096	7590	02/10/2023	EXAMINER	
PERKINS COIE LLP - SEA General			RASSAVONG, ERIC	
PATENT-SEA			ART UNIT	
P.O. BOX 1247			PAPER NUMBER	
SEATTLE, WA 98111-1247			3781	
			NOTIFICATION DATE	
			DELIVERY MODE	
			02/10/2023	
			ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentprocurement@perkinscoie.com

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Status of Claims

2. **Claims 1-20** are currently pending. **Claims 1, 6, and 10** are currently amended. **Claims 11-20** are newly added. No new subject matter is added.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claims 1-10** are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, because the specification, while being enabling for opening of a valve, does not reasonably provide enablement for “the specific location of valve opening with negative pressure within the system”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Examiner notes that the following 112(a) issues were discussed during the Interview with Attorney Williams, but the amendments to the claims do not seem to reflect, or be limited to recite, only the embodiment shown in Figs. 20A-20C. Regardless of the embodiment that Applicant intends to recite, the following 112(a) issues stand.

Regarding **claim 1 and 10**, the claim is not enabled due to the limitation “wherein upon opening of the valve *with the negative pressure in the first and second chambers*” (emphasis added). Examiner interprets this limitation to mean that the valve can only be a passively-opened one-way check valve to be opened with negative pressure in *both* the first and the second chambers. However, looking at the original disclosure of the current invention, there is single valve located between the second chamber and the aspiration catheter, namely valve 126 (see Fig. 20C). However, valve (126) is a stopcock valve operable externally by a user ([0051] of the Specification), thus it is incapable of being opened with negative pressure. Therefore, based on the disclosure, the valve (126) shown to be located between the second chamber and the aspiration catheter is not capable of opening *with the negative pressure in the first AND second chambers*. The scope of the claim is not enabled by the specification. For examination purposes, the limitation is interpreted to read as “wherein upon manually opening of the valve and wherein there is negative pressure in the first and second chambers ...” With such an interpretation, the claim would be enabled because valve (126) is located between the second chamber and the aspiration catheter and it is also capable of being manually opened while there is negative pressure in the first and second chambers.

Regarding **claims 3 and 4**, there is no evidence in the specification that would allow the valve recited in claim 1 to be any other type of valve such as an stopcock valve because a

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stopcock valve cannot be opened with the negative pressure. The only valve that is capable of opening with negative pressure would be a one-way check valve. Given that a stopcock valve cannot also be a valve opened with negative pressure, no prior art examination can be done on claims 3-4.

Regarding **claims 5-7**, from the interpretation of the valve of claim 1 being a one-way check valve, then the aspiration system “*further comprising a one-way valve configured to block flow from the first chamber to the second chamber and allow flow from the second to the first chamber*” would not be supported by the disclosure. The disclosure only shows a single valve located between the aspiration catheter and second chambers, namely valve 126 (see Figure 20A-C). Therefore, the disclosure does not provide support for a system that comprises two valves, wherein (i) the first valve is located between the aspiration catheter and the second chamber and opened by negative pressure in the second chamber, and (ii) the second valve is a one-way valve located between the first and second chambers and blocking fluid flow from the first chamber into the second chamber. Valve 472 blocks fluid flow from the second chamber into the first chamber, as shown in Fig. 4C, functioning opposite to what is required by claim 5. Examiner concludes that the embodiment recited in claim 5 is impossible because the claim effectively recites two one-way valves in the exact same location of the system acting opposite to each other. Claims 6-7 are rejected for being dependent from claim 5. No prior art rejection can be provided for claims 5-7.

Claim Rejections - 35 USC § 102

5. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction

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of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

7. **Claims 1, 8-11, 13, and 18** are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Heaton et al. (US 8535283 B2), hereinafter referred to as “Heaton”.

Regarding **claim 1**, Heaton teaches an aspiration system with accelerated response (reduce pressure system (100)), comprising: an aspiration pump (pump (102)) in communication with a first chamber (in communication with variable volume chamber (110)); an aspiration catheter (connection member (155)) configured for placement into fluid communication with the first chamber by way of an aspiration tube (in fluid communication with variable volume (110) via delivery tube (135), see Figure 1); a second chamber (fixed volume chamber (115)) in between the aspiration pump and the catheter (located between pump (102) comprising the variable volume (110) and connection member (155)); and a valve (inlet valve (140)) between the second chamber and the aspiration catheter (in between connection member (155) and fixed volume (115), see Figure 1); wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers (valve (140) can be any type of valve that restricts fluid flow into and out of the fixed chamber (115), see Col. 6 lines 20-27) (a reduced pressure is generated in fixed volume chamber (115) as

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variable volume chamber (110) expands from the compressed position to the uncompressed position, see Col. 9 lines 19-21) (the valve (140) can be closed to generate negative pressure within chamber (115) and bellows (110)), and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers (valve (140) can be open to provide negative pressure to the tissue site, see Col. 6 lines 22-27); wherein upon opening of the valve with the negative pressure in the first and second chambers (opening valve (140) with negative pressure in fixed volume (115) and variable volume (110)), see Col. 6 lines 22-27), fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber (opening valve (140) with negative pressure causes fluid to flow from fixed chamber (115) to rapidly flow into variable chamber (110)). Note that the current disclosure does not limit the definition for “rapid” and Heaton’s system is considered to be capable of meeting the claim function.

Regarding **claim 8**, Heaton further teaches wherein a negative pressure in the first chamber (a reduced pressure is generated in fixed volume chamber (115) as variable volume chamber (110) expands from the compressed position to the uncompressed position, see Col. 9 lines 19-21) causes fluid flow from the second chamber to the first chamber when the valve is opened (opening valve (140) with negative pressure causes fluid to flow from fixed chamber (115) to variable chamber (110)).

Regarding **claim 9**, Heaton further teaches wherein the first chamber (110) and the second chamber (115) are configured such that both the first chamber and the second chamber can both be at a negative pressure at the same time (a reduced pressure is generated in fixed volume chamber (115) as variable volume chamber (110) expands from the compressed

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position to the uncompressed position, see Col. 9 lines 19-21), and wherein upon opening the valve the negative pressure in the first chamber contributes to a rapid pressure drop in the catheter (opening valve (140) with negative pressure causes fluid to flow from fixed chamber (115) to rapidly flow into variable chamber (110)).

Regarding **claim 10**, Heaton teaches an aspiration system with accelerated response (reduce pressure system (100)), comprising: an aspiration pump (pump (102)) in communication with a first chamber (in communication with variable volume chamber (110)); an aspiration catheter (connection member (155)) configured for placement into fluid communication with the first chamber by way of an aspiration tube (in fluid communication with variable volume (110) via delivery tube (135), see Figure 1); a second chamber (fixed volume chamber (115)) in between the aspiration pump and the catheter (located between pump (102) comprising the variable volume (110) and connection member (155), see Figure 1); and a valve (inlet valve (140)) between the second chamber and the aspiration catheter (in between connection member (155) and fixed volume (115), see Figure 1), wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers (valve (140) can be any type of valve that restricts fluid flow into and out of the fixed chamber (115), see Col. 6 lines 20-27) (a reduced pressure is generated in fixed volume chamber (115) as variable volume chamber (110) expands from the compressed position to the uncompressed position, see Col. 9 lines 19-21) (the valve (140) can be close to generate negative pressure within chamber (115) and bellows (110)), and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers (valve (140) can be open to provide negative pressure to the tissue site, see Col. 6 lines 22-27); wherein upon

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opening of the valve with negative pressure in the first and second chambers (opening valve (140) with negative pressure in fixed volume (115) and variable volume (110), see Col. 6 lines 22-27), fluid flow at least partially from the second chamber into the first chamber causes rapid decrease in pressure in the aspiration catheter (opening valve (140) with negative pressure causes fluid to flow from aspiration catheter (155) to rapidly flow into pump (102)).

Regarding **claim 11**, Heaton further teaches a filter in the second chamber (filter housing (120) is connected to variable volume (110), see Figure 1).

Regarding **claim 13**, Heaton further teaches wherein the first chamber is fluidically coupled in serial to the second chamber (fixed chamber (115) is connected in series to variable volume (110), see Figure 1).

Regarding **claim 18**, Heaton further teaches wherein the first chamber is fluidically coupled in serial to the second chamber (fixed chamber (115) is connected in series to variable volume (110), see Figure 1).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
10. This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.
11. **Claims 12 and 17** are rejected under 35 U.S.C. 103 as being unpatentable over Heaton et al. (US 8535283 B2) in view of Barzell et. Al (US 20050054995 A1), hereinafter referred to as "Barzell".

Regarding **claim 12 and 17**, Heaton teaches all of the limitations, as discussed above in claim 10 and 11 and Heaton teaches a filter in the second chamber (filter (120) connected to variable volume (110), see Figure 1). However, Heaton does not explicitly disclose wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.

Barzell teaches a system and method for irrigating and collecting tissue from a body cavity in a patient (see Abstract) comprising a collection bag (22), tube (20), and a filter (filter (28), see Figures 1-5) includes a plurality of pores sized to inhibit clot material from flowing

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therethrough and to permit blood to flow therethrough (filter (28) is provided with a plurality of pores allowing the passage of fluid and particulate material of a given size. The pores in filter (28) have a size to restrict throughflow of particulate material of a predetermined size, see Paragraph [0039]).

Heaton and Barzell are analogous art because both deal with a medical device comprising a container for tissue collection.

It would have been obvious to a person having ordinary skill in the art before the effective filing date of the invention to modify the filter of Heaton and further include wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough, as taught by Barzell. Barzell teaches it allows for remove substantially all of the loose tissue and particulate material from the body cavity (see last line of paragraph [0033]).

Allowable Subject Matter

12. **Claims 2, 14-16, and 19-20** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. **Claims 4 and 6-7** are rejected under 112(a) as described above, but would be allowable if 112(a) issues are resolved and rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. The following is a statement of reasons for the indication of allowable subject matter:

Claims 2, 4, 14, and 19 would be allowable for reciting, *inter alia*, “the first chamber comprises a first barrel of a syringe; the pump comprises a plunger of the first syringe slidably received in the first barrel; and the second chamber comprises a second barrel”.

Heaton teaches all of the limitations as described above in the Final Rejection. However, Heaton fails to teach the first chamber comprises a first barrel of a syringe; the pump comprises a plunger of the first syringe slidably received in the first barrel; and the second chamber comprises a second barrel. The chambers in Heaton is a fixed volume container and a bellows pump located on top. There would need to be a device that discloses two syringes connected in series to read on this limitation or a syringe within a syringe in order to read on these limitations. There is no prior art that disclose such device. Therefore, the combination of limitations of claims 2, 4, 14, and 19 would be considered allowable. **Claims 6-7** would be allowable for depending from claim 4. **Claims 15-16** would be allowable for depending from claim 14. **Claim 20** would be allowable for depending from claim 19.

Response to Arguments

15. Applicant's arguments with respect to claims 1, 2, and 8-10 have been considered but are moot because the new ground of rejection does not rely on any reference applied in the prior rejection of record for any teaching or matter specifically challenged in the argument.

16. Applicant's arguments, see pg. 2 section B, filed 12/22/2022, with respect to 112(b) have been fully considered and are persuasive. The 112(b) of claims 6-7 has been withdrawn.

17. Applicant's arguments filed 12/22/2022 have been fully considered but they are not persuasive.

Specifically, Applicant argues in claims 1-10, on pg.2 section A, the specification enables all the features of claims 1-10 based on the Figures 1 and 20C which illustrates a fluid control device (126) that can comprise a valve. The examiner respectfully disagrees with the applicant that the disclosure in Figures 1 and 20C overcome the 112(a) rejection previously given. The

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examiner interprets the limitation “wherein upon opening of the valve *with the negative pressure in the first and second chambers*” to still mean that the valve can only be a passively opening one-way check valve to be opened with negative pressure. There needs to be a clear distinction that the valve is not open with negative pressure, but manually operated (i.e. stopcock valve). Therefore, as described above, the scope of the claim is not met by the specification and the 112(a) rejection of claims 1-10 would remain.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC RASSAVONG whose telephone number is (408)918-7549. The examiner can normally be reached Monday - Friday 9:00am-5:30pm PT.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is

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encouraged to use the USPTO Automated Interview Request (AIR) at

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas J. Weiss can be reached on (571)270-1775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/E.R./ (2/5/2023)

Examiner, Art Unit 3781

/SUSAN S SU/

Primary Examiner, Art Unit 3781

6 February 2023

Notice of References Cited	Application/Control No. 17/865,315		Applicant(s)/Patent Under Reexamination Merritt et al.	
	Examiner ERIC RASSAVONG		Art Unit 3781	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-8535283-B2	09-2013	Heaton; Keith Patrick	A61M1/98	604/319
*	B	US-8753322-B2	06-2014	Hu; Dean	A61M1/912	604/319
*	C	US-8808259-B2	08-2014	Walton; Edward William	A61M1/915	604/319
	D					
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Search Notes</i> 	Application/Control No. 17/865,315	Applicant(s)/Patent Under Reexamination Merritt et al.
	Examiner ERIC RASSAVONG	Art Unit 3781

CPC - Searched*		
Symbol	Date	Examiner
A61B17/12109, 17/221, 2017/22034, 2017/22079, 17/005	09/10/2022	/E.R./
A61F2/01	09/10/2022	/E.R./
A61M1/84,25/10	09/10/2022	/E.R./
A61B17/12109, 17/221, 2017/22034, 2017/22079, 17/005	02/05/2023	/E.R./
A61F2/01	02/05/2023	/E.R./
A61M1/84,25/10	02/05/2023	/E.R./

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
CPC and Text Searching Completed	09/10/2022	/E.R./
Inventor Name Search in PALM	09/10/2022	/E.R./
Consulted Primary Examiner Susan Su on Prior art	09/13/2022	/E.R./
Consulted Primary Examiner Susan Su on Prior art	02/02/2023	/E.R./
Updated Search	02/05/2023	/E.R./

/E.R./ Examiner, Art Unit 3781	
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<i>Search Notes</i> 	Application/Control No. 17/865,315	Applicant(s)/Patent Under Reexamination Merritt et al.
	Examiner ERIC RASSAVONG	Art Unit 3781

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/E.R./ Examiner, Art Unit 3781	
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Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

Based on PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17/865,315, Conf. No. 7298
	Filing Date	2022-07-14
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US03

U.S. PATENTS AND PUBLICATIONS						
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		20220142638		05-12-2022	Enright et al.	
		20220151647		05-19-2022	Dolendo et al.	
		20220152355		05-19-2022	Dolendo et al.	
		5653684		08-05-1997	Laptewicz et al.	
		5908435		06-01-1999	Samuels	
		4611594		09-16-1986	Grayhack et al.	
		9827084		11-28-2017	Bonnette et al.	
		20210137667		05-13-2021	Sonnette et al.	
		20180256177		09-13-2018	Cooper et al.	
		11013523		05-25-2021	Arad Hadar	
		11406801		08-09-2022	Fojtik et al.	
		11554005		01-17-2023	Merritt et al.	
		11559382		01-24-2023	Merritt et al.	
		6818006		11-16-2004	Douk et al.	
		9078682		07-14-2015	Lenker et al.	
		20140052161		02-20-2014	Cully et al.	
		20180042623		02-15-2018	Batiste	
		20180184912		07-05-2018	Al-Ali	
		20160262774		09-15-2016	HONDA	
		20120172918		07-05-2012	Fifer et al.	
		20050054995		03-10-2005	Barzell et al.	
		20030116731		06-26-2003	Hartley	
		5421824		06-06-1995	Clement et al.	
FOREIGN PATENT DOCUMENTS						

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

Based on PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17/865,315, Conf. No. 7298
	Filing Date	2022-07-14
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US03

Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵

EXAMINER SIGNATURE

Examiner Signature	/ERIC RASSAVONG/	Date Considered	02/05/2023
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

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☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2023-02-01
Name/Print	Matthew S. Williams	Registration Number	77,516

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Bibliographic Data

Application No: 17/865,315

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☐ No ☐ Met After Allowance

Verified and Acknowledged: /ERIC RASSAVONG/

Examiner's Signature

Initials

Title:

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED
DEVICES AND METHODS

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
07/14/2022	604	3781	111552-8018.US03
RULE			

APPLICANTS

Inari Medical, Inc., Irvine, CA, UNITED STATES

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Ben Merritt, San Clemente, CA, UNITED STATES

Jacqueline Macias, Fullerton, CA, UNITED STATES

Brian Michael Strauss, San Clemente, CA, UNITED STATES

Thomas Tu, Louisville, KY, UNITED STATES

CONTINUING DATA

This application is a CON of 16536185 08/08/2019 PAT 11559382

16536185 has PRO of 62718248 08/13/2018

16536185 has PRO of 62718269 08/13/2018

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

07/25/2022

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UNITED STATES

FILING FEE RECEIVED

\$6,160

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L86	23	("11013523" OR "11406801" OR "11554005" OR "11559382" OR "20030116731" OR "20050054995" OR "20120172918" OR "20140052161" OR "20160262774" OR "20180042623" OR "20180184912" OR "20180256177" OR "20210137667" OR "20220142638" OR "20220151647" OR "20220152355" OR "4611594" OR "5421824" OR "5653684" OR "5908435" OR "6818006" OR "9078682" OR "9827084").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/02/05 08:21 PM
L87	32	(Artificial Intelligence) More like doc: US-8535283-B2 Text: (AU-2008216871-B2 OR AU-2008216871-A1 OR CA-2674036-C OR WO-2008100438-A1 OR EP-2114483-A1 OR CA-2674036-A1 OR US-20080200905-A1 OR TW-I430818-B OR EP-2114483-B1 OR EP-2114483-B2 OR JP-5345555-B2 OR TW-200934541-A OR JP-2010517680-A OR US-20130338614-A1 OR BR-PI0806192-A2 OR EP-2992913-A1 OR US-9028458-B2 OR US-20150238665-A1 OR AU-2015268679-A1 OR US-10792402-B2).did.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 09:51 PM
L88	4411	A61M1/79.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR,	OR	ON	ON	2023/02/05 10:05 PM

L89	586	A61M1/79.cpc. AND container AND ((negative reduce) NEAR pressure)	GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 10:06 PM
L90	329	A61M1/79.cpc. AND container AND ((negative reduce) NEAR pressure) AND pores	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 10:08 PM
L91	244	A61M1/79.cpc. AND container AND ((negative reduce) NEAR pressure) AND pores AND small	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 10:08 PM
L92	42	A61M1/79.cpc. AND stopcock AND container	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 10:35 PM
L93	116	A61F2/01.cpc. AND A61M25/10.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 11:41 PM
L94	152	A61M1/84.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 11:41 PM
L95	1047	A61B17/221.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR,	OR	ON	ON	2023/02/05 11:41 PM

L96	517	A61B2017/22034.cpc. AND A61B17/12109.cpc.	GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 11:41 PM
L97	401	A61B2017/22079.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 11:41 PM
L98	439	A61B2217/005.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 11:41 PM
L99	152	A61M1/84.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 11:41 PM
L100	18	A61M1/84.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 11:41 PM
L101	697	A61B17/221.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 11:41 PM
L102	212	A61B2017/22034.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR,	OR	ON	ON	2023/02/05 11:41 PM

L103	90	A61B2017/22079.cpc. AND A61F2/01.cpc.	GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 11:41 PM
L105	96	A61B2217/005.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 11:41 PM
L106	116	A61M25/10.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 11:41 PM
L107	382	A61B17/221.cpc. AND A61M1/84.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 11:41 PM
L108	382	A61B17/221.cpc. AND A61M1/84.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 11:41 PM
L109	203	A61B2017/22034.cpc. AND A61M1/84.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/02/05 11:41 PM
L110	582	A61B2017/22079.cpc. AND A61M1/84.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD,	OR	ON	ON	2023/02/05 11:41 PM

			DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
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PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17/865,315, Conf. No. 7298
	Filing Date	2022-07-14
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US03

U.S. PATENTS AND PUBLICATIONS						
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		20220142638		05-12-2022	Enright et al.	
		20220151647		05-19-2022	Dolendo et al.	
		20220152355		05-19-2022	Dolendo et al.	
		5653684		08-05-1997	Laptewicz et al.	
		5908435		06-01-1999	Samuels	
		4611594		09-16-1986	Grayhack et al.	
		9827084		11-28-2017	Bonnette et al.	
		20210137667		05-13-2021	Sonnette et al.	
		20180256177		09-13-2018	Cooper et al.	
		11013523		05-25-2021	Arad Hadar	
		11406801		08-09-2022	Fojtik et al.	
		11554005		01-17-2023	Merritt et al.	
		11559382		01-24-2023	Merritt et al.	
		6818006		11-16-2004	Douk et al.	
		9078682		07-14-2015	Lenker et al.	
		20140052161		02-20-2014	Cully et al.	
		20180042623		02-15-2018	Batiste	
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		20160262774		09-15-2016	HONDA	
		20120172918		07-05-2012	Fifer et al.	
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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

CERTIFICATION STATEMENT

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OR

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	First Named Inventor	Ben Merritt
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	Attorney Docket Number	111552-8018.US03

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☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2023-02-01
Name/Print	Matthew S. Williams	Registration Number	77,516

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APPLICATION #
17/865,315

RECEIPT DATE / TIME
02/01/2023 04:54:21 PM ET

ATTORNEY DOCKET #
111552-8018.US03

Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	7298	FILED BY	JiYoung Anderson
PATENT CENTER #	61529607	FILING DATE	07/14/2022
CUSTOMER #	25096	FIRST NAMED INVENTOR	Ben Merritt
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Matthew Williams

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-2-1-IDS-SB08-111552-8018US3.PDF	3	Information Disclosure Statement (IDS) Form (SB08)	126 KB

Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-2-1-IDS-SB08-111552-8018US3.PDF	8477DF0C1DEACBB571943855D2C937D557E7D236B3AADA46 4ED87E9DA2120853DE276460779CF0ACDC9C70C6111B73250

BD3D29FDE17D961FFB4AE29400BF588

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



ELECTRONIC PAYMENT RECEIPT

APPLICATION #
17/865,315

RECEIPT DATE / TIME
02/01/2023 04:54:21 PM ET

ATTORNEY DOCKET #
111552-8018.US03

Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 7298

FILED BY JiYoung Anderson

PATENT CENTER # 61529607

AUTHORIZED BY Matthew Williams

CUSTOMER # 25096

FILING DATE 07/14/2022

CORRESPONDENCE
ADDRESS -

FIRST NAMED
INVENTOR Ben Merritt

Payment Information

PAYMENT METHOD
CARD / 3369

PAYMENT TRANSACTION ID
E202321G55063540

PAYMENT AUTHORIZED BY
JiYoung Anderson

FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
1806	SUBMISSION OF AN INFORMATION DISCLOSURE STATEMENT	260.00	1	260.00
TOTAL AMOUNT:				\$260.00

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New Applications Under 35 U.S.C. 111

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National Stage of an International Application under 35 U.S.C. 371

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17/865,315, Conf. No. 7298
	Filing Date	2022-07-14
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US03

U.S. PATENTS AND PUBLICATIONS						
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		6564828		05-20-2003	Ishida	
		5197485		03-30-1993	Grooters	
		20130035628		02-07-2013	Garrison et al.	
		8057497		11-15-2011	Raju et al.	
		20150173782		06-25-2015	Garrison et al.	
		20220211400		07-07-2022	Cox et al.	
		11433218		09-06-2022	Quick et al.	
		20040127936		07-01-2004	Salahieh et al.	
		20210022843		01-28-2021	Hauser	
		5158564		10-27-1992	Schnepp-Pesch et al.	
		20220347455		11-03-2022	Merritt et al.	
		20220346800		11-03-2022	Merritt et al.	
		20220346813		11-03-2022	Quick	
		20220346814		11-03-2022	Quick	
		3675657		07-11-1972	Gauthier	
		9216277		12-22-2015	Myers	
		9980813		05-29-2018	Eller	
		6451036		09-17-2002	Heitzmann et al.	
		20080234715		09-25-2008	Pesce et al.	
		20110034986		02-10-2011	Chou et al.	
		20190336142		11-07-2019	Torrie et al.	
		20190239910		08-08-2019	Brady et al.	
		20060217664		09-28-2006	Hattler et al.	
		20170252057		09-07-2017	Bonnette et al.	
		20170340867		11-30-2017	Accisano, II	
		11457936		10-04-2022	Buck et al.	
		11259821		03-01-2022	Buck et al.	
		11439799		09-13-2022	Buck et al.	
		20210315598		10-14-2021	Buck et al.	
		11529158		12-20-2022	Hauser	

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	Filing Date	2022-07-14
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US03

		20220362512		11-17-2022	Quick et al.	

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17/865,315, Conf. No. 7298
	Filing Date	2022-07-14
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US03

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2022-12-22
Name/Print	Matthew S. Williams	Registration Number	77,516

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**



ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
17/865,315

RECEIPT DATE / TIME
12/22/2022 10:27:23 AM ET

ATTORNEY DOCKET #
111552-8018.US03

Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 7298

FILED BY JiYoung Anderson

PATENT CENTER # 61340506

FILING DATE 07/14/2022

CUSTOMER # 25096

FIRST NAMED
INVENTOR Ben Merritt

CORRESPONDENCE
ADDRESS -

AUTHORIZED BY Matthew Williams

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2022-12-22- ResponseTo__NFOA-111552- 8018US3.PDF	10	Amendment/Request for Reconsideration-After Non- Final Rejection	117 KB
2022-12-22-IDS__SB08- 111552-8018US3.PDF	3	Information Disclosure Statement (IDS) Form (SB08)	128 KB

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Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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2022-12-22- ResponseTo_NFOA-111552- 8018US3.PDF	809B7028B7F06F4AB27425F70BBF7AF106E995CFB94F3F1325 1A37C58FFBFABAC0F7A3B2197568A782C378F421F47CC7907 E3886720AC4F4E4FEF4446E5BA043
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2022-12-22-IDS_SB08-111552- 8018US3.PDF	0605CD33FDB32FFF0689D6368888A6642D92A73A0D82A2A0F 652BDA889BDC66849C714AE76F369003B326831A331768F82F 83D4270C240B5F80667EBE98B1717
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ELECTRONIC PAYMENT RECEIPT

APPLICATION #
17/865,315

RECEIPT DATE / TIME
12/22/2022 10:27:23 AM ET

ATTORNEY DOCKET #
111552-8018.US03

Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 7298

FILED BY JiYoung Anderson

PATENT CENTER # 61340506

AUTHORIZED BY Matthew Williams

CUSTOMER # 25096

FILING DATE 07/14/2022

CORRESPONDENCE
ADDRESS -

FIRST NAMED
INVENTOR Ben Merritt

Payment Information

PAYMENT METHOD
CARD / 3369

PAYMENT TRANSACTION ID
E2022BLA28511380

PAYMENT AUTHORIZED BY
JiYoung Anderson

FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
1806	SUBMISSION OF AN INFORMATION DISCLOSURE STATEMENT	260.00	1	260.00
TOTAL AMOUNT:				\$260.00

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Ben Merritt et al.

Application No.: 17/865,315

Confirmation No.: 7298

Filed: July 14, 2022

Art Unit: 3781

For: SYSTEM FOR TREATING EMBOLISM AND
ASSOCIATED DEVICES AND METHODS

Examiner: Eric Rassavong

**AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION
UNDER 37 C.F.R. § 1.111**

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

In response to the Non-Final Office Action mailed on September 23, 2022, please amend the above-identified U.S. patent application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 6 of this paper.

AMENDMENTS TO THE CLAIMS

Please amend claims 1, 6, and 10, and add claims 11–20. the claims as follows:

1. (Currently Amended) An aspiration system with accelerated response, comprising:
an aspiration pump in communication with a first chamber;
an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;
a second chamber in between the aspiration pump and the catheter; and
a valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;
wherein upon opening of the valve with the negative pressure in the first and second chambers, fluid flow ~~between~~ at least partially from the second chamber and into the first chamber causes rapid aspiration into the second chamber.
2. (Original) The aspiration system of claim 1 wherein:
the first chamber comprises a first barrel of a first syringe;
the pump comprises a plunger of the first syringe slidably received in the first barrel; and
the second chamber comprises a second barrel of a second syringe.
3. (Original) The aspiration system of claim 1 wherein:
the valve comprises a stopcock valve; and
the aspiration tube comprises a first tubing section coupled to the second chamber and one side of the stopcock valve and a second tubing section coupled to the other side of the stopcock valve.

4. (Original) The aspiration system of claim 1 wherein:
the valve comprises a stopcock valve;
the aspiration tube comprises a first tubing section coupled to the second chamber and one side of the stopcock valve and a second tubing section coupled to the other side of the stopcock valve;
the first chamber comprises a first barrel of a first syringe;
the pump comprises a plunger of the first syringe slidably received in the first barrel; and
the second chamber comprises a second barrel of a second syringe, and wherein the second syringe further comprises a second plunger slidably received in the second barrel.
5. (Original) The aspiration system of claim 1, further comprising a one-way valve between the first chamber and the second chamber configured to block flow from the first chamber to the second chamber and allow flow from the second to the first chamber.
6. (Currently Amended) The aspiration system of claim ~~5~~4 wherein the first syringe comprises a secondary pressure source and the second syringe comprises a primary pressure source.
7. (Original) The aspiration system of claim 6 wherein the first plunger is rotationally received in the first barrel and the second plunger is rotatably received in the second barrel.
8. (Original) The aspiration system of claim 1 wherein a negative pressure in the first chamber causes fluid flow from the second chamber to the first chamber when the valve is opened.
9. (Original) The aspiration system of claim 1 wherein the first chamber and the second chamber are configured such that both the first chamber and the second chamber can both

be at a negative pressure at the same time, and wherein upon opening the valve the negative pressure in the first chamber contributes to a rapid pressure drop in the catheter.

10. (Currently Amended) An aspiration system with accelerated response, comprising:
an aspiration pump in communication with a first chamber;
an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;
a second chamber in between the aspiration pump and the catheter; and
a valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;
wherein upon opening of the valve with negative pressure in the first and second chambers, fluid flow ~~between~~ at least partially from the second chamber ~~and into~~ the first chamber causes rapid decrease in pressure in the aspiration catheter.

11. (New) The aspiration system of claim 1, further comprising a filter in the second chamber.

12. (New) The vacuum aspiration system of claim 11 wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.

13. (New) The vacuum aspiration system of claim 1 wherein the first chamber is fluidically coupled in serial to the second chamber.

14. (New) The vacuum aspiration system of claim 1 wherein:
the first chamber comprises a first barrel of a syringe;
the pump comprises a plunger of the first syringe slidably received in the first barrel; and
the second chamber comprises a second barrel.
15. (New) The vacuum aspiration system of claim 14 wherein the second chamber is configured to sealingly receive the first barrel.
16. (New) The vacuum aspiration system of claim 14, further comprising a filter in the second barrel.
17. (New) The aspiration system of claim 10, further comprising a filter in the second chamber, wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.
18. (New) The vacuum aspiration system of claim 10 wherein the first chamber is fluidically coupled in serial to the second chamber.
19. (New) The vacuum aspiration system of claim 10 wherein:
the first chamber comprises a first barrel of a syringe;
the pump comprises a plunger of the first syringe slidably received in the first barrel; and
the second chamber comprises a second barrel, wherein the second chamber is configured to sealingly receive the first barrel.
20. (New) The vacuum aspiration system of claim 19, further comprising a filter in the second barrel.

REMARKS

Claims 1–10 were pending when the present Office Action was mailed on September 23, 2022. In this response, claims 1, 6, and 10 have been amended to further clarify certain features of these claims and to expedite prosecution of this application. The foregoing amendments are made without commenting on or conceding the merits of the rejections of these claims and without prejudice to or disclaimer of pursuing the subject matter of these claims in a continuation or other related application. New claims 11–20 have been added in this response. Accordingly, claims 1–20 are currently pending.

In the Office Action dated September 23, 2022, claims 1–10 were rejected as follows:

- (A) Claim 1–10 were rejected under 35 U.S.C. 112(a);
- (B) Claims 6 and 7 were rejected under 35 U.S.C. 112(b); and
- (C) Claims 1, 2, and 8–10 were rejected under 35 U.S.C. § 103 over a combination of U.S. Patent No. 7,223,253 to Hogendijk (“Hogendijk”) and U.S. Patent Application Publication No. 2013/0281788 to Garrison (“Garrison”).

The undersigned attorney thanks the Examiner and his Supervisor for engaging in a telephone interview on December 6, 2022, to discuss the present Office Action, the Section 112(a) rejection, and the Section 103 rejection. Although no agreements were reached, the Examiner indicated that amending independent claims 1 and 10 generally as set forth herein would likely help move the prosecution of this application forward. The Applicant accordingly requests that this paper constitute the Applicant’s Interview Summary. If the Examiner notices any deficiencies in this regard, the Examiner is encouraged to contact the undersigned attorney so that any such deficiencies can be addressed.

A. Response to the Section 112(a) Rejection of Claims 1–10

Claims 1–10 were rejected under Section 112(a) as allegedly lacking enablement. Specifically, the Office Action alleges that the specification “while being enabling for opening of a valve, does not reasonably provide enablement for ‘the specific location of valve opening with negative pressure in the system.’” (Office Action pg. 2.) As discussed during the December 6th telephone interview, the Applicant respectfully submits that the specification enables all the features of claims 1–10. For example, Figures 1 and 20C illustrate a fluid control device 126 that can comprise a valve. (Present Application, ¶¶ [0049]–[0052], [0136], and [0137].) Accordingly, the Applicant respectfully submits that the Section 112(a) of claims 1–10 should be withdrawn.

B. Response to the Section 112(b) Rejection, Second Paragraph

Claims 6 and 7 were rejected under Section 112(b) as allegedly being indefinite. Without commenting on or conceding the merits of this rejection, claim 6 has been amended to address the alleged indefiniteness. Accordingly, the Section 112(b) rejection of claim 6 (and claim 7 depending therefrom) should be withdrawn.

C. Response to the Section 103 Rejection of Claims 1, 2, and 8–10 (Hogendijk and Garrison)

Claims 1, 2, and 8–10 were rejected under 35 U.S.C. § 103 over the combination of Hogendijk and Garrison. Without commenting on or conceding the merits of the rejection of these claims, independent claims 1 and 10 have been amended to further clarify the claimed subject matter.

The Applicant respectfully submits that amended claim 1 is patentable over Hogendijk and Garrison for at least the reason that these references fail to disclose or suggest all the features of this claim. For example, as discussed during the December 6th telephone interview, Hogendijk and Garrison, either alone or in combination, fail to disclose or suggest an aspiration system “wherein upon opening of the valve with the negative pressure in the first and second chambers,

fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.”

More specifically, with reference to Figures 1B and 6A–6C of Hogendijk, this reference discloses a blood aspiration system 20 including a “manifold 50 having inlet port 54 and outlet port 55,” a “pump 60 coupled to manifold 50,” and an “arterial line 30, venous line 40, and filter chamber 70 ... coupled to manifold 50.” (Hogendijk, col. 4: 13–21.) The manifold 50 includes inlet tubing 56 “in fluid communication with suction/infusion port 52” and that “is in fluid communication with” the pump 60 via a first check valve 80.” (*Id.* at 33–40.) “Additional aspiration may be provided at the treatment site via a syringe (not shown) coupled to suction/infusion port 52.” (*Id.* at col. 5: 24–27.) When the pump 60 is actuated, fluid flows “from inlet tubing 56 into pump chamber 65 and then may flow into outlet tubing 57.” (*Id.* at col. 8: 6–11.) “[I]f desired, suction-assisted aspiration and/or infusion may be applied through suction/infusion port 52 when slide valve 100 is in a closed position.” (*Id.* at col. 8: 28–31.)

The Office Action relies on the pump 60 and the additional syringe that may be applied through the port 52 for allegedly disclosing a “first chamber” and a “second chamber,” respectively, as recited in claim 1. **However, Hogendijk fails to disclose any “fluid flow at least partially from” the additional syringe applied through the port 52 “to” the pump 60 that “causes rapid aspiration” into the additional syringe, as recited in amended claim 1.** Rather, the pump 60 and the additional syringe applied through the port 52 are separately connected to the inlet tubing 56 such that aspiration via the pump 60 and the additional syringe applied through the port 52 **separately aspirate** the inlet tubing 56 without any fluid flow from the additional syringe applied through the port 52 to the pump 60. Garrison fails to cure the deficiencies of Hogendijk. Accordingly, for at least the foregoing reasons and the reasons discussed during the December 6th telephone interview, the Applicant respectfully submits that the Section 103 rejection of independent claim 1 (and claims 2, 8, and 9 depending therefrom) over Hogedijk and Garrison should be withdrawn.

Independent claim 10, as amended, includes some features generally similar to the features of amended independent claim 1 discussed above. Accordingly, claim 10 is patentable over Hogedijk and Garrison for at least the reasons discussed above with respect to independent claim 1 and during the December 6th telephone interview, and for the additional features of this independent claim.

D. New Claims 11–20

New claims 11–20 have been added in this response. New claims 11–16 depend from independent claim 1, and new claims 17–20 depend from independent claim 10. Accordingly, new claims 11–20 are patentable over the applied references for at least the reasons discussed above with reference to claims 1 and 10, and for the additional features of these dependent claims.

Conclusion

In view of the foregoing, the pending claims comply with 35 U.S.C. § 112 and are patentable over the applied art. The Applicant accordingly requests reconsideration of the application and respectfully submits that the application is in condition for allowance. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to contact Matthew S. Williams at (206) 359-3343.

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicant is not conceding that previously pending claims are not patentable over the cited references; instead, any alteration or characterizations are being made to facilitate expeditious prosecution of this application.

The Applicant reserves the right to later pursue any previously pending or other broader or narrow claims that capture any subject matter supported by the present disclosure, including subject matter that might be found disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that

the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any underpayment or credit any overpayment to our Deposit Account No. 50-0665, under Order No. 111552-8018.US03 from which the undersigned is authorized to draw.

Dated: December 22, 2022

Respectfully submitted,

By /Matthew S. Williams/
Matthew S. Williams
Registration No.: 77,516

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Phone: (206) 359-8000
Fax: (206) 359-7198

Attorney for Applicant



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/865,315	07/14/2022	Ben Merritt	111552-8018.US03	7298
25096	7590	12/12/2022	EXAMINER	
PERKINS COIE LLP - SEA General			RASSAVONG, ERIC	
PATENT-SEA			ART UNIT	PAPER NUMBER
P.O. BOX 1247			3781	
SEATTLE, WA 98111-1247			NOTIFICATION DATE	DELIVERY MODE
			12/12/2022	ELECTRONIC

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<i>Applicant-Initiated Interview Summary</i>	Application No. 17/865,315	Applicant(s) Merritt et al.		
	Examiner ERIC RASSAVONG	Art Unit 3781	AIA (First Inventor to File) Status Yes	Page 1 of 2

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
ERIC RASSAVONG	Examiner	Telephonic
SUSAN SU	Primary Examiner	
MATTHEW S. WILLIAMS	Attorney	

Date of Interview: 06 December 2022

Issues Discussed:

35 U.S.C. 112

Examiner and Attorney agreed that amending claims 1 and 10 to further clarify that the valve is not opened with negative pressure would overcome the 112 rejections.

35 U.S.C. 103

Examiner and Attorney agreed that amending claims 1 and 10 to more specifically describe how fluid flows into and out of the first and second chambers would overcome the prior art.

Drawings

Examiner and Attorney discussed the current invention being relevant to Figures 20A-20C of the application.

/E.R./ Examiner, Art Unit 3781	/SUSAN S SU/ Primary Examiner, Art Unit 3781
<p>Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04</p> <p>Please further see: MPEP 713.04 Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b) 37 CFR § 1.2 Business to be transacted in writing</p>	

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete

<i>Applicant-Initiated Interview Summary</i>	Application No. 17/865,315	Applicant(s) Merritt et al.		
	Examiner ERIC RASSAVONG	Art Unit 3781	AIA (First Inventor to File) Status Yes	Page 2 of 2

and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: BEN MERRITT ET AL.
 APPLICATION No.: 17/865,315
 FILED: JULY 14, 2022
 FOR: SYSTEM FOR TREATING EMBOLISM AND
 ASSOCIATED DEVICES AND METHODS

EXAMINER: ERIC RASSAVONG
 ART UNIT: 3781
 CONF. NO: 7298

Proposed Agenda

**DO NOT ENTER—FOR DISCUSSION
 PURPOSES ONLY**

Examiner Nguyen,

The present paper is an agenda for a telephone interview regarding U.S. Patent Application No. 17/865,315 scheduled for Tuesday, December 6, 2022 at 1:00 PM (Eastern). I will call you at 408-918-7549.

The proposed list of participants for the interview includes:

- Examiner Rassavong
- Matthew S. Williams (Reg. No. 77,516)

During the interview, the Applicant's representative plans to discuss:

(1) Discussion of the Section 112(a) rejection of claims 1–10. *See, e.g.,* Figures 20A–20C and paragraphs [0135]–[0138] of the present application.

(2) Discussion of the Section 103 rejection of claim 1 over U.S. Patent No. 7,223,253 to Hogendijk (“Hogendijk”) and U.S. Patent Publication No. 2013/0281788 to Garrison (“Garrison”).

(a) The Applicant respectfully submits that the Section 103 rejection of claim 1 should be withdrawn because Hogendijk and Garrison, either alone or in combination, fail to disclose or suggest all the claimed features. For example, Hogendijk fails to disclose or suggest at least the following features of claim 1: “wherein upon opening of the valve with negative pressure in the first and second chambers, **fluid flow between the second chamber and the first chamber** causes rapid aspiration into the second chamber.”

(b) With reference to Figures 1B and 6A–6C of Hogendijk, this reference discloses a blood aspiration system 20 including a “manifold 50 having inlet port 54 and outlet port 55,” a “pump 60 coupled to manifold 50,” and an “arterial line 30, venous line 40, and filter chamber 70 ... coupled to manifold 50.” (Hogendijk, col. 4: 13–21.) The manifold 50 includes inlet tubing 56 “in fluid communication with suction/infusion port 52, and further is in fluid communication with” the pump 60 via a first check valve 80.” (*Id.* at 33–40.) “Additional aspiration may be provided at the treatment site via a syringe (not shown) coupled to suction/infusion port 52.” (*Id.* at col. 5: 24–27.) When the pump 60 is actuated, fluid flows “from inlet tubing 56 into pump chamber 65 and then may flow into outlet tubing 57.” (*Id.* at col. 8: 6–11.) “[I]f desired, suction-assisted aspiration and/or infusion may be applied through suction/infusion port 52 when slide valve 100 is in a closed position.” (*Id.* at col. 8: 28–31.)

(c) The Office Action relies on the pump 60 and the “additional syringe” that “may also be applied through port (52) for allegedly disclosing a “first chamber” and a “second chamber,” as recited in claim 1. However, Hogendijk fails to disclose any “fluid flow between” the pump 60 and the additional syringe applied through port 52 that “causes rapid aspiration,” as recited in amended claim 1. Rather, the pump 60 and the additional syringe applied through port 52 are separately connected to the inlet tubing 56 such that aspiration via the pump 60 and the additional syringe applied through port 52 separately aspirate the inlet tubing 56 without any fluid flow between the pump 60 and the additional syringe applied through port 52.

(d) Garrison fails to cure the deficiencies of Hogendijk. Accordingly, for at least the foregoing reasons, the Applicant respectfully submits that the Section 103 rejection of independent claim 1 over Hogendijk and Garrison should be withdrawn.



UNITED STATES PATENT AND TRADEMARK OFFICE

USPTO Automated Interview Request (AIR)

Dec 1 2022

This paper requesting to schedule and/or conduct an interview is appropriate because:

This submission is requested to be accepted as an authorization for this interview to communicate via the internet. Recognizing that Internet communications are not secure, I hereby authorize the USPTO to communicate with the undersigned concerning scheduling of the interview via video conference, instant messaging, or electronic mail, and to conduct the interview in accordance with office practice including video conferencing.

Name(s) :
Matthew Williams

S-signature:
/Matthew Williams/

Registration Number:
77516

U.S. Application Number:
17865315

Confirmation Number:
7298

E-mail Address:
matthewwilliams@perkinscoie.com

Phone Number:
+1 2063593343

Proposed Time of Interview:
12-7-2022 11:00 AM ET

Alternative Proposed Time(s) of Interview:
12-7-2022 10:00 AM ET

Alternative Proposed Time(s) of Interview:
12-8-2022 11:00 AM ET

Preferred Interview Type:
Telephonic

I am the applicant or applicant's representative for this application.

Topic for Discussion:
Will send agenda in advance of interview.



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/865,315	07/14/2022	Ben Merritt	111552-8018.US03

CONFIRMATION NO. 7298

25096
PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

PUBLICATION NOTICE



OC000000136745784

Title:SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Publication No.US-2022-0346801-A1

Publication Date:11/03/2022

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/865,315	07/14/2022	Ben Merritt	111552-8018.US03	7298
25096	7590	09/23/2022	EXAMINER	
PERKINS COIE LLP - SEA General			RASSAVONG, ERIC	
PATENT-SEA			ART UNIT	
P.O. BOX 1247			PAPER NUMBER	
SEATTLE, WA 98111-1247			3781	
			NOTIFICATION DATE	
			DELIVERY MODE	
			09/23/2022	
			ELECTRONIC	

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DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claims 1-10** are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, because the specification, while being enabling for opening of a valve, does not reasonably provide enablement for “the specific location of valve opening with negative pressure within the system”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Regarding **claim 1 and 10**, the claim is not enabled due the limitation “wherein upon opening of the valve *with negative pressure in the first and second chambers*” (emphasis added). Examiner interprets this limitation to mean that the valve can only be a passively opening one-way check valve to be opened with negative pressure in *both* the first and the

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second chambers. However, looking at the original disclosure of the current invention, there are only two valves located between the second chamber and the aspiration catheter, namely valve 126 (see Fig. 1) and valve 472 (see Figs. 4A-4C). However, valve 126 is a stopcock valve operable externally by a user ([0051] of the Specification), thus it is incapable of being opened with negative pressure. Valve 472 is opened only when the second chamber has negative pressure but NOT when the first chamber 344 has negative pressure (see Figs. 4B and 4C). Instead, a negative pressure inside the first chamber 344 will likely cause the one-way valve 472 to close. Therefore, based on the disclosure, neither of the two valves shown to be located between the second chamber and the aspiration catheter is capable of opening *with negative pressure in the first AND second chambers*. The scope of the claim is not enabled by the specification. For examination purposes, the limitation is interpreted to read as “wherein upon opening of the valve with negative pressure in the second chamber ...” With such an interpretation, the claim would be enabled because valve 472 is located between the second chamber and the aspiration catheter and it is also capable of being opened with negative pressure in the second chamber.

Regarding **claims 3 and 4**, there is no evidence in the specification that would allow the valve recited in claim 1 to be any other type of valve such as an stopcock valve because a stopcock valve cannot be opened with negative pressure. The only valve that is capable of opening with negative pressure would be a one-way check valve. Given that a stopcock valve cannot also be a valve opened with negative pressure, no prior art examination can be done on claims 3-4.

Regarding **claims 5-7**, from the interpretation of the valve of claim 1 being a one-way check valve, then the aspiration system “*further comprising a one-way valve configured to block flow from the first chamber to the second chamber and allow flow from the second to the first chamber*” would not be supported by the disclosure. The disclosure only shows a single valve located between the first and second chambers, namely valve 472, but this valve is also the only valve that meets the requirement of claim 1 by opening with negative pressure from second chamber and by allowing fluid to flow from the aspiration catheter, past the first chamber, into the second chamber. Therefore the disclosure does not provide support for a system that comprises two valves, wherein (i) the first valve is located between the aspiration catheter and the second chamber and opened by negative pressure in the second chamber, and (ii) the second valve is a one-way valve located between the first and second chambers and blocking fluid flow from the first chamber into the second chamber. Valve 472 blocks fluid flow from the second chamber into the first chamber, as shown in Fig. 4C, functioning opposite to what is required by claim 5. Examiner concludes that the embodiment recited in claim 5 is impossible because the claim effectively recites two one-way valves in the exact same location of the system acting opposite to each other. Claims 6-7 are rejected for being dependent from claim 5. No prior art rejection can be provided for claims 5-7.

Claims 2 and 8-9 are rejected for being dependent from claim 1.

4. The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. **Claims 6 and 7** are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

Claims 6 and 7 recite the limitation “the second syringe” and “the second plunger” in line 2 of the claims respectfully. Claims 1 and 5 do not mention a second syringe or a second plunger. There is insufficient antecedent basis for this limitation in the claim. Since claims 6-7 are also rejected for lack of enablement because the claimed invention cannot exist, no prior art examination can be performed.

Claim Rejections - 35 USC § 103

6. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

7. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

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1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
9. This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.
10. **Claims 1-2 and 8-10** are rejected under 35 U.S.C. 103 as being unpatentable over Hogendijk (US 7223253 B2) in view of Garrison (US 20130281788 A1).

Regarding **claim 1**, Hogendijk teaches an aspiration system with accelerated response (blood aspiration system (20) with manually actuated pumps configured to selectively vary rates of aspiration, see Abstract) (see Figure 1-6), comprising:

an aspiration pump (pump (60), see Figure 1A) in communication with a first chamber (in communication with pump chamber (65), see Figure 1B);

an aspiration catheter (21, see Figure 2) configured for placement into fluid communication with the first chamber by way of an aspiration tube (blood aspiration system (20) may be used in conjunction with catheter (21), the blood outlet port (27) is coupled to blood inlet port (34) via tubing (30), see Figures 1-2) (see Col. 4 lines 21-33);

a second chamber in between the aspiration pump and the catheter (a syringe, not shown, may be coupled to suction port (52) located between pump (60) and catheter (21), see Col. 5 lines 24-27) (see Figures 1-2); and

the first and second chambers in negative pressure (in operation plunger (62) may retract and advance to selectively choose rates of aspiration and suction-assisted aspiration, an additional syringe, may also be applied through port (52), see Col. 8 lines 20-31), fluid flow between the second chamber and the first chamber causes rapid aspiration into the second chamber (as the plungers are retracted, varying rates of aspiration may be achieved, including rapid aspiration, based on the retraction of the plungers, see Col. 8 lines 20-31) (both syringes would have rapid aspiration of fluids).

However, Hogendijk does not explicitly teach a valve between the second chamber and the aspiration catheter and opening of the valve with negative pressure.

Garrison teaches an arterial access device (2010) connected to a receptacle (3100) and a source of aspiration (3125), wherein the receptacle is connected to a flow line (2025) and a valve (check valve (3419)) between the second chamber and the aspiration catheter (check valve (3419) is located between aspiration source (3125) and aspiration catheter (3105), see Figure 15), wherein upon opening of the valve with negative pressure (valve (3419) is a one way check valve that passively opens with negative pressure from the pump (3125), see Paragraph [0085]).

Hogendijk and Garrison are analogous art because both deal with an arterial access device having an aspiration system to suction clot material.

It would have been obvious to a person having ordinary skill in the art before the effective filing date of the invention to modify the blood aspiration system of Hogendijk and further include a one-way check valve located within the arterial tubing of the system, as taught by Garrison. Garrison teaches the chamber includes input and output valves, such that when the plunger is moved up and down there is a continuous source of aspiration into and out of the chamber without the need to remove and empty the chamber as would be needed with a syringe (see last line of Paragraph [0088]). Also the having a one-way valve would allow flow to be move in one direction and not allow for contamination.

Regarding **claim 2**, Hogendijk further teaches wherein: the first chamber (65) comprises a first barrel (lumen (66)) of a first syringe (pump (60) is a syringe, see Figure 1B); the pump comprises a plunger (62) of the first syringe slidably received in the first barrel (see Figure 1B); and the second chamber comprises a second barrel of a second syringe (an additional syringe, not shown, is attached to suction port (52), see Col. 5 lines 24-27) (the syringe essentially having a second barrel and plunger).

Regarding **claim 8**, Hogendijk and Garrison further teaches wherein a negative pressure in the first chamber causes fluid flow from the second chamber to the first chamber when the valve is opened (when one-way check valve (3419 of Garrison) is opened, fluid flow can occur from the second additional syringe attached to suction port (52) into syringe (60), see Figure 6B).

Regarding **claim 9**, Hogendijk and Garrison teaches wherein the first chamber and the second chamber are configured such that both the first chamber and the second chamber can both be at a negative pressure at the same time (syringe pump (60) provides negative pressure

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to chamber (65), see Col. 7 line 42-43) (external syringe connected to vacuum port (52) provides additional aspiration by supplying negative pressure through suction of the syringe, see Col. 8 lines 28-31), and wherein upon opening the valve (passive opening of one-way check valve (3419) of Garrison) the negative pressure in the first chamber contributes to a rapid pressure drop in the catheter (rapid pressure drop within chamber (65) draws fluid into the pump chamber (65), see Col. 8 lines 28-31).

Regarding **claim 10**, Hogendijk teaches an aspiration system with accelerated response (blood aspiration system (20) with manually actuated pumps configured to selectively vary rates of aspiration, see Abstract) (see Figure 1-6), comprising: an aspiration pump (pump (60), see Figure 1A) in communication with a first chamber (in communication with pump chamber (65), see Figure 1B); an aspiration catheter (21, see Figure 2) configured for placement into fluid communication with the first chamber by way of an aspiration tube (blood aspiration system (20) comprising the may be used in conjunction with catheter (21), the blood outlet port (27) is coupled to blood inlet port (34), see Figures 1-2) (see Col. 4 lines 21-33); a second chamber in between the aspiration pump and the catheter (a syringe, not shown, may be coupled to suction port (52) located between pump (60) and catheter (21), see Col. 5 lines 24-27) (see Figures 1-2); with negative pressure in the first and second chambers, fluid flow between the second chamber and the first chamber causes rapid decrease in pressure in the aspiration catheter (as the plungers are retracted, varying rates of aspiration may be achieved, including rapid aspiration, based on the retraction of the plungers, see Col. 8 lines 20-31) (both syringes would have rapid aspiration of fluids and decreased pressure). However, Hogendijk does not

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explicitly teach a valve between the second chamber and the aspiration catheter; and opening of the valve with negative pressure in the first and second chamber.

Garrison teaches an arterial access device (2010) connected to a receptacle (3100) and a source of aspiration (3125); wherein the receptacle compresses a flow line (2025) and a valve (check valve (3419)) between the second chamber and the aspiration catheter (check valve (3419) is located between aspiration source (3125) and aspiration catheter (3105), see Figure 15); wherein upon opening of the valve with negative pressure (opening valve (3419) is a one way check valve that passively opens with negative pressure from the pump (3125), see Paragraph [0085]).

Hogendijk and Garrison are analogous art because both deal with an arterial access device having an aspiration system to suction clot material.

It would have been obvious to a person having ordinary skill in the art before the effective filing date of the invention to modify the blood aspiration system of Hogendijk and further include a one-way check valve located within the arterial tubing of the system, as taught by Garrison. Garrison teaches the chamber includes input and output valves, such that when the plunger is moved up and down there is a continuous source of aspiration into and out of the chamber without the need to remove and empty the chamber as would be needed with a syringe (see last line of Paragraph [0088]). Also the having a one-way valve would allow flow to be move in one direction and not allow for contamination.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Vale (WO 2015189354 A1) teaches an aspiration system with accelerated response (see Abstract) , comprising: an aspiration pump (manual syringe (811), see Figure 65) in communication with a first chamber (first chamber of the syringe (811)); an aspiration catheter (801) configured for placement into fluid communication with the first chamber by way of an aspiration tube (first chamber of syringe (811) is in fluid communication with aspiration catheter (101) by way of a tube, as shown below); a second chamber (chamber located between rotating hemostasis valve (814) and syringe (811), see below) in between the aspiration pump (811) and the catheter (801) (see Figure 65). However, Vale fails to teach a valve between the second chamber and the aspiration catheter; wherein upon opening of the valve with negative pressure in the first and second chambers, fluid flow between the second chamber and the first chamber causes rapid aspiration into the second chamber.

Ogle (US 10478535 B2) teaches an aspiration system with accelerated response (see Figure 1), comprising: an aspiration pump (aspiration source (600)) in communication with a first chamber (aspiration source (600) include a syringe pump having a first chamber); an aspiration catheter (catheter system (100) having an access sheath (220) and a sheath body (222), see Figure 1) configured for placement into fluid communication with the first chamber by way of an aspiration tube (first chamber of aspiration syringe (600) is connected to access sheath (220) via aspiration line (230), see Figure 1). However, Ogle fails to disclose a second chamber in between the aspiration pump and the catheter; and a valve between the second chamber and the aspiration catheter; wherein upon opening of the valve with negative pressure in the first and second chambers, fluid flow between the second chamber and the first chamber causes rapid aspiration into the second chamber.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC RASSAVONG whose telephone number is (408)918-7549.

The examiner can normally be reached Monday - Friday 9:00am-5:30pm PT.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas J. Weiss can be reached on (571)270-1775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit:

<https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E.R./ (9/19/2022)
Examiner, Art Unit 3781

/SUSAN S SU/
Primary Examiner, Art Unit 3781
19 September 2022

<i>Notice of References Cited</i>	Application/Control No. 17/865,315		Applicant(s)/Patent Under Reexamination Merritt et al.	
	Examiner ERIC RASSAVONG		Art Unit 3781	Page 1 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20130281788-A1	10-2013	Garrison; Michi E.	A61B17/221	606/127
*	B	US-20140155830-A1	06-2014	BONNETTE; MICHAEL J.	A61M25/0026	604/150
*	C	US-20170196576-A1	07-2017	Long; Jerry	A61M3/0208	1/1
*	D	US-20070010787-A1	01-2007	Hackett; Steven S.	A61B17/22032	604/96.01
*	E	US-20170319221-A1	11-2017	CHU; Michael S.H.	A61B17/22	1/1
*	F	US-20110196309-A1	08-2011	Wells; John F.	A61M5/14216	604/173
*	G	US-20140296868-A1	10-2014	Garrison; Michi E.	A61B17/22	606/127
*	H	US-20010049486-A1	12-2001	Evans, Michael A.	A61M1/3621	604/35
*	I	US-20100217276-A1	08-2010	Garrison; Michi E.	A61M1/3613	604/9
*	J	US-20140257363-A1	09-2014	Lippert; John	A61B17/12031	606/200
*	K	US-20150173782-A1	06-2015	Garrison; Michi E.	A61M25/0662	606/127
*	L	US-20170056032-A1	03-2017	LOOK; DAVID M.	A61M1/74	1/1
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Notice of References Cited</i>	Application/Control No. 17/865,315		Applicant(s)/Patent Under Reexamination Merritt et al.	
	Examiner ERIC RASSAVONG		Art Unit 3781	Page 2 of 2

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*	A	US-20150133990-A1	05-2015	DAVIDSON; James	A61B17/221	606/200
*	B	US-20180104404-A1	04-2018	Ngo-Chu; Don Q.	A61M29/02	1/1
*	C	US-6719717-B1	04-2004	Johnson; Matthew S.	A61M1/34	604/9
*	D	US-10478535-B2	11-2019	Ogle; Matthew F	A61M25/0074	1/1
*	E	US-6960189-B2	11-2005	Bates; Mark C.	A61M1/7413	604/35
*	F	US-7004931-B2	02-2006	Hogendijk; Michael	A61M1/7413	604/129
*	G	US-7223253-B2	05-2007	Hogendijk; Michael	A61M1/81	604/9
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NON-PATENT DOCUMENTS

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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Search Notes</i> 	Application/Control No. 17/865,315	Applicant(s)/Patent Under Reexamination Merritt et al.
	Examiner ERIC RASSAVONG	Art Unit 3781

CPC - Searched*		
Symbol	Date	Examiner
A61B17/12109, 17/221, 2017/22034, 2017/22079, 17/005	09/10/2022	/E.R./
A61F2/01	09/10/2022	/E.R./
A61M1/84,25/10	09/10/2022	/E.R./

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
CPC and Text Searching Completed	09/10/2022	/E.R./
Inventor Name Search in PALM	09/10/2022	/E.R./
Consulted Primary Examiner Susan Su on Prior art	09/13/2022	/E.R./

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/E.R./ Examiner, Art Unit 3781	
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PE2E SEARCH - Search History (Prior Art)

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L6	6524	A61B2017/22079.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/08/31 05:04 PM
L7	26737	A61B2217/005.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD,	OR	ON	ON	2022/08/31 05:04 PM

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L9	16978	A61F2/01.cpc. AND A61M 25/10	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/08/31 05:31 PM
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L12	109	A61M1/84.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/08/31 05:31 PM
L13	1007	A61B17/221.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/08/31 05:31 PM
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L20	200	A61B2017/22034.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/08/31 05:33 PM
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L52	172	("4575371" "4781681" "4794928" "4921478"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/02 10:58 AM

L53	188	"5011488" "5102415"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/02 11:12 AM
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L54	62	("2002/0035347").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/02 11:22 AM
L55	68	("5011488" "5226888" "5385562" "5527292" "5569204" "5938645" "6849068" "20020177800" "20030050600").pn. OR ("7736355").urpn. AND (PGPB USPT	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/02 11:24 AM

L56	133	USOC).dbnm. ("2623520" "3612050" "3631848" "4013080" "4406656" "4946443" "5207648" "5267960" "5338300" "5370623" "5385562" "5484407" "5527292" "5591194" "5658309" "5776141" "5997523" "6120480" "6238430" "6676637" "6692473" "6740104" "6755803" "7033325" "7232452" "7316678" "7374560" "7604612" "7736355" "7850654" "7854746" "7967789" "7972294" "8021351" "8048032" "8142413" "8157760" "8172831" "8251978" "8292850" "8425549" "8465456" "8523801" "8708954" "8758325" "RE45380" "8996095" "9034007" "9144662" "RE45760" "RE45776" "9241699" "9265512" "20020091407" "20020173785" "20030050600" "20060259063" "20090264865" "20090281379" "20100217276" "20100268029" "20120095485" "20130116701" "20140025043" "20140296868" "20140358178" "20150173782" "20150174368" "20160220741").pn. OR ("9681882").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/02 11:26 AM
L57	11	A61B17/221.cpc. AND A61M1/84.cpc. AND A61F2/01.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/06 03:45 PM
L58	11	A61B2017/22034.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/06

		AND A61B17/221.cpc. AND A61M1/84.cpc. AND A61F2/01.cpc. AND A61B17/12109.cpc.	USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				03:45 PM
L59	11	A61B2017/22079.cpc. AND A61B2017/22034.cpc. AND A61B17/221.cpc. AND A61M1/84.cpc. AND A61F2/01.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/06 03:46 PM
L60	3862	(A61M25/10.cpc. A61B2217/005.cpc. A61B2017/22079.cpc. A61B2017/22034.cpc. A61B17/221.cpc. A61M1/84.cpc. A61F2/01.cpc. A61B17/12109.cpc.) AND rapid AND aspiration	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/06 03:46 PM
L61	653	(A61M25/10.cpc. A61B2217/005.cpc. A61B2017/22079.cpc. A61B2017/22034.cpc. A61B17/221.cpc. A61M1/84.cpc. A61F2/01.cpc. A61B17/12109.cpc.) AND rapid WITH aspiration	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/06 03:47 PM
L62	6	"2018148174".pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/07 10:48 AM
L63	6	"2015189354".pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/07 11:06 AM
L64	7	"2009082513".pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU,	OR	ON	ON	2022/09/07 11:55 AM

L65	4	"20150133990".pn.	SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/08 11:00 AM
L66	6	"5376101".pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/08 04:15 PM
L67	2013	(A61M25/10.cpc. A61B2217/005.cpc. A61B2017/22079.cpc. A61B2017/22034.cpc. A61B17/221.cpc. A61M1/84.cpc. A61F2/01.cpc. A61B17/12109.cpc.) AND rapid AND syringe AND chamber AND (two second multiple)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/08 04:24 PM
L68	340	(A61M25/10.cpc. A61B2217/005.cpc. A61B2017/22079.cpc. A61B2017/22034.cpc. A61B17/221.cpc. A61M1/84.cpc. A61F2/01.cpc. A61B17/12109.cpc.) AND rapid AND syringe AND chamber NEAR (two second multiple)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/08 04:24 PM
L69	2	"10952882".pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/08 04:40 PM
L70	490	("4301803" "4493707" "4771777" "4840690" "4865581" "4921478" "4921479" "4954126" "5007921" "5026390" "5031636" "5045061" "5061275" "5135484"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/08 04:40 PM

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L71	1173	rapid AND aspiration AND (catheter NEAR (dual two multiple))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/08 05:59 PM
L72	1152	rapid AND aspiration AND catheter AND (syringe NEAR (dual two multiple))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/08 06:00 PM
L73	38	(Artificial Intelligence) More like doc: US-20110196309-A1 <hr/> Text: (WO-2011068507-A1 OR US-20110130714- A1 OR ES-2644639-T3 OR WO-2021207122- A1 OR US- 20100312184-A1 OR US-8328787-B2 OR US-20220134014-A1 OR JP-2013521938-A OR US-20220134015- A1 OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT;	OR	ON	ON	2022/09/08 06:05 PM

		20150320964-A1 OR WO-2012116100-A1 OR US-20120271254- A1 OR JP-4618713-B2 OR CN-114642475-A OR EP-3159029-A1 OR US-20210308386-A1 OR US-11229750-B2 OR US-20110245779- A1 OR JP-2003502091- A OR US-8858518- B2).did.	IBM_TDB)				
L74	1	("2011/0196309").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/08 06:07 PM
L75	82	("2001/0049486").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/10 12:01 PM
L76	51	rapid AND aspiration AND catheter AND (syringe NEAR (series serial))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/14 07:04 PM
L77	676	(A61M25/10.cpc. A61B2217/005.cpc. A61B2017/22079.cpc. A61B2017/22034.cpc. A61B17/221.cpc. A61M1/84.cpc. A61F2/01.cpc. A61B17/12109.cpc.) AND rapid AND syringe AND (check NEAR valve)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/15 05:21 PM
L78	1245	(A61M25/10.cpc. A61B2217/005.cpc. A61B2017/22079.cpc. A61B2017/22034.cpc. A61B17/221.cpc. A61M1/84.cpc. A61F2/01.cpc. A61B17/12109.cpc.) AND (check NEAR valve)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/15 06:05 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

Doc code: IDS

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17/865,315 - Conf# 7298
	Filing Date	July 14, 2022
	First Named Inventor	Ben Merritt
	Art Unit	Not Yet Assigned 3781
	Examiner Name	Not Yet Assigned Eric Rassavong
	Attorney Docket Number	111552-8018.US03

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Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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	Attorney Docket Number	111552-8018.US03

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	Attorney Docket Number	111552-8018.US03

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EXAMINER SIGNATURE

Examiner Signature	/ERIC RASSAVONG/ (09/07/2022)	Date Considered	09/07/2022
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information that may be material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, Applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

COPIES OF REFERENCES

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2).

Those documents which are marked with a double asterisk (**) next to the Cite No. in the attached form PTO/SB/08 are not supplied because they were previously cited by or submitted to the Office in prior application number **16/536,185** and filed on **August 8, 2019** and relied upon in this application for an earlier filing date under 35 U.S.C. § 120.

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SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2022-09-06
Name/Print	Matthew S. Williams	Registration Number	77,516

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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EXAMINER SIGNATURE

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information that may be material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, Applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

COPIES OF REFERENCES

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2).

Those documents which are marked with a double asterisk (**) next to the Cite No. in the attached form PTO/SB/08 are not supplied because they were previously cited by or submitted to the Office in prior application number **16/536,185** and filed on **August 8, 2019** and relied upon in this application for an earlier filing date under 35 U.S.C. § 120.

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SIGNATURE			
A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.			
Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2022-09-06
Name/Print	Matthew S. Williams	Registration Number	77,516
<p>This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</p>			



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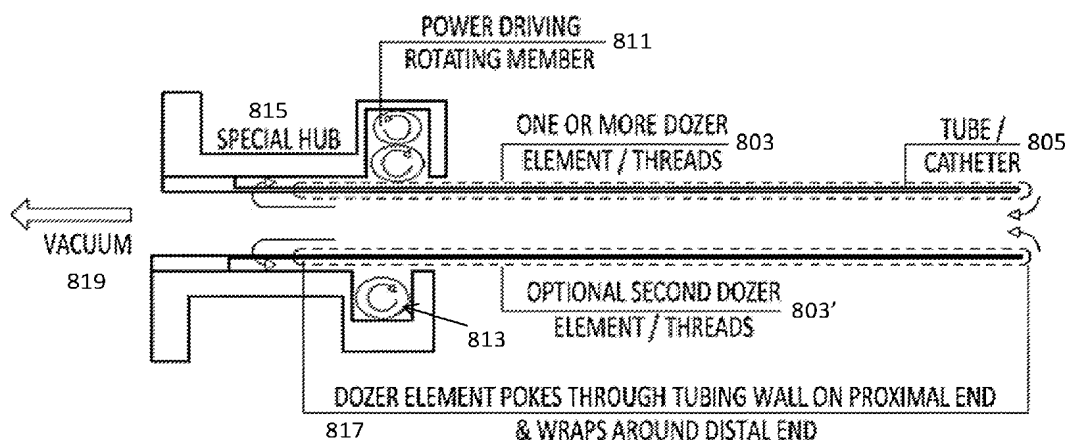
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FIG. 8A

(57) Abstract: Mechanical thrombectomy apparatuses (devices, systems, etc.) are configured for being positioned within a vessel and used to remove a thrombus, e.g., clot, from within a vessel. One such system includes an inverting tractor thrombectomy apparatus having a tractor comprising a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support by extending the tractor region and/or a puller coupled to the tractor distally beyond the end of the catheter.

INVERTING MECHANICAL THROMBECTOMY APPARATUSES AND METHODS OF USE IN THE VASCULATURE

FIELD

[0001] The apparatuses and methods described herein relate to inverting mechanical thrombectomy apparatuses and methods of their use.

BACKGROUND

[0002] It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue from within a vasculature, such as blood clots, may improve patient conditions and quality of life.

[0003] Many vascular system problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery.

[0004] When a thrombus forms, it may effectively stop the flow of blood through the zone of formation. If the thrombus extends across the interior diameter of an artery, it may cut off the flow of blood through the artery. If one of the coronary arteries is 100% thrombosed, the flow of blood is stopped in that artery, resulting in a shortage of oxygen carrying red blood cells, e.g., to supply the muscle (myocardium) of the heart wall. Such a thrombosis is unnecessary to prevent loss of blood but can be undesirably triggered within an artery by damage to the arterial wall from atherosclerotic disease. Thus, the underlying disease of atherosclerosis may not cause acute oxygen deficiency (ischemia) but can trigger acute ischemia via induced thrombosis. Similarly, thrombosis of one of the carotid arteries can lead to stroke because of insufficient oxygen supply to vital nerve centers in the cranium. Oxygen deficiency reduces or prohibits muscular activity, can cause chest pain (angina pectoris), and can lead to death of myocardium which permanently disables the heart to some extent. If the myocardial cell death is extensive, the heart will be unable to pump sufficient blood to supply the body's life sustaining needs. The extent of ischemia is affected by many factors, including the existence of collateral blood vessels and flow which can provide the necessary oxygen.

[0005] Clinical data indicates that clot removal may be beneficial or even necessary to improve outcomes. For example, in the peripheral vasculature, inventions and procedures can reduce the need for an amputation by 80 percent. The ultimate goal of any modality to treat these conditions of the arterial or venous system is to remove the blockage or restore patency, quickly, safely, and cost effectively. This may be achieved by thrombus dissolution, fragmentation, thrombus aspiration or a combination of these methods.

[0006] Mechanical thrombectomy devices may be particularly advantageous. Depending on the size, location and extent of a clot, it may also be particularly advantageous to mechanically retrieve and break apart the clot in a manner that is both safe and effective. There is a definite need for a thrombectomy device, and particularly a mechanical thrombectomy device that can be more effective in removing tissue such as clots from within a body. Described herein are apparatuses (devices, systems and kit) and methods of using them that may address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[0007] Described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and methods for using them to remove a thrombus, e.g., clot, from within a vessel. These mechanical thrombectomy apparatuses may be inverting tractor thrombectomy apparatuses. Typically, the mechanical thrombectomy apparatuses described herein are inverting tractor thrombectomy apparatuses that include a tractor (e.g., tractor region, tractor portion, etc.) comprising a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support. The elongate inversion support typically comprises a catheter having a distal end opening into which the tractor inverts. The flexible tractor inverts and rolls back into itself and may be drawn into the elongate inversion support in a conveyor-like motion; the outward-facing region rolls around to become an inward-facing region, e.g., within the lumen of the elongate inversion support. The rolling motion may thus draw a clot or other object within a vessel into the elongate inversion support.

[0008] Before these apparatuses can remove a clot from a vessel, however, they must be positioned within the vessel adjacent to the clot to be removed. As described herein, the inverting tractor thrombectomy apparatuses described herein may be accurately positioned either with or without the use of a guidewire or guide sleeve within a vessel by taking advantage of the rolling motion of tractor at the distal end of the apparatus. The arrangement of the tractor, elongate inversion support (e.g. which may be or may include a catheter) and the puller connected to the tractor may be used to easily and accurately position the apparatus

adjacent a clot and remove the clot in a manner that may be both easier and more efficient than other methods.

[0009] Further described herein are systems and methods for advancing an inverting tractor thrombectomy apparatus forward in the vasculature. These systems and methods may use the rolling motion of the tractor to move through the vasculature including over/around clot.

[0010] For example, described herein are systems and methods for removing a clot from a vessel using a mechanical thrombectomy apparatus. The mechanical thrombectomy apparatus may include an elongate inversion support (comprising or consisting of a catheter) that extends in a long axis from a proximal end to a distal end, a puller extending distally within the elongate inversion support (e.g. catheter) and a flexible and tubular tractor, wherein the tractor is coupled to a distal end region of the puller and further wherein the tractor is inverted over a distal end opening of the catheter so that the tractor extends proximally over the catheter. Illustrative methods using the apparatus may include: advancing the puller distally within the elongate inversion support (e.g., catheter) and within the vessel towards a clot, so that the tractor extends from the puller distally beyond the distal end opening of the catheter, forming a gap between the tractor and the distal end opening of the catheter; advancing the catheter distally over the puller and into the gap; and drawing the clot into the catheter with the tractor by pulling the tractor proximally within the catheter so that the tractor rolls and inverts over the distal end opening of the catheter.

[0011] Further illustrative methods include repeating the advancing steps one or more times. For example the method may include: advancing the puller distally within the elongate inversion support (e.g., catheter) and within the vessel towards a clot, so that the tractor extends from the puller distally beyond the distal end opening of the catheter, forming a gap between the tractor and the distal end opening of the catheter; advancing the catheter distally over the puller and into the gap; repeating the advance steps until the distal end opening of the catheter is adjacent to the clot; and drawing the clot into the catheter with the tractor by pulling the tractor proximally within the catheter so that the tractor rolls and inverts over the distal end opening of the catheter.

[0012] These illustrative methods for advancing the clot pulling apparatus may therefore be described as “inchworm” type advancement, as the tractor is extended from within the catheter to distally extend in the vessel, then the catheter may follow the tractor distally. In any of these methods, the tractor may be ‘reset’ back into the catheter (as it may otherwise be left deployed out of the catheter along vessel), by pulling it back into the catheter. For

example, the tractor may be pulled back into the catheter by pulling proximally on the puller once the catheter distal end opening is positioned against the distal-facing tractor (the region doubling-back or inverting over itself) so that the tractor can roll over the distal end opening. Resetting or repositioning the tractor in this manner may require that the apparatus be configured to prevent jamming (e.g., “anti-jamming”), including one or more of: having a lubricious and/or smooth tip, having a tip region that is more rigid than the more proximal regions of the tip, and/or having a tractor that is biased to have a first relaxed configuration that has an outer diameter that is greater than the inner diameter of the catheter and a second relaxed configuration that has an inner diameter that is greater than the outer diameter of the catheter, where the tractor converts between the first and second configurations by inverting over itself (e.g., over the distal end opening of a catheter). These configurations may prevent the tractor for buckling when pushed out of the distal end opening or when pulled back into the distal end opening of the catheter.

[00013] The repeated steps of inching forward by extending the tractor distally (e.g., pushing the puller coupled to the tractor distally, including distally out of the distal opening of the catheter), then advancing the catheter into the gap formed by the folded-over tractor, e.g., the gap between the distal end opening of the catheter and the tractor, may also include resetting the tractor by pulling the tractor back into the catheter once the distal end of the catheter has been advanced. The steps of advancing the tractor distally from the distal- end of the catheter and advancing the catheter behind the tractor (and optionally pulling the tractor back into the catheter by pulling proximally while holding the catheter fixed (or advancing it distally) may be repeated until the apparatus is adjacent to the clot; thereafter the clot can be removed as discussed above, by pulling the puller proximally to draw the tractor into the catheter.

[00014] In general, drawing the clot into the catheter may include advancing the catheter distally while pulling the pusher proximally. Further, the apparatus may be advanced distally (or retracted proximally) without the use of a guidewire or guide catheter. For example, advancing the puller distally may comprise advancing the puller without using a guidewire extending distal to the puller. Advancing the puller may comprise extending the distal end of the puller out of the distal end opening of the catheter. Alternatively the puller may remain in the catheter when advanced distally.

[00015] The tractor may be any appropriate tractor, including a woven, braided, or knitted tractor, or a tractor formed of a solid sheet of material (e.g., that may be cut or perforated). For example, advancing the puller may comprise extending the tractor distally within the

vessel, further wherein the tractor comprises a woven flexible and tubular tractor. Advancing the puller may comprise extending the tractor distally within the vessel, further wherein the tractor comprises a knitted tractor.

[00016] The systems described herein include a puller and tractor having a lumen (e.g., central lumen) through which a guidewire may be advanced. For example, advancing the puller may comprise extending the tractor distally within the vessel, further wherein the puller comprises a central lumen configured to pass a guidewire therethrough.

[00017] Further, the systems and methods described herein may be used (and performed) in any vessel within the body, including peripheral and neurovascular vessels. For example, these systems and methods may be used (performed) within an internal carotid artery (e.g., advancing the puller may comprise advancing the puller within an internal carotid artery).

[00018] Also described herein are systems including a mechanical thrombectomy apparatus that may be positioned within a vessel for removing a clot from within the vessel, in which the mechanical thrombectomy apparatus includes a puller within a first catheter that is within a second catheter, wherein the puller and second catheter are connected by a flexible and tubular tractor. For purposes of illustration, a method using such system may comprise: advancing the puller distally through the first catheter and the second catheter and within the vessel towards a clot, so that the flexible and tubular tractor extends from the puller beyond a distal end opening of the first catheter and beyond a distal end opening of the second catheter; advancing the outer catheter distally through the vessel by one or more of: holding the position of the first catheter within the vessel and pulling the puller proximally within the first catheter; or moving the first catheter distally relative to the puller; and drawing the clot into the first catheter with the flexible and tubular tractor by pulling the flexible and tubular tractor proximally within the first catheter so that the flexible and tubular tractor rolls and inverts over the distal end opening of the catheter. Any of these methods may also include repeating the advancing steps until the clot is adjacent to the distal end of the puller.

[00019] Drawing the clot into the catheter may further include advancing the first catheter distally while pulling the pusher proximally. Advancing the puller distally may include advancing the puller without using a guidewire extending distal to the puller. Advancing the puller may include extending the flexible and tubular tractor distally within the vessel further wherein the flexible and tubular tractor comprises a woven flexible and tubular tractor. Alternatively, advancing the puller may include extending the flexible and tubular tractor distally within the vessel further wherein the flexible and tubular tractor comprises a knitted flexible and tubular tractor.

[00020] Advancing the puller may comprise extending the flexible and tubular tractor distally within the vessel further wherein the puller has a central lumen configured to pass a guidewire therethrough, and drawing the clot into the first catheter may comprise uncoupling the flexible and tubular tractor from the second catheter.

[00021] Also described herein are mechanical thrombectomy apparatus for removing a clot from a vessel that include a motorized or motor-driven tractor. For example described herein are apparatuses including: a flexible catheter having a distal end and a distal end opening; a tractor comprising a flexible belt that extends within the catheter, inverts over the distal end opening of the catheter and extends along the outer diameter of the catheter; a power drive at a proximal end of the flexible catheter configured to drive the tractor around the catheter so that it inverts over the distal end opening of the catheter; and a guidewire lumen through the catheter and the tractor configured to pass a guidewire.

[00022] The flexible belt may comprise a flexible tube. In some variations, the tractor comprises a plurality of flexible belts that each extend within the catheter, invert over the distal end opening of the catheter and extend along the outer diameter of the catheter.

[00023] The the power drive may be configured to engage with the flexible belt on an outer surface of the catheter. The power drive may comprise an annular ring surrounding the catheter and the tractor.

[00024] Any of these apparatuses may include an outer catheter configured to enclose the flexible catheter and tractor, wherein the flexible catheter and tractor may be inserted through the body within the outer catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[00025] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00026] FIGS. 1A-1H illustrate an example of a mechanical thrombectomy apparatus for mechanically removing an object such as a clot form a body region. FIG. 1A shows an example of an elongate inversion support portion of an apparatus, configured as a catheter. For example, at least the distal end of the elongate inversion support may be configured as a catheter. FIG. 1B shows an enlarged view of a distal end (opening) of the catheter of the elongate inversion support of FIG. 1A, showing the aperture formed by the distal end

opening; FIG. 1C shows an example of a distal tractor region of a flexible tube (tractor tube) extending from a puller (the puller in this example is configured as a catheter. The tractor is shown in a first (e.g., un-inverted) configuration) and may be biased open, e.g., by heat setting, to have an outer diameter that is greater than the inner diameter of the catheter of the elongate inversion support, as shown in FIG. 1D. FIG. 1D shows the same distal tractor region of FIG. 1C with the expandable first end region expanded. This first configuration may be compressed down into the elongate inversion support and the distal end inverted over the catheter portion of the elongate inversion support, as shown in FIG. 1E. In FIG. 1E, the assembled mechanical thrombectomy apparatus with the elongate inversion support and the flexible tube forming the tractor is shown. The tractor extends through the catheter of the elongate inversion support and doubles back over the distal end opening of the catheter and extends over the outer diameter of the catheter. The outer portion of the tractor (extending along the outer diameter of the catheter) may be held in a collapsed configuration (as shown in FIG. 1E), or it may be expanded, as shown in FIG. 1F. Thus, the tractor may be biased so that in the second configuration (inverted over the distal end of the catheter), the tractor has a 'relaxed' outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. FIGS. 1G and 1H illustrate the use of the apparatus of FIGS. 1E and 1F to remove a clot by drawing the flexible tube proximally and/or advancing the catheter distally towards the clot so that the expandable first end region inverts as it is drawn into the distal end of the catheter, pulling the clot into the catheter.

[00027] FIG. 1I illustrates an alternative variation of a tractor and puller. In FIG. 1I, the tractor is shown attached to the distal end of a tapered or narrow puller; the distal end region is tapered, and includes a radiopaque marker at or near the attachment site to the tractor; the tractor may be knitted, braided, woven, etc. Thus, in some variations the distal end region of the puller may have a greater flexibility than the proximal end of the puller. The puller may be hollow (e.g., a catheter or hypotube) or solid (e.g., like a wire).

[00028] FIGS. 2A-2E illustrate a method of positioning a mechanical thrombectomy apparatus within a vessel and/or removing a clot from a vessel using the mechanical thrombectomy apparatus. In FIGS. 2A-2E the apparatus is shown inching distally within the vessel towards the clot using the tractor, so that the clot may be captured and removed by the tractor. In FIGS. 2A-2E the apparatus is advanced distally without the use of a guidewire.

[00029] FIGS. 3A-3D illustrate a method of positioning a mechanical thrombectomy apparatus within a vessel and/or removing a clot from a vessel using the mechanical thrombectomy apparatus similar to that shown in FIGS. 2A-2E only using a guidewire.

[00030] FIGS. 4A-4D illustrate a method of positioning a mechanical thrombectomy apparatus within a vessel and/or removing a clot from a vessel using the mechanical thrombectomy apparatus in which the distal end of the puller, to which one end of the tractor is attached, is extended distally from the catheter.

[00031] FIGS. 5A-5C illustrate a method of positioning a mechanical thrombectomy apparatus within a vessel and/or removing a clot from a vessel using the mechanical thrombectomy apparatus similar to that shown in FIGS. 4A-4D but include the use of a guidewire.

[00032] FIGS. 6A-6B illustrates another method of positioning a mechanical thrombectomy apparatus within a vessel and/or removing a clot from a vessel using the mechanical thrombectomy apparatus, in which the apparatus include a tractor that is connected (attached) to both the pusher and an outer catheter or element.

[00033] FIG. 7 illustrates one region (e.g., the internal carotid artery) in which the apparatuses and methods described herein may be used.

[00034] FIG. 8A-8B illustrate an example of a mechanical thrombectomy apparatus for removing a clot from a vessel that include a motorized or motor-driven tractor. FIG. 8A shows the apparatus in a side view, schematically illustrating the internal components. FIG. 8B is an example of a catheter and tractor(s) that may be used with an apparatus such as the one shown in FIG. 8A.

[00035] FIGS. 9A-9B illustrate a method of operating a mechanical thrombectomy apparatus for removing a clot from a vessel that include a motorized or motor-driven tractor, such as the one shown in FIGS. 8A-8B. FIG. 9C illustrates a motorized or motor-driven (e.g., “power driven) continuous tractor that is loaded into a larger catheter (e.g., an intermediate catheter).

DETAILED DESCRIPTION

[00036] Described herein are mechanical thrombectomy apparatuses, including manually drive and power-driven apparatuses, and methods of using them. In particular, described herein are methods of positioning these apparatuses within a vessel and/or removing clot with them that may include extending the tractor region and/or the puller distally of the distal end of the apparatus to assist in advancing the apparatus distally.

[00037] Any of the mechanical thrombectomy apparatuses described herein may have an inverting tractor that is configured to prevent jamming and grab a blood clot. These

apparatuses may include an elongate elongate inversion support support that supports an annulus over which the tractor inverts at the distal end. The tractor may comprise a flexible tube that doubles back over (e.g., inverts) over the distal end of the elongate inverting support (e.g., a catheter) so that it extends into the annulus opening of the elongate inverting support and an inner puller coupled to the inner end of the tractor that the tractor can be pulled proximally to pull and invert the tractor over the annulus at the distal end of the elongate inverting support to roll and capture a clot. The apparatus may include a guidewire lumen extending through the elongate inverting support, and/or tractor puller that is configured to pass a guidewire.

[00038] The apparatuses described herein may be adapted to prevent jamming, e.g., by including a coating (e.g., hydrophilic, lubricious coating, etc.) or the like to enhance the sliding and inverting of the tractor over the distal end. Further, any of these apparatuses may include one or more projections that are configured to enhance grabbing and/or maceration of a clot. Grabbing of a clot may be particularly, but not exclusively, helpful when the tractor is lubricious. Although lubricious tractors may resist jamming and require less force to operate, e.g., inverting over the distal end of the catheter, it may be more difficult to initially grab or grasp clot when the tractor is more lubricious. It may also be particularly helpful to include projections that are retracted along the length of the tractor adjacent to the outer diameter of the elongate inverting support (e.g., catheter), for example, when positioning the apparatus within a vessel, but extend the projections outward from the tractor when rolling and inverting to grab a clot.

[00039] In general, a mechanical thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an elongate inversion support having a distal end and a distal annulus, and a flexible tractor assembly at least partially inverted and configured to roll and invert over the distal annulus of the elongate inverting support.

[00040] In many of the examples described herein, the elongate inversion support is a catheter (or a portion of a catheter at the distal end) and the annulus is formed by the distal end opening of the catheter; the tractor extends within the catheter and doubles back over the distal end of the catheter to extend over the outer diameter of the catheter at the distal end of the catheter, although it may extend proximal for any appropriate distance (including between 1-30 cm, between 2-20 cm, greater than 1 cm, 2 cm, 3 cm, 4 cm, 5 cm, 6 cm, 7 cm, 8 cm, 9 cm, 10 cm, 11 cm, 12 cm, 15 cm, 20 cm, etc.). The end of the tractor within the catheter may be coupled to a puller (e.g., at a proximate puller region connected to the distal or inner end of the tractor). The tubular tractor may include an elongate lumen that is configured to

allow passage of a guidewire. The tubular tractor may also be configured to slide along the long axis within the catheter lumen and invert over the distal end opening of the catheter when the proximal end region is pulled proximally. The tractor may be referred to herein as a tractor assembly, tractor portion, tractor tube, or simply a tractor, and is typically positioned and longitudinally slideable within the catheter, and arranged so a portion of the tractor (sometimes referred to as the “distal tractor region” or “distal-facing” tractor region) doubles back over itself.

[00041] For example, FIG. 1A shows one variation of a catheter of an elongate inversion support that may form part of the apparatuses described herein. In this example, the elongate inversion support includes a catheter 100 having a distal end region 103 that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing hardness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1 mm, 0.8 mm, 0.5 mm, 0.3 mm, 0.2 mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00042] In FIG. 1A, the elongate inversion support is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include a elongate inversion support that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like (as will be described in greater detail below in reference to FIGS. 42A-43D) or may be skived. Thus, any of the apparatuses and methods described herein may be adapted for use with an elongate inversion support that

is not limited to catheters, including elongate inversion supports that include a portion of a catheter, or that include a ring or other structure forming the annulus at the distal end. In FIG. 1A the catheter 100 of the elongate inversion support may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00043] In some variations the distal end 105 of the elongate inversion support is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in some variations the distal tip (end) may be curved or radiused 109 as shown in FIG. 1B, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[00044] FIG. 1C shows an example of a flexible tractor 144 coupled to a puller 146. In this example to form a pullable tractor assembly 140, the tractor is shown integrated with the puller, forming the assembly. In FIG. 1C, the tractor is a tube of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The tractor is shown extended from the puller in a first configuration. It may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 144 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The puller 146 may typically be a less-expandable (or non-expandable) structure (tube, puller, etc.). In the example shown in FIG. 1C, the tractor 144 is configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first configuration to a radial diameter that is between 1.1 and 10 times the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained, as shown in FIG. 1D. In FIG. 1D, the tractor of FIG. 1C is shown in an expanded, relaxed, configuration. Thus the expandable tractor may be biased to expand open. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00045] In FIGS. 1C and 1D the tractor and puller have two portions, a tractor 144 and a less expandable (or non-expandable) proximal portion comprising the puller 146. The puller may be a separate region, such as a wire, catheter or hypotube, which is connected to an end region of the tractor (e.g., a flexible mesh, woven, braided, etc.), e.g., the distal end or near the distal end. The inverting region of the tractor, where it rolls and inverts over the distal end opening of the catheter may be referred to as the distal-facing region of the tractor, which may actively grab clot when rolling.

[00046] In FIG. 1E, the flexible tractor of FIG. 1C is shown with the tractor doubled back over itself an over the the distal end of the catheter of the elongate inversion support 101. The distal end region is collapsed down, e.g., onto the puller and the elongate inversion support, and may be held collapsed. In this example a tractor hold 188 may be used to hold the tractor collapsed down onto the outer diameter of the elongate inversion support. However, in an unconstrained or deployed configuration, as shown in FIG. 1F, the tractor in this second configuration (e.g., the portion that is inverted over the distal end of the catheter) has an outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. Thus, the tractor 144 may be biased so that it has a relaxed expanded configuration in the first configuration (as shown in FIG. 1C) that is greater than the inner diameter (ID) of the catheter of the elongate inversion support portion of the apparatus and the relaxed expanded configuration of the second configuration (shown in FIG. 1F) inverted over the catheter has an OD that is greater than the OD of the catheter. The tractor is expandable and may be coupled to the puller. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to a push/pull wire or catheter.

[00047] FIGS. 1G and 1H illustrate the removal of a clot using an apparatus such as the apparatus assembled from the components of FIGS. 1A and 1E. In this example the apparatus is configured as a thrombectomy apparatus including a catheter of an elongate inversion support 101 and a flexible tractor that extends over the distal end region of the catheter and doubles-over itself at the distal end of the catheter to invert so that the external tractor end region is continuous with an inner less-expandable (in this example, less-expandable includes non-expandable) second distal end region 146 (puller) that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The pusher/puller member that may be a rod or other member that is continuous with the distal end region of the tractor. In FIG. 1G the apparatus is shown positioned and deployed within the vessel 160 near a clot 155. The clot may be drawn into the catheter by pulling the tractor 140 proximally into the catheter 101, as indicated by the arrow 180 showing pulling of the inner portion of the flexible tractor (e.g., using a handle, not shown) resulting in rolling the tractor over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled into the catheter, shown by arrows 182. The end of the tractor outside of the catheter may be “loose” relative to the outer wall of the catheter. FIG. 1I illustrates another example of a tractor assembly 154 including a tractor 144 that is coupled to a puller 156. The puller in this example is tapered (having tapering region

161) and may therefore have a different flexibility of the distal end region than the proximal end region. For example the proximal end region may be less flexible than the narrower-diameter distal end region 195 to which the tractor is coupled. The assembly includes a radiopaque marker 165. The tractor may be attached to the puller by any appropriate means. For example, the tractor may be crimped, glued, fused, or otherwise attached to the puller, typically permanently.

[00048] In general the mechanical thrombectomy apparatuses described herein may be highly flexible, both before actuating and during operation. For example, the flexible tractor may not increase the stiffness/flexibility of the catheter of the elongate inversion support, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortuous vessels of the neurovasculature. Described herein are flexible tractor tube portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

ILLUSTRATIVE METHODS OF ADVANCING AN INVERTING TRACTOR APPARATUS

[00049] For purposes of better understanding the mechanical thrombectomy systems and apparatuses disclosed herein, various methods of their use will now be described. In one such method, a mechanical thrombectomy apparatus is be advanced distally within a vessel and may grab and engulf a clot that is located distally by using the tractor to extend distally ahead of the apparatus, and in some cases pull (e.g., against the vessel walls) to guide or draw the catheter distally forward. This method of advancement may be referred to as “inchworm” or “worm-like” motion within the vessel. For example, FIGS. 2A-2E illustrate a first method of advancing a mechanical thrombectomy apparatus and/or removing a clot from a vessel using the mechanical thrombectomy apparatus. In this example, the apparatus includes a catheter 205 extending proximally to distally, a puller 207 (shown as a thin tube or hypotube, though it may be a wire or rod, as mentioned above), extending distally within the catheter and a flexible and tubular tractor 209. The tractor is coupled to a distal end region of the puller 217

and the tractor is inverted over a distal end opening of the catheter 219 so that the tractor extends proximally over the outside (outer diameter) of the catheter. In operation, the apparatus may be advanced distally (e.g., towards a clot 213) in a vessel 211, as shown in FIGS. 2B-2D. In FIG. 2B, the puller is pushed distally 220 (shown by arrows on the left) to advanced distally within the catheter and within the vessel towards a clot, so that the tractor extends from the puller distally beyond the distal end opening of the catheter 218, forming a gap 219 between the tractor and the distal end opening of the catheter. This gap is an annular, distal-facing cavity (e.g. pouch) formed in the tractor, and into which the distal end opening of the catheter may be advanced, as shown in FIG. 2C. In FIG. 2C, the catheter is advanced distally over the puller and into the gap. Following this step, the tractor is extended further outside of the catheter, and is in contact with the walls of the vessel 211, through it does not have to be. The outer diameter of the expanded tractor may be narrower than the vessel inner diameter (ID) or it may be greater than then ID of the vessel (and may therefore touch against them).

[00050] When advancing the catheter distally 222 (shown in arrows on left) and into the gap, the puller may be held in position relative to the catheter. In variations in which the tractor contacts the outer diameter of the vessel, this contact may hold the tractor in place against the vessel wall.

[00051] The steps of FIGS. 2B and 2C may be repeated multiple times to continue to advance the apparatus distally, however, in some variations it may be beneficial to retract or reset the tractor back into the catheter, e.g., by withdrawing the puller proximally to pull the tractor back into the catheter. This is illustrated in FIG. 2D. In this example, the puller 207 is withdrawn proximally 224 (arrows on left), so that the tractor coupled to the puller 217 is pulled back into the catheter after inverting over the distal end opening of the catheter. It may be beneficial to perform this step after the catheter has been extended distally fully, e.g., until it pushes distally against the back of the inverting (bent-over) region, as shown in FIG. 2D. One the tractor has been sufficiently retracted, the steps shown in FIGS. 2B-2C may be repeated, as shown in FIG. 2E, until the distal end opening of the catheter is adjacent to the clot. After positioning next to the clot (and in some cases adjacent to it), vacuum may be applied to pull the clot into contact with the apparatus, and/or the device may be advanced by pushing the catheter distally while pulling the puller proximally to roll and invert the tractor into the catheter (see., e.g., FIG. 1H).

[00052] The method of advancing the apparatus described in FIGS. 2A-2E above may be particularly helpful in advancing the apparatus within a vessel even without the use of a

guidewire or equivalent (e.g., guide catheter). However this method may also be used with a guidewire, as illustrated in FIGS. 3A-3D. In this example, the apparatus 300 is otherwise the same as shown in FIGS. 2A-2E, but may include or be used with a guidewire 355. In general, the same steps may be performed as discussed above. Alternatively, before or after a cycle of inching forward as describe in FIGS. 2A-2E, the apparatus may be slid distally along the guidewire toward the clot. Thus, in some variations, this method may be used to help navigate the apparatus within congested or tortious regions where advancing by sliding may not be as effective.

[00053] Another method of advancing an apparatus distally using the tractor is illustrated in FIGS. 4A-4D. This method is also similar to that shown in FIGS. 2A-2E and 3A-3C above, but may extend the tractor portion even further distally using the pusher, so that the pusher extends past the distal end of the apparatus, out of the catheter. In contrast, in FIGS. 2A-2E, the pusher remains substantially within the catheter, thus smaller ‘steps’ may be taken by the device.

[00054] In FIG. 4A, the apparatus is similar to that discussed above, including a puller 407 that is connected at a distal end region 417 to a tractor 403. The tractor is inverted over the distal end opening of a catheter 405. The apparatus may be advanced within a vessel 411 towards a clot 413, as shown in FIG. 4B, by advancing the inner puller 407 distally 420 so that the puller distal end (and attached tractor) extends distally from the catheter distal end opening. The tractor may tent, forming a gap 419 or pouch between the distal end of the catheter and the distal face of the tractor (distal-facing end). In this example, the gap 419 is formed between the distal end of the catheter and the end of the puller. Thereafter, as shown in FIG. 4C, the catheter may be advanced distally 422 within the gap of the tractor. In both this example and the example shown in FIGS. 2A-2E, the puller and tractor may be advanced distal of the catheter distally while the outer portion of the tractor remains over the catheter, e.g. the second end of the tractor 414 that is shown extended over the outer diameter of the catheter remain proximal to the distal end of the catheter. Once positioned near the clot 413, the tractor may be rolled into the catheter by pulling proximally on the puller and (optionally) advancing the apparatus distally by pushing the catheter distally.

[00055] If the distal end of the apparatus (e.g., the distal-facing, inverting tractor) is not adjacent to the clot 413, the steps above can be repeated, either with or without retracting the tractor into the catheter (e.g., by pulling proximally on the puller). FIG. 4D illustrates an example of retracting the tractor into the catheter by pulling proximally on the puller 424.

[00056] FIGS. 5A-5C illustrate the method of FIGS. 4A-4C with a guidewire 515. The apparatus may be the same (e.g., may include a puller 507 coupled at a distal end 517 to a flexible tractor 503 that is inverted over the distal end opening of a catheter 505 and extending along the outer surface of the catheter). The steps may be the same as discussed above, including advancing the tractor and puller distally by pushing the puller distally 520 towards a clot 513, as shown in FIG. 5B. The catheter may then be advanced (by sliding over the guidewire) as shown in FIG. 5C into the gap or pouch formed by the tractor 519. Once positioned near the clot 513, the tractor may be rolled into the catheter by pulling proximally on the puller and (optionally) advancing the apparatus distally by pushing the catheter distally.

[00057] FIGS. 6A-6B illustrate another method for advancing an apparatus distally, in which both ends of the tractor 603 are coupled to axially movable elements. For example, in FIG. 6A the first end of the tractor 603 is coupled to a puller 607 within the catheter 605. In addition, the second end of the tractor is shown coupled to an outer axially movable member (second or outer catheter 619). This tri-axial system may be used to inchworm the apparatus distally by alternately holding and pulling on the various pullers and catheters. For example, in FIG. 6A, the tip of the apparatus may be advanced distally toward a clot by holding the catheter fixed, allowing the puller to float (e.g., not constraining it) and pulling the outer catheter proximally 640. As a result, the outer portion of the flexible tractor may be pulled proximally, pulling the puller and opposite end of the tractor distally, as shown in FIG. 6B. Thereafter, the puller may be held in place, the outer catheter may be free to move axially, and the catheter may be advanced distally into the gap formed by the tractor, which may drive the tractor distally (e.g., back to the configuration shown in FIG. 6A) and pull the outer catheter distally. These steps may be repeated as necessary. In some variations the outer catheter may be removably attached to the tractor, and the tractor may be pulled proximally to separate from the outer catheter.

[00058] A guidewire may also be used with this method. In this example, tip advancement of the apparatus may take advantage of the outer (e.g., guide) catheter stiffness (e.g., bending and column stiffness) to aid in catheter tip advancement. This may be particularly helpful in neurovascular regions, such as shown in FIG. 7.

[00059] FIG. 7 illustrate the uses of the methods described herein to advance the apparatus 701 within a neurovascular structure such as the internal carotid segment in the head. For example, the distal tip of the apparatus may be positioned at the distal tip of the internal carotid segment; once positioned, an advancement method such as one of those described

herein may be used drive the apparatus distally forward towards the clot. Such a method may create a pushing force forward from the internal carotid artery without sacrificing the trackability of the apparatus or the small outer diameter of the apparatus.

[00060] The apparatuses described herein may also be used to advance other apparatuses (including catheters and tubes). For example, any of these apparatuses and methods may be used in reverse (e.g. pulling proximally on an outer portion of the catheter) to pull an apparatus within the lumen of the tractor distally for delivery at an internal vessel site.

[00061] Thus, to advance a tool (e.g., a tube, etc.) into the patient, a tractor inserted into the body (which may be advanced as described herein, even for use without performing a thrombectomy or in addition to a thrombectomy) may be pulled from the outside of the catheter proximally (e.g., with an overtube or pull wire) to invert the tractor in the opposite direction from out of the catheter. As the tractor on the OD of the catheter is pulled proximally, it may advance a tool (e.g., tube) inside the apparatus to the target location in the patient. This mechanism could be used in a variety of applications including; passing mature clot or vessel lesion, placing an intubation system (e.g., in a throat), providing rectal or vaginal access, performing NOTES surgery, inserting a tool such as a trocar, inserting a scope into a body region (e.g., gastrointestinal region, colon, blood vessel lumen, etc.), inserting a robotic tool, crossing a calcified vessel, etc. Other applications of the apparatuses and methods of removing and/or placing material using the apparatuses described herein may include include removal of tissue, such as gall bladder removal and removal of fat (liposuction). For example a cutting or ablative tool may be passed down the middle of the apparatus, through the catheter, the puller and the tractor, and extended from the distal end, where it may be used to cut tissue that may then be pulled out of the body using the tractor by pulling the tractor proximally within the catheter. Note that this method may be used to remove both the tool and/or the cut tissue. Thus, despite referring to these apparatuses as mechanical mechanical thrombectomy apparatuses herein, any of these devices may be adapted for uses not limited to thrombectomy, and may alternatively be referred to as mechanical tractor apparatuses.

[00062] Also described herein are powered mechanical thrombectomy apparatuses in which the tractor may be driven by a driver such as an electrical motor. For example, FIG. 8A illustrates an example of a power driven tractor in a mechanical thrombectomy apparatus. The apparatus may drive the tractor continuously in a loop, thus the tractor may be configured as a closed loop, belt or toroid of material that extends around a catheter. The power drive may run the apparatus in either the forward or reverse directions. In FIG. 8A,

the tractor comprises a plurality of belts 803 that extend around and through the catheter 805. A drive motor 811 drives rotation of the belts. In FIG. 8A the drive motor drives a ring 813 that can therefor drive multiple belts forming the tractor or in some variations, a single torus that passes over the supporting catheter. The catheter may include holes or openings 817 into which the belts forming the tractor may reside. The belts extend along the length of the catheter 805. In this example, a hub 815 holds the proximal end of the catheter and holds the belts against the drive motor and/or drive ring that is driven by the drive motor, and may also connect to a vacuum 819.

[00063] FIG. 8B shows an enlarged view of a catheter and tractor that may be used with the apparatus shown in FIG. 8A. FIG. 8B shows the catheter 805 including a plurality of belts 803, 803' forming the tractor. The belts pass through an opening in the catheter at the proximal end, but roll over the distal end of the catheter, and extend along the outer and inner longitudinal axis.

[00064] FIGS. 9A-9B illustrates an example of operation of a power driven mechanical thrombectomy apparatus configured to grab a clot. In FIG. 9A, the apparatus 900 is similar to that shown in FIG. 8A, above, including a plurality of belts 903, 903' forming the tractor, and an internal catheter 905; the belts rotate down the length of the catheter. Note that the catheter may be rigid or flexible. The catheter may include channels, and/or notches or other guide along its length for guiding and/or enclosing the belts at various portions. In FIG. 9A, the apparatus is positioned adjacent to a clot 924. The clot may initially be grabbed using aspiration (e.g., vacuum). In FIG. 9B, the apparatus may be shown after grabbing the clot, and compressing it within the catheter.

[00065] Note that the power-driven mechanical thrombectomy apparatuses shown in FIGS. 9A and 9B do not include a puller, as the motor may act like a puller. In some variations a separate puller may be used.

[00066] As mentioned above, any of the apparatuses described herein may be used with an additional outer catheter, including the powered apparatuses described herein. For example, FIG. 9C illustrates an example of a powered apparatus 900 used with an intermediate catheter having a larger OD than the powered mechanical thrombectomy apparatus. In this example, the length of the apparatus is slightly greater or almost equal to the length of the intermediate catheter 930, so that just the distal end region of the apparatus, including the inverting tractor (belts) is accessible and/or sticks out 933 of the intermediate catheter. Alternatively, the apparatus may be retracted into the outer (intermediate) catheter slightly, or may extend substantially from the end of the outer catheter.

[00067] Any of the methods (including user interfaces) described herein may be implemented as software, hardware or firmware, and may be described as a non-transitory computer-readable storage medium storing a set of instructions capable of being executed by a processor (e.g., computer, tablet, smartphone, etc.), that when executed by the processor causes the processor to control perform any of the steps, including but not limited to: displaying, communicating with the user, analyzing, modifying parameters (including timing, frequency, intensity, etc.), determining, alerting, or the like.

[00068] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[00069] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[00070] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For

example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[00071] Although the terms "first" and "second" may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[00072] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising" means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term "comprising" will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

[00073] In general, any of the apparatuses and methods described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may alternatively be exclusive, and may be expressed as "consisting of" or alternatively "consisting essentially of" the various components, steps, sub-components or sub-steps.

[00074] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or "approximately," even if the term does not expressly appear. The phrase "about" or "approximately" may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For

example, if the value "10" is disclosed, then "about 10" is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that "less than or equal to" the value, "greater than or equal to the value" and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value "X" is disclosed the "less than or equal to X" as well as "greater than or equal to X" (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point "10" and a particular data point "15" are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[00075] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[00076] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the

above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

What is claimed is:

1. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:
 - a flexible catheter having a distal end and a distal end opening;
 - a tractor comprising a flexible belt that extends within the catheter, inverts over the distal end opening of the catheter and extends along the outer diameter of the catheter;
 - a power drive at a proximal end of the flexible catheter configured to drive the tractor around the catheter so that it inverts over the distal end opening of the catheter; and
 - a guidewire lumen through the catheter and the tractor configured to pass a guidewire.
2. The apparatus of claim 1, wherein the flexible belt comprises a flexible tube.
3. The apparatus of claim 1, wherein the tractor comprises a plurality of flexible belts that each extend within the catheter, invert over the distal end opening of the catheter and extend along the outer diameter of the catheter.
4. The apparatus of claim 1, wherein the power drive is configured to engage with the flexible belt on an outer surface of the catheter.
5. The apparatus of claim 1, wherein the power drive comprises an annular ring surrounding the catheter and the tractor.
6. The apparatus of claim 1, further comprising an outer catheter configured to enclose the flexible catheter and tractor, wherein the flexible catheter and tractor may be inserted through the body within the outer catheter.
7. A method of removing a clot from a vessel using a mechanical thrombectomy apparatus including a catheter extending from a proximal end to a distal end, a puller extending distally within the catheter and a flexible and tubular tractor, wherein the tractor is coupled to a distal end region of the puller and further wherein the tractor is inverted over a distal end opening of the catheter so that the tractor extends proximally over the catheter, the method comprising:

advancing the puller distally within the catheter and within the vessel towards a clot, so that the tractor extends from the puller distally beyond the distal end opening of the catheter, forming a gap between the tractor and the distal end opening of the catheter;

advancing the catheter distally over the puller and into the gap;

repeating the advance steps until the distal end opening of the catheter is adjacent to the clot; and

drawing the clot into the catheter with the tractor by pulling the tractor proximally within the catheter so that the tractor rolls and inverts over the distal end opening of the catheter.

8. The method of claim 7, wherein repeating further comprises comprising pulling the pusher proximally within the catheter to invert a portion of the tractor over the distal end opening of the catheter.
9. The method of claim 7, wherein drawing the clot into the catheter further comprises advancing the catheter distally while pulling the pusher proximally.
10. The method of claim 7, wherein advancing the puller distally comprises advancing the puller without using a guidewire extending distal to the puller.
11. The method of claim 7, wherein advancing the puller comprises extending the distal end of the puller out of the distal end opening of the catheter.
12. The method of claim 7, wherein advancing the puller comprises extending the tractor distally within the vessel, further wherein the tractor comprises a woven flexible and tubular tractor.
13. The method of claim 7, wherein advancing the puller comprises extending the tractor distally within the vessel, further wherein the tractor comprises a knitted tractor.
14. The method of claim 7, wherein advancing the puller comprises extending the tractor distally within the vessel, further wherein the puller comprises a central lumen configured to pass a guidewire therethrough.
15. The method of claim 7, wherein advancing the puller comprises advancing the puller within an internal carotid artery.

16. A method of removing a clot from a vessel using a mechanical thrombectomy apparatus having a puller within a first catheter that is within a second catheter, wherein the puller and second catheter are connected by a flexible and tubular tractor, the method comprising:
- advancing the puller distally through the first catheter and the second catheter and within the vessel towards a clot, so that the flexible and tubular tractor extends from the puller beyond a distal end opening of the first catheter and beyond a distal end opening of the second catheter;
 - advancing the outer catheter distally through the vessel by one or more of:
 - holding the position of the first catheter within the vessel and pulling the puller proximally within the first catheter; or moving the first catheter distally relative to the puller; and
 - drawing the clot into the first catheter with the flexible and tubular tractor by pulling the flexible and tubular tractor proximally within the first catheter so that the flexible and tubular tractor rolls and inverts over the distal end opening of the catheter.
17. The method of claim 16, further comprising repeating the advancing steps until the clot is adjacent to the distal end of the puller.
18. The method of claim 16, wherein drawing the clot into the catheter further comprises advancing the first catheter distally while pulling the pusher proximally.
19. The method of claim 16, wherein advancing the puller distally comprises advancing the puller without using a guidewire extending distal to the puller.
20. The method of claim 16, wherein advancing the puller comprises extending the flexible and tubular tractor distally within the vessel further wherein the flexible and tubular tractor comprises a woven flexible and tubular tractor.
21. The method of claim 16, wherein advancing the puller comprises extending the flexible and tubular tractor distally within the vessel further wherein the flexible and tubular tractor comprises a knitted flexible and tubular tractor.

22. The method of claim 16, wherein advancing the puller comprises extending the flexible and tubular tractor distally within the vessel further wherein the puller has a central lumen configured to pass a guidewire therethrough.
23. The method of claim 16, wherein advancing the puller comprises advancing the puller within an internal carotid artery.
24. The method of claim 16, wherein drawing the clot into the first catheter comprises uncoupling the flexible and tubular tractor from the second catheter.

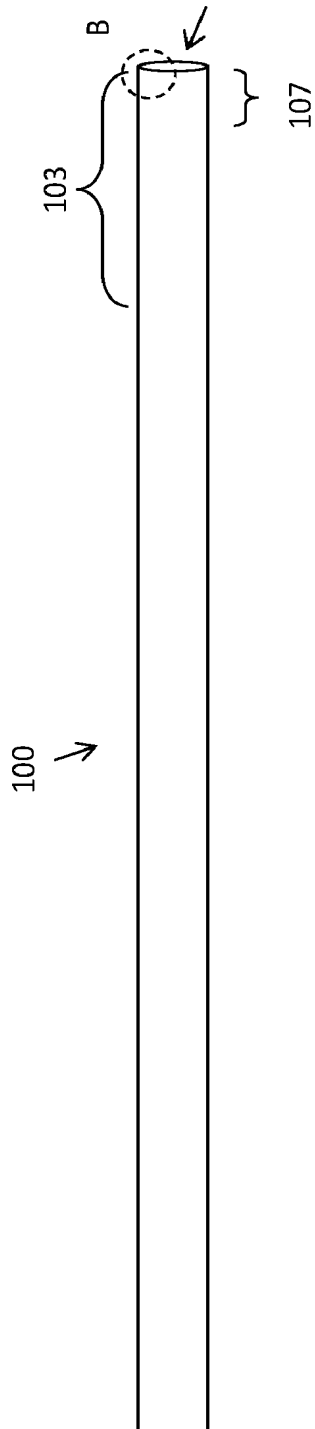


FIG. 1A

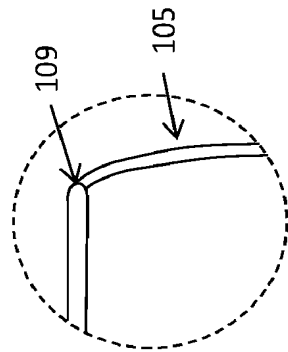


FIG. 1B

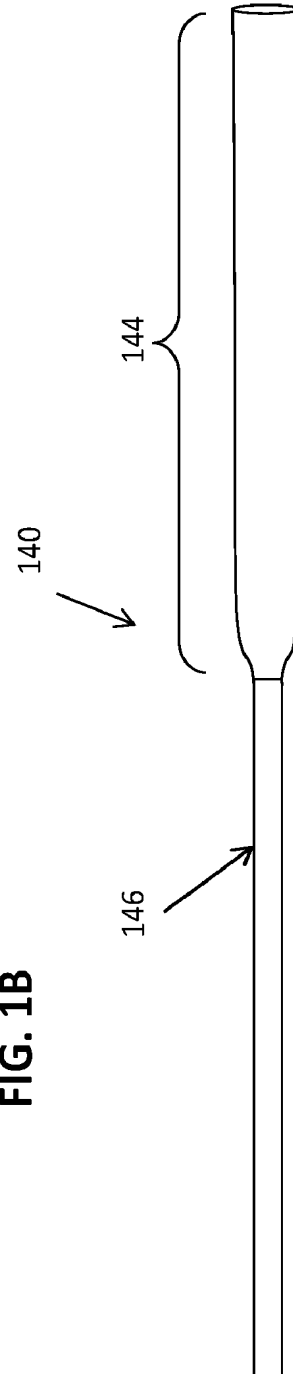


FIG. 1C

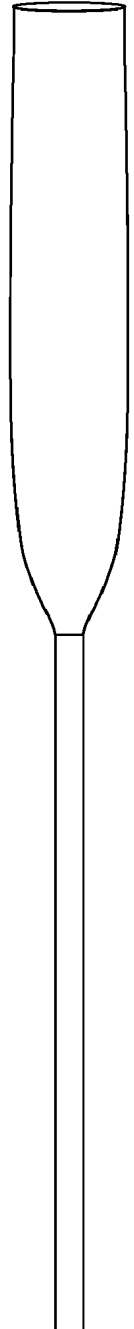


FIG. 1D

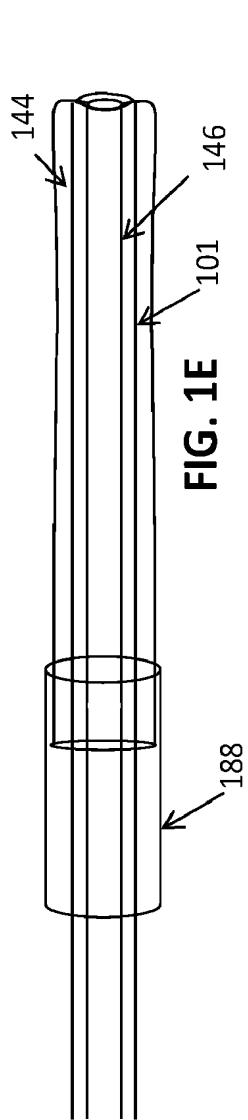


FIG. 1E

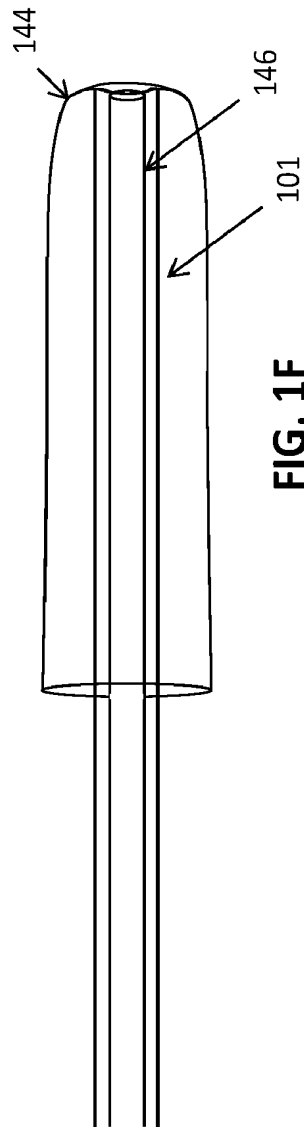


FIG. 1F

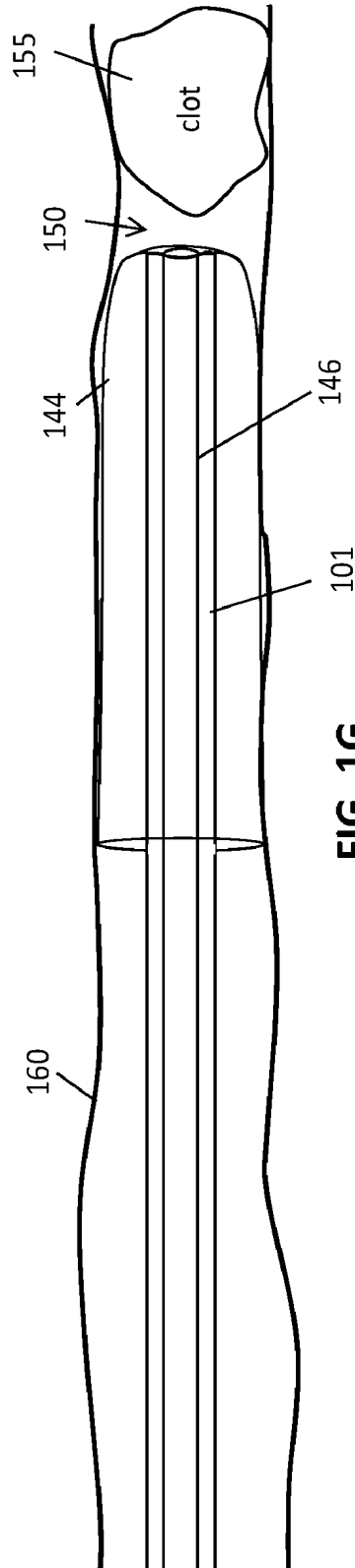


FIG. 1G

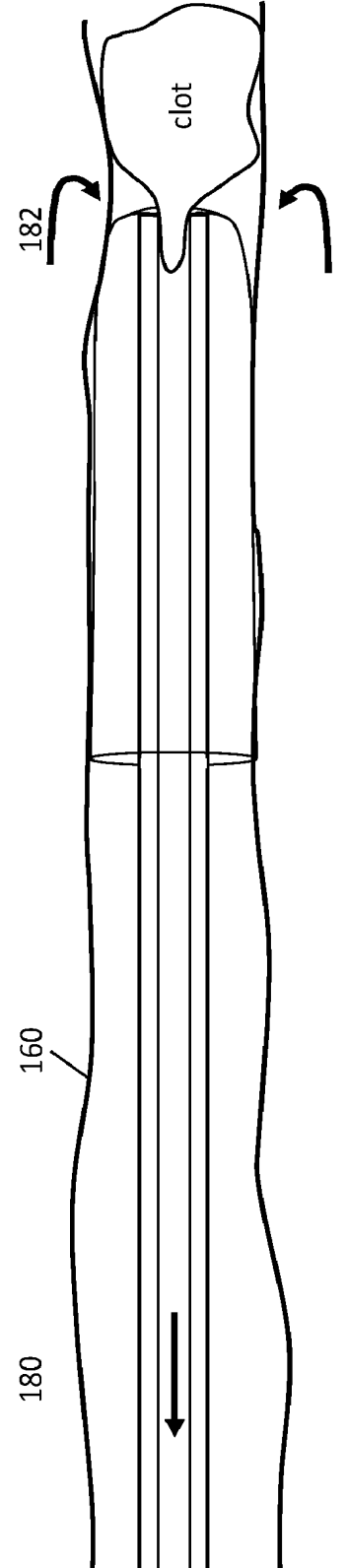


FIG. 1H

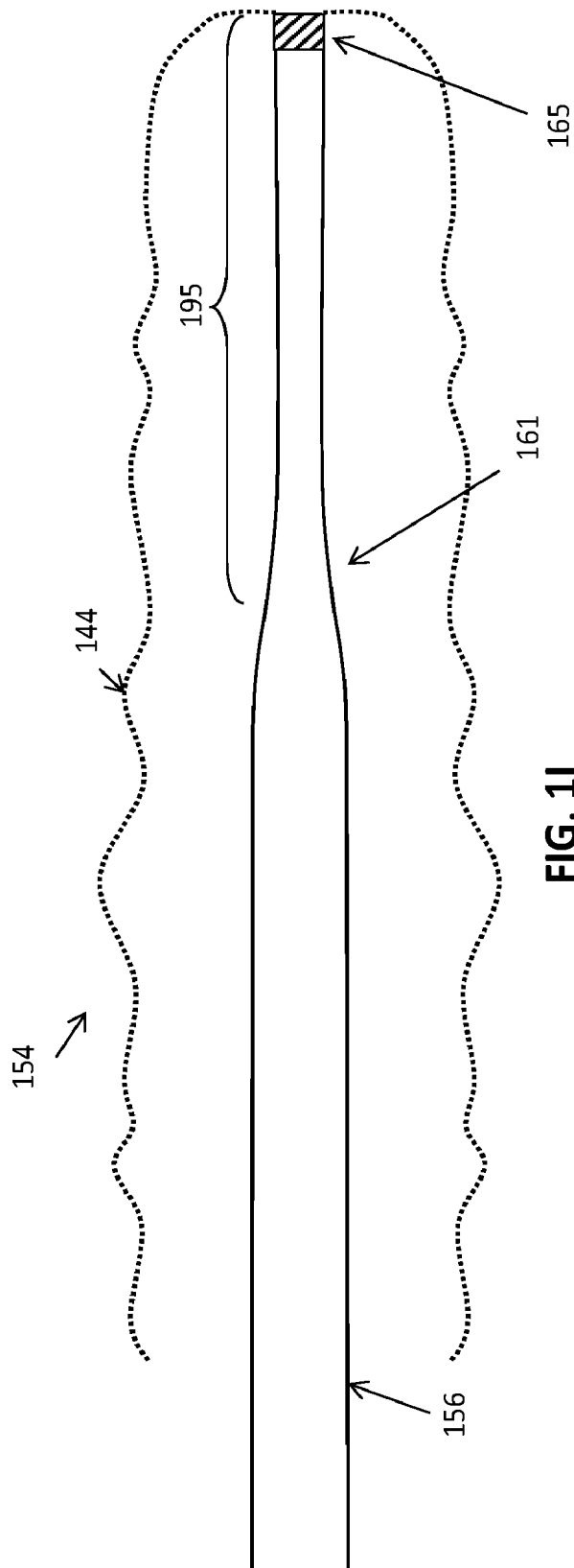


FIG. 1I

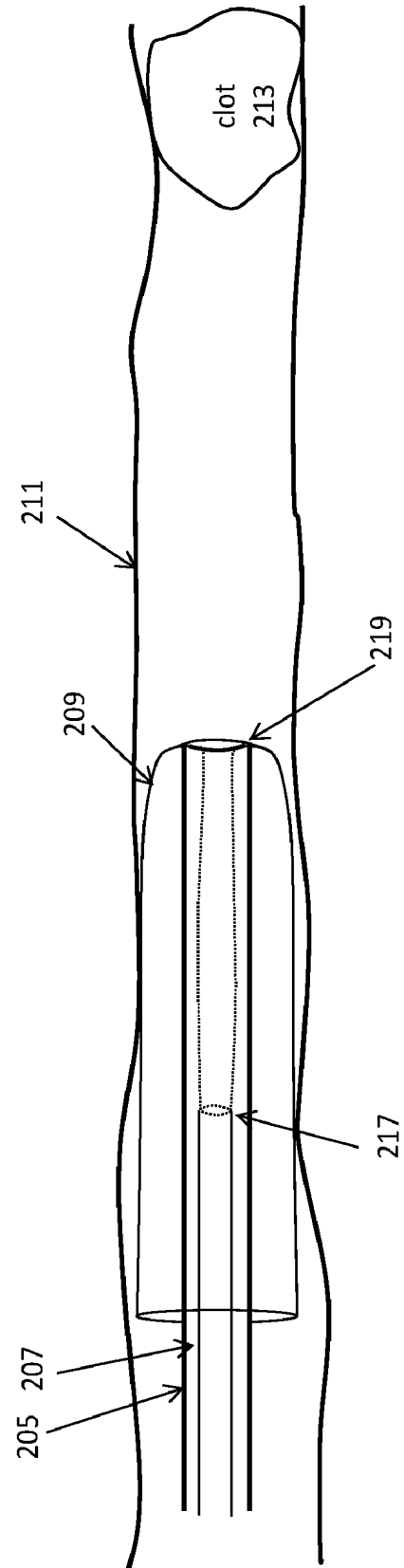
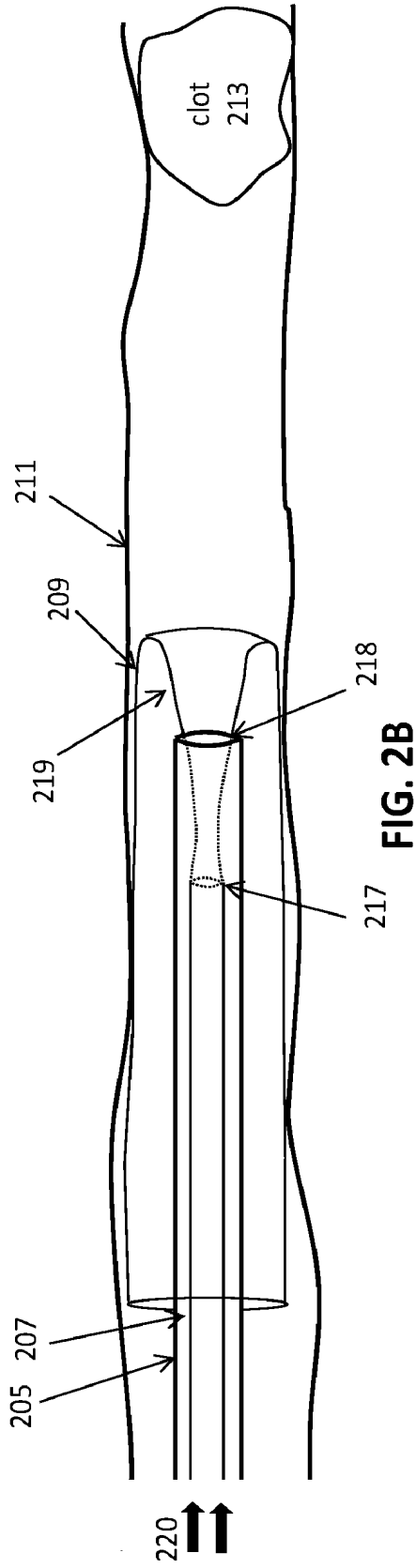
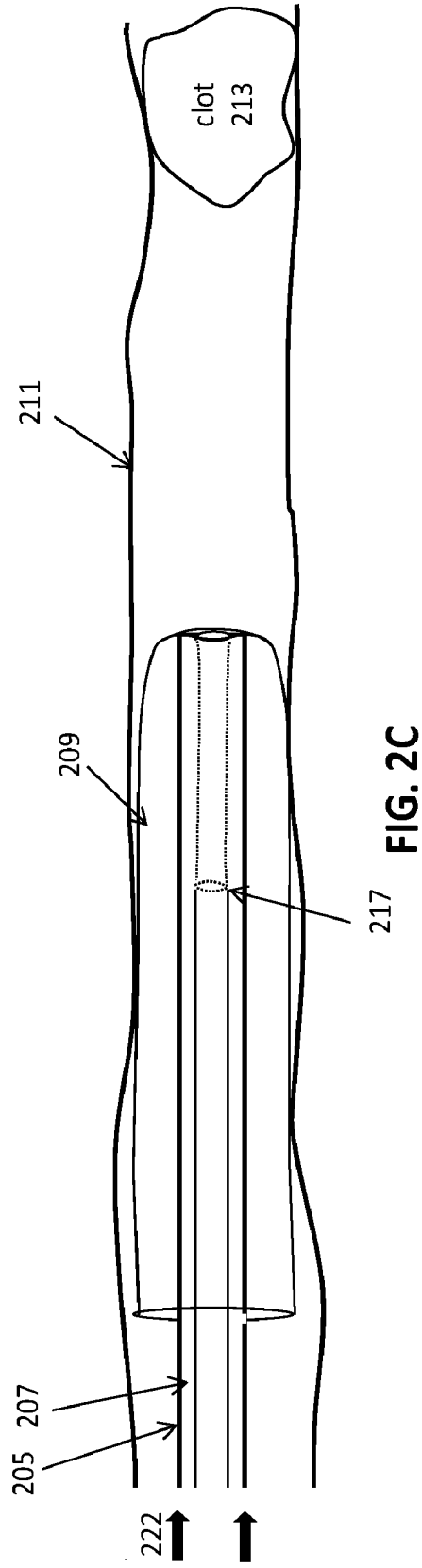
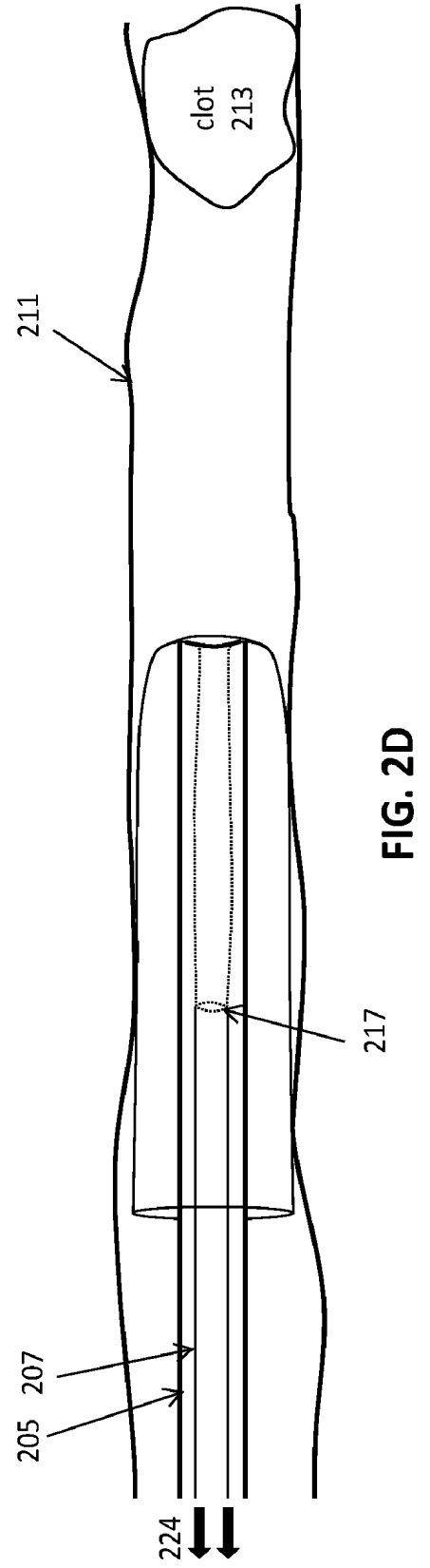


FIG. 2A



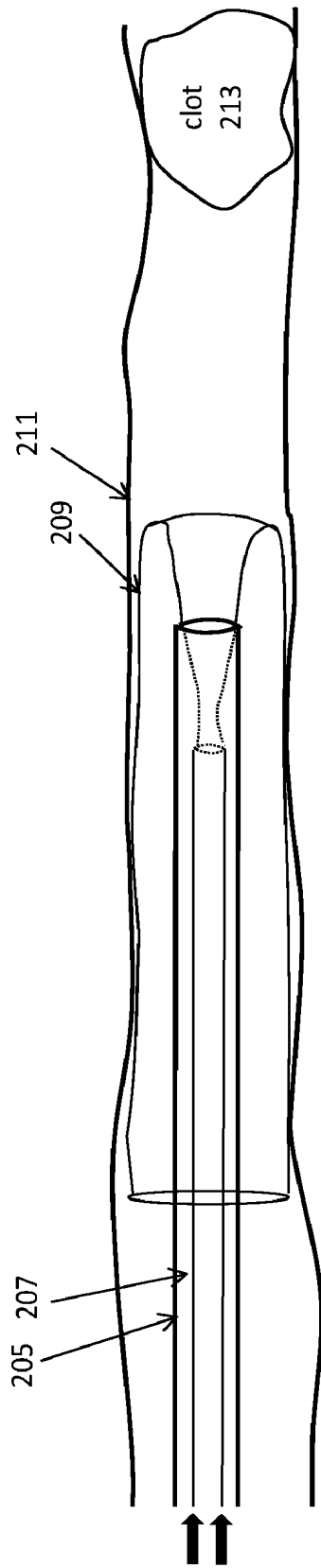


FIG. 2E

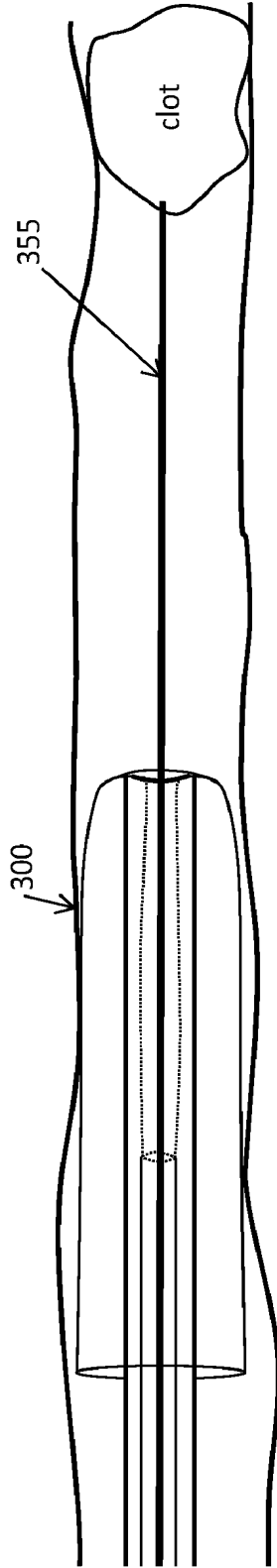


FIG. 3A

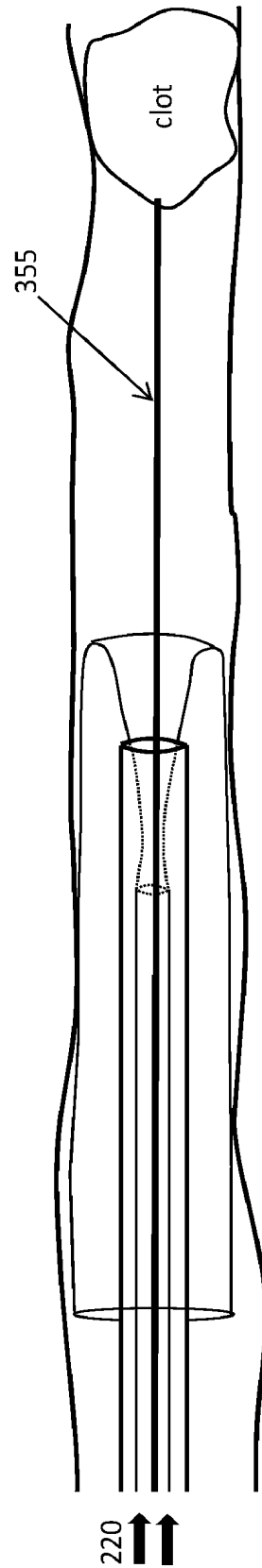


FIG. 3B

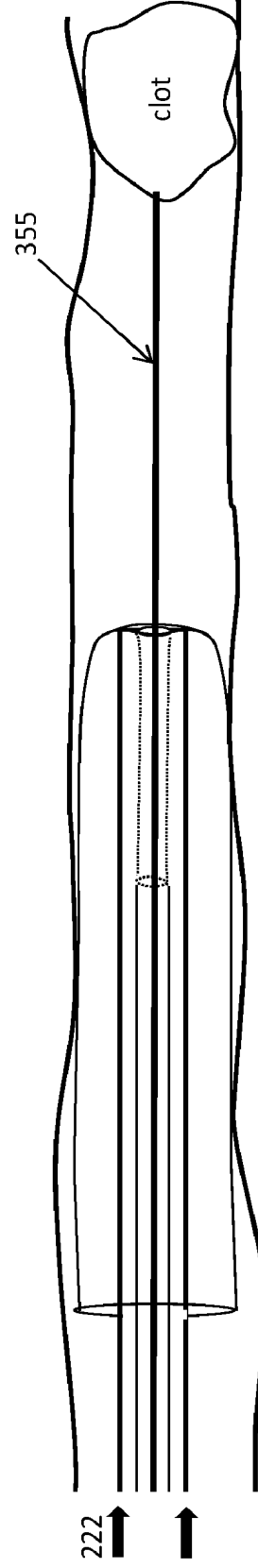


FIG. 3C

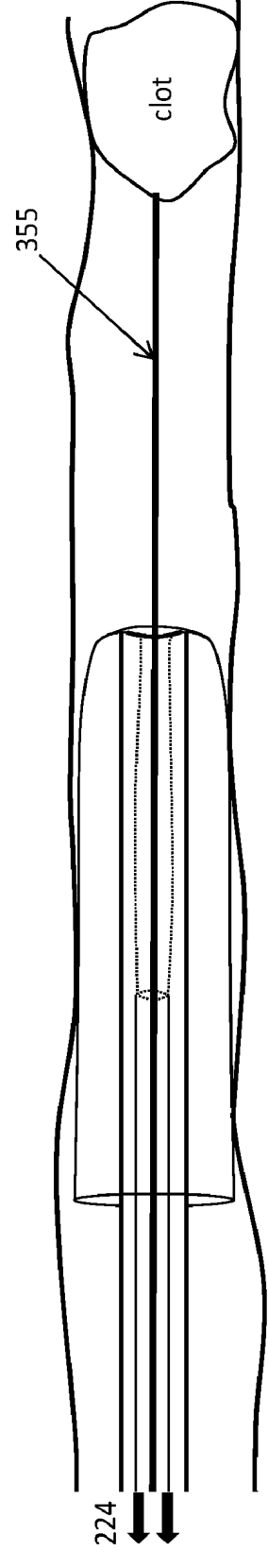
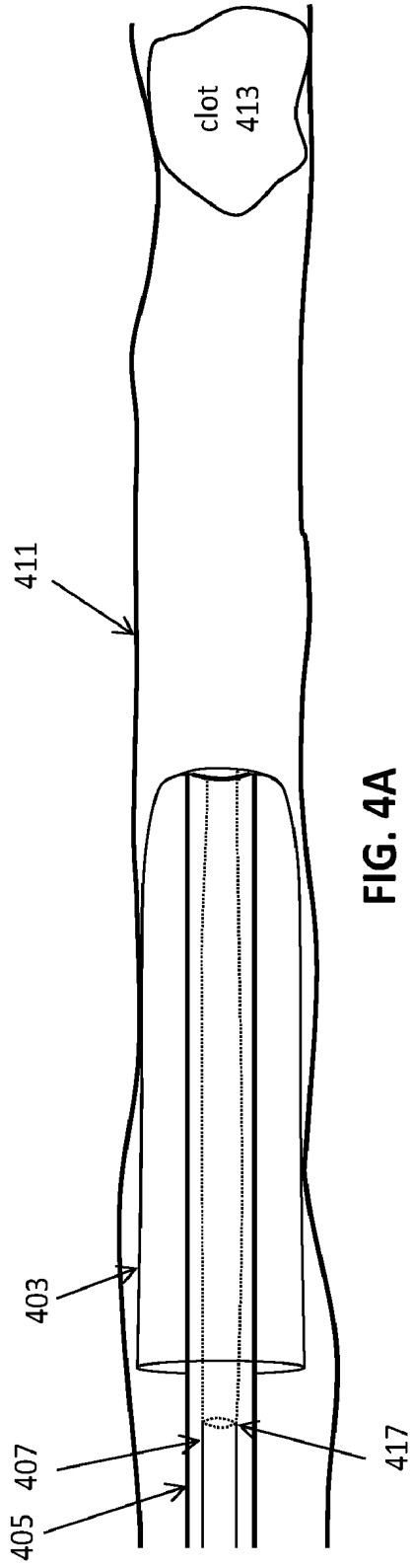
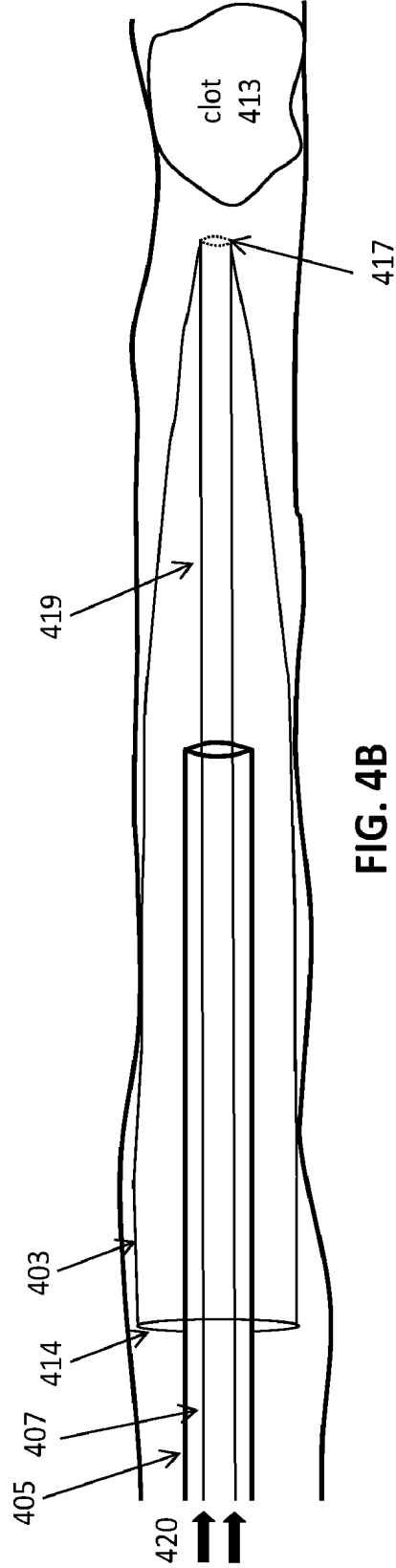
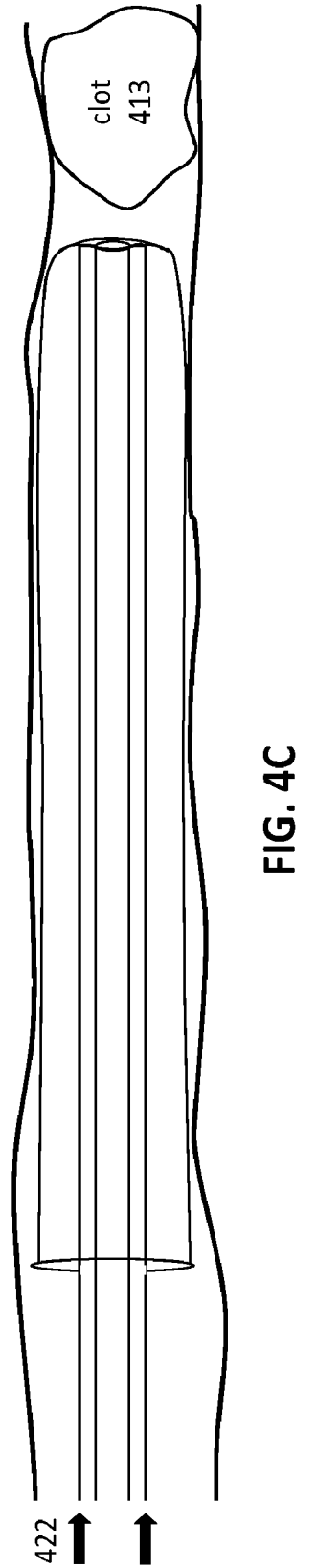


FIG. 3D



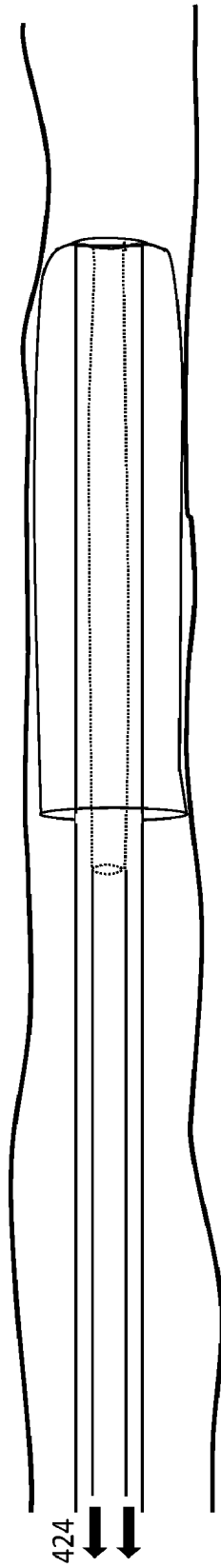


FIG. 4D

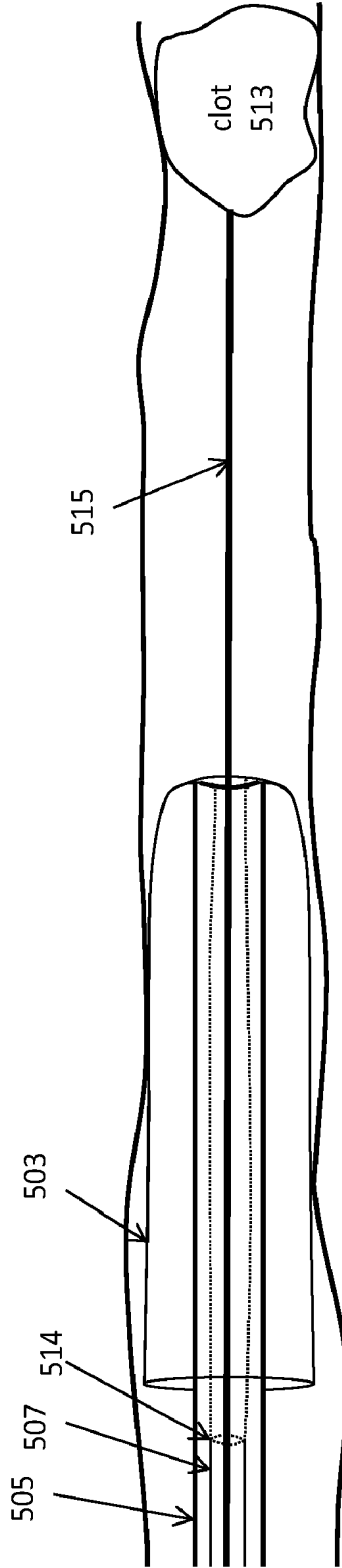


FIG. 5A

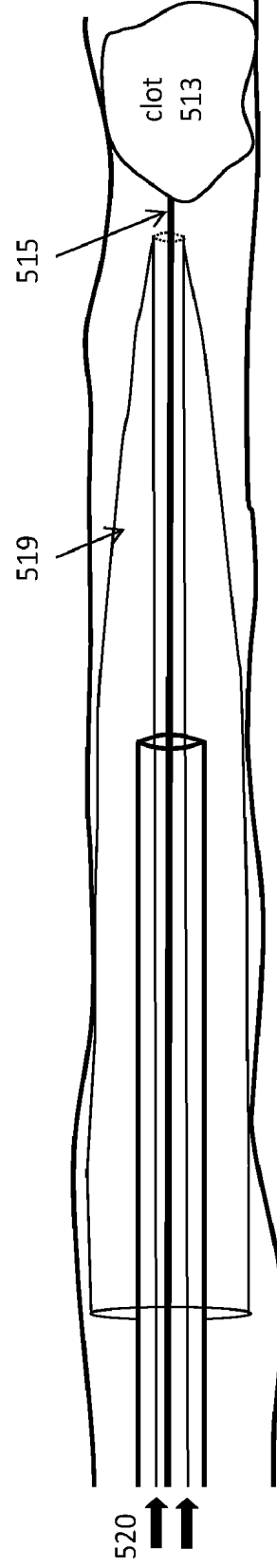


FIG. 5B

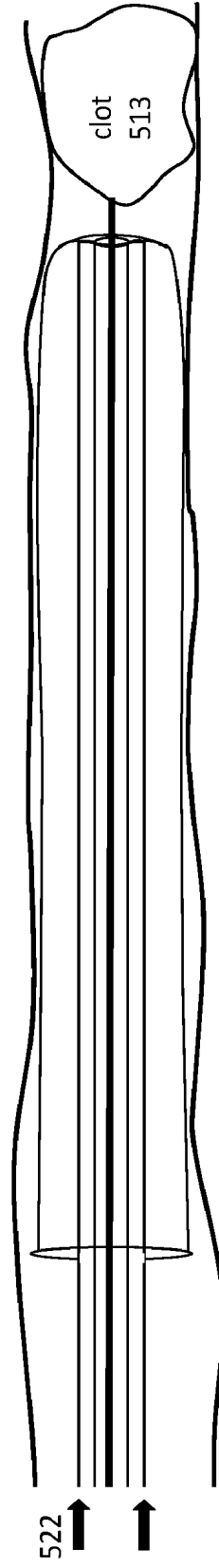


FIG. 5C

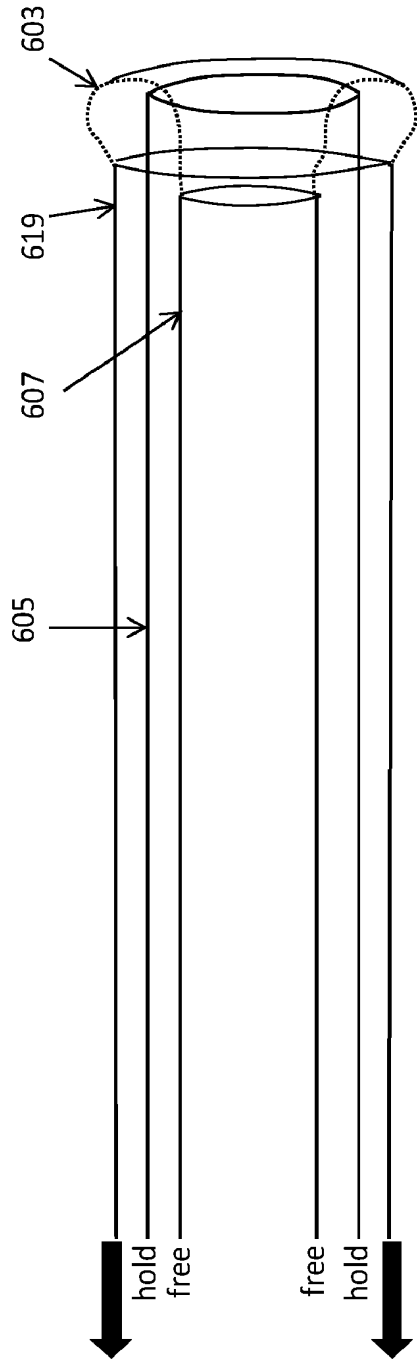


FIG. 6A

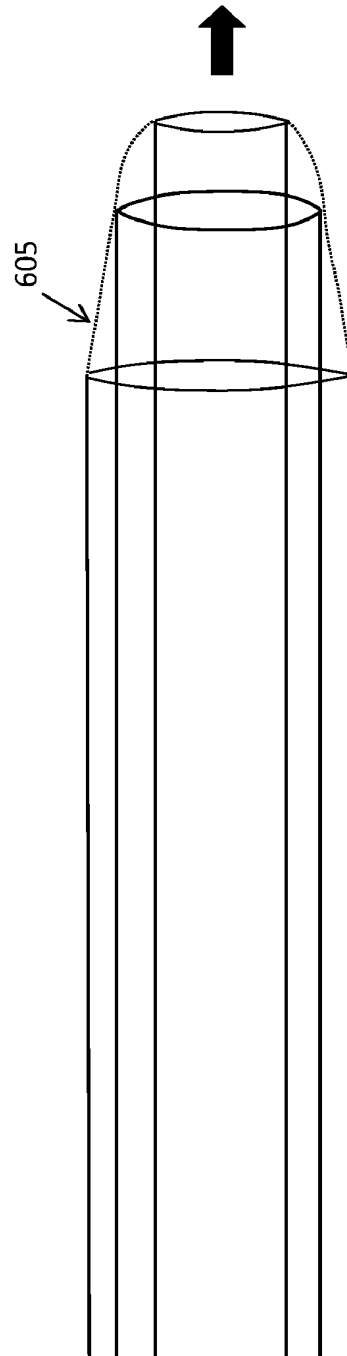
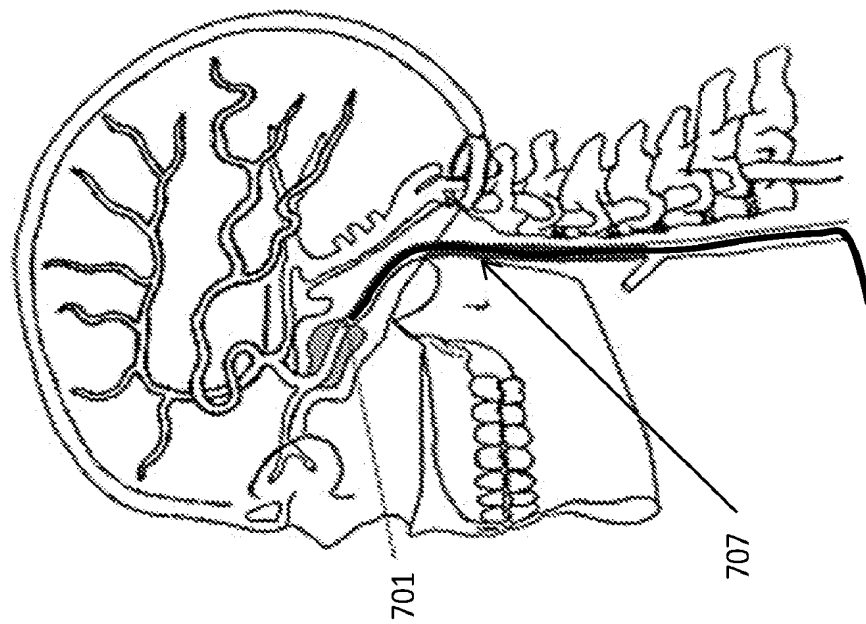


FIG. 6B



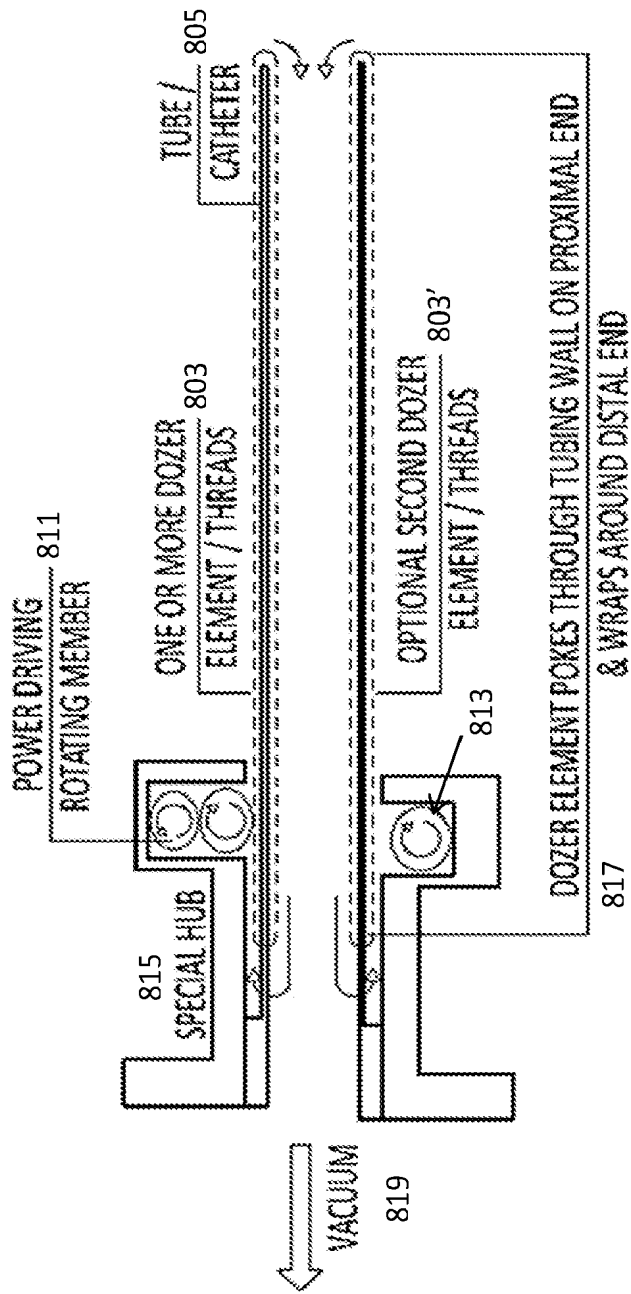


FIG. 8A

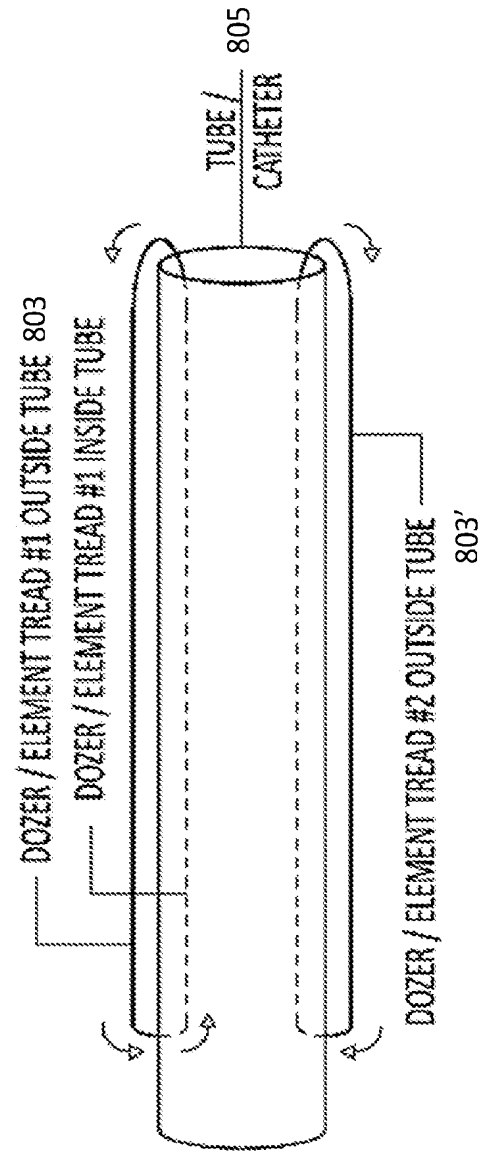


FIG. 8B

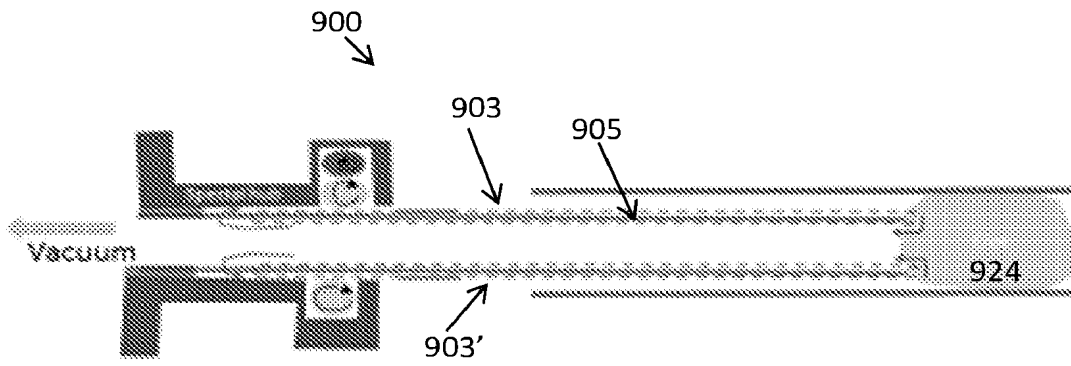


FIG. 9A

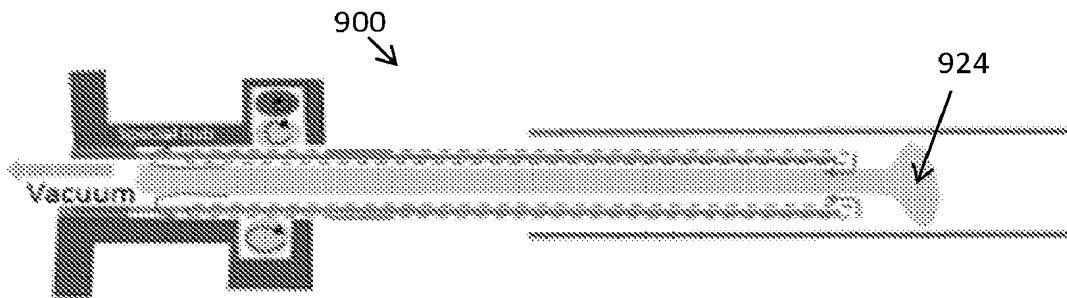


FIG. 9B

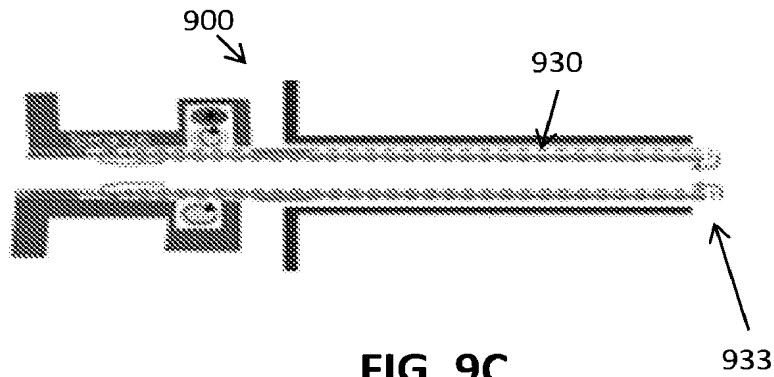
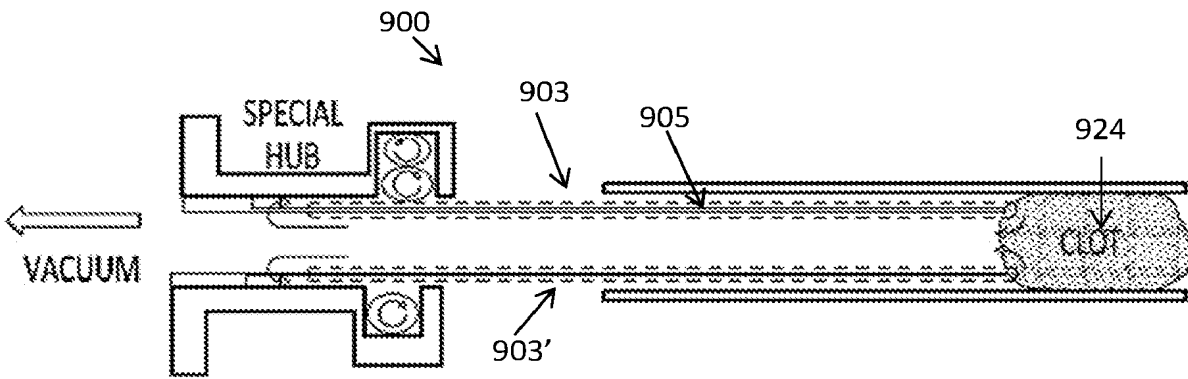
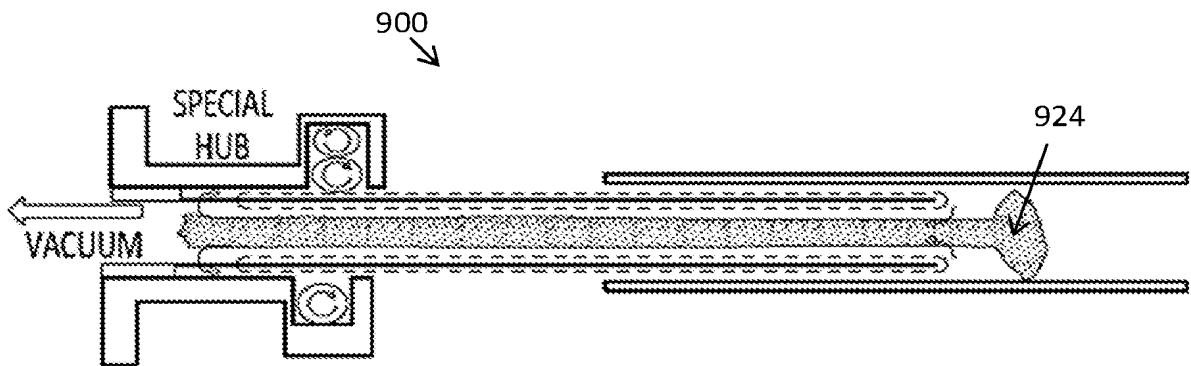
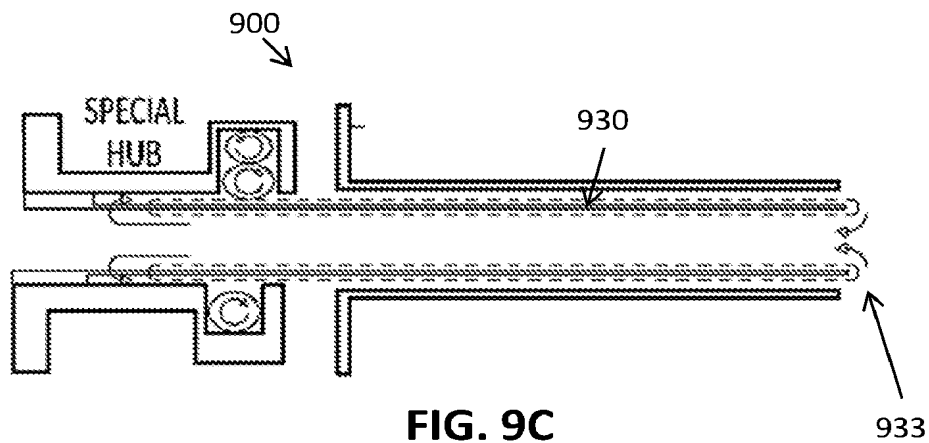


FIG. 9C

**FIG. 9A****FIG. 9B****FIG. 9C**

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61B17/22 A61B17/221
 ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19) paragraphs [0152], [0153], [0167] - [0170]; figures 10, 13B -----	1
A	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; figures page 8, line 12 - page 11, line 16 -----	1
A	US 2013/096571 A1 (MASSICOTTE ET AL.) 18 April 2013 (2013-04-18) abstract; figures -----	1
A	US 2006/089533 A1 (ZIEGLER ET AL.) 27 April 2006 (2006-04-27) figures ----- -/--	1

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

30 June 2017

Date of mailing of the international search report

07/07/2017

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040,
 Fax: (+31-70) 340-3016

Authorized officer

Giménez Burgos, R

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00/32118 A1 (ATROPOS LIMITED) 8 June 2000 (2000-06-08) figures	1
A,P	----- WO 2017/058280 A1 (GW MEDICAL LLC) 6 April 2017 (2017-04-06) the whole document -----	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/029440

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 7-24
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 7-24

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2017/029440

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2012009675 A2	19-01-2012	US 2014005712 A1 WO 2012009675 A2	02-01-2014 19-01-2012
GB 2498349 A	17-07-2013	EP 2802275 A1 GB 2498349 A US 2015005781 A1 WO 2013106146 A1	19-11-2014 17-07-2013 01-01-2015 18-07-2013
US 2013096571 A1	18-04-2013	US 2007038227 A1 US 2013096571 A1 WO 2007022055 A1	15-02-2007 18-04-2013 22-02-2007
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(54) Title: CLOT-ENGULFING MECHANICAL THROMBECTOMY APPARATUSES

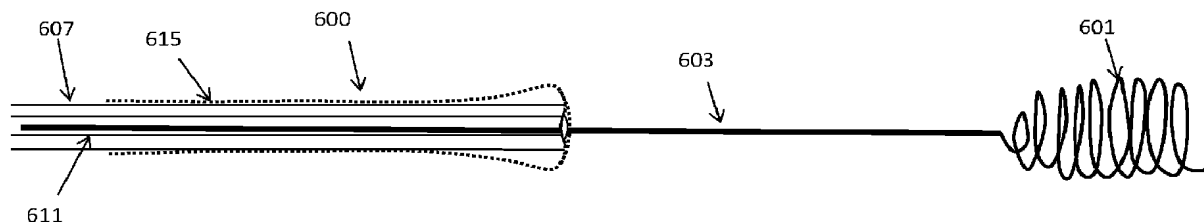


FIG. 61

(57) Abstract: Mechanical thrombectomy systems including an elongate catheter configured as an elongate inversion support, a flexible tractor configured to roll and invert over the distal end of the elongate inversion support, and a clot engaging member on the distal end of an elongate manipulator are described herein. These systems may capture a clot using the clot engaging member and draw the clot and clot engaging member and roll the flexible tractor into the catheter to remove the clot and clot engaging member from a vessel.

CLOT-ENGULFING MECHANICAL THROMBECTOMY APPARATUSES

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims priority to U.S. provisional patent application no. 62/327,024, filed on April 25, 2016 and titled “DOZER THROMBECTOMY SYSTEM”; U.S. provisional patent application no. 62/345,152, filed on June 3, 2016, and titled “DOZER THROMBECTOMY SYSTEM 2”; and U.S. provisional patent application no. 62/357,677, filed on July 1, 2016, and titled “DOZER THROMBECTOMY SYSTEM 3”.

[0002] This patent application may be related to U.S. patent application no 15/291,015, filed on October 11, 2016, titled “MECHANICAL THROMBECTOMY APPARATUSES AND METHODS”, which is a continuation of U.S. Patent Application No. 15/043,996, filed February 15, 2016, now U.S. 9,463,035, which claims priority to each of the following provisional patent applications: U.S. Provisional Patent Application No. 62/284,300, filed September 28, 2015; U.S. Provisional Patent Application No. 62/284,752, filed October 8, 2015; and U.S. Provisional Patent Application No. 62/245,560, filed October 23, 2015.

[0003] Each of these patents and patent applications is herein incorporated by reference in its entirety.

INCORPORATION BY REFERENCE

[0004] All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

[0005] The apparatuses described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses and methods for removing a clot, including removing a clot captured by a clot capture device (e.g., a clot engaging member on the distal end of an elongate manipulator) with a rolling tractor that pulls the clot and clot capture device into a catheter.

BACKGROUND

[0006] It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue from within a vasculature, such as blood clots, may improve patient conditions and quality of life.

[0007] Many vascular system problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery.

[0008] When a thrombus forms, it may effectively stop the flow of blood through the zone of formation. If the thrombus extends across the interior diameter of an artery, it may cut off the flow of blood through the artery. If one of the coronary arteries is 100% thrombosed, the flow of blood is stopped in that artery, resulting in a shortage of oxygen carrying red blood cells, e.g., to supply the muscle (myocardium) of the heart wall. Such a thrombosis is unnecessary to prevent loss of blood but can be undesirably triggered within an artery by damage to the arterial wall from atherosclerotic disease. Thus, the underlying disease of atherosclerosis may not cause acute oxygen deficiency (ischemia) but can trigger acute ischemia via induced thrombosis. Similarly, thrombosis of one of the carotid arteries can lead to stroke because of insufficient oxygen supply to vital nerve centers in the cranium. Oxygen deficiency reduces or prohibits muscular activity, can cause chest pain (angina pectoris), and can lead to death of myocardium which permanently disables the heart to some extent. If the myocardial cell death is extensive, the heart will be unable to pump sufficient blood to supply the body's life sustaining needs. The extent of ischemia is affected by many factors, including the existence of collateral blood vessels and flow which can provide the necessary oxygen.

[0009] Clinical data indicates that clot removal may be beneficial or even necessary to improve outcomes. For example, in the peripheral vasculature, interventions and procedures can reduce the need for an amputation by 80 percent. The ultimate goal of any modality to treat these conditions of the arterial or venous system is to remove the blockage or restore patency, quickly, safely, and cost effectively. This may be achieved by thrombus dissolution, fragmentation, thrombus aspiration or a combination of these methods.

[00010] Mechanical thrombectomy devices may be particularly advantageous. Depending on the size, location and extent of a clot, it may also be particularly advantageous to

mechanical retrieve and break apart the clot in a manner that is both safe and effective. There is a definite need for a thrombectomy device, and particularly a mechanical thrombectomy device that can be more effective in removing tissue such as clots from within a body. Described herein are apparatuses (devices, systems and kit) and methods of using them that may address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[00011] Described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and methods of using them to remove a thrombus, e.g., clot, including safely and easily removing a clot that is captured in a second clot-grabbing (e.g., thrombectomy) apparatus. The mechanical thrombectomy apparatuses described herein may be inverting tractor thrombectomy apparatuses. An inverting tractor apparatus may include a tractor (tractor region, tractor portion, etc.) comprising a flexible tube of material that inverts as it rolls over itself at a distal end. The tractor may be inverted and/or rolled over the end of a catheter. Thus, the flexible tractor may invert and fold back into itself and may be drawn into a catheter portion in a conveyor-like motion as it rolls around to transition from an outward-facing region of the tractor on an outside of the catheter to an inward-facing region within the lumen of the catheter. The rolling motion may draw a clot and/or clot connected to a clot-grabbing apparatus within a vessel into the catheter, which may also compress and/or macerate the clot. The apparatus, including the clot, and in some variations clot and a clot engaging member engaged with the clot, may then be removed from the body.

[00012] Any of these apparatuses may include, or may be used as part of a system with, a clot capture device having a clot engaging member (e.g., a “stentriever”) at the distal end of an elongate manipulator.

[00013] The mechanical thrombectomy apparatuses described herein may include pre-loaded inverting tractor thrombectomy apparatuses (e.g., devices, systems, etc.). Described herein are mechanical thrombectomy apparatuses, including inverting tractor thrombectomy apparatuses that may engulf a clot prior to pulling it (e.g., into the apparatus) and may be used in combination with other systems. Such apparatuses may invert over clot first, and may then pull the clot into the catheter. Any of these apparatuses may also incorporate aspiration.

[00014] Described herein are mechanical thrombectomy systems that include an elongate inversion support (typically comprising a catheter), a flexible tractor that inverts over the distal end opening of the elongate inversion support, a puller extending proximally to roll and

invert the tractor into the distal end opening, and a clot engaging member on the distal end of an elongate manipulator. The puller and tractor are configured to pass the elongate manipulator through a lumen extending continuously through the puller and the tractor. As described above, in operation, this may be used to slide the rolling thrombectomy portion (e.g., the elongate inversion support, a flexible tractor and a puller) over the elongate manipulator of the clot capture device (e.g., clot engaging member on the distal end of an elongate manipulator).

[00015] For example, described herein are mechanical thrombectomy systems including: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter; a puller connected to the first end of the tractor extending proximally; a clot engaging member on the distal end of an elongate manipulator; and a lumen extending continuously through the puller and the tractor and configured to pass the expandable elongate manipulator.

[00016] In any of these apparatuses (e.g., systems, devices, etc.), the tractor may be sufficiently soft such that without support from the catheter, it collapses radially under an axial compression of less than a small force (e.g., less than 50g of force, 100g of force, less than 150 g of force, less than 200g of force, less than 250 g of force, less than 300 g of force, etc.) when inverting.

[00017] Further, in any of these apparatuses, the tractor may be biased to expand to greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to greater than the inner diameter of the catheter in the un-inverted configuration.

[00018] The clot engaging member may be expandable. For example, the clot engaging member may be one or more of: a coil, a snare, a basket, or a frame. The elongate manipulator may be a wire, tube (e.g., hypotube), rod, etc.

[00019] Any appropriate flexible tractor may be used. For example, the tractor may be one or more of: a braided material, a knitted material, or a woven material. The tractor is typically a tube of material. The tractor may comprise steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric.

[00020] The catheter of the elongate inversion support may extend the full length of the inversion support, or it may be just at the end of the elongate inversion support. The catheter

may be soft (e.g., appropriate for neurovascular use), however the tip may be harder, to resist collapse. For example, the material hardness of catheter decreases over the distal end of the catheter until the distal end opening, wherein the distal end opening has a material hardness that is greater than a material hardness of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile.

[00021] The tractor may be lubricious and/or may comprise one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating. The tractor may be any appropriate length (e.g., between about 3 cm to 100 cm long, between about 10 cm to 200 cm long, between about 3 cm to 50 cm long, between about 200 cm to 500 cm long, etc.).

[00022] Any of these apparatuses may be configured to controllably deploy the tractor, which may be held compressed and/or against the catheter of the elongate inversion support until being deployed. For example, any of these apparatus may include a releasable attachment between the tractor and an outer surface of the catheter (e.g., a tractor hold), wherein the releasable attachment is configured to release when the tractor is pulled (e.g., proximally by the puller) with a force that is greater than a predetermined force threshold. The deployment force threshold may be between 50g and 500g of force (e.g., between 50g and 400g of force, between 100g and 400g of force, etc.).

[00023] Any of these apparatuses may include a sleeve extending over the catheter and tractor. The sleeve may be an outer or intermediate catheter.

[00024] A mechanical thrombectomy system for removing a clot from within a vessel may include: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter; a puller extending proximally within the catheter and connected to the first end of the tractor; an expandable clot engaging member on the distal end of an elongate manipulator, wherein the expandable clot engaging member comprises one or more of: a coil, a snare, a basket, or a frame; and a lumen extending continuously through the puller and the tractor and configured to pass the expandable elongate manipulator.

[00025] In operation, these systems may be used to withdraw a thrombus (clot) from within a vessel, including peripheral vessels or neurovascular vessels. For example,

described herein are methods of removing a clot from within a vessel using a mechanical thrombectomy apparatus. These methods generally include rolling the tractor into the catheter by pulling proximally on the tractor (e.g., by pulling on a puller that extends proximally and is attached to the first end of the tractor within the catheter) to roll the tractor into the catheter. The conveyor-belt like tractor motion, either alone or in conjunction with aspiration applied from the proximal end through the mechanical thrombectomy apparatus (e.g., catheter) and/or an outer catheter within which the mechanical thrombectomy apparatus is passed, may be used to pull a clot into the catheter. Typically when drawing the clot into the apparatus (e.g., into the catheter portion of the apparatus), the clot, or a clot and additional clot engaging member coupled to the clot, may be compressed as it is drawn into the apparatus.

[00026] In some cases, the clot may clog or jam in the apparatus. Described herein are methods of removing a clot from within a vessel using a mechanical thrombectomy apparatus, including methods configured to avoid or correct jamming and/or clogging of the apparatus. The method may include: positioning a distal end of the mechanical thrombectomy apparatus adjacent to the clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter; pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter and pull the clot into the catheter with the inverting tractor; withdrawing the catheter proximally away from the tractor and clot when the tractor jams on the distal end of the catheter; pulling the first end of the tractor proximally so that the tractor inverts over the clot within the vessel without rolling over the distal end opening of the catheter; and withdrawing the tractor and clot proximally from the vessel.

[00027] Any of the methods described herein may include releasing the tractor from a locked or secured position on the outside of the catheter of the apparatus. Thus, any of these apparatuses used herein may include a tractor hold that releasably secures the tractor to the outside of the catheter. For example, any of the methods described herein may include disengaging a second end of the tractor from a tractor hold that secures the second end of the tractor to an outer surface of the catheter by pulling the tractor proximally with a force greater than a deployment force and expanding the tractor against the vessel wall, wherein the second end of the tractor is disengaged before pulling the first end of the tractor proximally.

[00028] Once the clot and/or clot engaging member has been engulfed by the tractor, it may then be withdrawn back into the catheter, without requiring the tractor to invert over the catheter. For example, any of the methods described herein may also or alternatively include pulling proximally on the tractor to draw the tractor and clot into the catheter.

[00029] Pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter may comprise advancing the catheter while pulling the first end of the tractor. Alternatively or additionally, pulling the first end of the tractor proximally so that the tractor inverts over the clot may further comprise pulling the catheter proximally with the first end of the tractor. Alternatively or additionally, pulling the first end of the tractor proximally so that the tractor inverts over the clot may comprise pulling a puller at the proximal end of the mechanical thrombectomy apparatus proximally.

[00030] Withdrawing the catheter proximally away from the tractor may comprise pulling the catheter proximally a short distance or a substantial distance. For example, the catheter may be pulled proximally only sufficiently far to disengage the jam of the clot (and/or clot engaging member) from the catheter distal end opening. Alternatively or additionally, withdrawing the catheter proximally away from the tractor (the tractor distal-facing end) may include pulling the catheter beyond a second end of the tractor that is outside of the catheter.

[00031] Alternatively or additionally, the catheter may be pulled proximally with the first end of the tractor (e.g., the tractor puller) as the tractor is pulled proximally so that the tractor inverts over the clot within the vessel without rolling over the distal end opening of the catheter.

[00032] In any of the methods described herein the tractor may be expanded to that all or a portion of the tractor contacts the wall of the vessel. Thus, the tractor may be expanded when released (e.g., from the tractor hold) to contact the wall of the vessel. Any of the tractors described herein may be biased (e.g., heat set, etc.) so that it expands (when over the catheter) to approximately 1x or more (e.g., 1.1x, 1.2x, 1.3x, 1.4x, 1.5x, etc.) the diameter of the vessel. Contact between the vessel wall and the tractor may provide resistance that enhances the ability of the tractor to invert when the first end of the tractor is pulled proximally without inverting over the distal end opening of the catheter. Pulling the first end of the tractor proximally so that the tractor inverts over the clot may comprise pulling the first end of the tractor when the tractor has expanded to contact the vessel wall.

[00033] In any of the methods described herein, a guidewire, catheter or the like may be used to position the apparatus near, adjacent to, or on the clot. For example, positioning the distal end of the mechanical thrombectomy apparatus adjacent to the clot may comprise

sliding the mechanical thrombectomy apparatus over a guidewire or catheter passing through a lumen in the mechanical thrombectomy apparatus.

[00034] A method of removing a clot from within a vessel using a mechanical thrombectomy apparatus may include: positioning a distal end of the mechanical thrombectomy apparatus adjacent to the clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter; disengaging a second end of the tractor from a tractor hold that secures the second end of the tractor to an outer surface of the catheter by pulling the tractor proximally with a force greater than a deployment force and expanding the tractor against the vessel wall; pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter and pull the clot into the catheter with the inverting tractor; withdrawing the catheter proximally away from the tractor and clot when the tractor jams on the distal end of the catheter; pulling the tractor and clot proximally so that the tractor inverts over the clot within the vessel without rolling over the distal end opening of the catheter; pulling proximally on the tractor to draw the tractor and clot into the catheter; and withdrawing the tractor and clot proximally from the vessel.

[00035] Also described herein are methods of removing a clot from within a vessel using a mechanical thrombectomy apparatus in which a secondary clot-grabbing device (e.g., generally referred to herein as a clot engaging member), which may be a secondary device or a part of the mechanical thrombectomy apparatuses described herein, is removed with the clot. Any appropriate clot engaging member may be used. In particular, a clot engaging member may include an expandable/compressible clot engaging member that is configured a frame or wire. For example, a clot engagement member may be an expandable coil or plurality of coils, snare, basket, or frame. Any of these clot engagement members may include an elongate manipulator (e.g., an elongate wire, catheter, shaft, member, etc.) attached to the clot engagement member, such as the proximal end of the clot engagement member.

[00036] Any of the methods described herein may include tracking over the clot engaging member, including sliding over the elongate member attached to the clot engagement member. The mechanical thrombectomy apparatus may be guided to the clot and/or clot engagement member by sliding distally over an elongate member attached to a clot engagement member that has been previously coupled with a clot.

[00037] The clot engagement member may be coupled to the clot by passing into and/or through the clot. For example, the clot engagement member may be passed into the clot where it may engage with the clot material and expanded into the clot. Alternatively or additionally, the clot engagement member may be passed through the clot and expanded distally of the clot so that it may drive the clot proximally when the clot engagement member is pulled proximally, e.g., by pulling proximally on the elongate member coupled to the clot engagement member.

[00038] For example a method of removing a clot from within a vessel using a mechanical thrombectomy apparatus may include: engaging the clot with a clot engaging member on the distal end of an elongate manipulator; sliding the mechanical thrombectomy apparatus over the elongate manipulator to position the distal end of the mechanical thrombectomy apparatus adjacent to the clot, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter; pushing the catheter distally while holding the first end of the tractor within the catheter fixed relatively to the elongate manipulator so that the tractor rolls and inverts over the distal end of the catheter and pulls the clot and the clot engaging member into the catheter with the inverting tractor; and withdrawing the mechanical thrombectomy apparatus, clot and clot engaging member proximally from the vessel.

[00039] As mentioned, the clot engaging member may engage with the clot by expanding into the clot and/or beyond the clot. For example, engaging the clot with the clot engaging member on the distal end of the elongate manipulator may comprise expanding the engaging member within the clot. Engaging the clot with the clot engaging member on the distal end of the elongate manipulator may comprise expanding the engaging member on a distal side of the clot. In general, engaging the clot with the clot engaging member on the distal end of the elongate manipulator may comprise expanding the engagement member. For example, the engaging member may comprise an expandable coil(s), snare, basket, or frame.

[00040] In any of these methods in which a clot engaging member is used with the rolling mechanical thrombectomy apparatus, the apparatus may be advanced distally over the apparatus to capture the clot and clot engaging member. For example, in any of these methods pulling the first end of the tractor proximally may comprise advancing the catheter distally as the tractor is pulled proximally. Engulfing the clot and/or clot engaging member by advancing distally over the clot and/or clot engaging member may be particularly

beneficial compared to methods in which the clot and clot engaging member are drawn proximally to be engulfed.

[00041] In any of these apparatuses, pulling the first end of the tractor proximally may comprise pulling a puller proximally wherein the puller is coupled to the first end of the tractor. Alternatively or additionally, pulling the first end of the tractor proximally may comprise pulling the elongate manipulator proximally with the first end of the tractor.

[00042] Any of these methods may also include releasing the tractor from the catheter. For example, any of these methods may include disengaging a second end of the tractor from a tractor hold that secures the second end of the tractor to an outer surface of the catheter by pulling the tractor proximally with a force greater than a deployment force and expanding the tractor against the vessel wall.

[00043] A method of removing a clot from within a vessel using a mechanical thrombectomy apparatus may include: engaging the clot with a clot engaging member on the distal end of an elongate manipulator; sliding the mechanical thrombectomy apparatus over the elongate manipulator to position the distal end of the mechanical thrombectomy apparatus adjacent to the clot, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter; sliding the mechanical thrombectomy apparatus over the elongate manipulator to position the distal end of the mechanical thrombectomy apparatus adjacent to the clot, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter; and withdrawing the mechanical thrombectomy apparatus, clot and clot engaging member proximally from the vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

[00044] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00045] FIGS. 1A-1H illustrate an example of an apparatus for mechanically removing an object such as a clot from a body region (e.g., a rolling mechanical thrombectomy apparatus). FIG. 1A shows an example of an elongate inversion support portion of an apparatus,

configured as a catheter portion. For example, at least the distal end of the elongate inversion support may be configured as a catheter. FIG. 1B shows an enlarged view of a distal end (opening) of the catheter of the elongate inversion support of FIG. 1A, showing the aperture formed by the distal end opening; FIG. 1C shows an example of a distal tractor region of a flexible tube (tractor tube) extending from a puller (the puller in this example is configured as a catheter). The tractor is shown in a first (e.g., un-inverted) configuration) and may be biased open, e.g., by heat setting, to have an outer diameter that is greater than the inner diameter of the catheter of the elongate inversion support, as shown in FIG. 1D. FIG. 1D shows the same distal tractor region of FIG. 1C with the expandable first end region expanded. This first configuration may be compressed down into the elongate inversion support and the distal end inverted over the catheter portion of the elongate inversion support, as shown in FIG. 1E. In FIG. 1E, the assembled mechanical thrombectomy apparatus with the elongate inversion support and the flexible tube forming the tractor is shown. The tractor extends through the catheter of the elongate inversion support and doubles back over the distal end opening of the catheter and extends over the outer diameter of the catheter. The outer portion of the tractor (extending along the outer diameter of the catheter) may be held in a collapsed configuration (as shown in FIG. 1E), or it may be expanded, as shown in FIG. 1F. Thus, the tractor may be biased so that in the second configuration (inverted over the distal end of the catheter), the tractor has a 'relaxed' outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. FIGS. 1G and 1H illustrate the use of the apparatus of FIGS. 1E and 1F to remove a clot by drawing the flexible tube proximally and/or advancing the catheter distally towards the clot so that the expandable first end region inverts as it is drawn into the distal end of the catheter, pulling the clot into the catheter.

[00046] FIG. 1I illustrates an alternative variation of a tractor and puller. In FIG. 1I, the tractor is shown attached to the distal end of a tapered or narrow puller; the distal end region is tapered, and includes a radiopaque marker at or near the attachment site to the tractor; the tractor may be knitted, braided, woven, etc. Thus, in some variations the distal end region of the puller may have a greater flexibility than the proximal end of the puller. The puller may be hollow (e.g., a catheter or hypotube) or solid (e.g., like a wire).

[00047] FIGS. 2A-2G illustrate a method of capturing a clot with a rolling mechanical thrombectomy apparatus after it has jammed or clogged the catheter of the rolling mechanical thrombectomy apparatus.

[00048] FIGS. 3A illustrates an example of a rolling mechanical thrombectomy apparatus in which the clot has jammed while rolling the tractor into the distal end opening of the

catheter portion of the rolling mechanical thrombectomy apparatus, similar to that shown in FIG. 2B. FIG. 3B illustrates an example of the clot engulfed by the tractor as illustrated in FIGS. 2C-2F. As shown in FIG. 2F and 2G, the clot and tractor may then be drawn proximally out of the vessel, including by drawing proximally into the catheter first.

[00049] FIGS. 4A-4G illustrate an example of a rolling mechanical thrombectomy apparatus in which the clot has jammed while rolling the tractor into the distal end opening of the catheter portion of the rolling mechanical thrombectomy apparatus.

[00050] FIGS. 5A-5C illustrate examples of clot engaging members coupled to elongate manipulators that may be used with any of the apparatuses described herein.

[00051] FIGS. 6A-6H illustrate a method of capturing a clot engaged with a clot engagement member by advancing a rolling mechanical thrombectomy apparatus over the clot and clot engagement member.

[00052] FIG. 6I illustrates an example of a mechanical thrombectomy system for removing a clot from within a vessel.

[00053] FIGS. 7A-7B illustrate a method of capturing a clot engaged with a clot engagement member as described herein.

DETAILED DESCRIPTION

[00054] In general, described herein are mechanical thrombectomy apparatuses and methods of using them to remove clots. The mechanical thrombectomy apparatuses described herein may have an inverting tractor region and an elongate inversion support having a distal annulus over which the tractor rolls and inverts over itself. Any of these apparatuses and methods of using them may be configured to prevent premature deployment of the tractor. The elongate inversion support may be a catheter having a distal end opening. The tractor may comprise a flexible tube that may be formed of a sheet having openings, or may be a woven, braided, knitted, etc. material such as a fiber. The tractor may extend longitudinally within the elongate inversion support and may and double back (e.g., invert) over the annulus of the elongate inversion support (e.g., the distal end of a catheter) so that it extends along the midline of the apparatus; when the elongate inversion support is a catheter, the tractor may extend within the catheter lumen. The tractor may connect to an inner puller that is typically coupled to an end of the tractor (which may be referred to as the inner end or the distal end) that can be pulled proximally to pull and invert the tractor over the distal end so that it rolls over the distal end, which may capture a clot. The apparatus may include a guidewire lumen extending through the catheter, tractor and/or tractor puller.

[00055] In general, a mechanical thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an elongate inversion support having a distal end and a distal annulus, and a flexible tractor assembly at least partially inverted and configured to roll and invert over the distal annulus of the elongate inversion support.

[00056] In many of the examples described herein, the elongate inversion support is a catheter (or a portion of a catheter at the distal end) and the annulus is formed by the distal end opening of the catheter; the tractor extends within the catheter and doubles back over the distal end of the catheter to extend over the outer diameter of the catheter at the distal end of the catheter, although it may extend proximal for any appropriate distance (including between 1-30 cm, between 2-20 cm, greater than 1 cm, 2 cm, 3 cm, 4 cm, 5 cm, 6 cm, 7 cm, 8 cm, 9 cm, 10 cm, 11 cm, 12 cm, 15 cm, 20 cm, etc.). The end of the tractor within the catheter may be coupled to a pusher (e.g., at a proximate pusher region connected to the distal or inner end of the tractor). The tubular tractor may include an elongate lumen that is configured to allow passage of a guidewire. The tubular tractor may also be configured to slide along the long axis within the catheter lumen and invert over the distal end opening of the catheter when the proximal end region is pulled proximally. The tractor may be referred to herein as a tractor assembly, tractor portion, tractor tube, or simply a tractor, and is typically positioned and longitudinally slideable within the catheter, and arranged so a portion of the tractor (sometimes referred to as the “distal tractor region” or “distal-facing” tractor region) doubles back over itself.

[00057] For example, FIG. 1A shows one variation of a catheter that may form part of the apparatuses described herein. In this example, the catheter 100 includes a distal end region 103 that includes a distal end 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal tip (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing hardness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1 mm, 0.8 mm, 0.5 mm, 0.3 mm, 0.2 mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00058] FIG. 1A shows one variation of a catheter of an elongate inversion support that may form part of the apparatuses described herein. In this example, the elongate inversion support includes a catheter 100 having a distal end region 103 that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing hardness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1 mm, 0.8 mm, 0.5 mm, 0.3 mm, 0.2 mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00059] In FIG. 1A, the elongate inversion support is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include a elongate inversion support that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like (as will be described in greater detail below in reference to FIGS. 7A-8D) or may be skived. Thus, any of the apparatuses and methods described herein may be adapted for use with an elongate inversion support that is not limited to catheters, including elongate inversion supports that include a portion of a catheter, or that include a ring or other structure forming the annulus at the distal end. In FIG. 1A the catheter 100 of the elongate inversion support may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00060] In some variations the distal end 105 of the elongate inversion support is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in some variations

the distal tip (end) may be curved or radiused 109 as shown in FIG. 1B, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[00061] FIG. 1C shows an example of a flexible tractor 144 coupled to a puller 146. In this example to form a pullable tractor assembly 140, the tractor is shown integrated with the puller, forming the assembly. In FIG. 1C, the tractor is a tube of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The tractor is shown extended from the puller in a first configuration. It may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 144 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The puller 146 may typically be a less-expandable (or non-expandable) structure (tube, puller, etc.). In the example shown in FIG. 1C, the tractor 144 is configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first configuration to a radial diameter that is between 1.1 and 10 times the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained, as shown in FIG. 1D. In FIG. 1D, the tractor of FIG. 1C is shown in an expanded, relaxed, configuration. Thus the expandable tractor may be biased to expand open. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00062] In FIGS. 1C and 1D the tractor and puller have two portions, a tractor 144 and a less expandable (or non-expandable) proximal portion comprising the puller 146. The puller may be a separate region, such as a wire, catheter or hypotube, which is connected to an end region of the tractor (e.g., a flexible mesh, woven, braided, etc.), e.g., the distal end or near the distal end. The inverting region of the tractor, where it rolls and inverts over the distal end opening of the catheter may be referred to as the distal-facing region of the tractor, which may actively grab clot when rolling.

[00063] In FIG. 1E, the flexible tractor of FIG. 1C is shown with the tractor doubled back over itself and over the the distal end of the catheter of the elongate inversion support 101. The distal end region is collapsed down, e.g., onto the puller and the elongate inversion support, and may be held collapsed. In this example a tractor hold 188 may be used to hold the tractor collapsed down onto the outer diameter of the elongate inversion support. However, in an unconstrained or deployed configuration, as shown in FIG. 1F, the tractor in this second configuration (e.g., the portion that is inverted over the distal end of the catheter)

has an outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. Thus, the tractor 144 may be biased so that it has a relaxed expanded configuration in the first configuration (as shown in FIG. 1C) that is greater than the inner diameter (ID) of the catheter of the elongate inversion support portion of the apparatus and the relaxed expanded configuration of the second configuration (shown in FIG. 1F) inverted over the catheter has an OD that is greater than the OD of the catheter. The tractor is expandable and may be coupled to the puller. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to a push/pull wire or catheter.

[00064] FIGS. 1G and 1H illustrate the removal of a clot using an apparatus such as the apparatus assembled from the components of FIGS. 1A and 1E. In this example the apparatus is configured as a thrombectomy apparatus including a catheter of an elongate inversion support 101 and a flexible tractor that extends over the distal end region of the catheter and doubles-over itself at the distal end of the catheter to invert so that the external tractor end region is continuous with an inner less-expandable (in this example, less-expandable includes non-expandable) second distal end region 146 (puller) that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The pusher/puller member that may be a rod or other member that is continuous with the distal end region of the tractor. In FIG. 1G the apparatus is shown positioned and deployed within the vessel 160 near a clot 155. The clot may be drawn into the catheter by pulling the tractor 140 proximally into the catheter 101, as indicated by the arrow 180 showing pulling of the inner portion of the flexible tractor (e.g., using a handle, not shown) resulting in rolling the tractor over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled into the catheter, shown by arrows 182. The end of the tractor outside of the catheter may be “loose” relative to the outer wall of the catheter. FIG. 1I illustrates another example of a tractor assembly 154 including a tractor 144 that is coupled to a puller 156. The puller in this example is tapered (having tapering region 161) and may therefore have a different flexibility of the distal end region than the proximal end region. For example the proximal end region may be less flexible than the narrower-diameter distal end region 195 to which the tractor is coupled. The assembly includes a radiopaque marker 165. The tractor may be attached to the puller by any appropriate means. For example, the tractor may be crimped, glued, fused, or otherwise attached to the puller, typically permanently.

[00065] These apparatuses may be highly flexible, both before actuating and during operation. For example, in general, the flexible tractor may not increase the stiffness/flexibility of the catheter, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortuous vessels of the neurovasculature. Described herein are flexible tractor tube portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[00066] In any of the apparatuses described herein, in which the tractor is at least partially inverted over the distal end of the catheter so that the tractor extends on the outer surface of the catheter, the tractor may be releasably coupled to the outer diameter of the catheter to allow the apparatus to be inserted through a body, including through tortuous vessels in the body, prior to being deployed to remove a clot or other element from the vessel. The tractor may be a braided, woven or knit material tube of material that is inverted over the distal end of the catheter; alternatively the tractor may be formed of a sheet of material that include openings therethrough.

[00067] Any of the apparatuses described herein may be adapted to prevent premature deployment of the tractor, e.g., by including a tractor hold (e.g., a housing, a lock, a clamp, etc.) or the like to secure the outer end of the tractor against and/or relative to the elongate inversion support. For example, a tractor hold may secure the outer end of the tractor against a catheter into which the tractor inverts when pulled proximally by the puller.

[00068] The tractor hold may compress the tractor against the catheter. Typically, the threshold force for the tractor hold is determined by the force required to deploy the tractor within the lumen, which may depend upon the length of the apparatus, the diameter of the tractor and/or catheter, and the materials of the tractor and elongate inversion support (e.g., catheter). For example, the tractor hold may be configured to hold the second end of the tractor until the threshold force is applied, wherein the threshold force is between 100 g force and 2000 g force (e.g., between 50 g of force and 2000 g of force, between 50 g of force and 1500 g of force, between 40 g of force and 1000 g of force, between 50 g of force and 500 g of force, between 100g of force and 500 g of force, between 200 g of force and 500 g of

force, between 250 g of force and 500 g of force, between 50 g of force and 450 g of force, between 100 g of force and 450 g of force, between 100 g of force and 400 g of force, between 200 g of force and 400 g of force, etc.). The range of force appropriate to the threshold force may be important in proper functioning of the apparatus, particularly when the force is applied by pulling proximally on the puller and/or tractor; too little force for the threshold and the tractor will prematurely deploy; too much force and the apparatus will jam (e.g., by kinking the elongate inversion support).

[00069] In any of the variations described herein, the tractor may be biased to collapse and/or expand. For example, the tractor may be biased to collapse over the catheter outer diameter (e.g., the outer diameter of the elongate inversion support, including the distal end of the catheter); such tractors may also be biased to expand after inverting (e.g., within the catheter) over the distal end opening of the elongate inversion support. This arrangement may cause the tractor to form a distal-facing region that flares, trumpet-like, towards a clot distal to the device, which may help in capturing the clot and also may prevent jamming of the tractor. Alternatively or additionally, some or all of the tractor regions may be configured to expand over the outer diameter of the elongate inversion support.

[00070] The proximal end of the tractor hold may be attached to the catheter. The tractor hold may be fixed, fused, or integrally formed with the catheter.

[00071] Any of the apparatuses described herein may be used to withdraw a clot and/or a clot engaging member. For example, FIGS. 2A-2G illustrate removal of a clot using a rolling thrombectomy apparatus. The apparatus may also be referred to as an inverting thrombectomy apparatus. In any of the variations described herein a vacuum may be used to help secure the clot to the tractor.

[00072] In FIG. 2A, the rolling mechanical thrombectomy apparatus 200 is brought near to the clot 220. In this example, a guidewire 205 may be used to help position the apparatus adjacent to the clot. The guidewire may be left in place or removed. Alternatively, as described in variations in which a clot engaging member on the distal end of an elongate manipulator is used, the apparatus 200 may be directed over the elongate manipulator. In FIG. 2A, the rolling thrombectomy apparatus includes a tractor 203 that is configured to roll over the distal end opening of a catheter 207. In FIG. 2A, the tractor is held in tension by holding in a fixed position relative to the catheter at a second (outer) end of the tractor; a tractor hold (not shown in FIG. 2A) may be used to releasably hold an end of the tractor fixed relative to the catheter. When a force sufficient to overcome the deployment force (e.g., 100 g of force or greater, 200 g of force or greater, etc.) is applied by pulling 219 the first end of

the tractor, as shown in FIG. 2B. In FIG. 2B, the puller 209, coupled to the first end of the tractor within the catheter, is pulled to deploy the tractor. When deployed the tractor may expand away from the catheter and towards the wall(s) of the vessel 260.

[00073] As shown in FIG. 2B, the tractor may be rolled and inverted 282 into the catheter by pulling the first end of the tractor from within the catheter (e.g., by pulling 219 the puller proximally). The puller in FIGS. 2A-2G is shown as a hollow member (e.g., catheter, tube, etc.) but it may be a wire, cable, etc.

[00074] Occasionally, if the clot diameter is too large compared to the diameter of the distal end opening of the catheter, and/or if the clot is too stiff and difficult to compress, the clot 220 may jam in the distal end opening of the catheter after at least a portion of the clot has been grabbed by the tractor. This is illustrated in FIG. 2B and 2C. In this example the force required to pull the clot into the catheter may be too high (e.g., greater than the longitudinal compression strength of the catheter, such as greater than 500 g of force, greater than 600 g of force, greater than 700 g of force, greater than 800 g of force, greater than 900 g of force, greater than 1000 g of force, greater than 1100 g of force, greater than 1200 g of force, greater than 1300 g of force, greater than 1400 g of force, greater than 1500 g of force, etc. the threshold may depend on the catheter type and structure.

[00075] When the clot is jammed within the catheter distal end opening, as shown in FIG. 2B (and in FIG. 3A), the method may then proceed to engulf and remove the clot with the tractor by withdrawing the catheter and continuing to pull the first end of the tractor proximally by pulling the puller proximally. In FIG. 2C, the catheter distal end opening 209' is shown withdrawn a substantial distance, e.g., beyond the second (outer) end of the tractor; alternatively the catheter may be withdrawn just slightly relative to the tractor and/or may be withdrawn with the puller as the puller is withdrawn proximally.

[00076] As shown in FIG. 2D, when the puller is pulled proximally either with the catheter or with the catheter withdrawn proximally (as shown) so that the tractor cannot roll over the distal end opening of the tractor, the interference between the wall of the vessel 260 and the expanded tractor 251 may hold the tractor in place as the clot, which is still secured to the tractor either by the force of interaction between the tractor and the clot, and/or by suction (e.g., through the puller or other lumen connected to the tractor), is pulled proximally with the tractor. Thus, as shown in FIGS. 2D and 2E, the clot may be engulfed by the tractor and pulled proximally into the expanded tractor.

[00077] Ultimately, the tractor, clot and catheter may be removed proximally from the vessel. In some variations, as shown in FIG. 2F and 2G, the the clot may be pulled with the

tractor into the catheter once it has been fully engulfed by the tractor. As illustrated in FIG. 3A, the clot may be jammed so that it is unable to be pulled into catheter by rolling the tractor so that it inverts into the catheter, similar to what was described above for FIG. 2B. In FIG. 3B, the clot has been pulled proximally with the tractor but not rolled over the catheter distal end opening; instead, the catheter has been withdrawn and the clot pulled into the tractor to invert itself round and engulf the clot within the tractor. Thus, pulling back the catheter proximally, even without pulling the tractor proximally or while pulling both the tractor and the catheter proximally, may drag the clot proximally and invert the tractor over the clot, as shown. As mentioned above, it may be helpful to have the tractor expand radially within the vessel to contact the wall of the vessel. This may help lock the tractor in position as the catheter and/or tractor is pulled proximally. The tractor may include at least a portion of its length that has an element that expands to the vessel wall. Inverting the tractor over the clot in this manner may reduce the risk of creating emboli compared to other techniques, including aspiration-only techniques, and also may not require the additional cost and risk of delivering a secondary device, such as a clot engaging member prior to or with the rolling mechanical thrombectomy apparatuses described herein (see below with regard to FIGS. 5A-7B for examples in which a clot engaging member is used in addition to the rolling mechanical thrombectomy apparatuses described herein).

[00078] FIGS. 4A-4G illustrate another example of a method of capturing and/or removing a clot from a vessel using a rolling mechanical thrombectomy apparatus. In this example, rather than pulling the clot proximally into the tractor, the tractor (and catheter) may be advanced distally forward over the clot. For example, in FIG. 4A, a guide wire 405 (or other guide member) may be steered or driven distally to the clot 420. The guidewire may extend just to the clot or may pass at least partially through the clot. In some variations it may be beneficial to stop the guidewire prior to entering the clot, in order to avoid disrupting the clot. Once the guidewire is positioned, a rolling mechanical thrombectomy apparatus 400 may be positioned over the guidewire so that it is adjacent to the clot. The apparatus may include the catheter 401 and a tractor 403 that is coupled at a first end within the catheter to a puller (shown as a puller inner catheter 407). Optionally, the guidewire may be removed (as shown in FIG. 4C), leaving the rolling mechanical thrombectomy apparatus 400 behind.

[00079] The tractor may then be rolled into the catheter and inverted by either pulling proximally on the puller (coupled within the catheter to the first end of the tractor), or alternatively and/or additionally by moving the catheter distally against the tractor, as shown in FIGS. 4C and 4D. In this example, the tractor puller is held in a relatively fixed position

and the catheter is slowly advanced distally, towards the clot. The tractor therefore rolls and inverts 451 into the advancing catheter distal end, which may then travel up and into the clot 420, as shown in FIG. 4E. As the catheter advances, rolling the tractor so that it grabs and pulls the clot into the catheter distal end with the tractor, the tractor also envelops the clot and compresses it into the catheter inner lumen 460. Once the clot is engulfed and/or completely enveloped by the apparatus, the catheter forward (distal) motion may stop, as shown in FIG. 4F. Thereafter the catheter and tractor may be fixed in relative position (e.g., no motion relative to each other) and the apparatus slowly removed from out of the vessel, as shown in FIG. 4G, with the clot within the tractor and the tractor and clot within the lumen of the catheter.

[00080] As mentioned above, any of the methods and apparatuses described herein may be used with (and/or may integrate into them) a clot engaging member on the distal end of an elongate manipulator. Any type of clot engaging member may be used, and particularly those on the distal end of an elongate manipulator. For example, FIGS. 5A-5C illustrate different schematic variations of clot engaging member on the distal end of an elongate manipulator. In FIG. 5A the clot engaging member 501 is a coil that is on the distal end of an elongate manipulator 503. The coil may be expandable, e.g., may be compressed so that when released at or near the clot it may expand. The clot engaging member may be secured into the clot or through the clot so that, once expanded, it may help mechanically capture the clot.

[00081] FIG. 5B shows another example of a clot engaging member 501' on the distal end of an elongate manipulator 503'. In FIG. 5B, the clot engaging member includes a plurality of wires that may expand outward within the clot. Similarly, FIG. 5C illustrates another example of a clot engaging member 501'' on the distal end of an elongate manipulator 503''.

[00082] Any of the apparatuses described herein may be used in conjunction with a clot engaging member, and particularly a clot engaging member on the distal end of an elongate manipulator.

[00083] FIG. 6I illustrates an example of a mechanical thrombectomy system for removing a clot from within a vessel. In FIG. 6I, the apparatus (e.g., system) includes an elongate inversion support comprising a catheter 607 having a distal end and a distal end opening, a tractor 615 comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of

the tractor is pulled proximally within the catheter. The system also includes a puller 611 connected to the first end of the tractor that extends proximally within the catheter. The system also includes a clot engaging member 601 on the distal end of an elongate manipulator 603. The elongate member is shown passing through a lumen extending continuously through the puller and the tractor and configured to pass the expandable elongate manipulator. This system may be used to remove a clot.

[00084] For example, a clot engaging member on the distal end of an elongate manipulator may be advanced through a clot; the expansive/expandable clot engaging member on the distal end of the elongate manipulator may engage with a clot and lock the clot in place in the vessel. The rolling mechanical thrombectomy apparatus may then be delivered, e.g., over the elongate manipulator to the clot and the clot engaging member. Once near the clot, the tractor may be rolled into the distal end of the catheter by pulling the first end of the tractor (e.g., by pulling a puller) proximally and advancing the catheter distally and/or by holding the puller in a relatively fixed position and driving the catheter distally to roll the tractor and invert it into the catheter. Preferably, as illustrated in FIGS. 4A-4G above, the catheter may be advanced forward in the vessel and the proximal end of the tractor may be held and/or fixed (in a fixed longitudinal position). For example, the proximal end of the tractor may be a puller/catheter that is slid over the elongate manipulator and, once positioned adjacent to the clot, held in a fixed position relative to the elongate manipulator. Holding the proximal puller fixed to the elongate manipulator while advancing the catheter forward distally relative to the elongate manipulator may therefore invert the tractor over the clot and clot engaging member similar. This action may force the tractor to roll into the distal end opening of the catheter and grab and engulf the clot along with the clot engaging member. In this example, the clot engaging member may be in the clot and/or distal to the clot, and the elongate manipulator acts as a guide rail for the rolling mechanical thrombectomy apparatus as the catheter is advanced forward. This example is illustrated in FIGS. 6A-6I.

[00085] For example, in FIG. 6A, the clot engaging member 601 on the distal end of an elongate manipulator 603 is advanced distally into and through the clot 620. Thus, the clot engaging member engages the clot from the distal side of the clot, and may pull against the clot when drawn proximally. Alternatively, FIG. 6B shows an example in which the engaging member 601 on the distal end of an elongate manipulator 603 is deployed within the clot 620. The engaging member may engage the clot by expanding within the clot.

[00086] Once deployed, the engaging member and clot may be captured by a rolling mechanical thrombectomy apparatus, as shown in FIG. 6C. Once adjacent to the clot, the

apparatus may be advanced distally by driving the catheter 607 distally 609, as shown in FIG. 6D. The elongate manipulator 603 and the puller 611 coupled to the first end of the tractor may be held fixed relative to one another (and/or may be jointly pulled proximally) while the catheter 607 is pushed distally 609, as shown in FIG. 6E. This may therefore roll the tractor over the distal end of the catheter and capture the clot and clot engaging member, pulling it into the catheter 613 as shown in FIG. 6F. This process may be continued until the entire clot and clot engaging member is engulfed and held within the catheter, as shown in FIG. 6G. Once complete, the apparatus, clot and clot engagement member may be withdrawn proximally out of the vessel, as shown in FIG. 6H.

[00087] Alternatively, a clot engagement member may be deployed through a rolling mechanical thrombosis apparatus in order to engage with the clot before removing with the rolling mechanical thrombosis apparatus.

[00088] In any of the variations described herein, the tractor may be actuated by advancing the catheter portion distally over the clot and clot engagement member either with or without pulling the tractor (e.g., puller) proximally within the catheter. The tractor may grab the clot and clot engagement member and may be advanced forward distally over both the clot and the clot engagement mechanism. This technique may avoid dragging the clot engagement apparatus within the vessel and may provide active capturing. This may reduce the risk of any distal emboli on embolization of new territories. As mentioned above, in any of these variations suction/aspiration can be used in combination with any of these steps.

[00089] In any of these variations, the clot engaging mechanism may be pulled proximally into the pre-loaded dozer catheter, rather than advancing the apparatus over the clot engaging mechanism; as the clot engagement mechanism pulls into the pre-loaded tractor and catheter, the tractor may grab and encapsulate the clot as the clot and clot engagement mechanism is pulled proximally.

[00090] FIGS. 7A and 7B illustrate an example in which the clot engagement apparatus 703 is linked to the puller 705, so that the two may be moved or held motionless together, relative to the catheter 707, and/or the vessel. For example, in FIG. 7B, the apparatus is inserted into the vessel and adjacent to clot engagement mechanism and held motionless while the catheter is driven forward, allowing the tractor 713 to roll distally and into the catheter and capture the clot without requiring the clot and/or clot engagement mechanism to move within the vessel. This may reduce the risk for further embolization.

[00091] As mentioned above, any of the apparatuses and methods described herein may be used with aspiration (e.g., vacuum). For example, any of these methods described herein

may be may use a combination of aspiration and a tractor pull mechanism. For example, to initiate the grabbing of the clot by the tractor, the tractor may be rolled around a catheter wall and may make physical (e.g., direct) contact with the clot. A user may apply vacuum through the catheter (e.g., via a syringe or pump, etc.) prior to or at the same time as pulling tractor into the catheter. Alternatively or additionally, vacuum may be applied through the puller (e.g., a pulling catheter). If vacuum is applied prior to pulling the tractor the vacuum may be applied 1sec to 5min prior ensure the clot is in good contact with the distal end of the catheter. Preferred range of 5-60sec vacuum prior to activating/pulling dozer. The application of vacuum prior to pulling the braid will ensure the proximal most end of the clot is in contact with the catheter tip and some amount of the clot ($\geq 0.5\text{mm}$) is extruded into the lumen of the catheter tip. Next when the dozer is pulled there will be clot at the tip of the catheter for the braid/dozer to grab and pull in. Also, when the dozer is pulled there are resultant forces from the braid/dozer that put compression forces on the catheter tip encouraging the catheter tip to buckle and/or move proximally away from the proximal edge of the clot. The application of vacuum ensures that even if the catheter tip wants to move proximally when pulling the tractor that the clot will stay in contact with the clot and/or prevent the catheter tip from pulling back away from the clot. Once the tractor engages a grabs a few mm of clot the vacuum may be kept on or turned off.

[00092] Any of the methods (including user interfaces) described herein may be implemented as software, hardware or firmware, and may be described as a non-transitory computer-readable storage medium storing a set of instructions capable of being executed by a processor (e.g., computer, tablet, smartphone, etc.), that when executed by the processor causes the processor to control perform any of the steps, including but not limited to: displaying, communicating with the user, analyzing, modifying parameters (including timing, frequency, intensity, etc.), determining, alerting, or the like.

[00093] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features

or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[00094] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[00095] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[00096] Although the terms "first" and "second" may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[00097] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and

“comprising” means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term “comprising” will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

[00098] In general, any of the apparatuses and methods described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may alternatively be exclusive, and may be expressed as “consisting of” or alternatively “consisting essentially of” the various components, steps, sub-components or sub-steps.

[00099] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word “about” or “approximately,” even if the term does not expressly appear. The phrase “about” or “approximately” may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For example, if the value “10” is disclosed, then “about 10” is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that “less than or equal to” the value, “greater than or equal to the value” and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value “X” is disclosed the “less than or equal to X” as well as “greater than or equal to X” (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point “10” and a particular data point “15” are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[000100] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the

invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[000101] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term “invention” merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

What is claimed is:

1. A mechanical thrombectomy system for removing a clot from within a vessel, the apparatus comprising:
 - an elongate inversion support comprising a catheter having a distal end and a distal end opening;
 - a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter;
 - a puller connected to the first end of the tractor extending proximally;
 - a clot engaging member on the distal end of an elongate manipulator; and
 - a lumen extending continuously through the puller and the tractor and configured to pass the expandable elongate manipulator.
2. The system of claim 1, wherein the clot engaging member is an expandable clot engaging member.
3. The system of claim 1, wherein the clot engaging member comprises one or more of: a coil, a snare, a basket, or a frame.
4. The system of claim 1, wherein the tractor is sufficiently soft such that without support from the catheter, it collapses radially under an axial compression of less than 200g of force when inverting.
5. The system of claim 1, wherein the tractor is biased to expand to greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to greater than the inner diameter of the catheter in the un-inverted configuration.
6. The system of claim 1, wherein the elongate manipulator comprise a hypotube.
7. The system of claim 1, wherein the tractor comprises one or more of: a braided material, a knitted material, or a woven material.

8. The system of claim 1, wherein the tractor comprises steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric.
9. The system of claim 1, wherein the material hardness of catheter decreases over the distal end of the catheter until the distal end opening, wherein the distal end opening has a material hardness that is greater than a material hardness of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile.
10. The system of claim 1, wherein the tractor comprises one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating.
11. The system of claim 1, further comprising a releasable attachment between the tractor and an outer surface of the catheter, wherein the releasable attachment is configured to release when the tractor is pulled with a force that is greater than a predetermined force threshold.
12. The system of claim 1, further comprising a sleeve extending over the catheter and tractor.
13. The system of claim 1, wherein the elongate puller comprises a hypotube having an inner lumen that is continuous with a lumen through the tractor.
14. The system of claim 1, wherein the tractor is 3 cm to 50 cm long.
15. A mechanical thrombectomy system for removing a clot from within a vessel, the apparatus comprising:
 - an elongate inversion support comprising a catheter having a distal end and a distal end opening;
 - a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter;

a puller extending proximally within the catheter and connected to the first end of the tractor;

an expandable clot engaging member on the distal end of an elongate manipulator, wherein the expandable clot engaging member comprises one or more of: a coil, a snare, a basket, or a frame; and

a lumen extending continuously through the puller and the tractor and configured to pass the expandable elongate manipulator.

16. A method of removing a clot from within a vessel using a mechanical thrombectomy apparatus, the method comprising:

positioning a distal end of the mechanical thrombectomy apparatus adjacent to the clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter;

pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter and pull the clot into the catheter with the inverting tractor;

withdrawing the catheter proximally away from the tractor and clot when the tractor jams on the distal end of the catheter;

pulling the first end of the tractor proximally so that the tractor inverts over the clot within the vessel without rolling over the distal end opening of the catheter; and

withdrawing the tractor and clot proximally from the vessel.

17. The method of claim 16, further comprising disengaging a second end of the tractor from a tractor hold that secures the second end of the tractor to an outer surface of the catheter by pulling the tractor proximally with a force greater than a deployment force and expanding the tractor against the vessel wall, wherein the second end of the tractor is disengaged before pulling the first end of the tractor proximally.

18. The method of claim 16, further comprising pulling proximally on the tractor to draw the tractor and clot into the catheter.

19. The method of claim 16, wherein pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter comprises advancing the catheter while pulling the first end of the tractor.
20. The method of claim 16, wherein pulling the first end of the tractor proximally so that the tractor inverts over the clot further comprises pulling the catheter proximally with the first end of the tractor.
21. The method of claim 16, wherein pulling the first end of the tractor proximally so that the tractor inverts over the clot comprises pulling a puller at the proximal end of the mechanical thrombectomy apparatus proximally.
22. The method of claim 16, wherein pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter comprises engaging the clot with the tractor.
23. The method of claim 16, wherein withdrawing the catheter proximally away from the tractor comprises pulling the catheter proximally beyond a second end of the tractor that is outside of the catheter.
24. The method of claim 16, wherein pulling the first end of the tractor proximally so that the tractor inverts over the clot comprises pulling the first end of the tractor when the tractor has expanded to contact the vessel wall.
25. The method of claim 16, further wherein positioning the distal end of the mechanical thrombectomy apparatus adjacent to the clot comprises sliding the mechanical thrombectomy apparatus over a guidewire or catheter passing through a lumen in the mechanical thrombectomy apparatus.
26. A method of removing a clot from within a vessel using a mechanical thrombectomy apparatus, the method comprising:
 - positioning a distal end of the mechanical thrombectomy apparatus adjacent to the clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter;

disengaging a second end of the tractor from a tractor hold that secures the second end of the tractor to an outer surface of the catheter by pulling the tractor proximally with a force greater than a deployment force and expanding the tractor against the vessel wall;

pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter and pull the clot into the catheter with the inverting tractor;

withdrawing the catheter proximally away from the tractor and clot when the tractor jams on the distal end of the catheter;

pulling the tractor and clot proximally so that the tractor inverts over the clot within the vessel without rolling over the distal end opening of the catheter;

pulling proximally on the tractor to draw the tractor and clot into the catheter;

and

withdrawing the tractor and clot proximally from the vessel.

27. The method of claim 26, wherein pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter comprises advancing the catheter while pulling the first end of the tractor.
28. The method of claim 26, wherein pulling the first end of the tractor proximally so that the tractor inverts over the clot further comprises pulling the catheter proximally with the first end of the tractor.
29. The method of claim 26, wherein pulling the first end of the tractor proximally so that the tractor inverts over the clot comprises pulling a puller at the proximal end of the mechanical thrombectomy apparatus proximally.
30. The method of claim 26, wherein withdrawing the catheter proximally away from the tractor comprises pulling the catheter proximally beyond a second end of the tractor that is outside of the catheter.
31. The method of claim 26, wherein pulling the first end of the tractor proximally so that the tractor inverts over the clot comprises pulling the first end of the tractor when the tractor has expanded to contact the vessel wall.

32. The method of claim 26, further wherein positioning the distal end of the mechanical thrombectomy apparatus adjacent to the clot comprises sliding the mechanical thrombectomy apparatus over a guidewire or catheter passing through a lumen in the mechanical thrombectomy apparatus.
33. A method of removing a clot from within a vessel using a mechanical thrombectomy apparatus, the method comprising:
- engaging the clot with a clot engaging member on the distal end of an elongate manipulator;
 - sliding the mechanical thrombectomy apparatus over the elongate manipulator to position the distal end of the mechanical thrombectomy apparatus adjacent to the clot, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter;
 - pushing the catheter distally while holding the first end of the tractor within the catheter fixed relatively to the elongate manipulator so that the tractor rolls and inverts over the distal end of the catheter and pulls the clot and the clot engaging member into the catheter with the inverting tractor; and
 - withdrawing the mechanical thrombectomy apparatus, clot and clot engaging member proximally from the vessel.
34. The method of claim 33, wherein engaging the clot with the clot engaging member on the distal end of the elongate manipulator comprises expanding the engaging member within the clot.
35. The method of claim 33, wherein engaging the clot with the clot engaging member on the distal end of the elongate manipulator comprises expanding the engaging member on a distal side of the clot.
36. The method of claim 33, wherein engaging the clot with the clot engaging member on the distal end of the elongate manipulator comprises expanding the engagement member, further wherein the engaging member comprises an expandable coil, snare, basket, or frame.

37. The method of claim 33, further comprising pulling the first end of the tractor proximally as the catheter is pushed distally.
38. The method of claim 33, further comprising holding the first end of the tractor and the elongate manipulator fixed relative to the vessel while pushing the catheter distally.
39. The method of claim 33, further comprising pulling the first end of the tractor proximally and pulling the elongate manipulator proximally relative to the vessel while pushing the catheter distally.
40. The method of claim 33, further comprising disengaging a second end of the tractor from a tractor hold that secures the second end of the tractor to an outer surface of the catheter by pulling the tractor proximally with a force greater than a deployment force and expanding the tractor against the vessel wall.
41. A method of removing a clot from within a vessel using a mechanical thrombectomy apparatus, the method comprising:
- engaging the clot with a clot engaging member on the distal end of an elongate manipulator;
 - sliding the mechanical thrombectomy apparatus over the elongate manipulator to position the distal end of the mechanical thrombectomy apparatus adjacent to the clot, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter;
 - pushing the catheter distally while pulling the first end of the tractor and the elongate manipulator proximally within the catheter to roll and invert the tractor over the distal end of the catheter and advancing the catheter distally, to pull the clot and the clot engaging member into the catheter with the inverting tractor; and
 - withdrawing the mechanical thrombectomy apparatus, clot and clot engaging member proximally from the vessel.

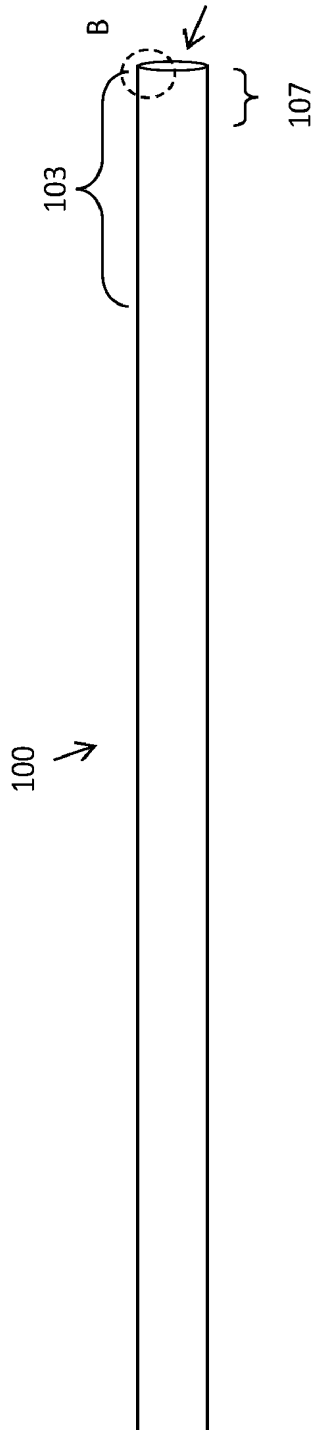


FIG. 1A

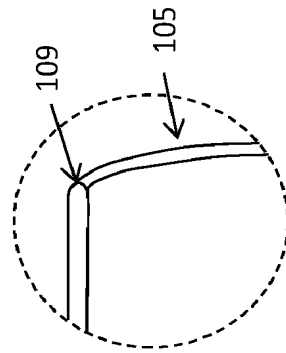


FIG. 1B

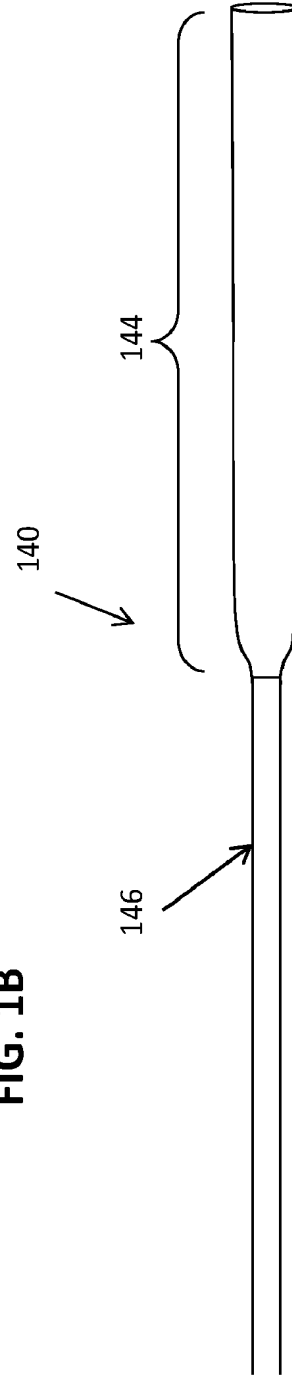


FIG. 1C

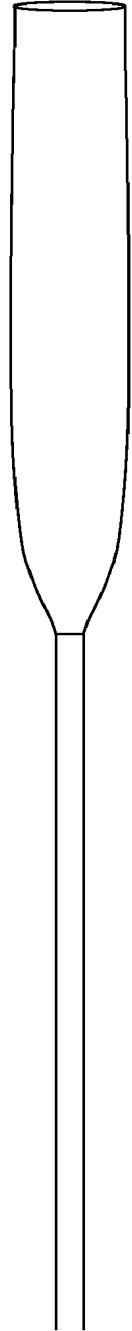
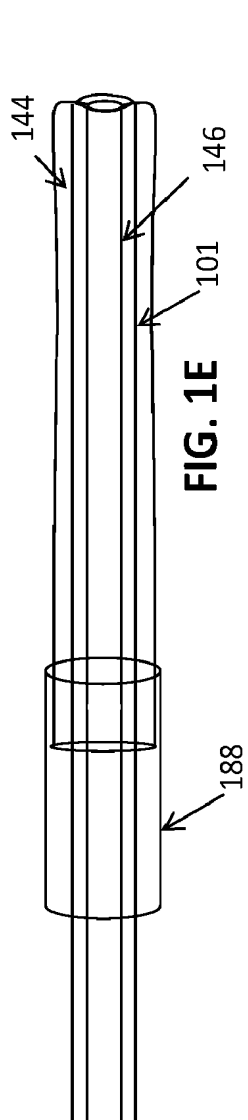
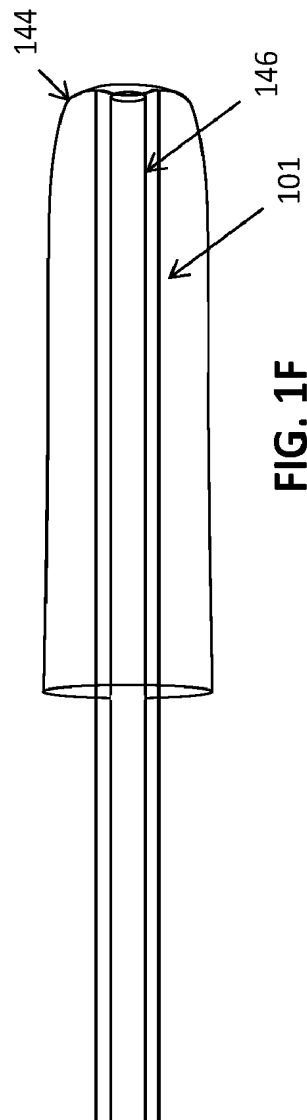
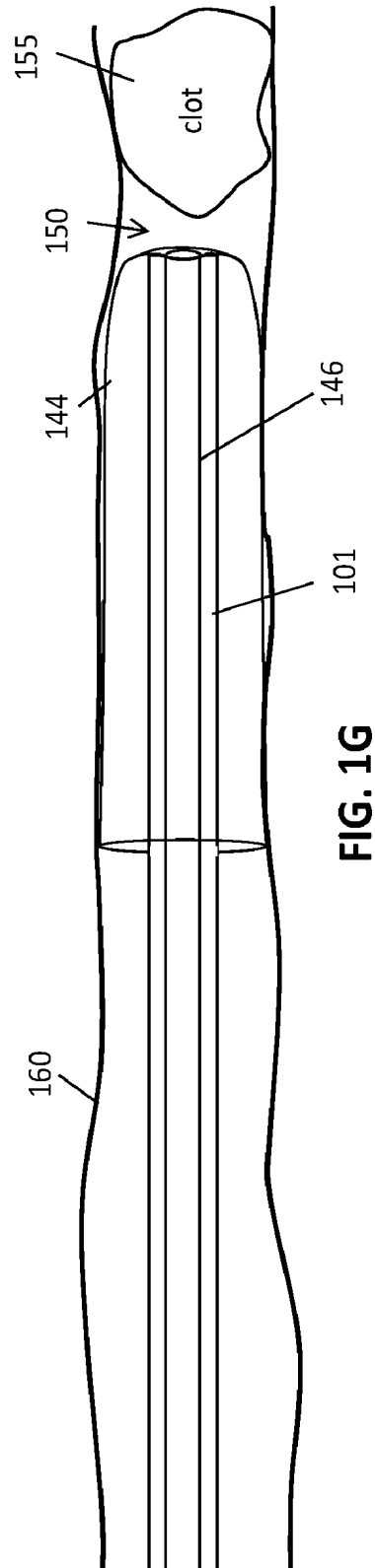
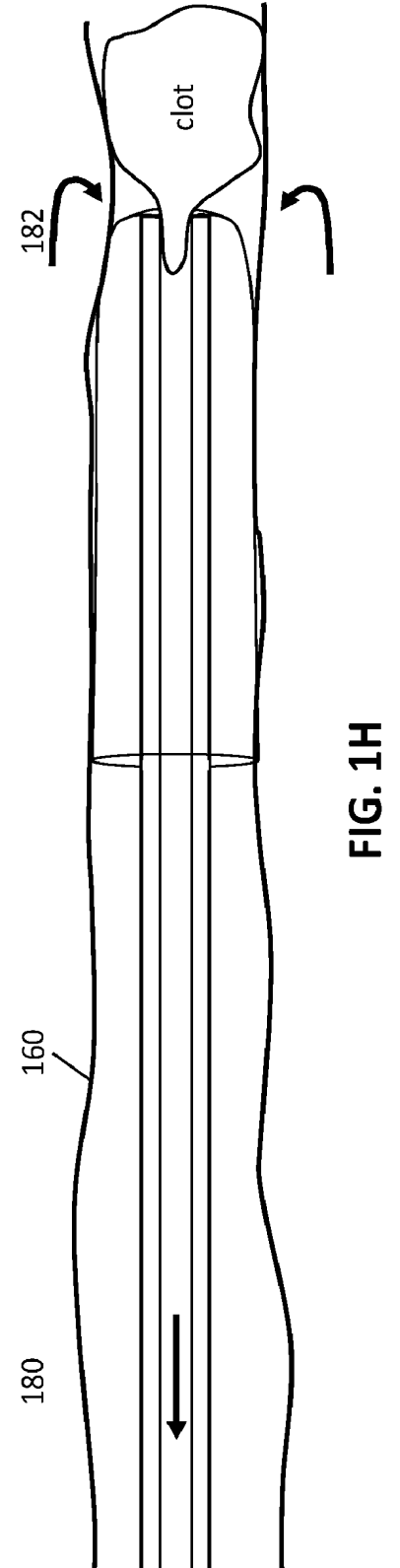


FIG. 1D



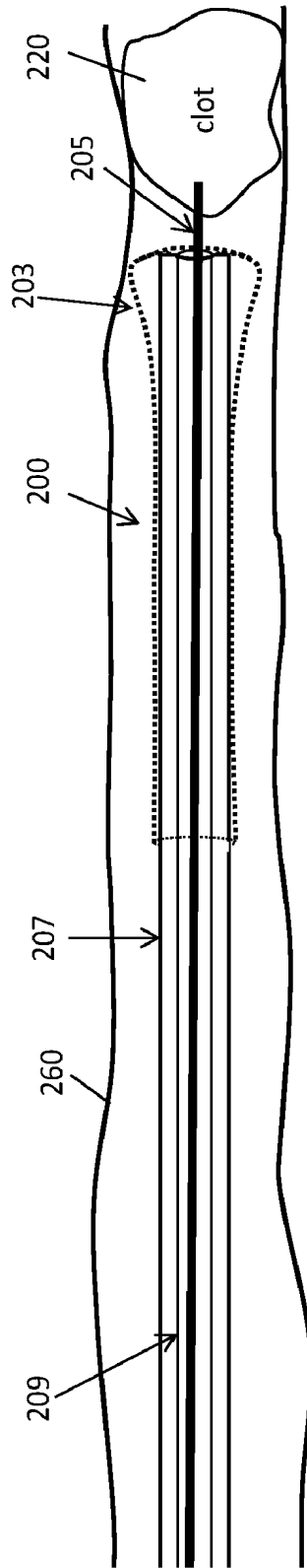


FIG. 2A

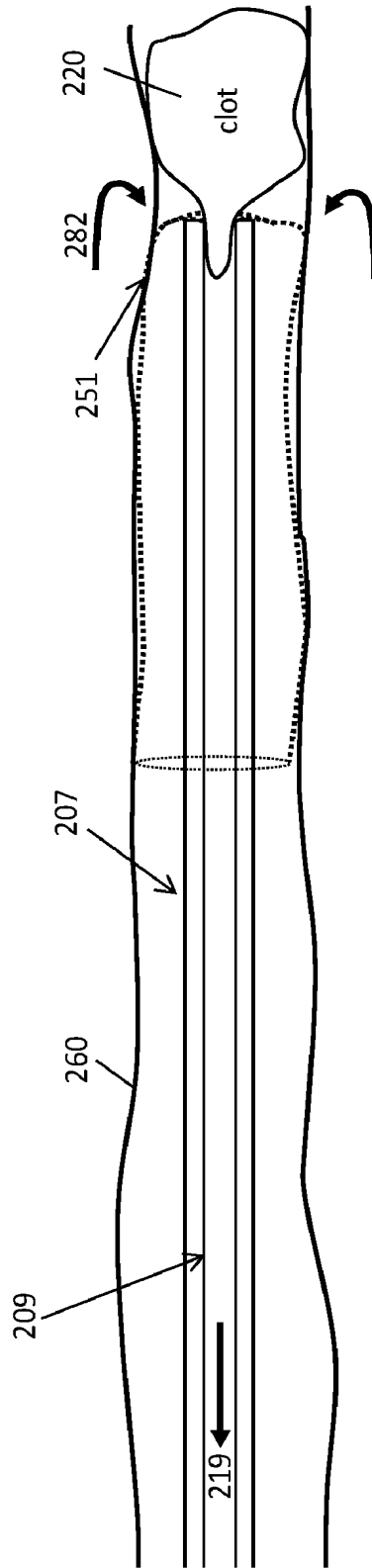


FIG. 2B

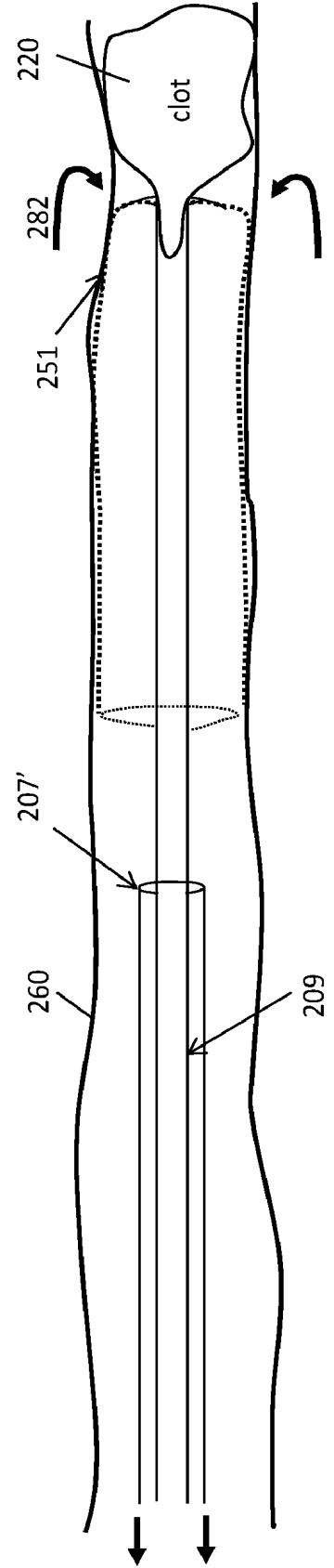


FIG. 2C

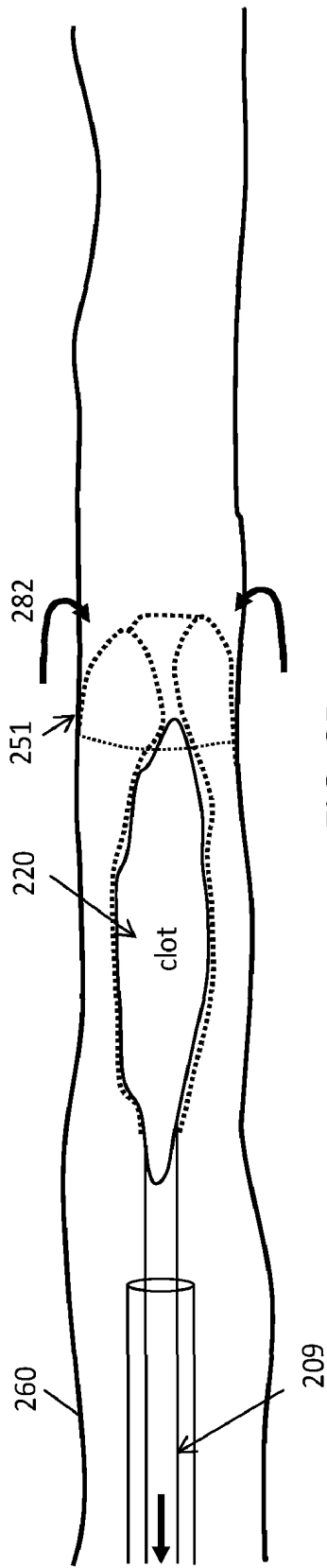


FIG. 2D

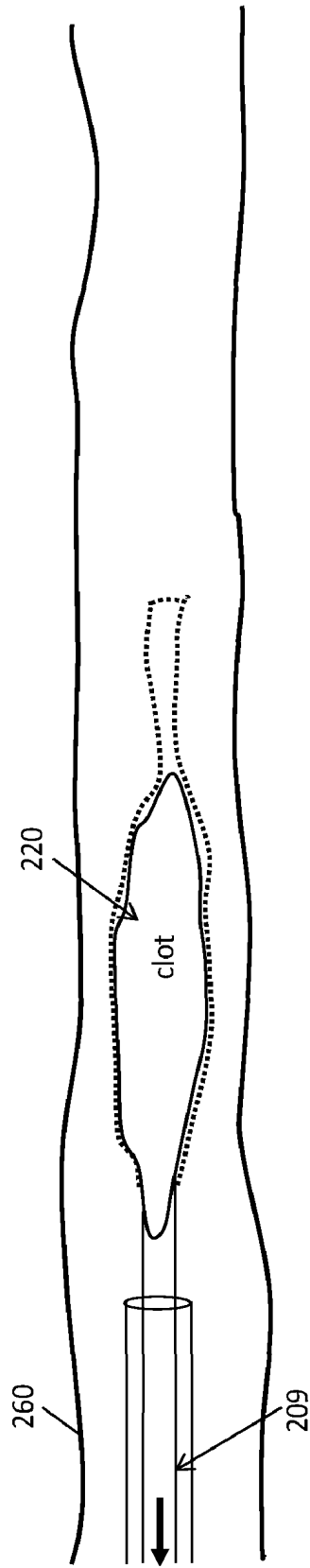


FIG. 2E

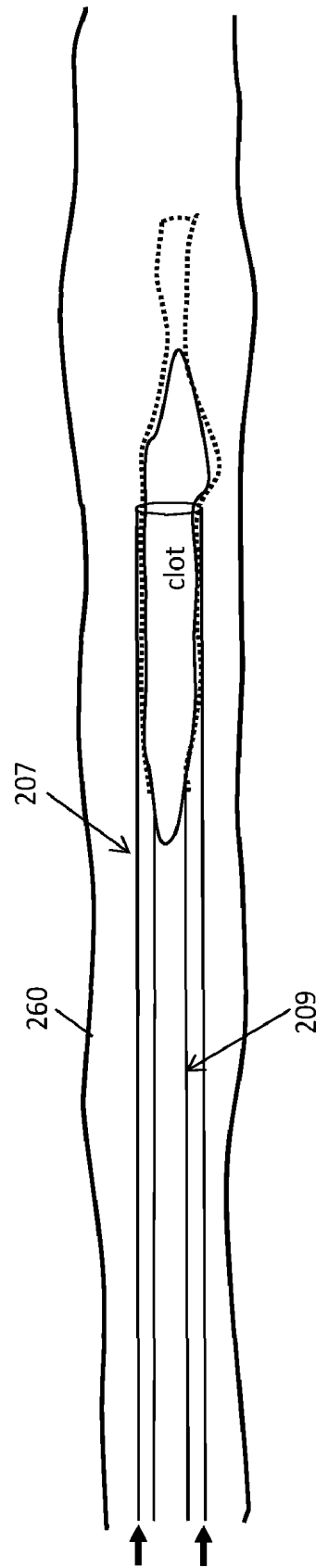


FIG. 2F

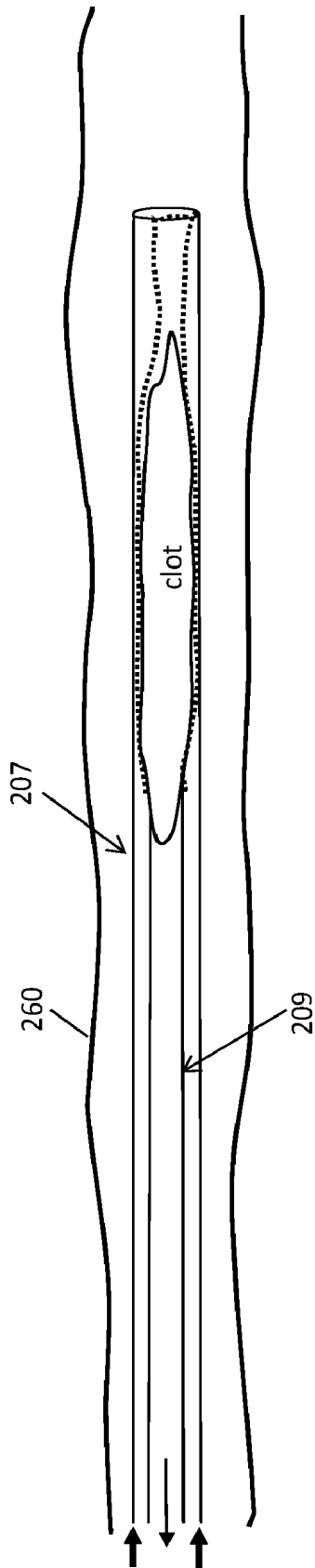


FIG. 2G

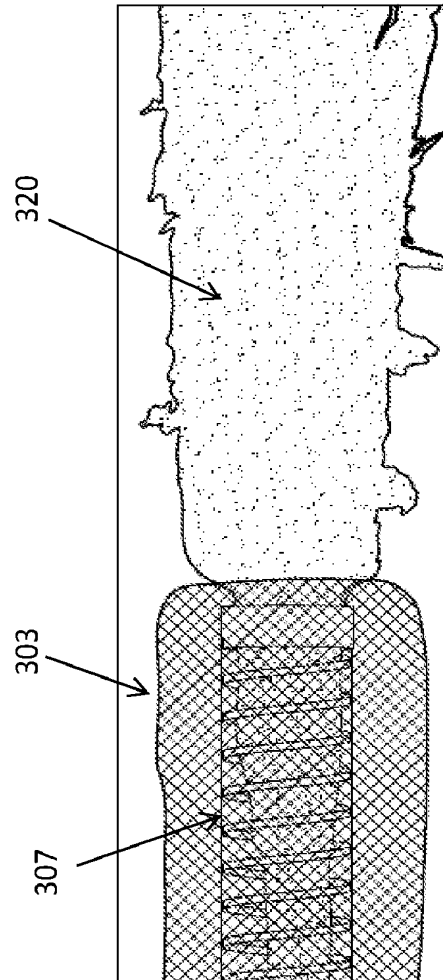


FIG. 3A

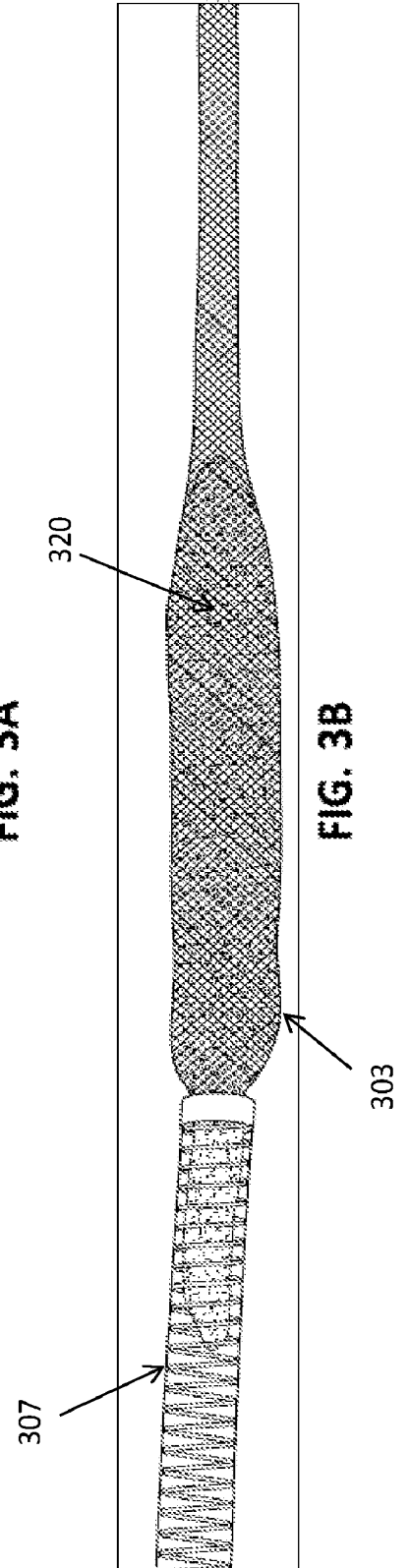


FIG. 3B

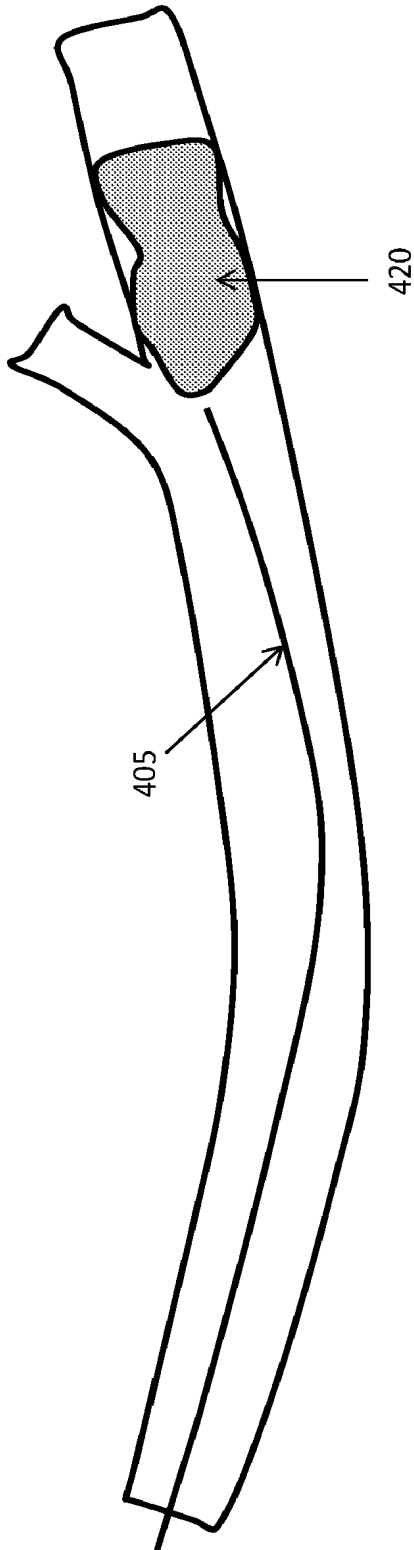


FIG. 4A



FIG. 4B

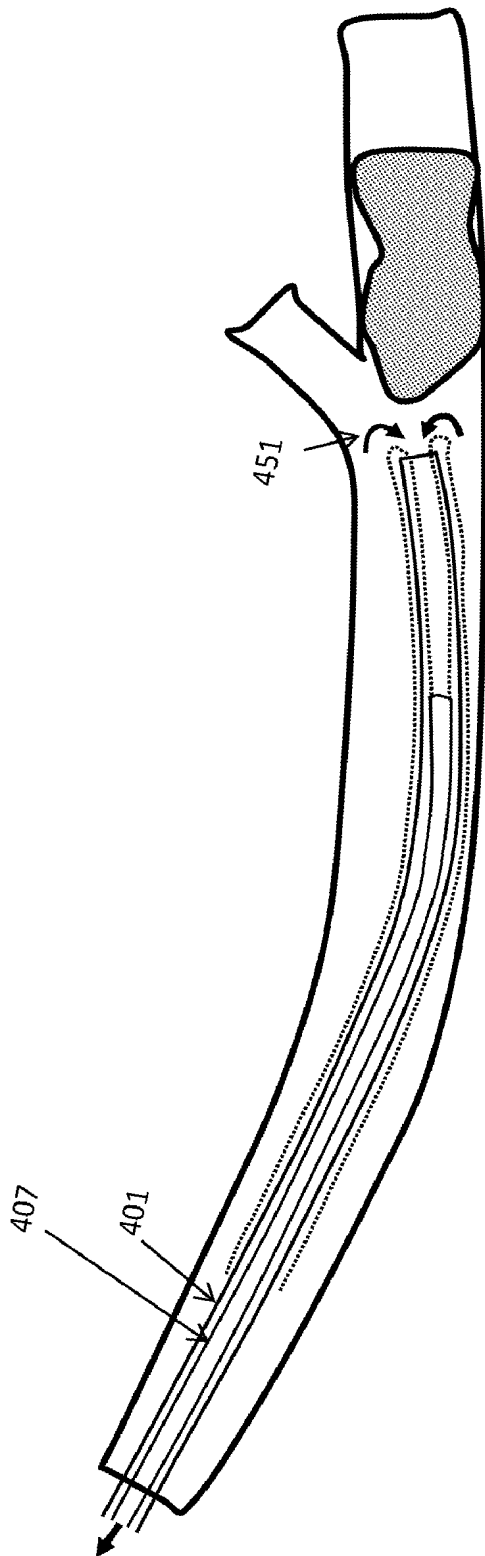


FIG. 4C

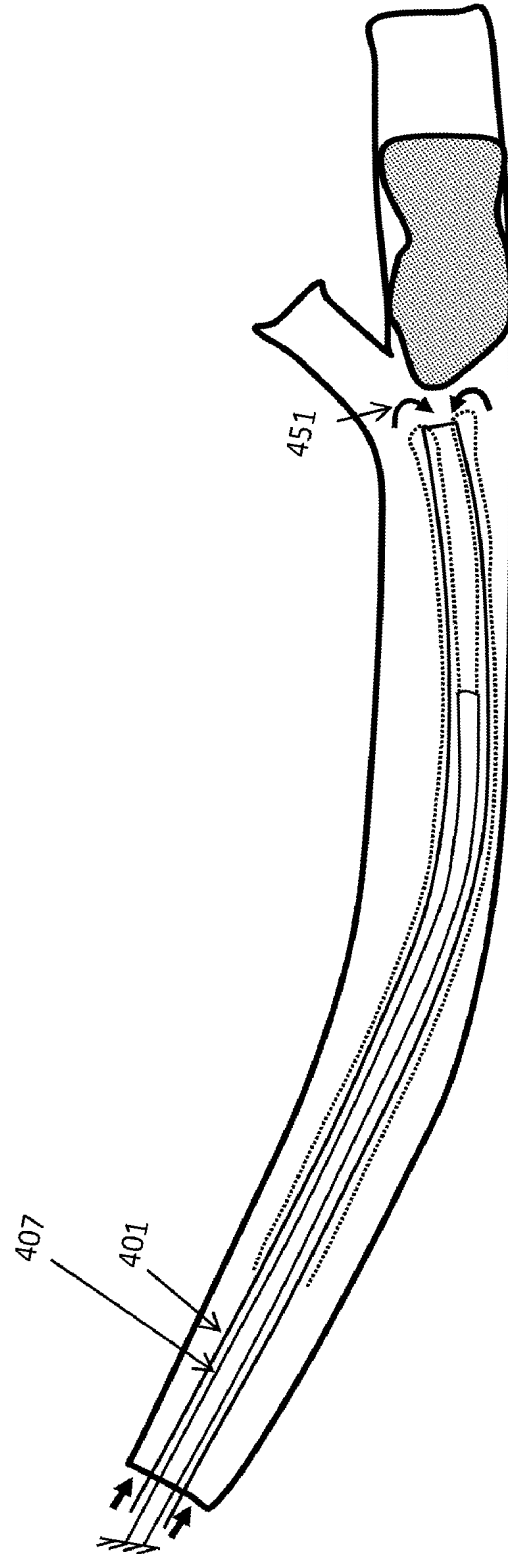


FIG. 4D

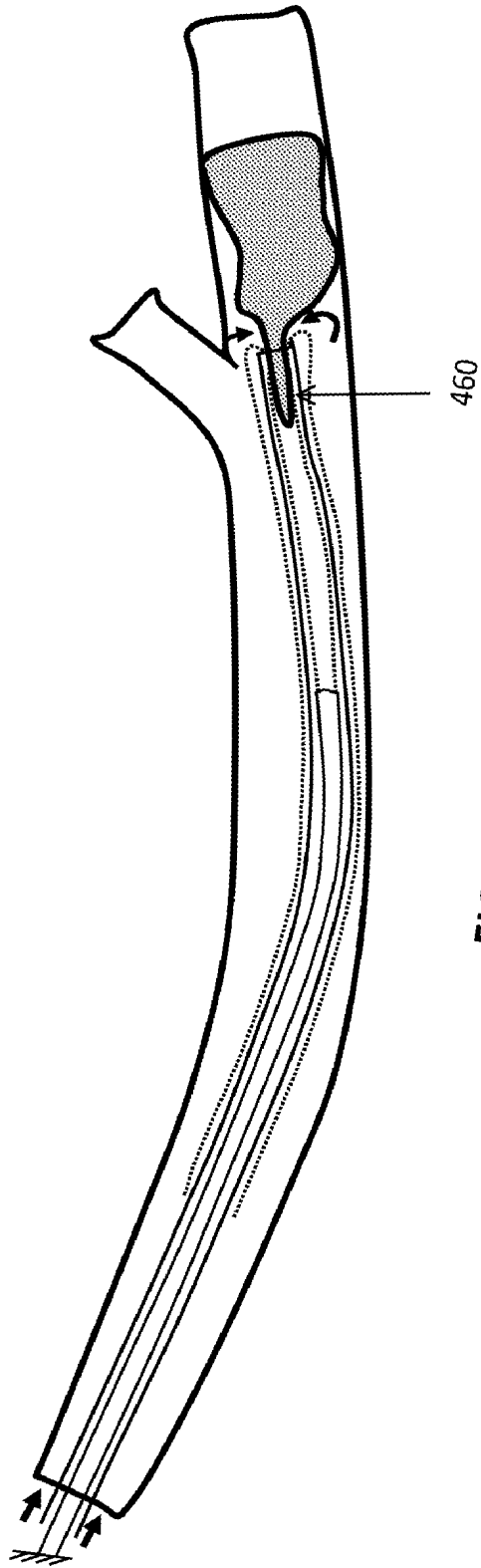


FIG. 4E

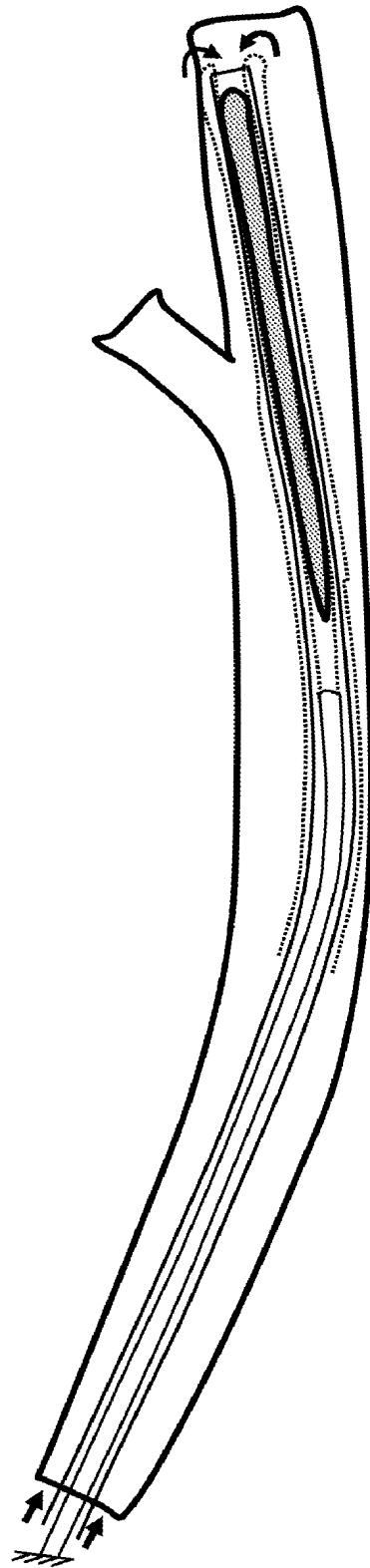


FIG. 4F

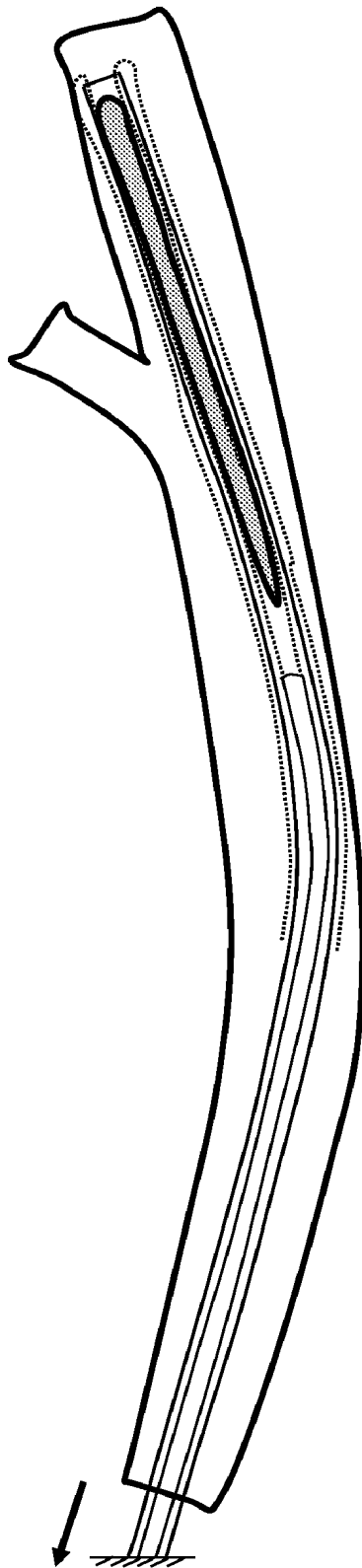


FIG. 4G

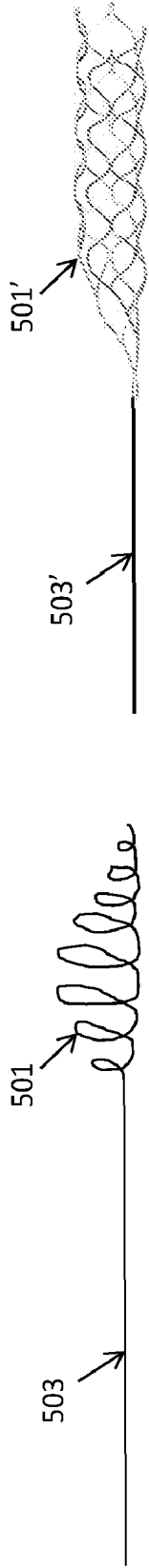


FIG. 5A

FIG. 5B

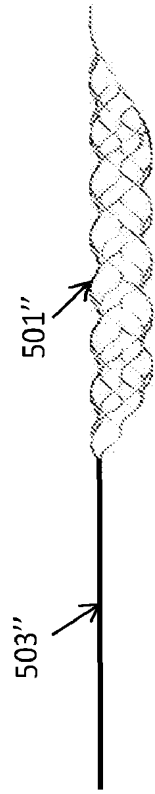


FIG. 5C

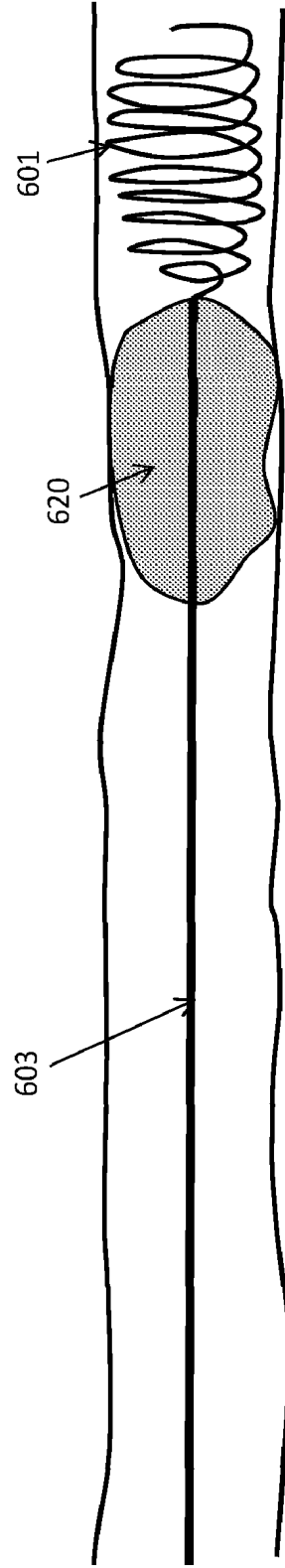


FIG. 6A



FIG. 6B

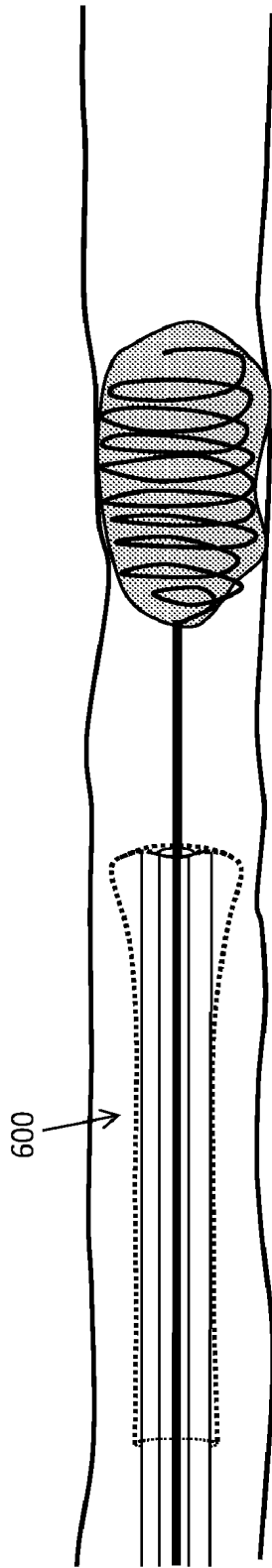


FIG. 6C

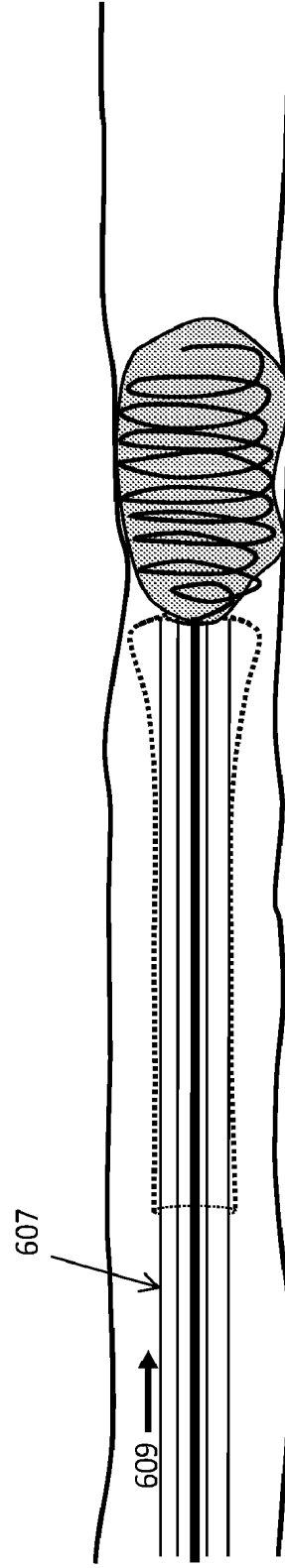


FIG. 6D

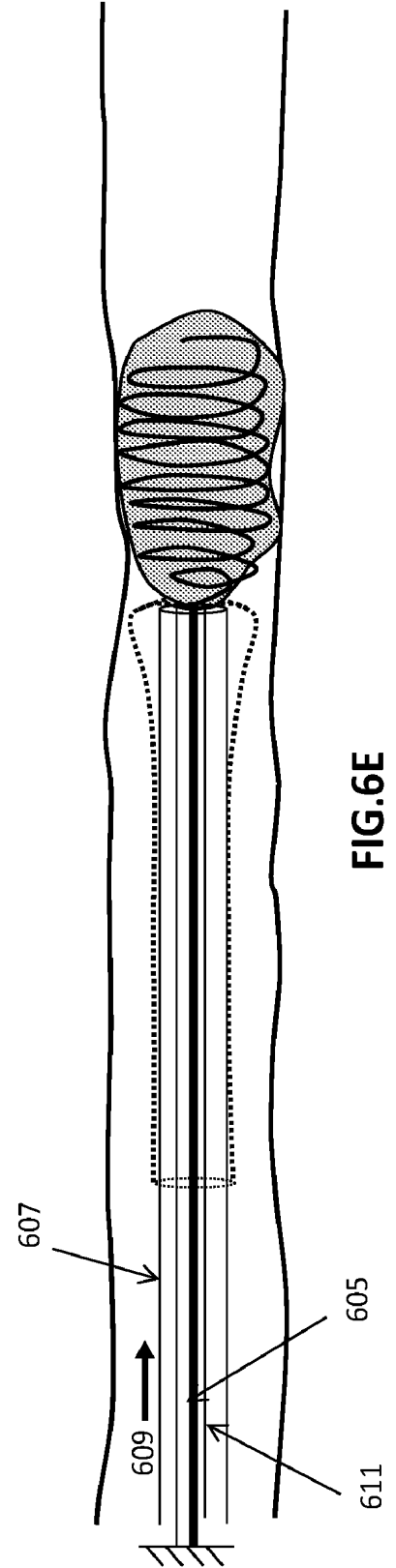


FIG. 6E

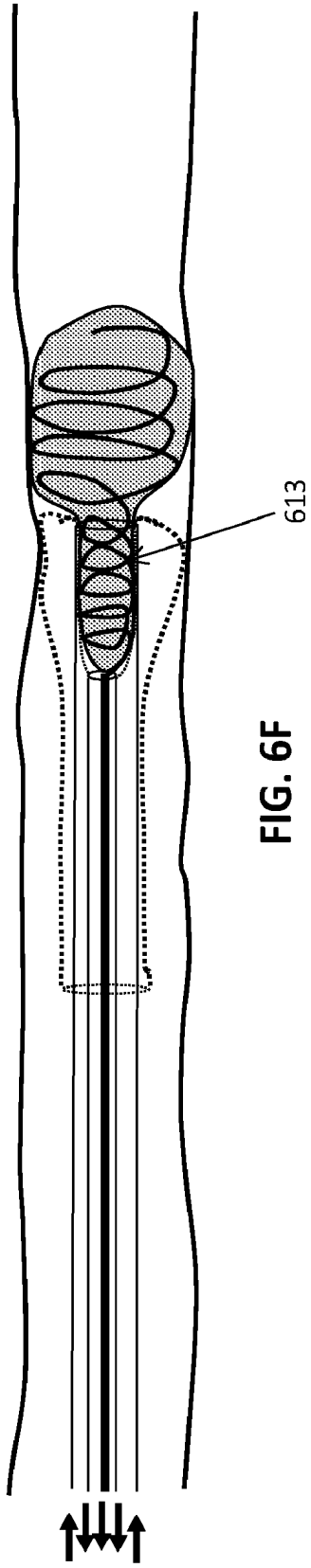


FIG. 6F

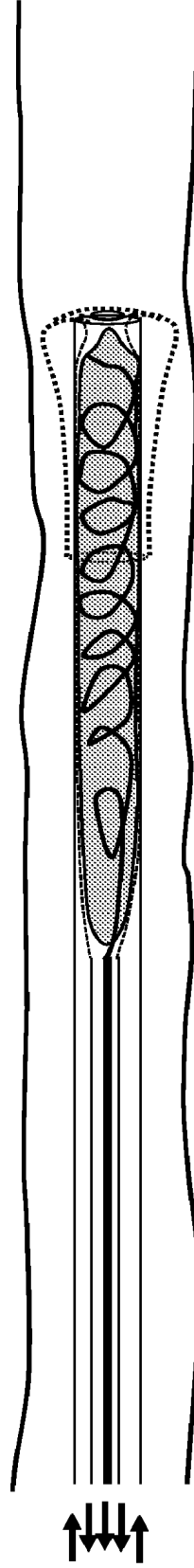


FIG. 6G

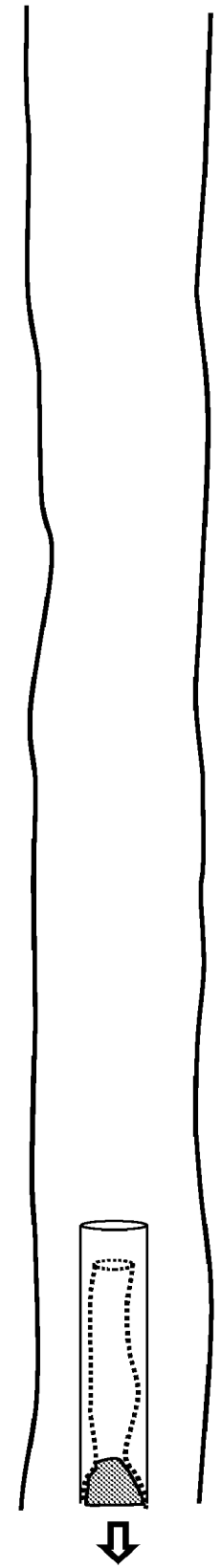


FIG. 6H

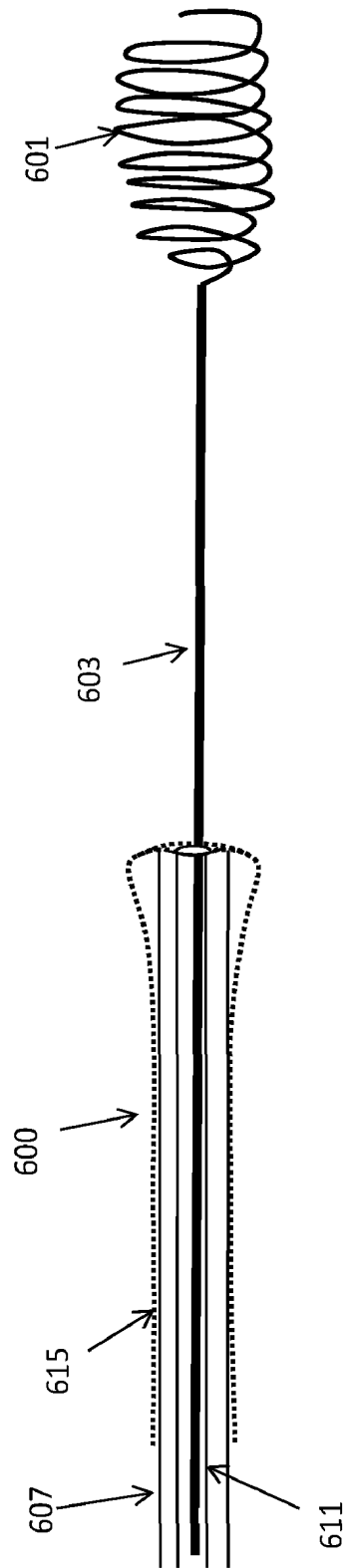


FIG. 6I

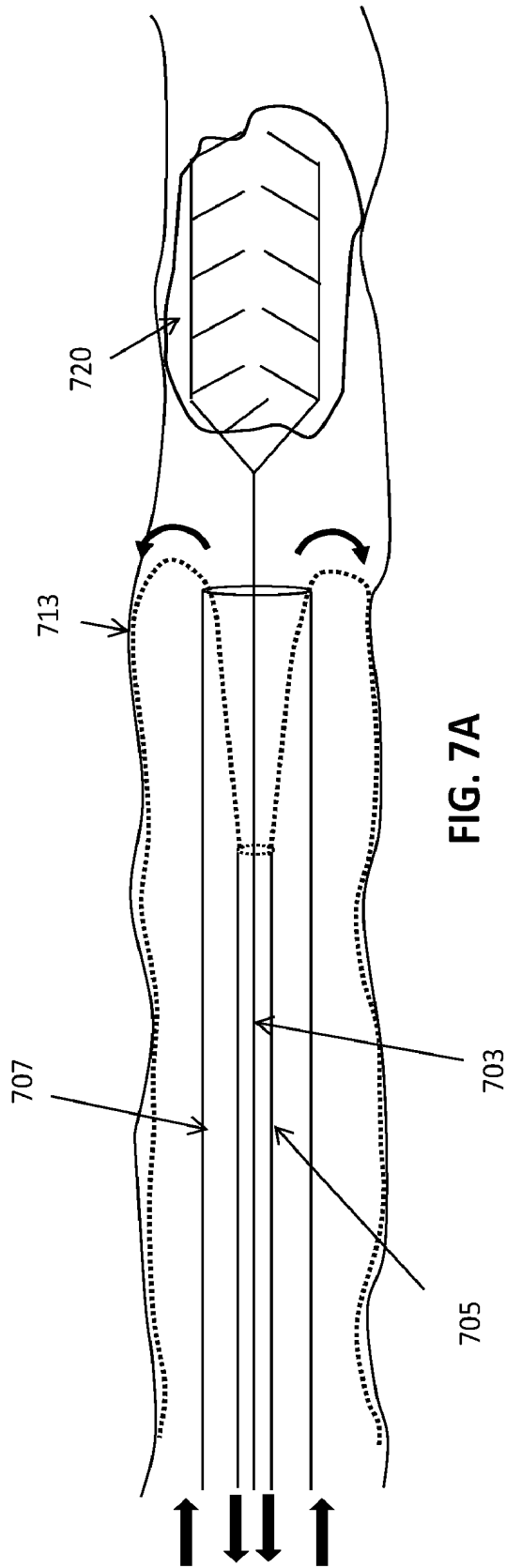


FIG. 7A

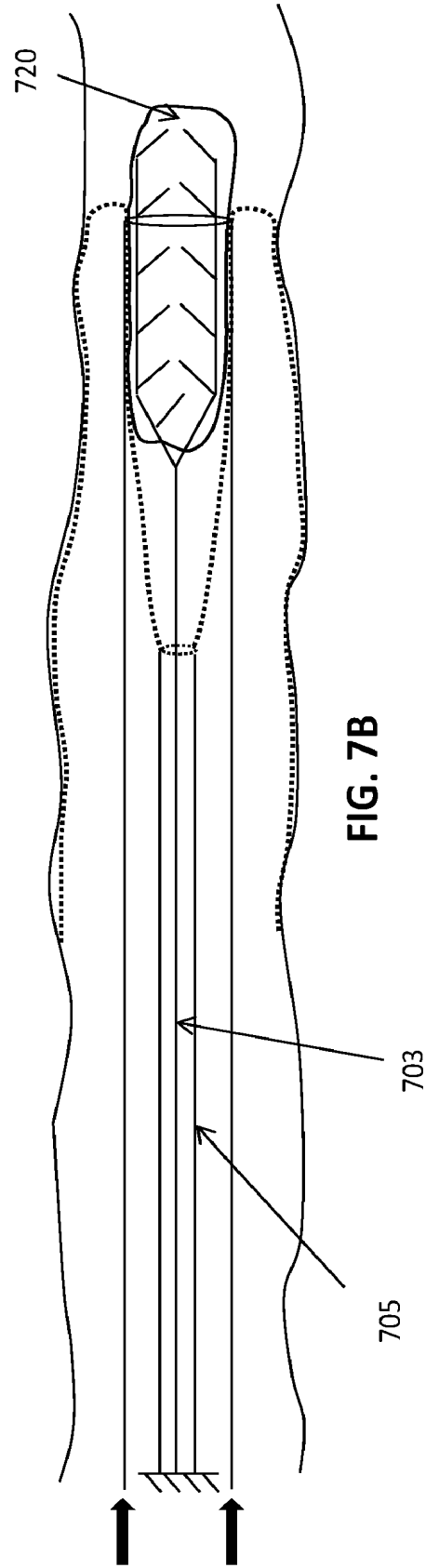


FIG. 7B

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61B17/22 A61B17/221
 ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19) paragraphs [0152], [0153], [0167] - [0170]; figures 10, 13B -----	1-15
Y	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; figures page 8, line 12 - page 11, line 5 -----	1-15
A	US 2006/195137 A1 (SEPETKA ET AL.) 31 August 2006 (2006-08-31) abstract; figures -----	1,15
A	US 2005/085826 A1 (NAIR ET AL.) 21 April 2005 (2005-04-21) figures ----- -/--	1,15

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

29 June 2017

Date of mailing of the international search report

07/07/2017

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040,
 Fax: (+31-70) 340-3016

Authorized officer

Giménez Burgos, R

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2012/049652 A1 (ENDO GROWTH (PROPRIETARY) LIMITED) 19 April 2012 (2012-04-19) figures -----	1, 15
A	US 4 243 040 A (BEECHER) 6 January 1981 (1981-01-06) figures -----	1, 15
X, P	WO 2017/058280 A1 (GW MEDICAL LLC) 6 April 2017 (2017-04-06) the whole document -----	1-15

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: **16-41**
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 16-41

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

Patent document cited in search report			Publication date		Patent family member(s)		Publication date	
WO 2012009675	A2	19-01-2012	US	2014005712	A1		02-01-2014	
			WO	2012009675	A2		19-01-2012	

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			US	2015005781	A1		01-01-2015	
			WO	2013106146	A1		18-07-2013	

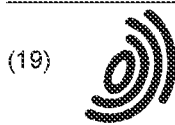
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			US	2014135814	A1		15-05-2014	
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			JP	2007508903	A		12-04-2007	
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			ZA	201302264	B		30-04-2014	

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			US	2017086864	A1		30-03-2017	
			WO	2017058280	A1		06-04-2017	



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(11) **EP 1 254 634 B1**

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23.07.2003 Bulletin 2003/30

(51) Int Cl.7: **A61B 17/00**

(21) Application number: **01850081.9**

(22) Date of filing: **03.05.2001**

(54) **Guiding tool for wound closure element**

Führungswerkzeug für Wundverschluss

Outil de guidage pour fermeture de plaie

(84) Designated Contracting States:
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MC NL PT SE TR**

(43) Date of publication of application:
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**WO-A-01/13800 US-A- 5 620 461
US-A- 5 649 950 US-A- 5 725 519**

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description

[0001] The present invention relates generally to sealing of a percutaneous incision or puncture in the wall of a vessel, duct, lumen or hollow organ in the body of a living being, by positioning a sealing device in said incision or puncture, where the incision or puncture is smaller than said sealing device. In particular the invention relates to a guiding tool for enabling the correct positioning of such a sealing device, ensuring a leak-proof sealing.

Background of the invention

[0002] In recent years a number of devices and apparatuses have been developed enabling the closure or occlusion of e.g. punctures in the femoral artery following catheterization. Instead of applying a pressure to the puncture site for a period of time sufficient for blood clot formation to occur, the new methods are e.g. based on providing a plug, commonly referred to as an "artery plug", in the puncture. The plug is made of a resorbable material, such that it can be left in place until the tissue has recovered properly and the wound or puncture is healed. The plug can be made of collagen, and applied to the outside of a vessel against a counteracting element, also made of a resorbable material, introduced into the interior of the vessel. A locking means secures the collagen plug in place. A device of this kind is disclosed in US-5,935,147 (Kenney et al). The sealing action is thus performed by the externally applied collagen plug. However, a certain percentage of applied plugs will not be leak-proof and often further compression by other devices or manually must be applied.

[0003] Alternatively, a plug can be made of two members such that a first member is positioned within a vessel and acts as the occluding member, and a second member is positioned outside the vessel and locked to the first member by a locking means. In order to ensure leak-proof action, the first member is larger than the puncture in all directions, i.e. it will cover a surface larger than the area of the puncture. In order to make this possible, the first member is foldable. A device of this kind is disclosed in our own EP-application EP-00850184.3 (corresponding to US patent application serial No. 09/704,726).

[0004] US-A-5 649 950 discloses a loading device for a collapsible occluder. This device has a conical lumen. US-A-5 649 950 corresponds to the preamble of claim 1.

[0005] The problem facing all systems wherein a folding or deformation of an element is needed in order to introduce the element into a vessel or through any tissue wherein the hole is smaller than the element itself, is that it can be difficult to achieve a reproducible unfolding, that accurately seals the hole from the inside. Also, in many cases the closure element is provided inside an introducer member such as a tube, in a folded state, already at the time of manufacture of the kit comprising

all components. If the kit is stored for extended periods of time, and even for shorter times, the folded closure element most likely does not unfold properly at the time of use. To avoid the risk of permanent deformation, the closure element could be inserted into the introducer device by the physician, but this would require an extra manipulation, and it might be very difficult to maintain the sterility of the devices in such a case.

Summary of the invention

[0006] Thus, in view of the problem with the prior art devices, it is the object of the present invention to improve the rate of successful sealing operations using wound closure devices, when foldable or deformable closure elements are introduced into a vessel through a hole, smaller than the element itself, and to enable the folding and unfolding operation to take place during the sealing operation, and to avoid manipulation of the closure element by the physician at the time of performing the sealing operation.

[0007] This object is achieved by the provision of a guiding tool which in a controlled manner deforms or folds a wound closure element such that it after having been introduced through a puncture, unfolds and regains its original shape in a reproducible and controllable manner, and thereby provides adequate sealing at an excellent rate of success, this procedure taking place at the time of performing the sealing operation. The guiding tool according to the invention is defined in claim 1.

Brief Description of the Drawings

[0008]

Fig. 1 a-c is a schematic illustration of a system for wound closure during operation thereof;

Fig. 2a illustrates an embodiment of the guiding tool not belonging to the invention in cross section;

Fig. 2b is a view in longitudinal cross section of a second embodiment of the inventive guiding tool;

Fig. 2c illustrates cross sections at A-E in Fig. 2b;

Fig. 2d is a perspective cut view in two different directions of a third preferred embodiment of the inventive guiding tool;

Fig. 3a is a cross section view of a closure element; and

Fig. 3b is a top view of a closure element.

Detailed Description of the Invention

[0009] Fig. 1a-c illustrates the procedure of inserting a wound closure (occlusion) element 2 in a blood vessel 4 and clamping it by means of a locking member 6. Thereby, an incision 8 is made in the blood vessel 4 in question, and an introducer tube 10 is inserted into the vessel 4, see Fig. 1a. Then, a folded, or in some other manner deformed closure element 2 is passed through said introducer tube 10 and into the vessel 4. The closure element 2 is secured to e.g. a suture 12, and some rigid elongated element 14 such as a steel pin or pusher rod (not shown) can be used to guide the closure element 2 through the tube 10 and into the vessel 4, where it unfolds. Once the closure element 2 has unfolded inside the vessel 4, the pusher rod and the introducer tube 10 are withdrawn from the vessel but maintained close to the exterior of the vessel 4. Then, the closure element 2 is pulled back using the suture 12, so as to be located in a position where it is held against the interior vessel wall 16, Fig. 1b. An essentially disk shaped locking element 18, having a central hole, is provided on the suture 12, the suture running through said hole, such that the locking member can be moved along the suture 12 to be brought into contact with the exterior vessel wall 20. By the provision of suitable friction enhancing means 19 on the very distal end of the suture, the locking element can be pushed against the wall of the vessel while engaging the portion of the suture having higher friction, and thereby cause a locking of the closure element, Fig. 1c. This principle is used in e.g. US-5,916,236.

[0010] It is important that the closure element unfolds in a reproducible way, such that it will contact the inner vessel wall around the circumference of the incision. If the closure element is delivered to the user in a folded state, in position inside the introducer, as a "kit" ready for use by a physician, and the kit has been stored on a shelf for some time, it may happen that the closure element has become permanently deformed, and will not assume the desired shape (which may be to regain its original shape) inside the vessel. Such an event would of course dramatically increase the risk that the closure element will not fulfill its function, and cause a leakage.

[0011] Therefore, in accordance with the present invention, there is provided a guiding tool that is connectable to an introducer of the type discussed above, the closure element being provided in said guiding tool in an unfolded state. Thereby the actual deformation or folding of the closure element, necessary to enable insertion through the incision (which is smaller than the closure element) and into the blood vessel, is not performed until the time of performing the operation of inserting the closure element. In this way, the closure element will not be subjected to a prolonged deformation during storage.

[0012] An embodiment not falling under the invention is illustrated in Fig. 2a. It comprises a body in the shown embodiment in the form of an elongated tube like mem-

ber 20 (although cylindrical outer symmetry is no requirement), having an inner lumen 22 that has a first diameter in the proximal end portion 24 and over a fraction of its length (up to the dotted line X), forming a space 26 in which an closure element (not shown) can be housed without being deformed. Over a second fraction of the length, from the dotted line X and up to the distal end 26 portion, the lumen becomes narrower, rendering the 22 lumen cone shaped over this portion. Finally there is a connection portion 28, connectable to an introducer tube (such as the tube 10 in Fig. 1a). The exit diameter is equal to or slightly smaller than the inner diameter of the introducer tube, i.e. small enough to enable passing the closure element into the blood vessel.

[0013] In Fig. 2b a second embodiment of the guiding tool according to the present invention is illustrated. It is adapted for a closure element 30 having the general shape shown in Figs. 3a and 3b. The closure element suitable for use with the illustrated embodiment of the guiding tool, has a thick mid portion 32, that is generally elongated, and has peripheral wings 34 or edges, which are substantially thinner, and thus more flexible than the mid portion 32. The peripheral shape is like a slightly distorted ellipse, but could in principle be circular, the wings 34 thereby forming rather a collar or a brim surrounding the mid portion. Other shapes are also possible. A suitable kind of closure element is disclosed and claimed in our copending EP-00850184.3. In view of its flexibility, the wings 34 or brim are foldable such that the entire element will have a smallest dimension in a folded state that fits well within an incision or puncture in a blood vessel, thereby enabling insertion into said vessel.

[0014] Thus, the embodiment of the guiding tool according to the present invention shown in Fig. 2b, comprises an essentially tubular element 42 having a proximal end 44 and a distal end 46 and a lumen 48 extending between said distal 46 end and said proximal end 44. There is further a wound closure element introduction opening 50 in the proximal end 44, and a wound closure element exit opening 52 in the distal end 46. The distal end is shaped so as to be connectable to an introducer tube, like the one described above in connection with Fig. 1.

[0015] The lumen 48 has inner walls 54 provided with wound closure element deformation surfaces 56, adapted to deform a wound closure element during passage thereof, past said surfaces 56, through the guiding tool, from an essentially undeformed or unfolded state to a deformed or folded state. The effect of this deformation/folding should be such that the overall dimension of the wound closure element is changed to render it capable of passing through the puncture in the blood vessel. Also, after passage through said incision or puncture it must regain a shape that is capable of providing a sealing action against the inner wall of the vessel.

[0016] In Fig. 2b there is also shown a pusher rod 51, having a fork like configuration, that is used to push the

closure element 30 through the introducer and into the blood vessel. This pusher rod is retracted once the element is properly located inside the vessel.

[0017] In the embodiment shown in Fig. 2b the deformation surfaces 56 have a specific design, illustrated by a sequence in Fig. 2c, which are cross section views through the lumen at the positions indicated with corresponding letters A, B, C, D, E in Fig. 2b. Thus, there is one guiding surface 56 for each wing on the closure element 30, and a guiding recess 60 in which the thicker mid portion 32 of the closure element 30 will run during its passage through the guiding tool. The guiding surfaces will initially have an orientation such that the wings 34 of the unfolded or undeformed closure element 30, when inserted into the guiding tool in the introduction opening, will rest thereon in a position and orientation causing no deformation (referred to as a "horizontal" orientation; position A in Fig. 2c). Thereby the nominal shape of the closure element 30 is preserved also during extended storage. In a direction towards the exit opening, the guiding surfaces will gradually become elevated (A-B-C-D-E in Fig 2c) from the initial, essentially horizontal orientation, and also curved such that they form what could be referred to as a "quasi-conical" lumen inside the tool. At the end of the lumen, near the exit opening, the guiding surfaces will have reached a state where the cross section of the lumen is essentially circular, and where the diameter corresponds to the inner diameter of the introducer tube.

[0018] Preferably, there are guiding rails 62 provided above the guiding surfaces 56, such that the wings or brims 34 of the closure element 30 will be kept down during the process of pushing it with the pusher rod through the guiding tool, thereby preventing inadvertent tilting or incorrect behavior of the closure element during the movement through said guiding tool. The rails are preferably integrated in the "roof" of the lumen. However, they can also be provided as an insert and attached by suitable means inside the lumen.

[0019] In a further variation of the above described embodiment, the interior lumen of the guiding tool essentially has a cross section that exactly corresponds to the cross section of the closure element. This lumen would then form a guiding slot inside the tool, whereby the slot would be shaped so as to gradually change from a cross section corresponding to the above mentioned "horizontal orientation" to an essentially circular cross section, the diameter of which would be smaller than the incision through which the closure element is to be inserted. There must however be a space above the closure element for the access by the pushing rod needed for advancing the closure element through the tool and the introducer.

[0020] The sequence A-E in Fig. 2c illustrates the folding process, and it is clearly seen that the closure element reaches a folded state where it conforms to the circular cross section of the introducer tube, which is connected to the guiding tool at the exit end thereof.

[0021] Another embodiment of the guiding tool is shown in Fig. 2d, showing perspective cuts through the device at two orientations perpendicular to each other. Like reference numerals are used for like elements in Figs. 2c and 2d. Like in the above described embodiment, this embodiment of the guiding tool comprises an essentially tubular element 42 having a proximal end 44 and a distal end 46 and a lumen 48 extending between said distal 46 end and said proximal end 44. There is further a wound closure element introduction opening 50 in the proximal end 44, and a wound closure element exit opening 52 in the distal end 46. The distal end is shaped so as to be connectable to an introducer tube.

[0022] Also in this embodiment, the lumen 48 has inner walls 54 also provided with wound closure element deformation surfaces 56, adapted to deform a wound closure element during passage thereof, past said surfaces 56, through the guiding tool, from an essentially undeformed state to a deformed state.

[0023] However, the deformation surfaces have a different design in this embodiment. Namely, one wall of the inner lumen is flat such that the closure element can be placed essentially flat thereon, in an unfolded state, e.g. during shelf storage, corresponding to the "horizontal orientation" discussed above in connection with Fig. 2b, but with the thicker mid portion facing upwards. Towards the exit opening the lumen is shaped as cone, much like in the first embodiment of Fig. 2a, whereby the final diameter of the inner lumen corresponds to a diameter smaller than the diameter of the opening in the blood vessel through which the closure element is to be introduced. About half-way along the conical portion of the lumen, there are provided a pair of deflection surfaces 64, having a "steeper" angle than the over-all cone angle of the lumen. These surfaces will engage the peripheral brim or collar portions of the closure element, such that they are deflected or bent downwards from the essentially flat initial position. Also, the pusher rod discussed above will cause the closure element not to lie completely flat, but slightly angled with the trailing edge at a slightly elevated position compared to the leading edge. Furthermore, said pusher rod will assist in keeping the leading edge forced against the flat surface.

[0024] In order to facilitate correct positioning of the closure element during insertion, also in this case there may be provided guiding rails like those described above.

[0025] The invention having been described with reference to preferred embodiments thereof can be subject to alterations and modifications by the man skilled in the art, and the scope of the invention is limited only by the appended claims.

55 Claims

1. A guiding tool for controllable and reversible folding or deformation of a wound closure element (2) be-

fore insertion of said wound closure element into a percutaneous incision or puncture in the wall (4) of a vessel, duct, lumen or hollow organ in the body of a living being, said incision or puncture being smaller than said wound closure element in an unfolded or undeformed state, said tool comprising a body (20) having a distal end (26) and a proximal end (24) and a lumen (22) extending between said distal end and said proximal end; a wound closure element introduction opening (50) in the proximal end, and a wound closure element exit opening (52) in the distal end;

characterized in that

said lumen has inner walls (54) provided with wound closure element guiding surfaces (56, 64) in the form of separate deflection elements protruding from the inner wall of said lumen, for reversibly reducing the spatial extension of a wound closure element during its passage through the guiding tool, by engaging a peripheral brim or collar portions of the closure element, such that they are deflected or bent downwards from an essentially flat initial position, whereby said wound closure element is capable of passing through said incision or puncture, and whereby it after passage through said incision or puncture assumes a shape that is capable of providing a sealing action against said incision or puncture.

2. The tool as claimed in claim 1, wherein said guiding surfaces (56) in the proximal end of said tool are essentially flat, and in a direction towards the distal end, gradually becomes elevated and also curved such that they form a quasi-conical lumen inside the tool, and wherein the guiding surfaces, at the distal end of the lumen, near the exit opening, will have reached a state where the cross section of the lumen is essentially circular.
3. The tool as claimed in claim 1 or 2, wherein there are guiding rails (62) provided above the guiding surfaces (56), such that wings or rims (34) of a closure element (30) will be kept down during the process of pushing through the guiding tool, said guiding rails (62) being arranged to prevent the closure element from inadvertent tilting or other incorrect behavior during its movement through the guiding tool.
4. The tool as claimed in claim 1, wherein said introduction opening is larger than said exit opening, and optionally is provided with a sealing plug (53) to prevent leakage of body fluid.
5. The tool as claimed in claim 1, wherein said guiding surfaces (56) gradually change from the proximal end, where they do not affect the nominal shape of the wound closure element (30), towards the distal end where they force the wound closure element

(30) to assume a shape that conforms to the inner lumen of an introducer tube, connectable to the distal end of said guiding tool.

6. The tool as claimed in claim 1, wherein said lumen is cone shaped at least in the distal region of said guiding tool, and has a large enough diameter in the proximal region of the guiding tool, that the nominal shape of the wound closure element (30) is not affected, and a small enough diameter in the distal end that the wound closure element conforms to the inner lumen of an introducer tube, connectable to the distal end of said guiding tool.
7. The tool as claimed in claim 1, wherein the proximal region of the tool is essentially cylindrical, forming a storage compartment for said closure element (30), in which the nominal shape of the wound closure element is not affected.
8. A system for the introduction and securing of a wound closure element into a percutaneous incision or puncture in the wall of a vessel, duct, lumen or hollow organ in the body of a living being, said incision or puncture being smaller than said wound closure element in an unfolded or undeformed state, said system comprising
 - a wound closure element (30);
 - an introducer tube (10) for introducing said wound closure element into said incision;
 - a pusher device for enabling the passage of said wound closure element through said introducer; and
 - a tool as claimed in claim 1, connectable to said introducer.

Patentansprüche

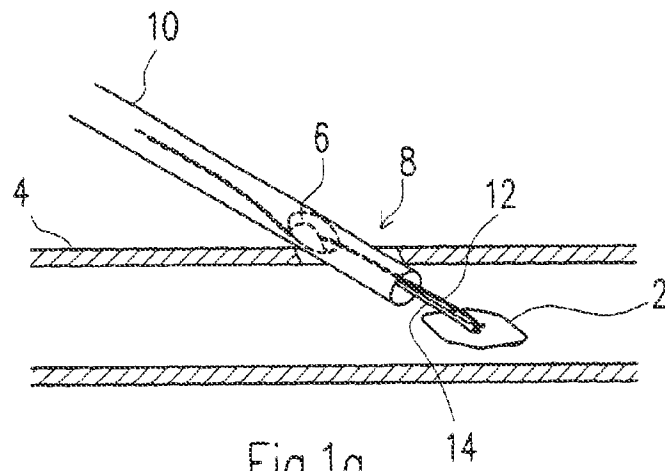
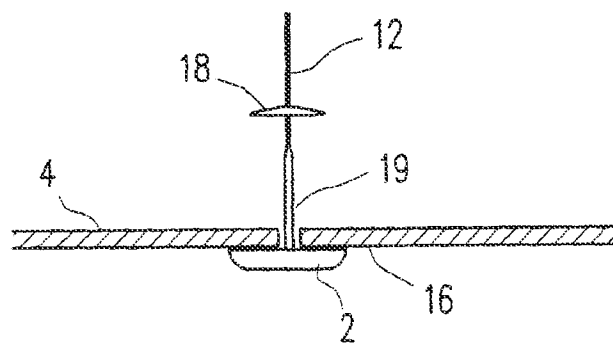
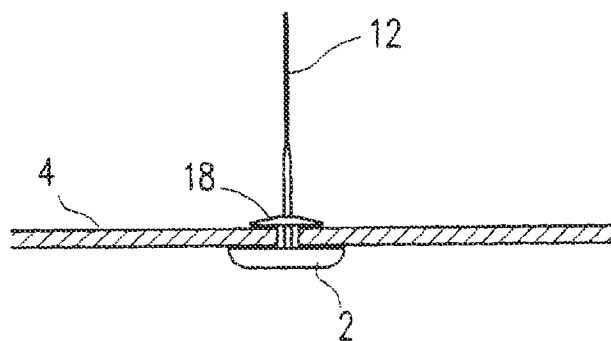
1. Führungswerkzeug zum gesteuerten und reversiblen Falten oder Verformen eines Wundverschlusselements (2) vor der Einführung dieses Wundverschlusselements in einen perkutanen Schnitt oder eine perkutane Punktur in der Wand (4) eines Gefäßes, eines Kanals, eines Lumens oder eines hohlen Organs im Körper eines Lebewesens, wobei der Schnitt oder die Punktur kleiner ist als das Wundverschlusselement in einem ungefalteten oder nichtverformten Zustand, wobei das Werkzeug einen Körper (20) mit einem distalen Ende (26) und einem proximalen Ende (24) sowie einem Lumen (22) aufweist, das sich zwischen dem distalen und dem proximalen Ende erstreckt, eine Einführöffnung (50) für das Wundverschlusselement in dem proximalen Ende und eine Ausgangsöffnung (52) für das Wundverschlusselement in dem distalen Ende;
dadurch gekennzeichnet, dass

- das Lumen Innenwände (54) hat, die mit Führungsflächen (56, 64) für das Wundverschlusselement in Form von separaten Abienelementen versehen sind, die von der Innenwand des Lumens hervorstehen, um die räumliche Ausdehnung eines Wundverschlusselements während seines Durchgangs durch das Führungswerkzeug durch Ineingriffbringen eines Außenrands oder Kragenbereichs des Verschlusselements reversibel zu reduzieren, so dass diese aus einer im Wesentlichen flachen anfänglichen Position abgelenkt oder nach unten gebogen werden, wobei das Wundverschlusselement durch den Schnitt oder die Punktur hindurchtreten kann und wobei es nach dem Durchtritt durch den Schnitt oder die Punktur eine Gestalt annimmt, die eine Dichtungswirkung gegen den Schnitt oder die Punktur bieten kann.
2. Werkzeug nach Anspruch 1, wobei die Führungsflächen (56) am proximalen Ende des Werkzeugs im Wesentlichen flach sind und in Richtung des distalen Endes nach und nach erhaben und auch gekrümmt werden, so dass sie ein quasi konisches Lumen innerhalb des Werkzeugs bilden, und wobei die Führungsflächen am distalen Ende des Lumens in der Nähe der Ausgangsöffnung einen Zustand erreicht haben werden, wo der Querschnitt des Lumens im Wesentlichen kreisförmig ist.
3. Werkzeug nach Anspruch 1 oder 2, wobei Führungsschienen (62) oberhalb der Führungsflächen (56) vorgesehen sind, so dass Flügel oder Kanten (34) eines Verschlusselements (30) während des Vorgangs des Hindurchdrückens durch das Führungswerkzeug unten gehalten werden, wobei die Führungsschienen (62) so angeordnet sind, dass ein unbeabsichtigtes Kippen oder anderweitiges unkorrektes Verhalten des Verschlusselements während seiner Bewegung durch das Führungswerkzeug hindurch verhindert wird.
4. Werkzeug nach Anspruch 1, wobei die Einführöffnung größer ist als die Ausgangsöffnung und optional mit einem Dichtungsverschluss (53) versehen ist, um ein Auslaufen von Körperflüssigkeit zu verhindern.
5. Werkzeug nach Anspruch 1, wobei die Führungsflächen (56) sich von dem proximalen Ende, wo sie die Nenngestalt des Wundverschlusselements (30) nicht beeinflussen, in Richtung des distalen Endes, wo sie das Wundverschlusselement (30) dazu zwingen, eine Gestalt einzunehmen, die sich dem inneren Lumen einer Einführröhre anpasst, verbindbar mit dem distalen Ende des Führungswerkzeugs, nach und nach verändern.
6. Werkzeug nach Anspruch 1, wobei das Lumen zu-
- mindest im distalen Bereich des Führungswerkzeugs kegelförmig ist und im proximalen Bereich des Führungswerkzeugs einen Durchmesser hat, der groß genug ist, um die Nenngestalt des Wundverschlusselements (30) nicht zu beeinflussen, und im distalen Ende einen Durchmesser hat, der klein genug ist, damit sich das Wundverschlusselement an das innere Lumen einer Einführröhre, verbindbar mit dem distalen Ende des Führungswerkzeugs, anpasst.
7. Werkzeug nach Anspruch 1, wobei der proximale Bereich des Werkzeugs im Wesentlichen zylindrisch ist und ein Aufbewahrungsabteil für das Verschlusselement (30) bildet, wobei die Nenngestalt des Wundverschlusselements nicht beeinträchtigt wird.
8. System zum Einführen und Sichern eines Wundverschlusselements in einen perkutanen Schnitt oder eine perkutane Punktur in der Wand eines Gefäßes, eines Kanals, eines Lumens oder eines hohlen Organs im Körper eines Lebewesens, wobei der Schnitt oder die Punktur kleiner ist als das Wundverschlusselement in einem ungefalteten oder nicht-deformierten Zustand, wobei das System Folgendes aufweist:
- ein Wundverschlusselement (30) ;
 - eine Einführröhre (10) zum Einführen des Wundverschlusselements in den Schnitt;
 - eine Druckeinrichtung zum Ermöglichen des Durchgangs des Wundverschlusselements durch die Einführröhre hindurch; und
 - ein Werkzeug nach Anspruch 1, das mit der Einführröhre verbindbar ist.

Revendications

1. Outil de guidage pour le repliement ou la déformation contrôlables et réversibles d'un élément de fermeture de plaie (2) avant l'insertion dudit élément de fermeture de plaie dans une incision percutanée ou un orifice dans la paroi (4) d'un vaisseau, d'un canal, d'une ouverture ou d'un organe creux dans le corps d'un être vivant, où ladite incision ou ledit orifice est plus petit que ledit élément de fermeture de plaie à l'état non replié ou non déformé, ledit outil comprenant un corps (20) avec une extrémité distale (26) et une extrémité proximale (24) et une ouverture (22) entre lesdites extrémités distale et proximale, une ouverture d'introduction (50) de l'élément de fermeture de plaie à l'extrémité proximale et une ouverture de sortie (52) de l'élément de

- fermeture de plaie à l'extrémité distale, **caractérisé en ce que** ledit passage présente des parois internes (54) offrant des surfaces de guidage (56, 64) de l'élément de fermeture de plaie sous la forme d'éléments déflecteurs distincts disposés en saillie sur la paroi interne dudit passage et destinés à réduire de manière réversible l'extension dans l'espace d'un élément de fermeture de plaie pendant son passage dans l'outil de guidage en agissant sur un bord ou collet périphérique de l'élément de fermeture de manière à ce qu'il soit fléchi ou replié vers le bas à partir d'une position initiale essentiellement plane, si bien que ledit élément de fermeture de plaie peut passer au travers de ladite incision ou dudit orifice et, après son passage dans ladite incision ou ledit orifice, reprendre une forme telle qu'il soit en mesure d'exercer une action de fermeture sur ladite incision ou ledit orifice.
2. Outil selon la revendication 1, où lesdites surfaces de guidage (56) dans l'extrémité proximale dudit outil sont essentiellement planes et, en direction de l'extrémité distale, remontent et se courbent progressivement de manière à former une ouverture pratiquement conique à l'intérieur de l'outil et où les surfaces de guidage, à l'extrémité distale de l'ouverture, près de l'ouverture de sortie, atteignent une position telle que la section de l'ouverture est essentiellement circulaire.
 3. Outil selon la revendication 1 ou 2, où il existe au-dessus des surfaces de guidage (56) des rails de guidage (62) tels que les ailes ou bords (34) de l'élément de fermeture (30) sont maintenus en position basse pendant l'opération de poussée au travers de l'outil de guidage, lesdits rails de guidage (62) étant disposés de manière à éviter que l'élément de fermeture ne puisse inopinément basculer ou mal se positionner pendant son mouvement au travers de l'outil de guidage.
 4. Outil selon la revendication 1, où ladite ouverture d'introduction est plus grande que ladite ouverture de sortie et peut en option être dotée d'un bouchon étanche (53) destiné à éviter l'épanchement des fluides corporels.
 5. Outil selon la revendication 1, où lesdites surfaces de guidage (56) changent progressivement, entre l'extrémité proximale, où elles n'affectent pas la forme nominale de l'élément de fermeture de plaie (30), et l'extrémité distale, où elles forcent l'élément de fermeture de plaie (30) à prendre une forme correspondant à l'ouverture interne d'un tube d'introduction pouvant être connecté à l'extrémité distale dudit outil de guidage.
 6. Outil selon la revendication 1, où ledit passage est de forme conique, au moins dans la région distale dudit outil de guidage, et possède un diamètre suffisamment grand dans la région proximale de l'outil de guidage pour que la forme nominale de l'élément de fermeture de plaie (30) ne soit pas affectée et un diamètre suffisamment petit dans la région distale pour que l'élément de fermeture de plaie corresponde à l'ouverture interne d'un tube d'introduction pouvant être connecté à l'extrémité distale dudit outil de guidage.
 7. Outil selon la revendication 1, où la région proximale de l'outil est essentiellement cylindrique, formant un compartiment de stockage pour ledit élément de fermeture de plaie (30), où la forme nominale de celui-ci n'est pas affectée.
 8. Système pour l'introduction et la fixation d'un élément de fermeture de plaie dans une incision percutanée ou un orifice dans la paroi d'un vaisseau, d'un canal, d'une ouverture ou d'un organe creux du corps d'un être vivant, ladite incision ou ledit orifice étant plus petit que ledit élément de fermeture de plaie à l'état non replié ou non déformé, ledit système comprenant
 - un élément de fermeture de plaie (30),
 - un tube d'introduction (10) pour introduire ledit élément de fermeture de plaie dans ladite incision,
 - un dispositif de poussage permettant de faire passer ledit élément de fermeture de plaie dans ledit tube d'introduction, et
 - un outil selon la revendication 1, pouvant être connecté audit tube d'introduction.



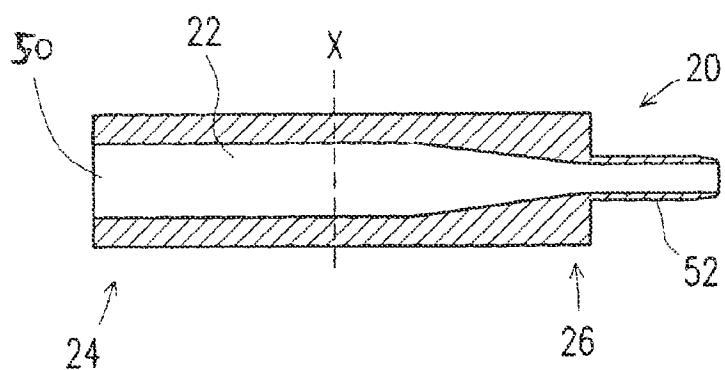


Fig.2a

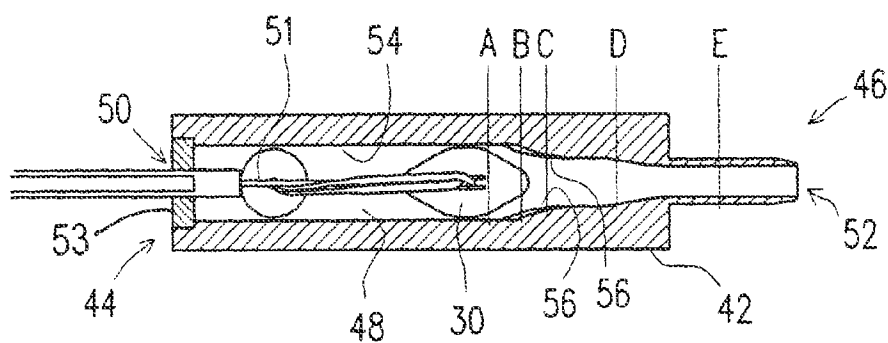


Fig. 2b

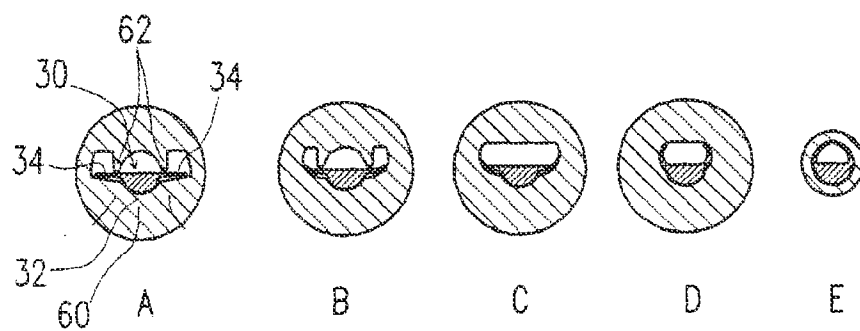


Fig.2c

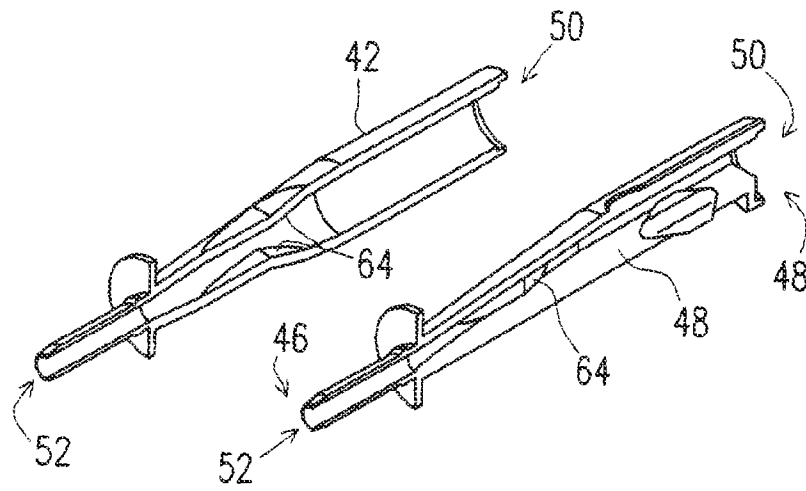


Fig. 2d

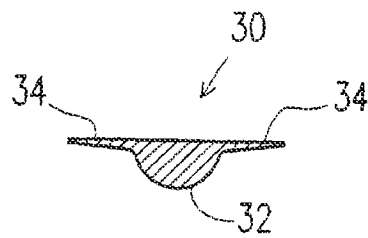


Fig. 3a

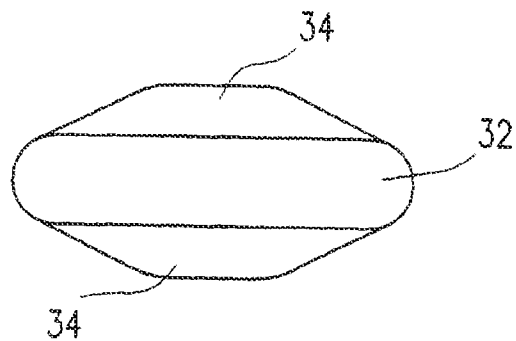


Fig. 3b



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- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

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(54) Title: AXIAL LENGTHENING THROMBUS CAPTURE SYSTEM

(57) Abstract: Systems and methods can remove material of interest, including blood clots, from a body region, including but not limited to the circulatory system for the treatment of pulmonary embolism (PE), deep vein thrombosis (DVT), cerebrovascular embolism, and other vascular occlusions.

AXIAL LENGTHENING THROMBUS CAPTURE SYSTEM

PRIORITY CLAIM

[0001] Any and all applications for which a foreign or domestic priority claim is identified in the Application Data Sheet as filed with the present application. This application claims the benefit under 35 U.S.C. § 120 as continuation of U.S. nonprovisional application no. 15/604531, filed May 24, 2017, which is a continuation-in-part application of U.S. Pat. App. No. 15/428,076 filed on February 8, 2017, which is a continuation-in-part application of U.S. Pat. App. No. 15/230,109 filed on August 5, 2016, which claims the benefit under 35 U.S.C. § 119(e) as a nonprovisional application of each of U.S. Provisional App. Nos. 62/202,074 filed on August 6, 2015, 62/273,418 filed on December 30, 2015, and 62/345,863 filed on June 6, 2016. Each of the aforementioned priority applications is hereby incorporated by reference in their entireties.

BACKGROUND

Field of the Invention

[0002] The invention relates to, in some aspects, systems and methods to remove materials of interest, including blood clots, from a body region, including but not limited to the circulatory system for the treatment of pulmonary embolism (PE), deep vein thrombosis (DVT), cerebrovascular embolism, and other vascular occlusions.

Description of the Related Art

[0003] It is understood that undesirable materials such as blood clots (which could be referred to as thrombi, thromboemboli, or emboli herein) in the blood vessels may partially or completely occlude blood vessels in areas of the coronary, cerebrovascular, pulmonary, peripheral venous, and peripheral arterial circulation resulting in myocardial infarction, stroke, pulmonary embolism, deep vein thrombosis, and infarction of an extremity respectively.

[0004] Various therapies and devices are known to either dissolve, debulk and/or aspirate the thromboemboli. For instance, anticoagulant agents such as heparin and warfarin help stabilize blood clots and prevent further forming of clots while thrombolytic agents such

as urokinase, streptokinase, and tPA assist in dissolving blood clots. These agents can be delivered via systemic infusion or catheter-based infusion to the intended location. While thrombolytic agents can be effective in dissolving blood clots, they require a long time duration in order for the agents to dissolve the blood clots; thus patients may need to remain in the hospital intensive care unit (ICU) during thrombolytic infusion. Relatively long lengths of stay can increase healthcare costs significantly. A major limitation for these thrombolytic agents is that they can potentially cause intracranial, gastrointestinal, retroperitoneal, and pericardial bleeding, among other sites, which can be often life-threatening and cause significant morbidity and mortality risks.

[0005] Mechanical debulking and/or aspiration devices can be used to remove the obstruction. These mechanical techniques can either macerate, aspirate, or a combination thereof in order to remove the blood clots. An advantage of mechanical therapy is that it can remove thrombus directly from the blockage area and immediately eliminates the obstruction and may be superior to thrombolytic agents in some cases. However, current mechanical therapies have some major limitations. There is minimal to no flow during the procedure thus there is little time before patients may become hemodynamically unstable. The debris removed from mechanical treatment can travel distally creating additional embolization. The small size devices are unable to remove large amount of blood clots in short time periods thus patients may become hemodynamically unstable.

[0006] Catheter-based removal of blood clots from larger blood vessels (e.g., pulmonary arteries) have had limited success compared to smaller blood vessels (e.g., coronary arteries). Catheter pulmonary embolectomy is where pulmonary emboli are removed percutaneously using several techniques. Fragmentation thrombectomy breaks blood clots into smaller pieces, most of which travel further downstream, resulting in distal embolization. It is sometimes used in combination with thrombolytics. With the rheolytic thrombectomy, high velocity saline jets create a Venturi effect and draw the fragments of the clot into the catheter. This method poses risk of hemolysis. Finally the aspiration techniques draw the clot into a catheter via suction. All of these techniques rely on the catheter used to remove the clots from blood vessels. The users use small catheters to remove or break up large amounts of blood clot. This procedure is therefore time-consuming and inefficient. Once the blood clots are broken into small pieces, the debris can migrate distally and create

unwanted emboli. Rheolytic therapy poses the risk of hemolysis. Additionally, the ability to suction is limited due the small catheter size suctioning large emboli. These limitations cause in some cases unnecessary duress to the user and risk to the patient.

[0007] Catheter-based removal of blood clots in general also has a major limitation when distal working space within a body lumen is limited. Conventional devices may require full axial and/or radial deployment and expansion to be functional, and as such flexibility to use such devices for a variety of clinical situations involving differing clot or other material sizes to be removed can be very limited. Therefore, conditions where there is limited distal space of blood vessels can render these conventional devices ineffective.

[0008] It is evident that all of the therapeutic options available to patients with blood clots or other undesirable material in blood vessels and other body lumens have limitations. Anticoagulation only limits propagation of clots but does not actively remove it. Thrombolytic therapy poses a risk of major bleeding. Catheter embolectomy is not effective to manage removal of material in large vessels. Additionally, these devices require distal space to fully deploy to be functional thus ineffective in tight distal spaces. Surgical embolectomy can be highly effective but highly invasive, and has a high rate of morbidity and mortality. There is a need for a direct mechanical treatment that is as or more effective as surgical embolectomy removing large blood clots but can be performed using endovascular techniques and restore immediate blood flow, and cause a lower incidence of complications.

SUMMARY

[0009] In some embodiments, disclosed herein is a capture system for selected materials within a body. The capture system can include a capture assembly configured to isolate unwanted material, e.g., a blood clot that can include a shape memory body such as made of, for example, a mesh material and having a distal end connected to a capture guide having a distal opening. The shape memory body can further include a proximal end connected to a first shaft, and a tubular sidewall between the proximal end and the distal end. The capture assembly can be configured to expand the capture guide and the distal opening end when the shape memory body proximal end is compressed in the delivery system. The shape memory body can be movable from a first configuration having a first axial length and a second configuration having a second axial length. The shape memory body can be

configured to roll out, invert, evert, and/or variably lengthen proximally or distally from the first configuration to the second configuration. The second axial length can be different from the first axial length. The width of the capture assembly can, in some cases not substantially change from the first configuration to the second configuration. The capture system can also include a control line configured to independently move the capture assembly from the first configuration to the second configuration. The first shaft can extend within the longitudinal axis of the capture assembly.

[0010] In some embodiments, disclosed herein is a material, e.g., a clot capture system. The system can include a first, outer tubular shaft comprising a central lumen, the first outer tubular shaft comprising a proximal portion and a distal portion, the distal portion more radially expandable than the proximal portion. The system can also include a second tubular shaft configured to be positioned within the central lumen of the first shaft. The system can also include a third tubular shaft configured to be positioned within a central lumen of the second shaft. The shape memory tubular body can include a first end, a second end, and an axial length therebetween, the first end having a proximal-facing opening and a ring-shaped capture guide attached to a circumference of the proximal-facing opening, the capture guide operably attached to the second tubular shaft, the second end attached to an outer wall of the third tubular shaft. The shape memory tubular body can be compressed within the central lumen of the second tubular shaft in a first delivery configuration. The shape memory tubular body can be transformable to a second configuration in which the first end and the capture guide is radially expanded up to a dynamic fold point, but the second end and a segment of the shape memory tubular body extends in a different direction, such as proximally past the dynamic fold point, and remains radially compressed within the central lumen of the second tubular shaft and the second end is positioned proximal to the first end and the shape memory tubular mesh body has a first expanded axial length. The shape memory tubular body can be transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, and a width of the shape memory tubular shaft along its second expanded axial length is the same or substantially the same as a width of the shape memory tubular shaft along its first expanded axial length. The first tubular shaft can be configured to be reversibly coupled with respect to the second tubular shaft in the delivery configuration and axially

movable with respect to the third tubular shaft in the second configuration. In some embodiments, the second expanded axial length is about or at least about, for example, 105%, 110%, 115%, 120%, 125%, 130%, 150%, 200%, 250%, 300%, 350%, 400%, 450%, 500%, or more of the first axial length. The capture system of Claim 1, wherein the shape memory body can be porous, semi-permeable, and non-porous, and include nitinol braided, woven, or non-woven mesh, or nitinol wire. In some embodiments, the tubular body is coated with a hydrophilic or hydrophobic agent, or noncoated, and may not include a shape memory metal or material. In some embodiments, the tubular mesh body is configured to invert, evert, or roll out with respect to the first, second, and/or third shaft. The system can also include a control line extending proximally from the capture guide, either terminating on a sleeve on one of the shafts or extending proximally to the proximal end of the system. In some embodiments, the system includes a suction element configured to operably connect with the proximal opening of the shape memory tubular body. The system can also include a mechanical thrombectomy element, such as a macerator. The system can also include a filter collection chamber configured to collect and filter blood obtained from the suction element.

[0011] The system can further include an expanding guide catheter configured to receive the capture assembly in the form of a kit. The expanding guide element can include an open funnel distal tip, that can be porous in some embodiments to allow flow around the funnel distal tip.

[0012] In some embodiments, disclosed herein is a material, such as a clot capture system that can include a first, outer tubular shaft comprising a central lumen; a second tubular shaft configured to be positioned within the central lumen of the first shaft, the second tubular shaft comprising a proximal portion and a distal portion, the distal portion more radially expandable than the proximal portion; a third tubular shaft configured to be positioned within a central lumen of the second shaft; a tubular mesh comprising a first end, a second end, and an axial length therebetween, the first end having a proximal-facing opening and a ring-shaped capture guide attached to a circumference of the proximal-facing opening, the capture guide operably attached to the second tubular shaft, the second end attached to an outer wall of the third tubular shaft. The tubular mesh can be compressed within the central lumen of the second tubular shaft in a delivery configuration. The tubular mesh can also be transformable to a second configuration in which the first end and the

capture guide is radially expanded but the second end and a portion, such as a minority, half, or a majority of the tubular mesh remains radially compressed within the central lumen of the second tubular shaft and the second end is positioned proximal to the first end and the tubular mesh has a first expanded axial length. The tubular mesh can be transformable to a third configuration in which the tubular mesh has a second expanded axial length greater than the first expanded axial length, wherein a width of the tubular mesh along its second expanded axial length is substantially the same as a width of the tubular mesh along its first expanded axial length, wherein the third tubular shaft extends distally through the proximal end opening as well as the second axial expanded length of the shape memory tubular body. In some embodiments, the tubular mesh is not under tension or substantially under tension in the second configuration or the third configuration defining an axial working range of the tubular mesh.

[0013] In some embodiments, a material, such as a clot capture system includes a first, outer tubular shaft comprising a central lumen; a second tubular shaft configured to be positioned within the central lumen of the first shaft, the second tubular shaft comprising a proximal portion and a distal portion, the distal portion more radially expandable than the proximal portion; a third tubular shaft configured to be positioned within a central lumen of the second shaft; a tubular body that may include shape memory materials that includes a first end, a second end, and an axial length therebetween, the first end having a proximal-facing opening and a ring-shaped capture guide attached to a circumference of the proximal-facing opening, the capture guide operably attached to the second tubular shaft via a sleeve circumscribing a portion of the second tubular shaft, the second end attached to an outer wall of the third tubular shaft. The shape memory tubular body can be compressed within the central lumen of the second tubular shaft in a delivery configuration. The shape memory tubular body can be transformable to a second configuration by axial movement of the second tubular shaft with respect to the first tubular shaft, in which the first end and the capture guide is radially expanded but the second end and a segment of the shape memory tubular body remains radially compressed within the central lumen of the second tubular shaft and the second end is positioned proximal to the first end and the shape memory tubular mesh body has a first expanded axial length. The shape memory tubular body can be transformable to a third configuration by movement of the second tubular shaft with respect

to the third tubular shaft, in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein a width of the shape memory tubular shaft along its second expanded axial length is substantially the same as a width of the shape memory tubular shaft along its first expanded axial length, wherein the third tubular shaft extends distally through the proximal end opening as well as the second axial expanded length of the shape memory tubular body. The shape memory tubular body can, in some cases, be transformable to a fourth configuration by movement of the second tubular shaft with respect to the third tubular shaft. The shape memory tubular body can have a third expanded axial length greater than the second expanded axial length, wherein a width of the shape memory tubular shaft along its third expanded axial length is less than the width of the shape memory tubular shaft along its second expanded axial length. The clot capture system can also include a sleeve that includes a metal or polymer, and the sleeve can be partially or fully radiopaque or radiolucent under fluoroscopy or other imaging.

[0014] Also disclosed herein is a method of performing a thrombectomy. The method can include, for example, accessing the interior of a blood vessel; advancing a thrombus capture device comprising a capture assembly through the blood vessel; positioning the thrombus capture device such that a distal end of the device is distal to the thrombus; actuating the capture assembly to isolate the thrombus within the capture device, wherein the capture assembly is movable from a first configuration having a first axial length and a second configuration having a second axial length, the second axial length being different from the first axial length, wherein the width of the capture assembly does not substantially change from the first configuration to the second configuration; and suctioning, macerating, and/or mechanically removing the thrombus.

[0015] In some embodiments, a method of performing a thrombectomy can include, for example, accessing the interior of a blood vessel; advancing an expanding guiding catheter through the blood vessel; positioning the expanding guiding catheter such that a distal end of the device is proximal to a thrombus; retracting the expanding guide catheter outer member to expand a funnel tip and exposing an expandable inner member; advancing a thrombus capture device comprising a capture assembly through the expanding guide catheter; positioning the thrombus capture device such that a distal end of the device is distal to or within the thrombus; and actuating the capture assembly to isolate the thrombus

within the capture device. The capture assembly can be movable from a first configuration having a first axial length and a second configuration having a second axial length, the second axial length being different from the first axial length. The width of the capture assembly may not substantially change from the first configuration to the second configuration. The method can also include retracting the capture assembly with the thrombus into an expanding guide catheter funnel tip and expandable inner body. The method can also include axially lengthening the thrombus capture device distally and retracting the thrombus into the funnel tip of the expanding guide catheter. The method can further include radially shortening the thrombus capture device to compress the thrombus and promote removal of the thrombus.

[0016] In some embodiments, disclosed herein is a clot capture system that can include a capture assembly configured to isolate a blood clot. The system can include a shape memory body that has a distal end connected to a capture guide comprising a distal or proximal opening. The shape memory body can also include a proximal end connected to a first shaft, and a sidewall between the proximal end and the distal end. The capture guide and the distal zone of the shape memory body opening end can also be fully or partially recaptured inside the outer sheath. The capture assembly can be configured to radially expand the capture guide and a distal zone of the shape memory body opening end while the shape memory body proximal end remains compressed in the delivery configuration. The capture assembly can be movable from a first configuration having a first axial length to a second configuration having a second axial length. The shape memory body can be configured to roll out, invert, evert, and/or variably lengthen proximally from the first configuration to the second configuration. The second axial length can be different from the first axial length. The width of the capture assembly can in some cases not substantially change from the first configuration to the second configuration.

[0017] Also disclosed herein is a capture assembly configured to isolate a blood clot including a shape memory body including a proximal end and a distal end connected to a capture guide including a distal opening, a proximal end connected to a shaft, and a sidewall between the proximal end and the distal end. The capture assembly can be configured to expand the capture guide and the distal shape memory body opening end while the shape memory body proximal end is compressed in the delivery configuration between a first shaft

and a second shaft, and movable from a first configuration having a first axial length and a second configuration having a second axial length. The shape memory body can be configured to roll out/unroll, invert, evert, and/or variably lengthen proximally from the first configuration to the second configuration. The second axial length can be different from the first axial length. In some cases, the width of the capture assembly does not substantially change from the first configuration to the second configuration. Furthermore, the shape memory body can be fully or partially recaptured inside the outer sheath once deployed. The system can also include a sleeve coupled a control line connected to the second shaft configured to move the capture assembly from the first configuration to the second configuration. The first shaft and the second shaft can be off-axis with respect to the capture assembly.

[0018] Also disclosed herein is a method of performing a thrombectomy. The method can include any number of the following: accessing the interior of a blood vessel; advancing a thrombus capture device comprising a capture assembly through the blood vessel; positioning the thrombus capture device such that a distal end of the device is distal to the thrombus; actuating the capture assembly to isolate the thrombus within the capture device, wherein the capture assembly is movable from a first configuration having a first axial length and a second configuration having a second axial length, the second axial length being different from the first axial length, wherein the width of the capture assembly does not substantially change from the first configuration to the second configuration; and suctioning the thrombus.

[0019] In some embodiments, the methods can include any number of the following: accessing the interior of a blood vessel; advancing an expanding guiding catheter through the blood vessel; positioning the expanding guiding catheter such that a distal end of the device is proximal to a thrombus; retracting the expanding guide catheter outer member to expand a funnel tip and exposing an expandable inner member; advancing a thrombus capture device comprising a capture assembly through the expanding guide catheter; positioning the thrombus capture device such that a distal end of the device is distal to or within the thrombus; actuating the capture assembly to isolate the thrombus within the capture device, wherein the capture assembly is movable from a first configuration having a first axial length and a second configuration having a second axial length, the second axial

length being different from the first axial length wherein the width of the capture assembly does not substantially change from the first configuration to the second configuration; and retracting the thrombus into an expanding guide catheter funnel tip and expandable inner body. In some embodiments, the capture guide is first recaptured into the outer sheath of the delivery catheter and then retract into the expanding guide catheter funnel tip and expandable inner body.

[0020] In some embodiments, disclosed herein is a clot capture system. The system can include a first tubular member comprising a central lumen. The system can include a second tubular member. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an end opening, the second end attached to the second tubular member. In some embodiments, at least part of the shape memory tubular body is compressed within the central lumen of the first tubular shaft in a first delivery configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end is radially expanded while the second end and a majority of the shape memory tubular body remains radially compressed within the central lumen of the first tubular shaft and the second end is positioned proximal to the first end and the shape memory tubular body has a first expanded axial length. In some embodiments, the shape memory tubular body is transformable to a third configuration via movement of the first tubular shaft with respect to the second tubular shaft in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein a width of the shape memory tubular body along its second expanded axial length is substantially the same as a width of the shape memory tubular body along its first expanded axial length.

[0021] The system can include a capture guide attached to the first end opening. In some embodiments, the capture guide at least partially circumscribes the first end opening. In some embodiments, the capture guide fully partially circumscribes the first end opening. The system can include an expandable cover element circumscribing the capture guide. In some embodiments, the expandable cover element is inflatable. The system can include a control line extending proximally from the capture guide. The system can include a sleeve attached to the first tubular shaft and the first end opening of the shape memory tubular body. In some embodiments, the shape memory tubular body is configured to invert, evert, or roll

out with respect to the first tubular shaft or the second tubular shaft. In some embodiments, the end opening of the shape memory tubular body is proximal-facing. In some embodiments, the shape memory tubular body comprises a mesh. In some embodiments, the shape memory tubular body is configured to allow fluid flow therethrough. In some embodiments, the second tubular member comprises a central lumen. The system can include an expanding guide element configured to receive the capture assembly. In some embodiments, the expanding guide element comprises an open funnel distal tip. In some embodiments, the open funnel distal tip is porous to allow flow. In some embodiments, the shape memory tubular body has a maximal length of between about 0.5cm and about 125cm. In some embodiments, the shape memory tubular body is transformable to a fourth configuration wherein the shape memory tubular body has a third axial expanded length greater than the second axial expanded length, wherein a width of the shape memory tubular body along its third expanded axial length is less than the width of the shape memory tubular body along its second expanded axial length.

[0022] In some embodiments, disclosed herein is a system for capturing material of interest within a body lumen. The system can include a first tubular member comprising a central lumen. The system can include a second tubular member. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an end opening, the second end attached to an outer wall of the second tubular member. In some embodiments, the shape memory tubular body is compressed within the central lumen of the first tubular shaft in a first delivery configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end opening and a first segment of the shape memory tubular body extending axially in a first direction from the first end opening is radially expanded to a fold point, while a second segment of the shape memory tubular body extends axially from the fold point to the second end of the shape memory tubular body in a second direction opposite the first direction, the second segment relatively radially compressed with respect to the first segment, the second end positioned proximal to the first end. In some embodiments, the shape memory tubular body is transformable to a third configuration via movement of the first tubular shaft with respect to the second tubular shaft in which the axial length of the first segment increases by a first amount, the shape memory tubular body has a second expanded

axial length greater than the first expanded axial length, wherein a width of the shape memory tubular body along its second expanded axial length is substantially the same as a width of the shape memory tubular body along its first expanded axial length.

[0023] In some embodiments, disclosed herein is a clot capture system. The system can include a first tubular member comprising a central lumen. The system can include a second tubular member. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an end opening, the second end attached to an outer wall of the second tubular member. In some embodiments, the shape memory tubular body is compressed within the central lumen of the first tubular shaft in a first delivery configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end opening and a first segment of the shape memory tubular body extending axially in a first direction from the first end opening is radially expanded to a fold point, while a second segment of the shape memory tubular body extends axially from the fold point in a second direction opposite the first direction to the second end, the second segment radially compressed with respect to the first segment, the second end positioned proximal to the first end. In some embodiments, the shape memory tubular body is transformable to a third configuration via movement of the first tubular shaft with respect to the second tubular shaft in which the axial length of the first segment increases by a first amount, the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein a width of the shape memory tubular body along its second expanded axial length is substantially the same as a width of the shape memory tubular body along its first expanded axial length.

[0024] In some embodiments, disclosed herein is a clot capture system. The system can include an outer sheath comprising a central lumen. The system can include a dual lumen shaft configured to be positioned within the central lumen of the outer sheath. The system can include an inner pusher configured to be positioned within a first lumen of the dual lumen shaft. The system can include an anchor pusher configured to be positioned within a second lumen of the dual lumen shaft. The system can include an anchor coupled to the anchor pusher. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening and a

capture guide attached to a portion of the opening. In some embodiments, the shape memory tubular body and the anchor are compressed in a first configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains radially compressed within the lumen of the dual lumen shaft and the shape memory tubular body has a first expanded axial length with a first cross-section, wherein the first cross-section is substantially similar to the cross-section of the capture guide. In some embodiments, the shape memory tubular body is transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein the shape memory tubular body encapsulates the anchor in the third configuration.

[0025] The system can include, for example, one, two, or more anchors. The anchors can have any desired configuration to stabilize or associate with a clot to facilitate removal, including a J-hook shape in some cases. The anchors can penetrate a clot or other material to be captured in some embodiments, or do not penetrate but rather circumscribe or otherwise stabilize or reversibly secure at least a portion of the clot or other material to be captured. In some embodiments, the anchors have a central longitudinal axis that is coaxial. The system can include three anchors, or more. In some embodiments, the cross-section of the anchor is round, ovoid, square, rectangular, or another cross section. In some embodiments, the anchor comprises nitinol. In some embodiments, the anchor forms an angle with the anchor pusher, wherein the angle is approximately 90 degrees. In some embodiments, the anchor forms an angle with the anchor pusher, wherein the angle is approximately 45 degrees. In some embodiments, the anchor forms an angle with the anchor pusher, wherein the angle is between 5 degrees and 135 degrees. In some embodiments, the diameter of the anchor is less than the diameter of the shape memory tubular body when radially expanded. In some embodiments, a portion of the anchor pusher is crescent shaped. In some embodiments, the capture guide comprises nitinol. In some embodiments, the capture guide comprises a central longitudinal axis and wherein the dual lumen shaft is offset from the central longitudinal axis. In some embodiments, the second end of the shape memory tubular body is coupled to the inner pusher. In some embodiments, the capture guide

forms a continuous loop. In some embodiments, the capture guide forms a non-continuous loop.

[0026] In some embodiments, disclosed herein is a clot capture system. The system can include an inner pusher. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening and a capture guide attached to at least a portion of the opening, the second end coupled to the inner pusher. In some embodiments, the shape memory tubular body and the capture guide are compressed in a first configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains radially compressed and the shape memory tubular body has a first expanded axial length with a first cross-section, wherein the first cross-section is substantially similar to the cross-section of the capture guide. In some embodiments, the shape memory tubular body is transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length. In some embodiments, the capture guide forms a continuous loop. In some embodiments, the capture guide forms a non-continuous loop.

[0027] Also disclosed herein is a method of using a clot capture system. The method can include any number of the following: positioning a system near a blood clot in the first configuration; transforming the shape memory tubular body to the second configuration; and transforming the shape memory tubular body to the third configuration to encapsulate the clot. The system can include an inner pusher. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening and a capture guide attached to at least a portion of the opening, the second end coupled to the inner pusher. In some embodiments, the shape memory tubular body and the capture guide are compressed in a first configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains radially compressed and the shape memory tubular body has a first expanded axial length with a first cross-section, wherein the first cross-section is substantially similar to the cross-section of the

capture guide. In some embodiments, the shape memory tubular body is transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length. In some embodiments, the blood clot is within the CNS.

[0028] Also disclosed herein is a method of using a clot capture system. The method can include any number of the following: positioning a system near a blood clot; transforming the shape memory tubular body to the second configuration; expanding the anchor; and transforming the shape memory tubular body to the third configuration to encapsulate the anchor. The system can include an outer sheath comprising a central lumen. The system can include a dual lumen shaft configured to be positioned within the central lumen of the outer sheath. The system can include an inner pusher configured to be positioned within a first lumen of the dual lumen shaft. The system can include an anchor pusher configured to be positioned within a second lumen of the dual lumen shaft. The system can include an anchor coupled to the anchor pusher. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening and a capture guide attached to a portion of the opening. In some embodiments, the shape memory tubular body and the anchor are compressed in a first configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains radially compressed within the lumen of the dual lumen shaft and the shape memory tubular body has a first expanded axial length with a first cross-section, wherein the first cross-section is substantially similar to the cross-section of the capture guide. In some embodiments, the shape memory tubular body is transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein the shape memory tubular body encapsulates the anchor in the third configuration. In some embodiments, deploying the anchor comprises securing the anchor within the clot. In some embodiments, transforming the shape memory tubular body to the third configuration to encapsulate the anchor further comprises encapsulating the clot. In some embodiments, the blood clot is a neurological blood clot.

[0029] In some embodiments, disclosed herein is a clot capture system. The system can include a first tubular member comprising a central lumen. The system can include a second tubular member. The system can include a plurality of axially spaced-apart anchors extending radially outwardly from the first tubular member or the second tubular member. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an end opening, the second end attached to the second tubular member. In some embodiments, at least part of the shape memory tubular body is compressed within the central lumen of the first tubular shaft in a first delivery configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end is radially expanded while the second end and a majority of the shape memory tubular body remains radially compressed within the central lumen of the first tubular shaft and the second end is positioned proximal to the first end and the shape memory tubular body has a first expanded axial length. In some embodiments, the shape memory tubular body is transformable to a third configuration via movement of the first tubular shaft with respect to the second tubular shaft in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein a width of the shape memory tubular body along its second expanded axial length is substantially the same as a width of the shape memory tubular body along its first expanded axial length.

[0030] In some embodiments, disclosed herein is a clot capture system. The system can include an anchor. The system can include a tubular body comprising a first end, a second end, and an axial length therebetween. The first end can have an opening. The tubular body and the anchor can be compressed in a delivery configuration. The tubular body and the anchor can be transformable to a deployed configuration in which the anchor and the shape memory tubular body first end are expanded but the shape memory tubular body second end and a majority of the shape memory tubular body remains compressed and the tubular body has a first expanded axial length. The shape memory tubular body can be transformable to a capture configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length. The shape memory tubular body can encapsulate the anchor, or a portion thereof, in the capture configuration. In some embodiments, the system can include two or more anchors. In some embodiments, the

two anchors have a central longitudinal axis that is coaxial. In some embodiments, the anchor is a stent like structure. In some embodiments, the anchor is a balloon. In some embodiments, the anchor is a disk. In some embodiments, the anchor comprises nitinol. In some embodiments, the anchor comprises a spherical balloon. In some embodiments, the anchor is configured to entangle a clot. In some embodiments, the anchor is coupled to the shape memory tubular body. In some embodiments, the anchor is a funnel. In some embodiments, the anchor is tapered from the distal end to the proximal end of the anchor. In some embodiments, the shape memory tubular body comprises a central longitudinal axis and wherein the anchor is offset from the central longitudinal axis. In some embodiments, the second end of the shape memory tubular body is coupled to an inner pusher.

[0031] In some embodiments, disclosed herein is a clot capture system. The system can include an anchor. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween. The first end can have an opening. The shape memory tubular body and the anchor can be configured to be compressed during delivery. The first end of the shape memory tubular body and the anchor can be configured to be expanded while the second end and a majority of the shape memory tubular body remains compressed. The shape memory tubular body can have a first expanded axial length with a first cross-section. The shape memory tubular body can be configured to be axially lengthened. In some embodiments, the system can include a pusher, wherein the second end of the shape memory tubular body is coupled to the pusher. In some embodiments, the anchor and the shape memory tubular body are fixed together.

[0032] In some embodiments, disclosed herein is a method of using a clot capture system. The method can include positioning any clot capture system disclosed herein near a blood clot. The method can include expanding the shape memory tubular body and the anchor. The method can include axially lengthening the shape memory tubular body to encapsulate the clot. In some embodiments, the blood clot is within the central nervous system.

[0033] In some embodiments, disclosed herein is a method of using a clot capture. The method can include positioning any clot capture system disclosed herein near a blood clot. The method can include transforming the shape memory tubular body and the

anchor to the deployed configuration. The method can include transforming the shape memory tubular body and the anchor to the capture configuration to encapsulate the anchor.

[0034] In some embodiments, disclosed herein is a clot capture system. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains compressed within the first lumen of the dual lumen shaft and the shape memory tubular body has a first expanded axial length with a first cross-section. In some embodiments, the first cross-section is substantially similar to a cross-section of the capture guide. In some embodiments, the cross-section of the shape memory tubular body is round. In some embodiments, the anchor forms an angle with the anchor pusher when expanded, wherein the angle is approximately 90 degrees. In some embodiments, the anchor forms an angle with the anchor pusher when expanded, wherein the angle is approximately 45 degrees. In some embodiments, the anchor forms an angle with the anchor pusher when expanded, wherein the angle is approximately 5 degrees. In some embodiments, wherein a diameter of the anchor is less than a diameter of the shape memory tubular body when expanded. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains compressed and the shape memory tubular body has a first expanded axial length with a first cross-section. In some embodiments, the first cross-section is substantially similar to a cross-section of the capture guide. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end is radially expanded while the second end and a majority of the shape memory tubular body remains compressed within the central lumen of the first tubular member and the second end is positioned proximal to the first end and the shape memory tubular body has a first expanded axial length. In some embodiments, a width of the shape memory tubular body along the second expanded axial length is substantially the same as a width of the shape memory tubular body along the first expanded axial length. In some embodiments, disclosed herein is a method of using a clot capture system. The method can include transforming the shape memory tubular body to the third configuration to encapsulate the blood clot. In some embodiments, the blood clot is within the central nervous system. In some embodiments, expanding the anchor

comprises securing the anchor within the blood clot. In some embodiments, transforming the shape memory tubular body to the third configuration to encapsulate the anchor further comprises encapsulating the blood clot.

[0035] In some embodiments, disclosed herein is a clot capture system. The system can include a shaft. The system can include a plurality of axially spaced-apart anchors comprising a reduced configuration and an expanded configuration. In some embodiments, the plurality of axially spaced-apart anchors extend radially outward from the shaft in the expanded configuration. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween. In some embodiments, the first end can include an opening. In some embodiments, the shape memory tubular body can be compressed in a compressed configuration. In some embodiments, the shape memory tubular body can be transformable to a first expanded configuration in which the first end is expanded. In some embodiments, the second end and a portion of the shape memory tubular body can be compressed in the first expanded configuration. In some embodiments, the shape memory tubular body can have a first expanded axial length in the first expanded configuration. In some embodiments, the shape memory tubular body can be transformable to a second expanded configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length. In some embodiments, the shape memory tubular body circumscribes the plurality of axially spaced-apart anchors in the second expanded configuration. In some embodiments, the plurality of axially spaced-apart anchors comprise three or more anchors. In some embodiments, the plurality of axially spaced-apart anchors are coaxial. In some embodiments, the plurality of axially spaced-apart anchors comprise nitinol. In some embodiments, an anchor of the plurality of axially spaced-apart anchors forms an angle with an anchor pusher when expanded, wherein the angle is approximately 90 degrees. In some embodiments, an anchor of the plurality of axially spaced-apart anchors forms an angle with an anchor pusher when expanded, wherein the angle is approximately 45 degrees. In some embodiments, a cross-section of an anchor of the plurality of axially spaced-apart anchors is less than a cross-section of the first end of the shape memory tubular body when expanded. In some embodiments, the plurality of axially spaced-apart anchors are coupled to an anchor pusher. In some embodiments, the second end of the shape memory tubular body is coupled to an inner pusher.

[0036] In some embodiments, disclosed herein is clot capture system. The system can include a shaft. The system can include an anchor comprising a reduced configuration and an expanded configuration. In some embodiments, the anchor extends outward from the shaft in the expanded configuration. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween. In some embodiments, the first end can have an opening. In some embodiments, the shape memory tubular body can be compressed in a compressed configuration. In some embodiments, the shape memory tubular body can be transformable to a first expanded configuration wherein the first end is expanded. In some embodiments, the second end and a portion of the shape memory tubular body can be compressed in the first expanded configuration. In some embodiments, the shape memory tubular body can have a first expanded axial length. In some embodiments, the shape memory tubular body can be transformable to a second expanded configuration in which the shape memory tubular body has a second expanded axial length. In some embodiments, the second expanded axial length is greater than the first expanded axial length. In some embodiments, the first cross-section is round. In some embodiments, the anchor forms an angle with an anchor pusher when expanded, wherein the angle is between 5 degrees and 135 degrees. In some embodiments, the system can include a second anchor. In some embodiments, the anchors are coaxial. In some embodiments, the second end of the shape memory tubular body is coupled to an inner pusher.

[0037] In some embodiments, disclosed herein is clot capture system. The system can include a shaft. The system can include an anchor configured to expand outwardly from the shaft. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween. In some embodiments, the first end can have an opening. In some embodiments, the shape memory tubular body can be compressed in a compressed configuration. In some embodiments, the shape memory tubular body can be transformable to a first expanded configuration wherein the first end is expanded while the second end and a portion of the shape memory tubular body remains compressed. In some embodiments, the shape memory tubular body can have a first expanded axial length in the first expanded configuration. In some embodiments, the shape memory tubular body can be transformable to a second expanded configuration wherein the shape memory tubular body has a second expanded axial length greater than the first expanded axial length. In some

embodiments, the shape memory tubular body surrounds the anchor in the second expanded configuration. In some embodiments, the system can include a second anchor. In some embodiments, the anchors are spaced axially apart along the longitudinal axis of the shaft. In some embodiments, the anchor is configured to entangle a clot. In some embodiments, a cross-section of the anchor is less than a cross-section of the first end of the shape memory tubular body when expanded.

[0038] In some embodiments, the shape memory tubular body can have a first expanded axial length in the first expanded configuration extending from the first end to a fold. In some embodiments, the fold forms the distal end of the shape memory tubular body in the first expanded configuration. In some embodiments, the first end and the second end are proximal to the distal end in the first expanded configuration. In some embodiments, the shape memory tubular body can circumscribes at least one anchor of the plurality of axially spaced-apart anchors in the second expanded configuration. In some embodiments, an anchor of the plurality of axially spaced-apart anchors forms an angle with an anchor pusher when the anchor is expanded, wherein the angle is approximately 90 degrees. In some embodiments, an anchor of the plurality of axially spaced-apart anchors forms an angle with an anchor pusher when the anchor is expanded, wherein the angle is approximately 45 degrees. In some embodiments, a cross-section of each of the plurality of axially spaced-apart anchors is less than a cross-section of the first end of the shape memory tubular body when the plurality of axially spaced-apart anchors and the first end of the shape memory tubular body are expanded. In some embodiments, the shape memory tubular body comprises a distal end in the first expanded configuration. In some embodiments, the first end and the second end are proximal to the distal end in the first expanded configuration. In some embodiments, a cross-section of the shape memory tubular body is round when the shape memory tubular body is expanded. In some embodiments, the anchor forms an angle with an anchor pusher when the anchor is expanded, wherein the angle is between 5 degrees and 135 degrees. In some embodiments, the first anchor and the second anchor are coaxial. In some embodiments, an anchor can be configured to expand. In some embodiments, the shape memory tubular body comprises a dynamic fold point between the first end and the second end in the first expanded configuration. In some embodiments, the first end and the second end are proximal to the dynamic fold point in the first expanded configuration. In some

embodiments wherein the first anchor and the second anchor are spaced axially apart along the longitudinal axis of a shaft. In some embodiments, a cross-section of the anchor is less than a cross-section of the first end of the shape memory tubular body when the anchor and the first end are expanded.

[0039] In some embodiments, the shape memory tubular body and the at least one anchor can be transformable to a second configuration in which the at least one anchor and the first end of the shape memory tubular body are expanded but the second end of the shape memory tubular body and a portion of the shape memory tubular body remains compressed such that the second end is positioned proximal to the first end and the first end overlaps with the portion of the shape memory tubular body that remains compressed. In some embodiments, the first end overlaps with the portion of the shape memory tubular body that remains compressed. In some embodiments, the shape memory tubular body can be transformable to a configuration in which the opening is expanded and a first segment of the shape memory body extending axially in a first direction from the opening is expanded to a fold point, the first segment having a first expanded axial length, and a second segment of the shape memory body extending axially from the fold point to the second end of the shape memory body in a second direction opposite the first direction such that the second segment of the shape memory tubular body extends at least partially within the first segment of the shape memory tubular body. In some embodiments, the second segment is relatively compressed with respect to the first segment. In some embodiments, the second end is positioned proximal to the first end. In some embodiments, the second segment of the shape memory tubular body extends at least partially within the first segment of the shape memory tubular body.

BRIEF DESCRIPTION OF THE FIGURES

[0040] Figure 1 illustrates examples of a catheter system, and various possible elements that can be included in a material capture system, according to some embodiments of the invention.

[0041] Figure 2 illustrates a close-up view of the thrombus capture systems of Figures 1 and 2.

[0042] Figure 3 illustrates an axially-lengthening thrombus capture (ALTC) system in the initial deployment configuration with the ALTC device expanded, according to some embodiments of the invention.

[0043] Figure 4 illustrates a close up view of the ALTC system distal segment position in the delivery configuration indicating the outer sheath and nose tip, according to some embodiments of the invention.

[0044] Figure 5 illustrates the distal end of an axial lengthening thrombus capture device at the initial deployment position, according to some embodiments of the invention.

[0045] Figure 6 illustrates the axial lengthen thrombus capture device retracting proximally to deploy and lengthen, according to some embodiments of the invention.

[0046] Figure 7 illustrates the axial lengthen thrombus capture device is fully deployed and the funnel tip of the guide catheter is positioned within the ALTC device, according to some embodiments of the invention.

[0047] Figures 8 and 9 illustrate different views of the initial deployment position of the ALTC Device and the funnel tip of the suction catheter, according to some embodiments of the invention.

[0048] Figure 10 illustrates the partially deployed ALTC Device, according to some embodiments of the invention.

[0049] Figure 11 illustrates an ALTC device deployed configuration where the funnel tip of the suction catheter is positioned inside the ALTC device, according to some embodiments of the invention.

[0050] Figure 12 illustrates the Axial Lengthening Thrombus Capture (ALTC) assembly wherein the distal end of the ALTC device is in the expanded (deployed) configuration and is fixed to the thrombus capture guide and capture pullwire, according to some embodiments of the invention. For purpose of illustration, the proximal end is in a collapsed configuration and extends proximally.

[0051] Figure 13 illustrates the axial lengthening thrombus capture device in the initial deployed configuration, according to some embodiments of the invention.

[0052] Figure 14 illustrates the thrombus capture element of the ALTC device that can include a stent or braided mesh, according to some embodiments of the invention.

[0053] Figures 15A-C illustrate an embodiment of the ALTC system, a distal portion of the ALTC System and a proximal portion of the ALTC System respectively.

[0054] Figure 16A illustrates another embodiment of the axial lengthening thrombus capture device in the delivery configuration, according to some embodiments of the invention.

[0055] Figure 16B illustrates the axial lengthening thrombus capture device in the initial deployed configuration wherein the outer sheath is retracted to expanded the axial lengthen thrombus capture device. The loop is coupled to the sleeve wherein it is coupled to the capture catheter shaft, according to some embodiments of the invention.

[0056] Figure 16C illustrates the axial lengthening thrombus capture device retracting proximally and lengthening, according to some embodiments of the invention.

[0057] Figure 16D illustrates the lengthening of the axial lengthening thrombus capture device and in some cases at full deployment, according to some embodiments of the invention.

[0058] Figures 17A-D illustrate different configurations of the ALTC device, according to some embodiments of the invention.

[0059] Figures 18A-B illustrate an embodiment of a distal portion of the axially-lengthening thrombus capture system with a cover element radially outward of, and partially or completely circumscribing the capture guide of the ALTC device, which can be in the shape of a ring as illustrated.

[0060] Figures 19A-C illustrates an embodiment of an axially-lengthening thrombus capture system, configured to allow the guidewire to distally exit the system prior to exiting the luer port at the proximal end of the system.

[0061] Figure 20A illustrates the expanding guide catheter system in the delivery configuration, according to some embodiments of the invention.

[0062] Figure 20B illustrates the expanding guide catheter system wherein the funnel tip is in deployed position and the obturator is positioned in the expanding guide catheter lumen, according to some embodiments of the invention.

[0063] Figure 20C illustrates the expanding guide catheter having a funnel tip, expanding distal segment and non-expanding proximal segment, according to some embodiments of the invention.

[0064] Figure 20D illustrates an obturator, according to some embodiments of the invention.

[0065] Figures 21A-C illustrate the expanding guide catheter system including the expanding guide catheter, outer cover and obturator, according to some embodiments of the invention.

[0066] Figure 21D illustrates an embodiment wherein a cover tip encapsulates the distal end of the outer cover of the expanding guide catheter system, according to some embodiments of the invention. Figures 21E-F illustrate an embodiment of a hemostasis valve for use within a hemostasis guide catheter system.

[0067] Figure 22 illustrates the outer sheath assembly of the capture device, according to some embodiments of the invention.

[0068] Figures 23 and 24 illustrate the distal end and proximal end of the outer sheath assembly respectively.

[0069] Figure 25 illustrates the capture catheter assembly, according to some embodiments of the invention.

[0070] Figure 26 illustrates the proximal end of the capture catheter, according to some embodiments of the invention.

[0071] Figure 27 illustrates an embodiment of a key cap feature to enable an anti-rotation of the hypotube pusher.

[0072] Figures 28 and 29 illustrates the suction catheter that can include a funnel tip, catheter shaft, and connector with seal, according to some embodiments of the invention.

[0073] Figure 30 illustrates the distal end of the suction catheter indicating the funnel tip and catheter shaft, according to some embodiments of the invention.

[0074] Figure 31 illustrates the proximal end of the suction catheter indicating the connector with seal and ports for use with filter chamber and access to flush catheter lumen, according to some embodiments of the invention.

[0075] Figures 32–41 illustrate different macerator designs and shapes, according to some embodiments of the invention.

[0076] Figure 42 illustrates a filter collection chamber that can include an inflow port to connect to a syringe, an outflow port to connect to the suction catheter, a plunger, a

filter to filter blood clot or debris and retain in the chamber and a chamber to collect blood clot or debris, according to some embodiments of the invention.

[0077] Figure 43 illustrates a blood clot lodging in the left side of pulmonary system, according to some embodiments of the invention.

[0078] Figure 44A and 44B illustrate blood clots residing in the left side pulmonary system and the capture device respectively, according to some embodiments of the invention.

[0079] Figure 45 illustrates the initial deployment configuration of the axial lengthening thrombus capture device positioned distal to the thrombus occluded area and a funnel tip positioned proximal to the thrombus occlusion, according to some embodiments of the invention.

[0080] Figure 46 illustrates the axial lengthening thrombus capture device lengthening proximally to capture the thrombus, according to some embodiments of the invention.

[0081] Figure 47 illustrates the axial lengthening thrombus capture device completely capturing the thrombus, and a funnel tip is inside the axial lengthening thrombus capture device.

[0082] Figure 48A illustrates the delivery configuration of the capture catheter device, according to some embodiments of the invention.

[0083] Figure 48B illustrates the initial deployment position of the axial lengthening thrombus capture device, according to some embodiments of the invention.

[0084] Figure 48C illustrates the lengthening of the axial lengthening thrombus capture device, according to some embodiments of the invention.

[0085] Figure 48D illustrate the final deployment of the axial lengthening thrombus capture device, according to some embodiments of the invention.

[0086] Figures 49A and 49B illustrate another embodiment of the axial lengthening thrombus capture device wherein the guidewire lumen and capture catheter is offset to the longitudinal axis of the axial lengthening thrombus capture device, according to some embodiments of the invention.

[0087] Figures 50A – 50G illustrate an embodiment of the retrieval of thrombus into the expanding guide catheter wherein the ALTC device lengthens distally and creates

additional space and the thrombus is redistributed and enable better retrieval into the expanding guide catheter. The funnel tip and expanding section of the expanding guide catheter also facilitate the ease of thrombus retrieval.

[0088] Figure 51 illustrates an embodiment of a system for removing blood clots.

[0089] Figure 52 illustrates the distal end of the capture device of the system of Figure 51 in the deployed configuration.

[0090] Figure 53 illustrates the distal end of the capture device of the system of Figure 51 in an initial deployed configuration.

[0091] Figure 54 illustrates the distal end of the capture device of the system of Figure 51 in a second configuration.

[0092] Figure 55 illustrates the distal end of the capture device of the system of Figure 51 in a third configuration.

[0093] Figure 56 illustrates an embodiment of the basket mesh element of the system of Figure 51. The basket mesh element can made of metallic materials such as Nitinol. The mesh element can be braided or laser cut.

[0094] Figure 57 illustrates an embodiment of a capture device element of the system of Figure 51.

[0095] Figures 58A- 58B illustrate embodiments of an expandable loop element of the system of Figure 51.

[0096] Figure 59 illustrates a view of a capture device opening for a system for neuro thrombus.

[0097] Figure 60 illustrates another view of a capture device opening of Figure 59.

[0098] Figure 61 illustrates an embodiment of a system.

[0099] Figure 62 illustrates a distal end of the capture device system of the system of Figure 61.

[0100] Figure 63 illustrates a proximal end of the system of Figure 61.

[0101] Figure 64 illustrates an anchor assembly of the system of Figure 61.

[0102] Figure 65 illustrates a side view of a distal end of the capture device and anchors of the system of Figure 61.

[0103] Figure 66 illustrates a top view of a distal end of the capture device and anchors of the system of Figure 61.

[0104] Figure 67 illustrates a front view of a distal end of the capture device of the system of Figure 61.

[0105] Figure 68A illustrates the capture device of the system of Figure 61 in an initial deployed configuration.

[0106] Figure 68B illustrates the capture device and first anchor release of the system of Figure 61 when the outer sheath retracts proximally.

[0107] Figure 68C illustrates the capture device, first anchor, and second anchor release of the system of Figure 61 when the outer sheath is retracted.

[0108] Figure 68D illustrates the capture device, first anchor, second anchor, and third anchor release of the system of Figure 61 when the outer sheath is retracted.

[0109] Figure 69A illustrates the capture device of the system of Figure 61 in an initial deployed configuration and the anchors are fully released.

[0110] Figure 69B illustrates the capture device of the system of Figure 61 lengthened proximally to encapsulate the first anchor.

[0111] Figure 69C illustrates the capture device of the system of Figure 61 lengthened proximally to encapsulate the anchors.

[0112] Figures 70A and 70B illustrate views of an embodiment of a pusher lock system.

[0113] Figures 71A-71D illustrate views of a pusher lock of the pusher lock system of Figure 70A.

[0114] Figure 72 illustrates a method of assembly an ALTC device to a capture guide.

[0115] Figure 73 illustrates an embodiment of an anchor.

[0116] Figure 74 illustrates an embodiment of an anchor.

[0117] Figure 75 illustrates a distal end of a capture device system including the anchor in a vessel of Figure 73.

[0118] Figure 76A illustrates the capture device of the system of Figure 75 in an initial deployed configuration and the anchor is fully expanded.

[0119] Figure 76B illustrates the capture device of the system of Figure 75 lengthened proximally to encapsulate a portion of the anchor.

[0120] Figure 76C illustrates the capture device of the system of Figure 75 lengthened proximally to encapsulate the anchor.

[0121] Figure 77A illustrates the capture device of the system of Figure 75 in an initial deployed configuration and the anchor is fully expanded.

[0122] Figure 77B illustrates the capture device of the system of Figure 75 lengthened proximally to encapsulate a portion of the anchor.

[0123] Figure 77C illustrates the capture device of the system of Figure 75 lengthened proximally to encapsulate the anchor.

[0124] Figure 78 illustrates a distal end of a capture device system including an embodiment of an anchor.

[0125] Figure 79 illustrates a distal end of a capture device system including an embodiment of an anchor.

[0126] Figure 80 illustrates the capture device system in a vessel of Figure 79.

[0127] Figure 81 illustrates a distal end of a capture device system including an embodiment of an anchor.

[0128] Figure 82 illustrates a distal end of a capture device system including an embodiment of an anchor.

[0129] Figure 83 illustrates the capture device system in a vessel of Figure 82.

[0130] Figure 84 illustrates a distal end of a capture device system including an embodiment of an anchor.

[0131] Figure 85 illustrates a distal end of a capture device system including an embodiment of an anchor.

[0132] Figure 86 illustrates the capture device system in a vessel of Figure 85.

[0133] Figure 87 illustrates a capture device system in a vessel.

[0134] Figures 88A-88R illustrate embodiments of an anchor.

[0135] Figure 89 illustrates an embodiment of a system designed for removing a blood clot.

[0136] Figure 90 illustrates a distal end of the system of Figure 89.

[0137] Figure 91 illustrates a distal end of a system including an embodiment of an anchor.

[0138] Figure 92 illustrates a distal end of a system including an embodiment of an anchor.

[0139] Figure 93 illustrates a distal end of a system including an embodiment of an anchor.

[0140] Figure 94 illustrates the capture device of the system of Figure 93 lengthened proximally to encapsulate the anchor.

[0141] Figure 95 illustrates a distal end of a system including an embodiment of an anchor.

[0142] Figures 96A-96B illustrate an embodiment of an expandable guide catheter.

DETAILED DESCRIPTION

[0143] The present invention provides, in some embodiments, systems and methods that can be delivered percutaneously in a body to retrieve and removal materials including blood clots, stones/calculi, and/or foreign materials in a body lumen, including a blood vessel, such as an arterial vessel or a venous vessel within the circulatory system. The present invention can, in some embodiments, also apply to nonvascular areas to treat, for example, gallstones, kidney stones, common bile duct stones, and the like.

[0144] Systems can be delivered percutaneously, via a cut-down approach, a thoracoscopic approach, or via other approaches, for example, using a catheter system 35, of which a perspective view of an embodiment is shown in Figure 1. Figure 1 also illustrates examples of various possible elements that can be included in a material capture system, according to some embodiments of the invention. As illustrated in Figure 1, included in some embodiments are any number of, such as one, two, or more of the following components: a first tubular member, such as an outer sheath 1, a second tubular member, such as a capture catheter 12, a third tubular member, such as a guidewire tube 6 an axial lengthening thrombus capture device 8, a suction catheter 2, and a filter collection chamber 5. The outer sheath 1 can, in some embodiments, be an elongate tubular member with a central lumen therethrough, and have a proximal end 1000 and a distal end 1001. The distal end 1001 of the

outer sheath 1 can be operably connected to a capture device (e.g., tubular mesh 8), which can be movably axially with respect to the outer sheath 1. In some embodiments, the outer sheath 1 has a relatively rigid proximal portion and a distal portion that is more flexible than the relatively rigid proximal portion, which can be advantageous to flexibly expand if necessary to accommodate the passage of large clots and/or other materials. The proximal end 1000 of the outer sheath 1 can connect to a proximal hub 1003 that may include any number of: the suction catheter 2, capture catheter 12, guidewire tube 6, and filter collection chamber 5. Non-limiting examples of other optional elements that can be included in the system (not shown in Figure 1) include a macerator tool (described elsewhere herein) and a discrete expanding guide catheter (described elsewhere herein). In some embodiments, the outer sheath 1 has a lumen configured to house the suction catheter 2, which in turn has a lumen configured to house the capture catheter 4, which in turn has a lumen configured to house the guidewire tube/guidewire lumen assembly 6 and the axial lengthening thrombus capture device (ALTC device) 8, which in turn has a lumen configured to house a guidewire (not shown) therethrough. An ALTC device as defined herein can include any structure, such as a net-like structure for example, configured to capture materials within a body location and axially lengthen and shorten through a working range, with or without radially shortening in width or diameter throughout that working range depending on the desired clinical result. In some embodiments, the outer sheath 1 has an inner diameter configured to house the capture catheter 12 coaxially therein, and the capture catheter 12, which in turn has a lumen configured to house the guidewire tube 6 and the body of the ALTC device 8. The ALTC device 8 can in some embodiments including a mesh net-like structure with a proximal-facing opening at one end that can be made of a shape memory metal or polymer, a non-shape memory metal such as stainless steel, or another non-shape memory fabric, embodiments of which are described in detail elsewhere herein. In some embodiments, conventional net-like structures such as used in IVC and other embolic filters can be utilized with systems and methods herein. In some embodiments, a thrombus capture device can be configured in some embodiments to axially lengthen throughout a working range, with or without radially shortening the device throughout the working range.

[0145] Figure 2 illustrates a close-up view of the proximal end 1000 of the thrombus capture systems of Figure 1. Illustrated is outer sheath 1 configured to, in some

embodiments, house suction catheter 2 therethrough. Also illustrated is the proximal end of the outer sheath 1 which can terminate in a connector 17 and hemostasis seal 190, of which another tube, such as the suction catheter 2 (and/or capture catheter 4) can be inserted coaxially into. The proximal end of the suction catheter 2 can also include a connector 3 having a seal, and a lumen of which the capture catheter 12 can be inserted into. The capture catheter 4 can also include a connector with a seal 18 at its proximal end. The guidewire tube 6 with a lumen to house a guidewire therethrough can be configured to fit coaxially within the capture catheter shaft 12. Also illustrated is an optional filter collection chamber 5 with a lumen fluidly connected to a lumen of the suction catheter 2. A proximal hub 17 is also illustrated, as well as a flush port 20. In some embodiments, suction is not required (and as such a suction catheter 2 is not included in the system), and the clot or other materials can be captured either mechanically, hydraulically and/or maceration via the ALTC device 8.

[0146] Figure 3 illustrates an axially-lengthening thrombus capture system 35 in the initial deployment configuration with the ALTC device 8 radially expanded, according to some embodiments of the invention. Also illustrated is nose tip 7 distal to the ALTC device 8. Relative axial movement of the outer tube 1 with respect to capture catheter 4 can allow for transformation of a first end (e.g., an expanded proximal end with a proximal-facing opening, or distal or laterally facing opening in other embodiments) of the ALTC device 8 from a radially compressed to a radially expanded configuration. In some embodiments, the proximal end opening of the ALTC device 8 includes a capture guide 11 that takes the form of, in some embodiments, a radially expandable shape memory partial or full ring-like annular structure that expands once free of the sidewall of the outer tube 1 along with a portion of the ALTC device mesh 8 attached to the capture guide 11. In the illustrated configuration, however, a significant portion of the surface area and/or the axial length of the mesh of the ALTC device remains in a compressed configuration within the lumen of the capture catheter 4, as the other end of the ALTC device mesh 8 is still operably attached, such as fixed to the outer diameter sidewall of the guidewire catheter 6.

[0147] Figure 4 illustrates a close up view of the distal end of the ALTC catheter system 35 in the delivery configuration including the distal end 1001 of the outer sheath 1 and nose tip 7, which can be atraumatic and tapered as shown, according to some embodiments of the invention.

[0148] The ALTC Device 8 can function to retrieve and capture materials such as thromboemboli. The capture catheter 4 is shown, along with the ALTC Device 8, capture catheter shaft body 12, pull wire 10, and thrombus capture guide 11.

[0149] As illustrated in Figures 5-9 for example, a thrombus capture guide 11 can attach to a portion, such as an open end of the ALTC Device 8 and one, two, or more capture pull wires 10 where the capture pull wires are positioned inside the side lumen of the suction catheter 2 or outside of the lumen in other embodiments, and extends proximally. The distal end of the capture pullwire 10 can be connected to the proximal end of the ALTC device 8 at the capture guide 11 as illustrated. The capture pullwire 10 can extend proximally through the length of the outer sheath 1, and the proximal end of the pullwire 10 can be pushed or pulled allow a user to control, such as adjust the axial length of the ALTC device 8, for example when axially elongating the ALTC device in a proximal direction. In some embodiments, the capture pullwire 10 and the capture guide 11 are the only elements attached to the proximal end of the ALTC device 8. In some embodiments, the capture pullwire 10 and the capture guide 11 can be made into a single component such as a Loop. In some other embodiments, the capture guide and the proximal end of the ALTC device is sutured in place using silk or polymeric filaments such as Ultra-High Molecular Weight polyethylene, Nylon, PET, PTFE. In some embodiments, the open end of the ALTC device is covered with a low durometer film or coating and is then folded over the capture guide 11 and suture to secure the assembly. In another embodiment, the open end of the ALTC device 8, capture guide 11 and sutured assembly is coated with a low durometer polymeric materials. Another method to secure the wire ends is to apply polymeric fabric either on the outer or inner surface of the tubular structure and secure via suturing in place with suture filaments. The fabric can be at least one piece initially wrapped either on the inner or outer surface of the tubular structure and then folded over to the opposite side to secure and protect with wire ends. The two sides of the fabric can secured to the tubular structure using suture filament. Other means of securing the fabric to the tubular structure such as thermal bonding, press, lamination, chemicals, mechanical securement, and lasers can be used in some embodiments. The closed end of the ALTC device can be attached to an outer surface of the guidewire tube 6, which in turn can be positioned within a lumen of the capture catheter shaft 12. As such, axial elongation of the ALTC device in a distal direction can be achieved by, for

example, movement of the guidewire tube 6 and pullwire 10 distally with respect to the capture catheter shaft 12. The axial elongation of the ALTC device in a proximal direction can be achieved by, for example, movement of the capture pullwire and capture catheter shaft proximally. The Thrombus Capture Guide 11 can be formed, for example, from metallic, shape memory, or other appropriate materials. In some embodiment, the thrombus capture guide 11 can include a loop configuration and be formed from nitinol shape memory wire of various geometries such as round, oval, elliptical, flat, and the like. The thrombus capture guide 11 can be formed of different shapes such as a circular loop, oval loop, z-shape, etc. In some embodiment, the loop 11 can be shaped set either into coils, multiple full circles, full circle or partial circles where the ends of the wire formed into two legs. The partial circle can be from, for example, 180 degrees to 359 degrees or 220 degrees to 359 degrees. The legs can be configured to be off-axis to the loop such that it can be right angle, acute or obtuse angle relative to the loop. It can be arcuate and form a partial or full ring as illustrated, and can circumscribe or otherwise form an outer diameter, and define the proximal-most end of the ALTC Device 8. The thrombus capture guide 11 can in some embodiments include a single loop or multiple loops positioned along the length of the ALTC Device 8 and not necessarily be present or have the entire guide 11 at the proximal-facing end opening end of the ALTC device 8. In some embodiments, the thrombus capture guide 11 does not include a loop. The ALTC Device tubular structure can be configured to be compressed and positioned within the Capture Catheter Shaft 12 lumen during introduction into the vascular system where the Capture Catheter Shaft 12 is configured to be positioned coaxially within and extend through the tubular structure and thrombus capture guide 11.

[0150] As illustrated in Figure 5, the Axial Lengthening Thrombus Capture Device (ALTC Device) 8 can be in some embodiments a generally tubular net-like mesh structure that is collapsible, expandable and configured to axially lengthen or shorten, such as within a working range, while maintaining or substantially maintaining its diameter within the working range to retrieve and capture foreign or otherwise unwanted materials within the body, including the vascular system such as blood clots, thrombus and/or foreign materials.

[0151] As shown, for example, in Figure 6, it can also be possible to lengthen the ALTC Device 8 in an appropriate direction, such as distally, by pushing the capture catheter 12 relative to the guidewire shaft 6, thereby allowing additional reserve radially compressed

length of the tubular mesh 8 to radially expand out of the confines of the lumen of the capture catheter 12 to axially lengthen the Thrombus Capture Device 8 and maintain its constant or substantially constant diameter through a working range. The other end of the ALTC device 8 at its radially compressed end can be fixed to the outer sidewall of the guidewire tube 6. A combination technique of, for example, manipulating the Capture Pull wire 10 attached to the Capture Catheter shaft 12 movement (Figure 6) can position the ALTC device at a desired location within the body lumen, and movement of the guidewire catheter 6 axially with respect to the capture catheter shaft 12 will also axially lengthen or shorten the ALTC Device 8 while maintaining its diameter through a working range. When the ALTC Device 8 is in the deployed (expanded) configuration, the ALTC Device 8 can also be stretched beyond the working range to an extended axial length to reduce its diameter.

[0152] Figure 7 illustrates the axial lengthening thrombus capture device 8 is fully deployed such that the attachment site 128 of the ALTC device 8 on the guidewire lumen 6 outer diameter is distal to the distal end of the capture catheter shaft 12 and the funnel tip 9 of the suction catheter is positioned within the ALTC, according to some embodiments of the invention.

[0153] Figures 8 and 9 illustrate different views of the initial deployment position of the ALTC Device 8 and the funnel tip of the optional suction catheter 2, according to some embodiments of the invention.

[0154] Figure 10 illustrates the partially deployed ALTC Device, according to some embodiments of the invention, where the ALTC device 8 is axially lengthened while maintaining its width normal to the axial direction.

[0155] Figure 11 illustrates an ALTC device deployed configuration where the funnel tip of the suction catheter is positioned inside the ALTC device, according to some embodiments of the invention.

[0156] As illustrated, a Guidewire Lumen Assembly 6 can include a nose tip 7, shaft, lumen, and a proximal connector and port where a guidewire can be inserted therethrough. The central lumen can have a distal opening in some embodiments. The guidewire tube 6 can be used to navigate and track over the guidewire in the vascular system. The guidewire tube 6 can extend coaxially within the lumen of the catheter shaft 12. A nose tip 7 can form or otherwise connect to the distal end of the guidewire tube 6 shaft to aid

tracking the system through the vascular system, and can be atraumatic in some embodiments. The guidewire tube 6 can be made of polymeric materials such as, and not limited to Polyimide, Nylon, Polyurethane, Pebax, Polyethylene, PET, PTFE or ePTFE. The guidewire tube 6 can have, in some embodiments, radiopaque markers along its length for use to indicate the location of the ALTC Device, initial deployment, partial deployment, final deployment, the percent of length deployed and/or any combination thereof.

[0157] Figure 12 illustrates the Axial Lengthening Thrombus Capture (ALTC) assembly 8 without the outer sheath, capture catheter 4, or guidewire catheter 6 present for clarity. As illustrated, end 800 with proximal-facing opening 802 of the ALTC device 8 is in the expanded (deployed) configuration and is fixed to the thrombus capture guide 11 and capture pullwire 10, according to some embodiments of the invention. For purpose of illustration, a reserve portion of unexpanded mesh 81 including end 804 is in a collapsed configuration and extends proximally toward attachment site 128.

[0158] In some embodiments, the tubular mesh structure 8 can axially lengthen or shorten without reducing or substantially reducing its diameter through a working length/axial range because the radially expanded portion of the tubular mesh structure is subject to none or minimal tension as it elongates or shortens axially through that axial working range. Not to be limited by theory, this can be accomplished at least in part because the tubular mesh structure can elongate axially throughout the working range by unrolling, everting, or otherwise expanding or transforming a radially compressed reserve segment of tubular mesh, such as unexpanded mesh 81. As such, an expanded “end” opposite the end of the radially expanded device with the capture guide and proximal end opening, such as dynamic fold point 88 of the radially expanded portion of the tubular mesh 8 may not be the absolute end of the tubular mesh fixed to a tubular shaft at zone 128, but rather an intermediate dynamic fold point 88 that is not fixed at that point to a tubular shaft, and as such not under any, or not substantially under any tension. The radially compressed reserve segment of tubular mesh 81 thus extends back in a different or the opposite direction (e.g., proximally in some cases) and ends at the terminal fixation point to the tubular shaft (e.g., at location 128). If it has not exceeded the working length of the expanded tubular shaft, the distance between the dynamic fold point 88 and the distal end of the entire catheter system

(e.g., the nose tip) can increase as the radially expanded portion of the tubular mesh 8 lengthens, and the radially compressed reserve segment is used up.

[0159] Once the compressed reserve segment 81 of tubular mesh 8 is nearly or completely expanded to, or almost to its actual end at 128 and the tubular mesh 8 is axially elongated beyond its working length range, further axial elongation can start to exert significantly increased tension on the fully axially expanded tubular mesh structure 8, causing it to assume a configuration in which it radially contracts as it further axially lengthens.

[0160] A tubular net-like structure with one open end as disclosed above and elsewhere herein can be highly advantageous as a relatively small axial segment of the tubular mesh can be radially expanded and be fully functional to capture emboli and/or other materials in tight working environments, such as in obstructed body lumens with limited space to maneuver distal to the treatment location of interest. If it is desired that a greater axial length of radially expanded tubular mesh is required, such as to capture a relatively long length thromboemboli, the compressed reserve segment of tubular mesh can be unrolled, everted or otherwise expanded or transformed to a specific axial length as desired. Having a compressed reserve segment that can be stored along the length of the catheter system in a compact manner can be very advantageous in providing a long effective capture length tubular mesh without requiring the entire capture system to have a long fixed length as would be required in conventional filters/nets, which can be fixed at both ends and thus are functional and fully radially expanded when the first end is spaced apart from the second end at a single specific axial distance.

[0161] As illustrated in Figure 12, some or most of the axial length of the ALTC device, e.g., the tubular mesh structure 8 remains radially compressed as part of the reserve segment between the outer diameter of the guidewire catheter 6 and the inner diameter of the shaft 12 of the capture catheter (distance between of which is length L12B), with the radially expanded portion of the tubular mesh structure 8 being defined along the axial length between proximal end 800 with proximal-facing opening 802 and the dynamic fold point 88 (distance between of which is length L12A), the sum of L12A and L12B amounting to the absolute length of the tubular mesh 8. In this initial configuration, the length L12B of the

radially compressed reserve segment 81 can be about, or at least about 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, or more of the absolute length of the tubular mesh 8.

[0162] Figure 13 illustrates the axial lengthening thrombus capture device 35 in the initial deployed configuration, according to some embodiments of the invention, with the radially expanded segment of the mesh 8 between end 800 and dynamic fold point 88 and the reserve compressed segment (not shown) extending axially proximally past end 800 to fixation point 128 on the outer surface of the guidewire shaft (not shown). Figure 14 illustrates the thrombus capture element 15 of the ALTC device that can include a stent, braided, woven, laser cut, or other mesh such as a net-like structure, according to some embodiments of the invention. The tubular mesh structure need not necessarily be porous, and can be covered by nonporous or other layers. The ALTC Device tubular mesh structure 8 can be made of any suitable polymeric materials such as but not limited to polyethylene terephthalate (PET), polyethylene (PE) polypropylene (PP), nylon, silk, UHMWPE, PTFE, Kevlar, cotton, and/or metallic materials including superelastic material, nitinol, stainless steel, cobalt-chromium-nickel-molybdenum-iron alloy, or cobalt-chrome alloy, Chronichrome, or Elgiloy. The tubular structure can be braided, extruded, woven, knitted, laser cut, dip, film cast from a polymeric and/or metallic flat sheet, metallic filaments, polymeric filament or fabric in some embodiments. The tubular structure can be film cast with laser cut holes in some embodiments. The tubular structure can also be braided from polymeric and/or metallic filaments or any combination thereof. In some cases, the tubular structure can be made of nitinol wire mesh having multiple wire strands. Furthermore, the tubular structure can include at least one wire strand made of high radiopaque material such as tantalum, platinum, gold or nitinol drawn filler tube with a platinum core to enable viewing the tubular structure under fluoroscopy. In some embodiments, the tubular structure can include one, two, or more radiopaque markers. Depending of the diameter of the ALTC device, the number of wire strands can range from, for example, 1 to 576 wire strands. The ALTC Device can have 2, 4, 144, 288, or another number of wire strands in some embodiments. In some embodiment, the ALTC device is configured to have one wire strand. The wire strand diameter can range from, for example, .0002" up to .015". In some embodiments, the wire strand diameter is about 0.001". The tubular structure can be impermeable in some sections, permeable in other sections and/or a combination thereof. The

tubular structure can be non-coated, or coated with one, two, or more anti-thrombogenic agents such as heparin to prevent clotting, or other therapeutic agents. The tubular structure can also be coated with a hydrophilic or hydrophobic agent. The tubular structure can have different pore sizes to assist with capturing small emboli or larger pore sizes to allow perfusion or blood flow. The tubular structure can have uniform pore sizes through the entire length or a combination of different pore sizes along its entire length. For example, when utilized as a cerebral protection filter, the ALTC device pore size can be sufficiently large to capture clinical relevant emboli size as small as, for example, about 200, 175, 150, 125, 100, 75, 50 microns or less while maintaining perfusion or blood flow. During retrieval, the ALTC device 8 can be repositioned to a particular section of the tubular structure that has smaller pore size and retrieve the blood clots/thrombus. In some embodiments, the ALTC device can deploy and enmesh within the blood clot to capture the blood clot in, for example, the neurovascular system. During retrieval, the ALTC device can lengthen sufficiently beyond the captured thrombus to create a protection filter distal to the captured thrombus. This can be clinically beneficial to prevent thrombus from dislodging during retrieval and thereby prevent secondary stroke. The ALTC Device tubular structure 8 proximal end can, in some embodiments, attach to the guidewire tube 6 outer surface, such as near attachment site 128. In some embodiments the proximal end of the ALTC Device tubular structure can be wrapped and sutured with polymeric filaments and encapsulated with low durometer polymeric material to fixably secure the wire ends to the shaft, such as the guidewire lumen assembly. Other means of attachment to secure the wire ends such as mechanically, thermally or chemically bonding the polymer to secure the wire ends can be used. In another embodiment, the ALTC Device proximal end can be fixed to the outer surface of the guidewire shaft using adhesive and is sandwiched between the outer surface of the guidewire shaft and cover tubes.

[0163] Figures 15A-C illustrate another embodiment of a clot capture system, a distal portion of the ALTC System and a proximal portion of the ALTC System respectively. Figure 15A schematically illustrates the catheter system 35, while Figure 15B shows the distal nose tip 7 operably connected to the distal end of the guidewire shaft 6 that includes a lumen for a guidewire to pass therethrough. One end of the ALTC device 8 can be fixably attached to the guidewire shaft 6 at one or more locations 128 and the other end 800 that

includes proximal or distal-facing opening 802 is attached to capture guide 11, such as in the form of a loop 11, and it is movable axially distally and proximally via capture guide 11. Loop can include, for example, one, two, or more linear segments that extend proximally from the loop 11 onto the capture catheter shaft 12, which are in turn secured proximally to the capture catheter shaft 12 by the sleeve 30. The sleeve 30 in some embodiments can be present instead of the pullwire(s) extending proximally all the way through the device. This can in some cases be advantageous ergonomically and allow for more streamlined control at the proximal end for a user. . The axially expanded length of the tubular mesh 8 is shown extending from end 800 to dynamic fold point 88, with the reserve length of compressed tubular mesh (not shown) running proximally along the outer sidewall of the guidewire shaft 6 to its end at fixation point 128. Figure 15C illustrates an embodiment of the proximal end of the system, including one or more flush ports 13, hub 55 of the outer sheath 1, hub 155 of the capture catheter 12, and hypotube pusher 14, and proximal-most hub 15 with a lumen configured to slide a guidewire therethrough. The hypotube pusher 14 can in some embodiments be coextensive with, such as welded or otherwise attached to the third tubular member (e.g., the guidewire tube 6), and when manipulated by an operator effect axial movement of the guidewire tube 6 in a proximal or distal direction. In some embodiments, there can be an integral guidewire tube 6 from the proximal most hub 15 to the distal nose tip 7. The third tubular member 14 can be configured to be placed within a lumen of a second tubular member (e.g., capture catheter shaft 12), such as at its proximal end at hub 155. The second tubular member can be configured to be placed within a lumen of a first tubular member (e.g., outer sheath 1), such as its proximal end at hub 55. In some embodiments, hub 55 and hub 155 can include complementary threads or other reversible locking features to allow for the outer sheath 1 to be reversibly coupled to the capture catheter 12 to allow for axial movement of the two tubular members in concert with each other. Uncoupling the hubs 55, 155 can allow for axial movement of the capture catheter 12 with respect to the outer sheath 1 and vice versa.

[0164] Still referring to Figures 15A-C, in some embodiments as illustrated, if a sleeve 30 is present, no separate pullwire extends from the capture guide 11 proximally to the proximal end of the system. In some such embodiments, axial movement of the capture catheter shaft 12 proximally with respect to the guidewire tube shaft 6 facilitates radial

expansion of at least a portion of the ALTC device 8 and positioning of the ALTC device 8 within a body lumen. Axial lengthening and/or shortening of the ALTC device 8 in some embodiments can be effectuated by movement of the guidewire tube 6 (of which the other end of the ALTC device not attached to the capture catheter 12 via sleeve 30 is attached to, such as at attachment site 128) with respect to the capture catheter 12 and/or movement of the capture catheter 12 with respect to the guidewire tube 6.

[0165] Figure 16A illustrates another embodiment of a distal portion of the axial lengthening thrombus capture device 35 in the delivery configuration, according to some embodiments of the invention.

[0166] Figure 16B illustrates the axial lengthening thrombus capture device in the initial deployed configuration wherein the outer sheath 1 is retracted, e.g., proximally to radially expand an end that includes the proximal-facing opening 802 of the axial lengthen thrombus capture device (e.g., tubular mesh 8) to dynamic fold point 88 which serves as the effective expanded distal end of the tubular mesh 8. The capture guide 11 and associated terminal wires 10 are operably coupled to the sleeve 30, and the sleeve 30 is coupled to the outer wall of the capture catheter shaft 12, according to some embodiments of the invention. The compressed reserve length segment (not shown) of the tubular mesh, such as about or at least about 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90% or more of the absolute axial length of the ALTC device 8 (e.g., tubular mesh) taking into account folds remains inverted, rolled up, and/or otherwise radially compressed and circumscribed by the inner sidewall of the capture catheter shaft 12, up to the point where the other end of the ALTC device 8 is attached on an outer diameter of the guidewire tube 6 at attachment site 128. As illustrated, the dynamic fold point 88 varies along the length of the tubular mesh 8 depending on the length of the compressed reserve length segment that is expanded. The dynamic fold point 88 “floats” and is not directly attached to the guidewire shaft 6 nor the capture catheter shaft 12, and as such moves axially proximally when the expanded segment of the tubular mesh 8 axially lengthens.

[0167] As such, when the guidewire shaft 6 with distal nose tip 7 is maintained in a constant position, axial elongation of the expanded tubular mesh 8 results in an increase in the axial distance D between the distal nose tip 7 and the dynamic fold point 88, so distance D3 is greater than D2, which is in turn greater than D1. Furthermore, as shown in Figure 16B

the first end 800 of the tubular mesh is distal to the unexpanded end of the tubular mesh (at location 128) fixed to the outer sidewall of the guidewire tube 6, but moves closer proximally in Figure 16C and becomes proximal to the unexpanded end of the tubular mesh at Figure 16D while the dynamic fold point 88 moves proximally but is still slightly distal to the unexpanded distal end of the tubular mesh 8 in Figure 16D, where the expanded axial length is even greater, or in some cases at its maximum working length. As noted, the diameter/width of the expanded tubular mesh remains constant or relatively constant between Figures 16A-D. Upon exhaustion of the compressed reserve segment which has transformed into expanded tubular mesh, continued axial expansion can result in increased tensile forces on the tubular mesh, resulting in a configuration in which radial contraction begins to occur.

[0168] Figures 17A-D illustrate different configurations of the ALTC device, according to some embodiments of the invention. During delivery, the capture guide 11 (e.g., ring-shaped in some embodiments) connected to the expanded end 800 of the tubular mesh 8 can be configured to collapse within the outer sheath 1 lumen during introduction into the vascular system and is configured to radially expand first when the outer sheath 1 retracts proximally while the length of reserve tubular mesh structure 81 of the ALTC device 8 extending proximally from the dynamic fold point 88 to fixation point 128 on the guidewire shaft 6 remains compressed in the capture catheter shaft 12 lumen. The dynamic fold point 88 serves as the effective expanded distal end of the tubular mesh 8. Upon further retracting the thrombus capture guide 11 via pulling the Capture Pull Wire 10 (or sleeve 30 as shown) and capture catheter shaft 12 proximally, the portion of the ALTC Device 8 tubular structure that is compressed within the Capture Catheter Shaft 12 lumen expands and can transform via, e.g., roll out proximally, inversion, and/or eversion, and axially lengthening the ALTC Device 8. Advance of the Capture Catheter Shaft 12 distally can collapse at least a portion of the ALTC Device 8 tubular structure into the Capture Catheter Shaft 12 lumen, as previously shown in Figures 7 - 9. The ALTC Device's ability to expand, roll out, axially lengthen and maintaining a substantially constant diameter through a working range creates a cavity (or pocket) within the sidewall of the radially expanded segment of the ALTC Device 8 to retrieve and capture foreign materials such as, for example, blood clots/thrombus. In another embodiment a sleeve 30 (Figures 16A-D and 17A-D) can be used to couple, such as permanently, the Capture Pull Wire 10 to a portion of the Capture Catheter shaft 12 to enable

both components to operate together. Coupling the Capture Pull Wire 10 and the Capture Catheter shaft 12 can allow the user to manage the capture device more efficiently and easily. In another embodiment, the capture guide 11 takes the form of a loop and can attach to the Sleeve 30, which is coupled to the Capture Catheter Shaft 12.

[0169] Figures 18A-B illustrate an embodiment of a distal portion of the axially-lengthening thrombus capture system with a cover element 80 radially outward of, and partially or completely circumscribing the capture catheter shaft 12 or loop 11 of the ALTC device, which can be in the shape of a ring as illustrated. In some embodiments, the cover element 80 can function to protect one or more of the capture guide, ALTC device, and the luminal wall of the lumen being treated. The ring 80 can also be configured to provide a seal against the luminal wall, e.g., of the vessel, to prevent leakage or migration or embolization of unwanted material around the tubular mesh 8. In some embodiments, the cover 80 can also include a skirt portion. The cover 80 can be axially and/or radially expandable, such as an inflatable balloon, a soft polymer, a gel, a foam, a textile fabric, shape memory, and/or include other materials. If the cover 80 is expandable, it can be configured to reversibly contract to allow for fluid flow around the cover 80 once the procedure is completed. Also as illustrated is sleeve 30 serving to attach the capture guide 11 connected to one or more wires 10. Sleeve 30 can include one or more apertures 307 that serve as relatively radiolucent markers, and/or the sleeve 30 could be made of a radiopaque material in some embodiments. Also as illustrated, the capture catheter 12 as well as guidewire tube 6 can extend through the tubular mesh 6 from first end 800 through dynamic fold point 88. The reserve segment of compressed tubular mesh is not shown for clarity.

[0170] Figures 19A-C illustrate an embodiment of an axially-lengthening thrombus capture system, configured to allow the guidewire 350 to distally exit the system prior to exiting the luer/proximal-most port 15 at the proximal end of the system. The guidewire's proximal end can exit the system through an aperture or slot 351 in the sidewall once it passes the reversibly couplable hemostasis seals 55, 155 of the outer sheath 1 assembly and the capture catheter 12 respectively. In some embodiments, the guidewire 350 is configured to exit sideways, that is laterally. In some embodiments, a keyed cap 36 is positioned distal to the hemostasis seals 55, 155, which is in turn proximal to a shaft 14, which can serve as a hypotube pusher connected to or coextensive with the guidewire tube

and be made of metal in some embodiments. The shaft 34 can include a sidewall groove 351 fully or partially axially from the port 15 to the hub 155 and/or one, two, or more discrete slots as illustrated.

[0171] Such embodiments can be advantageous, for example, to utilize a shorter length guidewire needed when the delivery system overall length increases. In some embodiments, when the ALTC capture device increase in length, the hypotube is also lengthened to accommodate thus increase the distance for user to manage the guidewire and system. The side guidewire feature can minimize the distance resulting in better handling, and the proximal end of the guidewire 350 need not necessarily extend past the proximal end of the entire system, such as at port 15. As such, the guidewire as part of the system can advantageously have a total length in some embodiments that is the same as, or even less than the axial length of the entire material capture system from proximal port 15 to distal nose tip 7, which may otherwise not be possible.

[0172] The guidewire 350 can be located near the hemostasis seals 55, 155 area during the procedure, and as such the entire procedure/operation can be done with the user not needing to look down to see where the components are located. As such, the user can hold the hemostasis seals 55, 155 housing in one hand while at the same time manipulating the guidewire 350 and hypotube pusher 14 with the other hand in the general area without substantially moving away from the area. The users can hold and maneuver the hypotube pusher 14 or hold and maneuver the guidewire 350 or hold both the hypotube pusher 14 and guidewire 350 at the same time. In some embodiments, the inner diameter of the shaft 14 with groove can be generally larger than the guidewire 350 that allows the guidewire 350 to exit laterally. The keyed cap 36 with a boss profile can mate to the groove of the metal shaft 14 to prevent the metal shaft 14 from rotating and still allow the shaft 34 to slide back and forth axially.

[0173] In some embodiments, an Expanding Guide Catheter 50 (shown in Figures 20-21 for example) is a discrete catheter that can be utilized together with the clot capture system, and functions to assist in retrieving the ALTC Device 8 (and associated catheter system 35) and capture blood clots and other undesired materials. In some embodiments, the Expanding Guide Catheter 50 can include a first tubular member, such as an outer sheath 49 with a proximal end, a distal end, a lumen extending from the proximal end and the distal

end, and a port on the proximal end, which can be coaxial as illustrated or offset from the longitudinal axis of the outer sheath 49. A second tubular member, such as inner catheter 54 can have a proximal end, a distal end, and a lumen extending from the proximal end to the distal end and can be configured to be placed within the lumen of the outer sheath 49. The inner catheter 54 can also have a proximal port, a removable obturator 51 positionable in the inner catheter lumen, distal expandable funnel tip 52, expandable shaft section 53 proximal to the funnel tip 52, an inner shaft 54, and connectors with seal 55. The obturator 51 can be used to aid in inserting and navigating the Expanding Guide Catheter 50 in the vascular system. The obturator 51 can be made of polymeric materials such as Polyethylene, Nylon, Pebax, Polyurethane, PET or PTFE for example. The obturator 51 can have a tapered distal end in some embodiments to aid in introducing the Expanding Guide Catheter 50 in the vasculature or other body lumen. Alternatively, other embodiments of the obturator 51 includes an expandable member such as a balloon operably connected to the distal end. Expansion of the expandable member, such as inflating the balloon can create a smooth tip transition. The balloon can be made of polymeric materials such Nylon, Polyurethane, PET, etc. Inflating the balloon can also secure the balloon obturator to the guide catheter such that when applying axial load proximally to the obturator shaft will articulate the tip of guiding catheter. The funnel tip 52, illustrated for example in Figures 20B-C, can include a distal funnel-like segment, and be adjacent to an expandable proximal segment 53 wherein it is connected to a more proximal portion of the inner shaft 54. The funnel tip 52 can be, in some embodiments, made of either polymeric and/or metallic materials. It can be either tubular in shape, woven or braided. The braid configurations can be, in some cases, 1x1 or 1x2 or 2x1 or 2x2 or any combination thereof. The picks per inch (PPI) can range from, in some embodiments, 5 to 60. The number can be, in some embodiments, from one wire filament up to 288 wire filaments. The wire shape can be, e.g., round, flat, oval, rectangular or square. The wire diameter can be, e.g., from .0005" up to .015". The flat wire thickness can be, e.g., from .0005" up to .010" and the wire width can be, e.g., from .001" up to .030". The funnel tip 52 distal segment can have various shapes or configurations to allow better retrieving the blood clots or thrombus. In some embodiments, the funnel tip 52 distal segment has a large open end where it contacts the vessel wall when expanded and transitions to smaller opening proximal segment 53. The distal segment open end can range from, in some embodiments,

about 5 mm to about 80 mm in diameter. The funnel tip distal segment 52 also has, in some embodiments, openings or holes (perforations) along the side to allow blood flow. The funnel distal segment 52 can have either one layer of braid or multiple layers. In some embodiments, the funnel distal segment has two layers. In some one layer embodiments, the most distal open end of the funnel does not have the wire end terminate or exposed such that the wire ends are located at the proximal end of the funnel assembly. The funnel tip proximal segment 53 can be configured such that it is capable of expanding and receive the ALTC device and captured blood clots or thrombus. The proximal segment 53 can be configured to expand to receive object that is larger than its inner diameter and recovery after passage. The proximal segment 53 can include a PTFE inner layer and compliance and/or low durometer polymeric materials such as Polyurethane, Silicone, Tecoflex, Pebax 25D and/or 35D or braid and/or non-braided such as Pebax/Propel/BaSO₄ outer layer. The proximal segment 53 can also include other lower durometer polymeric materials. The composite funnel tip and proximal segment can be laminated via dipped coat, spray or reflow process or any combination thereof. The braid materials can be either metallic and/or polymer and/or combination thereof. The braid configurations can be, e.g., 1x1 or 1x2 or 2x1 or 2x2 or any combination thereof. The picks per inch (PPI) can range from, for example, 5 to 60. The number can be, e.g., from one wire filament up to 288 wire filaments. The wire cross-sectional shape can be, for example, round, flat, oval, rectangular or square. The wire diameter can be, e.g., from .0005" up to .015". The flat wire thickness can be, e.g., from .0005" up to .010" and the wire width can be, e.g., from .001" up to .030". In some embodiments, an advantageous feature is the ability to expand and contract without buckling under compression. The inner diameter can range from, e.g., 2F to 30F. In some embodiments, the inner diameter can range from, e.g., 6F to 18F. The expanded length section can be up to the entire catheter length. In some embodiments, the length is about 20cm. The funnel distal 52 and proximal segment 53 can also be made as one component wherein the braid configuration is continuous. Coupled to or continuous with the funnel tip proximal segment 53, the inner shaft 54 can be made from materials such as and not limited to Nylon, Polyurethane, Pebax, Polyethylene, PET, PTFE, or ePTFE. The inner shaft 54 can be braided or non-braided. The outer shaft 49 can function to slide over and collapses the funnel tip and provide support during introduction into the vasculature. The outer shaft 49

retracts to deploy the funnel tip. The outer shaft 49 can be made of polymeric materials such as Nylon, Polyurethane, Pebax, Polyethylene, PET, PTFE, ePTFE, FEP or combination thereof. The outer shaft 49 diameter can range from, e.g., 4F to 34F. The outer shaft 49 inner diameter can range from, for example, 3F to 32F. In some embodiments, the inner diameter has substantially the same throughout the lumen shaft. In some embodiments, the inner diameter at the distal end is larger than the proximal end inner diameter. The change in inner diameter can be in one location, two or more locations. The outer diameter is substantially the same throughout the entire length of the outer sheath shaft. In some embodiments, the outer shaft 49 is about 22F or smaller in diameter. The outer shaft 49 can include a radiopaque marker at the distal end or radiopaque filler along its shaft length for visibility under fluoroscopy. In some embodiment, the outer shaft can be deflectable (via, for example, one, two, or more pullwires on the distal end) at various locations and multiple deflectable directions along the shaft length to accommodate various tortuous paths such as entry into the right atrium, right ventricle, main pulmonary artery, and left and right pulmonary artery for pulmonary embolism applications.

[0174] Still referring to Figures 20A-20D, in some embodiments the expanding guide catheter 50 can be utilized to retrieve blood clots or thrombus. The expanding guide catheter 50 and obturator 51 can be introduced over a wire into the vasculature and advanced near the treatment area. The obturator 51 is removed. The outer member 49 of the expanding guide catheter is retracted proximally to expand the funnel tip 52 and the expandable section 53 of the guide catheter 50. In some embodiments, the guide outer shaft 49 is inserted into the vessel together with the obturator 51 and the obturator 51 is removed once the outer shaft 49 is in a desired position. The inner guide member can include the funnel tip 52, proximal segment 53 and the inner shaft 54 is then inserted into the outer shaft 49 up to the distal tip of the outer shaft 49. The outer shaft 49 can then be retracted (or the inner shaft 54 advanced) to expand and deploy the distal funnel 52 and the proximal segment 53. The capture catheter system 35 is inserted over the wire and through the lumen of the expanding inner guide member 54. Once the ALTC Device 8 is deployed and captures the blood clots, the ALTC Device 8 is retracted along with the captured blood clots into the funnel tip 52 and expanding guide inner member 53, (shown later in Figure 50). When high resistance is encountered at the funnel tip due to the large blood clot position at the tip, the guidewire lumen can

advances distally to lengthen the ALTC Device. Lengthening the ALTC device can create additional space within the ALTC device such that the blood clot volume is redistributed thereby reduces the large blood clots pooled at the tip of expanding guide catheter. The expanding guide catheter distal section also allows larger clots to be captured due to its expandability increasing the lumen size. Continuing to retract the ALTC device will retrieve additional captured blood clots inside the expanding guide catheter. Repeated lengthening of the ALTC during the procedure will continue to redistribute the clot and retrieve inside the Expanding Guide Catheter, advantageously allowing for improved thrombus processing and redistribution. In some embodiments, a kit can include a capture catheter system 35 as described herein and configured to be reversibly placed within, and move axially with respect to an inner lumen of a discrete expanding guide catheter system 50 as described herein.

[0175] Figure 21D illustrates an embodiment wherein a cover tip 710 encapsulates the distal end of the outer cover of the expanding guide catheter system, according to some embodiments of the invention. In some embodiments, a guide catheter is part of a hemostasis guide system that can include one or more obturators, an inner shaft member, an outer shaft member, and a hemostasis valve disposed within a housing of the system. The inner shaft member can include a non-expandable braided proximal segment, a distal expandable segment and a braided funnel distal end which can be as described elsewhere herein. The inner shaft member can be positioned within the lumen of the outer shaft member. The outer shaft member can have, for example, a braided polymeric configuration with a flexible kink resistance distal segment. The inner shaft and outer shaft member can be attached to the housing body. The housing body can be, for example, at a proximal end of the guide catheter system. The hemostasis valve can be disposed within the housing body. The hemostasis valve can be in some embodiments a flexible disc-like valve. The hemostasis valve can be configured to provide hemostasis and prevent leakage, such as with nothing inside. In some embodiments, the system can be configured for use with a 0.035" guidewire, 5Fr catheter, and include sizes between about 12F and about 17F, such as about 12F, 16F, or 17F. The hemostasis valve can include two surfaces, an upper surface and a lower surface. The upper surface and lower surface can be opposing surfaces in some embodiments. The upper surface can include a slit extending partially across the upper surface and a depth into the valve without protruding all the way through the thickness of the

lower surface. The lower surface can include a slit extending across the lower surface and a depth into the valve without protruding all the way through the thickness of the upper surface. In some embodiments, the valve has a diameter of between about 0.50" and about 1.00", such as about 0.5", 0.6", 0.7", 0.8", 0.9", or 1.0". In some embodiments, the valve has a thickness of between about 0.050" and about .0100", such as about 0.075". In some embodiments, the slits can have a depth/thickness of between about 0.020" and about 0.060", such as about 0.040". The midpoint of a slit can be in some cases at or proximate the center of the surface of the disc. The upper slit and the lower slits can intersect at, for example, a point location within the valve. The slits can extend beyond the intersection point by a desired distance, such as between about .001" and about .010" or approximately .005" beyond the intersection point. In some embodiments, the arrangement of the slits along the valve permits insertion and removal of shafts therethrough while preventing leakage of blood or air back across the valve. The upper and lower slits can have long axes that intersect at an angle. The angle could be in some embodiments between about 45 degrees and about 135 degrees, or about 45, 60, 75, or 90 degrees in some cases.

[0176] Figures 22-24 illustrate the outer sheath assembly 1 of the capture device, according to some embodiments of the invention. The outer sheath 1 can function to contain, protect, and deliver the Axial Lengthening Thrombus Capture Device (tubular mesh 8 (not shown) to the desired anatomical location, such as in a radially compressed configuration. As shown in Figure 22, the Outer Sheath 1 can include a soft atraumatic distal tip, a shaft body that can be tubular in some embodiments, an interior channel/lumen configured to house and reversibly couple at its proximal end a second tubular member, such as a capture catheter as described elsewhere herein, and a proximal connector with a seal 55 and flush tube/port 13. The Outer Sheath 1 can be made from suitable medical grade materials, including but not limited to Nylon, Polyurethane, Pebax, Polyethylene, PET, PTFE, ePTFE, PEEK, PEBAX/Propell and polypropylene. The polymeric materials can include radiopaque materials such as, for example, barium sulfate, bismuth subcarbonate or bismuth trioxide to enable viewing under fluoroscopy. The radiopaque materials can form one, two, or more discrete marker elements in some embodiments, such as at the distal tip, and/or spaced apart at regular or irregular intervals along the length of the outer sheath 1. The outer diameter of the outer sheath 1 can range from, for example, 3F to 30F. The inner diameter of the outer

sheath 1 can range from, for example, 2F to 28F. In some embodiments, the inner diameter is substantially constant throughout the interior channel, e.g., the lumen shaft. In some embodiments, the inner diameter at the distal end is about or at least about 10%, 20%, 30%, 40%, 50%, or more than the proximal end. The change in inner diameter can be, for example, stepwise or gradual in one location or two or more locations. The outer diameter can be substantially the same the entire length of the catheter, in some embodiments. The outer sheath 1 working length can be, in some cases, from about 10cm to about 150cm. In some embodiment, the Outer Sheath 1 working length is about 135cm in some embodiments. The Outer Sheath 1 shaft can be braided or non-braided. In some embodiments, the Outer Sheath 1 shaft can be deflectable (via, for example, one, two, or more pullwires on the distal end) at various locations and multiple deflectable directions along the shaft length to accommodate various tortuous paths such as entry into a left or right heart atrium, heart ventricle, main pulmonary artery, and left and right pulmonary artery for pulmonary embolism applications, or a vein such as the great saphenous vein, superficial femoral, common femoral, SVC, IVC, or other upper or lower extremity, visceral, or other superficial or deep veins for deep venous thrombosis removal applications. The distal end of the shaft of the outer sheath 1 can be configured to deflect up to 360 degrees in some cases. Additionally, the distal tip of the Outer Sheath 1 can be configured to deflect or bias toward or away from the vessel wall. The distal tip of the outer sheath 1 can include one, two, or more radiopaque markers to indicate tip location. Alternatively, the distal tip can include radiopaque materials such as, for example, Barium Sulfate, Bismuth Subcarbonate or Bismuth Trioxide. Figure 23 and 24 illustrate the distal end and proximal end of the outer sheath assembly respectively. As shown in Figure 26, the proximal end of the outer sheath 1 connects to the outer sheath connector 55 with seal and coupler to a capture catheter connector, and flush port 13.

[0177] Figure 25 illustrates the capture catheter assembly 12, according to some embodiments of the invention, showing catheter shaft 12 and outer sheath 1. Figure 26 illustrates the proximal end of the capture catheter, according to some embodiments of the invention, showing a connector with seal 155 operably connected to a flush port 13.

[0178] Figure 27 illustrates an embodiment of a key cap 36 feature to prevent or inhibit rotation of the hypotube pusher 14. As illustrated, the key cap 36 can be a tubular member with a lumen to fit the hypotube pusher 14 therethrough. The lumen is non-circular

in some embodiments, and/or have a non-circular zone, or otherwise configured to prevent or limit rotation. In some embodiments, the lumen includes teeth or other projections into the lumen as shown to prevent undesired rotation of the hypotube pusher. In some embodiments, the lumen or a portion thereof has a square, rectangular, triangular, oval, pentagonal, hexagonal, or other non-circular geometry, and configured to limit rotation.

[0179] In some embodiments, as illustrated in Figures 28-29 for example, an optional suction catheter 2 can function to aspirate thrombus within the ALTC Device 8. The suction catheter 2 can include in some embodiments a distal funnel tip 9, elongate shaft body 16, and proximal connector with seal 3. Figure 30 illustrates a close-up view of the funnel tip 9 which can be attached at the suction catheter shaft 16 distal end to aid in retrieving the thrombus and allow efficient suction. The funnel tip 9 can be made of, for example either polymeric and/or metallic materials. It can be tubular in shape, woven or braided, in some embodiments. Funnel tip 9 can be in various configurations to allow better retrieval and suction. In some embodiments, the funnel tip 9 has a funnel shape with a first, larger distal diameter, a transition section, and a second, smaller proximal diameter as illustrated. The suction catheter shaft 16 creates a pathway for the aspirated thrombus to travel proximally and exit the body and in some embodiments into the optional filter collection chamber. The shaft can be of various diameters, lengths and/or geometries to aid in the removal of materials such as blood clots. The suction catheter shaft can be made from suitable materials such as and not limited to Nylon, Polyurethane, Pebax, Polyethylene, PET, PTFE, ePTFE, PEEK, and polypropylene. In some embodiments, the suction catheter Shaft distal end is expandable so to accommodate large amount of blood clots. The suction catheter 2 can attach to the proximal end of filter collection chamber 5 to enable thrombus aspiration (or removal). In some embodiments, the suction catheter shaft 16 is deflectable at one, two, or more locations along the shaft length to accommodate various tortuous paths such as entry into the right atrium, right ventricle, main pulmonary artery, and left and right pulmonary artery. A proximal flush port 13 is also illustrated.

[0180] In some embodiments, a mechanical thrombectomy tool such as macerator 19 shown in Figures 32-41 for example, can function to disrupt and break up the thrombus within the ALTC Device 8. The macerator 20 can include a disruptor 19, shaft 22 and proximal connector with seal 21. Adjustable Touhy knob 23 distally is also shown just

proximal to disruptor 19. The disruptor 19 can be attached to the distal end of the shaft 22. The macerator 20 can have various end effector tip configurations as illustrated in Figures 35-41 depending on the desired clinical result to break up the thrombus within the ALTC Device 8, including a bulbous shape (Figure 36), proximal and distal bulbs with a narrow waist (Figure 37), a plurality of proximal and distal bulbs with a narrow waist each offset by an angle, such as about 90 degrees (Figure 38), a flower petal design with petals radiating radially outwardly from a central hub (Figure 39), a hemi-petal design (Figure 40), or a substantially linear design orthogonal from the longitudinal axis of the shaft 22 (Figure 41). The disruptor 19 collapses during insertion through the suction catheter 2 system and expands once exiting the catheter. The disruptor 19 can be made of, for example, metallic materials such as stainless steel, Nitinol, cobalt chrome, etc. The macerator can be activated either by manual rotation, manipulation and/or a motorized handle.

[0181] To macerate the thrombus, the macerator 19 is inserted through the suction catheter 2 and position within the ALTC Device 8. A manual technique applies to the luer connector 21 of the macerator 19 by rotating the luer connector 21 causing the disruptor 20 to rotate thereby breaking up the thrombus. Alternatively, the macerator 19 can be used with a motorized handle (not shown). Traversing the disruptor 20 axially through the entire length of the ALTC device 8 can aid in breaking up the thrombus.

[0182] The filter collection chamber 5 (Figure 42) can function to suction and collect the blood clots. The filter collection chamber 5 can include, for example, a collection chamber 325, filter 324, plunger 323, inflow port 327 and outflow port 326. The filter collection chamber 5 can have an outflow port 326 attaching to the suction catheter 2 connector and an inflow port 327 where a syringe or a similar device can attach for aspiration. The collection chamber 325 has a filter system 324 residing inside the chamber 325 to allow filtering the blood and thrombus. The chamber 325 also has a plunger 323 for use in injecting fluid such as saline to fill the chamber 325 and push filtered blood back into the vasculature. The plunger 323 can serve as a seal on one side of the chamber.

[0183] To aspirate the thrombus from the system, the suction catheter 2 is attached to the filter collection chamber 5 (Figure 42). A large syringe attaches to the proximal end of the filter collection chamber 5. Applying suction using the syringe causes the thrombus and blood clots to migrate into the filter collection chamber 5. Once all the

thrombus is contained within the chamber 5, close stopcock, detach the syringe and fill with saline and reattach the syringe to the filter collection chamber 5. Alternatively, an extension tube and external saline filled syringe can be used to fill saline into the suction syringe. Injecting via the syringe will push saline into the chamber 325 causing the plunger 323 to push the blood back into the vasculature. The chamber 325 will return the blood and leave the thrombus inside the chamber 325. Alternatively, the filter collection chamber 5 can be detached without returning filtered blood to the system. Once the thrombus is removed, retract the suction catheter 2 inside the outer sheath 1. Retract the ALTC Device 8 into the outer sheath 1 and remove the entire system from the body.

[0184] Catheter systems as described herein can be utilized for a variety of indications depending on the desired clinical result. In some embodiments, the use is not limited to venous systems and can apply to other arterial, venous, or nonvascular areas such as neurovascular, peripheral vascular, cardiovascular, temporary embolic protection device for a cardiovascular procedure such as valve replacement, carotid protection, pulmonary protection during deep vein thrombectomy or embolectomy), or retrieval of an implant, medical device, or other material.

[0185] Figure 43 illustrates a blood clot lodging in the left side of the pulmonary system. Shown is the right pulmonary artery 251, left pulmonary artery 252, inferior vena cava 253, left iliac artery 254, right iliac artery 255, a pulmonary embolus 256 in the left pulmonary artery 252 distally, and the superior vena cava 257.

[0186] Figure 44A and 44B illustrate blood clots residing in the left side pulmonary system and the capture device respectively, according to some embodiments of the invention. In addition to the anatomical features illustrated in Figure 43, also shown is the guide catheter 264, right ventricle 266, and right atrium 267. As shown in Figure 44B, capture devices as described and illustrated herein can advantageously be utilized when there is very limited distal space, as the device is functional throughout a wide working axial range as discussed elsewhere herein.

[0187] Figures 45-47 illustrate capture of a thrombus within a vessel, according to some embodiments. Figure 45 illustrates the initial deployed configuration of the axial lengthening thrombus capture device (e.g., tubular mesh) 8 with end 800, dynamic fold point 88, and reserve radially compressed segment (not shown) terminating proximally at point

128 where the radially compressed segment is fixably attached to the outer sidewall of the guidewire lumen 6 is shown. The expanded segment of the tubular mesh 8 is positioned distal to the thrombus 73 occluded area and the expanding guide catheter 50 including distal funnel tip 52 with proximal expandable section, inner catheter 54 and outer catheter 49, or in some embodiments suction catheter funnel tip positioned proximal to the thrombus occlusion 73, according to some embodiments of the invention. In some embodiments, expanding guide catheter 50 as described elsewhere herein or a suction catheter can be utilized depending on if suction is desired. Also shown proximally is inner sheath 54 and outer sheath 49 of expanding guide catheter 50. Actuation of capture pullwire 10 alone or with capture catheter 12 such as axially in an appropriate direction (or capture catheter coupled to the outer sheath (not shown) in embodiments with a sleeve as previously described) can result in axial lengthening or shortening of the ALTC device 8 depending on the desired clinical result. Figure 46 illustrates the axial lengthening tubular mesh 8 expandable segment lengthening proximally to capture the thrombus, according to some embodiments of the invention, with the associated radially compressed segment shortening reciprocally. Figure 47 illustrates the axial lengthening thrombus capture device completely capturing the thrombus, and the expanding guide catheter funnel tip or alternatively the suction catheter funnel tip is inside the axial lengthening thrombus capture device. Subsequent suction via the suction catheter 2 in embodiments where suction is utilized can be performed to remove the blood clot or thrombus. The ALTC Device can lengthen to have a maximal length that covers the entire length of catheter system from, e.g., about 0.5cm to about 125cm. In some embodiments, the ALTC device may lengthen to about or at least about 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 20, or more centimeters. Depending on vessel diameter, the outer diameter of the ALTC device can range from, in some embodiments, about 1 millimeter up to about 80 millimeters. For example, large vessels such as the inferior vena cava, superior vena cava, descending, and ascending aorta, the diameter can range up to about 60, 70, 80, 90, 100 millimeters or more. Small vessels in the neurovascular system can be, for example, as small as about or less than about 5, 4.5, 4, 4.5, 3, 2.5, 2, 1.5, 1, 0.5, or less millimeters in diameter. The diameter of the ALTC device can achieve the similar effect of reducing or stretching the ALTC device diameter. In some embodiments, suction is not utilized or required, and the ALTC device envelops the clot, which can be mechanically pulled back into the capture

catheter. In some embodiments, the ALTC device can be utilized to treat, for example, a clot in the carotid or cerebral arterial or venous circulation. The vessels to be treated could include, for example, the Circle of Willis, left or right common carotid or internal carotid arteries, anterior cerebral arteries, anterior communicating arteries, middle cerebral artery, posterior communicating arteries, carotid siphon, basilar arteries, vertebral arteries, or ophthalmic arteries for example, or any branches thereof. In some embodiments, the ALTC device can be utilized to treat, for example, a femoral vein, a brachial vein, a pulmonary vein, a breast vein, a cerebral vein, a brain sinus vein, a renal vein, a portal vein, a jugular vein, or another vein.

[0188] Figure 48A illustrates another delivery configuration of the clot capture system 35 that can include features as previously described, according to some embodiments of the invention. Figure 48B illustrates the initial deployment position of the axial lengthening thrombus capture device, according to some embodiments of the invention, and reversible coupling of the hub 55 of the capture catheter 155 to the hub 55 of the outer sheath. Figure 48C illustrates the further lengthening of the expanded segment of the axial lengthening thrombus capture device, according to some embodiments of the invention, with reciprocal shortening of the reserve compressed segment 81. As illustrated, the guidewire tube 6 with nose tip 7 is maintained in position while the capture catheter reversibly coupled to the outer sheath can be withdrawn proximally. Figure 48D illustrate the final deployment of the axial lengthening thrombus capture device at its maximal working length, according to some embodiments of the invention.

[0189] In some embodiments, systems and devices as disclosed herein can involve a general percutaneous technique, a cut-down procedure, or minimally invasive technique such as transapical, thoracoscopic, laparoscopic, or other techniques, for example, and not limited to transfemoral, transradial and/or internal jugular venous access. The technique can also apply to the arterial system, including neurovascular, cardiovascular, and peripheral vascular applications, as well as for use as an embolic protection device such as for a cardiovascular procedure such as valve replacement or repair for example. In some embodiments, a thrombectomy system can be delivered downstream of the aortic root, such as prior to the aortic arch, and a variable-length shape memory mesh structure such as an ALTC device with an open proximal end and closed distal end expanded prior to the index

cardiovascular procedure, to capture downstream emboli, calcifications, or other debris. In some embodiments, the system can be deployed to prevent embolization during a deep vein thrombectomy or pulmonary embolectomy, for example. In another embodiment, the system can be deployed to prevent embolization or retrieval during acute ischemic stroke. Systems and methods as disclosed herein can also be utilized in non-vascular anatomy such as the biliary tree to capture gallstones, common bile duct stones, and pancreatic duct stones, for example, in the ureters or bladder to capture kidney stones, or in the fallopian tubes to capture ova or other materials, or in the gastrointestinal tract such as the esophagus, stomach, duodenum, jejunum, ileum, or colon to capture, for example, foreign bodies. Described herein are some embodiments of using the venous system to access the pulmonary artery to treat pulmonary embolism. The technique can also apply to other areas of the vasculature. Initial puncture to access the femoral vein. A short access guidewire is inserted into the femoral vein. Next, an appropriate 5F or 6F introducer sheath is inserted. The guidewire is exchanged for a 180cm, 260cm or 300cm guidewire and advance pass the inferior vena cava, right atrium, right ventricle and the pulmonary artery to access the occluded treatment area. A longer length introducer/guiding catheter may be necessary to cross the tricuspid and pulmonary valve. Once the guidewire passes through the occluded treatment area, the 5F or 6F introducer sheath is exchanged for a long guiding catheter and position proximally near the occluded area. The catheter system 35 is inserted over the wire and through the guiding catheter and advance distally to the occluded area. The catheter system 35 can also utilize the outer sheath deflectable features to navigate through the vasculature without the use of a guiding catheter. Next, the catheter system's nose tip 7 passes through the occluded treatment area and positioned distal to the occluded treatment area. The Outer Sheath 1 is retracted to deploy the thrombus capture guide 11. The outer sheath 1 is retracted past the thrombus and positioned proximal to the thrombus (occluded area). The Suction Catheter 2 advances distally outside the Outer Sheath 1 and positions proximally to the occluded area, if suction is utilized.

[0190] To retrieve and capture materials such as blood clots or thrombus, the Thrombus Capture Guide 11 retracts by pulling the Capture Pullwire 10 proximally while push/pull Capture Catheter 12 to axially lengthen the ALTC Device 8 over the thrombus without substantially decreasing the device diameter. As needed, advancing the Capture

Catheter shaft 12 distally while pulling the Capture Pullwire will allow the ALTC Device 8 to axially lengthen to capture the thrombus. Furthermore, the expandable Funnel Tip 9 of the Suction Catheter 2 (or the funnel tip of the expanding guide catheter) can be positioned at the proximal end of the occluded area to support and minimized thrombus movement. This maneuver continues until all thrombus is inside the ALTC Device 8. Once the thrombus is completely within the ALTC Device 8, pulling the ALTC Device 8 away from the occluded area can restore immediate blood flow while containing the thrombus inside the ALTC Device 8.

[0191] In some embodiments, the capture catheter shaft 12 and the guidewire tube 6 are configured to be positioned side-by-side adjacent (e.g., offset and not coaxial, and not passing within the opening 802 or other radially expanded portion of the tubular mesh 6) to the ALTC Device 8 and capture guide (shown, for example, in Figures 49A and 49B). Also illustrated is the dynamic fold point 88, reserve radially compressed segment 81 and compressed end at 128 fixed to the outer wall of the guidewire tube 6.

[0192] Figures 50A – 50G illustrate the retrieval of thrombus into the expanding guide catheter wherein the ALTC device lengthens distally and creates additional space and the thrombus is redistributed and enable better retrieval into the expanding guide catheter. The funnel tip 52 and expanding section 53 of the expanding guide catheter also facilitate the ease of thrombus retrieval. For example, when the ALTC Device (e.g., tubular mesh 8) captures the blood clot inside, the ALTC Device 8 can advantageously stretch axially and compress radially beyond its working length (e.g., when the reserve radially compressed segment has been completely expanded, and/or by distal advance of the guidewire tube 6), effectively squeezing the blood clot radially to decrease its diameter/width. Fresh blood clots are typically soft and deformable. Applying axial stretching to the ALTC device can squeeze out the fluid that is within the blood clot, thereby reducing the size of blood clot and allowing blood clots to be removed from the vascular system more easily. The ability of the ALTC Device to lengthen dynamically also provides another clinically effective way to remove the large clot burden by redistributing the volume of blood clot or thrombus, as shown, for example, in Figure 50A – 50G. For example, with respect to current interventional devices such as filters and baskets, when blood clots or thrombus is collected and retrieved into a catheter such as a guiding catheter or sheath, the blood clot or thrombus can gather together

or pooled at base of the filter or basket into a large “ball-like” shape and prevent the large “ball-like” thrombus to enter the lumen of the guiding catheter or sheath. A similar effect can occur when aspiration/suction is attempted using a smaller inner diameter guide catheter. However, the ALTC device can lengthen serially from the distal end to create additional length and space within the ALTC Device (as shown, for example, in Figures 50B, 50D, and 50F). By lengthening the ALTC Device’s distal end, the blood clot or thrombus is redistributed within the ALTC device thereby reducing the ball-like size of the blood clot, thrombus, or other material for better retrievable inside the guiding catheter lumen (Figures 50C, 50E, 50G). These steps can be repeated for about or at least about 2, 3, 4, 5, or more cycles until all the blood clot and thrombus is retrieved in the catheter in a compacted form. Furthermore, the use of an expanding guide catheter with an expandable distal section in concert with the ALTC device can allow more efficient blood clot or thrombus removal, as illustrated, for example, in Figures 50A and 50C. The effectiveness of the ALTC Device 8 can be further demonstrated in an extreme vascular condition where there is minimal to no distal space available for conventional thrombectomy catheters to fully axially expand in order to be functional. The distal space beyond the distal end of the thrombectomy system can be in some cases less than about 3cm, 2cm, 1cm, 5mm, or less. In other words, the ALTC Device 8 can be delivered in a first, radially compressed configuration, and compressed by the outer sheath. Upon removal of the outer sheath, the ALTC Device 8 can transform into a radially expanded configuration and configured to capture thromboemboli even though the device may be in an axially compressed configuration. The ALTC Device 8 can then be axially expanded, such as, for example, at least about 1.25x, 1.5x, 2x, 2.5x, 3x, 3.5x, 4x, 4.5x, 5x, 5.5x, 6x, 6.5x, 7x, 8x, 9x, 10x, or more with respect to its fully functional axially compressed length while still maintaining a constant or substantially constant radially expanded diameter through a working range, such as between about 1cm and about 50cm, between about 1cm and about 20cm, between about 1cm and about 10cm, between about 1cm and about 5cm, or between about 1cm and about 3cm in some embodiments. In some embodiments, the ALTC device 8 has an open proximal end during delivery, and/or throughout its working axial length. The Thrombus Capture Guide 11 can advantageously deploy initially in the tight space while the ALTC device body remains inside the Capture Catheter shaft 12. Subsequently, the Thrombus Capture Guide retracts proximally to begin

deploying the ALTC Device 8. The potential axially expanded length of the ALTC Device 8 is not necessarily limited and in some embodiments could extend to the entire length of the catheter system. The ALTC Device 8 can be collapsed and contained within the Capture Catheter shaft 12 and Outer Sheath 1 during introduction into the vasculature and expands when the Outer Sheath 1 retracts proximally to deploy the ALTC Device 8. The Capture Catheter shaft 12 can be made from suitable materials such as and not limit to Nylon, Polyurethane, Pebax, Polyethylene, PET, PTFE, ePTFE, PEEK, polypropylene. It is also advantageous and possible in some embodiments that the Capture Catheter shaft 12 is deflectable at various locations and multiple deflectable directions along the shaft length to accommodate various tortuous paths such as entry into the right atrium, right ventricle, main pulmonary artery, left and right pulmonary artery as previously described.

[0193] A perspective view of another embodiment of a capture system is shown in Figure 51. Figure 51 also illustrates non-limiting examples of various possible elements that can be included in a material capture system, according to some embodiments of the invention. As illustrated in Figure 51, included in some embodiments are any number of, such as one, two, or more of the following components: a thrombus capturing device or ALTC device 201 having any of the features described herein, e.g., a pusher wire or inner pusher 202, a first tubular member such as an outer sheath 203, a loop or capture guide 204, and a coupler 205. The ALTC device 201 can attach to the capture guide 204. In some embodiments, the capture guide 204 comprises a metallic material, such as Nitinol. The capture guide 204 can be in the form of, for example, a loop, as shown, or any closed shape including an oval, ellipse, or polygon. The capture guide 204 can be in the form of an open shape such as any linear or non-linear segment. The ALTC device 201 and the capture guide 204 can be coupled such as being sutured together. The ALTC device 201 and the capture guide 204 can be encapsulated in a low durometer polymeric material. The capture guide 204 can be coupled to the outer sheath 203 via the coupler 205. The proximal end of the ALTC device 201 (not shown) can be coupled to the inner pusher 202.

[0194] The outer sheath 203 can, in some embodiments, be an elongate tubular member with a central lumen therethrough, and have a proximal end 2000 and a distal end 2001, both shown in Figure 51. The distal end 2001 of the outer sheath 203 can be operably connected to a capture device (e.g., tubular mesh as described herein), which can be movably

axially with respect to the outer sheath 203. The proximal end 2000 can include any number of, such as one, two, or more of the following components: a hemostasis assembly 206, a flush port 207, and a collapsed segment 208. The outer sheath 203 extends proximally and can be coupled to the hemostasis assembly 206. The inner pusher 202 extends proximally and can be coupled to a luer. In some embodiments, the inner pusher 202 can have a lumen to allow passage of a guidewire. In some embodiments, the inner pusher 202 is a solid shaft.

[0195] Figure 52 shows the distal end 2001 of the ALTC device 201 in a deployed configuration. In some embodiments, the ALTC device 201 in the initial deployed configuration has a low profile. A portion of the ALTC device 201 is extended while the remaining length of the ALTC device 201 is collapsed and contained within the outer sheath 203 as previously described. In some methods of use, the ALTC device 201 can be collapsed and tracked through a sheath or guide catheter (not shown) to the intended treatment area. In some embodiments, the guide catheter can be retracted proximally to initially deploy the ALTC device 201 and the capture guide 204. For instance, the retraction of the guide catheter can cause the capture guide 204 to expand. The capture guide 204 can include a compressed or constrained configuration while within the guide catheter. During the initial deployment, the capture guide 204 is released from a constrained position to a neutral position. In the neutral position, the capture guide 204 creates a perimeter for the ALTC device 201. In the case of a loop or other circular configuration, the capture guide 204 can create a constant diameter. In the case of other shapes or configurations, the capture guide 204 can create a constant cross-section. Alternatively or in combination, in other methods of use, the ALTC device 201 can be advanced distally from the guide catheter to deploy the ALTC device 201.

[0196] In some cases, only a small fractional portion of the ALTC device 201, such as less than about 50%, 45%, 40%, 35%, 30%, 25%, 20%, 15%, 10%, 5%, or less of the axial length of the device can be initially deployed and fully functional. The small portion can correspond to an amount of the ALTC device 201 which allows the capture guide 204 to assume the neutral position. During the deployment of the capture guide 204, a length of the ALTC device 201 can be retained within the outer sheath 203. The ALTC device 201 can follow a curve from the capture guide 204 to the outer sheath 203. Retracting the outer sheath 203 can lengthen the ALTC device 201 while maintaining a constant diameter or cross-section provided by the capture guide 204.

[0197] Figure 53 illustrates an embodiment of an ALTC device 201 in the initially deployed configuration. As illustrated in Figure 53, the ALTC device 201 can be in some embodiments a generally tubular structure, and in some cases a net-like mesh structure that is collapsible within the outer sheath 203. The ALTC device 201 is expandable to the diameter or cross-section provided by the capture guide 204. The ALTC device 201 can be axially lengthened or shortened, such as within a working range, by releasing the ALTC device 201 from the outer sheath 203. The ALTC device 201 can be axially lengthened or shortened while maintaining or substantially maintaining the diameter or cross-section provided by the capture guide 204. The ALTC device 201 can be deployed to form a generally tubular or cylindrical shape of varying axial lengths. The ALTC device 201 can be axially lengthened or shortened to retrieve and capture foreign or otherwise unwanted materials within the body, including the vascular system such as blood clots, thrombus and/or foreign materials. In some embodiments, an outer sheath is not present and a loader can be utilized to prepare the ALTC device 201 for delivery in a low crossing-profile configuration.

[0198] As shown, for example, in Figures 54 and 55, the ALTC device 201 can be axially lengthened. Figure 54 illustrates the ALTC device 201 in a second configuration. The ALTC device 201 is in the second configuration wherein the deployed and expanded ALTC device 201 is longer than the initial deployed configuration in the axial direction. The remaining collapsed ALTC device 201 length resides inside the outer sheath 203 and is shorter than the initial deployed configuration. The outer sheath 203 can be retracted to axially lengthen the ALTC device 201. As the outer sheath 203 is retracted, the capture guide 204 is retracted since the capture guide 204 is coupled to the outer sheath 203 via the coupler 205. As the capture guide 204 is retracted, the ALTC device 201 is advance from the collapsed portion 208 to the expanded portion. The outer sheath 203 can be retracted proximally to axially lengthen the ALTC device 201. Alternatively or in combination, in other methods of use, the capture guide 204 can be retracted to axially lengthen the ALTC device 201, such as be retracting the outer sheath 203. The diameter or cross-section of the ALTC device 201 can remain constant or substantially constant between the initial deployed configuration and the second configuration.

[0199] Alternatively or in combination, in other methods of use, the inner pusher 202 is advanced distally to advance the proximal end of the ALTC device 201. As described

herein, the proximal end of the ALTC device 201 is coupled to the inner pusher 202. In the second configuration, the inner pusher 202 is advanced distally to release a portion of ALTC device 201 from the outer sheath 203.

[0200] Figure 55 illustrates an embodiment of an ALTC device 201 in a third configuration. The ALTC device 201 is in the third configuration wherein the deployed and expanded ALTC device 201 is longer than the second configuration in the axial direction. The remaining collapsed ALTC device 201 length resides inside the outer sheath 203 and is shorter than the second configuration. The outer sheath 203 can be retracted proximally to axially lengthen the ALTC device 201. The diameter or cross-section of the ALTC device 201 can remain constant or substantially constant between the second configuration and the third configuration. Alternatively or in combination, in other methods of use, in the third configuration, the inner pusher 202 is advanced distally to a greater extent. In the third configuration, the inner pusher 202 is advanced distally to release a longer portion of ALTC device 201 from the outer sheath 203.

[0201] Figure 56 illustrates an embodiment of the material capture, e.g., basket mesh element 209. The basket mesh element 209 can be a component of the ALTC device 201. The basket mesh element 209 can be a structural mesh that provides an appropriate shape as described herein. The basket mesh element 209 can comprise Nitinol or other materials. The basket element can be braided, weave, wireform or laser cut. The basket mesh element 209 can include a first end that couples to the capture guide 204. The basket mesh element 209 can be coupled to the capture guide 204 via a suture or other mechanical means including welding, clips, flanges, adhesive, lamination, etc. The basket mesh element 209 and the capture guide 204 can be encapsulated within a low durometer polymeric material. The second end of the basket mesh element 209 can be coupled to the inner pusher 202. The second end can be folded inward to couple to the inner pusher 202. The second end can be inverted to couple to the inner pusher 202. The second end 202 can form a tube within a tube configuration of the ALTC device 201.

[0202] Figure 57 illustrates an embodiment of the ALTC device 201. The ALTC device 201 has an expanded portion when the ALTC device 201 is deployed (e.g., initial deployed configuration, second configuration, third configuration, etc.). The expanded portion has a constant diameter or cross-section as described herein. The expanded portion,

or a portion thereof, is coupled to the capture guide 204. The expanded portion is coupled to the outer sheath 203 via the capture guide 204 and the coupler 205. The ALTC device 201 has a collapsed portion 208. The collapsed portion 208 can reside within the lumen of the outer sheath 203. The collapsed portion 208 can be retained within the outer sheath 203 when the expanded portion is in the deployed configuration. The collapsed portion 208, or a portion thereof, can be coupled to the inner pusher 202. The collapsed portion 208 is everted as shown. During axial lengthening of the ALTC device 201, a portion of the collapsed portion 208 can roll-out at a distal region to transition between the collapsed portion 208 and the expanded portion.

[0203] Figures 58A and 58B illustrate embodiments of the capture guide 204. Figure 58A illustrates the capture guide 204. Figure 58B illustrates the capture guide 244, which can include any of the features of capture guide 204. The capture guide 204 can form a continuous shape. The capture guide 204 can include leg elements 210. The leg elements 210 can transition the capture guide 204 from an axial direction to a perimeter shape. The perimeter shape can be circular as shown in Figure 58A. The capture guide 204 can form a continuous loop. The capture guide 244 can include a non-continuous perimeter. As shown in Figure 58B, the capture guide 244 can include a non-continuous loop. The capture guide 204, 244 can be made of a metallic material. In some embodiments, the capture guide 204, 244 is formed of a shape-memory material. In some embodiments, the capture guide 204, 244 is formed from Nitinol. The capture guide 204, 244 can be formed of a spring-like material such as a metal. The capture guide 204, 244 can be circular, elliptical, semi-circular, or any combination thereof. The capture guide 204, 244 can include a pre-shaped curve. The pre-shaped curve can be formed during the manufacturing of the capture guide 204, 244. The pre-shaped curve can be a neutral or expanded shape of the capture guide 204, 244. Upon release of a constraint, the capture guide 204, 244 will assume the pre-shaped curve. The capture guide 204, 244 can have any curved shape. The capture guide 204, 244 can have a single radius of curvature or multiple portions having different radii of curvature. The capture guide 204, 244 can be considered spring loaded based in part of the material and the shape of the capture guide 204, 244. In some embodiments, the anchors can include non-continuous shapes, such as hooks with sharp or atraumatic segments or tips in some cases.

[0204] The capture guide 204, 244 can have two or more leg elements 210. The leg elements 210 can be adjacent or adjoining within the guide catheter during delivery. The leg elements 210 can be relatively parallel or side-by-side during delivery in the collapsed configuration. The collapsed leg elements 210 can define a different diameter or cross-section as compared to the fully expanded or neutral configuration of the capture guide 204, 244. In some embodiments, the collapsed leg elements 210 enable the capture guide 204, 244 to have a smaller diameter or cross-section while collapsed within the guide catheter. For example, when the capture guide 204, 244 is fully expanded, the circular portion of the capture guide 204, 244 defines a diameter. For non-circular capture guide 204, 244, the capture guide 204, 244 can define a cross-section when fully expanded. Upon collapsing the leg elements 210, the circular portion of the capture guide 204, 244 defines a diameter that is smaller than the previous expanded configuration. The capture guide 204 can comprise one segment as shown in Figure 58A with two ends that form a continuous loop configuration. The capture guide 244 can comprise multiple segments as shown in Figure 58B and form a non-continuous loop.

[0205] During expansion, the leg elements 210 can bias the capture guide 204, 244 outward to assume the neutral configuration of the capture guide 204, 244. The leg elements 210 can be positioned at an angle relative to each other in the neutral configuration of the capture guide 204, 244. The leg elements 210 can include one or more bends to facilitate folding of the capture guide 204, 244. The one or more bends can enable the capture guide 204, 244 to fold in a low profile configuration along the longitudinal axis of the guide catheter.

[0206] Figure 59 shows one aspect of the opening of the ALTC device 201. The end of the ALTC device 201, or a portion thereof, attaches to the capture guide 204. While the capture guide 204 is shown in Figure 59, any capture guide or feature thereof can be coupled to the end of the ALTC device 201. The end of the ALTC device 201 and the capture guide 204 form an assembly. The assembly can be encapsulated within a low durometer polymeric material to form a polymeric coating or ring 245. The polymeric coating can encapsulate the assembly completely or a portion thereof. In the illustrated embodiment, the polymeric coating encapsulates a portion of the end of the ALTC device 201 and the capture guide 204. The polymeric coating can encapsulate the rounded portion of

the capture guide 204 having a constant or substantially constant diameter. The polymeric coating can encapsulate the entire ALTC device 201, or any portion thereof. The area where the polymeric coating is void/not present can allow for easy movement. For instance, the area between the leg elements can be void. The void area can facilitate collapse of the capture guide 204. In some embodiments, the polymeric coating can be selectively applied. In some embodiments, the polymeric coating can form a ring or a portion of a ring. The polymeric coating can be applied to the outside of the material capture element, e.g., basket mesh element 208. The polymeric coating can be applied to the inside of the basket mesh element 208. The polymeric coating can be applied to the entire basket mesh element 208 to encapsulate the basket mesh element 208.

[0207] Figure 60 shows one aspect of the opening of the ALTC device 201. The ALTC device 201 can include a central, longitudinal axis. The outer sheath 203 can include a longitudinal axis. The inner pusher 202 can extend along the longitudinal axis of the outer sheath 203. The central, longitudinal axis of the ALTC device 201 can be offset from the longitudinal axis of the outer sheath 203. The central, longitudinal axis of the ALTC device 201 can be offset from the longitudinal axis of the inner pusher 202. The capture guide 204 can define the offset. For instance, the central, longitudinal axis of the ALTC device 201 can include the central point of the circle created by the capture guide 204. The central point of the capture guide 204 can be offset from the outer sheath 203. As described herein, the end of the ALTC device 201 is coupled to the inner pusher 202. The ALTC device 201 axially lengthens by releasing a portion of the ALTC device 201 from the outer sheath 203. The ALTC device 201 that is released follows a portion of the inner pusher 202 as shown in Figure 59. The released portion of the ALTC device 201 curves outward and assumes the diameter of the capture guide 204. The ALTC device 201 can form an everted shape with a portion of the ALTC device 201 collapsed near the inner pusher 202 and a portion of the ALTC device 201 expanded to the diameter or cross-section of the capture guide 204. In some embodiments, the shape of the ALTC device 201 can resemble a tube within a tube. In some embodiments, the ALTC device 201 can be considered telescoping.

[0208] A perspective view of another system is shown in Figure 61. Figure 62 shows the proximal end of the system and Figure 63 shows the distal end of the system. Figure 64 shows a subassembly of the system. Figures 61-64 also illustrates non-limiting

examples of various possible elements that can be included in a material capture system, according to some embodiments of the invention. As illustrated in Figure 61, included in some embodiments are any number of, such as one, two, or more of the following components: an anchor assembly 221, a corewire and basket assembly 222, an anchor and pusher assembly 223, a proximal catheter assembly 224, and a distal catheter assembly 225. The anchor assembly 221 can include about or at least about one, two, three, four, five, or more anchors 241 configured to secure a clot. The anchor and pusher assembly 223 includes one or more anchors 241 and the anchor pusher 240. The anchors can be coupled to the pusher as described herein. The corewire and basket assembly 222 can include a corewire 242 and the ALTC device 201. The proximal catheter assembly 224 can include a shaft with one, two, or more lumens, e.g., the dual lumen shaft 243. Figure 61 illustrates a dual lumen shaft 243 of the system. The dual lumen shaft 243 can be attached to the hemostasis housing 206 described herein. The dual lumen shaft 243 can be coupled to the capture guide 204 via the coupling 205. The illustrated embodiment shows a dual lumen shaft, but other configurations are contemplated. In some embodiments, the shaft has a single lumen. In some embodiments, the shaft is a multi-lumen shaft. The shaft can have about or more than about one lumen, two lumens, three lumens, four lumens, five lumens, six lumens, seven lumens, etc. In some embodiments, the anchor 241 is a single loop. In some embodiments, the anchor 241 is a continuous loop. In some embodiments, the anchor 241 has a closed perimeter. In some embodiments, the anchor 241 has an open perimeter. In some embodiments, the anchor 241 forms a circular shape. In some embodiments, the anchor 241 forms an oval. In some embodiments, the anchor 241 forms any round, closed shape.

[0209] Figure 62 illustrates the proximal end of the system including the corewire and basket assembly 222, the anchor and pusher assembly 223, and the proximal catheter assembly 224. The corewire and basket assembly 222 and the anchor and pusher assembly 223 can reside in separate lumens of the dual lumen shaft 243. The system can include the corewire 242. The corewire 242 can include any of the features or function as the inner pusher 202. The corewire 242 can be coupled to a pusher lock 246. The anchor pusher 240 can extend through the pusher lock 246. The pusher lock 246 can be movable along the shaft of the anchor pusher 240. In some embodiments, the pusher lock 246 can limit the expansion of the anchors 241. In some embodiments, the pusher lock 246 can provide a tactile response

when the anchors 241 are deployed by abutting the anchor and pusher assembly 223 with the pusher lock 246.

[0210] Figure 63 illustrates the distal catheter assembly 225. The distal catheter assembly 225 can include any of the features described herein. The distal catheter assembly 225 can include the ALTC device 201. The distal catheter assembly 225 can include the coupler 205 between the outer shaft 203 and the capture guide 204.

[0211] Figure 64 illustrates the anchor assembly 221. The anchor assembly 221 can comprise one or more anchors 241. The anchor assembly 221 can comprise about or at least about one anchor, two anchors, three anchors, four anchors, five anchors, six anchors, seven anchors, eight anchors, nine anchors, ten anchors, or more than ten anchors 241. The illustrated embodiment shows three anchors, but other configurations are contemplated. The anchor assembly 221 can include the anchor pusher 240. The anchor pusher 240 can include an elongate member comprising a shaft. The anchor pusher 240 can be extended proximally within the dual lumen shaft 243. The anchor pusher 240, or a portion thereof, can pass proximally through the proximal catheter assembly 224. The anchor pusher 240, or a portion thereof, can pass proximally through the pusher lock 246. The anchor pusher 240, or a portion thereof, can be connected to the luer hub. The anchor assembly 221 can be contained in the dual lumen shaft 243. The one or more anchors 241 can be coupled at a distal end of the anchor pusher 240. The one or more anchors 241 can be one anchor or a plurality of anchors 241. The anchors can be connected to the anchor pusher 240 in series, and regularly or irregularly spaced apart. In some embodiment, the diameter of the anchor 241 when expanded is smaller than the diameter of the capture guide 204 when expanded. In some embodiment, the diameter of the anchor 241 when expanded is smaller than the ALTC device 201 when expanded. The anchor 241 can be designed to fit within the ALTC device 201 when the ALTC device 201 is expanded. In some embodiments, the anchors can form symmetric or asymmetric loop shapes to circumscribe and stabilize a portion of the clot. In some embodiments, the anchors can be a mesh or braided element. In some embodiments, the anchor can be a balloon. In some embodiment, there can be a combination of braided mesh and balloon. In some embodiments, the anchors 241 can have a portion that extend radially outwardly from the elongate member in which they are attached.

[0212] Figure 65 illustrates a side view of the distal end of the ALTC device 201 and the anchors 241. The anchors 241 can include or be similar to any of the features of capture guide 204, 244 described herein. Each anchor 241 can form a continuous shape, or a discontinuous shape in other embodiments. Each anchor 241 can include leg elements 228. The leg elements 228 can transition the anchor 241 from an axial direction to a perimeter shape. The perimeter shape can be circular as shown in Figure 64. The anchor 241 can form a continuous loop. The anchor 241 can include a non-continuous perimeter such as a non-continuous loop. The anchor 241 can be made of a metallic material. In some embodiments, the anchor 241 is formed of a shape-memory metal such as Nitinol. The anchor 241 can be circular, elliptical, semi-circular, or any combination thereof. Each anchor 241 can include a pre-shaped curve. Two or more anchors 241 can have the same pre-shaped curve. Two or more anchors 241 can have a different pre-shaped curve. The pre-shaped curve can be formed during the manufacturing of the anchors 241. The pre-shaped curve can be a neutral or expanded shape of the anchors 241. Upon release of a constraint, the anchors 241 can assume the pre-shaped curve. The pre-shaped curve of the anchors 241 can be similar to the pre-shaped curve of the capture guide 204. The anchors 241 can have a different radius of curvature from the capture guide 204. As described herein, the anchors 241 can have a smaller diameter than the capture guide 204. Alternatively, the anchors can have the same or larger diameter than the capture guide. In some embodiments, the anchors include barbed elements to attach to a clot. In some embodiments, the anchors are atraumatic and do not include any barbed or other sharp surfaces.

[0213] The anchor 241 can have two or more leg elements 228. The leg elements 228 can be adjacent or adjoining within the guide catheter during delivery, and relatively parallel to the . The leg elements 228 can be relatively parallel or side-by-side during delivery in the collapsed configuration. The collapsed leg elements 228 can define a different diameter or cross-section as compared to the fully expanded or neutral configuration of the anchor 241. In some embodiments, the collapsed leg elements 228 allow the anchor 241 to have a smaller diameter or cross-section while collapsed within the guide catheter. For example, when the anchor 241 is fully expanded, the circular portion of the anchor 241 defines a diameter. For non-circular anchors 241, the anchor 241 can define a cross-section when fully expanded. Upon collapsing the leg elements, the circular portion of the anchor

241 defines a diameter that is smaller than the previous expanded configuration. The anchor 241 can comprise one segment as shown in Figure 64 that forms a continuous loop configuration. The anchor 241 can comprise multiple segments similar to capture guide 244 shown in Figure 58B. The anchors 241 have a outwardly curving shape relative to the two or more leg elements 228.

[0214] The anchor 241 can include an expanded position as shown in Figure 65. In the case of a shape memory material the expanded position can be a neutral position of the material. The anchor 241 can be configured to fold or bend during delivery. The anchor 241 can assume a low-profile configuration during delivery. The expanded anchor 241 can have any shape including round, circular, elliptical, etc. The anchors 241 expand to their pre-formed shape upon removal of a constraint, such as outer sheath 203, delivery catheter, or other constraining structure.

[0215] The expanded position of an anchor 241 can be defined by angle theta θ . In some embodiments, the angle theta is measured from the leg element 228 to the circular portion of the anchor 241. In some embodiments, the angle theta is measured from the horizontal to the vertical extension of the anchor 241. In some embodiments, the angle theta is measured from the dual lumen shaft 243 to the expanded portion of the anchor 241. In some embodiments, the angle theta determines the vertical or substantially vertical orientation of the anchor 241. Each anchor 241 of a plurality of anchors 241 can have the same angle theta. If the anchors 241 are arranged in a series, the angle theta can be uniformly the same. Two or more anchors 241 can have the same angle theta, or angles that are within about 30, 25, 20, 15, 10, 5, 4, 3, 2, 1, or less degrees of each other.

[0216] Each anchor 241 of a plurality of anchors 241 can have a different angle theta. Two or more anchors 241 can have the different angle theta. If the anchors 241 are arranged in a series, the series of anchors 241 can also have different variations in the angle theta. For example, the first anchor 241 can have a first angle theta such as about or at least about 45 degrees, such as between about 0 and 90 degrees, between about 15 and 75 degrees, or between about 30 and 60 degrees in some cases. The next or immediately adjacent anchor 241 can have a second angle theta such as 135 degrees. The next or immediately adjacent anchor 241 can have a third angle theta such as 45 degrees. The series can continue to

alternate between 45 degrees and 135 degrees or other desired angles. In some embodiments, the series of anchors can have different diameter.

[0217] In some embodiments, two or more anchors 241 can form a mirror image. In some embodiments, two or more anchors 241, 241 can extend from the dual lumen shaft 243 such that the circular portion of one anchor 241 substantially projects onto the circular portion of the other anchor 241. In some embodiments, two or more anchors 241 can be identical or substantially identical in orientation. In some embodiments, two or more anchors 241 can be coaxial. In some embodiments, two or more anchors 241 have different orientations relative to the dual lumen shaft 243. In some embodiments, two or more anchors 241 are not coaxial. In some embodiments, a first anchor 241 has a first axis extending through the circular portion of the first anchor 241 and the second anchor 241 has a second axis extending through the circular portion of the second anchor 241. In some embodiments, the first axis and the second axis can be skewed. In some embodiments, the first axis and the second axis are perpendicular. In some embodiments, the first axis and the second axis are parallel. In some embodiments, the first axis and the second axis are coaxial.

[0218] In some embodiments, the angle theta can range from 5 degrees to 175 degrees. Examples of the angle theta include 5 degrees, 10 degrees, 15 degrees, 20 degrees, 25 degrees, 30 degrees, 35 degrees, 40 degrees, 45 degrees, 50 degrees, 55 degrees, 60 degrees, 65 degrees, 70 degrees, 75 degrees, 80 degrees, 85 degrees, 90 degrees, 95 degrees, 100 degrees, 105 degrees, 110 degrees, 115 degrees, 120 degrees, 125 degrees, 130 degrees, 135 degrees, 140 degrees, 145 degrees, 150 degrees, 155 degrees, 160 degrees, 165 degrees, 170 degrees, 175 degrees, etc., and ranges incorporating any two of the aforementioned values. Examples of the angle theta can be in the range of 0-20 degrees, 20-40 degrees, 40-60 degrees, 60-80 degrees, 80-100 degrees, 100-120 degrees, 120-140 degrees, 140-160 degrees, 160-180 degrees, etc. In some embodiments, the angle theta can be approximately 90 degrees. In such embodiment, the anchor 241 can be approximately vertical relative to the dual lumen shaft 243. In some embodiments, the angle theta can be approximately 45 degrees. In such embodiment, the anchor 241 can form an acute angle relative to the dual lumen shaft 243. In some embodiments, the angle theta can be approximately 135 degrees. In such embodiment, the anchor 241 can form an obtuse angle relative to the dual lumen shaft 243.

[0219] The anchor and pusher assembly 223, or a portion thereof, can be moved within the dual lumen shaft 243. In some embodiments, the anchor and pusher assembly 223 can be moved coaxially within a lumen of the dual lumen shaft 243. The anchor and pusher assembly 223 can be moved independently from the corewire and basket assembly 222. In some embodiments, the anchor and pusher assembly 223 can be moved simultaneously with the corewire and basket assembly 222. In some embodiments, the anchor and pusher assembly 223 can be advanced distally or proximally relative to the dual lumen shaft 243. In some embodiments, the anchor and pusher assembly 223 does not impact the movement of the ALTC device 201. The one or more anchors 241 can be moved independently of the ALTC device 201. As described herein, the one or more anchors 241 can be moved relative to a stationary ALTC device 201. As described herein, the ALTC device 201 can be moved relative to a stationary anchor 241.

[0220] Figure 66 illustrates a top view of the distal end of the ALTC device 201 and the anchors 241. The one or more anchors 241 can be coupled to a distal pusher 226. In some embodiments, the leg extensions 228 of the anchors 241 are coupled to the distal pusher 226. In some embodiments, the angle theta is measured from the distal pusher 226 to the expanded portion of the anchor 241. In the illustrated embodiment, each anchor 241 is coupled to the distal pusher 226. The movement of the distal pusher 226 causes simultaneous movement of all anchors 241 coupled thereto. In alternative embodiments, two or more distal pushers 226 are provided. Each of the two or more distal pushers 226 controls the movement of one or more anchors 241. The two or more distal pushers 226 can move independently such that two or more anchors 241 can move independently. Other configurations are contemplated. The distal pusher 226 can be coupled to a crescent pusher 227. In some embodiments, the crescent pusher 227 can provide rigidity to the distal pusher 226. The distal pusher 226 and the crescent pusher 227 can be affixed via welding, adhesive, mechanical interference, etc.

[0221] Figure 67 illustrates a front view of the distal end of the ALTC device 201 and the anchors 241. The dual lumen shaft 243 is shown in cross section. In some embodiments, the dual lumen shaft 243 provides a lumen for the anchor and pusher assembly 223 and a lumen for the corewire and basket assembly 222. The two lumens can be separated

such that movement of one assembly does not impact the movement of the other assembly. Other configurations are contemplated.

[0222] The corewire and basket assembly 222 includes the corewire 242. The corewire 242 is shown disposed in one lumen of the dual lumen shaft 243. The corewire 242 can include any of the feature or functions of the inner pusher 202 described herein. The compressed basket or compressed ALTC device 201 is disposed in the same lumen of the dual lumen shaft 243 as the corewire 242. The compressed ALTC device 201 can have any of the features or function as the collapsed segment 208 described herein. The outer shaft of the dual lumen shaft 243 is shown.

[0223] The anchor and pusher assembly 223 can include the distal pusher 226 and the crescent pusher 227 described herein. The crescent pusher 227 can be coupled to the anchor pusher 240, described herein. In some embodiments, the distal pusher 226, the crescent pusher 227, and the anchor pusher 240 are integrally or monolithically formed. In some embodiments, the distal pusher 226 is a portion of the anchor pusher 240. The crescent shape of the crescent pusher 227 may prevent rotation of the crescent pusher 227 within the dual lumen shaft 243. The crescent pusher 227 is shown a lumen of the dual lumen shaft 243.

[0224] The anchors 241 can be coupled to the anchor pusher 240, such that movement of the anchor pusher 240 causes movement of the one or more anchors 241. The anchors 241 can be coupled to the distal pusher 226, such that movement of the distal pusher 226 causes movement of the one or more anchors 241. In some embodiments, the anchors 241 can be welded to the distal pusher 226. The anchors 241 are arranged such that the anchors 241 are coaxial along central longitudinal axis 230. As shown in the illustrated embodiment, only one anchor is visible from the front view due to the coaxial nature of the anchors 241.

[0225] The ALTC device 201 is expanded as shown in Figure 67. The outer diameter 232 of the anchor 241 can be smaller than the inner diameter 233 of the basket or ALTC device 201 in order for the ALTC device 201 to capture the anchors 241. The ALTC device 201 can capture one or more anchors depending on the axial length of the ALTC device 201. The axial length of the ALTC device 201 is adjustable based on the release of the ALTC device 201 from the dual lumen shaft 243. As a longer portion of the ALTC device 201 is released, the ALTC device 201 axially lengthens. As described herein, the ALTC

device 201 remains at a constant diameter or cross-section as the ALTC device 201 lengthens. The capture guide 204 maintains the shape of the expanded ALTC device 201 as the ALTC device 201 axially lengthens. The capture guide 204 is smaller in diameter than the outer diameter 232 of the anchor 241.

[0226] The capture guide 204 can function as a centering device to center the system within the vessel. The capture guide 204 can be a similar diameter or cross-sectional shape as the vessel. In some methods of use, the capture guide 204 is smaller than the diameter of the blood vessel when the capture guide 204 is expanded. In some methods of use, the capture guide 204 is approximately equal to the diameter of the blood vessel when the capture guide 204 is expanded. In some methods of use, the ALTC device 201 is smaller than the diameter of the blood vessel when the ALTC device 201 is expanded. In some methods of use, the ALTC device 201 is approximately equal to the diameter of the blood vessel when the ALTC device 201 is expanded. In some methods of use, the ALTC device 201 contacts the vessel wall of the blood vessel. In some methods of use, the ALTC device 201 does not contact the vessel wall.

[0227] The capture guide 204 can include the central longitudinal axis 231. In some embodiments, the dual lumen shaft 243 can be offset from the central longitudinal axis 231. In some embodiments, the dual lumen shaft 243 can be coaxial with the central longitudinal axis 231 (not shown). The anchor 241 can include the central longitudinal axis 230. In some embodiments, the dual lumen shaft 243 can be offset from the central longitudinal axis 230. In some embodiments, the dual lumen shaft 243 can be coaxial with the central longitudinal axis 230 (not shown). In some embodiments, the central longitudinal axis 230 of the anchor 241 can be offset from the central longitudinal axis 231 of the capture guide 204. In some embodiments, the central longitudinal axis 230 of the anchor 241 can be coaxial with the central longitudinal axis 231 of the capture guide 204 (not shown). In some embodiments, the dual lumen shaft 243 can be positioned near an edge of the capture guide 203. Other configurations are contemplated.

[0228] Figures 68A-69C illustrate capture of a clot within a vessel, according to some embodiments. Figure 68A illustrates the ALTC device 201 in the initially deployed configuration. As illustrated in Figure 68A, the ALTC device 201 can be in some embodiments a generally semi-spherical mesh structure when initially deployed. The mesh

structure is initially collapsible within a guide catheter or outer sheath 203. The guide catheter delivers the ALTC device 201 to the desired location within the body of the patient. The capture guide 204 is released from the constrained condition within the guide catheter or outer sheath 203. The capture guide 204 expands to have a cross-sectional shape. In some embodiments, the capture guide expands to a round or circular shape.

[0229] The ALTC device 201 is expandable to the diameter or cross-section provided by the capture guide 204. In some methods of use the ALTC device 201 is expanded by removal of a constraint. The ALTC device 201 can be released from a guide catheter. The guide catheter can be retracted to allow the capture guide 204 to expand. In some methods of use, the ALTC device 201 can be released from within the dual lumen shaft 243 by retraction of the dual lumen shaft. As described herein, one end portion of the ALTC device 201 is coupled to the capture guide 204. The ALTC device 201 can include a tubular mesh with a distal end. The ALTC device 201 can include a dynamic fold point as described herein such that the tubular mesh becomes everted upon release from the dual lumen shaft 243. The ALTC device 201 can include a reserve radially compressed segment within the dual lumen shaft terminating proximally at a point coupled to the inner pusher 202. In some methods of use, the expanded segment of the ALTC device 201 is positioned distal to the blood clot. The outer sheath 203 is positioned proximally, within, or adjacent to the blood clot.

[0230] Figure 68B shows the ALTC device 201 in the initially deployed configuration. As described herein, the corewire and basket assembly and the anchor and pusher assembly can be independently actuated. The first anchor 241 can be released when the outer sheath 203 retracts proximally. The first anchor 241 can include a shape memory material such that the first anchor 241 assumes an expanded configuration. The first anchor 241 can expand such that the first anchor 241 is defined by the angle θ . The first anchor 241 expands from a low profile configuration to an expanded configuration. The low profile configuration can enable the anchor 241 to reside within the outer sheath 203 during delivery. In some additionally or alternative methods of use, the first anchor 241 can be released when the anchor pusher 240 advances distally.

[0231] The released anchor can be firmly secured to the clot. In some methods of use, the first anchor 241 can become entangled in the clot. In some methods of use, the first

anchor 241 can reside against the clot. In some methods of use, the first anchor 241 can be designed to push the clot. In some methods of use, the first anchor 241 can be designed to perform a sweeping motion through the clot. The sweeping motion can be over an arc of the angle θ , or a portion thereof. The sweeping motion can break the clot, or a portion thereof.

[0232] Figure 68C shows the ALTC device 201 in the initially deployed configuration. The second anchor 241 can be released when the outer sheath 203 retracts proximally. In some methods of use, the second anchor 241 can be released when the anchor pusher 240 advances distally. The second anchor 241 can include a shape memory material such that the second anchor 241 assumes an expanded configuration. The second anchor 241 can expand such that the second anchor 241 is defined by the angle θ . As described herein, the first anchor 241 and the second anchor 241 can have the same or different orientation for the angle θ .

[0233] Figure 68D shows the ALTC device 201 in the initially deployed configuration. In some methods of use, the third anchor 241 can be released when the outer sheath 203 retracts proximally. In additional or alternative embodiments, the third anchor 241 can be released when the anchor pusher 240 is advanced distally. The third anchor 241 can include a shape memory material such that the third anchor assumes an expanded configuration. The third anchor 241 can expand such that the third anchor 241 is defined by the angle θ . As described herein, the first anchor 241, the second anchor 241 and the third anchor 241 can have the same or different orientation for the angle θ .

[0234] The first anchor 241, the second anchor 241 and the third anchor 241 can be designed to be secured to the clot. The arrangement of the anchors 241 can be designed to facilitate engagement with the clot. For instance, the number of anchors, the spacing of the anchors, the cross-section dimension of the anchors, the shape of the anchors, the orientation of the anchors relative to the anchor pusher, the angle θ , the shape of the leg extension, the rapidness of the shape memory material to assume the neutral shape, the stiffness of the material, as well as other factors can be optimized to facilitate engagement of the anchors 241 with the clot.

[0235] The ALTC device 201 and the anchors 241 can retract proximally to remove the clot. In some methods of use, the ALTC device 201 can catch emboli or debris

that dislodges during removal of the clot. In some methods of use, the ALTC device 201 is positioned downstream in a vessel to catch debris. The curved distal end of the ALTC device 201 can function as a net. In some methods of use, the anchors 241 can disrupt the clot to enable easier removal of the clot. In some methods of use, the sweeping motion of deploying the anchors 241 can break apart the clot.

[0236] Figures 69A-69C illustrates the axial lengthening sequence of the ALTC device 201, according to some embodiments. The dual lumen sheath 243 can be retracted to axially lengthen the ALTC device 201. As the dual lumen sheath 243 is retracted, the capture guide 204 is retracted since the capture guide 204 is coupled to the dual lumen sheath 243 via the coupler 205. As the capture guide 204 is retracted, the collapsed portion 208 becomes the expanded portion. The dual lumen sheath 243 can be retracted proximally to axially lengthen the ALTC device 201. Alternatively or in combination, in other methods of use, the capture guide 204 can be retracted to axially lengthen the ALTC device 201, such as by retracting the dual lumen sheath 243. The diameter or cross-section of the ALTC device 201 remains constant between the initial deployed configuration shown in Figure 69A and the expanded configurations shown in 69B and 69C. In additional or alternative methods of use, the corewire 242 can be actuated to axially lengthen the ALTC device 201. The corewire 242 can be positioned within the dual lumen shaft 243. Actuation of the corewire 242 such as axially in the appropriate direction will release the constrained portion of the ALTC device 201. The movement of the corewire 242 can result in axial lengthening or shortening of the ALTC device 201.

[0237] Figure 69A illustrates the system after deployment of the anchors 241. In some methods of use, the anchors 241 are deployed before axial lengthening of the ALTC device 201. In some methods of use, one or more steps of releasing an anchor and axially lengthening can occur in any order. In some methods of use, the first anchor is deployed and then the ALTC device 201 is axially lengthened to cover the first anchor. In some methods of use, the first and second anchors are deployed before the ALTC device 201 is axially lengthened to cover the first anchor or the second anchor. In some methods of use, the first, second, and third anchors are deployed before the ALTC device 201 is axially lengthened to cover the first anchor, the second anchor, or the third anchor. In some embodiments, two or more steps can occur simultaneously. In some methods of use, the first anchor is deployed

and the ALTC device 201 is axially lengthened to cover the first anchor simultaneously. In some methods of use, the first and second anchor are deployed and the ALTC device 201 is axially lengthened to cover either the first anchor or the second anchor simultaneously. In some methods of use, the first, second, and third anchors are deployed and the ALTC device 201 is axially lengthened to cover the first anchor, the second anchor, or the third anchor simultaneously.

[0238] Figure 69B illustrates the axial lengthening of the expanded portion of the ALTC device 201. The ALTC device 201 is lengthening proximally to capture the clot secured by the first anchor 241. The compressed or constrained segment of the ALTC device 201 is shortening within the dual lumen shaft 243 reciprocally. The dual lumen sheath 243 can be retracted to axially lengthen the ALTC device 201, as described herein. The ALTC device 201 can encapsulate the first anchor 241. The first anchor 241 can be sized to fit within the ALTC device 201 once the ALTC device 201 is axially lengthened.

[0239] Figure 69C illustrates the axial lengthening of the expanded portion of the ALTC device 201. The ALTC device 201 is lengthening proximally to capture the clot secured by the first anchor 241, the second anchor 241, and the third anchor 241. The compressed or constrained segment of the ALTC device 201 is shortening within the dual lumen shaft 243 reciprocally. Figure 69C illustrates the axial lengthening ALTC device 201 is sufficient to completely capture the clot. The ALTC device 201 and the anchors 241 can retract proximally to remove the clot.

[0240] The ALTC device 201 can be axially lengthened, such as within a working range, by releasing the ALTC device 201 from the sheath, which can have one, two, or more lumens in the sheath 243. The ALTC device 201 can be axially lengthened or shortened while maintaining or substantially maintaining the diameter or cross-section provided by the capture guide 204. The ALTC device 201 can be axially lengthened or shortened to retrieve and capture foreign or otherwise unwanted materials within the body, including the neurovascular system such as blood clots, thrombus and/or foreign materials.

[0241] The ALTC device 201 described herein can be sized to fit within a vessel of the neurovascular system, including any vessel noted elsewhere herein. As one example, the ALTC device 201 can be used to treat arteries, veins, and non-vascular lumens or regions. In some embodiments, the device can be configured to treat cerebral venous sinus thrombosis

and cavernous sinus thrombosis. A thrombus, commonly called a clot, is the product of blood coagulation due to aggregated platelets and red blood cells connected by a fibrin protein to block a blood vessel. The thrombus can travel (embolize), such as propagating toward the heart, lungs or other organs. The removal of thrombus can reduce the risk of a stroke, myocardial infarction, and/or pulmonary embolisms. The ALTC device 201 can lengthen to have a maximal length that covers the entire length of anchors 241, e.g., from about 0.01 mm to about 100 mm. Depending on vessel diameter, the outer diameter of the ALTC device 201 can range from, in some embodiments, from about 0.01 millimeter up to about 10 millimeters. The diameter of the ALTC device can achieve the similar effect of reducing or stretching the ALTC device diameter. In some embodiments, suction is not utilized or required, and the ALTC device envelops the clot, which can be mechanically pulled back into the capture catheter. In some embodiments, the mechanical thrombectomy systems and methods as disclosed herein can be used in combination with, and/or coated with a therapeutic agent such as, for example, one or more anti-thrombotic or anti-platelet agents such as heparin, hirudin, warfarin, dabigatran, and/or enoxaparin; tPA, streptokinase, or urokinase, an anti-proliferative agent such as paclitaxel (Taxol), rapamycin (Sirolimus), zotarolimus, or tacrolimus; and the like depending on the desired clinical result.

[0242] Figures 70A and 70B illustrate views of an embodiment of a pusher lock system. The pusher lock system can be utilized with any of the system described herein. Figure 70A also illustrates non-limiting examples of various possible elements that can be included in a material capture system, according to some embodiments of the invention. As illustrated in Figure 70A, included in some embodiments are any number of, such as one, two, or more of the following components: a hemostasis seal 260, a pusher lock 261, and a pusher 262. The hemostasis seal 260 can include a plurality of seals at spaced apart locations in the pusher lock system. The hemostasis seal 260 can be similar to the seals shown in Figure 21E and 21F. The pusher lock 261 can include any of the features of pusher lock 246 described herein. The pusher 262 can include any of the features of the inner pusher 202. The pusher 262 can include any of the features of the corewire 242 described herein. The pusher 262 can include any of the features of the anchor pusher 240 described herein.

[0243] Referring first to the system shown in Figures 70A-B, the pusher 262 can include any of the features of the inner pusher 202 described herein. The pusher 262 can

extend from the proximal end to the distal end. In some embodiments, the pusher extends from the nosetip of the catheter to the proximal end. In some embodiments, the pusher 262 is a single shaft. In some embodiments, the pusher 262 comprises one or more subcomponents. The pusher 262 can include an inner guidewire lumen shaft extending from the distal end toward the proximal end. The pusher 262 can include a pusher tube extending from the proximal end. The inner guidewire lumen shaft can be attached to a pusher tube to form a unitary structure. Other configurations are contemplated. The pusher 262 can comprise any material suitable to axially lengthen the ALTC device 201, as described herein. In some embodiments, the pusher 262 or a component thereof, comprises a metal such as stainless steel or titanium. In some embodiments, pusher tube can comprise stainless steel.

[0244] The pusher 262 can be positioned coaxially within a shaft. In some embodiments, the pusher 262 is placed within a middle shaft. The guidewire lumen shaft and the pusher tube assembly are positioned coaxially within the middle shaft. The pusher tube is extended beyond the middle shaft. The pusher tube can slide coaxially with respect to the middle shaft to either lengthen or shorten the ALTC device 201. During clinical use, if there is no locking mechanism for the pusher 262, the user can inadvertently actuate the pusher tube or the middle shaft prematurely, which will deploy the ALTC device 201. The pusher lock 261 helps to secure the pusher tube to the middle shaft during insertion of the catheter. The pusher lock 261 can be unlocked after unsheathing the ALTC device 201. The pusher lock 261 can be unlocked when the user is ready for lengthening the ALTC device 201.

[0245] In some alternative and additionally embodiments, the guidewire lumen shaft and the pusher tube assembly are positioned coaxially within the outer sheath 203. The pusher tube is extended beyond the outer sheath 203. The pusher tube can slide coaxially with respect to the outer sheath 203 to either lengthen or shorten the ALTC device 201. In some embodiments, the pusher tube extends beyond the outer sheath 203, as shown in Figure 51. During clinical use, if there is no locking mechanism for the pusher 252, the user can inadvertently actuate the pusher tube or the outer sheath 203 prematurely, which will deploy the ALTC device 201. The pusher lock 251 helps to secure the pusher tube to the outer sheath 203 during insertion of the catheter. The pusher lock 261 can be unlocked after unsheathing the ALTC device 201. The pusher lock 261 can be unlocked when the user is ready for lengthening the ALTC device 201.

[0246] Referring now to the system shown in Figure 62, the pusher 262 can include any of the features of the corewire 242 described herein. The pusher 262 can include any of the features of the anchor pusher 240 described herein. The pusher 262 can extend from the proximal end to the distal end. The pusher 262 can include an inner guidewire lumen shaft extending from the distal end toward the proximal end. The pusher 262 can include a pusher tube extending from the proximal end. Other configurations are contemplated.

[0247] The pusher 262 is positioned coaxially within a shaft. In some embodiments, the pusher 262 is placed within a middle shaft of the dual lumen shaft 243. The guidewire lumen shaft and the pusher tube assembly are positioned coaxially within the middle shaft. The pusher tube is extended beyond the middle shaft. The pusher tube can slide coaxially with respect to the middle shaft to either lengthen or shorten the ALTC device 201. During clinical use, if there is no locking mechanism for the pusher 262, the user can inadvertently actuate the pusher tube or the middle shaft of the dual lumen shaft 243 prematurely, which will deploy the ALTC device 201. The pusher lock 261 helps to secure the pusher tube to the middle shaft during insertion of the catheter. The pusher lock 261 can be unlocked after unsheathing the ALTC device 201. The pusher lock 261 can be unlocked when the user is ready for lengthening the ALTC device 201.

[0248] In some alternative or additional embodiments, the pusher 262 is placed within an upper shaft of the dual lumen shaft 243. The guidewire lumen shaft and the pusher tube assembly are positioned coaxially within the upper shaft. The pusher tube is extended beyond the upper shaft. The pusher tube can slide coaxially with respect to the upper shaft to deploy the anchors 241. During clinical use, if there is no locking mechanism for the pusher 262, the user can inadvertently actuate the pusher tube or the dual lumen shaft 243 prematurely, which will deploy the anchors 241. The pusher lock 261 helps to secure the pusher tube to the dual lumen shaft 243 after during insertion of the catheter. The pusher lock 261 can be unlocked after unsheathing the ALTC device 201. The pusher lock 261 can be unlocked after unsheathing the first anchor 241. The pusher lock 261 can be unlocked when the user is ready to deploy the anchors 241.

[0249] The method can include one or more of the following steps in any order. The delivery catheter can be prepared. The delivery catheter can be prepared at the bedside of

a patient. The delivery catheter can be prepared according to one or more instructions. In some methods of use, the pusher lock 261 can be locked in position. The pusher lock 261 can be locked in position on the pusher 262. In some embodiments, the pusher lock 261 is locked in position by rotating the lock cap 263. In some embodiments, the pusher lock 261 can be locked by rotating clockwise. In some embodiments, the pusher lock 261 can be locked by rotating counterclockwise.

[0250] In some methods of use, a guidewire is positioned within a patient. In some methods of use, the inner guidewire lumen shaft of the pusher 262 can be guided over the guidewire. In some methods of use, the pusher tube of the pusher 262 can be guided over the guidewire. In some methods of use, the system is advanced over the guidewire. In some methods of use, the delivery catheter is advanced to the intended area for treatment. In some methods of use, the delivery catheter is retracted. In some methods of use, the outer sheath 203 is retracted to deploy the ALTC device 201.

[0251] In some methods of use, the pusher lock 251 is unlocked. In some methods of use, the pusher lock 261 is unlocked by rotating the lock cap 263 counterclockwise. In some methods of use, the pusher lock 261 is unlocked by rotating the lock cap 263 in an opposite direction. Upon unlocking the pusher lock 261, the ALTC device 201 can be lengthened. In some methods of use, the ALTC device is lengthened by axially actuating the middle shaft. In some methods of use, the ALTC device is lengthened by axially actuating the pusher tube. In some methods of use, the ALTC device is lengthened by axially actuating the outer sheath. In some methods of use, the ALTC device is lengthened by axially actuating the dual lumen shaft. The pusher lock 261 can be used to affix the pusher tube to the middle shaft as needed.

[0252] Figures 71A-71D illustrate views of a pusher lock 261 of the pusher lock system of Figure 70A. As illustrated in Figure 71A-71D, included in some embodiments are any number of, such as one, two, or more of the following components: the lock cap 263, a collet 264, and a lock body 265. The lock cap 263 and the lock body can include mating threads. In the illustrated embodiment, the lock cap 263 includes female threads and the lock body 265 includes male threads. The collet 264 is disposed between the lock cap 263 and the lock body 265. The pusher 252, or a portion thereof, is designed to be placed within the collet 264. The pusher 252 can extend through an opening in the lock cap 263, through the collet

264, and through an opening in the lock body 265. The lock cap 263 also includes a ramped surface designed to interact with the collet. As the lock cap 262 is rotated, the collet 264 can be brought into engagement with the ramped surface. Further rotation can cause the collet to collapse or tighten onto the pusher 252. Other configurations are contemplated.

[0253] Figure 72 illustrates a flow chart of an embodiment of a method 300. In some embodiments, the method can assemble the end of the ALTC device 201 to the capture guide 204. The method can include one or more of the following steps, in any order. The step 301 can include mixing a thermoplastic and/or polyurethane, e.g., Pellethane solution. The solution is mixed using, e.g., a thermoplastic polyurethane, e.g., Pellethane and, e.g., a cyclic ester such as Tetrahydrofuran (THF). The mixture of Pellethane and Tetrahydrofuran (THF) ratio can range from, e.g., between about 1:1 and about 1:20 of Pellethane to THF. The ratio of Pellethane to Tetrahydrofuran can be, for example, about, at least about, or no more than about 1:1, 1:2, 1:3, 1:4, 1:5, 1:6, 1:7, 1:8, 1:9, 1:10, 1:11, 1:12, 1:13, 1:14, 1:15, 1:16, 1:17, 1:18, 1:19, 1:20, or ranges including any two of the aforementioned values. The step 302 can include trimming the ALTC device 201. The end of the ALTC device 201 can be squared trim. The step 302 can include loading the ALTC device 201 on the dipping mandrel. The dipping mandrel can be made of polymeric and/or metallic materials such as HDPE, PTFE, stainless steel, etc. The mandrel can be non-coated or coated to allow ease of manufacturing. The step 303 can include dipping the ALTC device 201 in the solution. The ALTC device mounted on a dipping mandrel is slowly dipped into the Pellethane/THF solution. The step 303 can include drying the ALTC device 201. The ALTC device 201 can hang to allow to dry, or dried using other mechanisms. The step 304 can involve removing the ALTC device 201. The step 304 can involve trimming the excess Pellethane. The dipped end of the ALTC device 201 can encapsulate and fix the wire ends of the basket mesh element 209 from movement. The dipped end can prevent the wire ends of the basket mesh element 209 from being exposed. The ALTC device 201 is removed from the dipping mandrel. The excess Pellethane is trimmed close to the edge of the ALTC device 201.

[0254] The step 305 can include punching or otherwise creating one or more apertures in the Pellethane coating. The dipped area of ALTC device 201 can be punched to create holes at predetermine location to allow placement of the capture guide. Other methods of making holes in the coating are contemplated. The step 306 can include inserting the

capture guide 204 into the punched hole. The capture guide 204 is inserted into the punched hole. The capture guide 204 can be woven through two or more holes. The capture guide can be threaded from one side of the ALTC device 201 to the other side of the ALTC device 201. The step 307 can include folding the edge of the ALTC device to cover the capture guide 204. The dipped coat edge of the ALTC device 201 is folded to cover the wire loop of the capture guide 204. The folding can protect and prevent the encapsulated wire ends of the basket mesh element 209 from protruding. The step 308 can include suturing the ALTC device 201 and the capture guide 204. The ALTC device 201 is sutured to the capture guide 204 using suture materials. Suture materials can include, for example, PET, PTFE, HMWPE, or other materials known in the art. The step 309 can include suturing around the edge of the ALTC device. The step 309 can include suture the back stitch around the edge.

[0255] The step 310 can include loading the ALTC device onto the forming mandrel. When the suturing is completed, the ALTC device 201 is then loaded onto the forming mandrel. The step 311 can include thermally forming the stitched ALTC edge. The step 311 can include thermally forming the stitched ALTC device edge using appropriate heating. The forming mandrel can be either polymeric or metallic materials such as PTFE, stainless steel, etc. The step 312 can include dipping the ALTC device and capture device. The ALTC device and capture device can be dipped in the Pellethane solution from step 301. The ALTC device and capture device can be dipped in another solution. The dipping process can include dipping the ALTC device 201 and capture guide 204 into the Pellethane/THF solution. The dipping can secure the assembly of the ALTC device 201 and capture device 204. The step 312 can include loading the assembly of the ALTC device 201 and capture device 204 onto the dipping mandrel. The dipping mandrel can be the same dipping mandrel of steps 302, 303. The dipping mandrel can be a different mandrel. The dipping mandrel for this step 312 can be made of polymeric and/or metallic materials such as HDPE, PTFE, stainless steel, etc. The mandrel for this step 312 can be non-coated or coated to allow ease of manufacturing. In some methods of use, a film or sheet of material can be used in addition or in place of one or more dipping steps. The film can be an extruded polymeric film. The sheet can be a sheet of low durometer polymer such as pellethane, polyurethane, tecothane, etc. The film or sheet can be used and place over the end of the ALTC device. In some methods of use, a film or sheet of material can be used in addition thermally forming the edge of the

ALTC device 201. The film or sheet can be thermally fused. The film or sheet can be laminated together. Other manufacturing methods are contemplated.

[0256] Figures 73-94 illustrate embodiments of anchors. The anchors described herein can be used in conjunction with, or in place of, anchors 241. The one or more anchors described herein can form an anchor assembly 221 described herein. The anchor assembly 221 can include about or at least about one, two, three, four, five, or more anchors configured to secure a clot. In some embodiments, two or more anchors of the anchor assembly 221 can be the same. In some embodiments, two or more anchors of the anchor assembly 221 can be different. In some embodiments, two or more anchors of the anchor assembly 221 can be selected from anchors described herein. In some embodiment, the diameter of the anchor when expanded is smaller than the ALTC device 201 when expanded. In some embodiment, the anchor can be designed to fit within the ALTC device 201 when the ALTC device 201 is expanded. In some embodiments, the anchor can be designed to substantially the same or larger than the ALTC device 201. In some embodiments, the distal end of the ALTC device 201 has a flexible, atraumatic extension forming the distal end of the system. In some embodiments, the distal end of the ALTC device 201 has an anchor. In some embodiments, the anchor can have any shape to entangle a portion of the clot. In some embodiments, the anchor can have any shape to stabilize a portion of the clot. In some embodiments, the anchor can have any shape to provide radial support to the clot. In some embodiments, the anchor can have any shape to provide axial support to the clot. In some embodiments, the anchor can have any shape to move a portion of the clot, such as distally toward the ALTC device 201 or proximally away from the ALTC device 201. In some embodiments, the anchor can rotate. In some embodiments, the anchor can move axial to break up the clot.

[0257] The systems described herein can include the guidewire lumen 6, which can advance distally to lengthen the ALTC device 201. Referring to Figure 5, the outer sheath 1 has an inner diameter configured to house the capture catheter 12 coaxially therein, and the capture catheter 12, which in turn has a lumen configured to house the guidewire tube 6 and the body of the ALTC device 8. The systems described herein can include the pusher 202 or corewire 242. Alternatively or in combination, in other methods of use, an end of the ALTC device 201 is coupled to the inner pusher 202. In the second configuration, the inner pusher 202 is advanced distally to release a portion of ALTC device 201 from a sheath.

As the inner pusher 202 is advanced distally, a portion of the collapsed portion 208 becomes the expanded portion of the ALTC device 201. As the inner pusher 202 is advanced distally, the ALTC device 201 is axially lengthened. In additional or alternative methods of use, the corewire 242 can be actuated to axially lengthen the ALTC device 201. The corewire 242 can be positioned within the dual lumen shaft 243. Actuation of the corewire 242 such as axially in the appropriate direction will release the constrained portion of the ALTC device 201. The movement of the corewire 242 can result in axial lengthening or shortening of the ALTC device 201. In some embodiments, the systems described herein can include a fixed guidewire. In some embodiments, the systems described herein can be advanced along a guidewire. In some embodiments, the systems described herein can slide along a guidewire. In some embodiments, the systems described herein can include a lumen configured to slide along a guidewire. In some embodiments, the guidewire is a shaft. In some embodiments, the guidewire has a lumen. In some embodiments, the guidewire is a needle. In some embodiments, the guidewire is solid. In some embodiments, the guidewire is flexible. In some embodiments, the guidewire functions to guide the system within the body of the patient. In some embodiments, the guidewire functions to deploy one or more components of the device.

[0258] The system can include a dual axial lengthening basket and anchor capture device as described here. The anchors can be any configuration such as stent-like, balloon, coils, loops, wire forms into various geometric shapes (not shown), etc. such as the embodiments described herein. In some methods of use, the anchors can function to secure the emboli, thrombus or debris and allow for removal. In some methods of use, the anchors can function to break up the emboli, thrombus or debris. In some embodiments, the ALTC device 201 and the one or more anchors move or translate together. In some embodiments, the ALTC device 201 and the one or more anchors move or translate independently or separately. In some embodiments, one or more anchors can move as a unit with another anchor. In some embodiments, one or more anchors can move independently or separately from another anchor.

[0259] Figure 73 illustrates an embodiment of an anchor 401. The anchor 401 can include any of the features of anchors described herein. In some embodiments, the anchor 401 can comprise symmetric loop shapes. In some embodiments, the anchor 401 can

comprise asymmetric loop shapes. In some embodiments, the anchor 401 can comprise polygonal shapes or generally polygonal shapes. In some embodiments, the anchor 401 comprises generally hexagonal shapes. In some embodiments, the anchor 401 has a constant diameter. In some embodiments, the anchor 401 has two or more diameters. In the illustrated embodiments, the anchor 401 has an alternating larger diameter and smaller diameter. In some embodiments, the smaller diameter is more than 50% of the larger diameter, the smaller diameter is more than 60% of the larger diameter, the smaller diameter is more than 70% of the larger diameter, the smaller diameter is more than 80% of the larger diameter, the smaller diameter is more than 90% of the larger diameter, the smaller diameter is approximately equal to the larger diameter, etc. It is also understood the anchor can have various length. For example, the anchor can have sufficient length such that the anchor is partially deploy to accommodate the length of the clot. Furthermore, the remainder of the anchor is compressed with the delivery catheter and can be lengthen and expand to accommodate longer length clot as needed.

[0260] In some embodiments, the anchor 401 can be a mesh, braid or other network of wire or thread. In some embodiments, the anchor 401 can have an interlaced structure. In some embodiments, the anchor 401 can be formed from parallel or axial wires or threads 402. The parallel or axial wires or threads can be coupled or otherwise connected at junctions 403. The junctions 403 can couple two or more wires or threads 402 together. In some embodiments, the junctions 403 can be staggered to form the mesh structure. In some embodiments, the anchor 401 forms a helix. In some embodiments, the anchor 401 forms a double helix. In some embodiments, the anchor 401 forms a helical structure. In some embodiments, the anchor 401 forms an irregular mesh. In some embodiments, the anchor 401 forms a regular mesh. In some embodiments, the anchor 401 forms a fully connected structure. The anchor 401 can comprise a repeating or tessellating shape such as triangles, squares, or hexagons. The anchor can be laser-cut.

[0261] The anchor 401 can include an flexible tip 404. The flexible tip 404 can function as atraumatic soft tip. The opposite end of the anchor 401 is attached to the anchor pusher 240 and function in a similar manner described herein. The flexible tip 404 can be disposed within the outer sheath 203 described herein. The anchor pusher 240 can be disposed within the dual lumen shaft 243 described herein. The anchor pusher 240 can be

disposed within any lumen of any device, shaft or catheter described herein. The anchor can be offset to the ALTC device. The anchor can be coaxial to the ALTC device. The anchor pusher 240 and the anchor 401 can be coupled together such that movement of the anchor pusher 240 causes movement of the anchor 401. In some embodiments, the flexible tip 404, anchor 401 and the anchor pusher 240 is cannulated for an “over the wire” configuration. The anchor pusher 240 can be guided over a guidewire for placement of the anchor 401.

[0262] Figure 74 illustrates an embodiment of an anchor 405. The anchor 405 can include any of the features of anchors described herein, including anchor 401. In some embodiments, the anchor 405 can be a mesh, braid, laser cut or other network of wire or thread 406. In some embodiment, the anchor is made from one wire or thread. In some embodiments, the anchor 405 can be formed from parallel or axial wires or threads 406. The parallel or axial wires or threads can be coupled or otherwise connected at junctions 407. The junctions 407 can couple two or more wires or threads 406 together. In some embodiments, the junctions 407 can be staggered to form the mesh structure. In some embodiments, the junctions 407 can couple all of the wires or threads 406 together. In some embodiments, the junctions 407 can form a plurality of discrete subsections. In the illustrated embodiments, the anchor 405 can include three subsections formed from two junctions 407. Other configurations are contemplated (e.g., the anchor 405 includes two subsections formed from one junction 407, the anchor 405 can include four subsections formed from three junctions 407, the anchor 405 include five subsections formed from four junctions 407, etc.). In the illustrated embodiments, the anchor 405 has an alternating larger diameter and smaller diameter formed by the junctions 407. In some embodiments, the smaller diameter is less than 50% of the larger diameter, the smaller diameter is less than 40% of the larger diameter, the smaller diameter is less than 30% of the larger diameter, the smaller diameter is less than 20% of the larger diameter, the smaller diameter is less than 10% of the larger diameter, etc. It is also understood the anchor is not limited to metal only but other materials such as polymeric materials PTFE, PET, Nylon, Polyethylene, PEEK, Polypropylene, Polyimide.

[0263] Figure 75 illustrates a distal end of a capture device system including the anchor 401. The system can be placed within a vessel 408. The vessel can be any target vessel within the body of a patient. In some embodiments, the vessel is in the central nervous system or a coronary or peripheral vessel as described elsewhere herein. The system is placed

near an obstruction 409 or other source of debris or material. In some embodiments, the obstruction is a blood clot. In some embodiments, the obstruction is a neurological blood clot. In some embodiments, the obstruction is an emboli. In some embodiments, the obstruction is a foreign body.

[0264] Figure 75 illustrates the system with the anchor 401 and the ALTC device 201 deployed. In some methods of use, one or more steps of releasing an anchor 401 and axially lengthening can occur in any order. In some methods of use, the anchor 401 is deployed before axial lengthening of the ALTC device 201. In some embodiments, the anchor forms only a single loop. In some embodiments, the single loop functions in a similar manner to the anchor 401. In some methods of use, the anchor 401 is deployed by axial movement of the anchor pusher 240. The anchor pusher 240 can release the anchor 401 from a sheath such as dual lumen sheath 243 described herein. In some methods of use, the anchor 401 is deployed and then the ALTC device 201 is axially lengthened to cover the anchor 401. In some methods of use, the anchor 401 is deployed before the ALTC device 201 is axially lengthened to cover the anchor 401. In some methods of use, the anchor 401 is partially deployed before the ALTC device 201 is axially lengthened to cover the anchor 401. In some methods of use, the anchor 401 is not deployed before the ALTC device 201 is axially lengthened. In some methods of use, the anchor 401 is deployed after the ALTC device 201 is axially lengthened. In some methods of use, the anchor 401 is partially deployed after the ALTC device 201 is partially axially lengthened. In some methods of use, the anchor 401 is deployed and the ALTC device 201 is axially lengthened simultaneously. In some methods of use, the anchor 401 is deployed and the ALTC device 201 is axially lengthened independently. In some methods of use, the anchor 401 is fixed and the ALTC device 201 is axially lengthened. In some methods of use, the ALTC device 201 is fixed and the anchor 401 is deployed or expanded. In some methods of use, the anchor 401 is only deployed if covered by the ALTC device 201. In some methods of use, the anchor 401 is only deployed the ALTC device 201 provides distal protection. The anchors described herein can function in any manner described herein.

[0265] In some methods of use, the ALTC device 201 is positioned distally to the anchor 401. In some methods of use, the ALTC device 201 is positioned downstream in the direction of blood flow. The direction of blood flow is shown in Figure 75 by the red arrow.

In some methods of use, the ALTC device 201 is positioned distal to the obstruction or clot. In some methods of use, the ALTC device 201 is positioned to capture fragments of the obstruction. In some methods of use, the ALTC device 201 provides distal protection during clot removal. In some methods of use, alternatively, the ALTC device 201 is positioned proximally to the anchor 401. In some methods of use, the ALTC device 201 is positioned upstream to the anchor 401. In some methods of use, alternatively, two or more ALTC device 201 are utilized. In some methods of use, one ALTC device 201 is positioned distally and one ALTC device 201 is positioned proximally. In some methods of use, the two ALTC device 201 can move toward each other. In some methods of use, the two ALTC device 201 can meet at an intermediate location. The systems described herein can include one or more ALTC devices 201. The systems described herein can include one or more ALTC devices 201 positioned as described herein. In some embodiment, the anchor 401 can position distal to the ALTC device 201 (not shown).

[0266] In some methods of use, the anchor 401 is positioned distally to the ALTC device 201. In some methods of use, the anchor can function to block emboli. In some methods of use, the anchor 401 is positioned downstream in the direction of blood flow, or upstream in other embodiments. The direction of blood flow is shown in Figure 75 by the arrow. In some methods of use, the anchor 401 is positioned distal to the obstruction or clot. In some methods of use, the anchor 401 is positioned to capture fragments of the obstruction. In some methods of use, the ALTC device 201 is lengthened for clot removal. In some methods of use, alternatively, two or more the anchors 401 are utilized. In some methods of use, one, two, or more anchors 401 are positioned distally and one, two, or more anchors 401 are positioned proximally of the ALTC device 201. In some methods of use, the two anchors 401 can move toward each other. In some methods of use, the two anchors 401 can meet at an intermediate location. The systems described herein can include one, two, or more anchors 401. The systems described herein can include one, two, or more anchors 401 positioned as described herein.

[0267] In some embodiments, the anchor is deployed adjacent to the clot. In some embodiments, the anchor is deployed within the clot. In some embodiments, the anchor is deployed distal to the clot. In some embodiments, the anchor is deployed proximal to the clot. In some methods of use, the anchor 401 deploys within the obstruction or clot. In some

methods of use, the anchor 401 is positioned to entangle the obstruction. In some methods of use, the anchor 401 is positioned distally to the obstruction or downstream in the direction of blood flow. In some methods of use, the anchor 401 can move proximally through the obstruction. In some methods of use, the anchor 401 is positioned proximally to the obstruction or upstream in the direction of blood flow. In some methods of use, the anchor 401 can move distally through the obstruction. In the illustrated embodiment, the obstruction or clot can pass through the anchor 401. In the illustrated embodiment, the obstruction or clot can be caught in the anchor 401. In some methods of use, the anchor 401 moves after deployment. For instance, the anchor 401 can move distally therefore moving the obstruction distally. The anchor 401 can move proximally therefore moving the obstruction proximally. In some embodiments, the anchor 401 can rotate. After deployment of the anchor 401, the obstruction and the anchor 401 can move together as a unit. After deployment of the anchor 401, the obstruction, the anchor 401, and the ALTC device 201 can move together as a unit. In some methods of use, the anchor 401 moves after axially lengthening of the ALTC device 201. In some methods of use, the anchor 401 moves before axially lengthening of the ALTC device 201.

[0268] Figures 76A-76C illustrates the axial lengthening sequence of the ALTC device 201, according to some embodiments. The ALTC device 201 can be lengthened in any manner described herein. In some methods of use, the ALTC device 201 can be lengthened by retraction of a constraining member such as a sheath. As the sheath is retracted, the capture guide 204 is expanded. After the capture guide 204 is expanded, a portion of the ALTC device 201 is expanded. In some methods of use, the sheath dual lumen sheath 243 can be retracted to axially lengthen the ALTC device 201. In some embodiments, for the dual lumen sheath 243 in some cases, there may be no outer sheath required to constrain the device. In some embodiments, the dual lumen sheath 243 constrains the ALTC device 201. In some embodiments, the dual lumen sheath 243 constrains the anchors. In some embodiments, the dual lumen sheath 243 is loaded with the ALTC device 201. In some embodiments, the dual lumen sheath 243 is loaded with the one or more anchor. In some embodiments, the ALTC device 201 and the one or more anchor are loaded in a single lumen of a single lumen sheath. In some embodiments, the ALTC device 201 and the one or more anchor are loaded in a single lumen of a dual lumen sheath. In some embodiments, the ALTC

device 201 and the one or more anchor are loaded in separate lumens of a sheath. In some embodiments, the ALTC device 201 and the one or more anchor are advanced from a single lumen of a single lumen sheath. In some embodiments, the ALTC device 201 and the one or more anchors are advanced from a single lumen of a dual lumen sheath. In some embodiments, the ALTC device 201 and the one or more anchors are advanced from separate lumens of a sheath. In some embodiments, the device would be loaded in a sheath/guide/microcatheter in advance. Effectively, in some cases the guide/microcatheter can be used as a sheath.

[0269] In some embodiments, the ALTC device 201 maintains the diameter of the capture guide 204. In some methods of use, the ALTC device 201 can be lengthened by extension of a member such as a pusher 202 or corewire 242. Alternatively or in combination, in other methods of use, the inner pusher 202 is advanced distally to advance an end of the ALTC device 201. As described herein, an end of the ALTC device 201 is coupled to the inner pusher 202. In the second configuration, the inner pusher 202 is advanced distally to release a portion of ALTC device 201 from a sheath. As the inner pusher 202 is advanced distally, a portion of the collapsed portion 208 becomes the expanded portion of the ALTC device 201. As the inner pusher 202 is advanced distally, the ALTC device 201 is axially lengthened.

[0270] Figure 76A illustrates the system after deployment of the anchor 401. In some methods of use, the anchor 401 is deployed before axial lengthening of the ALTC device 201. The capture guide 204 is expanded and a portion of the ALTC device 201 is expanded. Figure 76A illustrates the axial lengthen device or ALTC device 201 with an expandable anchor 401 positioned near the opening end of the ALTC device 201. In some embodiments, the expandable anchor 401 can be independently movable such that expandable anchor 401 can retract proximally or distally while the ALTC device 201 is stationary. In some embodiments, alternatively, the anchor 401 and the ALTC device 201 can move together as one unit. In some embodiments, the ALTC device 201 and the expandable anchor 401 are collapsed in the delivery configuration. In some embodiments, the ALTC device 201 and the expandable anchor 401 are expanded when deployed within the target vessel.

[0271] Figure 76B illustrates the axial lengthening of the expanded portion of the ALTC device 201. In some methods of use, the ALTC device 201 is lengthening proximally to encapsulate the anchor 401. In some methods of use, the anchor 401 has captured an obstruction or clot. In some methods of use, the ALTC device 201 is lengthening proximally to encapsulate the obstruction or clot. In some methods of use, the ALTC device 201 is lengthening proximally to encapsulate only a portion of the anchor 401. The collapsed portion 208 of the ALTC device 201 is shortened as the ALTC device 201 is axially lengthened. In some methods of use, the ALTC device 201 is not lengthened proximally to encapsulate a portion of the anchor 401. In some methods of use, the ALTC device 201 and the anchor 401 remain in the position shown in Figure 76A during clot removal.

[0272] Figure 76C illustrates the axial lengthening of the expanded portion of the ALTC device 201. The ALTC device 201 is lengthening proximally to capture the clot secured by the anchor 401. In some methods of use, the ALTC device 201 is lengthening proximally to circumscribe the entire anchor 401. The collapsed portion 208 of the ALTC device 201 is shortened as the ALTC device 201 is lengthened. For instance, collapsed portion 208 has a smaller axial length in Figure 76C than in Figure 76B. Figure 76C illustrates the axial lengthening ALTC device 201 is sufficient to completely capture the clot. In some methods of use, the ALTC device 201 and the anchor 401 can retract proximally to remove the clot. In some methods of use, the ALTC device 201 and the anchor 401 can retract proximally while the configuration shown in Figure 76A. In some methods of use, the ALTC device 201 and the anchors 401 can retract proximally while the ALTC device 201 does not circumscribe the entire anchor 401.

[0273] In Figure 76C, the deployed and expanded ALTC device 201 is longer, e.g., in length, than the deployed and expanded ALTC device 201 in Figure 76B. The collapsed portion 208 resides inside the outer sheath 203 or dual lumen shaft 243 and is shorter in Figure 76C than in Figure 76B. The diameter or cross-section of the ALTC device 201 can remain constant or substantially constant during axially lengthening. The diameter or cross-section of the ALTC device 201 can in some cases remain constant between the initial deployed configuration shown in Figure 76A and the expanded configurations shown in 76B and 76C. In some embodiments, two or more steps can occur simultaneously. In some

methods of use, the anchor 401 is partially deployed and the ALTC device 201 is axially lengthened to cover the anchor 401 simultaneously.

[0274] Figures 77A-77C illustrate additional views of the system. The anchor 405, or any of the anchors described herein, can be deployed in a similar manner as anchor 401. In some embodiments, the ALTC device 201 is axially lengthened with the expandable anchor 401 positioned near the opening end of the ALTC device 201. In some embodiments, the ALTC device 201 is extended over the expandable anchor 401. In some embodiments, the ALTC device 201 is positioned distal to the obstruction, clot, emboli, and/or foreign body for distal protection. In some embodiments, the ALTC device 201 is positioned distally or downstream in the direction of blood flow. In some embodiments, the expandable anchor 401 is deployed within the obstruction. In some embodiments, the ALTC device 201 retracts proximally over the expandable anchor 401 and the obstruction. In some embodiments, the obstruction is removed. In some embodiments, the ALTC device 201 is positioned distal to the obstruction for distal protection. In some embodiments, the expandable anchor 401 deploys within the obstruction and retracts to remove the obstruction while the ALTC device 201 remains in position. In some embodiments, the ALTC device 201 retracts subsequently to remove emboli. In some embodiments, the expandable anchor 401 and the ALTC device 201 retract as one unit to remove the obstruction. In some embodiments, the ALTC device 201 is retracted over the expandable anchor and obstruction and the entire device is removed.

[0275] Figure 78 illustrates another embodiment of an anchor 410. The anchor 410 can include any of the features of anchors described herein. In some embodiments, the anchor 410 can include a balloon. Balloon materials can be compliant, semi-compliant, or non-compliant. In some embodiments, the anchor 410 can comprise a spherical balloon. In some embodiments, the anchor 410 can comprise an oblong balloon. In some embodiments, the anchor 410 can include one or more shaped ends, including conical, square, spherical, tapered, etc. In some embodiments, the anchor 410 can include a dog bone shaped with proximal and distal areas of increased diameter balloon or stepped balloon having two or more different diameters. In some embodiments, the anchor 410 can include an axially or radially offset balloon. In some embodiments, the anchor 410 can comprise any shape including a conical balloon, tapered balloon, stepped balloon, square balloon, polygonal balloon, etc. In some embodiment, the balloons can be in series or in parallel or

circumferentially or radially. Additional balloon shapes are disclosed in U.S. Patent Application No. 11/851,848, filed Sept. 7, 2007 and published July 23, 2013 as U.S. Patent No. 8491623 (“Vogel”), which is incorporated by reference in its entirety. In some embodiments, the anchor 410 has a diameter. In some embodiments, the anchor 410 has two or more diameters. In some embodiments, the smaller diameter is more than 50% of the larger diameter, the smaller diameter is more than 60% of the larger diameter, the smaller diameter is more than 70% of the larger diameter, the smaller diameter is more than 80% of the larger diameter, the smaller diameter is more than 90% of the larger diameter, the smaller diameter is approximately equal to the larger diameter, etc. In some embodiments, two or more anchors 410 have the same shape. For instance, two or more anchors 410 can be spherical. In some embodiments, two or more anchors 410 can be identical. In some embodiments, two or more anchors 410 have a different shape. For instance, the first anchor 410 can be spherical and the second anchor 410 can be oblong. In some embodiments, two or more anchors 410 have a different diameter or cross-section. Figure 78 illustrates the ALTC device 201 with a single balloon. In some embodiments, the balloon is independently movable relative to the ALTC device 201. In some embodiments, the balloon and ALTC device 201 can also be retracted as one unit. Figure 79 for example illustrates balloons 410 are positioned in series. In some embodiment, the balloons can position side-by-side, in parallel, circumferentially, and/or radially. Further in some embodiments, the balloons’ shape and diameter can be configured so that there are gaps between the balloons to allow potential blood flow.

[0276] In some embodiments, the anchor 410 can be inflated. In some embodiments, an inflation medium such as gas or liquid is supplied to the anchor 410. In some embodiments, the anchor 410 can be inflated to form a rigid body. In some embodiments, the anchor 410 can be inflated to transmit a force to the obstruction, such as force to compress or move the obstruction. In some embodiments, the anchor 410 can be deflated. The inflation medium can be removed from the anchor 410. In some embodiments, the anchor 410 has a rough or textured outer surface. In some methods of use, the anchor 410 becomes entangled with the obstruction or clot described herein. In some embodiments, the anchor 410 has a smooth outer surface. In some embodiments, the anchor 410 can compress the obstruction or clot thereby opening the blood vessel. The anchor 410 can apply a

compressive force on the obstruction during inflation of the anchor 410. In some embodiments, the anchor 410 can be self-deployed. In some embodiments, the anchor 410 can include a shape memory material to deploy the anchor 410.

[0277] Figure 79 illustrates an embodiment including a plurality of anchors, such as a first anchor 410, a second anchor 410, a third anchor 410, and a fourth anchor 410. The system can include one or more of the anchors 410. In the illustrated embodiment, the system includes four anchors 410 but other configurations are contemplated (e.g., two anchors, three anchors, five anchors, six anchors, seven anchors, eight anchors, nine anchors, ten anchors, etc.). In some embodiments, two or more anchors 410 are inflated simultaneously. For instance, the anchors 410 can be coupled such that fluid can flow between the anchors 410. In some embodiments, two or more anchors 410 are inflated independently. For instance, each anchor can be separately supplied fluid for inflation, or include a common inflation lumen. In some embodiments, two or more anchors 410 are inflated in series. In some embodiments, two or more anchors 410 are inflated in parallel. In some embodiments, two or more anchors 410 are deflated simultaneously. In some embodiments, two or more anchors 410 are deflated independently. In some embodiments, two or more anchors 410 are deflated in series. In some embodiments, two or more anchors 410 are deflated in parallel. The two or more anchors 410 can be coupled via an inflation lumen 411. The inflation lumen 411 can allow delivery of the fluid to inflate the anchors.

[0278] Figure 79 illustrates the ALTC device 201 with a series of balloons positioned near the opening end of the ALTC device 201. In some embodiments, the balloons are independently movable relative to the ALTC device 201. In some embodiments, the balloons and the ALTC device 201 can also retracted as one unit. In some embodiments, the balloons function as anchors as described herein to entangle the clot. In some embodiments, the balloons function to compress the clot to open the target vessel. Other functions for the balloons are contemplated. In some embodiments, the balloons have a uniform size and shape, but can be positioned adjacent each other in order of increasing or decreasing diameter, or have different shapes in some embodiments.

[0279] Figure 80 illustrates the system within the vessel 408 with the obstruction 408 after deployment of the anchors 410. In some methods of use, the anchors 410 are inflated before axial lengthening of the ALTC device 201. In some methods of use, one or

more steps of deploying or inflating anchors 410 and axially lengthening can occur in any order. In some methods of use, the anchors 410 are inflated and then the ALTC device 201 is axially lengthened to cover the anchors 410. In some methods of use, two or more anchors 410 can be inflated before the ALTC device 201 is axially lengthened. In some methods of use, the anchors 410 are fixed such that the anchors 410 need not be inflated. In some methods of use, one or more anchors 410 are deflated before the ALTC device 201 is axially lengthened. In some methods of use, one or more anchors 410 are inflated after the ALTC device 201 is axially lengthened. In some methods of use, the anchors 410 are inflated and the ALTC device 201 is axially lengthened simultaneously. In some methods of use, the anchors 410 are inflated and the ALTC device 201 is axially lengthened independently. In some methods of use, the anchors 410 are only inflated if covered by the ALTC device 201.

[0280] Figure 80 illustrates the ALTC device 201 positioned distal to the obstruction. Figure 80 illustrates the balloons expanding within the obstruction. In some embodiments, one or more anchors 410 are positioned distally to the obstruction before inflation. After inflation, the one or more distal anchors 410 can push the obstruction proximally. In some embodiments, one or more anchors 410 are positioned proximally to the obstruction before inflation. After inflation, the one or more distal anchors 410 can push the obstruction distally toward the ALTC device 201.

[0281] In some methods of use, the ALTC device 201 is positioned distally to the anchors 410. In some methods of use, the ALTC device 201 provides distal protection during clot removal, akin to a filter in some cases. In some methods of use, the anchors 410 inflate within the obstruction. In some methods of use, the anchors 410 are positioned to entangle the obstruction. In some methods of use, the anchors 410 move after deployment. In some methods of use, the anchors 410 move simultaneously. In some methods of use, the anchors 410 move independently, or all in concert in some cases. In some methods of use, the anchors 410 move distally therefore moving the obstruction distally. In some methods of use, the anchors 410 move toward the ALTC device 201. After deployment of the anchors 410, the obstruction and the anchors 410 can move together as a unit. In some methods of use, the anchors 410 move after axially lengthening of the ALTC device 201. In some methods of use, the anchors 410 move before axially lengthening of the ALTC device 201.

[0282] Figure 81 illustrates an embodiment of an anchor 415. The anchor 415 can include any of the features of anchors described herein. In some embodiments, the anchor 415 can comprise a disk. In some embodiments, the anchor 415 can be arcuate shaped such as round or circular, or ovoid. In some embodiments, the anchor 415 can have a constant or variable diameter. In some embodiments, the anchor 415 can be any shape, including a polygon, elliptical, etc. In some embodiments, the anchor 415 can be entirely flat or have flat surfaces. In some embodiments, the anchor 415 can be concave, convex, or another curved shaped. For instance, a first surface 416 of the anchor 415 can be concave and a second surface 417, opposite the first surface can be concave. For instance, a first surface 416 of the anchor 415 can be convex and a second surface 417, opposite the first surface can be convex. In some embodiments, the anchor 415 can have a smooth outer surface. In some embodiments, the anchor 415 can include a roughened or porous outer surface. The anchor can conform when contacting a surface such as a vessel wall.

[0283] In some embodiments, the anchor 415 can be deployed similar to anchor 241. In some embodiments, the anchor 415 can self-deploy. In some embodiments, the anchor 415 can include a shape memory material to deploy the anchor 415. In some embodiments, the anchor 415 can be inflated. In some embodiments, an inflation medium such as gas or liquid is supplied to the anchor 415. In some embodiments, the anchor 415 can be deflated. Figure 81 illustrates the ALTC device 201 with a single disk positioned proximal to the ALTC device 201. In some embodiments, the expandable disk is independently movable relative to the ALTC device 201. In some embodiments, the expandable disk and ALTC device 201 can also be retracted as one unit. In some embodiment, the anchor 415 is adjacent, side-by-side or offset to the ALTC device 201. In some embodiment, the anchor 415 is coaxial or in-line to the ALTC device.

[0284] Figure 82 illustrates an embodiment including a first anchor 415, a second anchor 415, a third anchor 415, a fourth anchor 415, a fifth anchor 415, and a sixth anchor 415. The system can include one, two, or more of the anchors 415. In the illustrated embodiment, the system includes six anchors 415 but other configurations are contemplated (e.g., about, at least about, or no more than about two anchors, three anchors, four anchors, five anchors, seven anchors, eight anchors, nine anchors, ten anchors, etc.). In some embodiments, the anchor 415 comprises a helix or helical structure. For instance, the first

anchor 415 can be joined with the second anchor 415 to form a helix. A helical anchor is disclosed, for example, in Figure 6A of PCT/IB2014/066389, filed Nov. 27, 2014 and published June 4, 2015 as WO 2015/079401 (“Yachia”), which is incorporated by reference in its entirety.

[0285] In some embodiments, two or more anchors 415 are deployed simultaneously. In some embodiments, two or more anchors 415 are deployed independently. For instance, the first anchor 415 and the second anchor 415 can be deployed independently. In some embodiments, two or more anchors 415 are deployed in series. For instance, the first anchor 415 can be deployed before the second anchor 415. In some embodiments, two or more anchors 415 are deployed in parallel. Figure 82 illustrates the ALTC device 201 with a series of expandable disks positioned proximal to the ALTC device 201. In some embodiments, the expandable disks are independently movable relative to the ALTC device 201. In some embodiments, the expandable disks and ALTC device 201 can also be retracted as one unit.

[0286] Figure 83 illustrates the system within the vessel 408 with the obstruction 409. In some methods of use, one or more steps of deploying or inflating anchors 415 and axially lengthening can occur in any order. In some methods of use, the anchors 415 are deployed before axial lengthening of the ALTC device 201. In some methods of use, one or more anchors 415 are deployed before the ALTC device 201 is axially lengthened to cover the anchors 410. In some methods of use, one or more anchors 415 are deployed after the ALTC device 201 is axially lengthened. In some methods of use, the anchors 415 are deployed and the ALTC device 201 is axially lengthened simultaneously. In some methods of use, the anchors 415 are only deployed if covered by the ALTC device 201. Figure 83 illustrates the ALTC device 201 positioned distal to the obstruction and the expandable disks deployed within the obstruction. The single disk embodiment shown in Figure 81 can be deployed within the obstruction in a similar manner. In some methods of use, the ALTC device 201 is positioned distally to the anchors 415. In some methods of use, the ALTC device 201 provides distal protection during clot removal. In some methods of use, the anchors 415 deploy within the obstruction or clot. In some methods of use, the anchors 415 move after deployment.

[0287] Figure 84 illustrates an embodiment of an anchor 420. The anchor 420 can include any of the features of anchors described herein. In some embodiments, the anchor 420 can comprise a funnel. In some embodiments, the anchor 420 can include a round or circular opening. In some embodiments, the anchor 420 can taper from a larger diameter or cross-section to a smaller diameter or cross-section. In some embodiments, the anchor 420 can taper along the length of the anchor 420. In some embodiments, the anchor 420 can be any generally conical shape. In some embodiments, the anchor 420 can include an inflection point. In some embodiments, the anchor 420 can include a radially outward flare. In some embodiments, the anchor 420, or a surface thereof, is concave. In some embodiments, the anchor 420, or a surface thereof, is convex. In some embodiments, the anchor 420 can have a smooth outer surface. In some embodiments, the anchor 420 can include a roughened or porous outer surface. In some embodiment, the anchor 420 is adjacent, side-by-side or offset to the ALTC device 201. In some embodiment, the anchor 420 is coaxial or in-line to the ALTC device.

[0288] In some embodiments, the anchor 420 is formed as a mesh or braid, laser cut or stent structure. The funnel shape of the anchor 420 can in some cases assist in retrieving and containing the obstruction or clot. In some embodiments, the anchor 420 comprises structural features to assist in the deployment of the funnel shape, such as to hold the rim 421 of the funnel shape open. In some embodiments, the anchor 420 can include struts comprising a shape memory or self-expanding material such as nitinol, or other stent structure, mesh, and/or webbing. In some embodiments, the anchor 420 can be deployed similar to anchor 241. In some embodiments, the anchor 420 can be self-deployed. In some embodiments, the anchor 420 can include a shape memory material to deploy the anchor 420. The anchor 420 can include a rim 421. The rim 421 can include any of the features of the capture guides described herein.

[0289] In some embodiments, the proximal end opening of the anchor 420 includes the rim 421 that takes the form of, in some embodiments, a radially expandable shape memory partial or full ring-like annular structure. The rim 421 expands once freed or released from a constraining member such as any sheath or tube described herein. In some embodiments, the rim 421 is coupled with a portion of a mesh, interlaced structure, or covering 422. In some other embodiments, the rim 421 and the proximal end of the covering

422 can be sutured in place using silk or polymeric filaments such as Ultra-High Molecular Weight polyethylene, Nylon, PET, PTFE. In some embodiments, the covering 422 comprises with a low durometer polymeric material.

[0290] The rim 421 and/or the covering 422 can be formed, for example, from metallic, shape memory, or other appropriate materials. In some embodiment, the rim 421 can include a loop configuration and be formed from nitinol shape memory wire of various geometries such as round, oval, elliptical, flat, and the like. The rim 421 can be formed of different shapes such as a circular loop, oval loop, z-shape, etc. In some embodiment, the rim 421 can be shaped set either into coils, multiple full circles, full circle or partial circles where the ends of the wire formed into two legs. The partial circle can be from, for example, 180 degrees to 359 degrees or 220 degrees to 359 degrees. The legs can be configured to be off-axis to the loop such that it can be right angle, acute or obtuse angle relative to the loop. It can be arcuate and form a partial or full ring as illustrated, and can circumscribe or otherwise form an outer diameter, and define the proximal-most end of the anchor 420. The anchor 420 can in some embodiments include a single loop or multiple loops positioned along the length of the covering 422. The anchor 420 can be configured to be compressed and positioned within a lumen of a shaft during introduction into the vascular system where the anchor 420 is configured to be positioned coaxially within the obstruction or clot. In some methods of use, the anchor 420 is configured to be deployed to entangle with the obstruction or clot.

[0291] Figure 84 illustrates the ALTC device 201 with an expandable funnel like anchor. In some embodiments, the funnel shaped anchor is positioned proximal to the ALTC device 201. In some embodiments, the funnel shaped anchor is independently movable relative to the ALTC device 201. In some embodiments, alternatively, the anchor and ALTC device 201 can move as one unit.

[0292] Figure 85 illustrates an embodiment including a plurality of anchors, such as a first anchor 420, a second anchor 420, a third anchor 420, a fourth anchor 420, and a fifth anchor 420. The system can include one or more of the anchors 420. In the illustrated embodiment, the system includes five anchors 420 but other configurations are contemplated (e.g., two anchors, three anchors, four anchors, six anchors, seven anchors, eight anchors, nine anchors, ten anchors, etc.). In some embodiments, two or more anchors 420 are deployed simultaneously. In some embodiments, two or more anchors 420 are deployed

independently. For instance, the first anchor 420 and the second anchor 420 can be deployed independently. In some embodiments, two or more anchors 420 are deployed in series. For instance, the first anchor 420 can be deployed before the second anchor 420. In some embodiments, two or more anchors 420 are deployed in parallel. Figure 85 illustrates the ALTC device 201 with expandable funnel like anchors. In some embodiments, the funnel shaped anchors are positioned proximal to the ALTC device 201. In some embodiments, the funnel shaped anchors are independently movable relative to the ALTC device 201. In some embodiments, alternatively, the anchors and ALTC device 201 can move as one unit.

[0293] Figure 86 illustrates the system within the blood vessel 408 and the obstruction 409. In some methods of use, one or more steps of deploying one or more anchors 420 and axially lengthening can occur in any order. In some methods of use, one or more anchors 420 are deployed before axial lengthening of the ALTC device 201. In some methods of use, the anchors 420 are deployed before the ALTC device 201 is axially lengthened to cover the anchors 420. In some methods of use, one or more anchors 420 are deployed after the ALTC device 201 is axially lengthened. In some methods of use, the anchors 420 are deployed and the ALTC device 201 is axially lengthened simultaneously. In some methods of use, the anchors 420 are deployed and the ALTC device 201 is axially lengthened independently. In some methods of use, the anchors 420 are only deployed if covered by the ALTC device 201. In some methods of use, the ALTC device 201 is positioned distally to the anchors 420. In some methods of use, the ALTC device 201 provides distal protection during clot removal. In some methods of use, the anchors 420 deploy within the obstruction or clot. In some methods of use, the anchors 420 move after deployment.

[0294] Figure 86 illustrates an embodiment in which the anchors 420 face forward. The anchors 420 can taper inward from a distal end 423 to a proximal end 424. The rim 421 of each anchor 420 can be located at the distal end 423 of each anchor 420. Figure 87 illustrates a system with anchors 420 deployed within a vessel 408 comprising an obstruction 409. Figure 87 illustrates an embodiment in which the anchors 420 face backward. The anchors 420 can taper inward from the proximal end 424 to a distal end 423. The rim 421 of each anchor 420 can be located at the proximal end 424 of each anchor 420. In some embodiments, the anchors 420 have a single configuration, e.g., all anchors 420 face

forward as shown in Figure 86, all anchors 420 face backward as shown in Figure 87. In some embodiments, two or more anchors 420 have a different configuration, e.g., the first anchor 420 faces forward and the second anchor 420 faces backward. In some embodiments, the anchor 420 can switch between facing forward and facing backward. In some embodiments, the anchors 420 can be configured to roll out, invert, evert, and/or variably lengthen proximally or distally between facing forward and facing backward. In some embodiments, one or more anchors 420 can be configured to switch between facing forward and facing backward. In some embodiments, one or more anchors 420 can be fixed as either facing forward or facing backward. Figures 86 and 87 illustrate the ALTC device 201 positioned distal to the obstruction. Figures 86 and 87 illustrate the expandable funnel shape anchors deployed within the obstruction.

[0295] The anchors described herein can have any shape. Other expandable shapes and/or geometric anchors are contemplated. In some embodiments, the anchor can be shaped as a coil. In some embodiments, the anchor can be shaped as a loop. In some embodiments, the anchor can be shaped as a clover. In some embodiments, one or more anchors are offset to the ALTC device 201. In some embodiments, the anchor can be coaxial to the ALTC device 201 wherein the anchors can be attached to the shaft of the ALTC device 201. In some embodiments, this configuration allows the anchor and the axial lengthen device move as one unit.

[0296] U.S. Patent Application No. 14/602,014, filed Jan. 21, 2015 and published Aug. 9, 2016 as U.S. Patent No. 9408620 (“Rosenbluth”); U.S. Patent Application No. 08/723,619, filed Oct. 20, 1996 and published Apr. 20, 1999 as U.S. Patent No. 5895398 (“Wensel”); U.S. Patent Application No. 08/968146, filed Nov. 12, 1997 and published Sept. 7, 1999 as U.S. Patent No. 5947985 (“Imran”); U.S. Patent Application No. 09/756476, filed Jan. 8, 2001 and published Dec. 16, 2003 as U.S. Patent No. 6663650 (“Sepetka”); U.S. Patent Application No. 09/789332, filed Feb. 20, 2001 and published Jan. 11, 2005 as U.S. Patent No. 6840950 (“Sanford”); U.S. Patent Application No. 12/581,960, filed Oct. 20, 2009 and published Jan. 10, 2012 as U.S. Patent No. 8092486 (“Berrada”); U.S. Patent Application No. 11/580,546, filed Oct. 13, 2006 and published Aug. 28, 2012 as U.S. Patent No. 8252017 (“Paul”); U.S. Patent Application No. 12/564892, filed Sept. 22, 2009 and

published Oct. 30, 2012 as U.S. Patent No. 8298252 (“Krolik”) are all incorporated by reference herein in their entireties.

[0297] In some embodiments, the clot treatment device described by Rosenbluth et al. can be used in place of, or in combination with, the anchors described herein. Referring now to Figures 88A-88H, embodiments of an anchor 425 are disclosed. Referring to FIG. 88A, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by a cylindrical disk shape with a rounded triangular cross-section. Referring to FIG. 88B, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by a cylindrical disk shape with a rounded triangular cross-section wherein the diameter of the disk increases along the length of the anchor 425 thus forming a conical exterior extent. Referring to FIG. 88C, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by a cylindrical disk shape with a rectangular cross-section. Referring to FIG. 88D, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by a cylindrical disk shape with a linear (non-rounded) triangular cross-section. Referring to FIG. 88E, some of the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by a cylindrical disk shape with a rounded cross-section and others have a rectangular cross section. Referring to FIG. 88F, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 alternate between cylindrical disk shape with a T-shaped cross-section and a flare-shaped cross-section. Referring to FIG. 88G, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by a partial cylindrical disk shapes. Referring to FIG. 88H, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by tabs and bumps or protuberances arising from the cylindrical surface of the anchor 425. In some embodiments, the anchors described herein provide greater surface area along the anchor than an anchor that is uniformly cylindrical. In some methods of use, the increased surface area facilitates the treatment and/or retrieval of the obstruction or clot.

[0298] In some embodiments, the anchor 425 can have a generally cylindrical shape that, during use, provides a flow lumen for blood across a clot. The anchor 425 is not, however, limited to a generally cylindrical shape. For example, the shape can be generally

conical, generally concave or generally convex along its axis, so long as such shapes provide the aforesaid lumen for blood flow. In some embodiments, the anchor 425 also has a series of radially extending portions 426 which are separated by generally cylindrical portions 427. In some embodiments, the clot treatment device 425 can be porous so as to allow the flow of blood therethrough. In some embodiments, the anchor 425 is made from a mesh or braided material. The material can be a superelastic material such as nitinol or an alternative material such as cobalt chrome alloy. In some embodiments, the anchor 425 can be made from a wire lattice, wire braid or stent. In some embodiments, the anchor 425 can be self expanding.

[0299] In some embodiments, the anchor radially expands into the clot. In some methods of use, at least a portion of the anchor expands distal of the clot. As shown in some figures herein, at least one of the anchors of a plurality of anchors can be located distal to the clot upon expansion of the anchors. In some methods of use, upon expansion of the anchor, blood flowthrough the clot is restored. More specifically, the blood is now free to move through the mesh of the anchor and exit the anchor distal to the clot. As a result, the acute condition of blockage is corrected thus immediately improving the circulation of oxygenated blood in the patient. The expansion, inflation, or deployment of the anchors described herein can impinge or cut into the clot material. This entanglement can enhance the subsequent removal of the clot since portions of the clot collect between the radially extending portions 426; through the pores of the mesh forming the radially extending portions 426; along the longitudinal cylindrical sections 427 between the radially extending portions 426 of the anchor 425; and/or within the anchor 425 itself.

[0300] In some methods of use, the deployment of the anchor 425 results in an outwardly expanding generally cylindrical force being urged against an inner surface of the clot. In some methods of use, this force pushes the clot material outwardly and creates a lumen through which blood flow is restored. In some methods of use, the outwardly expanding generally cylindrical force can vary in magnitude along the axis of the anchor, due in part to the shape of the anchor. In some embodiments, the deployment of the anchor changes the angular orientation of the anchor with respect to the axis of the system. In some methods of use, this angular change or twisting can improve or enhances adherence of clot material to the anchor 425.

[0301] The clot treatment devices disclosed in Rosenbluth may be included in a system with the ALTC device 201 described herein. The ALTC device 201 can surround the clot treatment devices similar to the anchors described herein. After the clot treatment device has been expanded, the ALTC device 201 can be axially lengthened to capture the clot. In one embodiment, the clot treatment device and the ALTC device 201 are pulled back simultaneously in a proximal direction. This is followed by the entire system being withdrawn.

[0302] The clot and foreign body removal device of Wensel can be used in place of, or in combination with, the anchors described herein. Referring now to Figures 88I-88J, embodiments of the anchor 428 are disclosed. The anchor 428 can be a clot capture coil. In some embodiments, the coil is made from a flexible solid elastic or superelastic material which has shape memory, e.g., it can deform to a straight position and then return to a resting coil configuration. In some embodiments, the coil is made out of a solid nitinol wire with a diameter of, e.g., about 0.0005 inches to about 0.038 inches. Nitinol is preferred in some cases because of its superelasticity and its shape memory. However, other solid materials that are also elastic or superelastic and have shape memory could also be used such as some synthetic plastics, metallic alloys, and the like. The diameter of the coils can vary depending on the size of the vessel occluded. The diameter can range from about 1 mm for small vessels to about 30 mm for large vessels such as the pulmonary arteries or inferior vena cava. The length of the coil can also vary but typically ranges from about 3 to about 300 mm in the proximal to distal direction. Because the nitinol coil is superelastic, the coil can be extended to a completely straight configuration with the use of minimal force and then reform to its natural resting configuration when the force is removed. In some embodiments, the coil is made out of a solid biphasic material which changes shape upon heating or the passage of electric current. In some embodiments, the coil is cone-shaped.

[0303] In some embodiments, the anchors described herein can comprise a shape memory body. The anchor can comprise a single wire or multiple wires. The anchor can comprise one or more loops. The anchor can comprise one or more helices. In some embodiments, the loops and/or helices can have an increasing diameter from proximal to distal end of the anchor. In some embodiments, the loops and/or helices can have a

decreasing diameter from proximal to distal end of the anchor. In some embodiments, the loops and/or helices can have a variable diameter from proximal to distal end of the anchor.

[0304] The apparatus of Imran can be used in place of, or in combination with, the anchors described herein. Referring now to Figure 88K, an embodiment of the anchor 429 is disclosed. The anchor 429 can include a brush. The brush is formed on the distal extremity of the flexible elongate tubular member. The brush is comprised of a plurality of radially extending bristles formed of a suitable soft material such as Nylon with the brush having an outer diameter corresponding generally to the inner diameter of the lumen defined by the wall. The distal extremity is provided with a plurality of randomly disposed ports interposed between the bristles for supplying irrigation liquid to the brush. With irrigation liquid being supplied through the ports and aspiration taking place through the aspiration port, the brush can be rotated by rotating the proximal extremity of the therapeutic catheter. By moving the catheter back and forth, the bristles can come into engagement with the wall throughout the entire length of the chamber to remove the plaque in small particles. As the small particles are removed they can be aspirated from the chamber through the aspiration port.

[0305] The obstruction removal device of Sepetka can be used in place of, or in combination with, the anchors described herein. Referring now to Figures 88L-88M, the obstruction removing device 430 has an engaging element 431 extending from an insertion element 432. The engaging element 431 is movable from a collapsed position to an expanded position. When the engaging element 431 is contained within a sheath or other member, the engaging element 431 is in a relatively straight configuration. The engaging element 431 has a distal portion, which forms a relatively closed structure, which can catch or trap the obstruction, or any part thereof, to prevent migration of the obstruction or part thereof. The engaging element has a proximal portion which is formed with smaller coils than the distal portion. The proximal portion engages the obstruction as described below. The engaging element 431 preferably has a number of markers which provide an indication as to how much of the engaging element extends from the sheath. For example, markers may indicate when the engaging element 431 is $\frac{1}{2}$, $\frac{3}{4}$ or fully exposed. In this manner, the user may quickly advance the engaging element 431 through the sheath without inadvertently exposing and advancing the engaging element 431 out of the sheath. The markers can also be used to

provide a controlled diameter of the engaging element 431 since the diameter of the engaging element is known for the various positions corresponding to the markers. The markers may also be used to size the vessel in which the engaging element 431 is positioned by observing when the engaging element 431 engages the vessel walls and determining the size of the engaging element 431 using the markers.

[0306] The engaging element 431 is preferably made of a superelastic material, such as nitinol, and has a diameter of, in some cases, about 0.005-0.018 inch, about 0.005-0.010 inch or about 0.008 inch. The engaging element 431 can have a rounded, atraumatic tip to prevent damage to the vessel and facilitate advancement through the vessel and/or sheath. A radiopaque wire, such as platinum ribbon having a width of 0.004 inch and a thickness of 0.002 inch, is preferably wrapped around the engaging element 431 to improve radiopacity. The device is preferably self-expanding but may also be expanded with an actuator. The actuator is preferably a thin filament which is tensioned to move the device to the expanded position. An advantage is that the filament extends through the same lumen as the device thereby minimizing the overall size of the device. It is understood that throughout discussion of the devices and methods herein that any of the anchors described herein may be expanded using the actuator rather than being self-expanding. The obstruction removal device shown in Figure 88M has a first section with larger diameter coils than a second section. A third section also has larger coils than the second section with the second section positioned between the first and third sections. The obstruction removal device may have a number of alternating small and large sections which can enhance the ability of the obstruction removal device to engage various obstructions. The obstruction removal device can have four large sections with relatively large coils and three sections having smaller coils, but other configurations are contemplated with different numbers of sections.

[0307] The expansion elements of Sanford can be used in place of, or in combination with, the anchors described herein. Referring now to Figures 88N, an anchor 433 is shown. The anchor 433 can include a helical expansion ring connected to the inlet of the anchor. Expansion ring has a proximal end and a distal end. The distal end can be fixed to guidewire. Alternately, the anchor could have resilient, expansion material embedded in its inlet. The anchor can include inclined “sail” at its inlet. The sail acts as an expansion mechanism to expand the anchor when exposed to blood flow. In some embodiments, the

anchor has its inlet coated with a hydrogel coating which swells upon contact with blood and acting to expand the inlet of filter.

[0308] The filter devices of Berrada can be used in place of, or in combination with, the anchors described herein. Referring now to Figures 88O, the anchor 434 can be an everting filter. Everting filter includes a flexible, mesh, filter body. The filter body may be formed of a plurality of wires or strands which can be used to form the mesh filter body through a variety of methods, for example, braiding, knitting, weaving, helically winding, and counterwinding. The mesh can be fused at some or all of the fiber or strand intersection points. The mesh can also be electrospun, and formed of sheet or film having holes formed by laser drilling, punching, dissolving components selectively, and the like. The strands can be formed of material such as wire, which can be metallic wire or polymeric wire. The wire may be substantially circular in cross section or may have any number of square, rectangular or irregular cross sectional profiles. The mesh is preferably self-expanding. The self-expanding mesh can be formed totally or in part from self-expanding Nitinol, Elgiloy, titanium, or stainless steel wires and the like, and combinations thereof. The self-expanding mesh can also be formed of engineering polymers, for example, liquid crystal polymer, PEEK, polyimide, polyester, and the like. A preferred mesh is formed of Nitinol wires, which can be heat set to the desired expanded shape. The mesh can preferably be heat set to a desired bias shape. Another mesh is highly elastic, and preformed by mechanical overstress to the desired expanded shape. The mesh is preferably made radiopaque by means of plating, core wires, tracer wires, or fillers that have good X-ray absorption characteristics compared to the human body. The mesh may be either partly or totally radiopaque.

[0309] The filter body may be seen to have a plurality of pores or openings between the filter body strands or wires. The pores have an average pore size over the filter body, where the individual pore sizes may vary depending upon the location over the filter body. The filter body also has a proximal opening formed in filter body proximal region. The filter body may also be considered to have an interior within the filter body and an exterior defined outside of the filter body. The everted shape of filter defines an everted cavity or concave region bounded by filter body everted surface region or cavity side walls and the filter body distal-most extent. It may be seen from inspection of Figure 88O that axially translating proximal ring relative to distal ring while holding the filter body diameter

consistent may change the degree of eversion of filter body. The filter material occupying distal-most region may therefore change with the degree of eversion of filter, with different locations of filter body being distal-most varying as a function of the degree of eversion. The length of a distal cavity will increase with increasing eversion.

[0310] The filter devices of Paul can be used in place of, or in combination with, the anchors described herein. Referring now to Figures 88P-88Q, the anchor 435 and anchor 436 are everted. The anchor 435 is everted to form a proximally facing concave geometry. The filter portion may be everted by moving the control wires proximally, thereby pulling the first end of the filter portion back over the rest of the filter portion. Further, the filter portion may also be made of a shape memory material such that the filter portion has two defined geometries. For example, the mesh material may be made of a shape memory alloy so that the mesh material is biased into a straight tubular geometry in a non-everting state at a first temperature. The first temperature being controlled, for example, by fluid flowing through the guiding member across the medical device. At a second temperature, such as the ambient temperature inside the vessel, the filter portion is biased into a proximally facing concave geometry. When the filter portion is biased into the proximally facing concave geometry, the filter portion everts causing the filter portion to expand against the inner wall of the vessel. While the medical device is expanded against the inner wall of the vessel, the filter portion serves to collect emboli that may break free from the stenosed area preventing such emboli from blocking smaller vessels downstream of the medical device. When everted, the first end of the filter portion is biased against the inner wall of the vessel forcing the fluid to flow through the proximally facing concave geometry formed by the filter portion. Therefore, emboli are trapped in the distal region of the proximally facing concave geometry. The medical device remains in this expanded state during the interventional procedure to capture any emboli that break free from the stenosis. After the interventional procedure is completed, the medical device may be removed. To trap the emboli in the filter portion, the control wires may be pulled further proximally drawing the filter portion against the guiding member.

[0311] For anchor 436, the control wires extend through the tubular geometry of the filter portion. Accordingly, the control wires form a frame structure along the length of the filter portion. The control wires may be made of a synthetic material, a stainless steel, or a shape memory alloy, such as Nitinol. The shape memory characteristics of the control wire

may be used to support the first end of the filter portion against the inner wall of the vessel. Supporting the filter portion against the wall of the vessel ensures that the fluid will flow through the proximally facing concave geometry formed by the everted filter portion, thereby causing emboli to be trapped by the medical device.

[0312] The cages of Krolik can be used in place of, or in combination with, the anchors described herein. Referring now to Figure 88R, the anchor 437 can include a macerator cage. Generally, the macerator cage includes a closed proximal or first end and an open distal or second end. The cage may include a plurality of struts extending between the first and second ends and/or around a periphery of the cage, thereby defining a cylindrical or other tubular outer wall including a plurality of apertures.

[0313] The open distal end of the cage may include a plurality of distally protruding elements or distal tips 438. The cage includes at least two different types of struts. For example, the cage may include a plurality of relatively thick struts that extend substantially continuously along a length of the cage e.g., in a first helical configuration between the first and second ends. In addition, the cage may include a plurality of relatively thin struts, which may connect adjacent thick struts together. As shown, the thin struts are not substantially continuous as are the thick struts, but may extend in a discontinuous pattern helically and/or circumferentially around the cage. Optionally, the thin struts may also have bends or other features, e.g., relatively thinned or perforated portions, that allow the struts to bend relatively easily compared to the thick struts. The apertures may be defined by the spaces between the thick struts and the thin struts, thereby defining a desired pore size for the cage.

[0314] The distal tips 438 on the open end may provide a substantially atraumatic distal end for the cage, e.g., to prevent puncture or other damage to a wall of a body lumen within which the cage is deployed. In addition or alternatively, the distal tips 438 may be sufficiently flexible to allow the distal tips to twist helically and/or interlock with one another during use. The distal tips 438 may facilitate engaging and/or removing obstructive material within a body lumen. Alternatively, the distal tip 438 can include a series of slots or indentations spaced apart along a length of the distal tip e.g., that may allow the distal tips to entangle with each other and/or with the obstructive material captured or otherwise engaged by the distal tips to facilitate removal. For example, when the cage is rotated, the distal tips

438 and obstructive material may be wound together, e.g., such that portions of other distal tips and/or obstructive material may enter the slots and the distal tips 438 become interlocked with one another.

[0315] During distal advancement, the cage may be concurrently advanced and rotated, e.g., manually or using a driveshaft. This may cause the distal tips 438 of the cage to track along the inside wall of the body lumen, e.g., in a helical manner as the cage is advanced. When thrombus or other obstructive material is encountered, the distal tips 438 may pass between the material and the wall of the body lumen, thereby positioning the material inside the cage. In some methods of use, the anchors described herein are rotated. In some methods of use, the anchors described herein are translated.

[0316] The distal tips 438 of the cage may facilitate separation and/or capture of material within the cage. For example, the edges of the distal tips may provide distal leading edges of the cage that are not a substantially smooth cylinder but define an undulating surface. Consequently, the distal tips 438 of the cage may act as a saw by repeatedly making contact with the material as the cage is rotated, which may increase the chance of material being dislodged from the wall of the body lumen and/or captured within the cage. To further ensure that the leading edge of the cage passes between the unwanted material and the wall of the body lumen, the distal tips 438 and/or edges of the struts may also act as blades shearing along the wall of the body lumen to draw adherent material into the cage. Thus, the struts may cut or otherwise separate the interface between the body lumen and the obstructive material.

[0317] The distal tips 438 may be formed such that they conform substantially to the cylindrical shape of the cage, e.g., defining a diameter similar to the rest of the expanded cage, although alternatively the distal tips 438 may be biased radially outwardly, e.g., to ensure that the distal tips 438 pass between the wall of the body lumen and the obstructive material and/or enhance engagement of the distal tips against the wall of the body lumen. Alternatively, the distal tips 438 may be biased to extend radially inwardly, e.g., laterally inwardly, relative to a central longitudinal axis of the apparatus, e.g., to prevent substantial risk of damage to the wall of the body lumen.

[0318] The systems described herein are intended for use in any size vessel. The systems can be deployed in vessels with a diameter about 10 μm , 20 μm , 30 μm , 40 μm , 50

μm, 60 μm, 70 μm, 80 μm, 90 μm, 100 μm, 200 μm, 300 μm, 400 μm, 500 μm, 600 μm, 700 μm, 800 μm, 900 μm, 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm, 15 mm, 16 mm, 17 mm, 18 mm, 19 mm, 20 mm, 21 mm, 22 mm, 23 mm, 24 mm, 25 mm, between 1 mm and 8 mm, between 10 μm, and 1 mm, between 100 μm and 1 mm, between 100 μm and 10 mm etc. The anchors can have a diameter or cross-section about 10 μm, 20 μm, 30 μm, 40 μm, 50 μm, 60 μm, 70 μm, 80 μm, 90 μm, 100 μm, 200 μm, 300 μm, 400 μm, 500 μm, 600 μm, 700 μm, 800 μm, 900 μm, 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm, 15 mm, 16 mm, 17 mm, 18 mm, 19 mm, 20 mm, 21 mm, 22 mm, 23 mm, 24 mm, 25 mm, less than 10 mm, less than 1 mm, less than 100 μm, less than 10 μm, etc. The ALTC device 201 can have a diameter or cross-section about 10 μm, 20 μm, 30 μm, 40 μm, 50 μm, 60 μm, 70 μm, 80 μm, 90 μm, 100 μm, 200 μm, 300 μm, 400 μm, 500 μm, 600 μm, 700 μm, 800 μm, 900 μm, 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm, 15 mm, 16 mm, 17 mm, 18 mm, 19 mm, 20 mm, 21 mm, 22 mm, 23 mm, 24 mm, 25 mm, less than 10 mm, less than 1 mm, less than 100 μm, less than 10 μm, etc., or ranges incorporating any two of the aforementioned values. It is contemplated that different sizes of the systems will be available for selection by the user based on the obstruction and the target vessel.

[0319] A perspective view of another embodiment of a capture system is shown in Figure 89. Figure 89 also illustrates non-limiting examples of various possible elements that can be included in a material capture system, according to some embodiments described herein. As illustrated in Figure 89, included in some embodiments are any number of, such as one, two, or more of the following components: a thrombus capturing device or ALTC device 201 having any of the features described herein, e.g., a pusher wire or inner pusher 202, a first tubular member such as an outer sheath (not shown), and an anchor such as any of the anchors described herein. Figure 89 illustrates an anchor 450. In some embodiments, the ALTC device 201 can attach to the anchor 450. In some embodiments, the anchor 450 functions as the capture guide 204 described herein. In some embodiments, the anchor 450 comprises a metallic material, such as Nitinol. The anchor 450 can be in the form of, for example, a loop, as shown, or any closed shape including an oval, ellipse, or polygon. The anchor 450 can be in the form of an open shape such as any linear or non-linear segment. The

ALTC device 201 and the anchor 450 can be coupled such as being sutured together. The ALTC device 201 and the anchor 450 can be encapsulated in a low durometer polymeric material. The anchor 450 can be coupled to the outer sheath 203. The proximal end of the ALTC device 201 can be coupled to an inner pusher 202 as described herein. The anchor 450 can have any of the features of anchors described herein, including anchor 401.

[0320] The anchor 450 can be connected to an anchor pusher 451. The anchor pusher 451 can, in some embodiments, be an elongate tubular member with a central lumen therethrough, and have a proximal end and a distal end, both shown in Figure 89. The distal end of the anchor pusher 451 can be operably connected to the anchor 450 (e.g., tubular mesh as described herein). In some embodiments, anchor 450 can be fixed or stationary with respect to the anchor pusher 451. In some embodiments, anchor 450 can be move axially with respect to the anchor pusher 451. The proximal end can include any number of, such as one, two, or more of the following components: a hemostasis assembly 206, a flush port 207, and a collapsed segment 208. The anchor pusher 451 extends proximally and can be coupled to the hemostasis assembly 206. The anchor pusher 451 extends proximally and can be coupled to a luer. In some embodiments, the anchor pusher 451 can have a lumen to allow passage of a guidewire. In some embodiments, the anchor pusher 451 is a solid shaft.

[0321] Figure 89 also shows the distal end of the ALTC device 201 in a deployed configuration. In some methods of use, a portion of the ALTC device 201 is axially extended while the remaining length of the ALTC device 201 is collapsed and contained within a sheath as previously described. In some methods of use, the ALTC device 201 can be collapsed and tracked through a sheath or guide catheter (not shown) to the intended treatment area. In some embodiments, the guide catheter can be retracted proximally to initially deploy the ALTC device 201 and the self expandable anchor 450. For instance, the retraction of the guide catheter can cause the anchor 450 to expand. The anchor 450 can include a compressed or constrained configuration while within the guide catheter. During the initial deployment, the anchor 450 is released from a constrained position to a neutral position. In the neutral position, the anchor 450 creates a perimeter for the ALTC device 201. In the case of a loop or other circular configuration, the anchor 450 can create a constant diameter. In the case of other shapes or configurations, the anchor 450 can create a constant

cross-section. Alternatively or in combination, in other methods of use, the ALTC device 201 can be advanced distally from the guide catheter to deploy the ALTC device 201.

[0322] In some cases, only a small fractional portion of the ALTC device 201, such as less than about 50%, 45%, 40%, 35%, 30%, 25%, 20%, 15%, 10%, 5%, or less of the axial length of the device can be initially deployed. The small portion can correspond to an amount of the ALTC device 201 which allows the anchor 450 to assume the neutral position. During the deployment of the anchor 450, a length of the ALTC device 201 can be retained within the outer sheath 203. The ALTC device 201 can follow a curve from the anchor 450 to the outer sheath 203. Retracting the outer sheath 203 can lengthen the ALTC device 201 while maintaining a constant diameter or cross-section provided by the anchor 450. In some embodiments, the proximal end of the ALTC device 201 is fixed relative to the anchor 450. In some embodiments, the ALTC device 201 can axially lengthen by releasing the compressed portion 208 as described herein. In some methods of use, the ALTC device 201 is axially lengthened. In some methods of use, the ALTC device 201 is not axially lengthened. The ALTC device 201 can serve as distal protection without further axially lengthening. In some embodiments, the ALTC device 201 is deployed before the anchor 450. In some embodiments, the ALTC device 201 is deployed after the anchor 450.

[0323] Figure 89 illustrates a system including a dual ALTC device 201 and anchor 450. The anchor functions to replace the nitinol. In some methods of use, the ALTC device 201 and the anchor 450 retract together. In some methods of use, the ALTC device 201 and the anchor 450 move as a unit. In some embodiments, the distal end consists of axial lengthen device wherein the opening end attaches to an expandable anchor. The ALTC device 201 comprises a proximal opening. In some embodiments, the capture guide 204 is replaced with an anchor, such as anchor 450. The proximal opening of the ALTC device 201 is coupled to the anchor 450 such that the ALTC device 201 and the anchor move together. In some embodiments, the distal end of the axial lengthen device is fixed to the pusher 202 that extends proximally. The ALTC device 201 can be coupled to the pusher 202. The pusher 202 can push the compressed portion 208 from the sheath 451 to cause axially lengthening of the ALTC device 201. The pusher 202 can extend to the proximal end of the system to be controlled by the user. In some embodiments, the proximal end of the expandable anchor attaches a pusher tube 451 extending proximally and attaches to a hemostasis housing. In

some embodiments, the proximal end of the anchor 450 is coupled to the anchor pusher 451. The anchor pusher 451 can extend proximally and attach to the hemostasis housing as described herein. The system can be designed for thrombectomy. The system can include a distal basket or ALTC device 201 and anchor 450. The anchor 450 can be made of wireform, laser cut or stent-like structure. The materials can be such as shape memory, stainless steel, Cobalt Chromium.

[0324] Figure 90 illustrates the distal end of the system of Figure 89. The system includes the ALTC device 201 and the expandable anchor 450. In some embodiments, the ALTC device 201 and the anchor 450 are fixed and move as one unit. In some embodiments, the distal end of the expandable anchor 450 attaches to the opening end of the ALTC device 201. In some embodiments, the proximal end of the anchor 450 attaches to the catheter shaft 451. In some embodiments, the distal end of the ALTC device 201 extends through the anchor 450. In some embodiments, the distal end of the ALTC device 201 extends through the anchor 450 centrally or along a longitudinal axis. In some embodiments, the distal end of the ALTC device 201 extends through the anchor 450 along an axis offset from the longitudinal axis of the anchor 450. The distal end of the ALTC device 201 can be the compressed portion 208 as described herein. In some embodiments, the distal end of the ALTC device 201 is coupled to a pusher wire 202. In some embodiments, the distal end of the ALTC device 201 is coupled to the pusher wire 202 or other device described herein.

[0325] In some embodiments, alternatively, the distal end of the expandable anchor 450 is separated from the opening end of the ALTC device 201. In some embodiments, the proximal end of the expandable anchor 450 attaches to distal end of catheter shaft. In some embodiments, the body of the ALTC device 201 extends through the anchor 450 centrally and attaches to the pusher 202. The pusher 202 can be contained within the pusher tube 451, sheath 203, dual lumen sheath 243 or other constraining member described herein. The anchor 450 can be designed to collapse within the pusher tube 451. The ALTC device 201 can be designed to collapse within the pusher tube 451. In some methods of use, the ALTC device 201 can be released from the pusher tube 451 by proximal movement of the pusher tube 451. In some methods of use, the anchor 450 can be released by proximal movement of the pusher tube 451. In some methods of use, the ALTC device 201

can be released from the pusher tube 451 by distal movement of the pusher 202. In some methods of use, the anchor 450 can be released by distal movement of the pusher 202.

[0326] Figure 91 illustrates another embodiment of a capture system, which can have any of the features described herein. The capture system includes an anchor 452. The anchor 452 can have any of the features of anchors described herein, including anchor 405. A portion of the anchor 452 can be contained within the pusher tube 451. In some embodiments, the ALTC device 201 can attach to the anchor 452 as described herein.

[0327] Figure 92 illustrates another embodiment of a capture system, which can have any of the features described herein. The capture system includes an anchor 453. In some embodiments, the ALTC device 201 can attach to the anchor 453 as described herein. In some embodiments, the anchor 453 is formed as a stent structure. The anchor 453 can include a plurality of struts. Each strut can be connected to the ALTC device 201 at one or more locations. In the illustrated embodiment, each strut is connected to the ALTC device 201 at two locations but other configurations are contemplated (e.g., one location, three locations, four locations, five locations, a plurality of locations, etc.). In some embodiments, the struts can be equally spaced. In some embodiments, the struts are not equally spaced. In some embodiments, the struts can include a zig-zag pattern or bends 454. In some embodiments, the bends 454 can improve flexibility of the capture system. In some embodiments, the bends 454 can allow the capture system to turn. In some embodiments, the bends 454 can be located near a proximal end of the anchor 453. In some embodiments, the bends 454 can be located near a distal end of the anchor 453. In some embodiments, the struts of the anchor 453 assist in retrieving and containing the obstruction or clot. In some embodiments, the struts comprise a shape memory or self-expanding material such as nitinol. In some embodiments, the anchor 453 can be self-expanded.

[0328] Figures 93-94 illustrate another embodiment of a capture system, which can have any of the features described herein. The capture system includes anchor 455. In some embodiments, the struts 456 of the anchor 455 can be straight. In some embodiments, the struts 456 can include a straight portion. In some embodiments, the straight portion is near a proximal end of the anchor. Figures 93-94 illustrates the axial lengthening of the expanded portion of the ALTC device 201. The ALTC device 201 is lengthening proximally. The compressed or constrained segment of the ALTC device 201 is shortened within the

pusher tube 241. In some embodiments, the pusher tube 241 can be retracted to axially lengthen the ALTC device 201, as described herein. The ALTC device 201 and the anchor 455 can be retracted as a unit. Figure 93 illustrates the axial lengthening device and the expandable anchor in the initial configuration. Figure 94 illustrates the axial lengthening device and the expandable anchor wherein the axial lengthening device is lengthened.

[0329] Figure 95 illustrates another embodiment of a capture system, which can have any of the features described herein. The capture system includes an anchor 457. In some embodiments, a portion of the anchor 457 is connected to the ALTC device 201. The anchor 457 can include one or more distal tips 458. In some embodiments, one or more distal tips 458 are not connected to the ALTC device 201. The distal tips 458 can function as distal tips described herein.

[0330] The distal tips 458 may provide a substantially atraumatic distal end, e.g., to prevent puncture or other damage to a wall of a body lumen within which the anchor 457 is deployed. The distal tips 458 may facilitate engaging and/or removing obstructive material within a body lumen. Alternatively, the distal tips 458 can entangle with each other and/or with the obstructive material captured or otherwise engaged by the distal tips 458 to facilitate removal. The distal tips 458 may facilitate separation and/or capture of material. The distal tips 458 of the anchor 457 may act as a saw by repeatedly making contact with the material, which may increase the chance of material being dislodged from the wall of the body lumen and/or captured within the anchor 457. To further ensure that the leading edge of the anchor 457 passes between the unwanted material and the wall of the body lumen, the distal tips 458 and/or edges may also act as blades shearing along the wall of the body lumen to draw adherent material into the anchor 457. Thus, the distal tips 458 may cut or otherwise separate the interface between the body lumen and the obstructive material. The distal tips 458 may be formed such that they conform substantially to the cylindrical shape of the ALTC device 201, e.g., defining a diameter similar to the rest of the ALTC device 201. In some embodiments, the distal tips 458 may be biased radially outwardly or biased to extend radially inwardly. Other configurations of the distal tips 458 are contemplated.

[0331] In some embodiments, the systems described herein comprise a fixed ALTC device 201. In some embodiments, the ALTC device 201 is inserted into the patient in the initial configuration. For instance, the capture guide 204 described herein can be fixed

such that the ALTC device 201 assumes the initial configuration. In some embodiments, the ALTC device 201 does not lengthen. In some embodiments, the axial length of the ALTC device 201 is fixed. In some embodiments, the anchor is fixed. In some embodiments, the anchor is inserted into the patient in the expanded or inflated configuration. In some embodiments, the anchor does not expand or inflate within the body of the patient. In some embodiments, the anchor has a fixed shape or configuration. In some embodiments, the system includes a clot buster or debulking at the front end. In some embodiments, the clot buster moves distally to break apart the clot. In some embodiments, the clot buster is a portion of the anchor. In some embodiments, the clot buster is separate device.

[0332] Figure 96A-96B illustrate an expandable guide catheter 460. The guide catheter 460 includes an expandable distal end, configured to be positioned away from a user, within a body of a patient. The guide catheter 460, or at least the distal end, can feature at least a dual braid layer including an outer layer and an inner layer. In some embodiments, the expandable guide catheter 460 can include a dual layer structure. In some embodiments, the expandable guide catheter 460 can include an outer braid layer 461. In some embodiments, the outer braid layer 461 is coated with a material such as one or more polymeric materials. In some embodiments, the expandable guide catheter 460 can include an inner braid layer 462. In some embodiments, the inner braid layer 462 is not coated with a polymeric material. In some embodiments, a portion of the inner braid layer 462 is not coated. In some embodiments, a distal portion of the inner braid layer 462 is not coated. In some embodiments, a length of the inner braid layer 462 is not coated. In some embodiments, the entire length of the inner braid layer 462 is not coated. In some embodiments, a portion of the outer braid layer 461 is coated. In some embodiments, a distal portion of the outer braid layer 461 is coated. In some embodiments, a length of the outer braid layer 461 is coated. In some embodiments, the entire length of the outer braid layer 461 is coated. In some embodiments, the outer braid layer 461 remains coated or encased with the polymer during the procedure.

[0333] In some embodiments, the outer braid layer 461 is coated with a polymer. The polymer can be any material including Pellethane, Silicone, Tecoflex, Tecothane, Latex, Pebax. The polymer can function akin to a slip layer. The polymer can facilitate the sliding of the catheter against a target vessel. In some embodiments, the inner braid layer 462 is not coated with a polymer, instead, retains the mesh-like structure as shown. The inner braid

layer 462 advantageously provides decreased surface area, decreased surface contact, and/or decreased friction relative to an object within the lumen of the catheter. For instance, the mesh-like structure of the inner braid layer 462 has less surface area to contact the object within the lumen than a solid, inner wall. The inner braid layer 462 allows for a retrieval catheter, one or more anchors, the obstruction, or the ALTC device 201 to more easily slide axially when withdrawn proximally through the lumen. In some methods of use described herein, the ALTC device 201 can be axially lengthened over one or more anchors before retraction into the guide catheter 406. In some methods of use described herein, the ALTC device 201 can be axially lengthened over an obstruction such as a clot before retraction into the guide catheter 406. In some methods of use described herein, the ALTC device 201 can provide distal protection as the ALTC device 201 is retracted into the guide catheter 460.

[0334] In some embodiments, the guide catheter 460 has a funnel shape at the distal end. In some embodiments, distal refers to the portion of the guide catheter 460, or component thereof, which is furthest from the user during use, while proximal refers to the portion of the guide catheter 460 or component thereof which is closest to the user. In some embodiments, the distal end of the guide catheter 460 is positioned within the body of the patient and the proximal end is outside the body of the patient.

[0335] In some embodiments, the expandable guide catheter 460 can include any of the features of the ALTC device 201 described herein. In some embodiments, the mesh can be made from metallic materials such as individual non-elastic wires. In some embodiments, the mesh can be made from elastic elements. In some embodiments, the mesh can be made from a combination of elastic and non-elastic wires. In some embodiments, the dual braid can be made of either polymeric or metallic materials. In some embodiments, the metallic materials can be Nitinol, stainless steel, steel, shape memory alloy, elastic alloy, Nickel Titanium alloy, etc. In some embodiments, the braid wire diameter can range from .0005" to .030", e.g., .0005", .001", .0015", .002", .0025", or .003", between .0005"- .0015", between .001"- .002", between .0015"- .0025", between .002"- .003" etc. Other configurations of braid wire diameter are contemplated. The braid wire can be woven in any pattern. In some embodiments, the guide catheter 460 can include at least one polymer layer. The at least one polymer layer can be applied to any surface of the braid wire. The braid wire can include one or more woven patterns, for instance a first wave pattern in a first portion of the

guide catheter 460 and a second wave pattern in a second portion of the guide catheter 460. The woven pattern can be a typical over under pattern, e.g., two over, two under; one over, one under, etc. The woven pattern can form a tubular braid. In some embodiments, the guide catheter 460 can include multiple layers of braid wire.

[0336] The braid wire can form a mesh. In some embodiments, the cross-section of the wire can be any shape including round, polygonal, elliptical, etc. The shape of the wire can be flat, square, ribbon, round, etc. In some embodiments, the total braid angle can range from 10 degrees to 170 degrees. In some embodiments, the total braid angle is 0 degrees, 10 degrees, 20 degrees, 30 degrees, 40 degrees, 50 degrees, 60 degrees, 70 degrees, 80 degrees, 90 degrees, 100 degrees, 110 degrees, 120 degrees, 130 degrees, 140 degrees, 150 degrees, 160 degrees, 170 degrees, 180 degrees, between 0-45 degrees, between 45-90 degrees, between 90-135 degrees, between 135-180 degrees, etc. In some embodiments, the braid density can range from 5 PPI to 60 PPI. In some embodiments, the braid density is less than 5 PPI, 5 PPI, 10 PPI, 15 PPI, 20 PPI, 25 PPI, 30 PPI, 35 PPI, 40 PPI, 45 PPI, 50 PPI, 55 PPI, 60 PPI, 65 PPI, 70 PPI, 75 PPI, 80 PPI, between 0-20 PPI, between 20-40 PPI, between 40-60 PPI, between 60-80 PPI, etc. In some embodiments, the inner diameter can range from 1F to 30F. In some embodiments, the inner diameter is less than 1F, 1F, 2F, 3F, 4F, 5F, 6F, 7F, 8F, 9F, 10F, 11F, 12F, 13F, 14F, 15F, 16F, 17F, 18F, 19F, 20F, 21F, 22F, 23F, 24F, 25F, 26F, 27F, 28F, 29F, 30F, 31F, 32F, 33F, 34F, 35F, between 0F-5F, between 5F-10F, between 15F-20F, between 20F-25F, between 25F-30F, between 30F-35F, etc. In some embodiments, the outer diameter can range from 2F up to 33F. In some embodiments, the outer diameter is less than 1F, 1F, 2F, 3F, 4F, 5F, 6F, 7F, 8F, 9F, 10F, 11F, 12F, 13F, 14F, 15F, 16F, 17F, 18F, 19F, 20F, 21F, 22F, 23F, 24F, 25F, 26F, 27F, 28F, 29F, 30F, 31F, 32F, 33F, 34F, 35F, between 0F-5F, between 5F-10F, between 15F-20F, between 20F-25F, between 25F-30F, between 30F-35F, etc.

[0337] In some embodiments, the expandable guide catheter 460 can include a shaft. In some embodiments, the expandable guide catheter 460 can include a shaft that expands under compression. In some embodiments, the expandable guide catheter 460 can include a shaft that lengthens under compression. In some embodiments, the expandable guide catheter 460 can include a shaft that expands upon release of a constraint. In some embodiments, the expandable guide catheter 460 can include a shaft that expands due to

temperature. In some embodiments, the expandable guide catheter 460 can include a shaft that expands to assume a neutral configuration.

[0338] In some embodiments, the expandable guide catheter 460 can include an inverted structure. In some embodiments, one end of the braid begins at the proximal end and extends to the distal end where it folds inward and extends back to the proximal end. In some embodiments, the dual braid extends from the proximal end to the distal end. In some embodiments, the braid at the distal end can be continuous. In some embodiments, the braid at the distal end can be discontinuous. In some embodiments, one end of the braid begins at the proximal end and extends to the distal end wherein it folds inward and extends back to the proximal region. In some embodiments, one end of the braid begins at the proximal end and extends to the distal end wherein it folds outward and extends back to the proximal region. The outer braid layer 461 and the inner braid layer 462 are concentric.

[0339] In some embodiments, the outer layer braid 461 is encapsulated with polymeric materials. In some embodiments, the polymer layer can have uniform wall thickness. In some embodiments, the polymer layer can have uniform density. In some embodiments, the polymer layer can have uniform wall thickness throughout the entire catheter length. In some embodiments, the polymer layer can have non-uniform wall thickness. In some embodiments, the proximal end of the catheter wall thickness is thicker than the wall thickness at the distal end. In some embodiments, the polymeric material can have the same softness (durometer) through the catheter length. In some embodiments, the polymeric material can have different or a variety of softness (durometer) through the catheter length. In some embodiments, the polymeric material is expandable. In some embodiments, the polymeric material is flexible. In some embodiments, the outer layer composite is expandable. In some embodiments, polymeric materials can be any elastomer materials such as Polyurethane, Pellethane, Silicone, Tecoflex, Tecothane, Latex, Pebax and/or combination thereof. In some embodiments, the polymer can be coupled to the braid material through any methods known in the art. In some embodiments, the polymer can be coated, molded, dipped or thermally fused onto the braid.

[0340] In some embodiments, the guide catheter 460 has a funnel shape at distal end. In some embodiments, the guide catheter outer braid is encapsulated from the proximal end to the distal end near the funnel. In some embodiments, the funnel outer and inner braid

layer is not encapsulated with polymer. In some embodiments, the funnel outer braid is encapsulated with polymer. In some embodiments, the inner braid layer can be encapsulated with polymer and the outer layer is not.

[0341] The guide catheter 460 can function as an access system. In some embodiments, the guide catheter 460 is introduced in a compressed diameter configuration. In some embodiments, after introduction, the guide catheter 460 may be radially expanded to accommodate passage of larger diameter surgical instruments therethrough such as ALTC device 201 and/or the anchors described herein.

[0342] The guide catheter 460 can be useful for forming and enlarging access area in target locations within a patient's body. In some embodiments, the guide catheter 460 is delivered in a small diameter configuration and expanded. In some embodiments, only a distal end or a funnel end is expanded. In some embodiments, the guide catheter 460 can change the size of the lumen that the guide catheter 460 is inserted into, such as enlarging a vessel by pressing against the vessel wall. The guide catheter 460 can include a polymeric coating that facilitates sliding contact with the vessel wall.

[0343] In some embodiments, passage of the ALTC device 201 through the guide catheter 460 can cause expansion of the guide catheter 460. In some embodiments, the collapsed ALTC device 201 can be sized to fit within the guide catheter 460. In some embodiments, the expanded ALTC device 201 can be sized to fit within the guide catheter 460. In some embodiments, the expanded ALTC device 201 can be retracted through the guide catheter 460. In some embodiments, the one or more expanded anchors can be retracted through the guide catheter 460. In some embodiments, the one or more expanded anchors can be sized to fit within the guide catheter 460. The uncoated inner braid layer 462 reduces sliding contact between the guide catheter 460 and any components passed therethrough.

[0344] In some embodiments, the guide catheter 460 can function as a variable sized cannula. In some embodiments, the guide catheter 460 can function as a tissue dilator. In some embodiments, the guide catheter 460 can change shape during axial compression of the braid. In some embodiments, axial shortening can cause radial expansion of the guide catheter 460. In some embodiments, the guide catheter 460 can be variably expanded based on the amount of compressive force. In some embodiments, the guide catheter 460 is self-

expanding. In some embodiments, the guide catheter 460 is expanded by a mechanism e.g., pull strings, release from a constraint, application of compressive force, application of tension, etc. In some embodiments, the guide catheter 460 is a shape memory material.

[0345] In some embodiments, the guide catheter 460 can facilitate the removal of a blockage within the vasculature of a patient. In some embodiments, the guide catheter 460 can surround the one or more anchors that are entangled in the clot. In some embodiments, the surface of the clot can slide easily within the guide catheter, due in part, to the inner surface of the guide catheter 460. In some embodiments, the guide catheter 460 can slide easily within the target vessel, due in part, to the outer surface of the guide catheter 460. In some embodiments, the guide catheter 460 can be collapsed after receiving the one or more anchors. In some embodiments, the guide catheter 460 can surround the ALTC device 201 which itself encapsulates the obstruction. In some embodiments, the outer surface of the ALTC device 201 can slide easily within the guide catheter, due in part, to the inner surface of the guide catheter 460. In some embodiments, the guide catheter 460 can be collapsed after receiving the ALTC device 201.

[0346] Systems and methods can be utilized or modified for use in connection with those described herein can be found, for example, in U.S. Patent Application No. 11/101,224, filed Apr. 7, 2005 and published July 2, 2013 as U.S. Patent No. 8475487 (“Bonnette”); U.S. Patent Application No. 12/738,702, filed Oct. 27, 2008 and published Oct. 21, 2010 as U.S. Patent Pub. No. 20100268264 (“Bonnette ‘264”) are all incorporated by reference herein in their entireties.

[0347] In some methods of use, the ALTC device 201 is used in combination with a thrombectomy catheter, such as an AngioJet® thrombectomy device or potentially an aspiration catheter may be used to remove the embolic debris. In some methods of use, one or more anchors described herein is used in combination with a thrombectomy catheter or an aspiration catheter, such as an AngioJet® thrombectomy device. The use of the AngioJet®, a rheolytic cross stream thrombectomy catheter, can include an inherent ability to remove thrombus of larger diameter than the catheter’s diameter. However, the disruptive strength of the device falls off with the radial distance from the catheter. Hence, at some radial distance the clot can be stronger than the disruptive force generated by the AngioJet® cross stream

flow patterns. In the case of organized thrombus, this radial distance from the catheter can be smaller than for softer thrombus.

[0348] Water jet thrombectomy procedures in general can be limited in ability in some cases. However, adding mechanical disruption such as by use of the anchors described herein can unexpectedly and synergistically improve water jet ablation. By combining mechanical agitation, e.g., abrasive intimate contact of thrombus by a flexible and expandable anchor component and an ALTC device 201, with a rheolytic thrombectomy catheter (AngioJet®), a variety of thrombus can be cleared than can be cleared by mechanical agitators or rheolytic cross stream thrombectomy catheters individually.

[0349] Another aspect and feature of some embodiments of the devices of the present disclosure is a device having the ability to capture large and small embolic debris. Another aspect and feature of the devices of the present disclosure is a device having the ability to temporarily capture debris which may later be removed by manual aspiration or by the use of an AngioJet® thrombectomy device and catheter or which may be treated by thrombolytics. Another aspect and feature of the devices of the present disclosure is a device having the ability to macerate debris to a clinically insignificant size (depending on the area of the body) or to a size which can be pharmacologically treated or removed by another device, such as an AngioJet® thrombectomy device and catheter. Another aspect and feature of the devices of the present disclosure is a device having the ability to macerate non-embolic debris, such as a stationary thrombus, by pulling the device through such an obstruction.

[0350] Systems and methods can be utilized or modified for use in connection with those described herein can be found, for example, in U.S. Patent Application No. 14/774,735, filed Mar. 17, 2014 and published Jan. 28, 2016 as U.S. Pub No. 20160022290 (“Johnson”); U.S. Patent Application No. 13/741,845, filed Jan. 15, 2013 and published Jan. 2, 2014 as U.S. Patent Pub. No. 20140005712 (“Martin”) are all incorporated by reference herein in their entireties.

[0351] An intravascular ultrasound (IVUS) transducer disclosed in Johnson can be incorporated into the systems described herein. In some embodiments, an intravascular ultrasound (IVUS) transducer can be added to or incorporated into the delivery system and method. A pressure sensor can be used to measure the pressure at various positions within the vasculature, which can be used to determine blood flow, while the intravascular ultrasound

(IVUS) transducer can be used to measure fluid flow and/or provide imaging within the vessel. In some embodiments, the pressure sensor and/or IVUS transducer can be incorporated into the guidewire at one or more locations, such as the distal end or distal portion of a guidewire, as well as being incorporated into intermediate and proximal portions of the guidewire. The guidewire with the pressure sensor and/or the IVUS transducer can be used much like a normal guidewire to help navigate the delivery device through the vasculature, with the added benefit of providing pressure measurements and ultrasound imaging to help in the navigation, to visualize the device placement site, and to monitor and ensure proper device deployment. In some embodiments, the IVUS transducer generates image slices as it is advanced and retracted which can then be assembled together to form a three dimensional reconstruction of the vasculature and/or the device within the vasculature. In some embodiments, the guidewire with the pressure sensor and/or IVUS transducer can be fastened to a catheter in a similar manner to that described below for a catheter having a pressure sensor and/or IVUS transducer that is fastened to another catheter.

[0352] Use of the ultrasound imaging system can allow the operator to deliver the device without fluoroscopy or using less fluoroscopy, thereby reducing the radiation exposure to the patient, while allowing more accurate evaluation of the vasculature, aiding placement of the device and allowing confirmation that device placement was proper. The imaging can be used to aid in the deployment of the filters or other devices. The imaging can also be used to aid in the retrieval of the deployed devices by providing visualization of, for example, the retrieval features on the deployed device and of the retrieval features, such as loops on a snare, of the retrieval device. The vasculature and implant location can be imaged prior to deployment, after deployment and/or during deployment. The imaging can be used during the retrieval process. The imaging can be used to aid in positioning of the filter or device within the vasculature. The imaging can be used to image the deployment location and determine the appropriate sizing of the filter or other device. The imaging can be used to help estimate treatment duration.

[0353] Although imaging systems described above have been primarily described as ultrasound based, other imaging systems can be used instead or in addition. For example, the imaging system can be based on intravascular ultrasound (IVUS), Forward-Looking

IVUS (FLIVUS), optical coherence tomography (OCT), piezoelectric micro-machined ultrasound traducer (PMUT), and/or FACT.

[0354] Other components described by Martin can also be incorporated into the systems described herein. All or some of the device can be designed to increase their ability to adhere to the obstruction. For example, the wires may be coupled to an energy source (e.g., RF, ultrasonic, or thermal energy) to “weld” to the obstruction. Application of energy to the device can allow the surrounding portion to deform into the obstruction and “embed” within the obstruction. Alternatively, the device can impart a positive charge to the obstruction to partially liquefy the obstruction sufficiently to allow for easier removal. In another variation, a negative charge could be applied to further build thrombus and nest the device for better pulling force. The wires can be made stickier by use of a hydrophilic substance(s), or by chemicals that would generate a chemical bond to the surface of the obstruction. Alternatively, the filaments may reduce the temperature of the obstruction to congeal or adhere to the obstruction.

[0355] Another aspect applicable to variations of the devices can be to configure the devices (whether the traversing filament or the surrounding portion) for better adherence to the obstruction. One such mode includes the use of coatings that bond to certain clots (or other materials causing the obstruction.) For example, the wires may be coated with a hydrogel or adhesive that bonds to a thrombus. Accordingly, as the device secures about a clot, the combination of the additive and the mechanical structure of the device may improve the effectiveness of the device in removing the obstruction. Coatings may also be combined with the capturing portions or catheter to improve the ability of the device to encapsulate and remove the obstruction (e.g., a hydrophilic coating).

[0356] Such improvements may also be mechanical or structural. Any portion of the capturing portion can have hooks, fibers, or barbs that grip into the obstruction as the device surrounds the obstruction. The hooks, fibers, or barbs can be incorporated into any portion of the device. However, it will be important in some embodiments that such features do not hinder the ability of the practitioner to remove the device from the body.

[0357] In addition to additives, the device can be coupled to an RF, microwave, magnetic, thermal, cryo, or other power source, to allow electrical, current, ultrasound or RF

energy to transmit through the device and induce clotting or cause additional coagulation of a clot or other obstruction.

[0358] The methods described herein may also include treating the obstruction prior to attempting to remove the obstruction. Such a treatment can include applying a chemical or pharmaceutical agent with the goal of making the occlusion shrink or to make it more rigid for easier removal. Such agents include, but are not limited to chemotherapy drugs, or solutions, lytic agents such as tPA, urokinase, or streptokinase for example, an anticoagulant, a mild formalin, or aldehyde solution.

[0359] Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings. Therefore, it should be understood at this time that the inventions may be practiced otherwise than as specifically described herein. It is contemplated that various combinations or subcombinations of the specific features and aspects of the embodiments disclosed above may be made and still fall within one or more of the inventions. Further, the disclosure herein of any particular feature, aspect, method, property, characteristic, quality, attribute, element, or the like in connection with an embodiment can be used in all other embodiments set forth herein. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the disclosed inventions. Thus, it is intended that the scope of the present inventions herein disclosed should not be limited by the particular disclosed embodiments described above. Moreover, while the inventions are susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the inventions are not to be limited to the particular forms or methods disclosed, but to the contrary, the inventions are to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the various embodiments described. Any methods disclosed herein need not be performed in the order recited. The methods disclosed herein include certain actions taken by a practitioner; however, they can also include any third-party instruction of those actions, either expressly or by implication. For example, actions such as “inserting a catheter transfemorally” includes “instructing the insertion of a catheter transfemorally.” The ranges disclosed herein also encompass any and all overlap, sub-ranges, and combinations thereof. Language such as “up to,” “at least,”

“greater than,” “less than,” “between,” and the like includes the number recited. Numbers preceded by a term such as “approximately”, “about”, and “substantially” as used herein include the recited numbers (e.g., about 10% = 10%), and also represent an amount close to the stated amount that still performs a desired function or achieves a desired result. For example, the terms “approximately”, “about”, and “substantially” may refer to an amount that is within less than 10% of, within less than 5% of, within less than 1% of, within less than 0.1% of, and within less than 0.01% of the stated amount.

WHAT IS CLAIMED IS:

1. A clot capture system, comprising:
 - an anchor,
 - a tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening,
 - wherein the tubular body and the anchor are compressed in a delivery configuration,
 - wherein the tubular body and the anchor are transformable to a deployed configuration in which the anchor and the shape memory tubular body first end are expanded but the shape memory tubular body second end and a majority of the shape memory tubular body remains compressed and the tubular body has a first expanded axial length,
 - wherein the shape memory tubular body is transformable to a capture configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein the shape memory tubular body encapsulates the anchor, or a portion thereof, in the capture configuration.
2. The clot capture system of Claim 1, further comprising two or more anchors.
3. The clot capture system of Claim 2, wherein the two anchors have a central longitudinal axis that is coaxial.
4. The clot capture system of Claim 1, wherein the anchor is a stent like structure.
5. The clot capture system of Claim 1, wherein the anchor is a balloon.
6. The clot capture system of Claim 1, wherein the anchor is a disk.
7. The clot capture system of Claim 1, wherein the anchor comprises nitinol.
8. The clot capture system of Claim 1, wherein the anchor comprises a spherical balloon.
9. The clot capture system of Claim 1, wherein the anchor is configured to entangle a clot.
10. The clot capture system of Claim 1, wherein the anchor is coupled to the shape memory tubular body.
11. The clot capture system of Claim 1, wherein the anchor is a funnel.

12. The clot capture system of Claim 1, wherein the anchor is tapered from the distal end to the proximal end of the anchor.

13. The clot capture system of Claim 1, wherein the shape memory tubular body comprises a central longitudinal axis and wherein the anchor is offset from the central longitudinal axis.

14. The clot capture system of Claim 1, wherein the second end of the shape memory tubular body is coupled to an inner pusher.

15. A clot capture system, comprising:

an anchor;

a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening,

wherein the shape memory tubular body and the anchor are configured to be compressed during delivery,

wherein the first end of the shape memory tubular body and the anchor are configured to be expanded while the second end and a majority of the shape memory tubular body remains compressed, wherein the shape memory tubular body has a first expanded axial length with a first cross-section,

wherein the shape memory tubular body is configured to be axially lengthened.

16. The clot capture system of Claim 15, further comprising a pusher, wherein the second end of the shape memory tubular body is coupled to the pusher.

17. The clot capture system of Claim 15, wherein the anchor and the shape memory tubular body are fixed together.

18. A method of using a clot capture system, comprising:

positioning the system of Claim 15 near a blood clot;

expanding the shape memory tubular body and the anchor; and

axially lengthening the shape memory tubular body to encapsulate the clot.

19. The method of Claim 18, wherein the blood clot is within the central nervous system.

20. A method of using a clot capture system, comprising:

positioning the system of Claim 1 near a blood clot;

transforming the shape memory tubular body and the anchor to the deployed configuration;

transforming the shape memory tubular body and the anchor to the capture configuration to encapsulate the anchor.

21. A clot capture system, comprising:

an outer sheath comprising a central lumen;

a dual lumen shaft configured to be positioned within the central lumen of the outer sheath;

an inner pusher configured to be positioned within a first lumen of the dual lumen shaft;

an anchor pusher configured to be positioned within a second lumen of the dual lumen shaft,

an anchor coupled to the anchor pusher,

a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening and a capture guide attached to a portion of the opening,

wherein the shape memory tubular body and the anchor are compressed in a first configuration,

wherein the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains radially compressed within the lumen of the dual lumen shaft and the shape memory tubular body has a first expanded axial length with a first cross-section, wherein the first cross-section is substantially similar to the cross-section of the capture guide,

wherein the shape memory tubular body is transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein the shape memory tubular body encapsulates the anchor in the third configuration.

22. The clot capture system of Claim 21, further comprising two anchors.

23. The clot capture system of Claim 22, wherein the two anchors have a central longitudinal axis that is coaxial.

24. The clot capture system of Claim 21, further comprising three anchors.
25. The clot capture system of Claim 21, wherein the cross-section is round.
26. The clot capture system of Claim 21, wherein the anchor comprises nitinol.
27. The clot capture system of Claim 21, wherein the anchor forms an angle with the anchor pusher, wherein the angle is approximately 90 degrees.
28. The clot capture system of Claim 21, wherein the anchor forms an angle with the anchor pusher, wherein the angle is approximately 45 degrees.
29. The clot capture system of Claim 21, wherein the anchor forms an angle with the anchor pusher, wherein the angle is between 5 degrees and 135 degrees.
30. The clot capture system of Claim 21, wherein the diameter of the anchor is less than the diameter of the shape memory tubular body when radially expanded.
31. The clot capture system of Claim 21, wherein a portion of the anchor pusher is crescent shaped.
32. The clot capture system of Claim 21, wherein the capture guide comprises nitinol.
33. The clot capture system of Claim 21, wherein the capture guide comprises a central longitudinal axis and wherein the dual lumen shaft is offset from the central longitudinal axis.
34. The clot capture system of Claim 21, wherein the second end of the shape memory tubular body is coupled to the inner pusher.
35. A clot capture system, comprising:
- an inner pusher element;
 - a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening and a capture guide attached to at least a portion of the opening, the second end coupled to the inner pusher element,
 - wherein the shape memory tubular body and the capture guide are compressed in a first configuration,
 - wherein the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains radially compressed and the shape memory tubular body has a first expanded axial length

with a first cross-section, wherein the first cross-section is substantially similar to the cross-section of the capture guide,

wherein the shape memory tubular body is transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length.

36. The clot capture system of Claim 35, wherein the capture guide forms a continuous loop.

37. The clot capture system of Claim 35, wherein the capture guide forms a non-continuous loop.

38. A method of using a clot capture system, comprising:

positioning the system of Claim 35 near a blood clot in the first configuration;
transforming the shape memory tubular body to the second configuration; and
transforming the shape memory tubular body to the third configuration to encapsulate the clot.

39. The method of Claim 38, wherein the blood clot is within the CNS.

40. A method of using a clot capture system, comprising:

positioning the system of Claim 21 near a blood clot;
transforming the shape memory tubular body to the second configuration;
expanding the anchor; and
transforming the shape memory tubular body to the third configuration to encapsulate the anchor.

41. The method of Claim 40, wherein deploying the anchor comprises securing the anchor within the clot.

42. The method of Claim 40, wherein transforming the shape memory tubular body to the third configuration to encapsulate the anchor further comprises encapsulating the clot.

43. The method of Claim 40, wherein the blood clot is a neurological blood clot.

44. A clot capture system, comprising:

a first tubular member comprising a central lumen;
a second tubular member;
a plurality of axially spaced-apart anchors extending radially outwardly from the first tubular member or the second tubular member; and

a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an end opening, the second end attached to the second tubular member,

wherein at least part of the shape memory tubular body is compressed within the central lumen of the first tubular shaft in a first delivery configuration,

wherein the shape memory tubular body is transformable to a second configuration in which the first end is radially expanded while the second end and a majority of the shape memory tubular body remains radially compressed within the central lumen of the first tubular shaft and the second end is positioned proximal to the first end and the shape memory tubular body has a first expanded axial length,

wherein the shape memory tubular body is transformable to a third configuration via movement of the first tubular shaft with respect to the second tubular shaft in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein a width of the shape memory tubular body along its second expanded axial length is substantially the same as a width of the shape memory tubular body along its first expanded axial length.

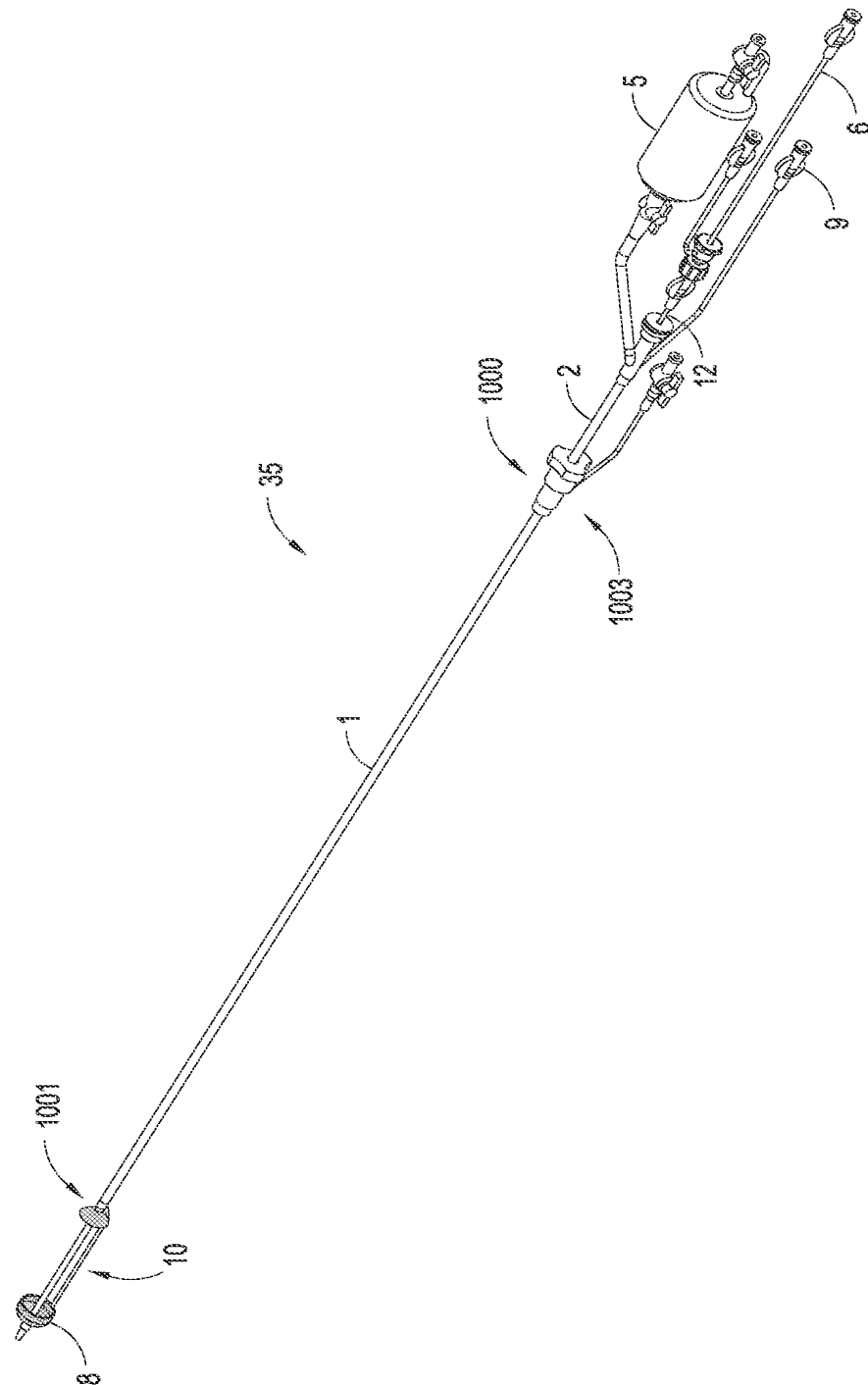


FIG. 1

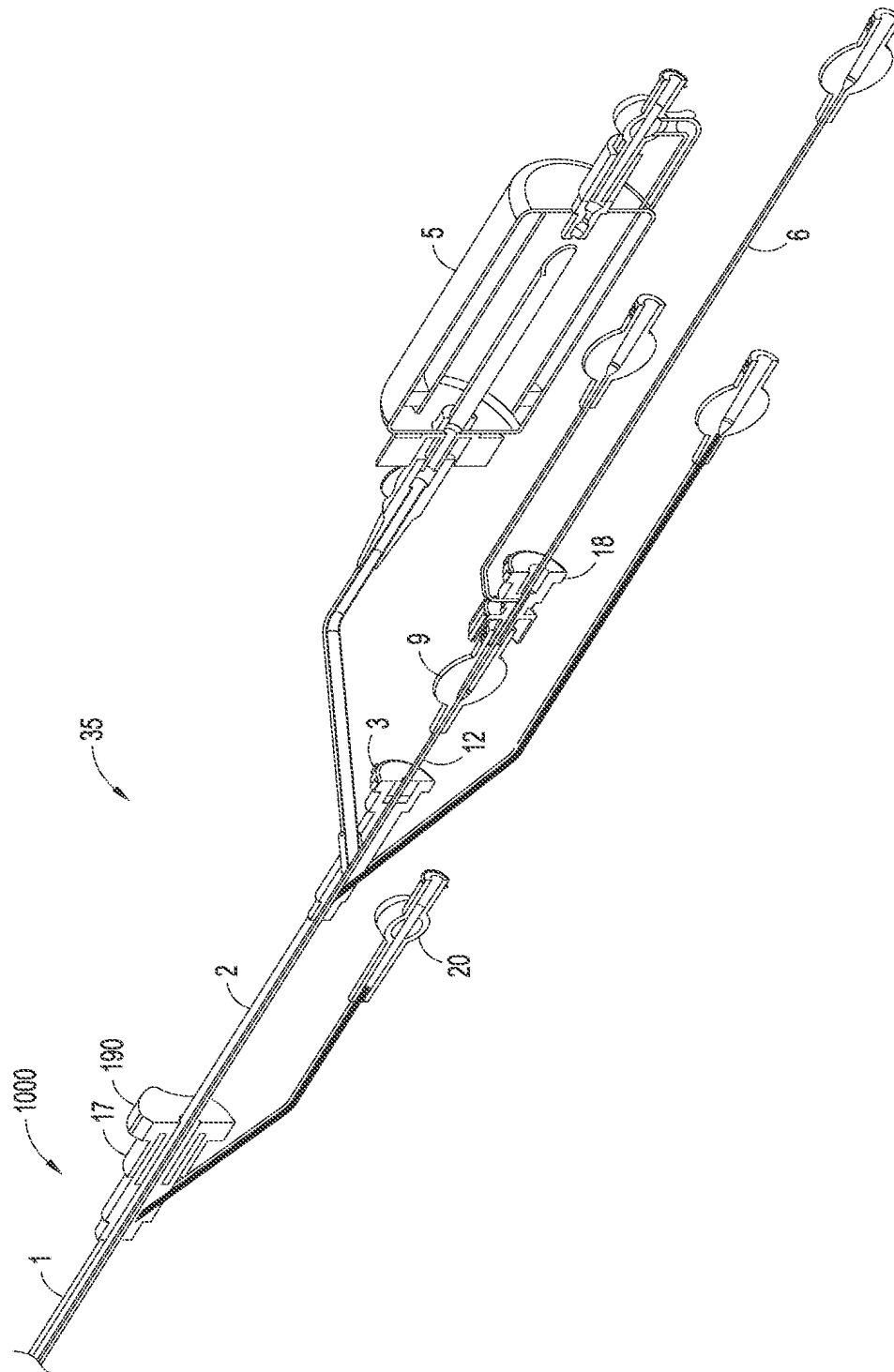


FIG. 2

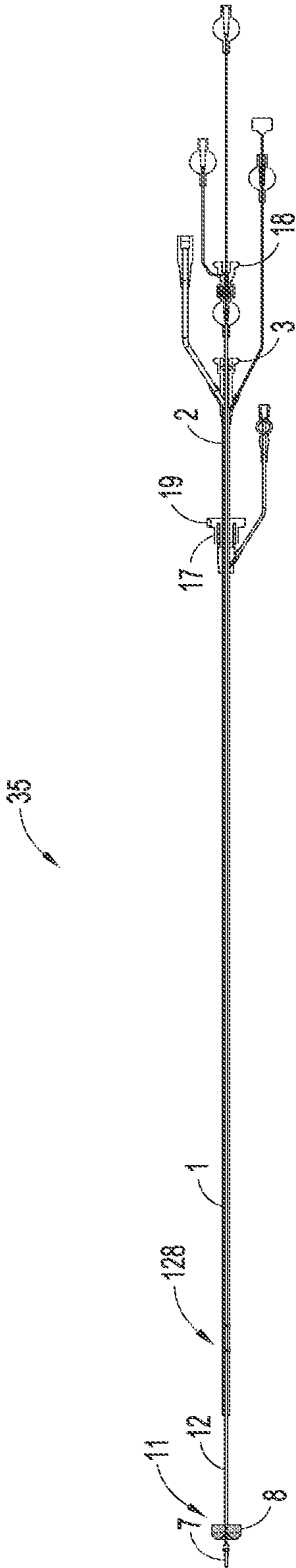


FIG. 3

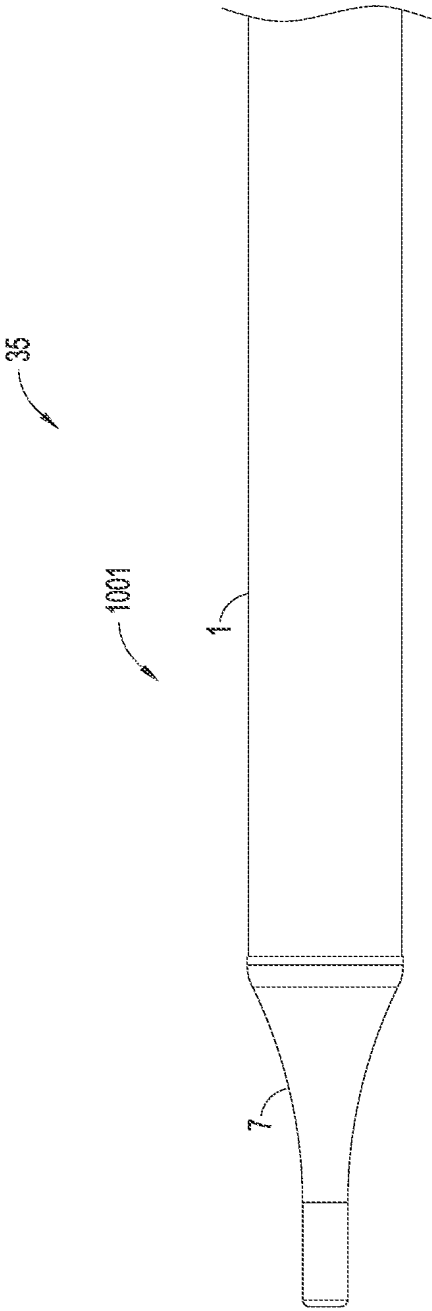


FIG. 4

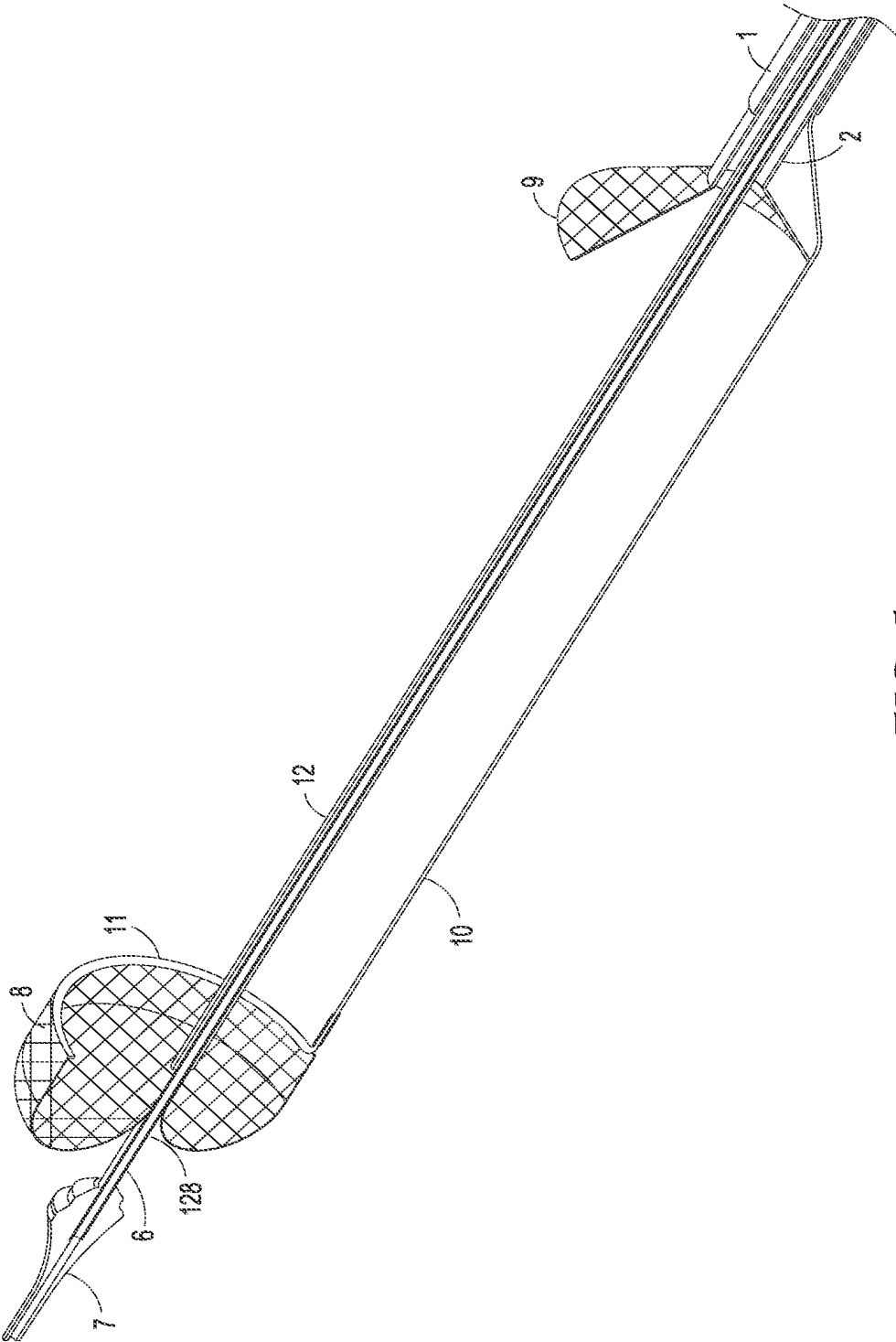


FIG. 5

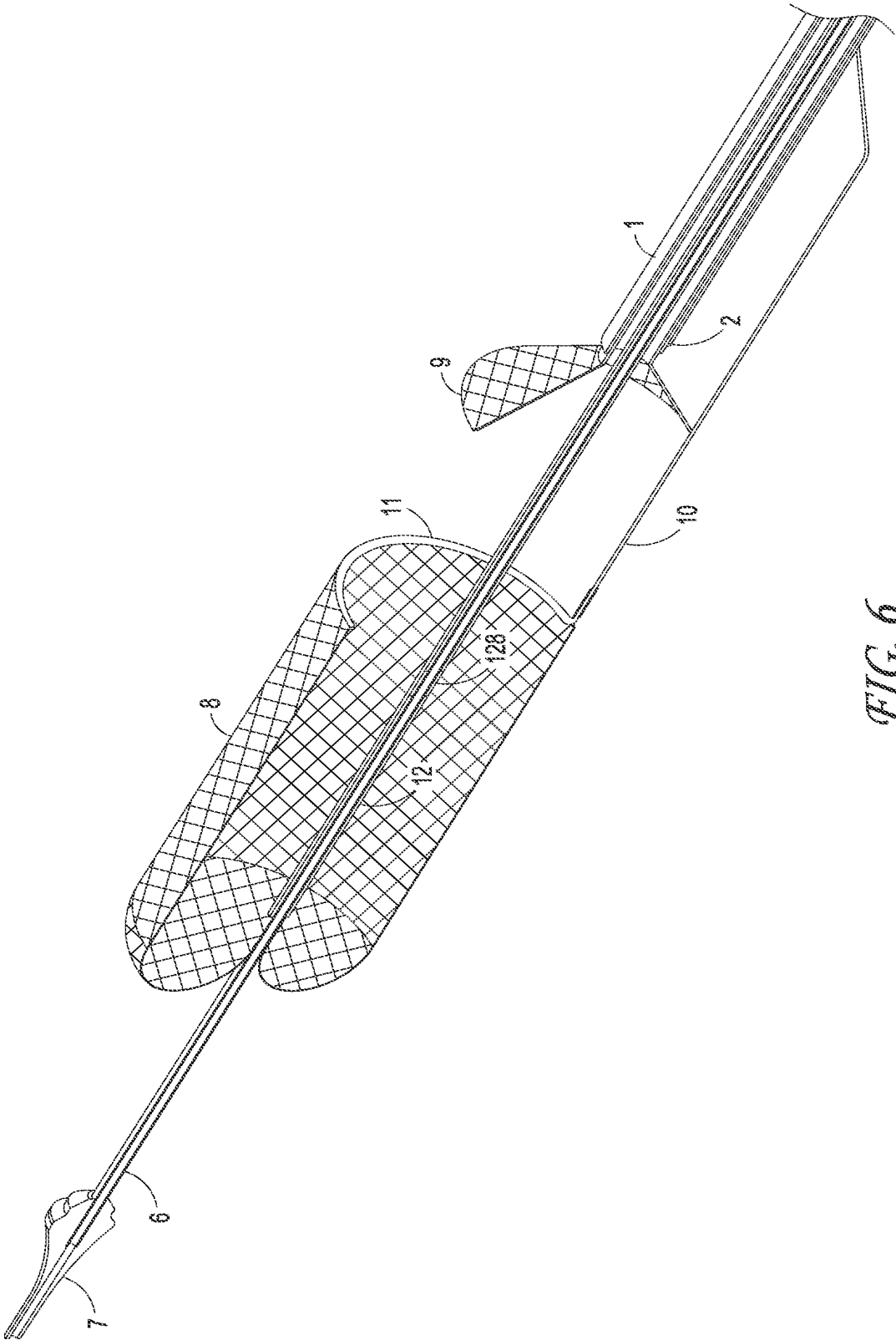
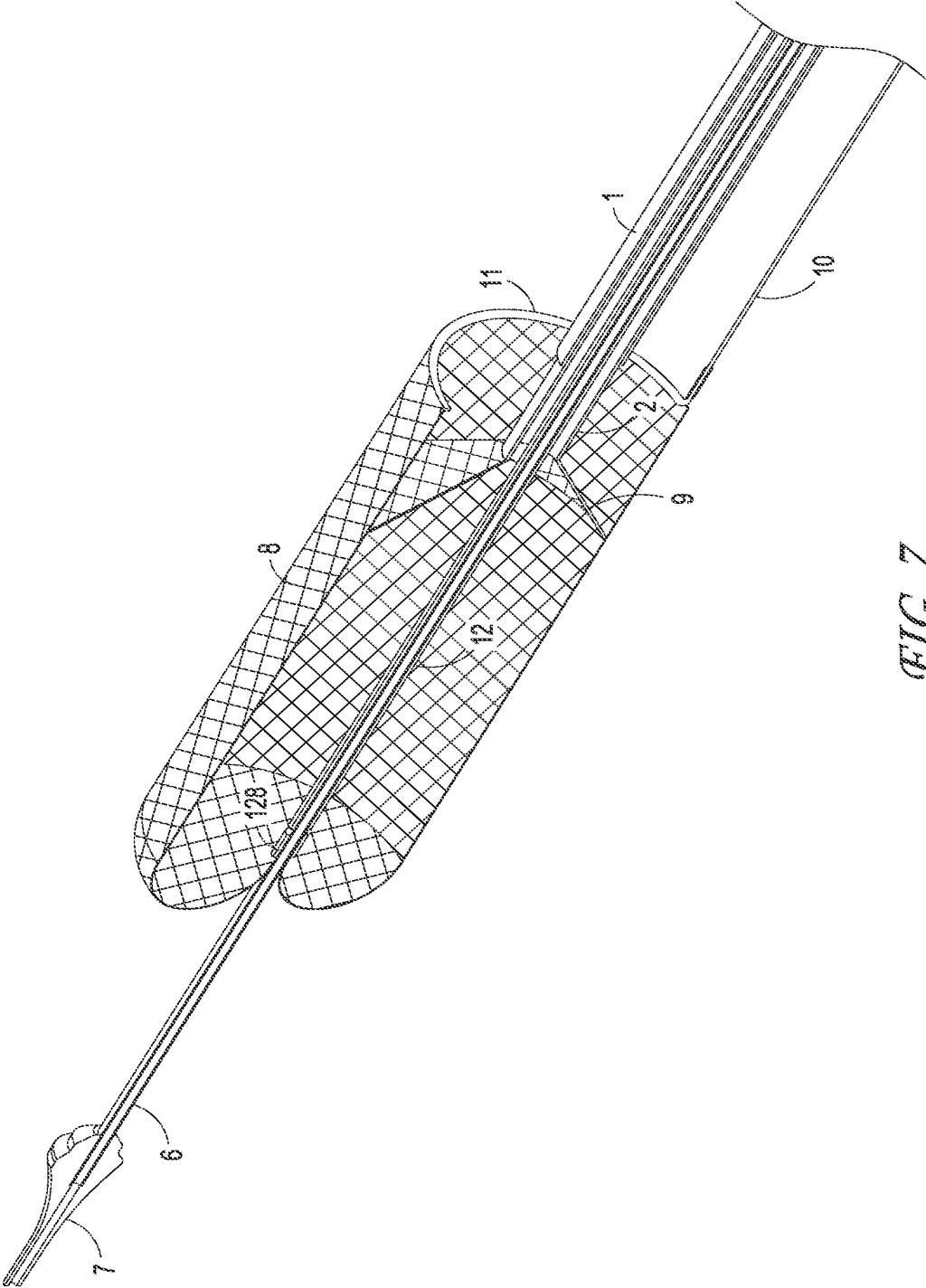


FIG. 6



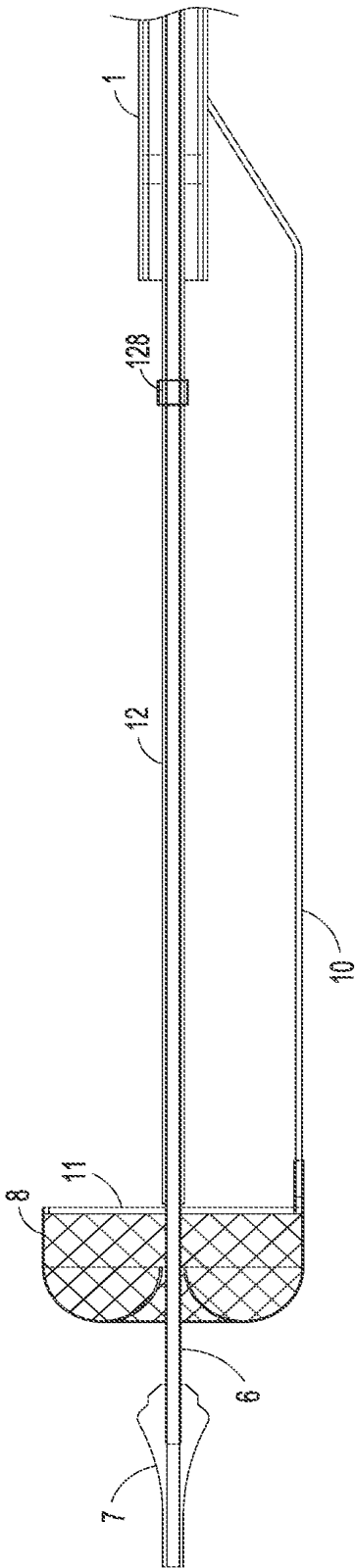


FIG. 8

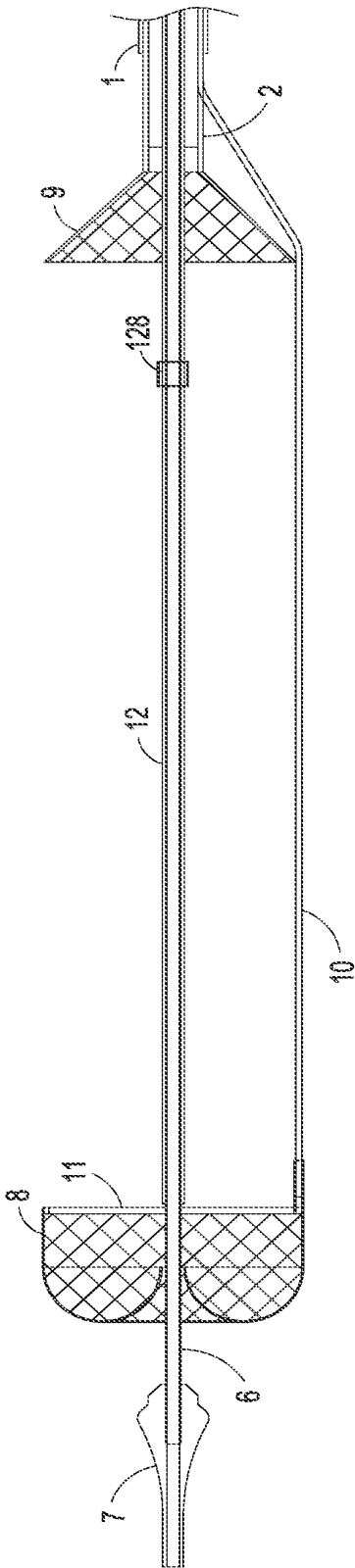


FIG. 9

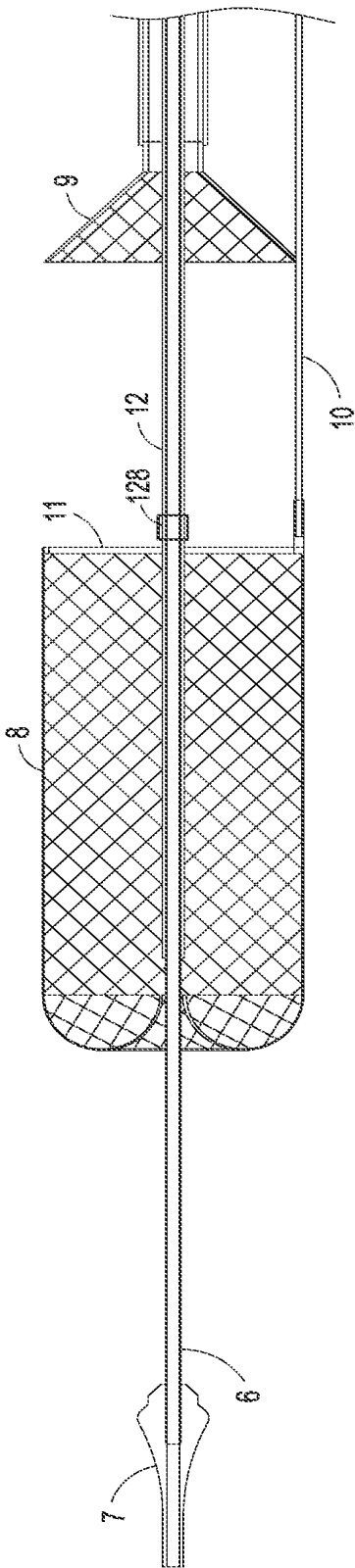


FIG. 10

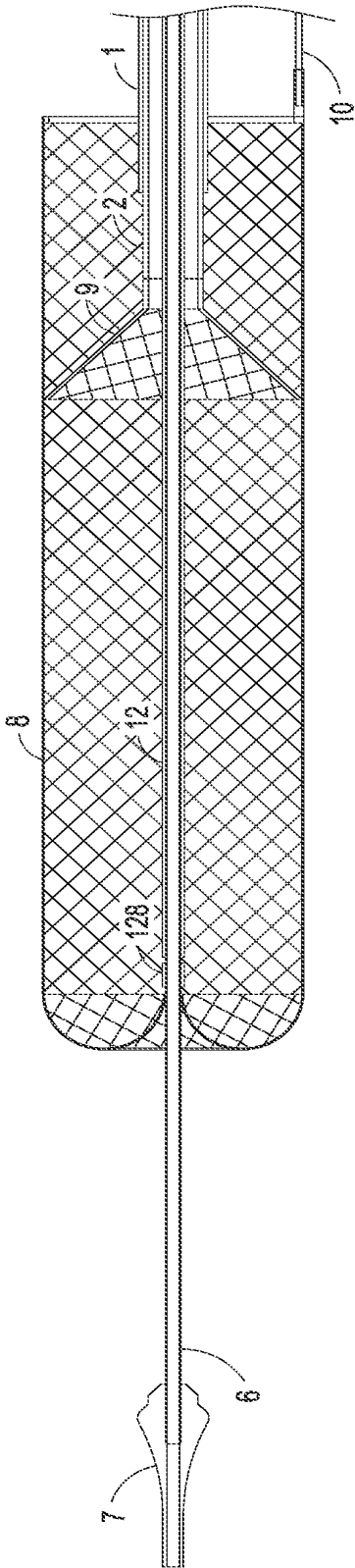
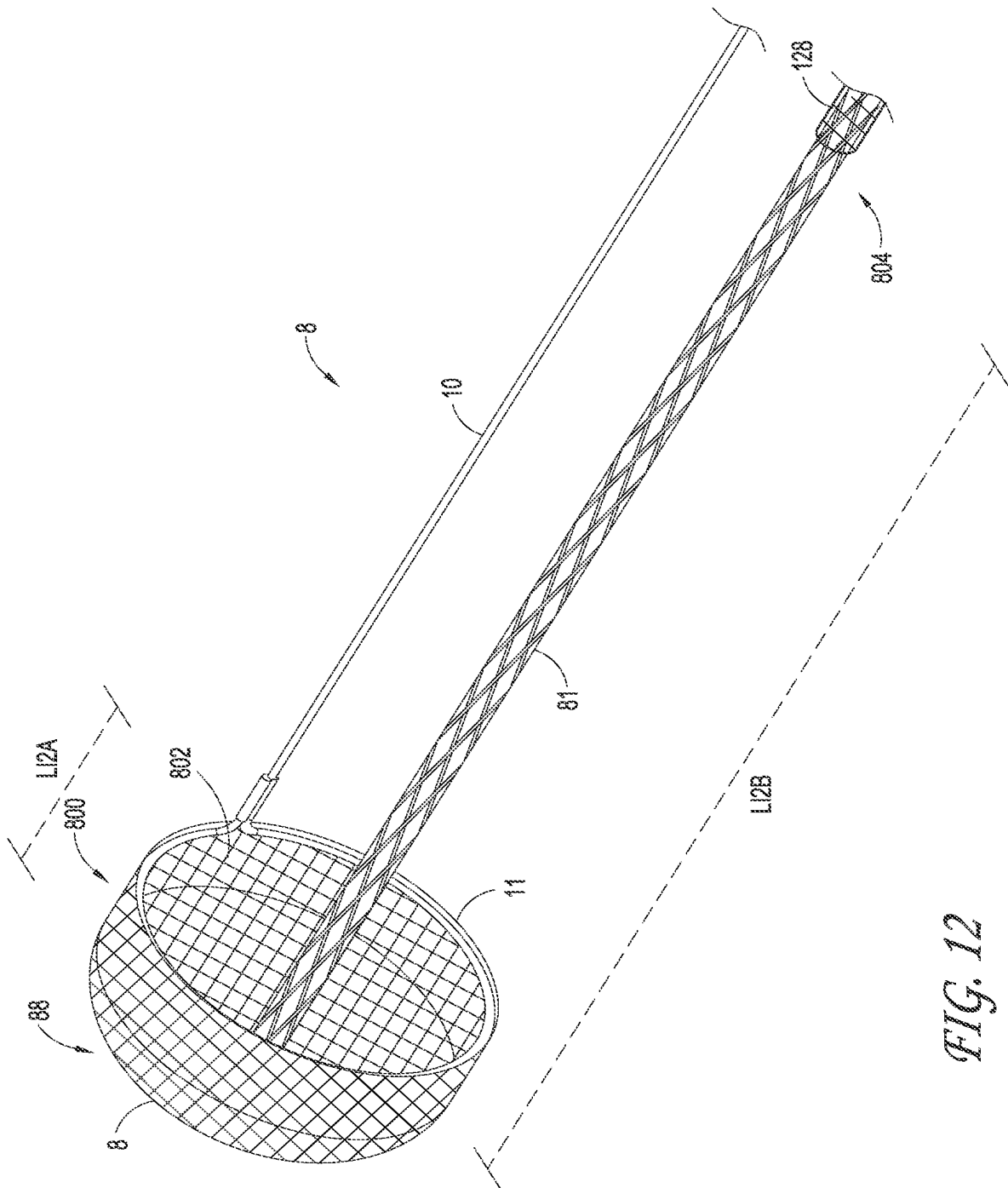


FIG. 11



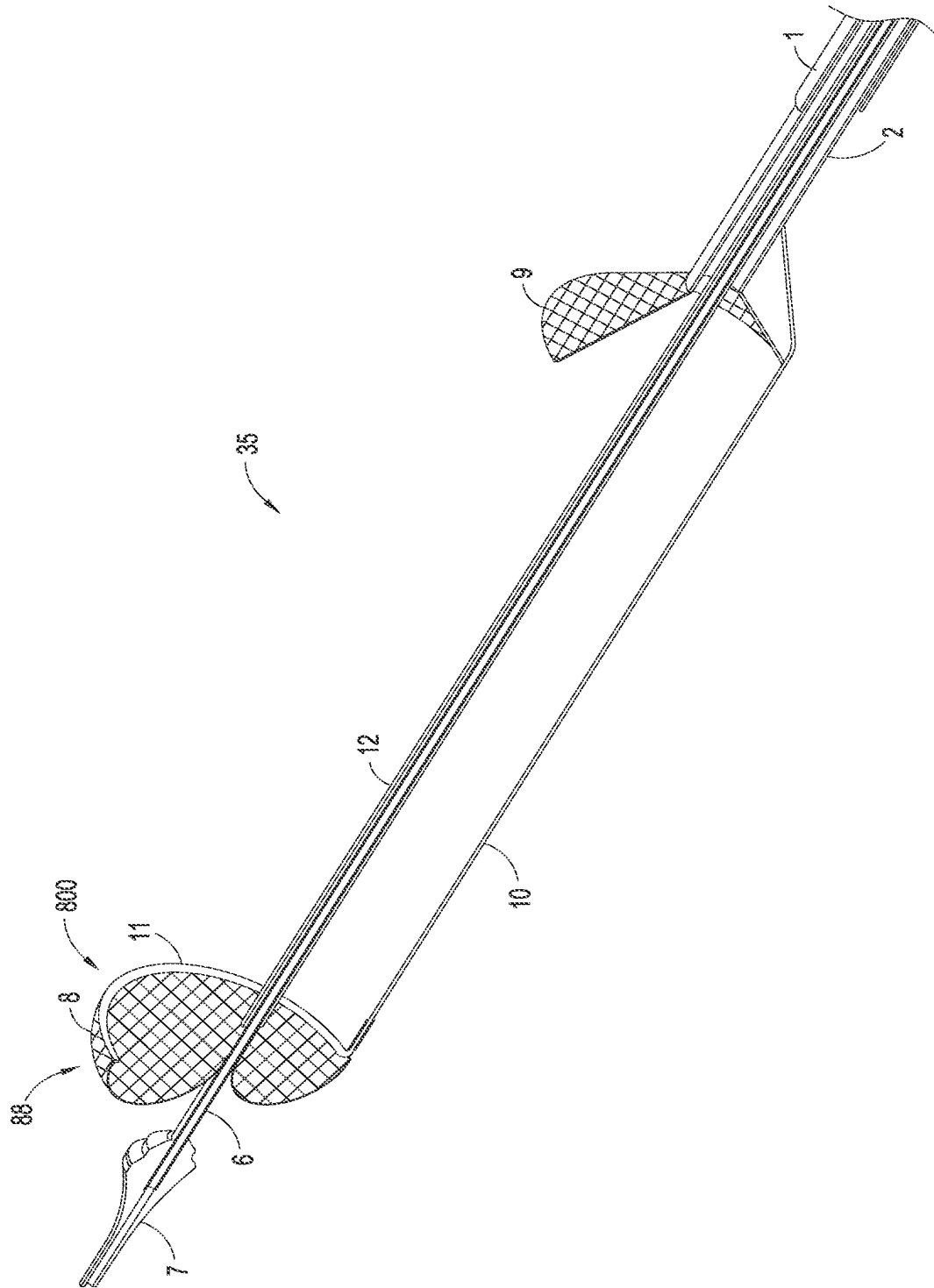


FIG. 13

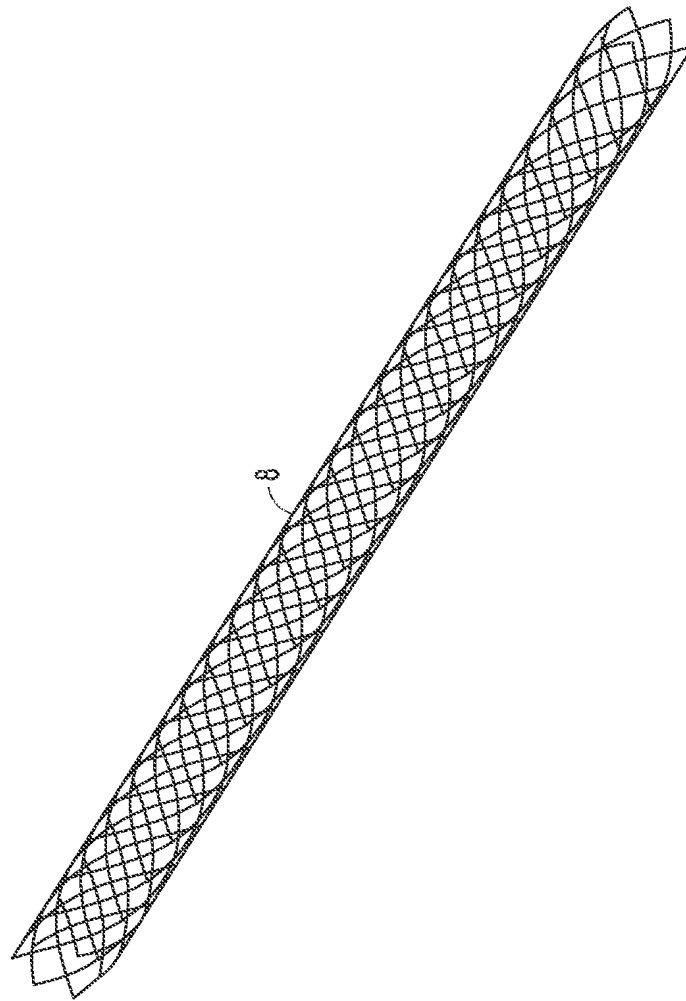


FIG. 14

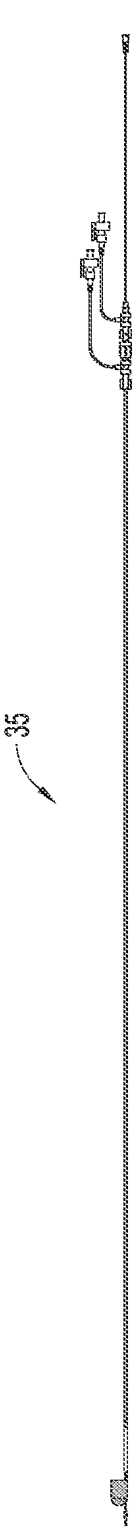


FIG. 15A

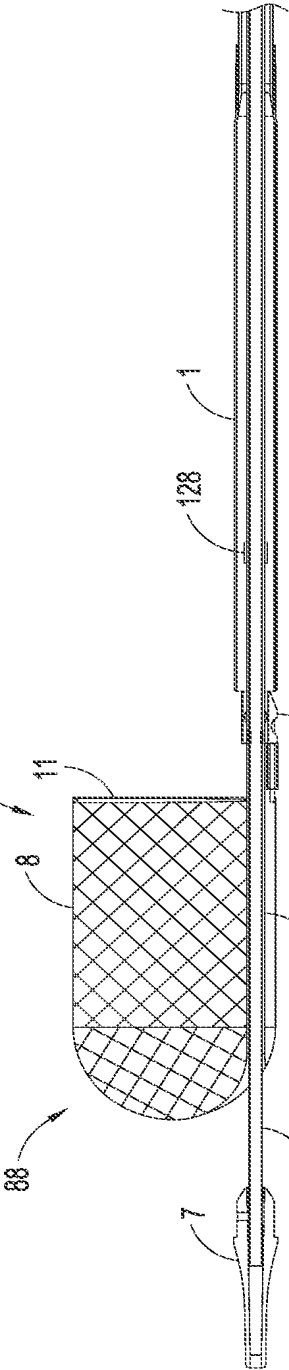


FIG. 15B

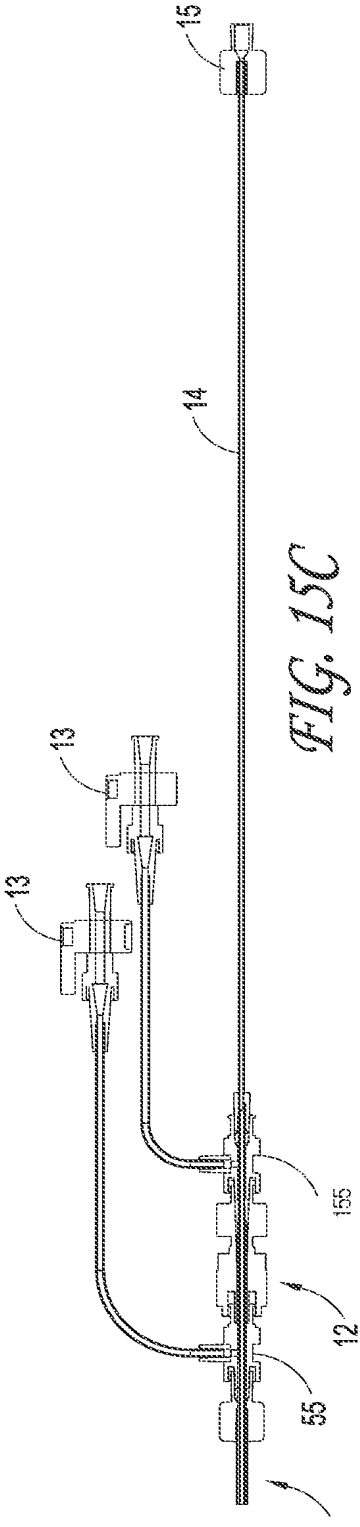


FIG. 15C

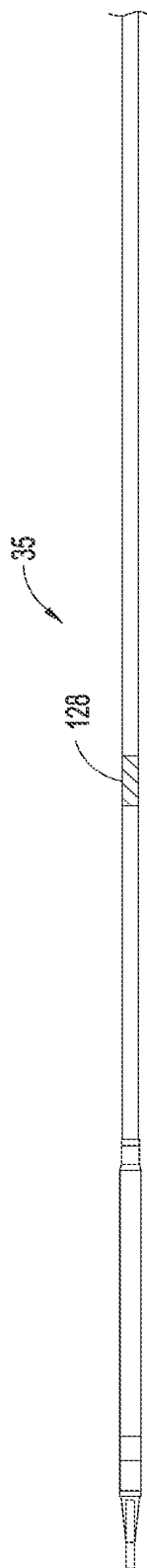


FIG. 16A

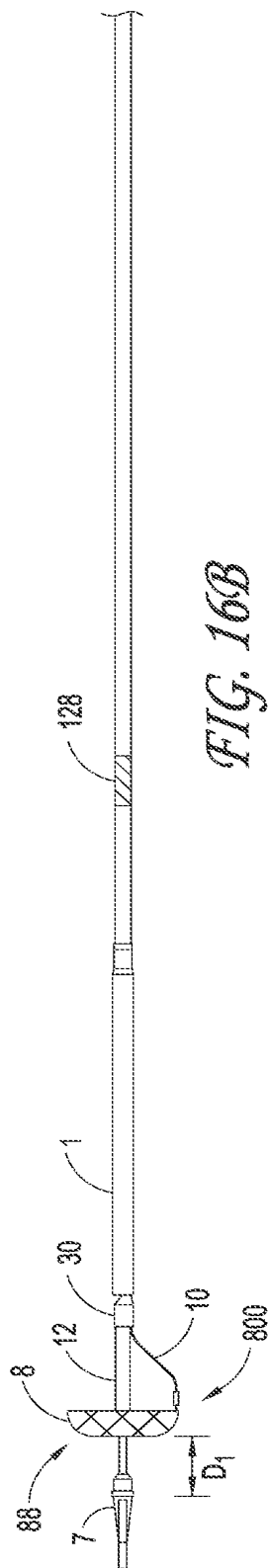


FIG. 16B

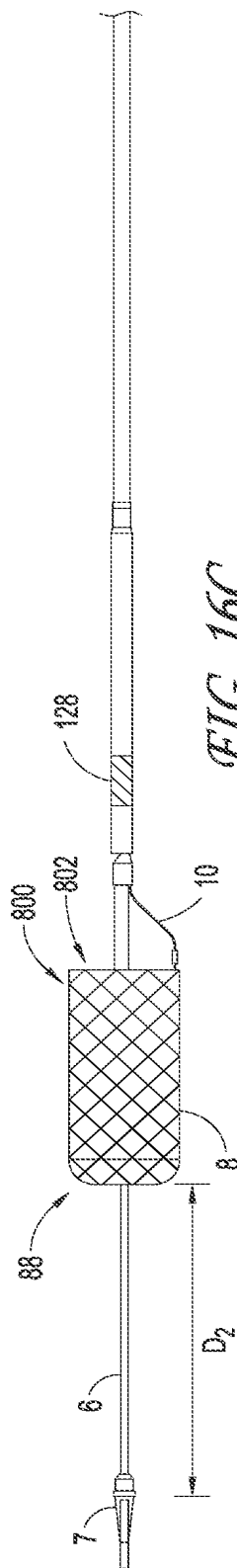


FIG. 16C

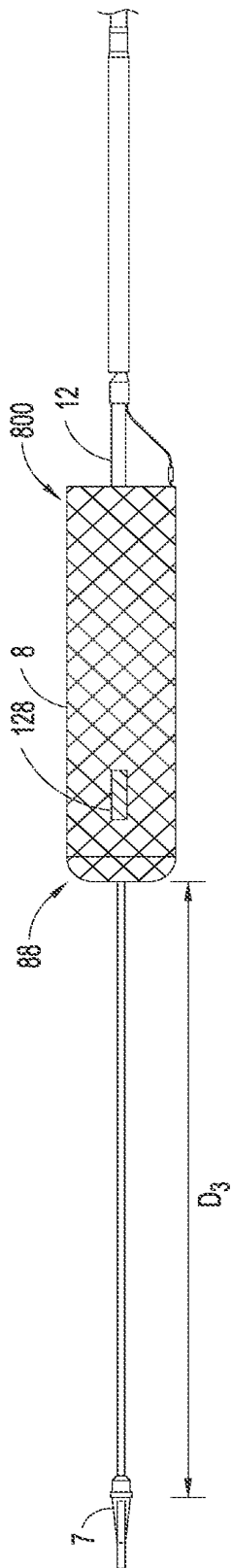
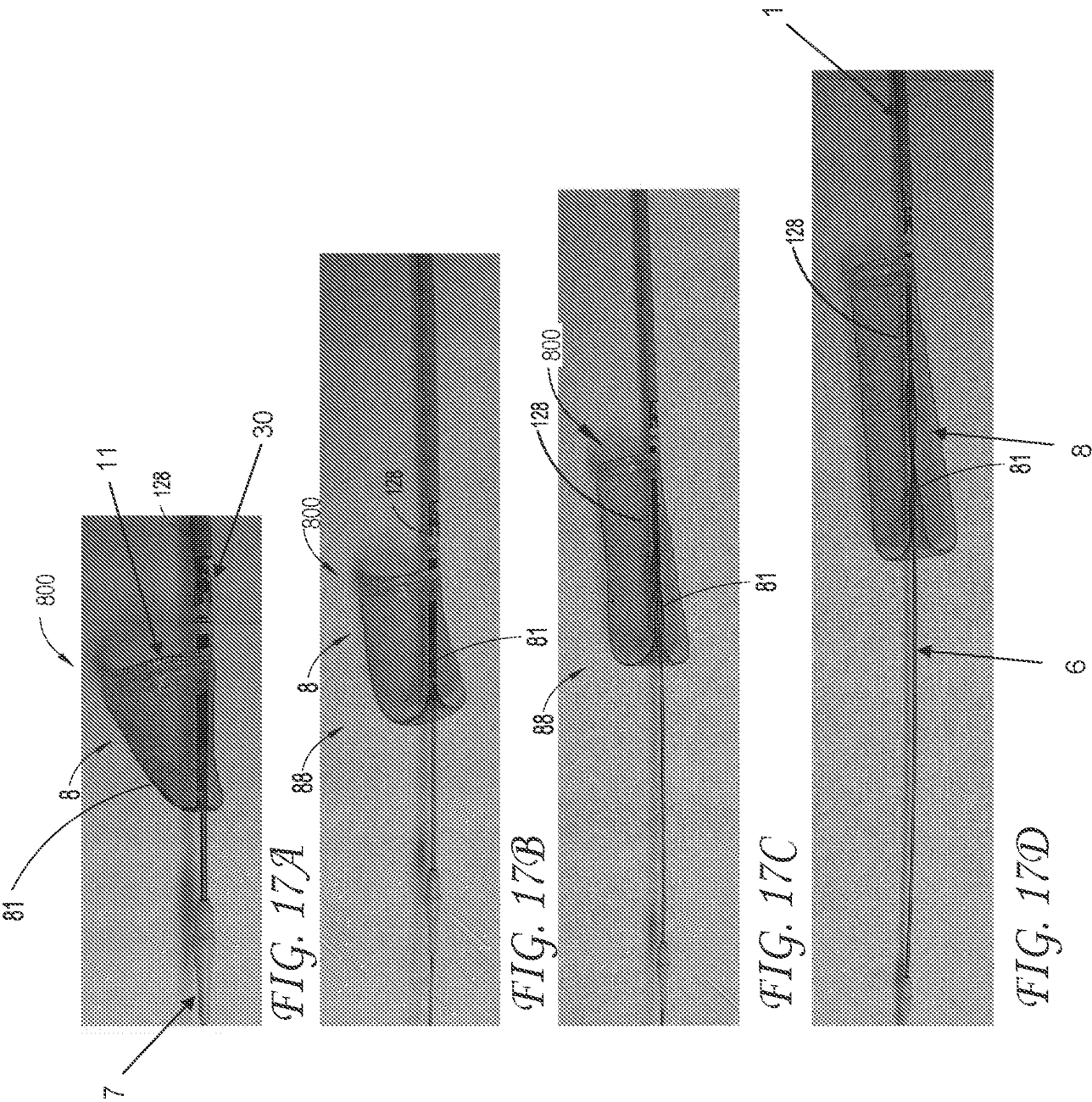


FIG. 16D



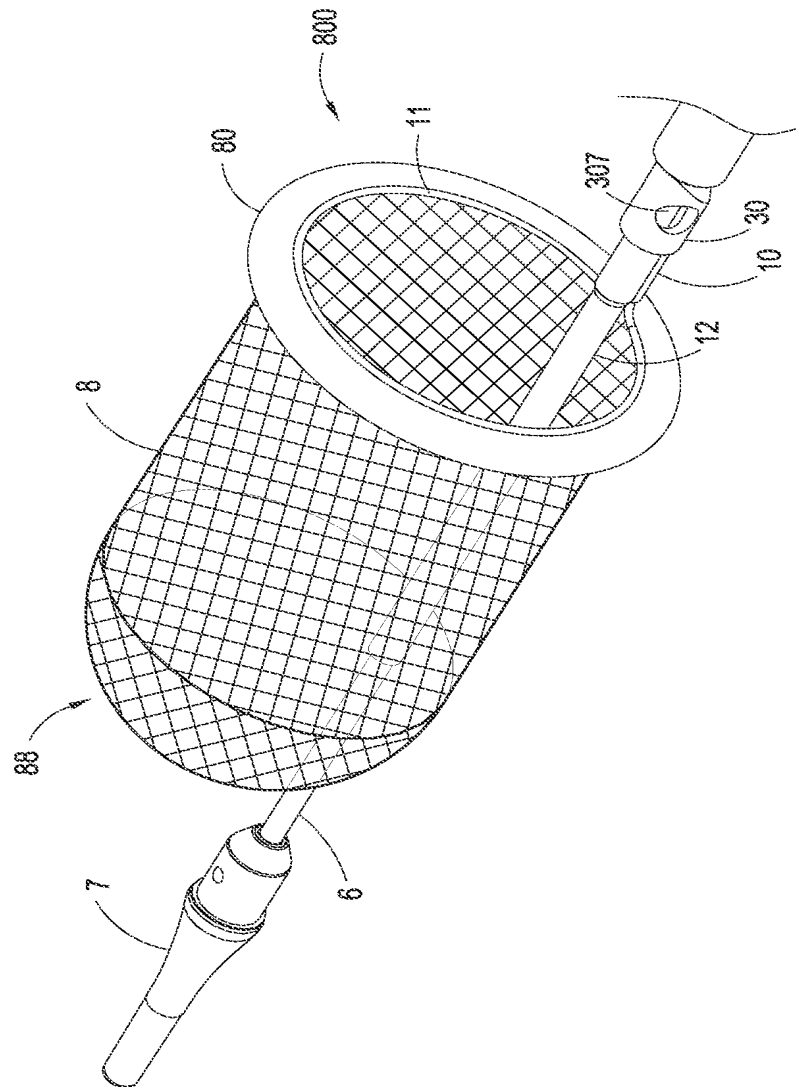


FIG. 18A

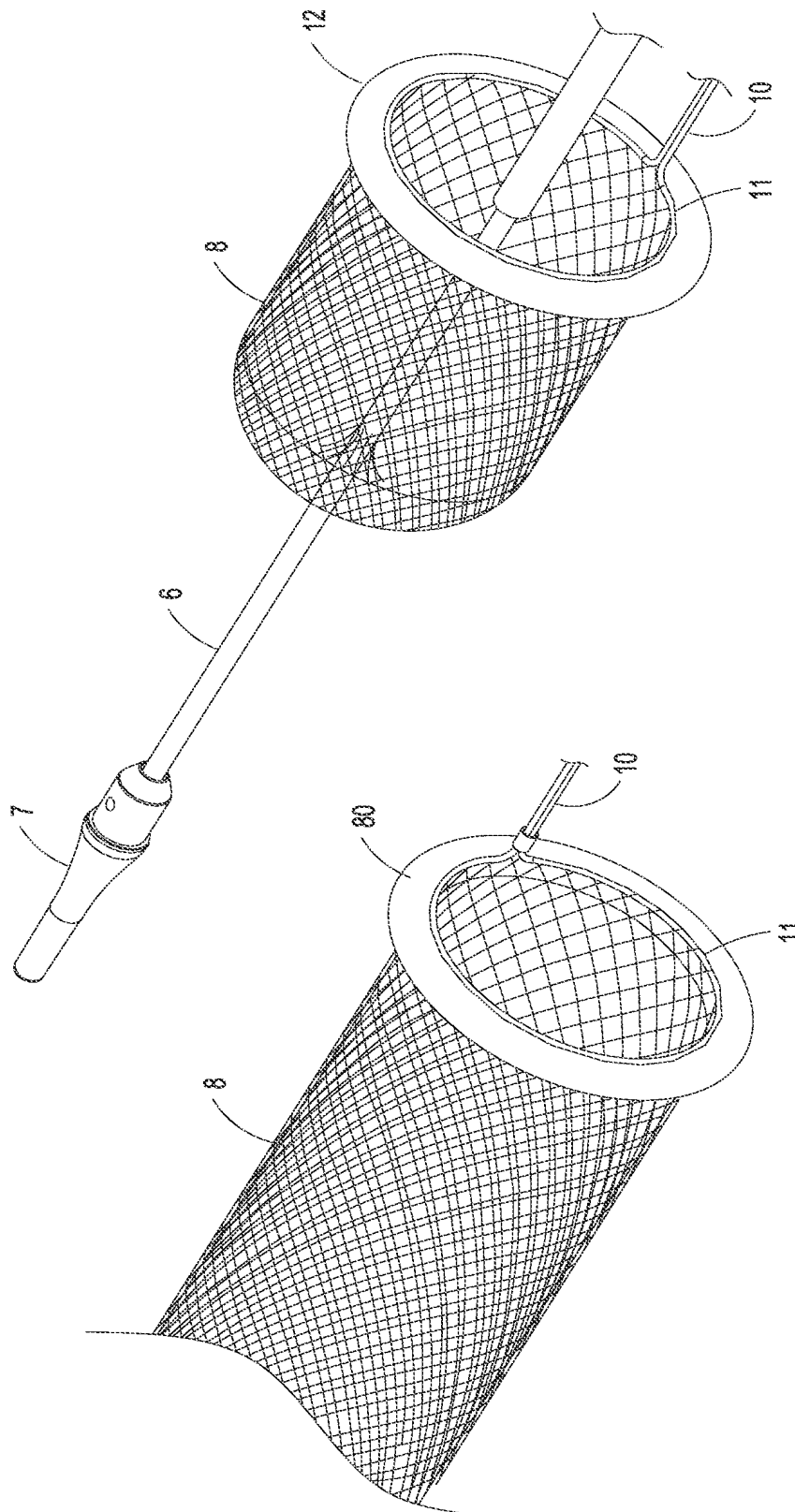


FIG. 18B

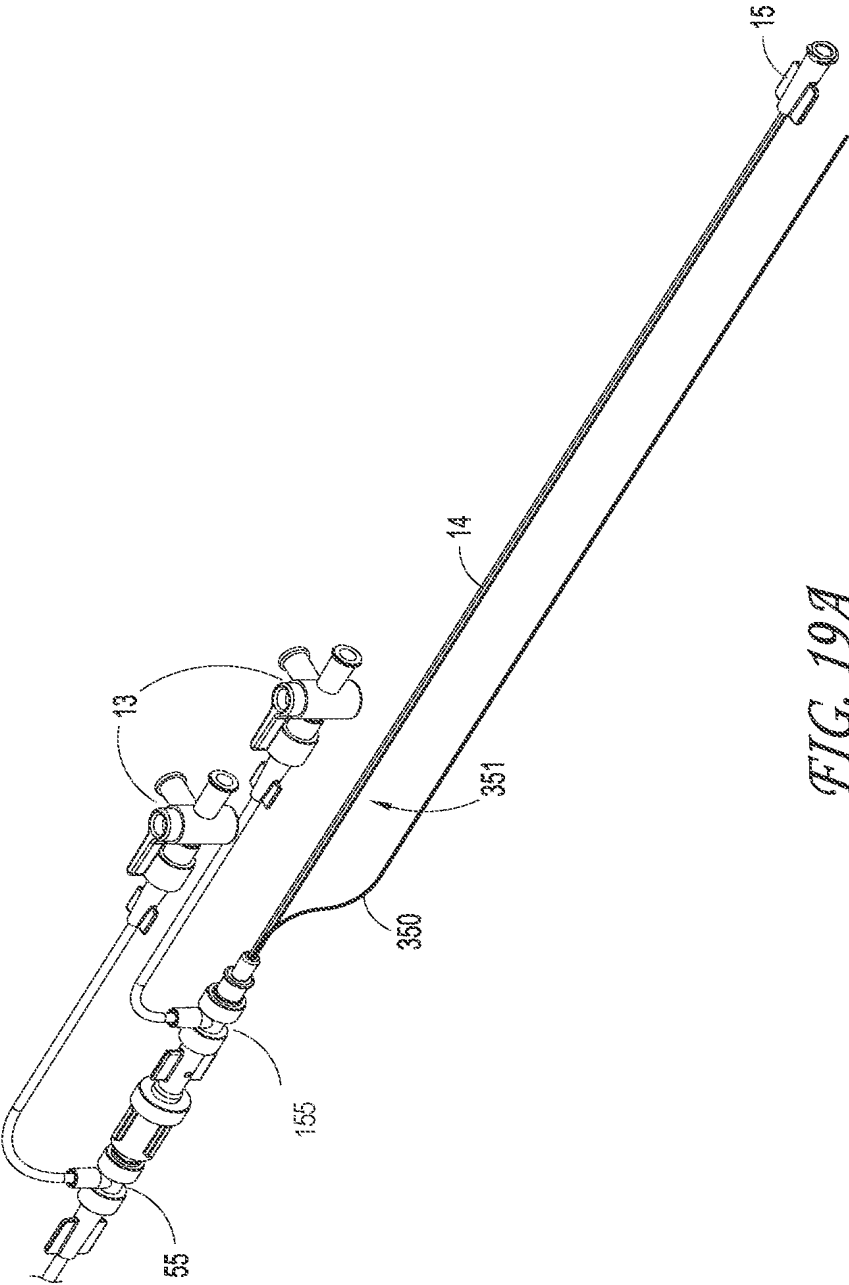
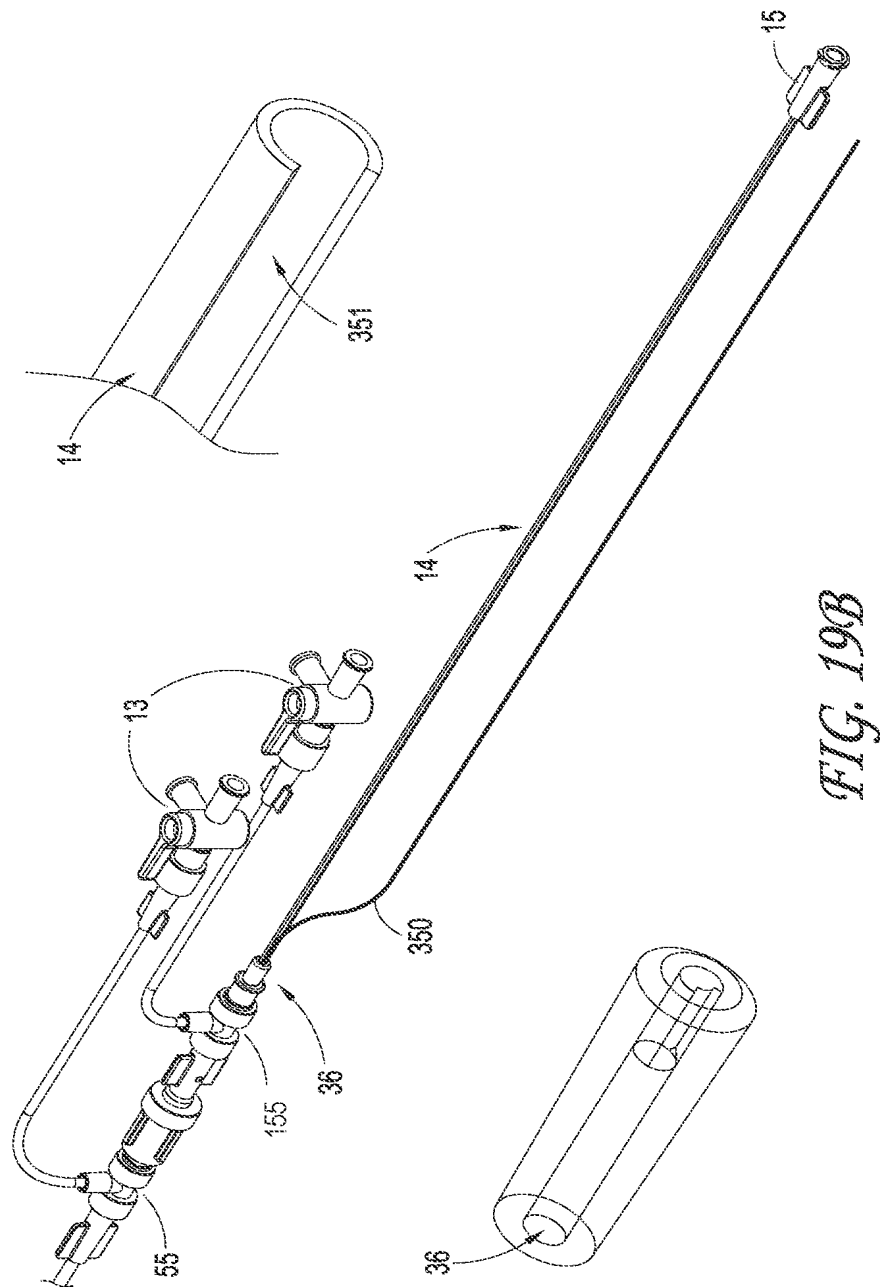


FIG. 19A



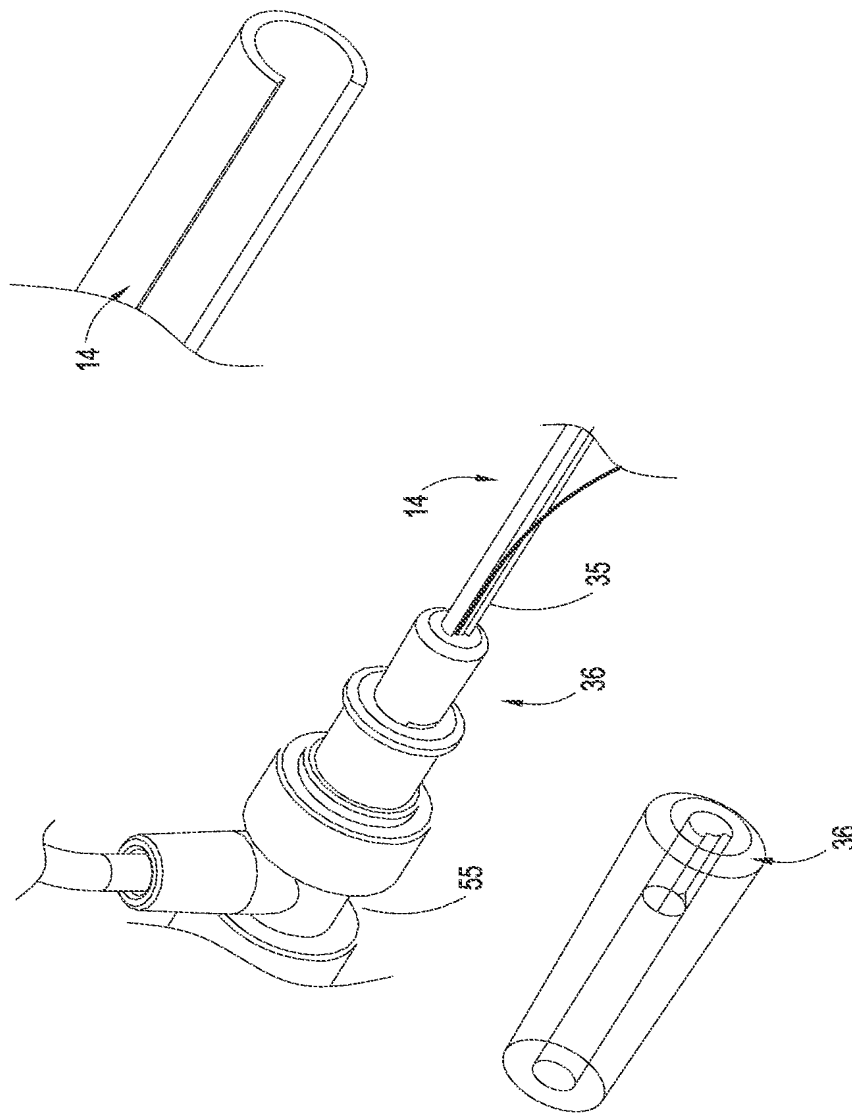


FIG. 19C

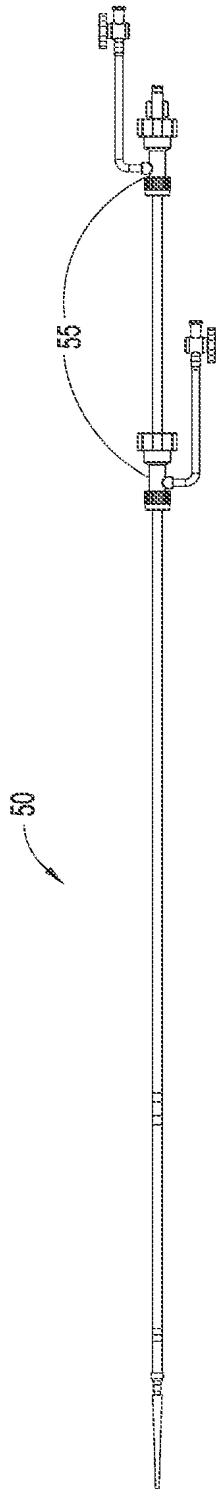


FIG. 20A

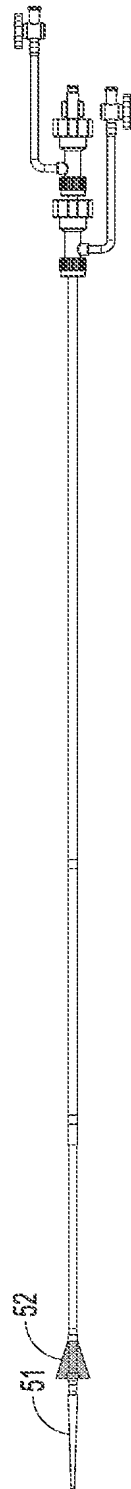


FIG. 20B

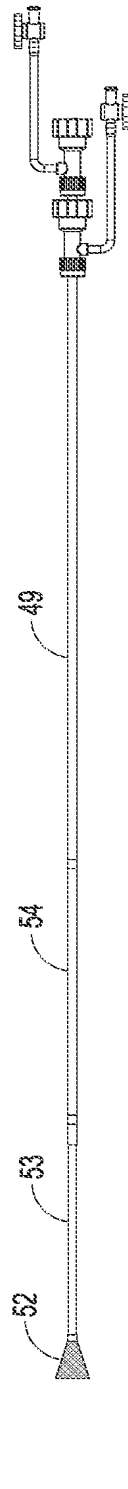
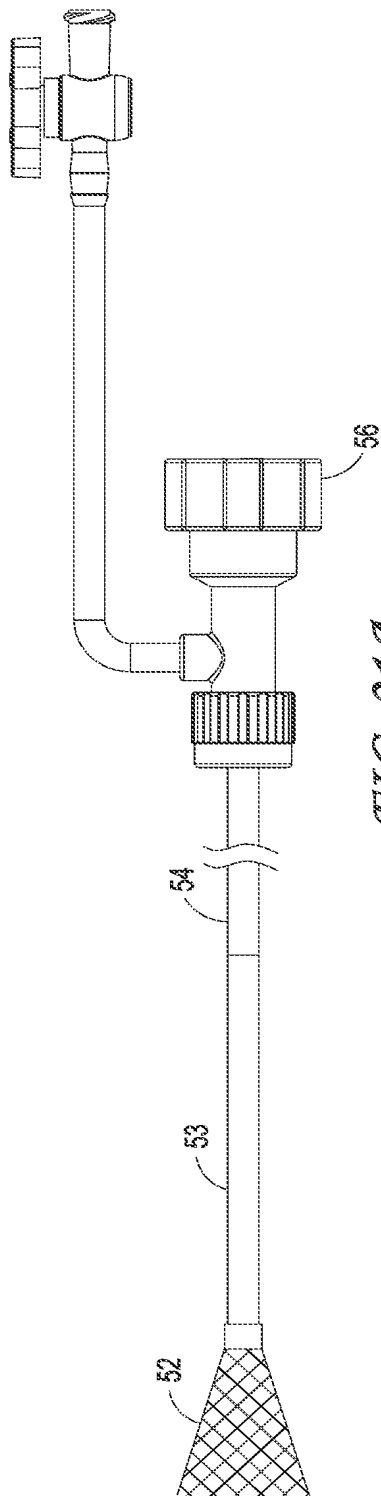
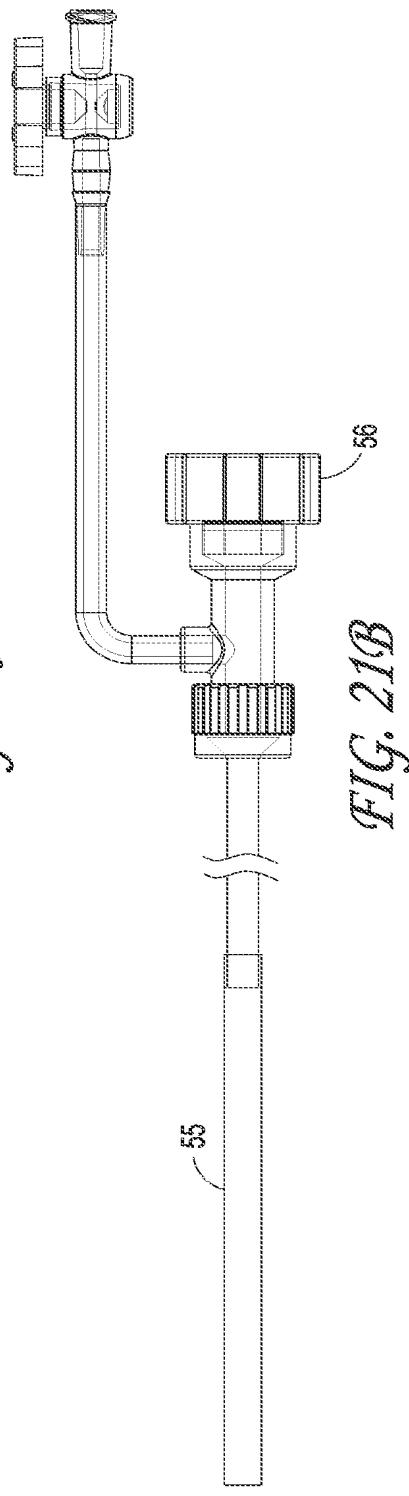
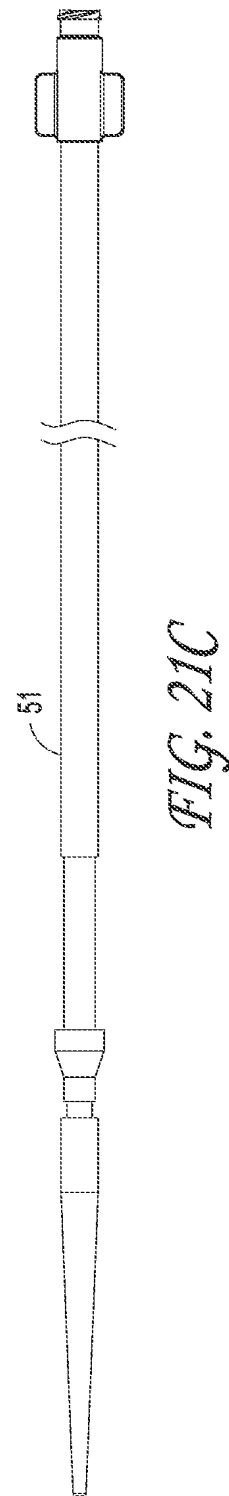
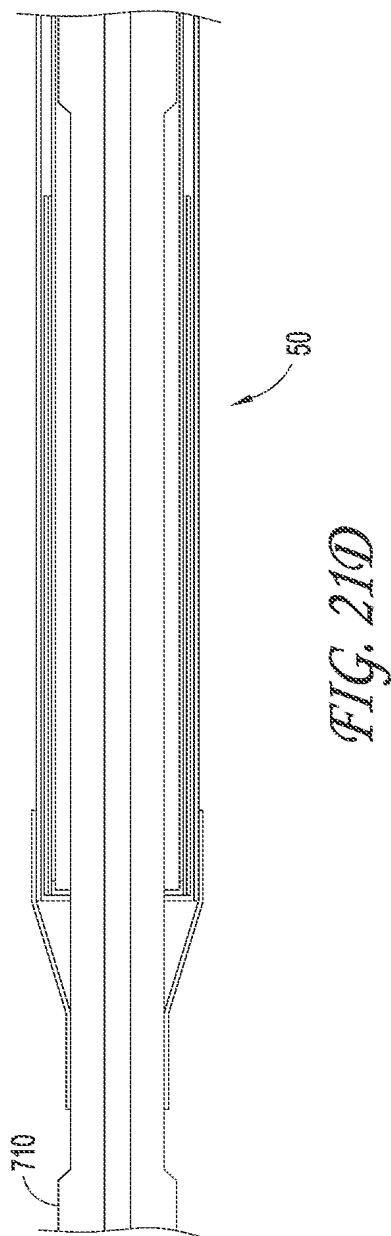


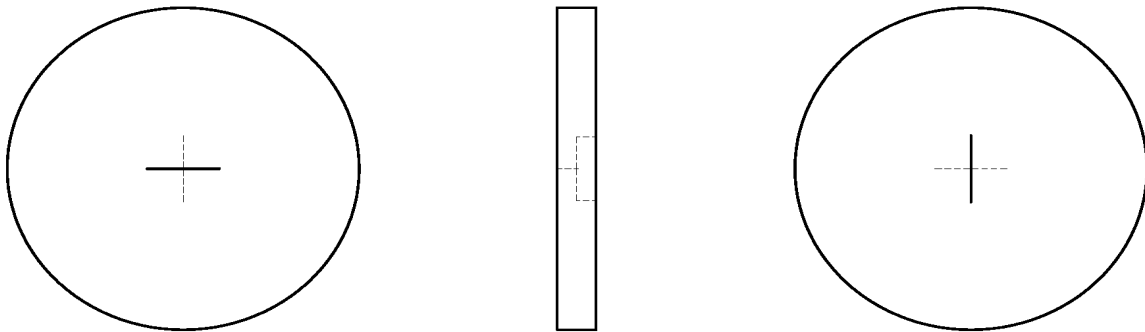
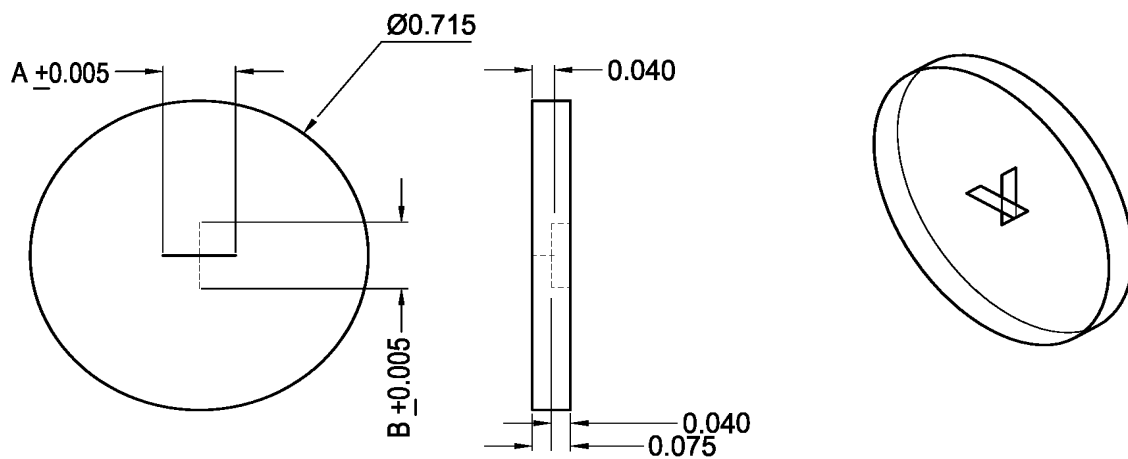
FIG. 20C

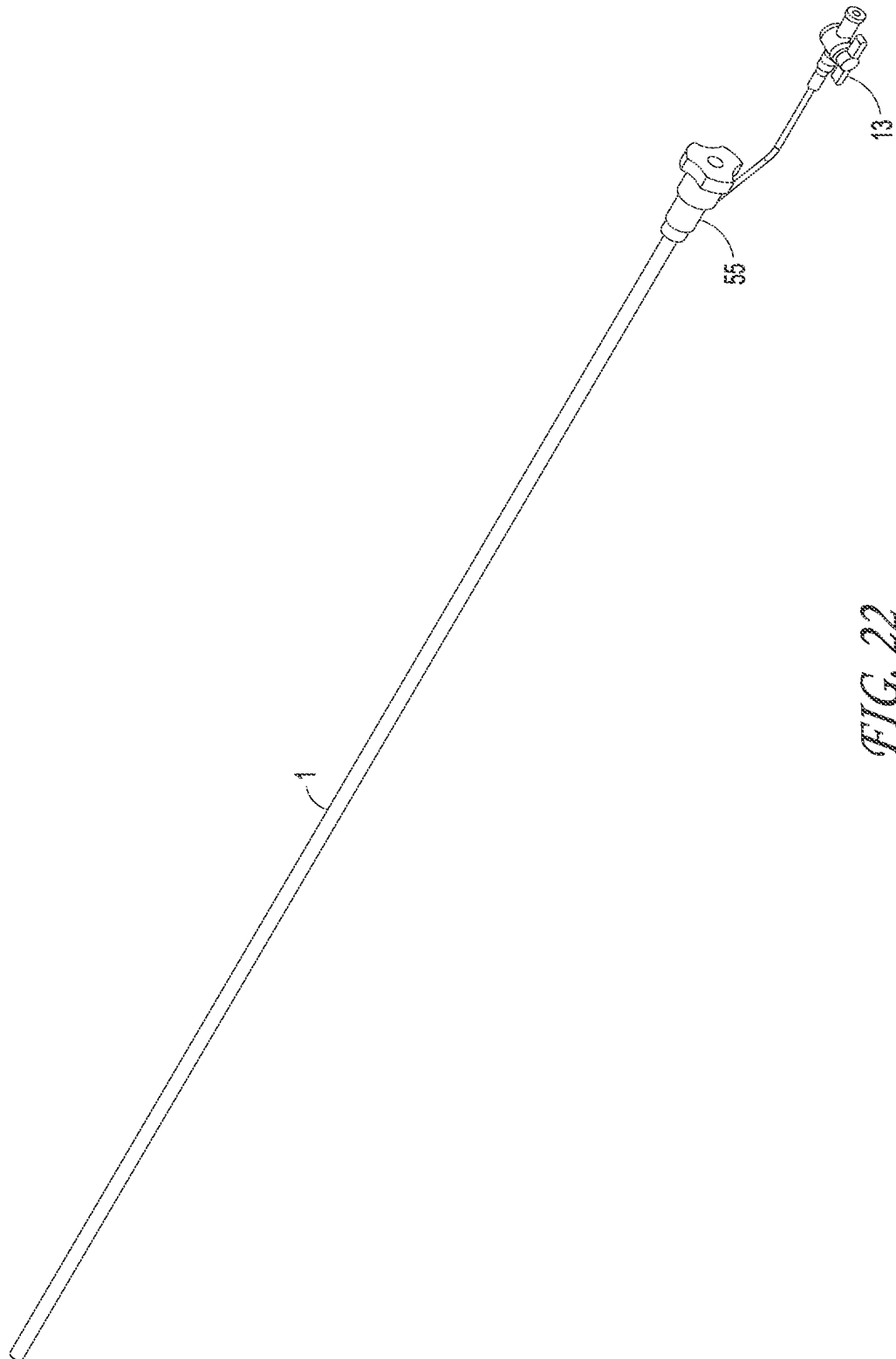


FIG. 20D





*FIG. 21E**FIG. 21F*



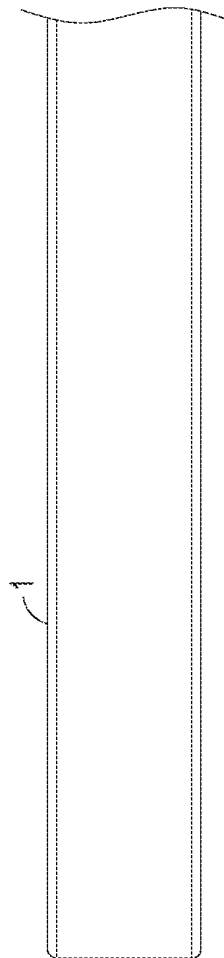


FIG. 23

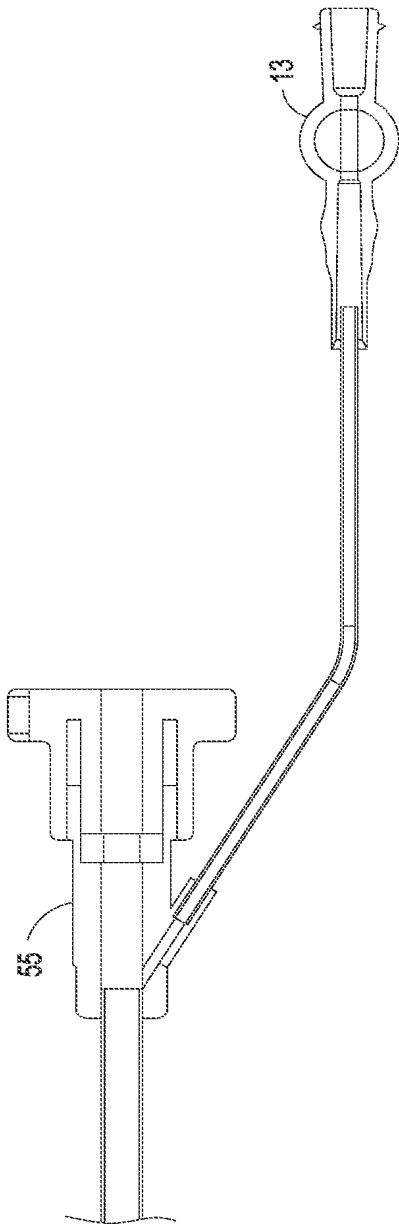


FIG. 24

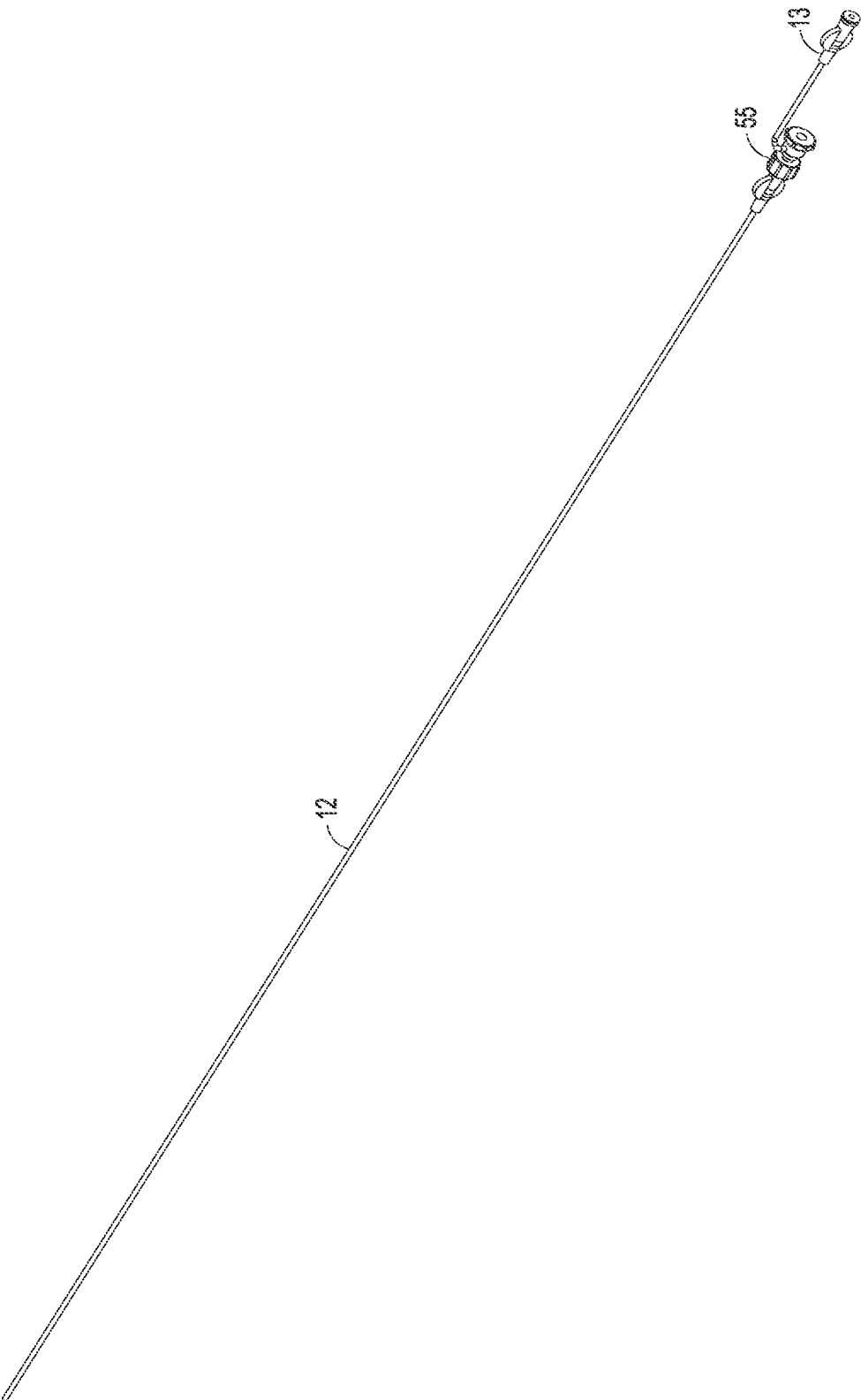


FIG. 25

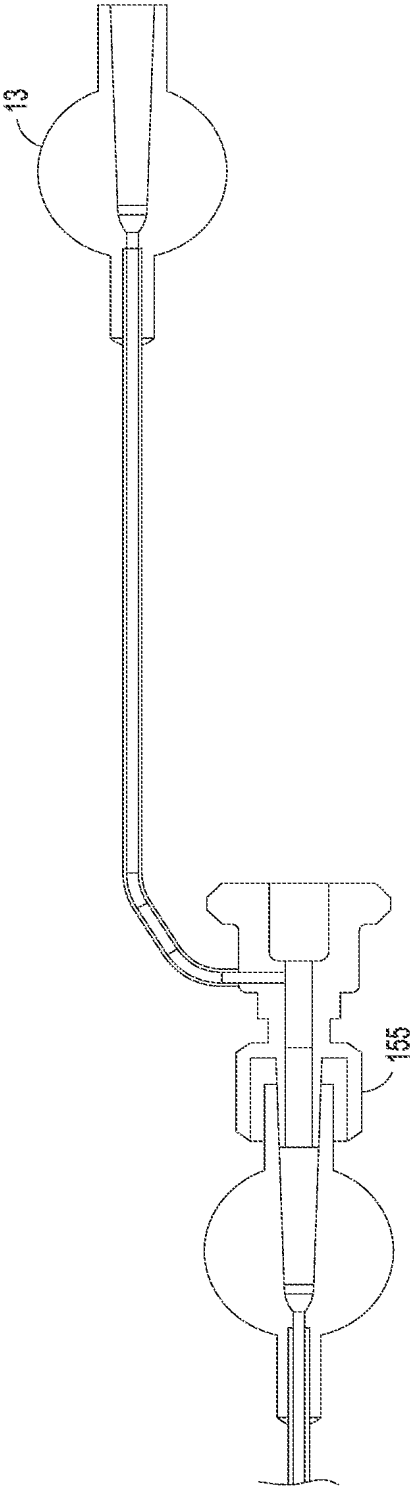
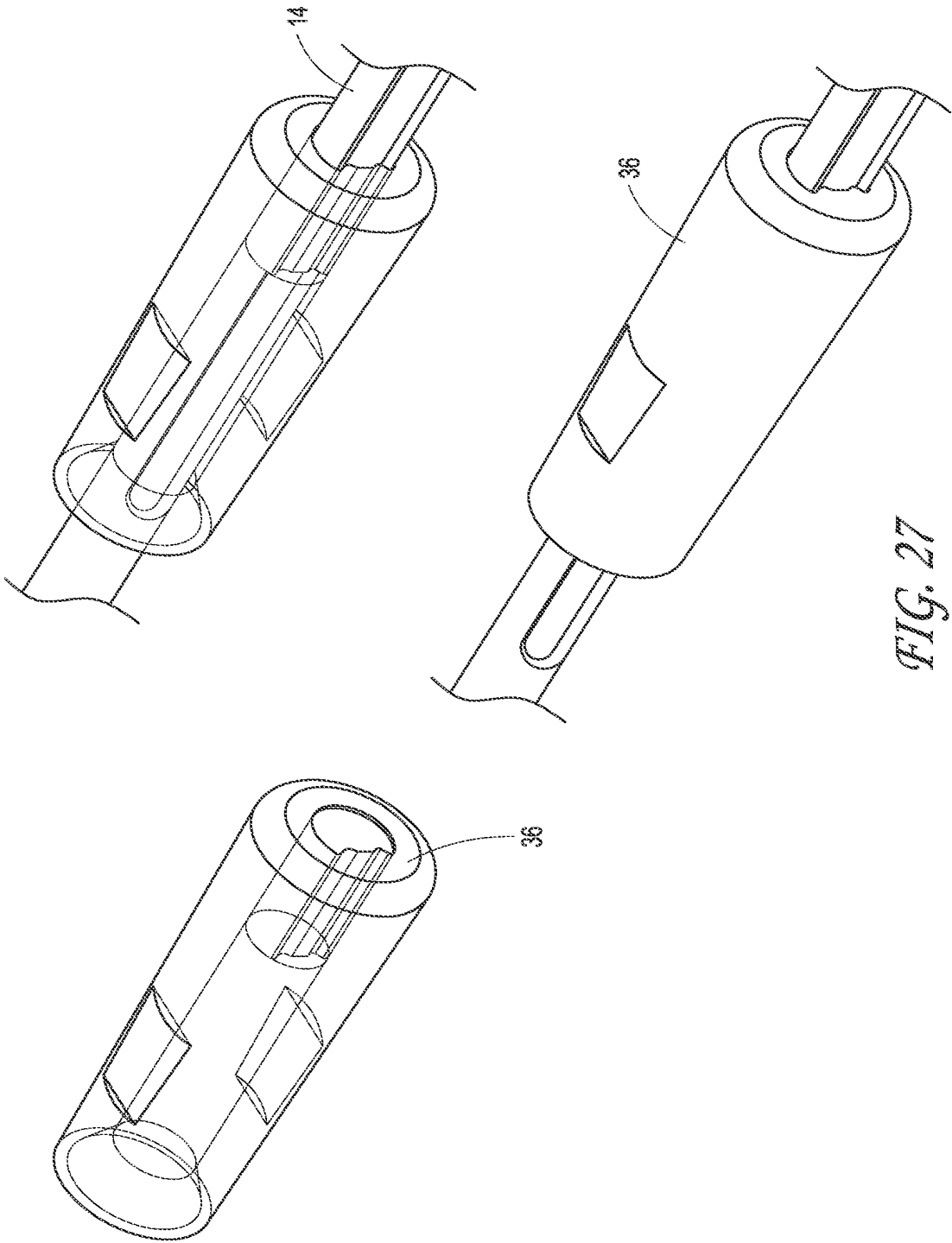


FIG. 26



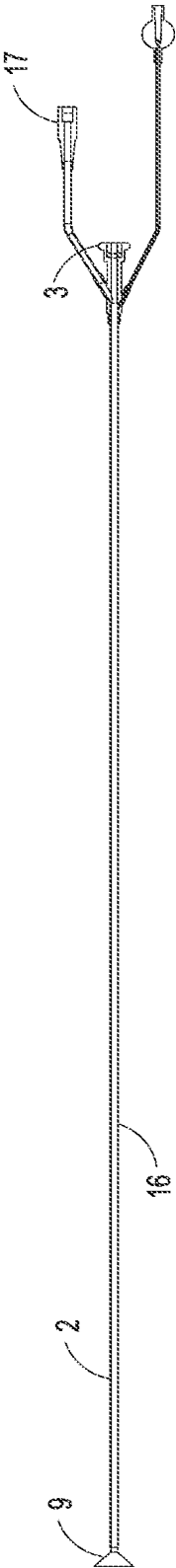


FIG. 28

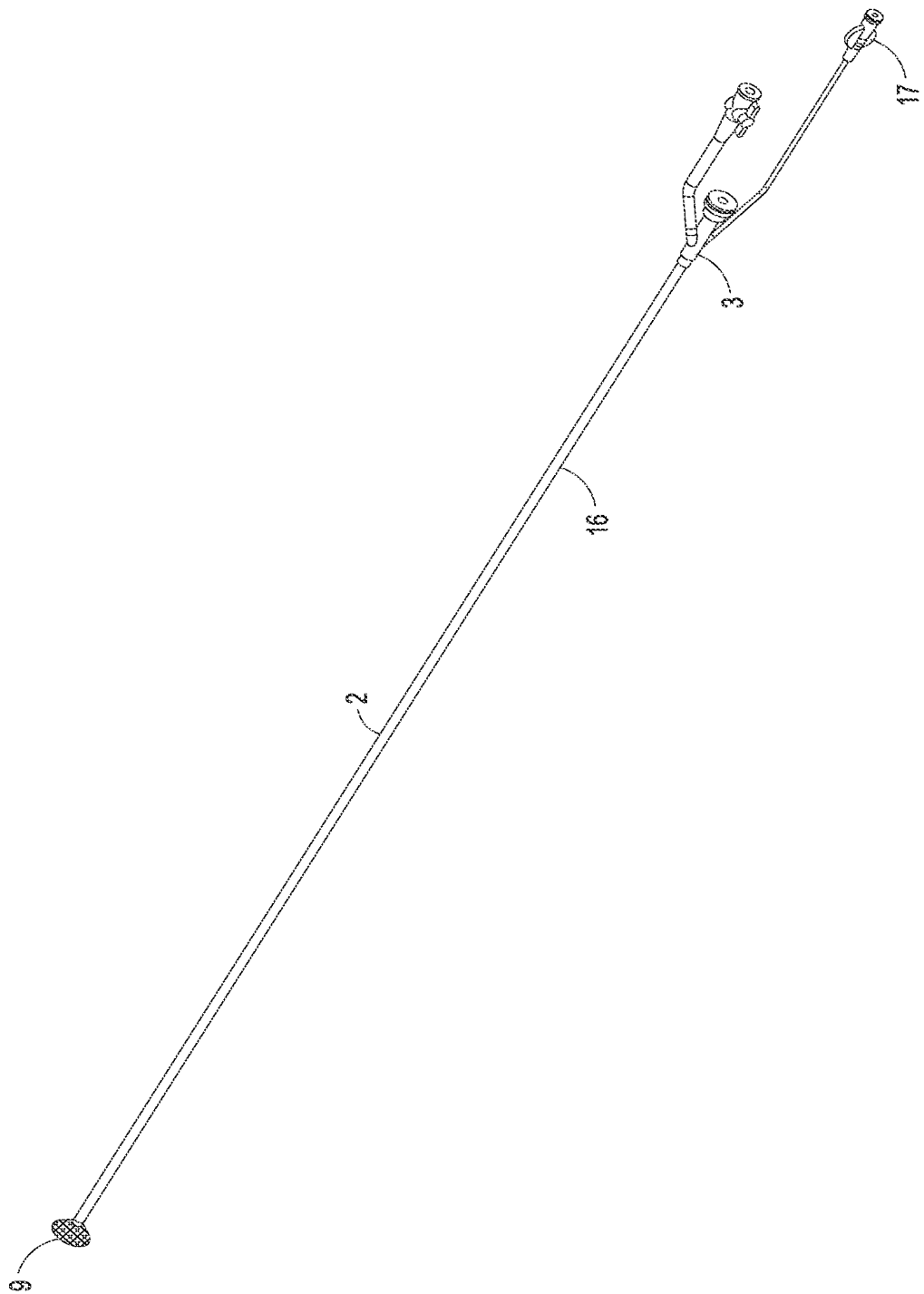


FIG. 29

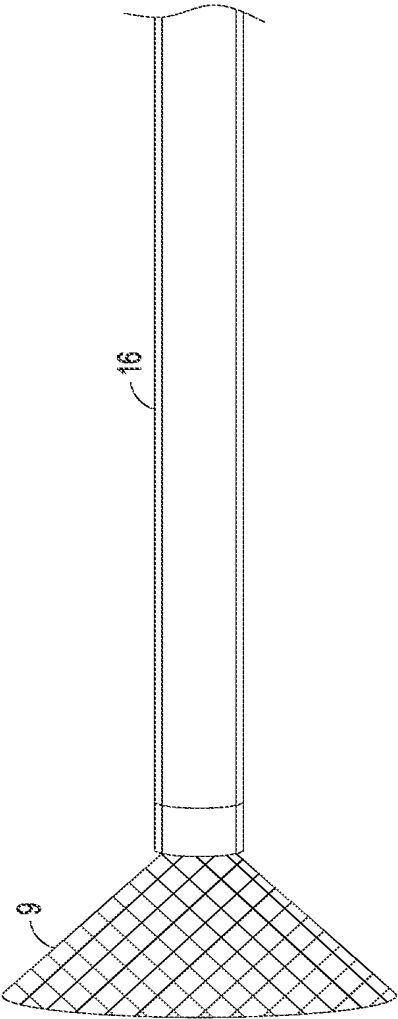


FIG. 30

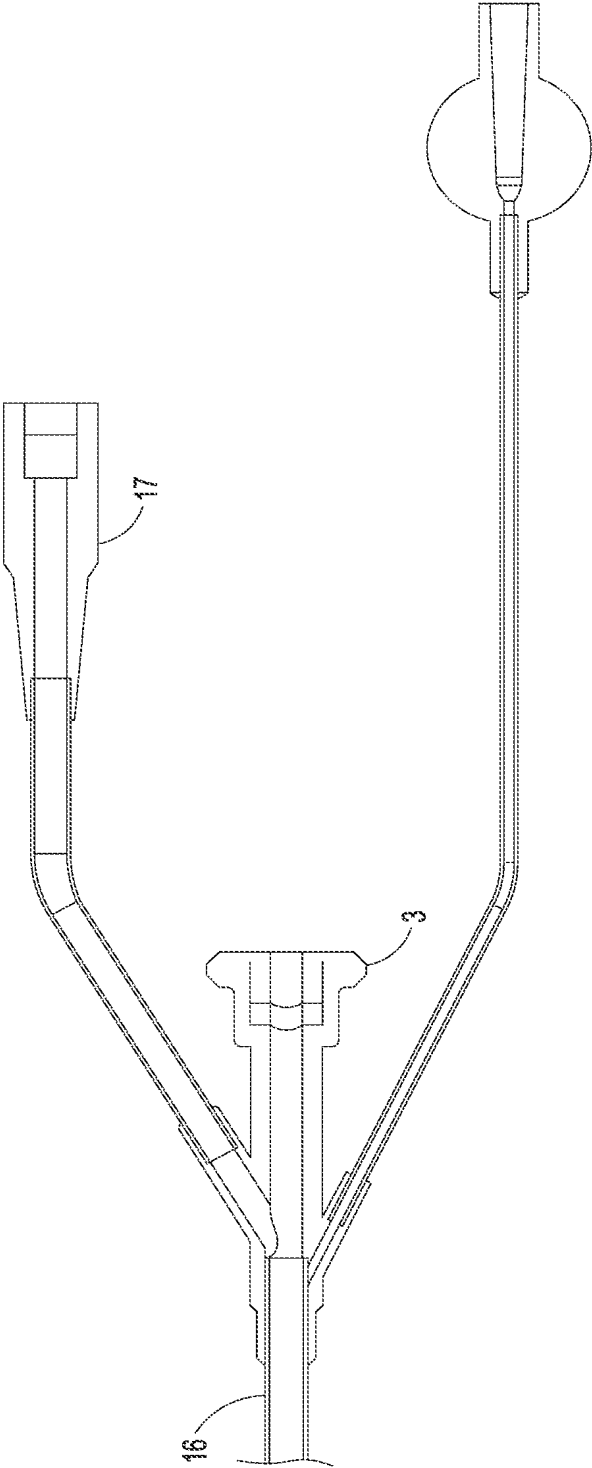


FIG. 31



FIG. 32

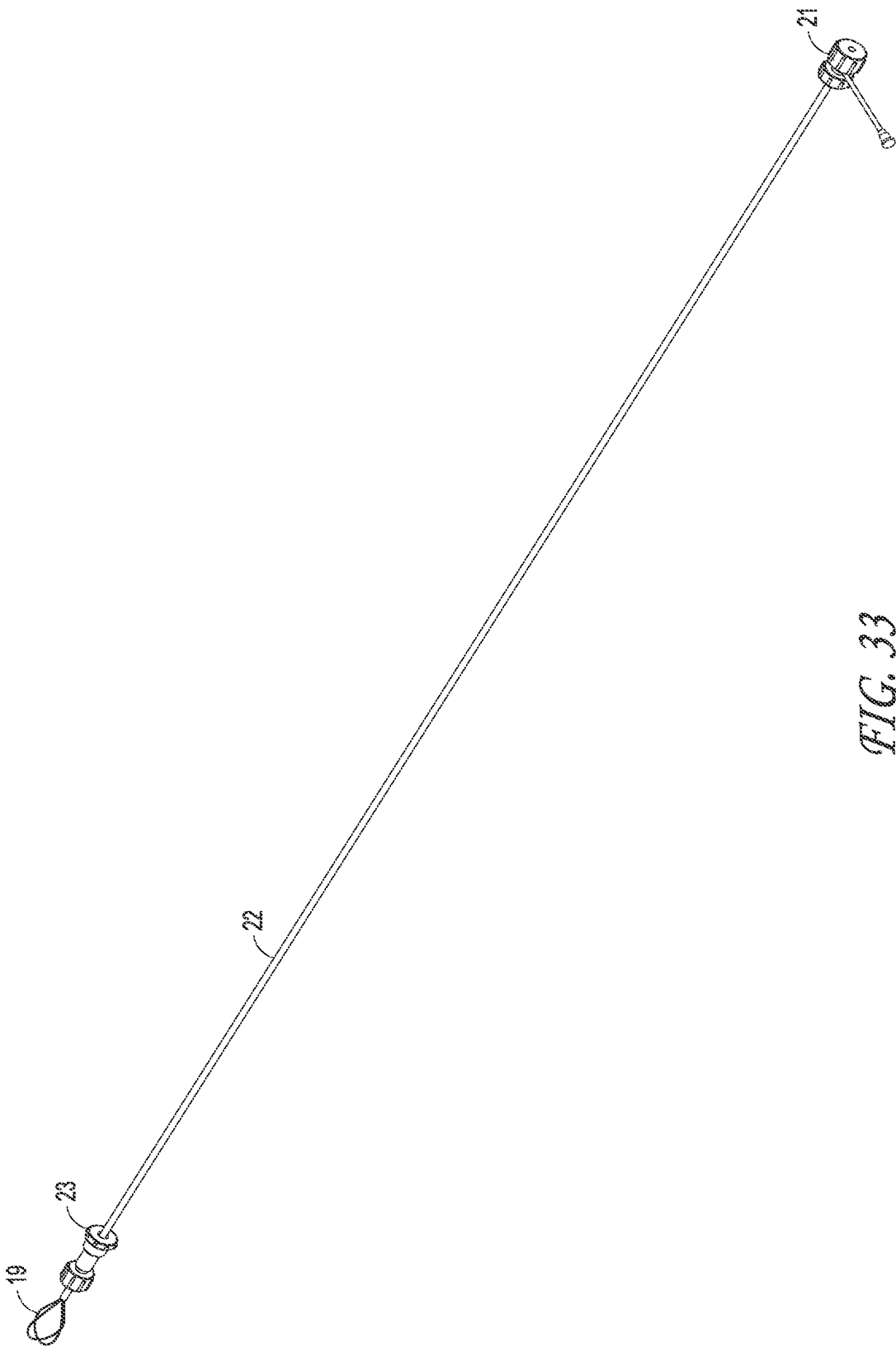


FIG. 33

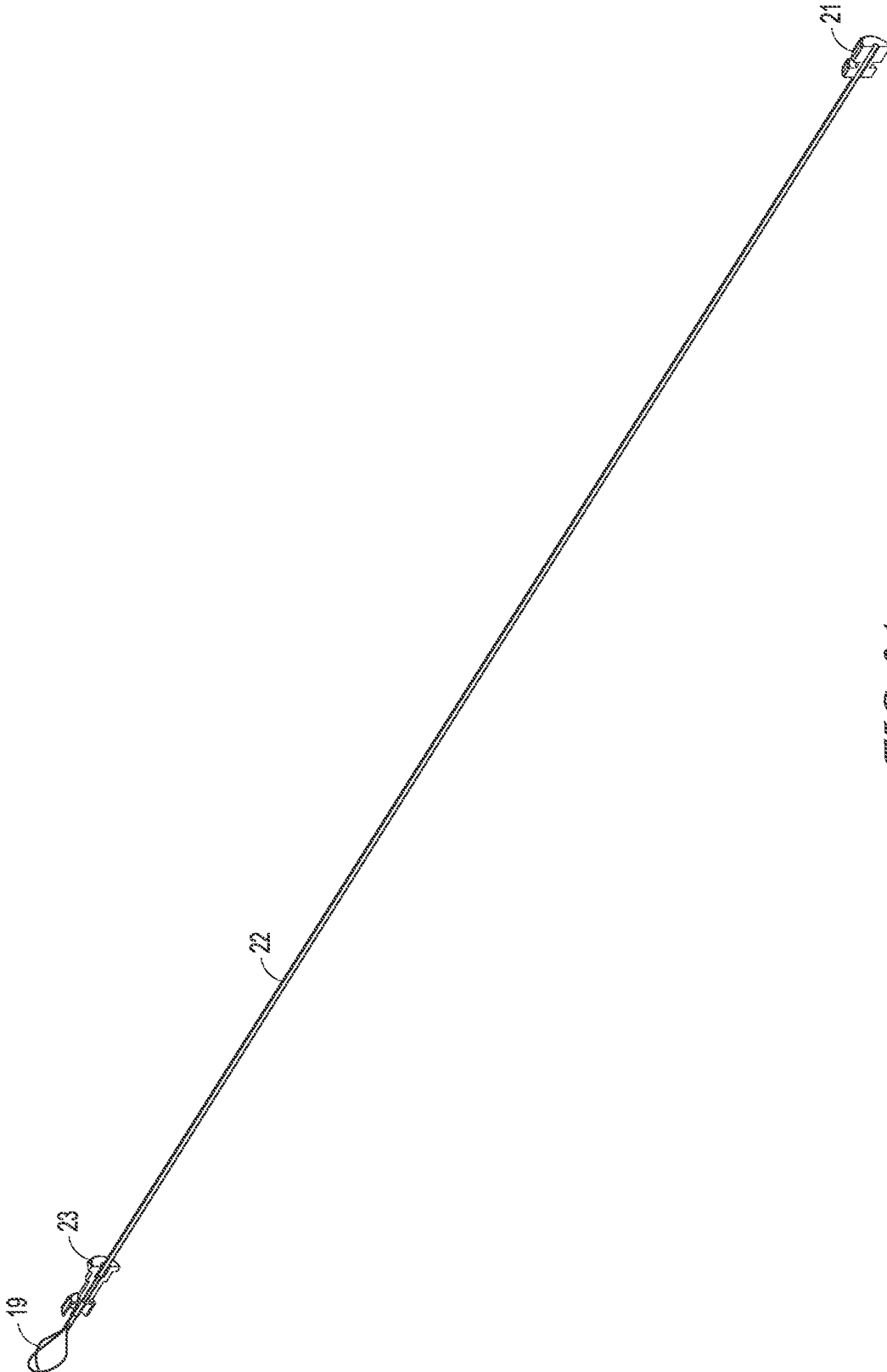


FIG. 34

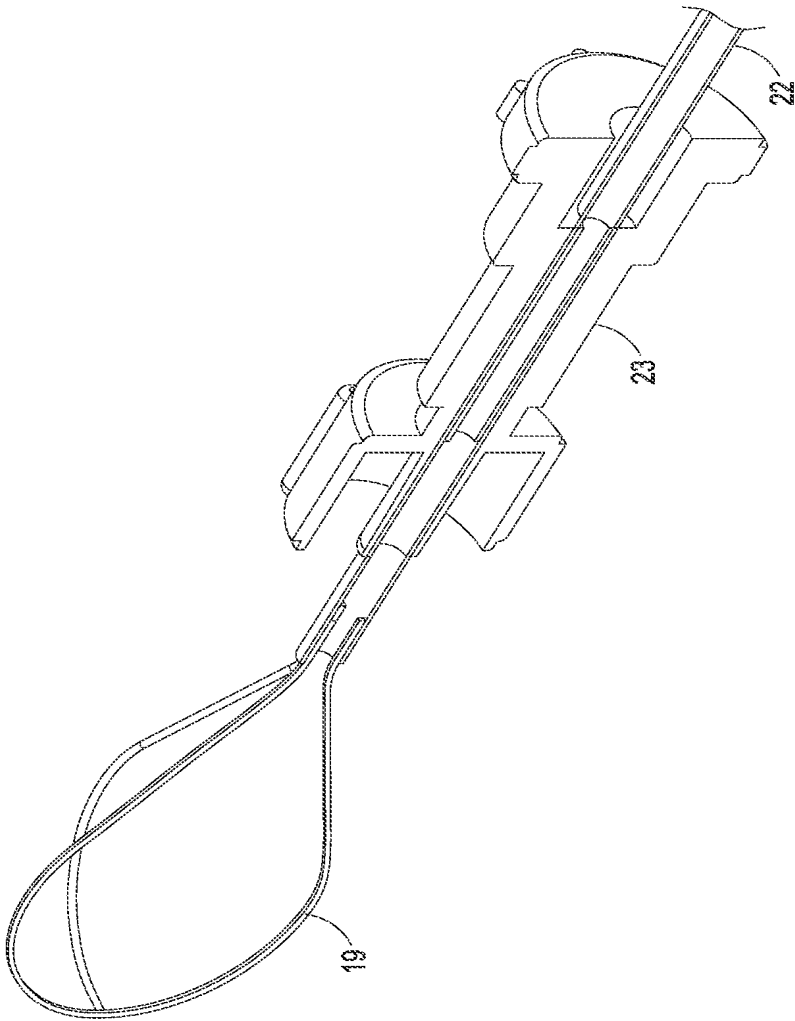


FIG. 35

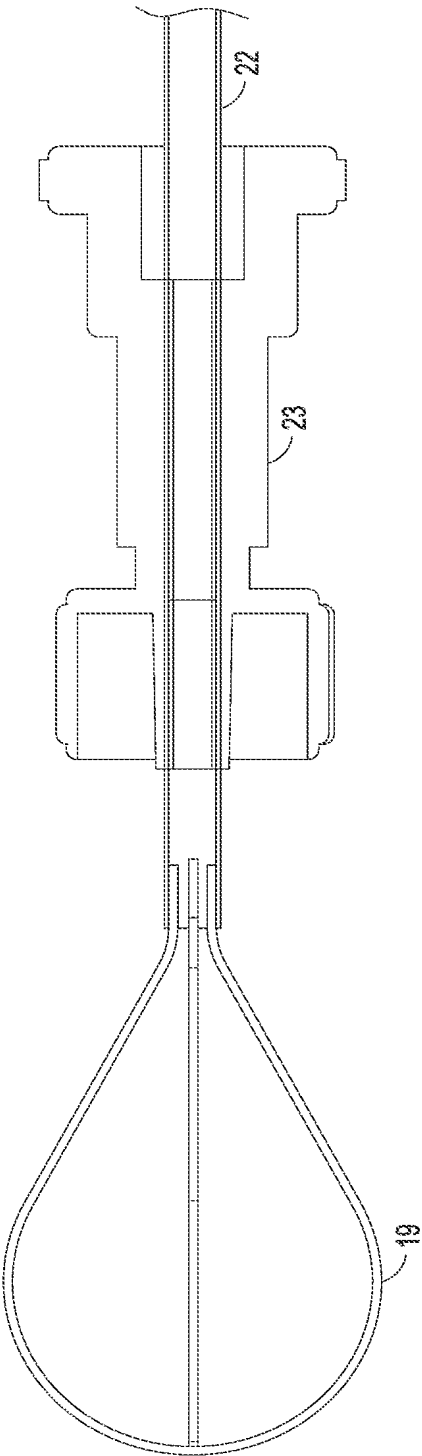


FIG. 36

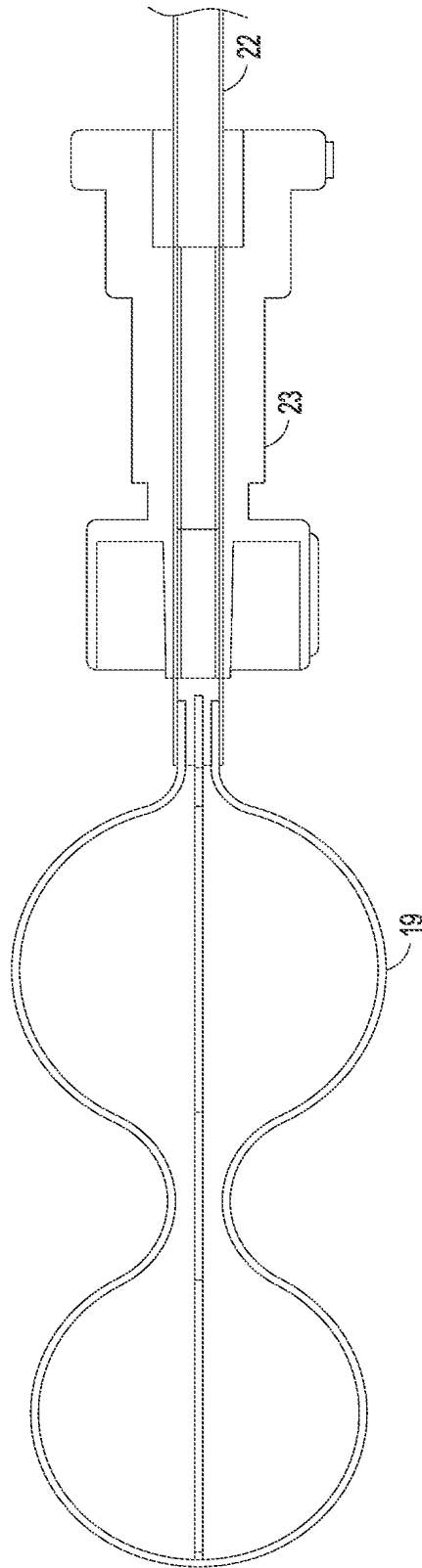


FIG. 37

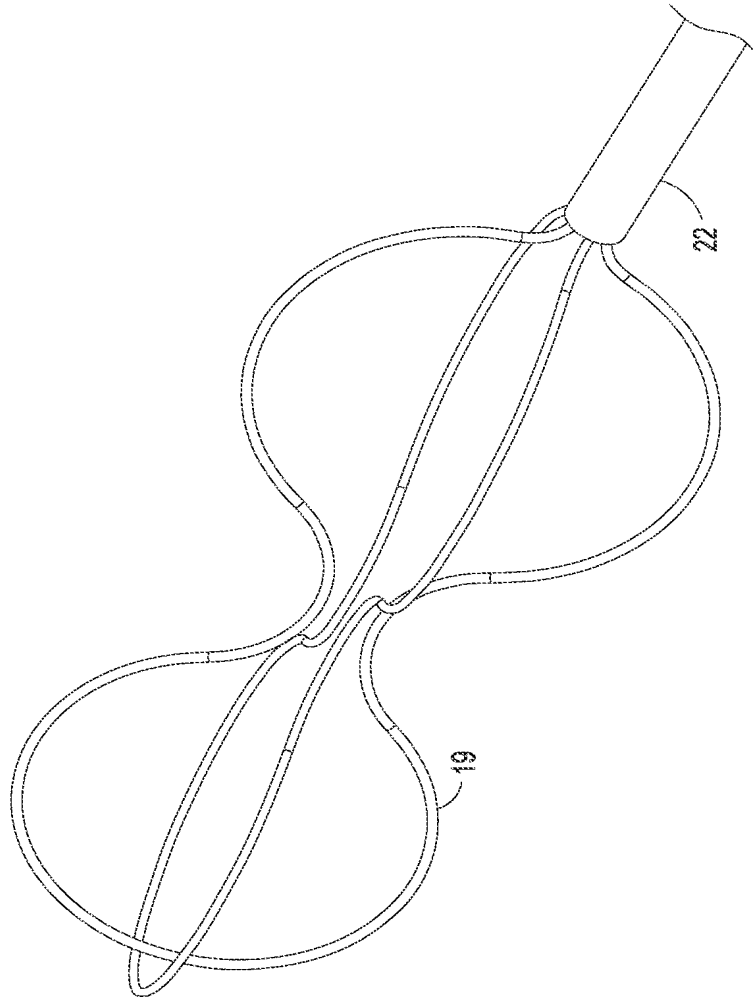


FIG. 38

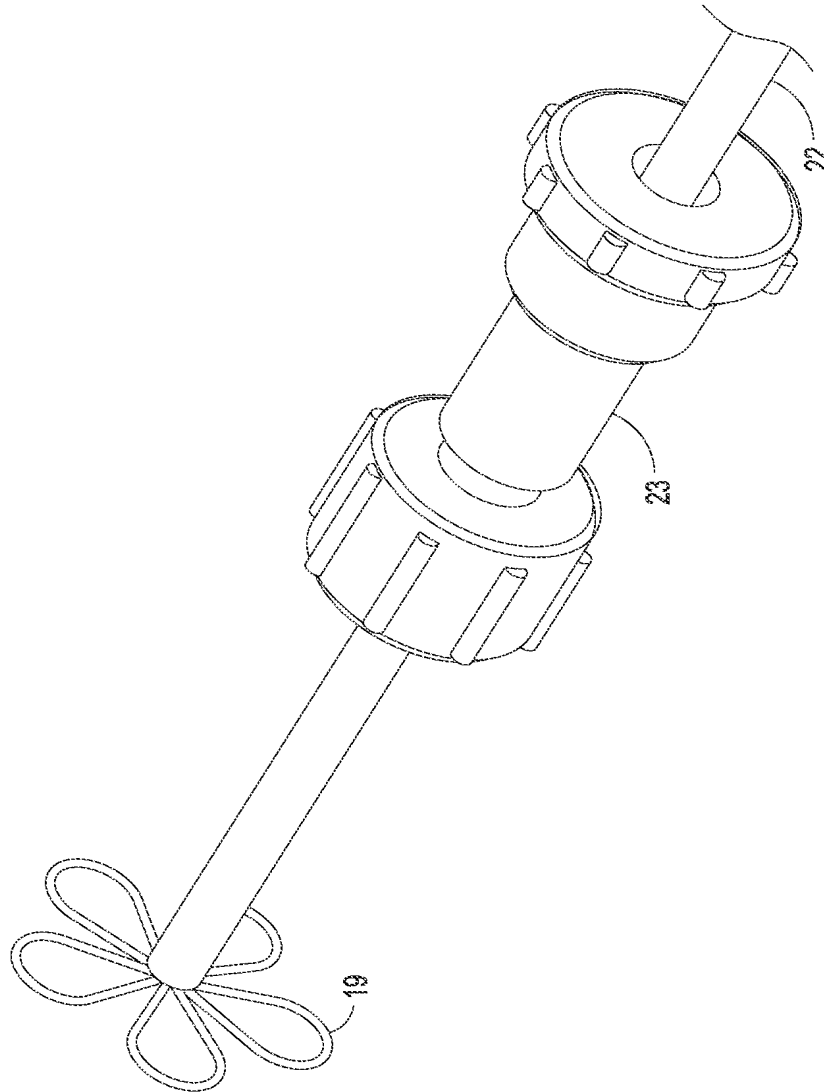


FIG. 39

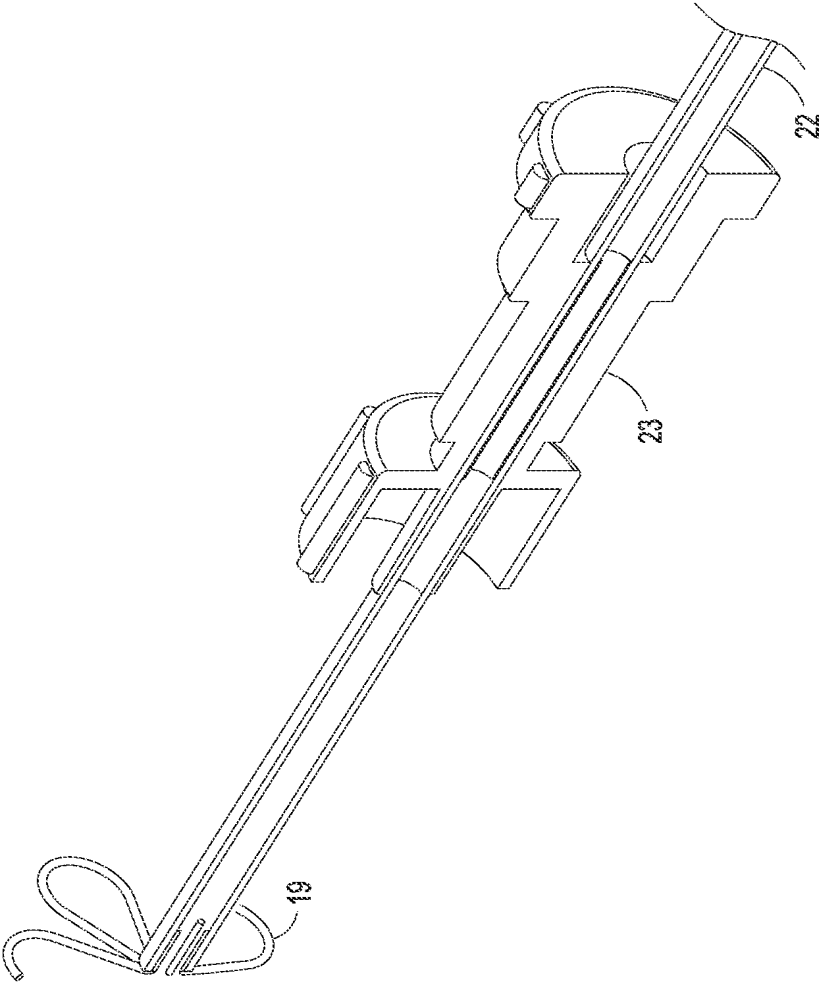


FIG. 40

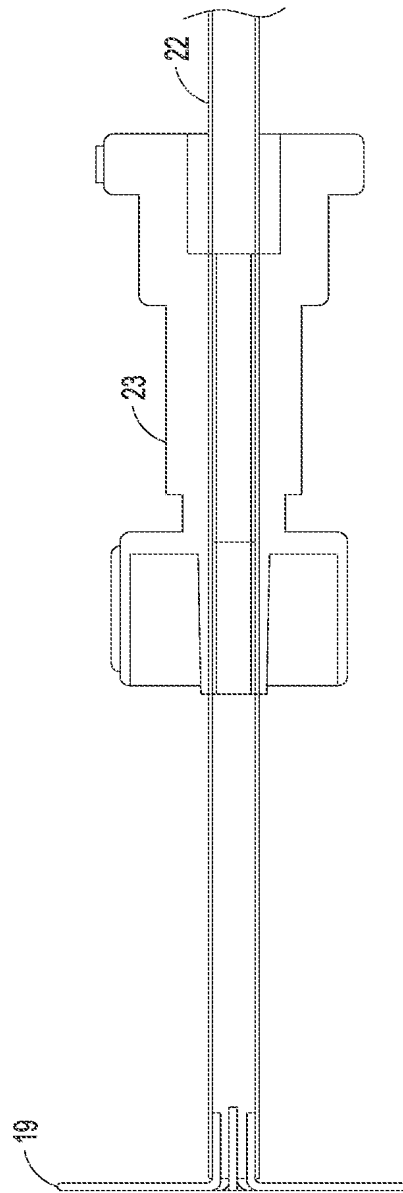


FIG. 41

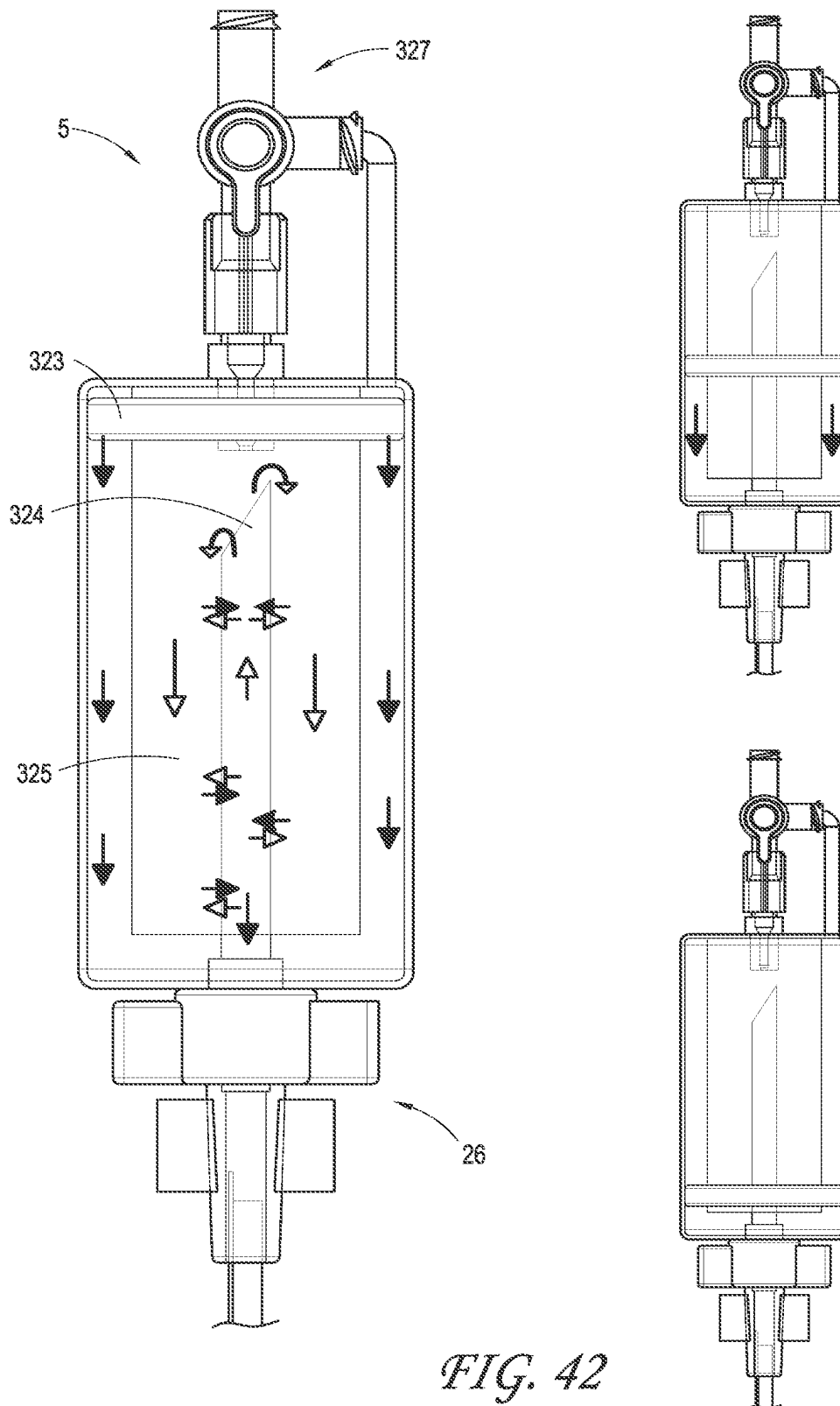
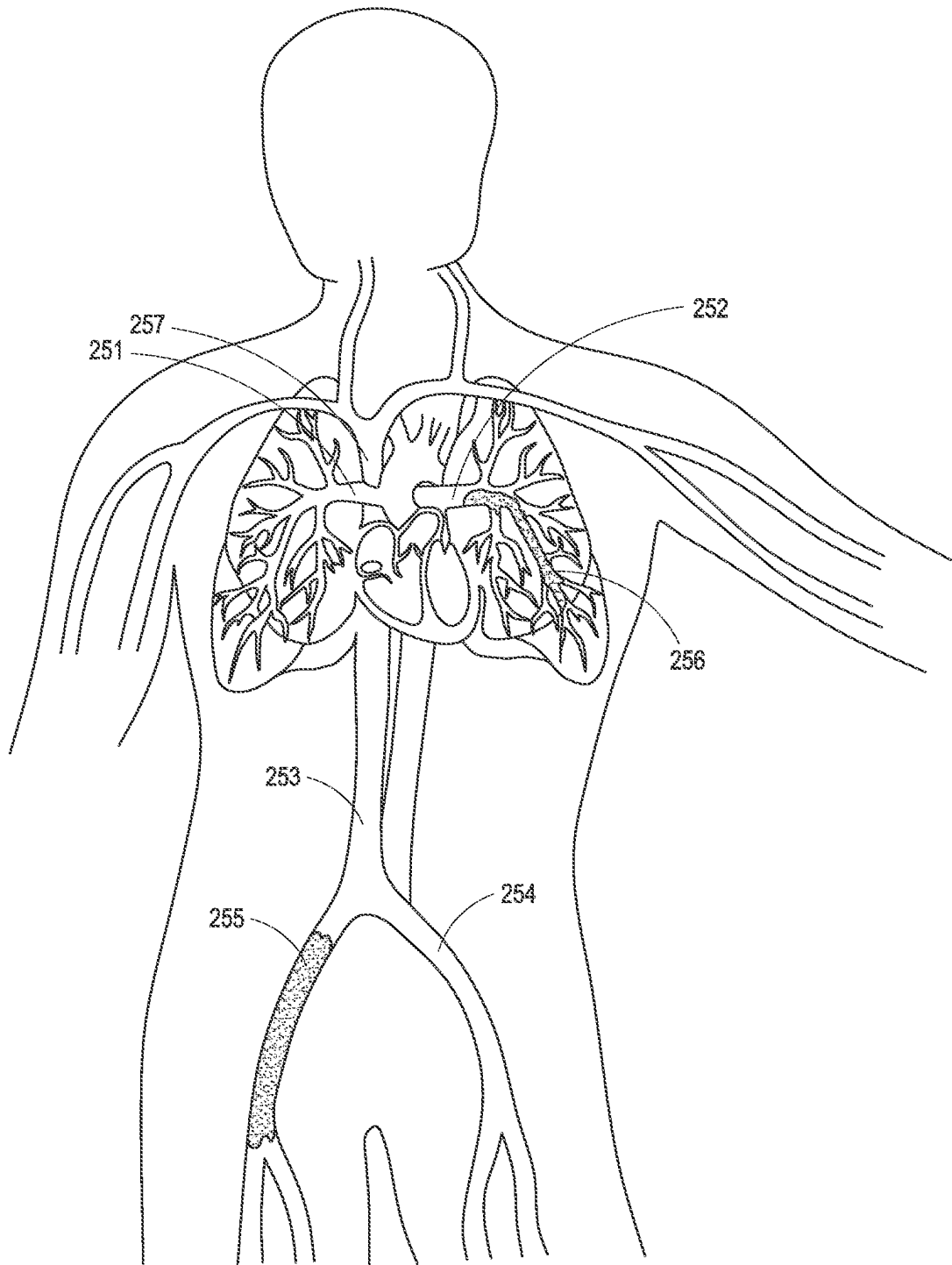


FIG. 42

*FIG. 43*

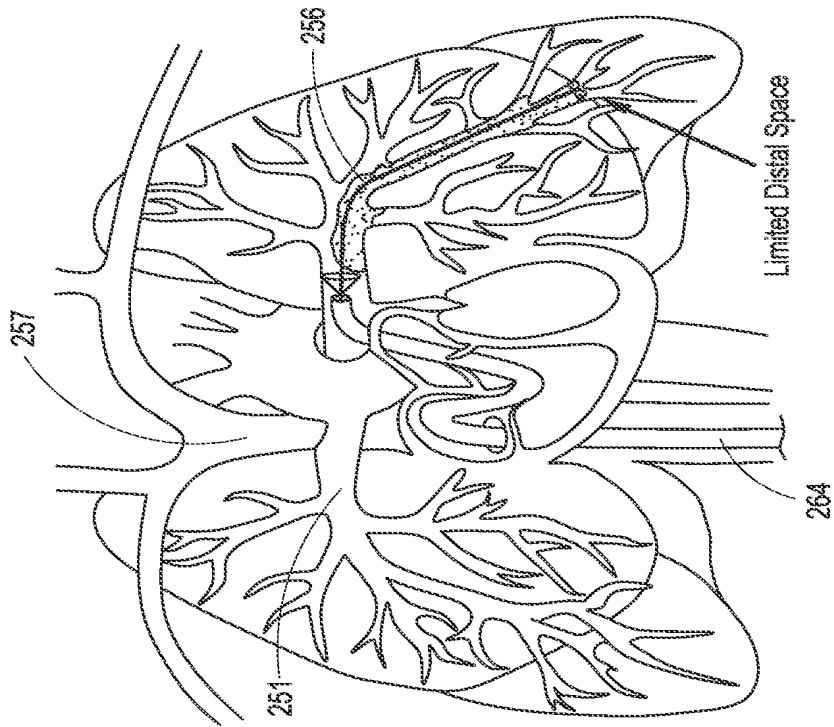


FIG. 44B

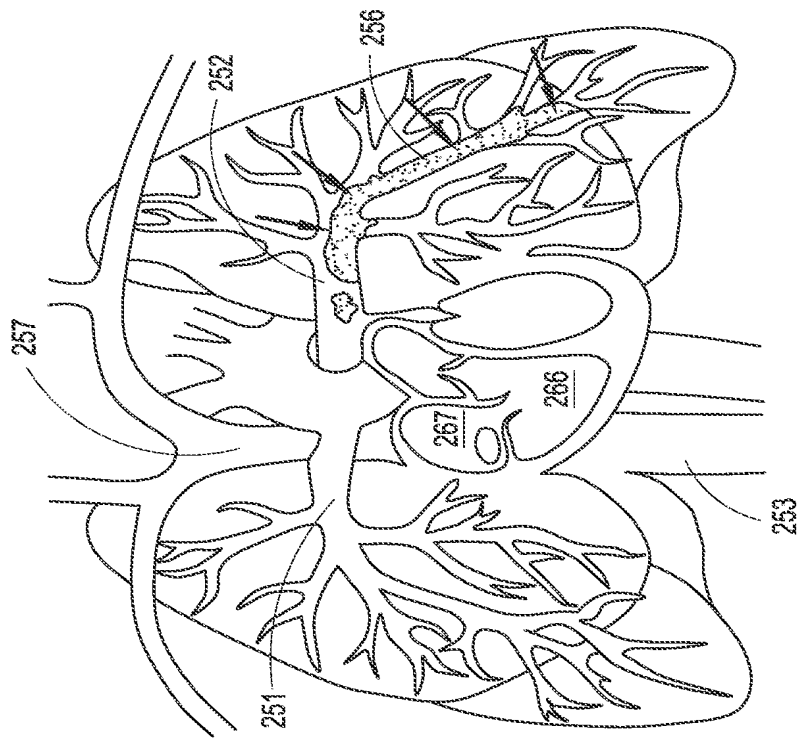


FIG. 44A

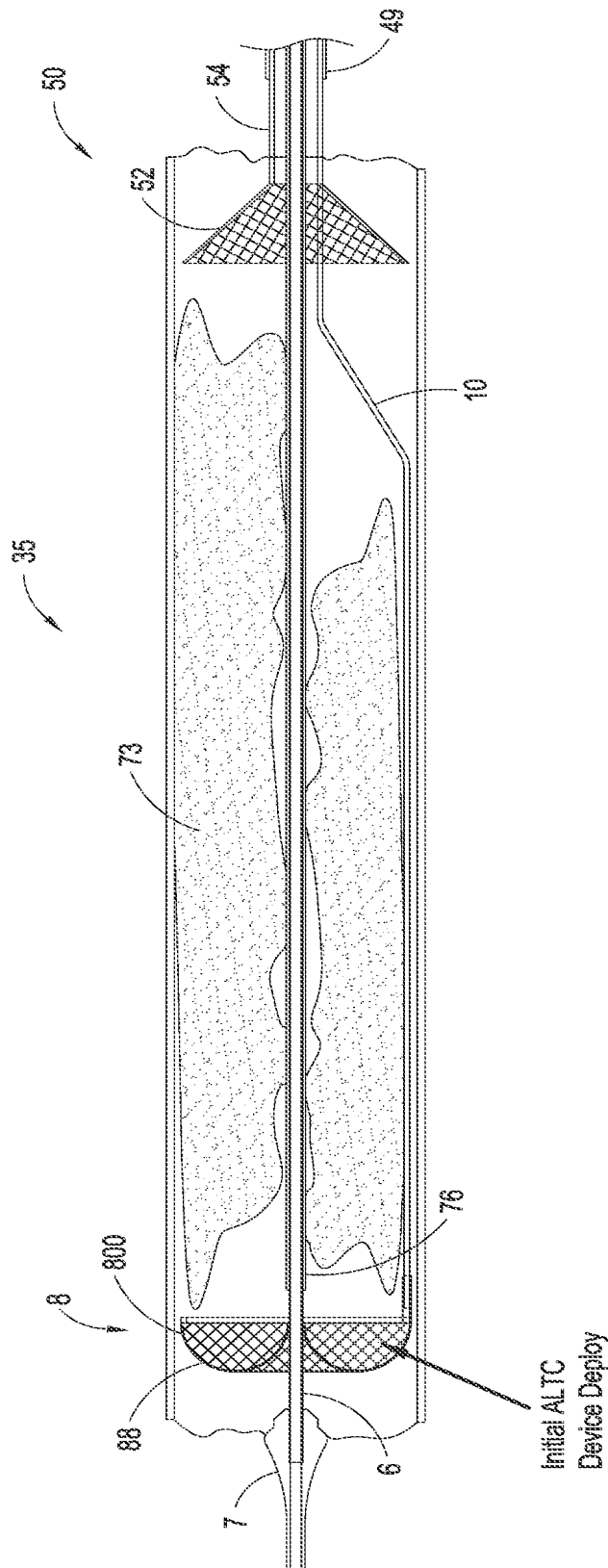
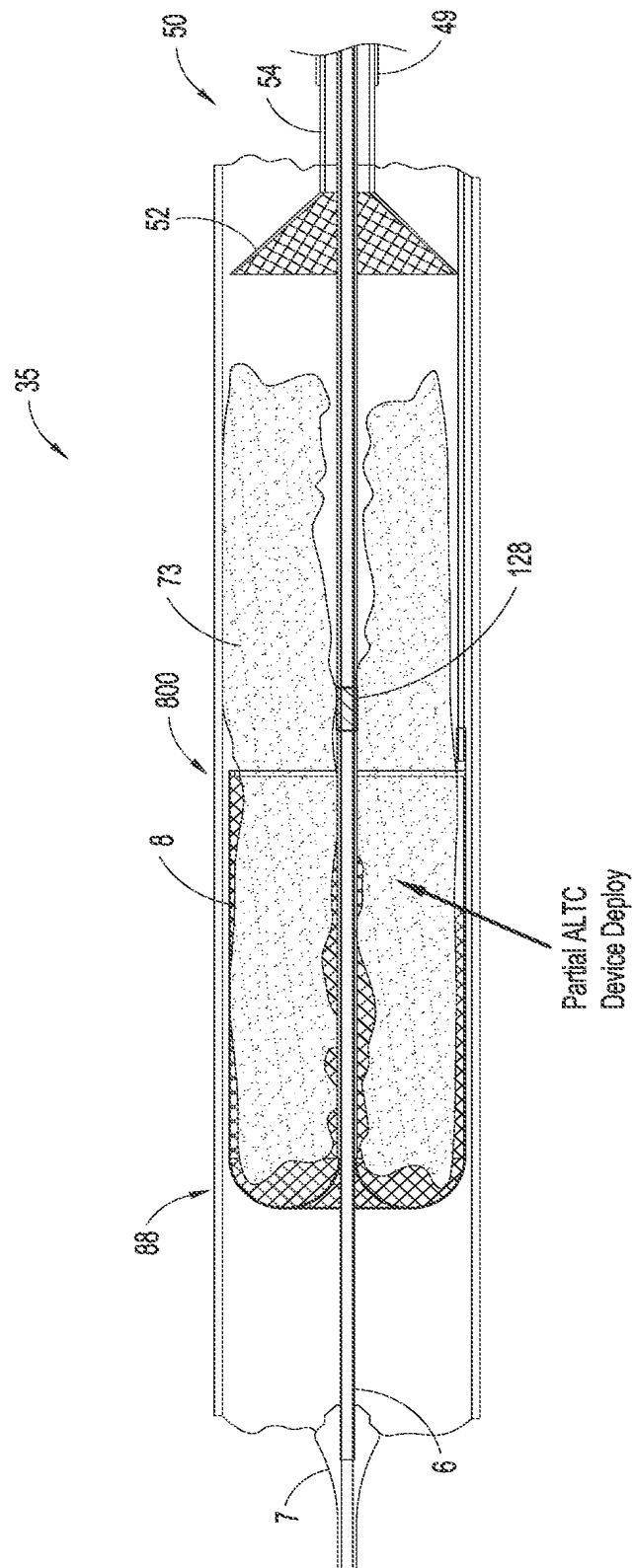


FIG. 45



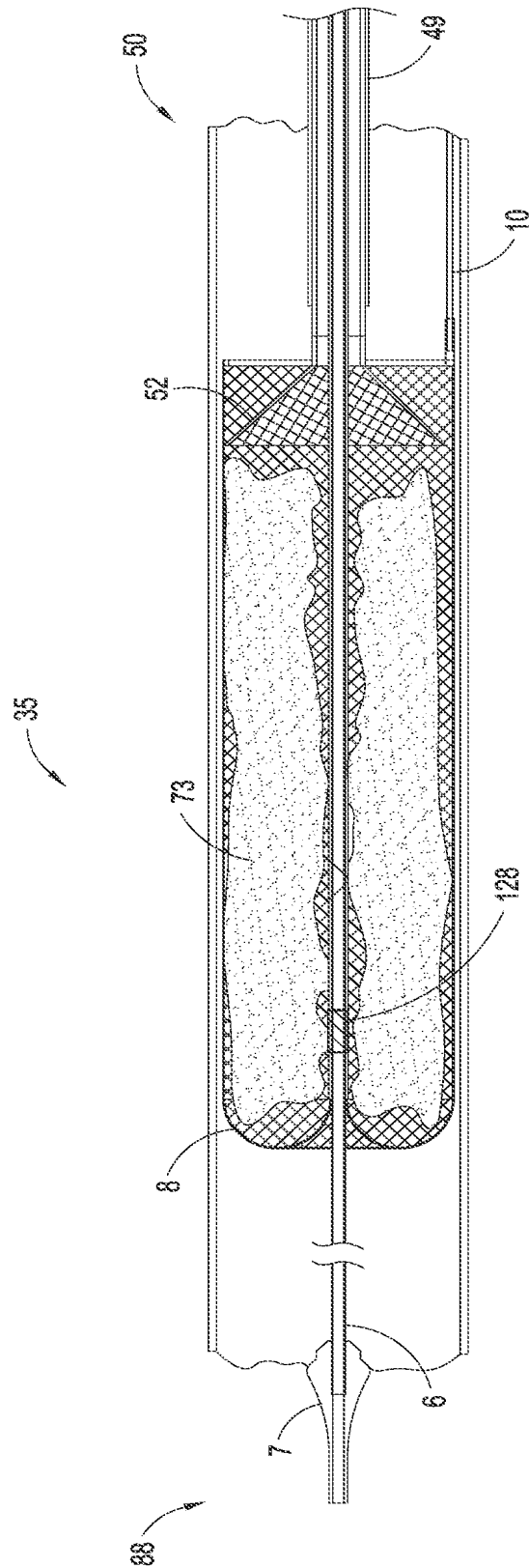
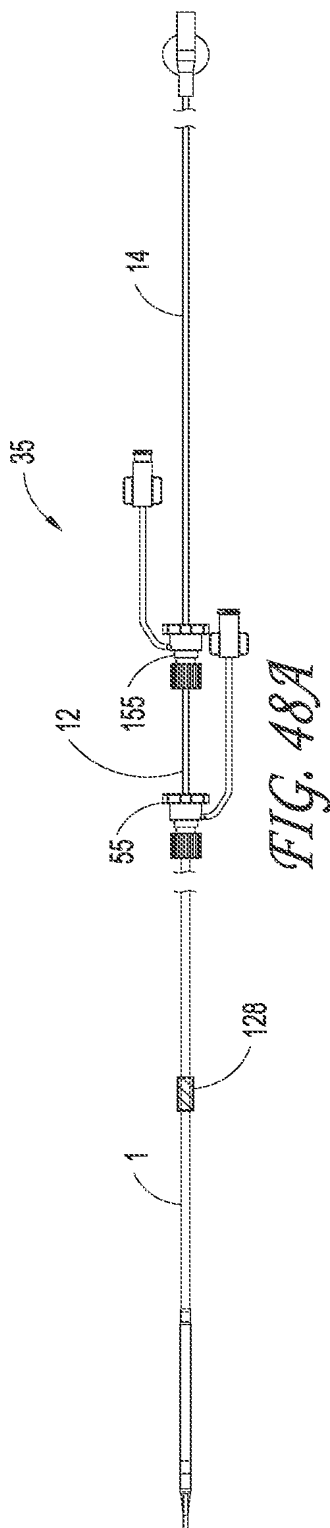
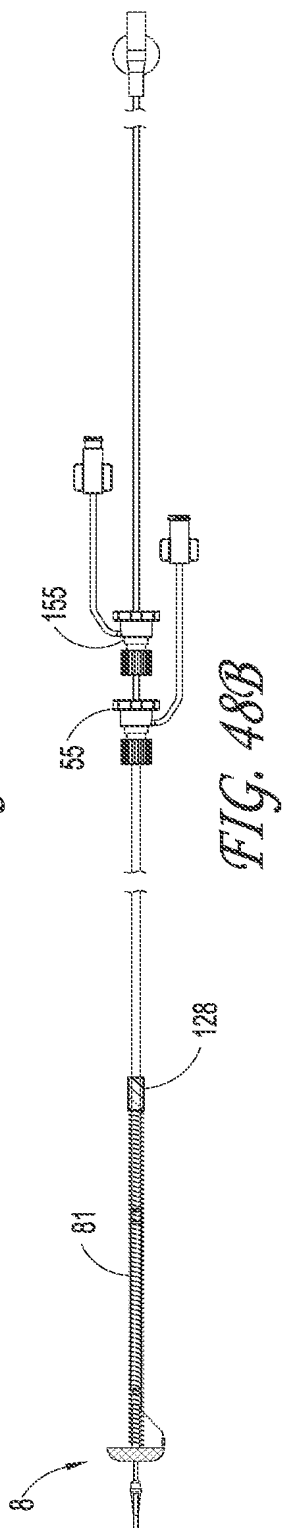
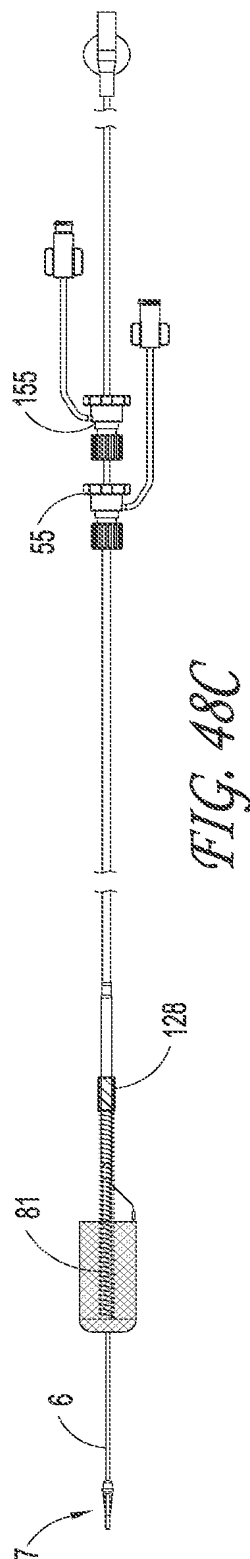
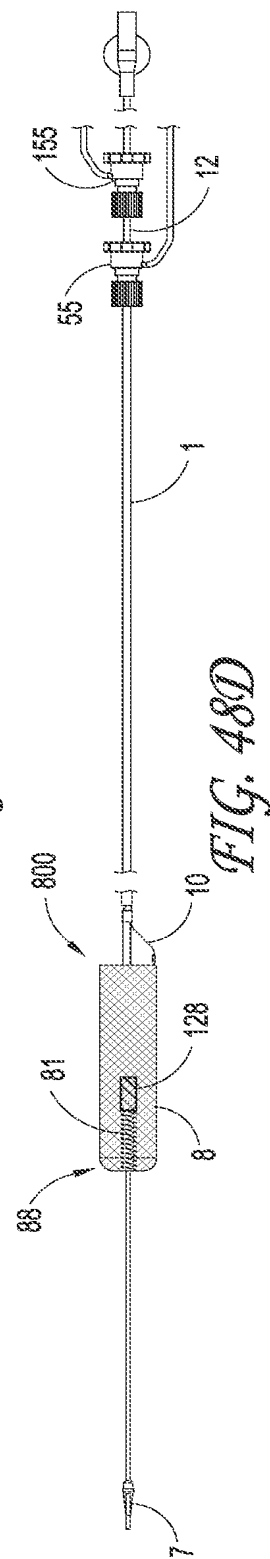


FIG. 47



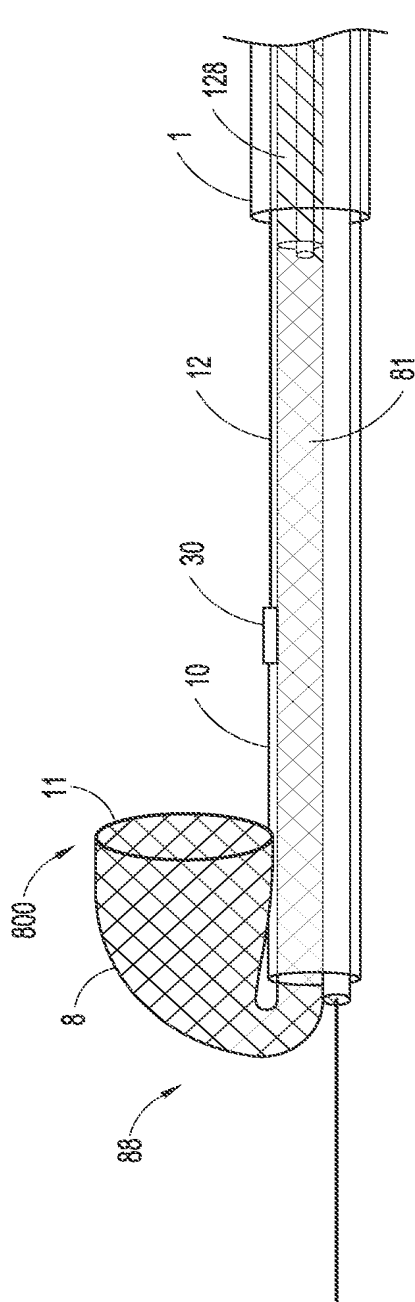


FIG. 49A

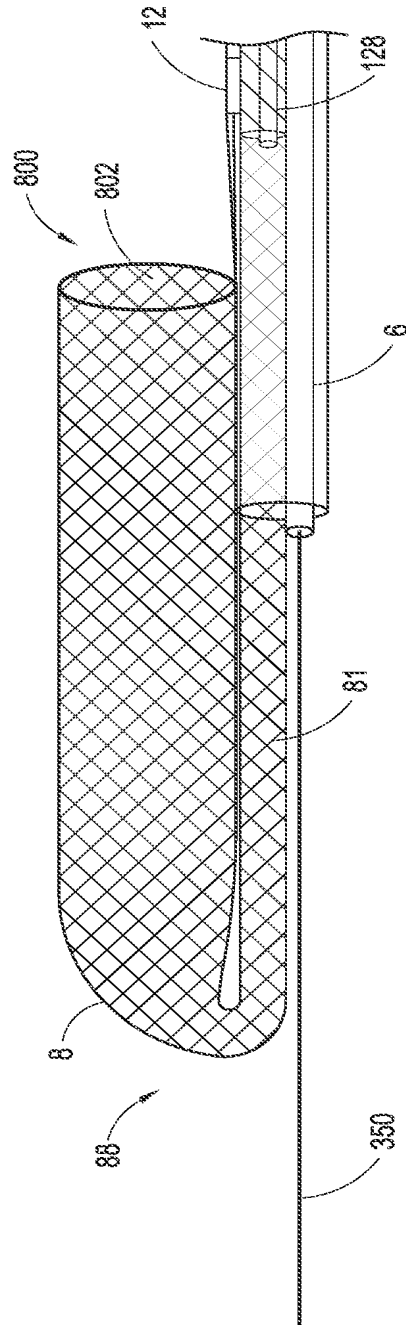


FIG. 49B

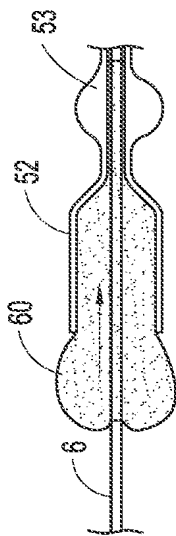


FIG. 50A

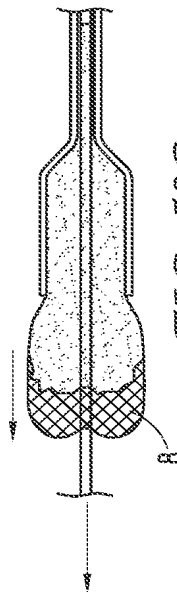


FIG. 50B

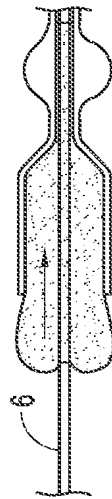


FIG. 50C

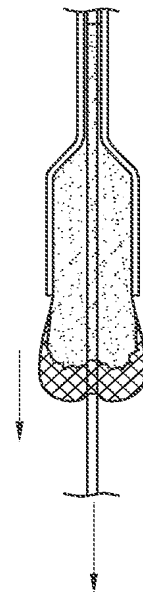


FIG. 50D



FIG. 50E

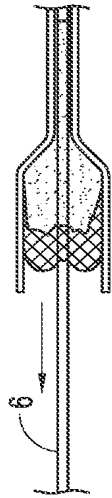


FIG. 50F

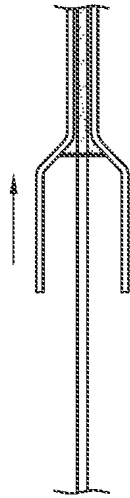


FIG. 50G

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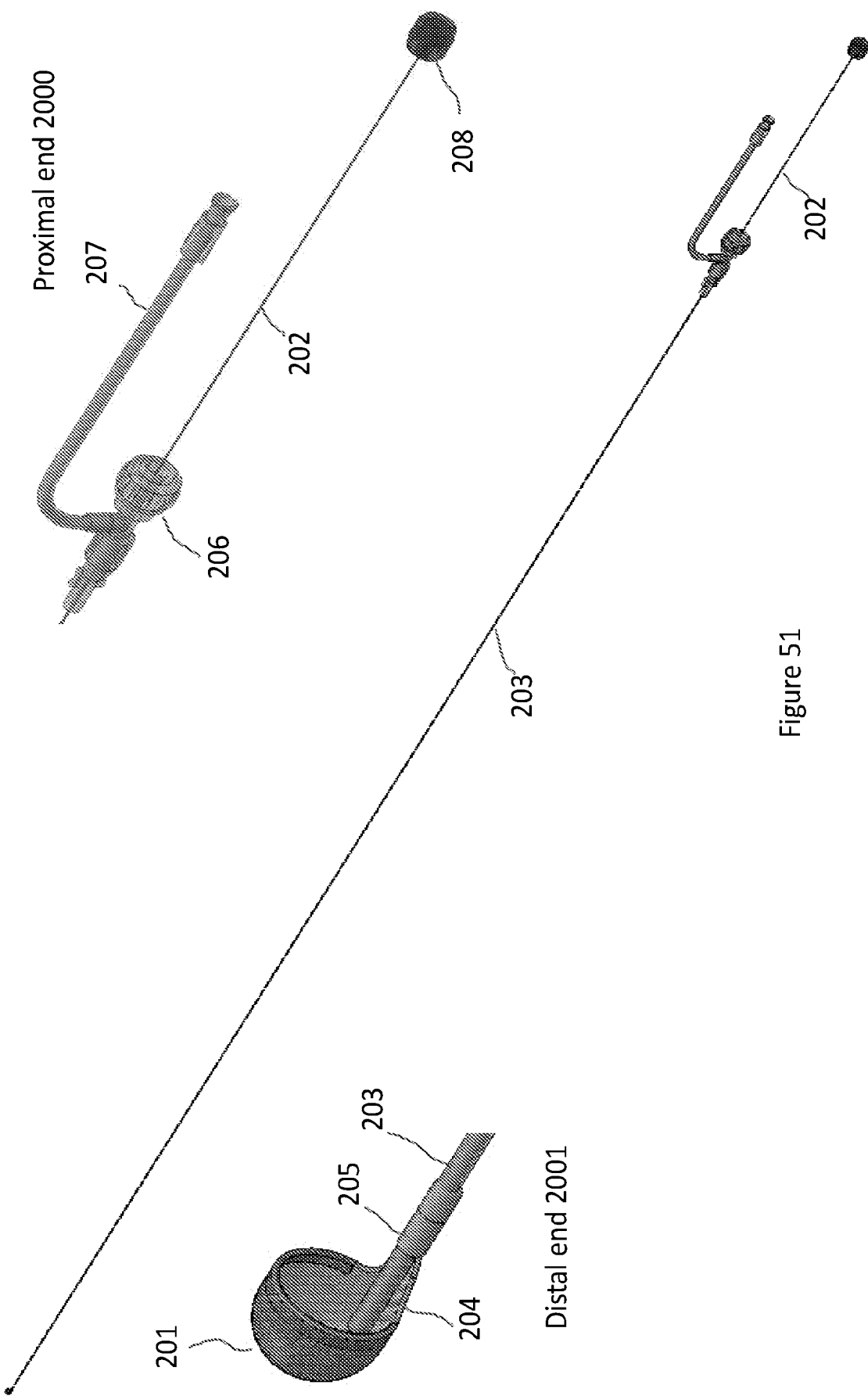


Figure 51

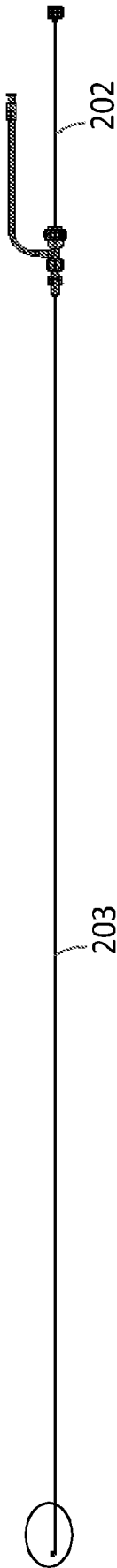
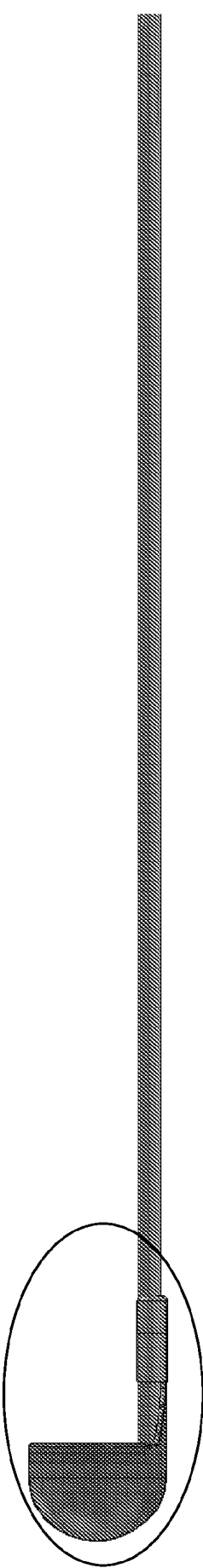
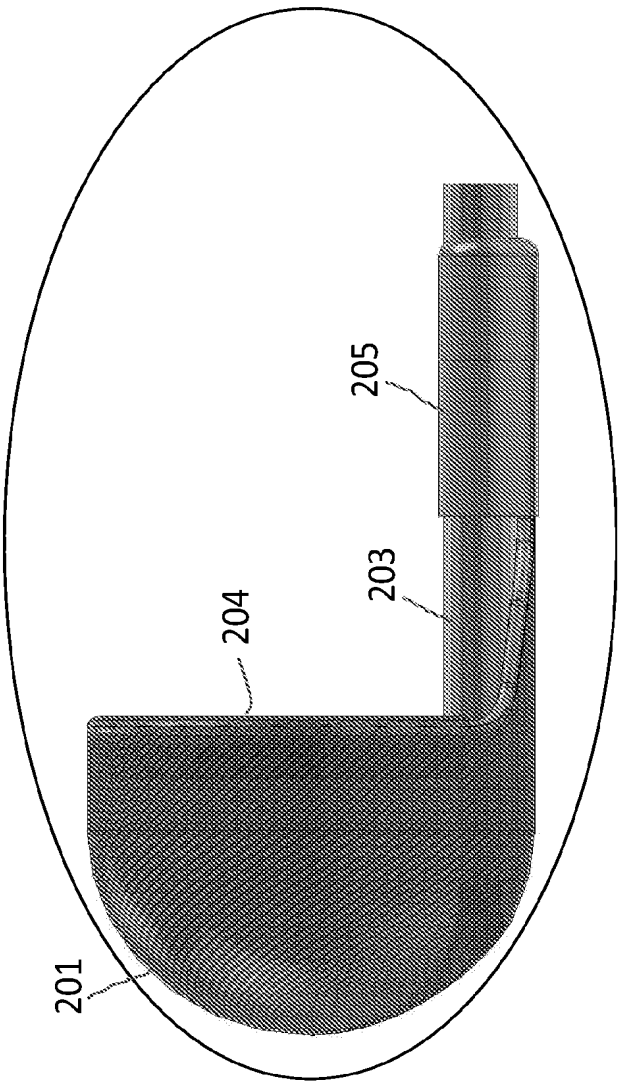
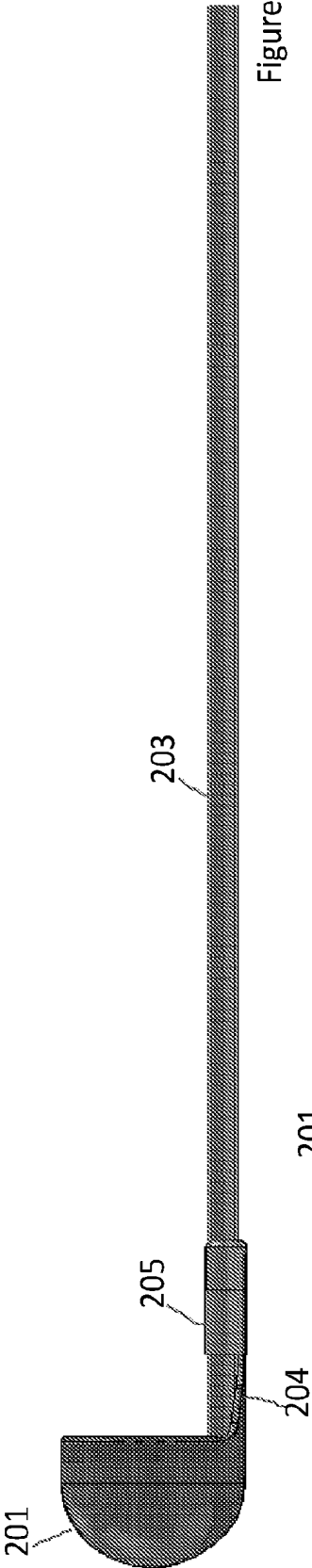
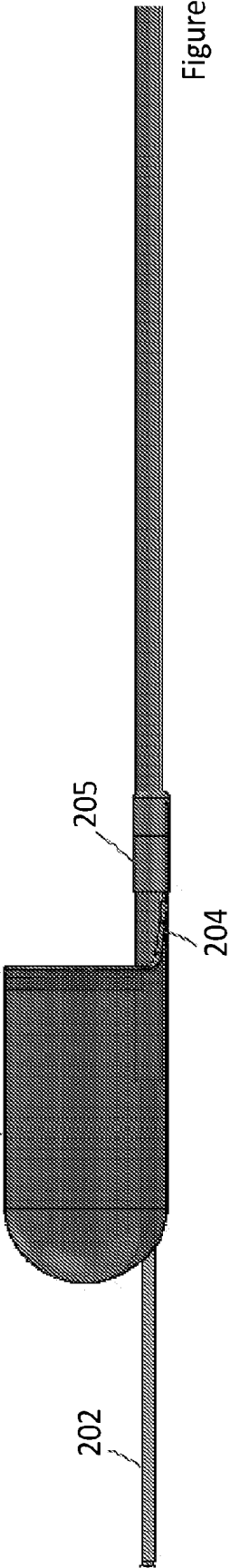
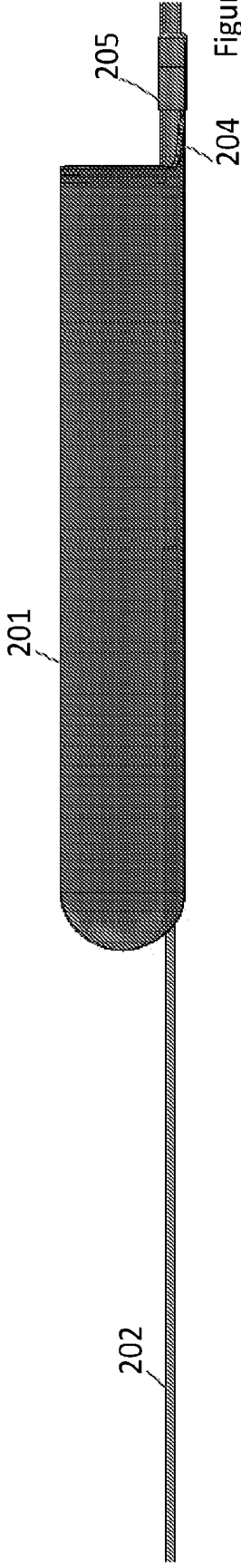


Figure 52



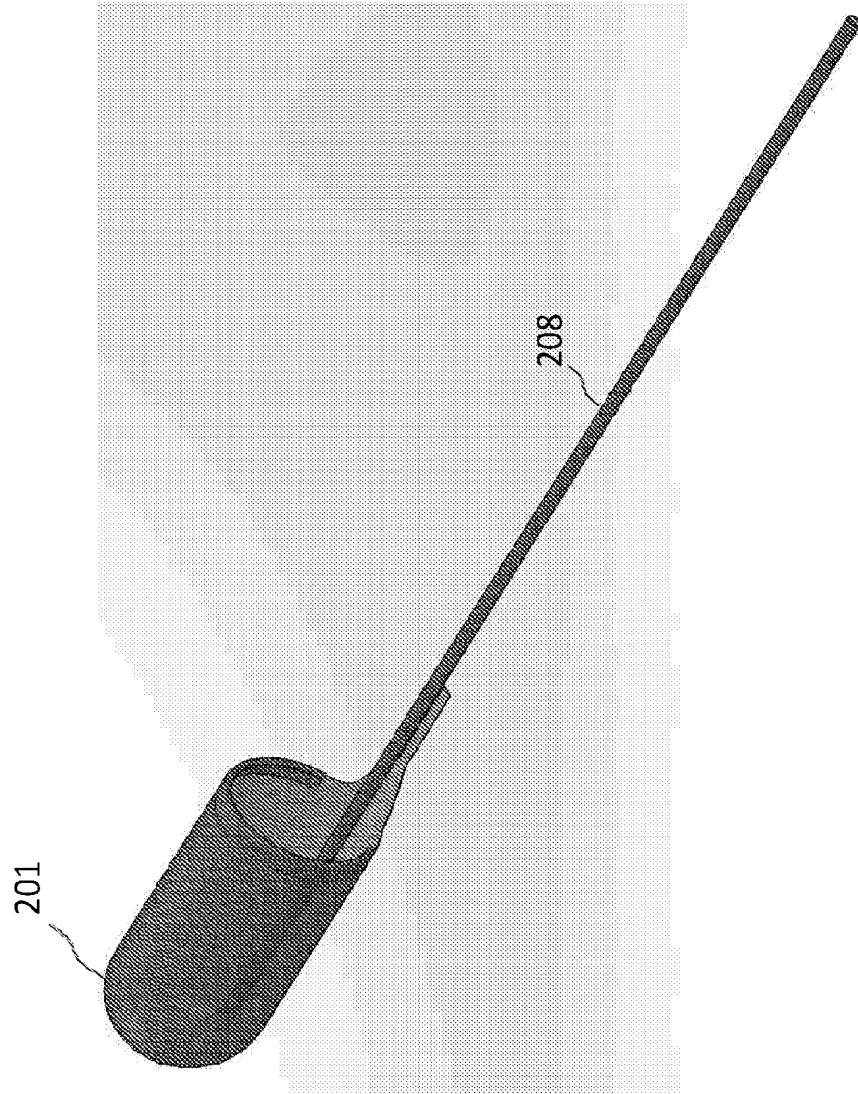


Figure 57

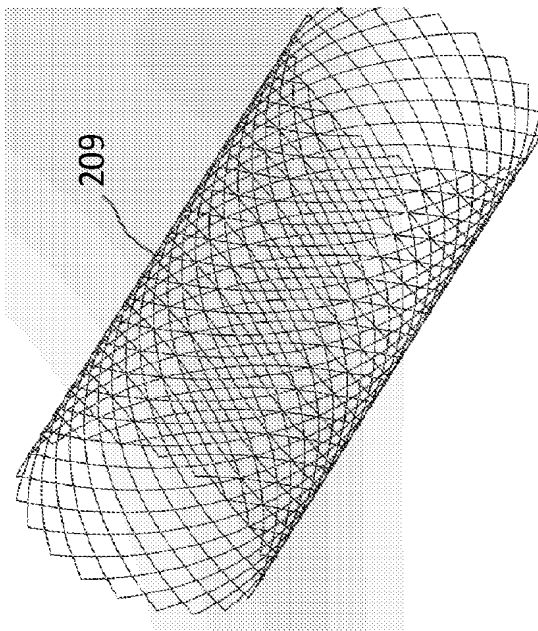


Figure 56

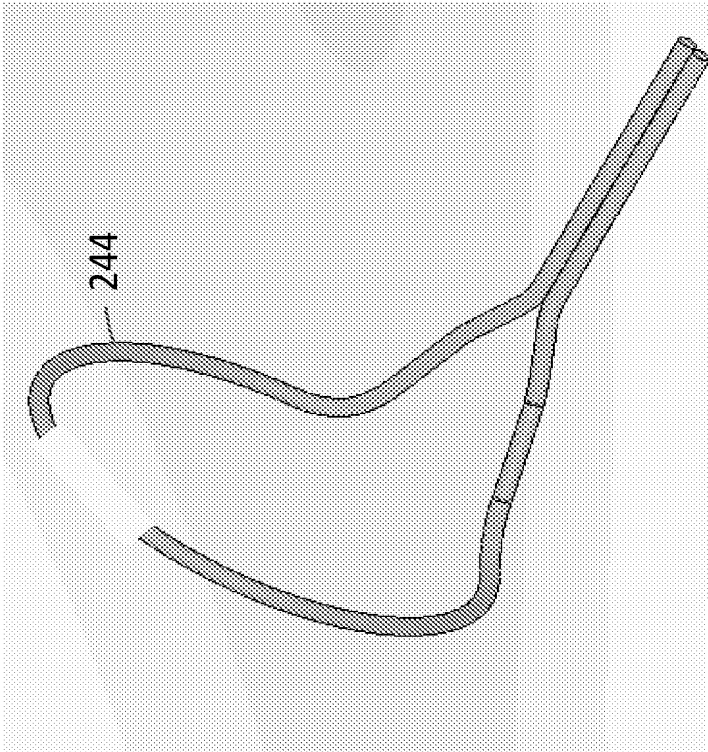


Figure 58B

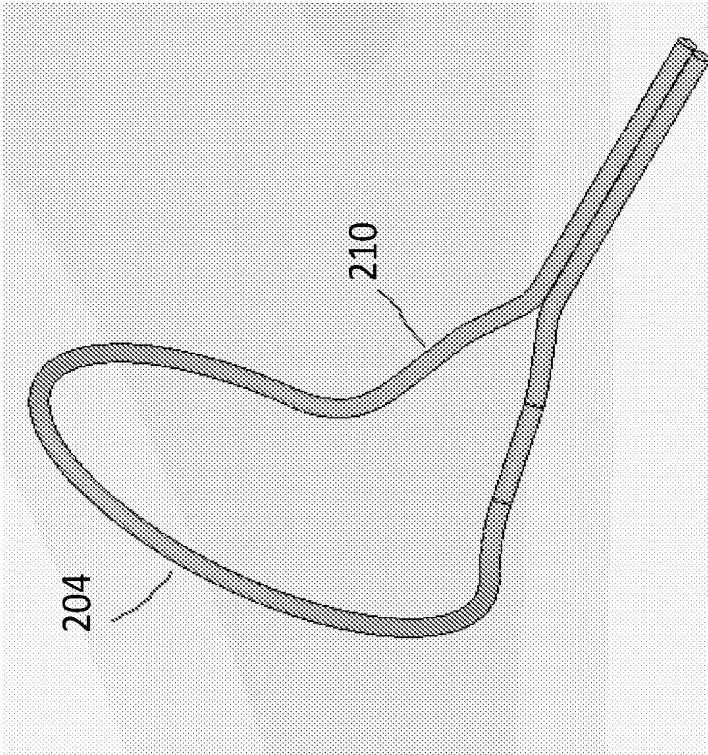


Figure 58A

Figure 60

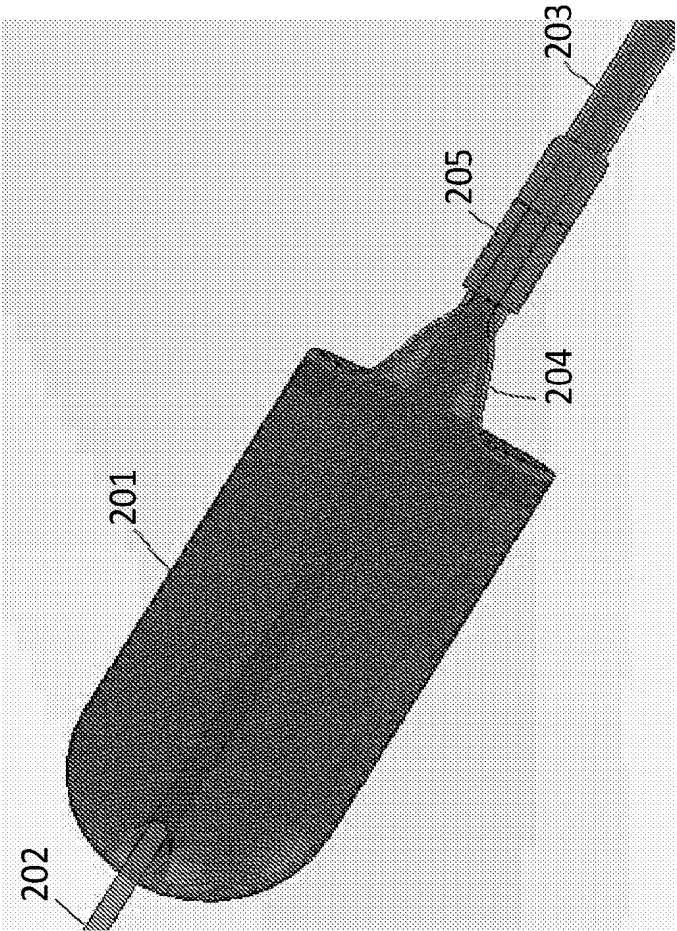
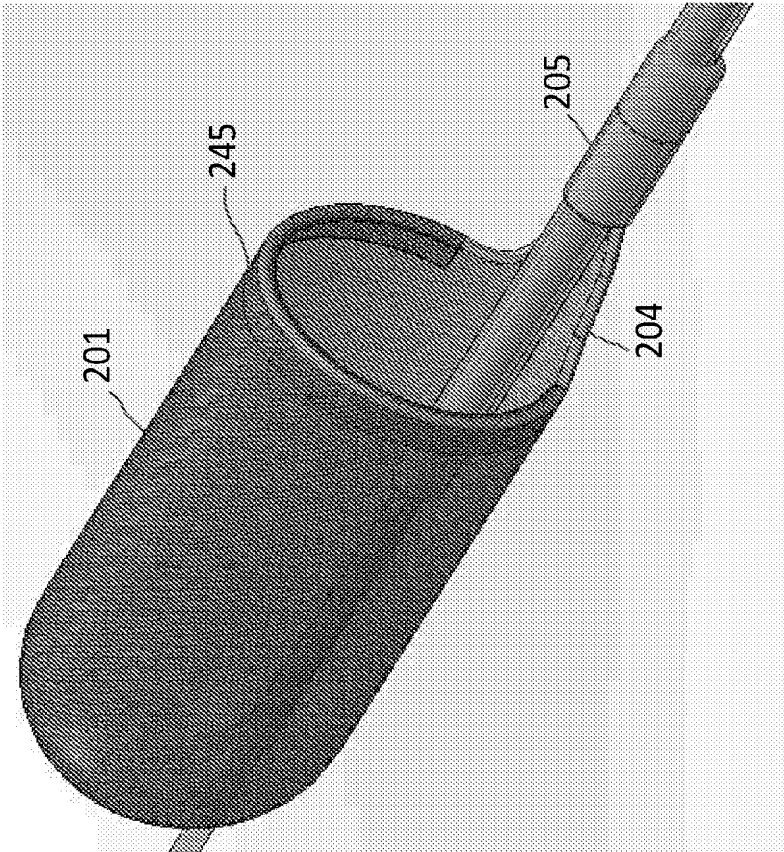
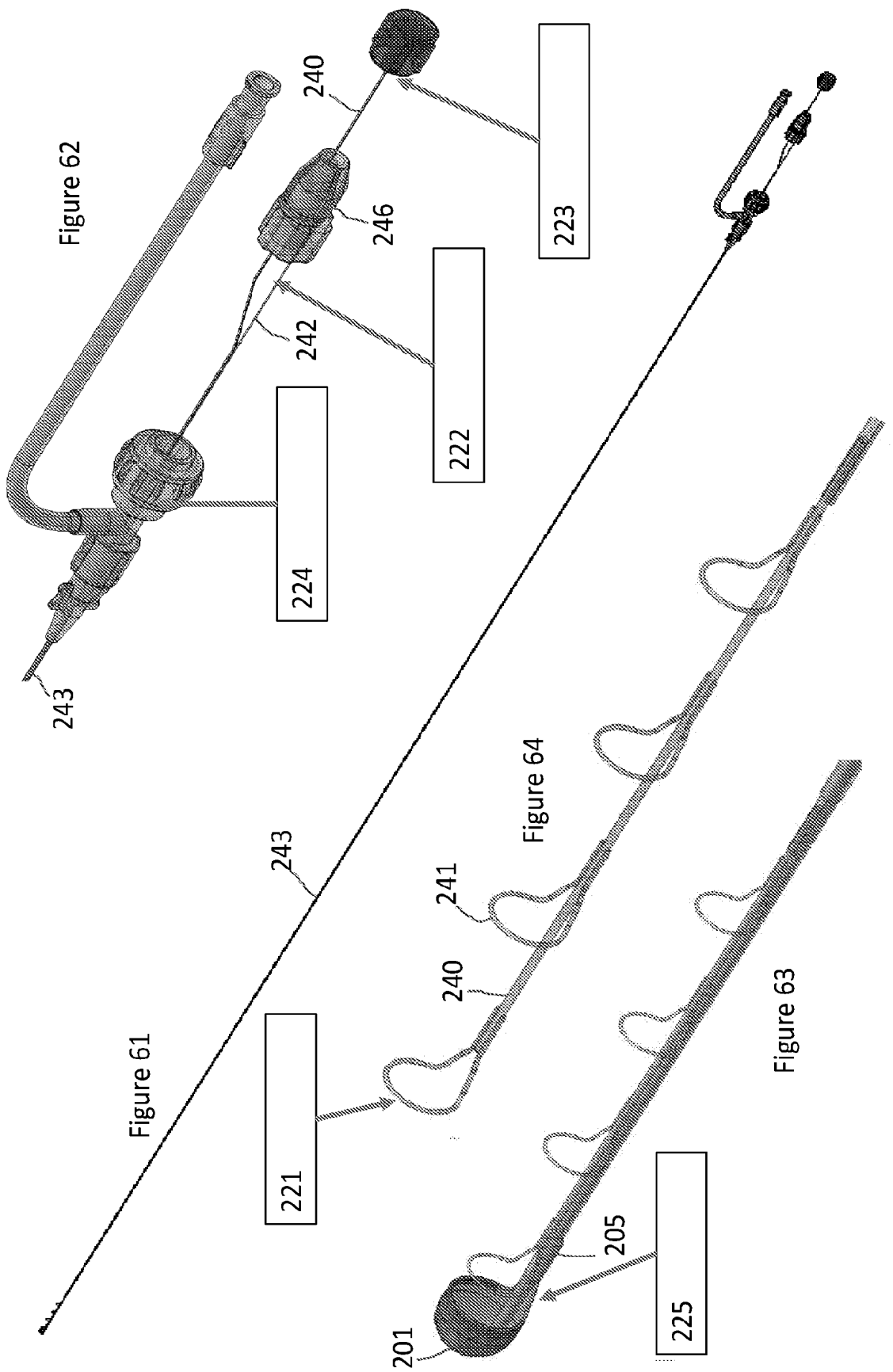


Figure 59



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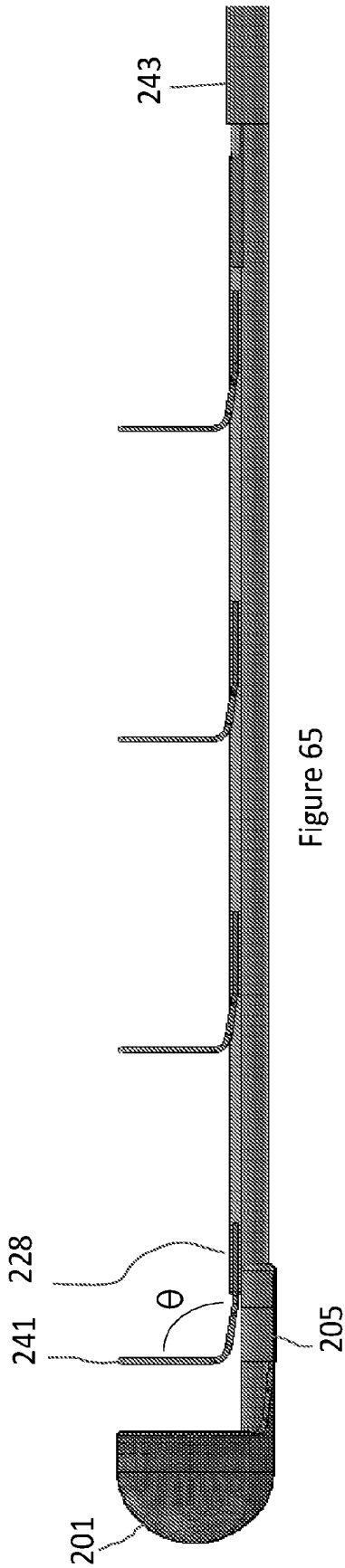


Figure 65

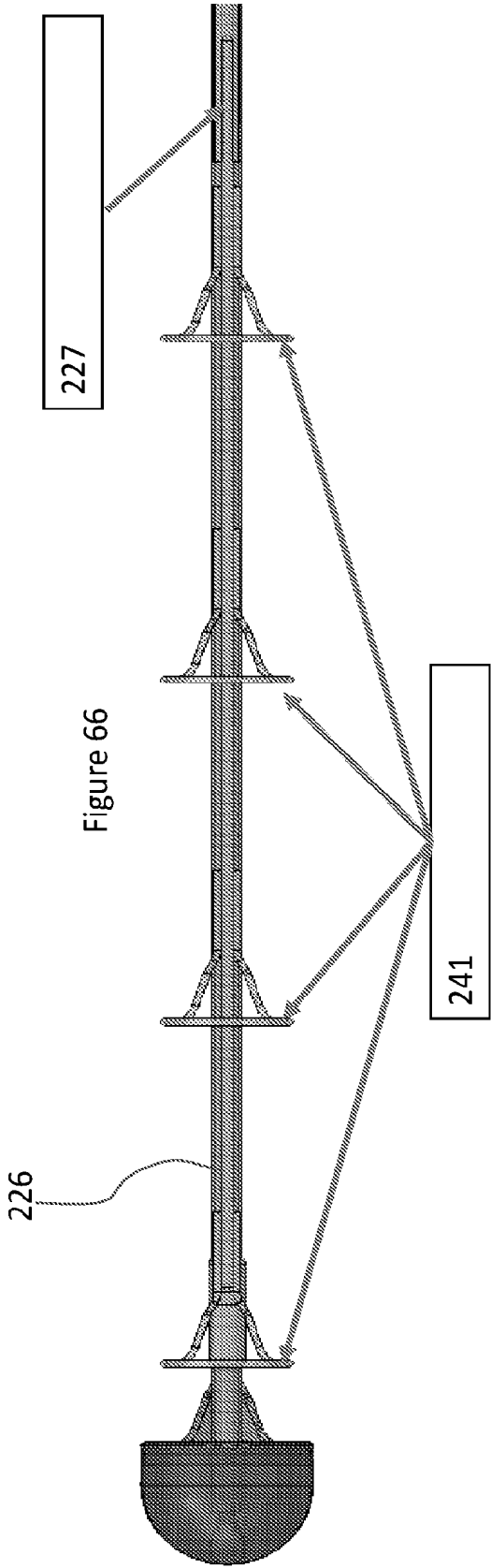
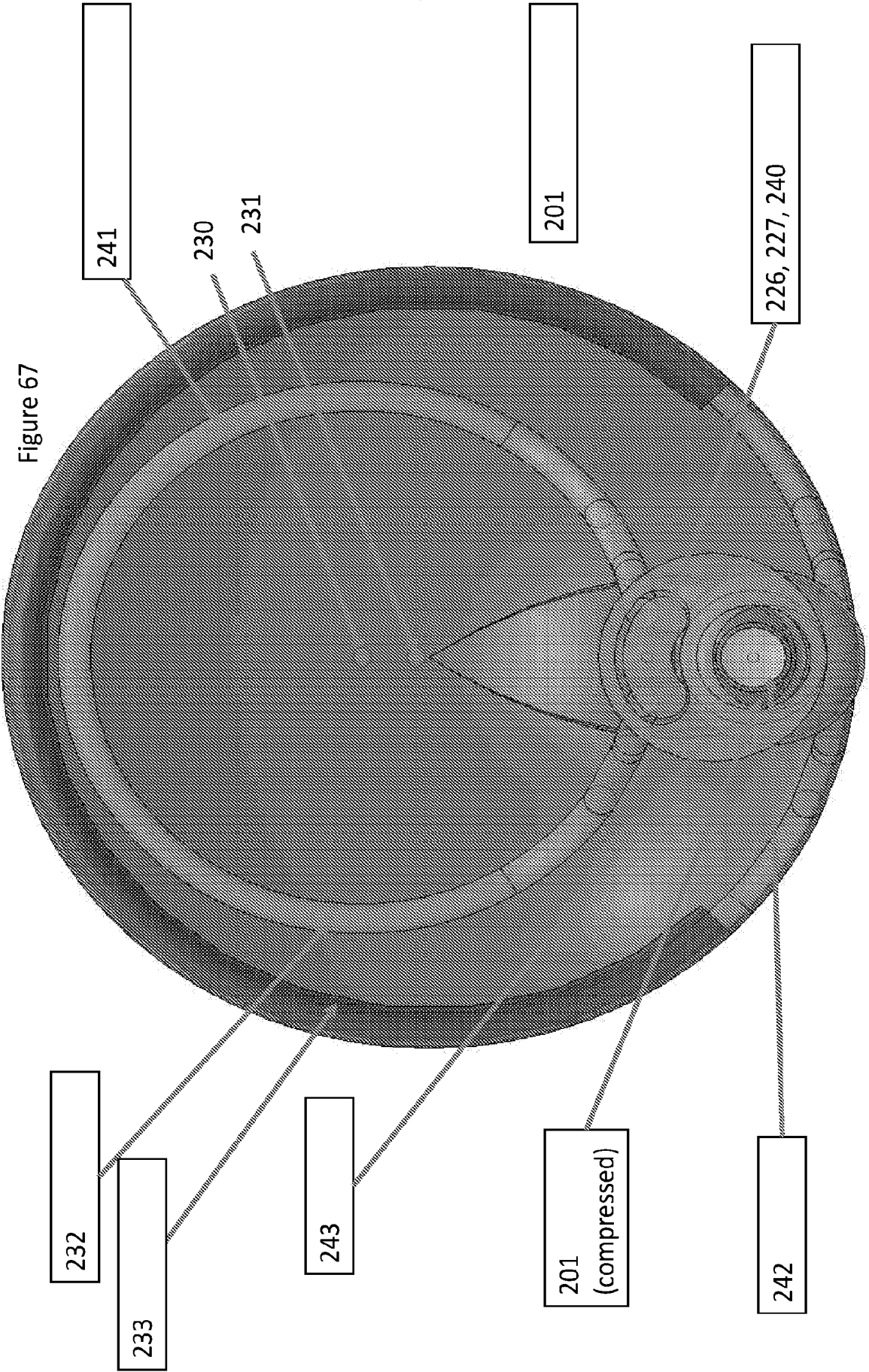


Figure 66



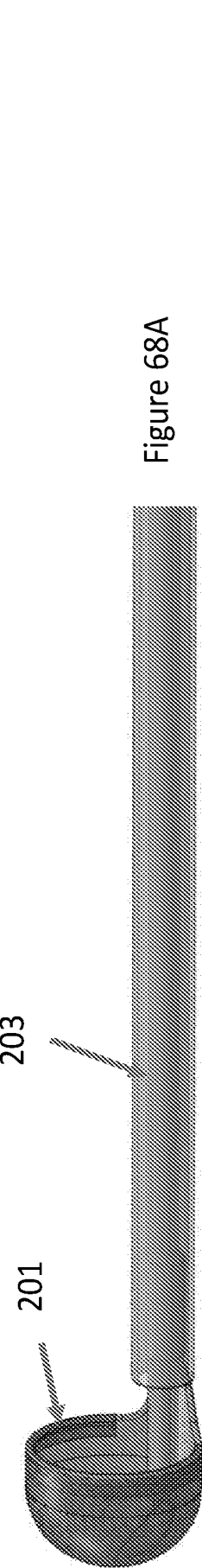


Figure 68A

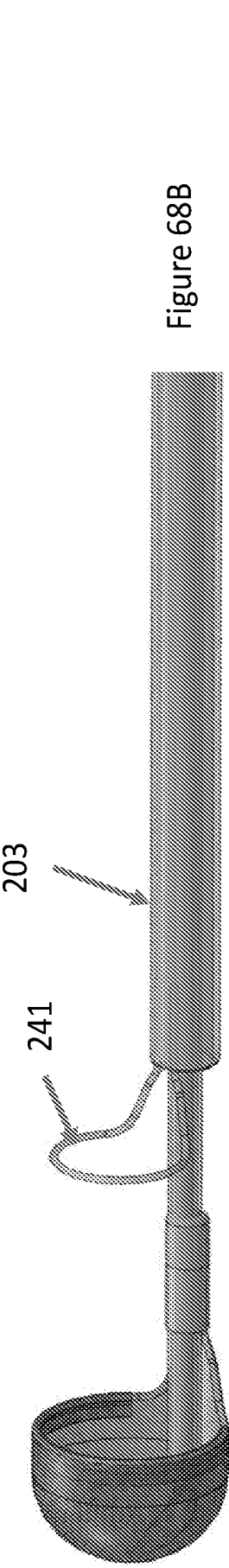


Figure 68B

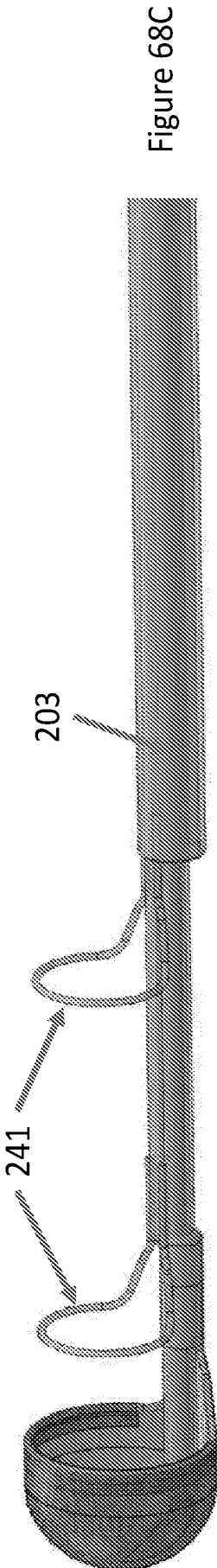


Figure 68C

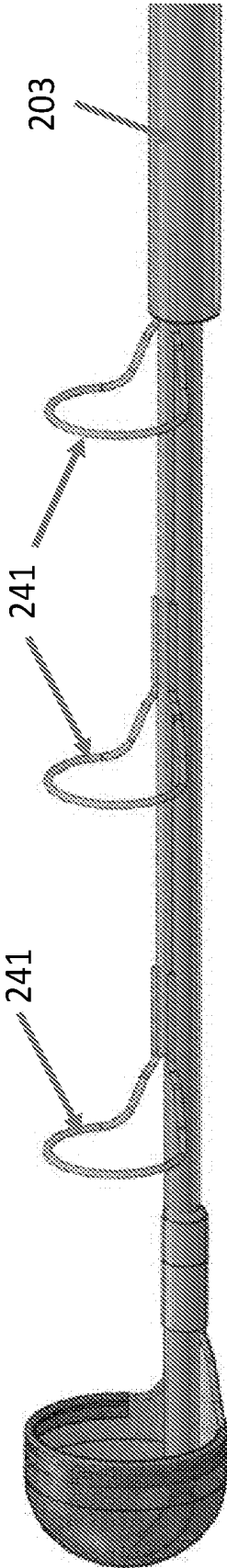
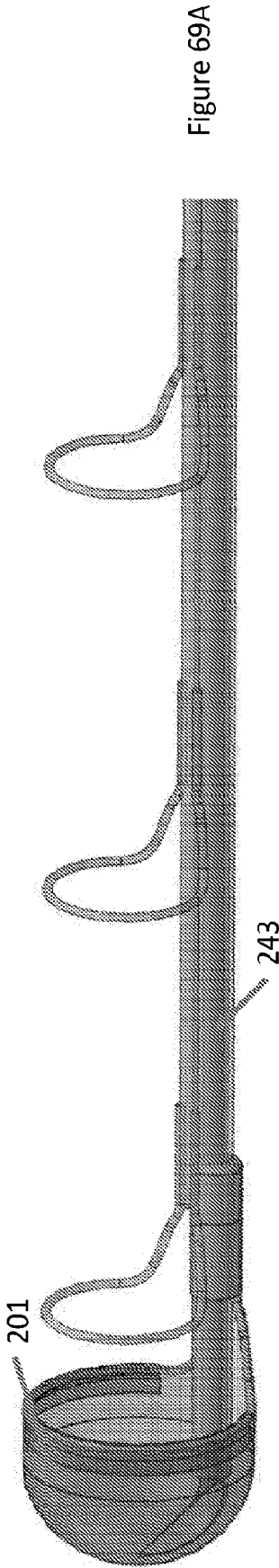
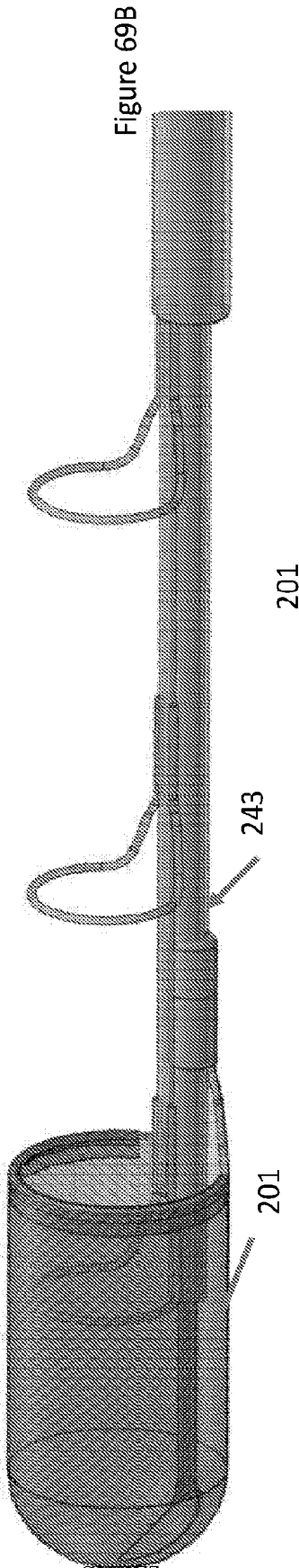
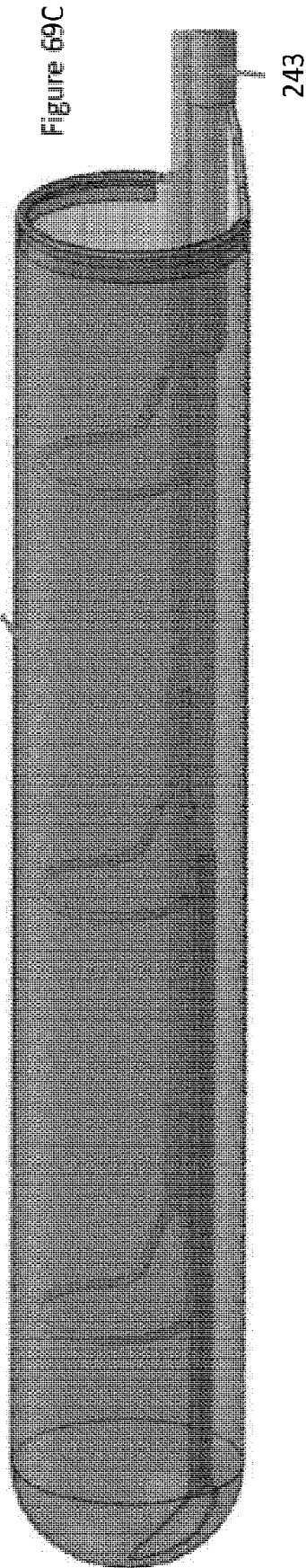
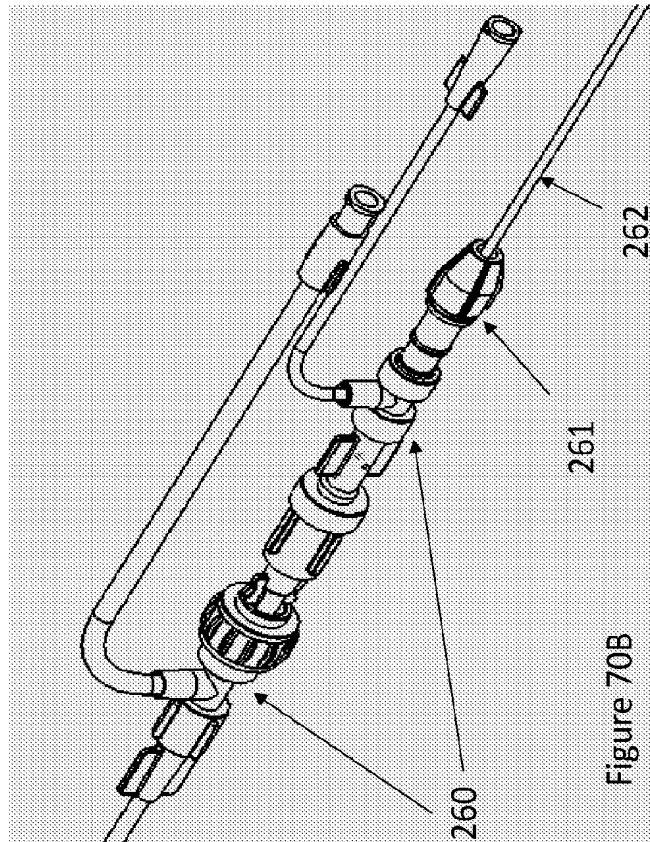
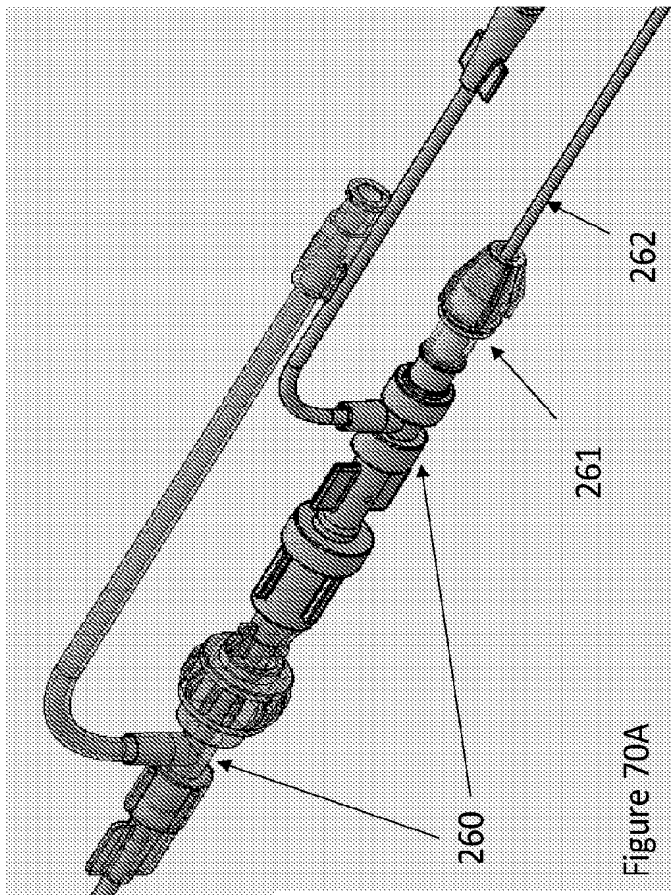
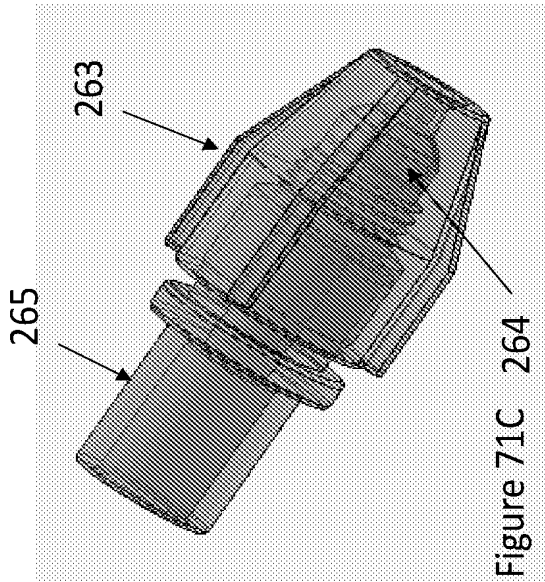
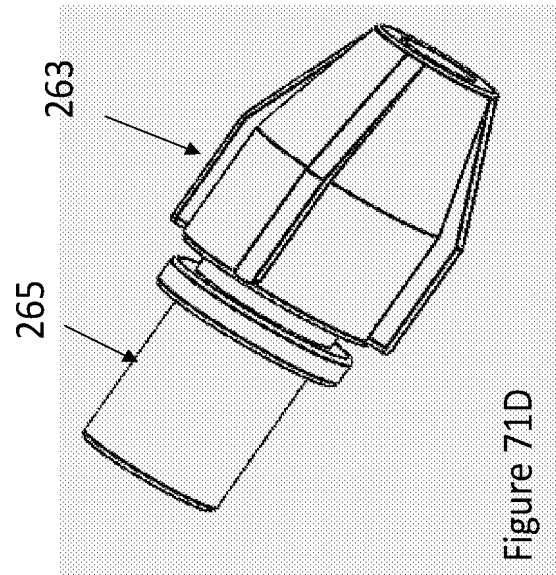
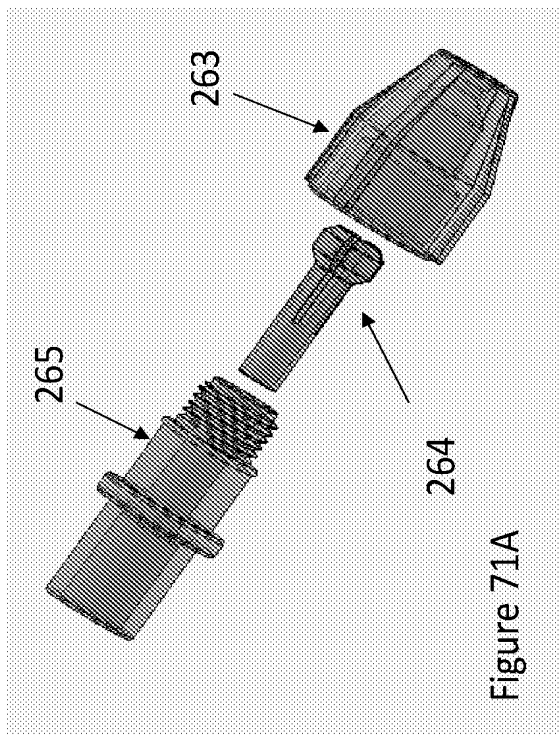
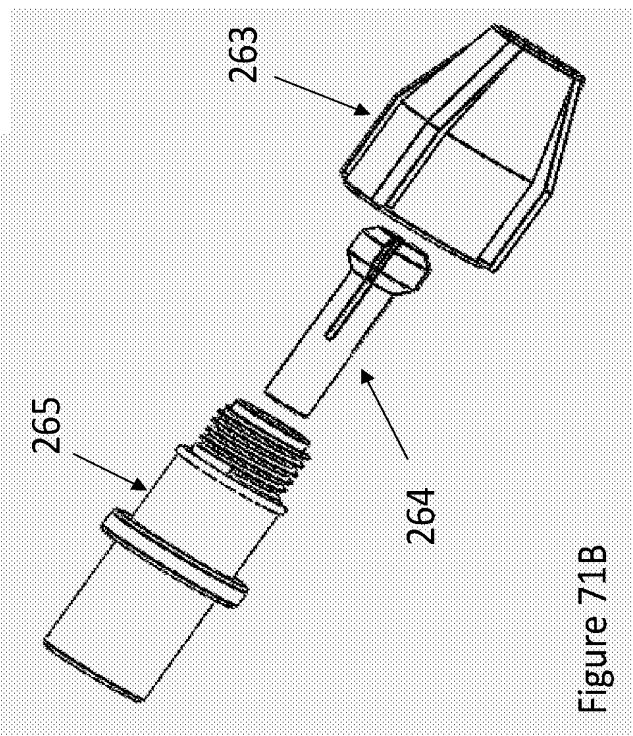


Figure 68D







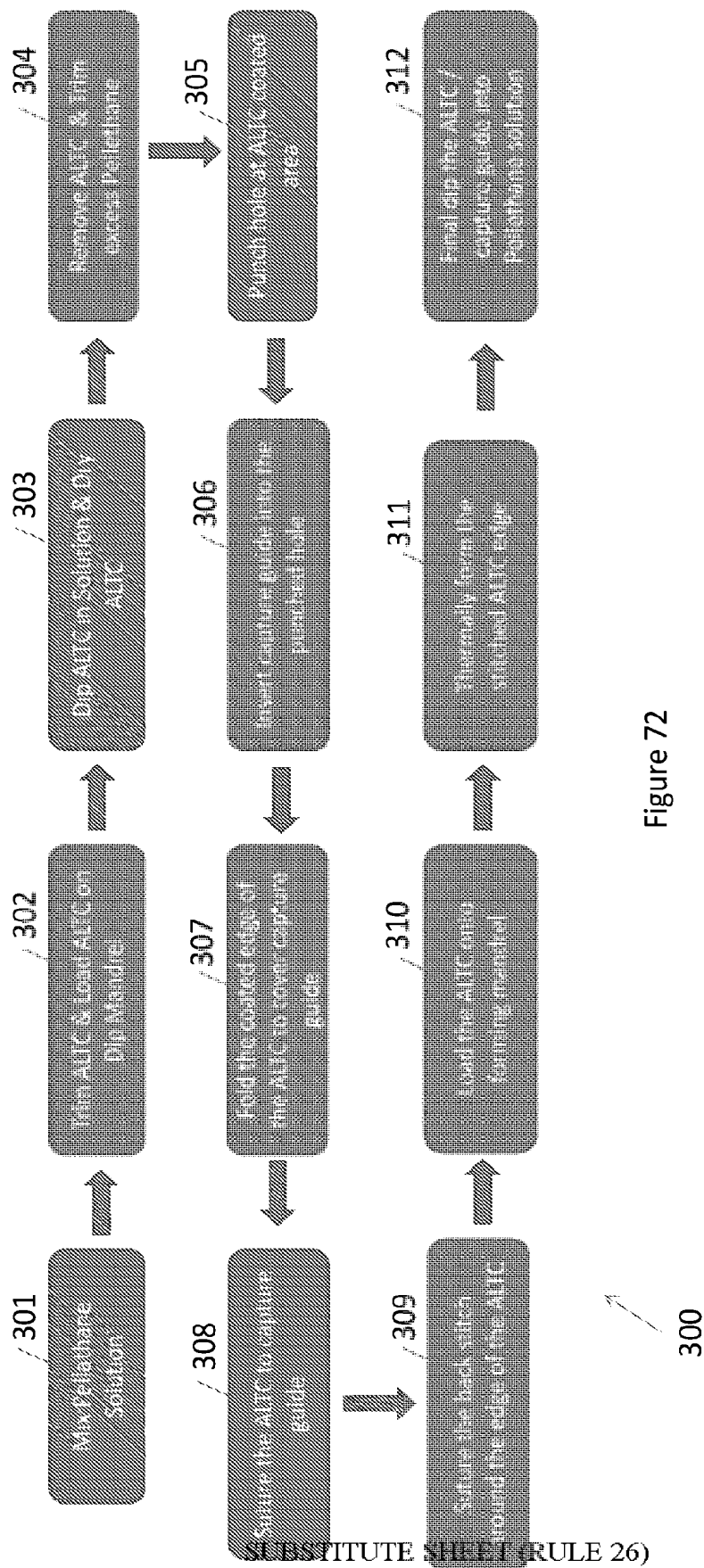


Figure 72

Figure 73

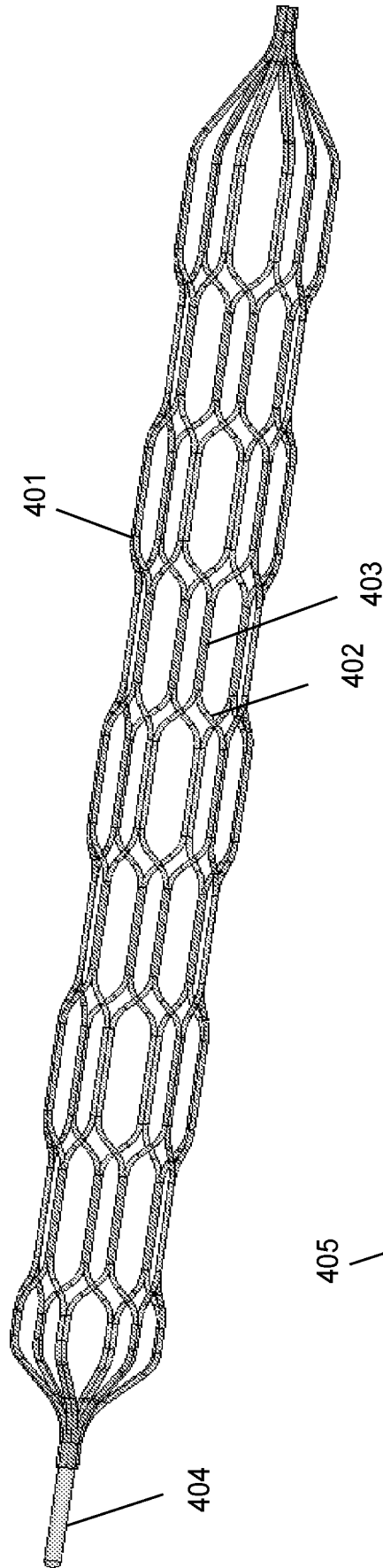
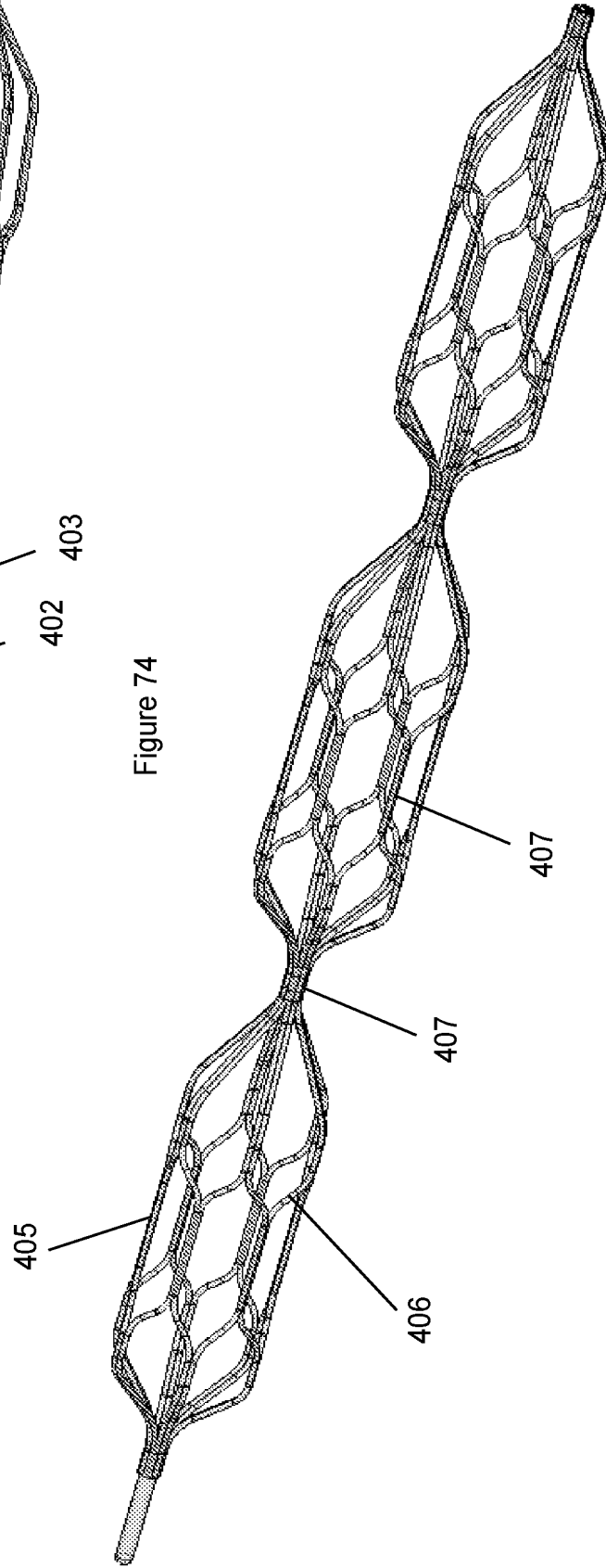
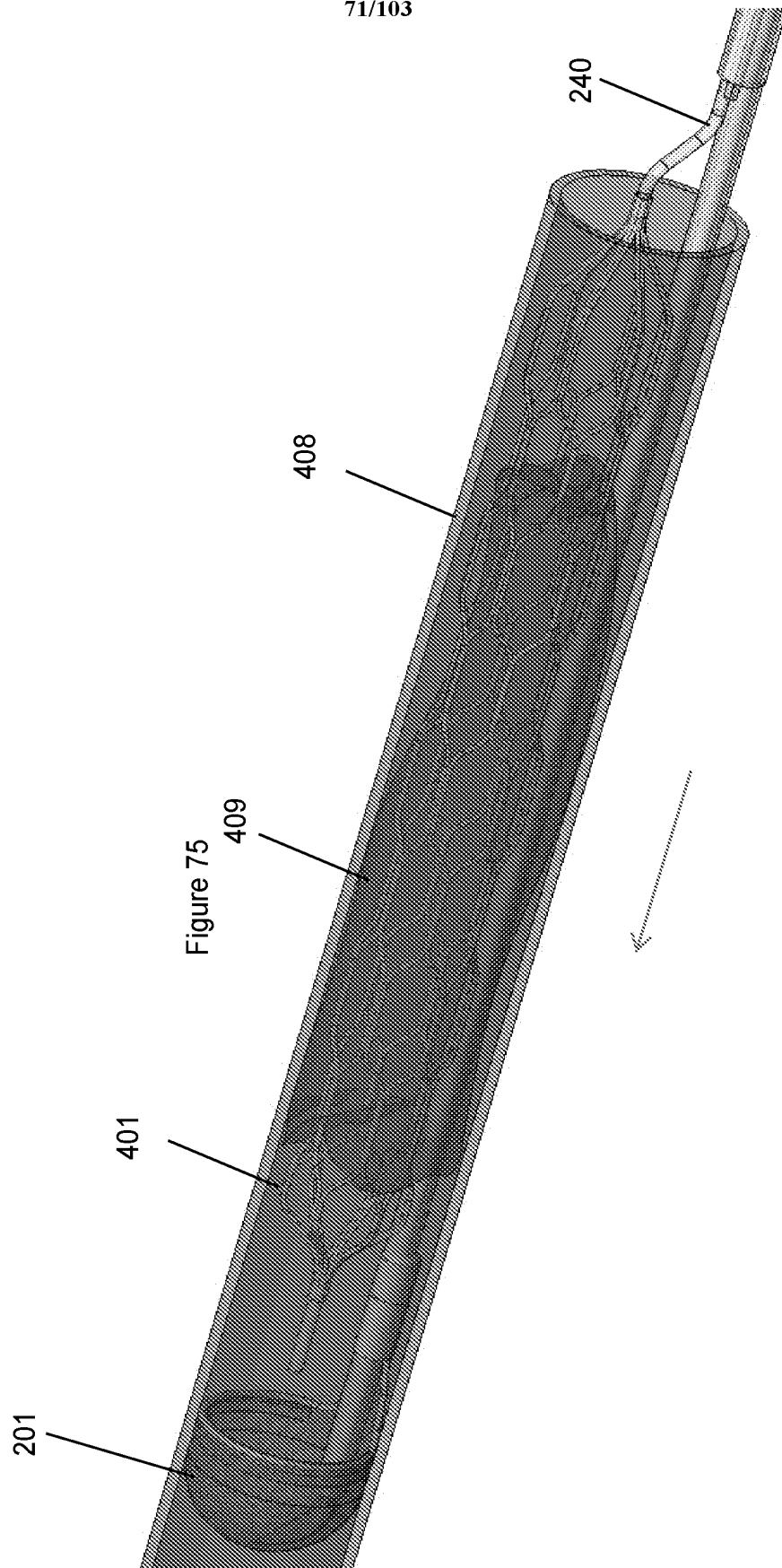
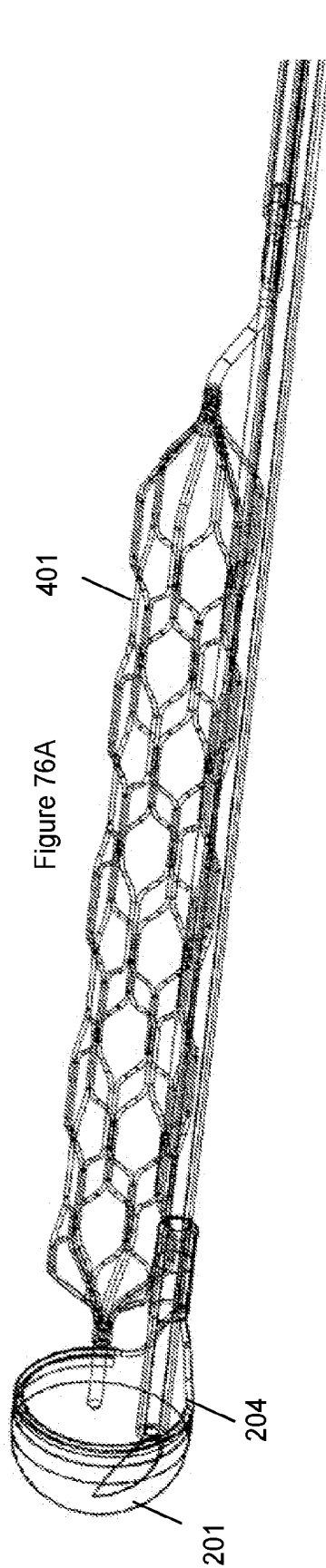
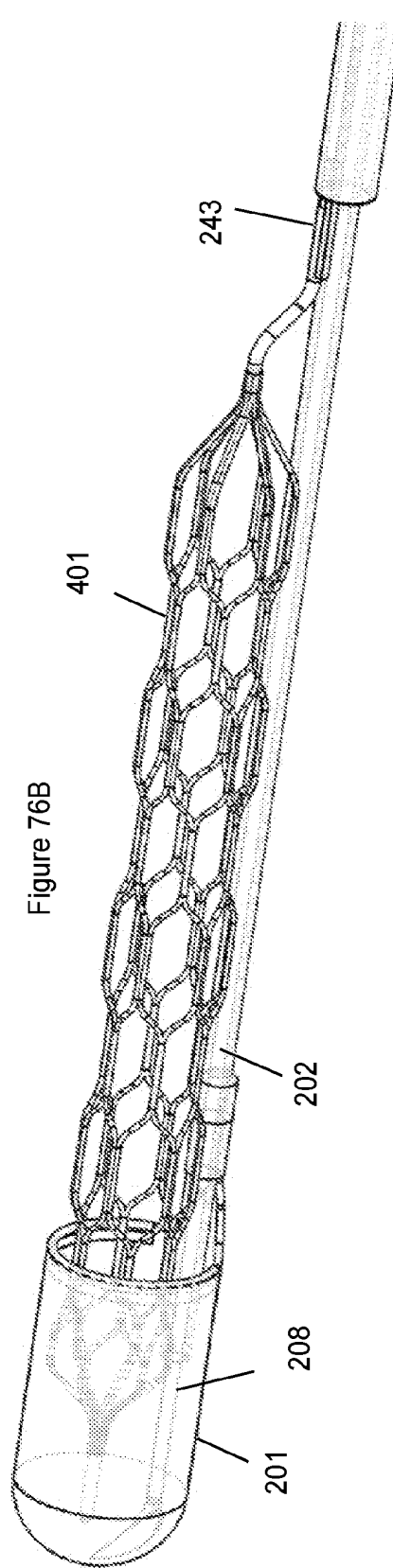
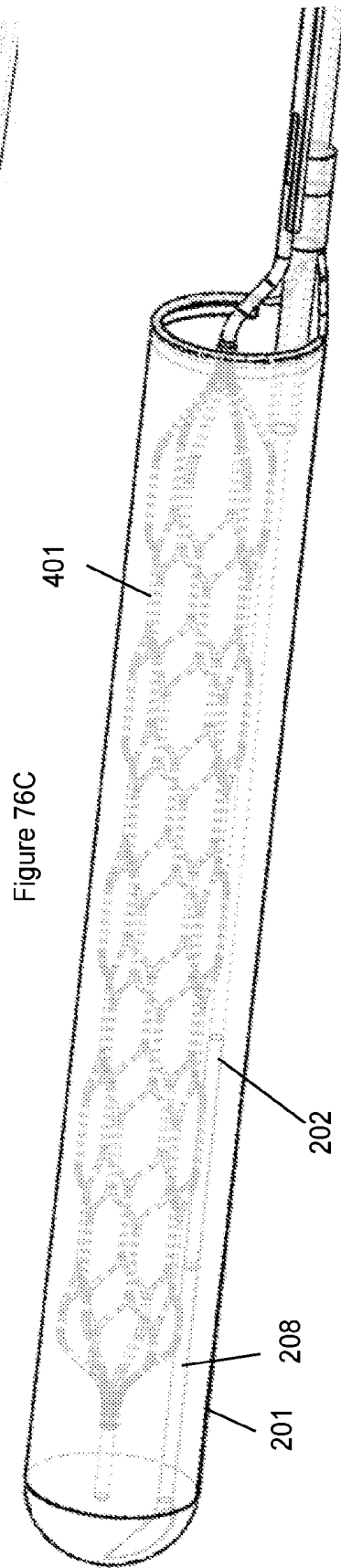


Figure 74







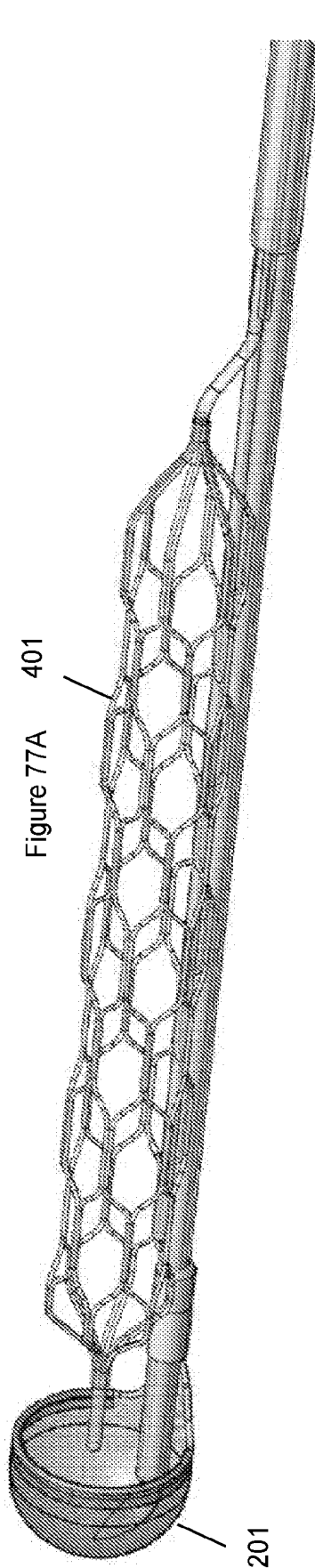
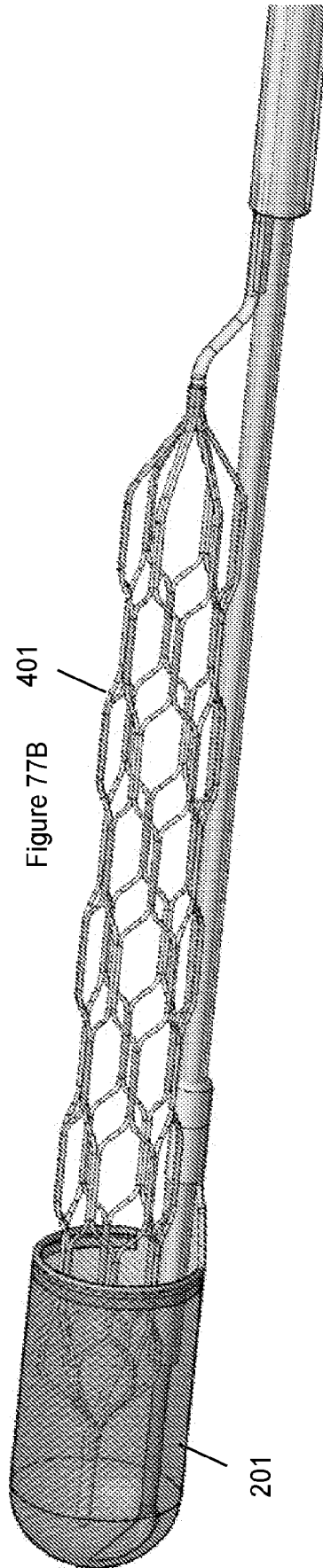
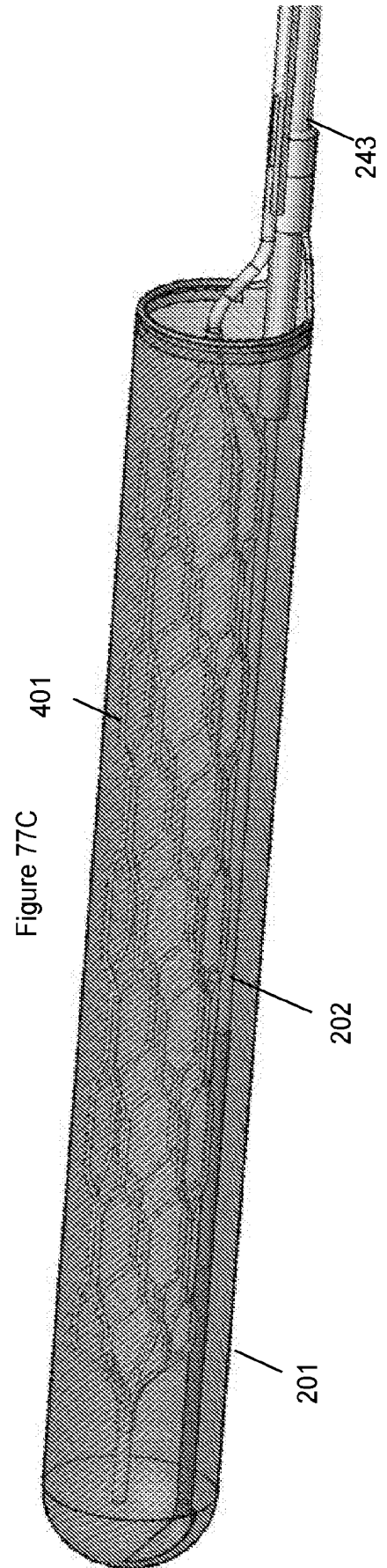


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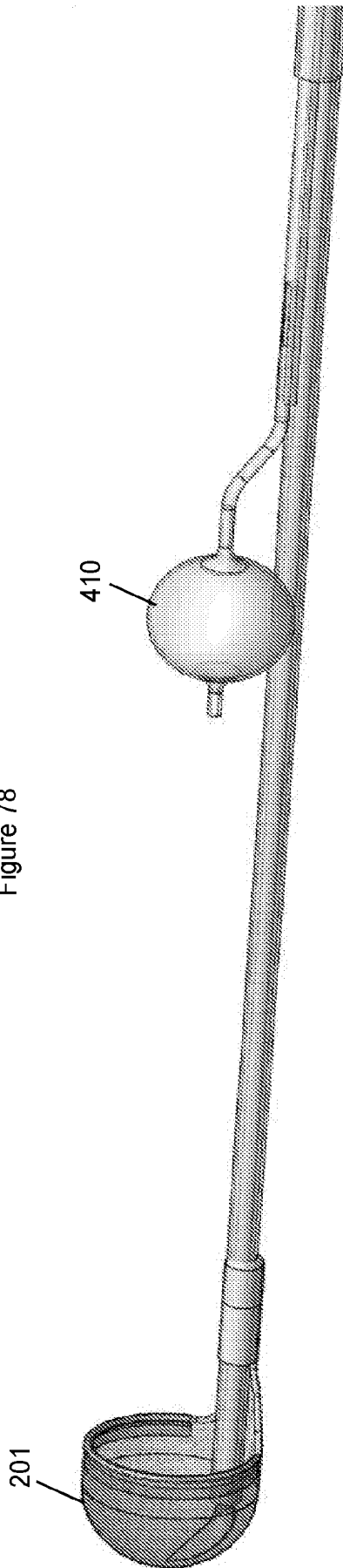
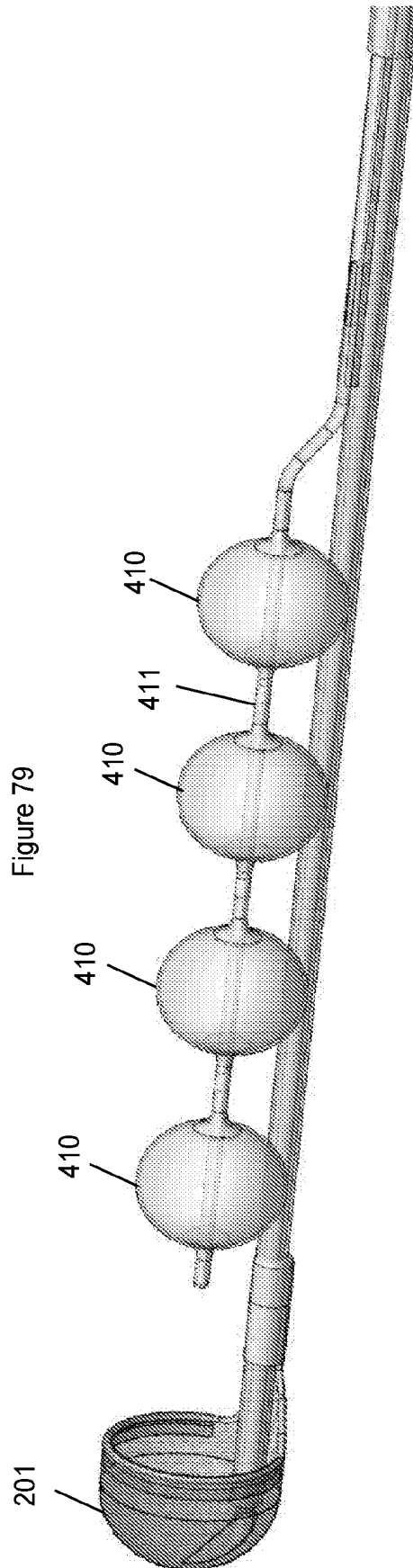


Figure 79



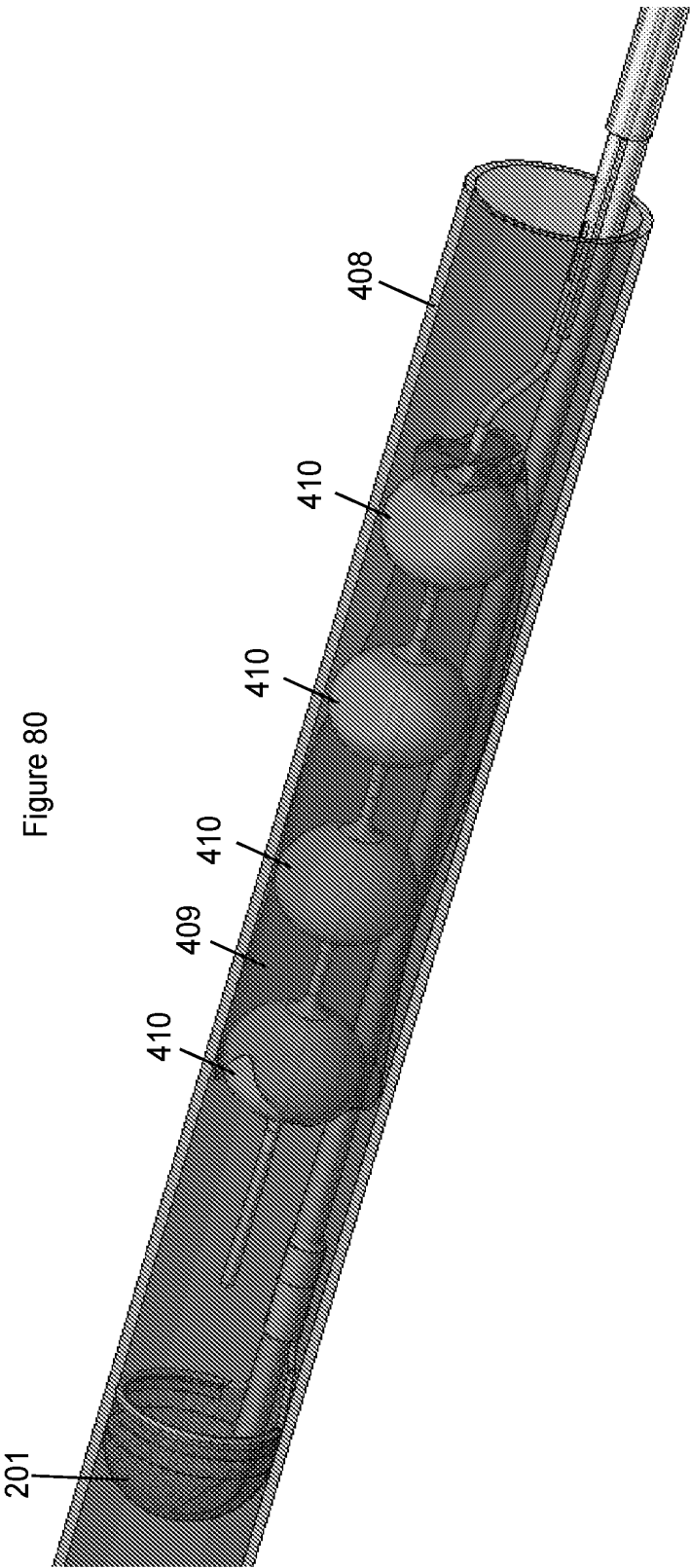


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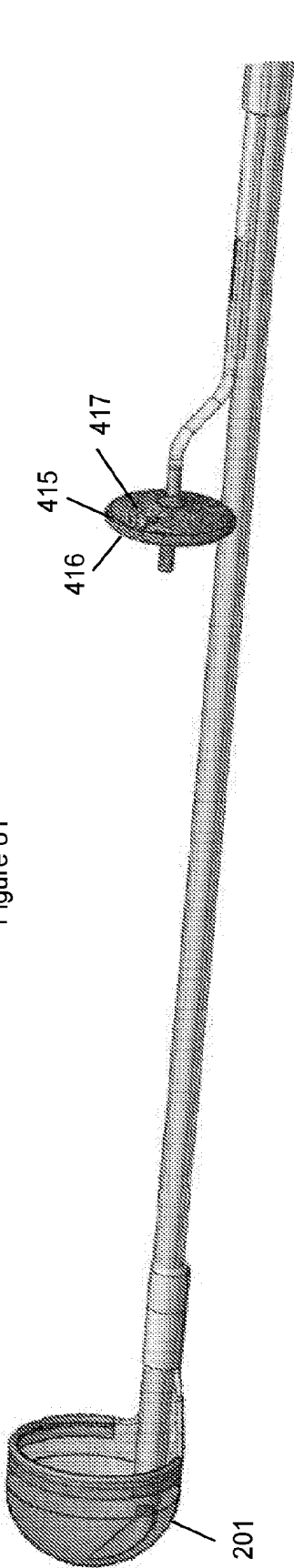


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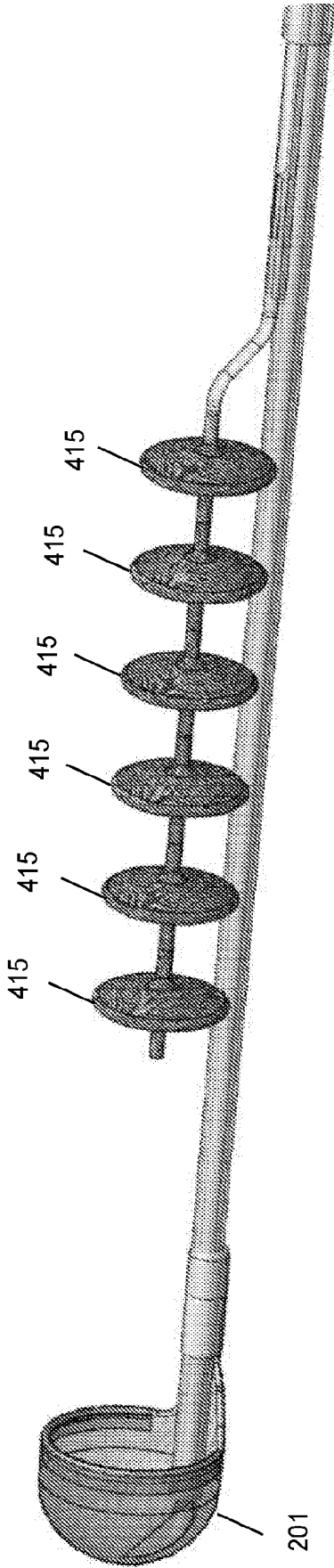


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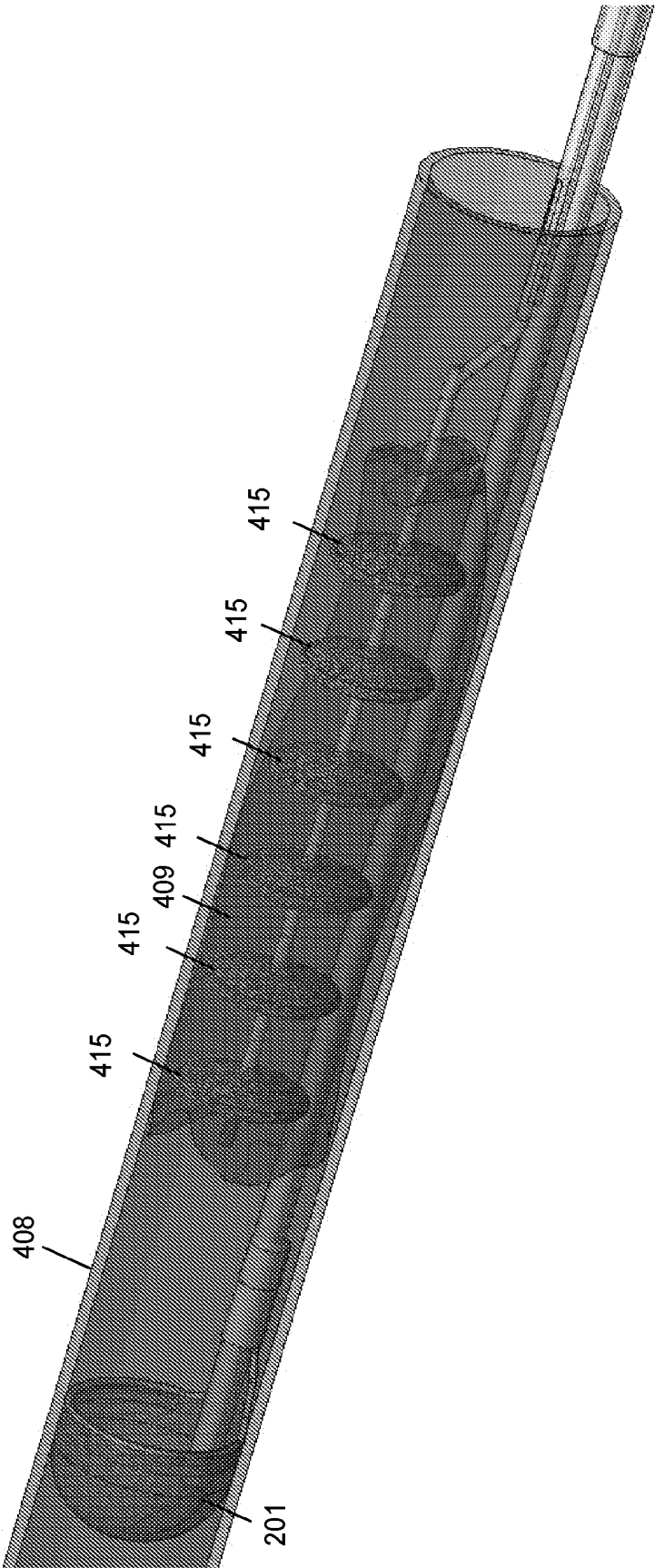


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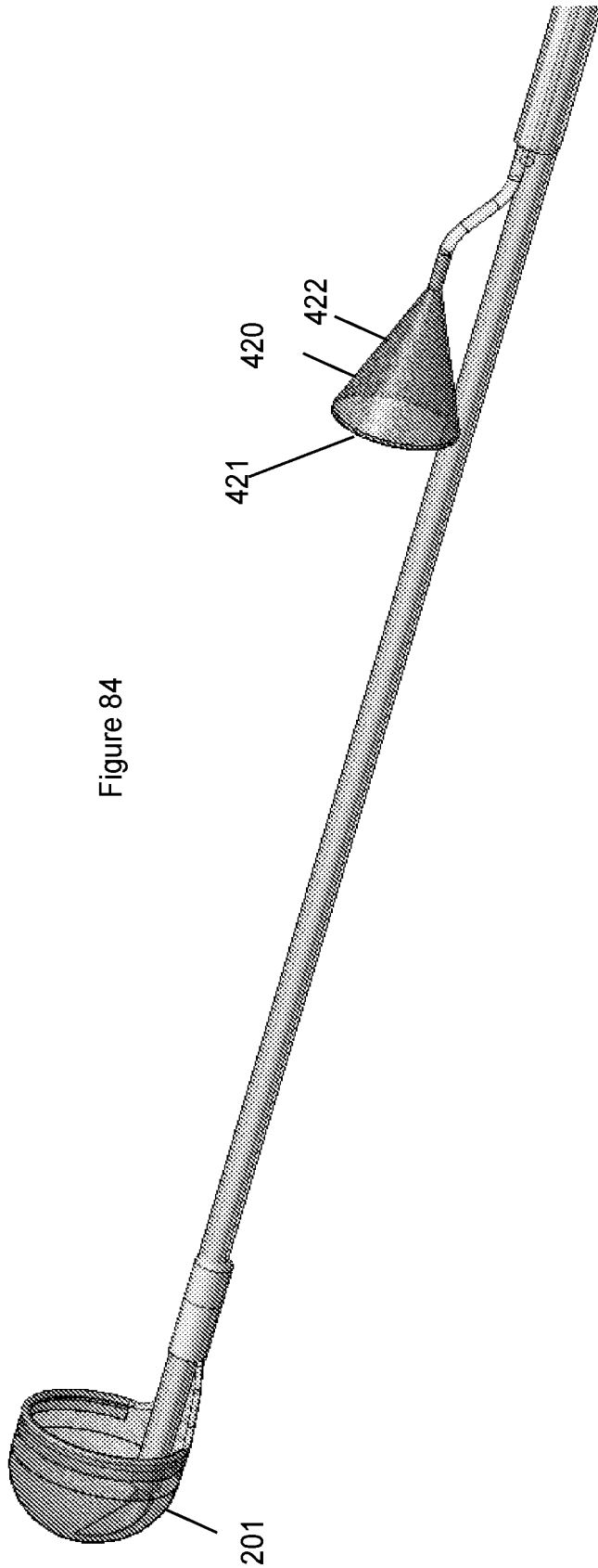
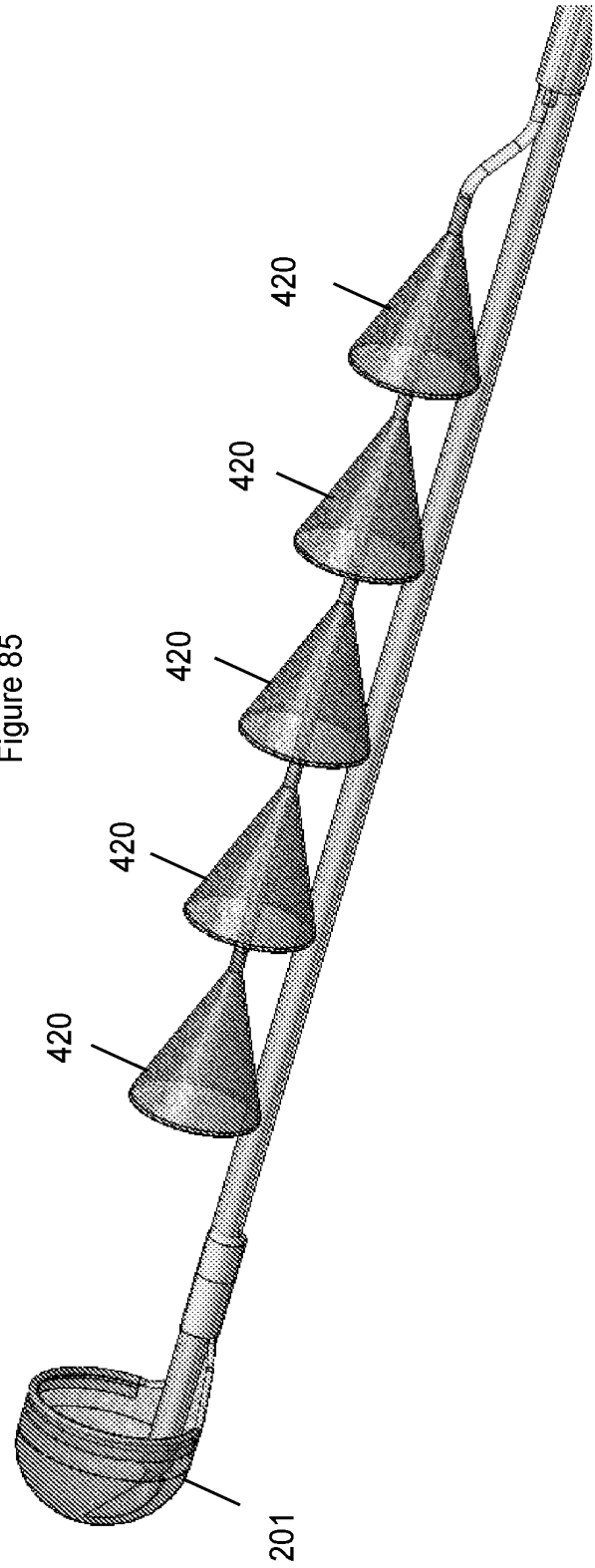


Figure 85



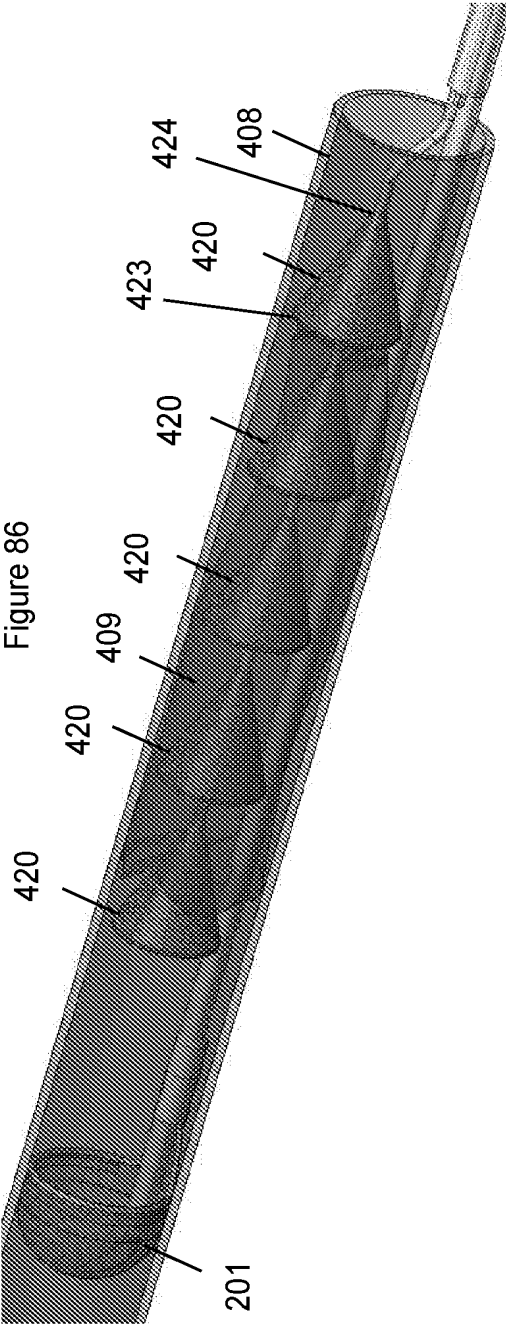
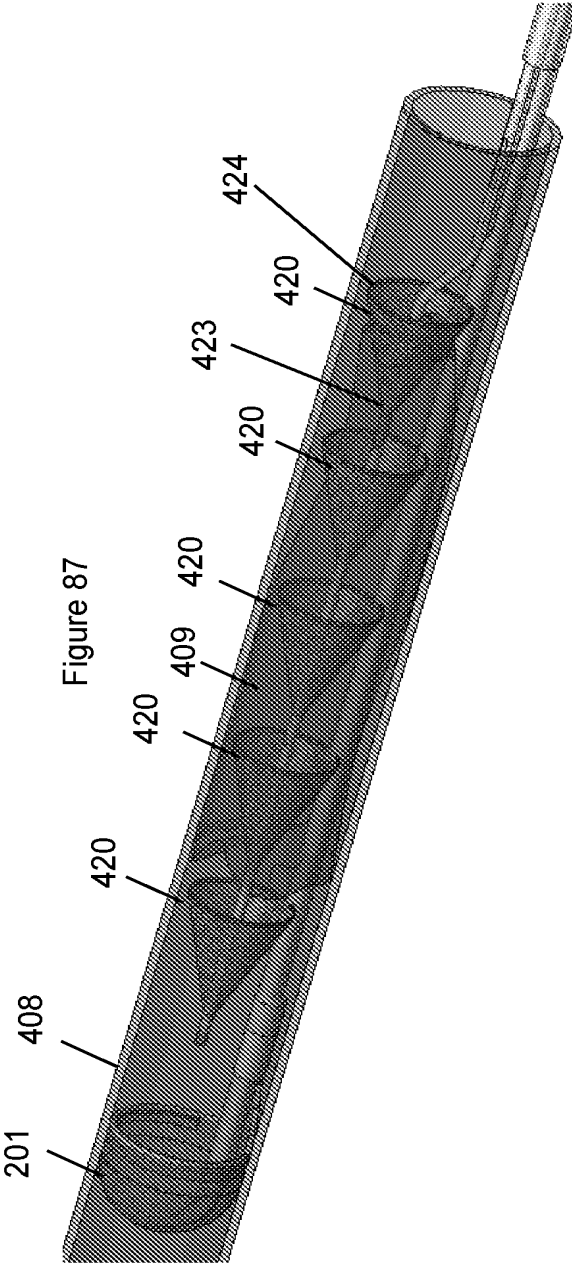


Figure 88A

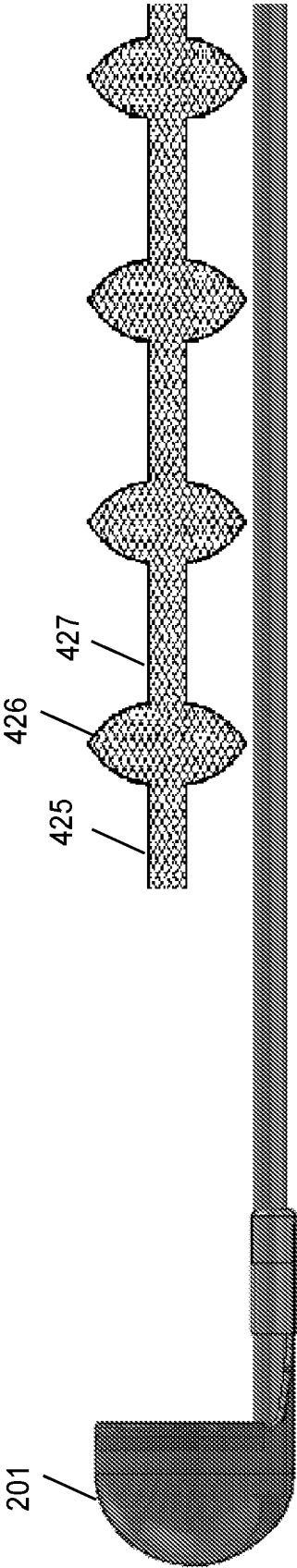


Figure 88B

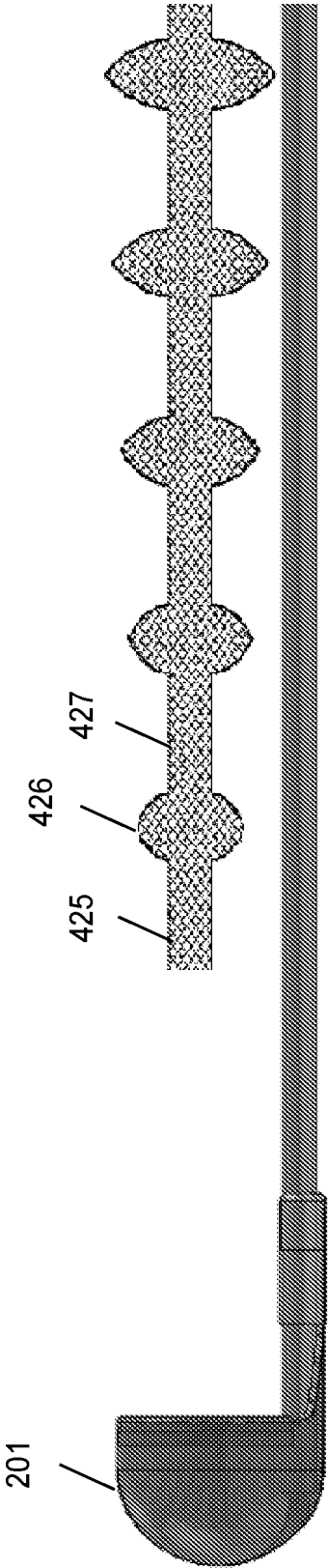


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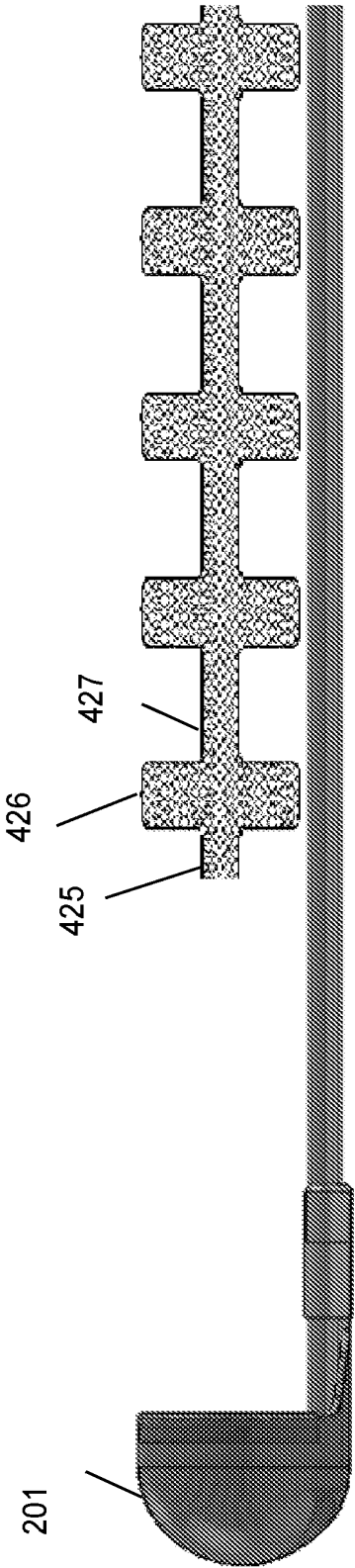


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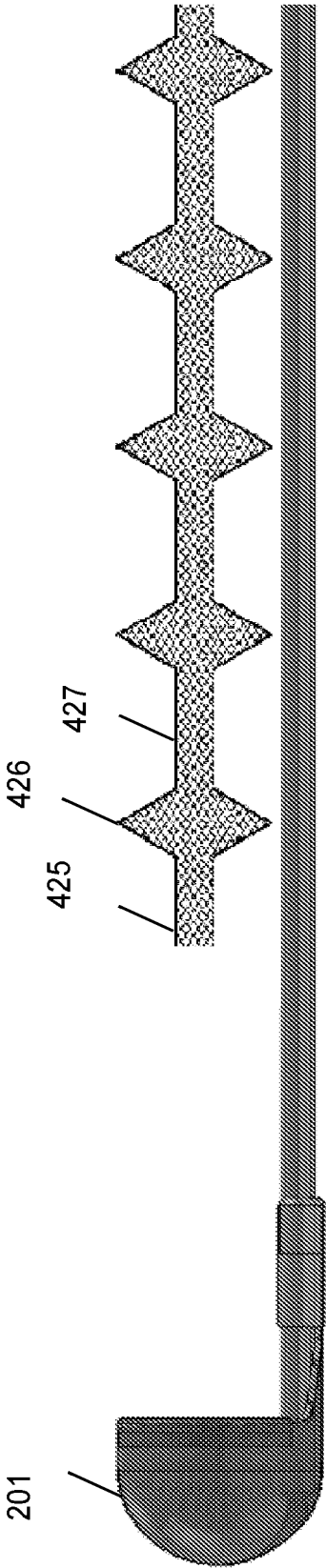


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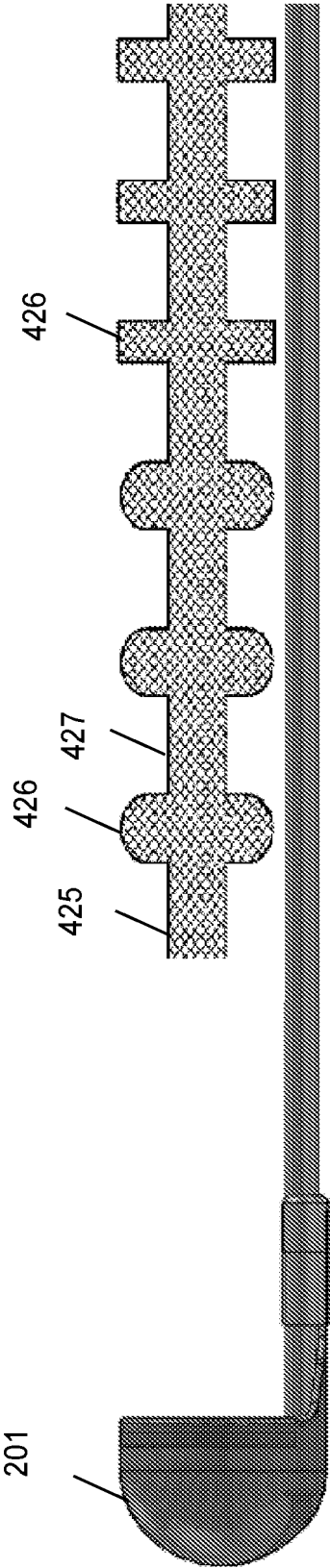


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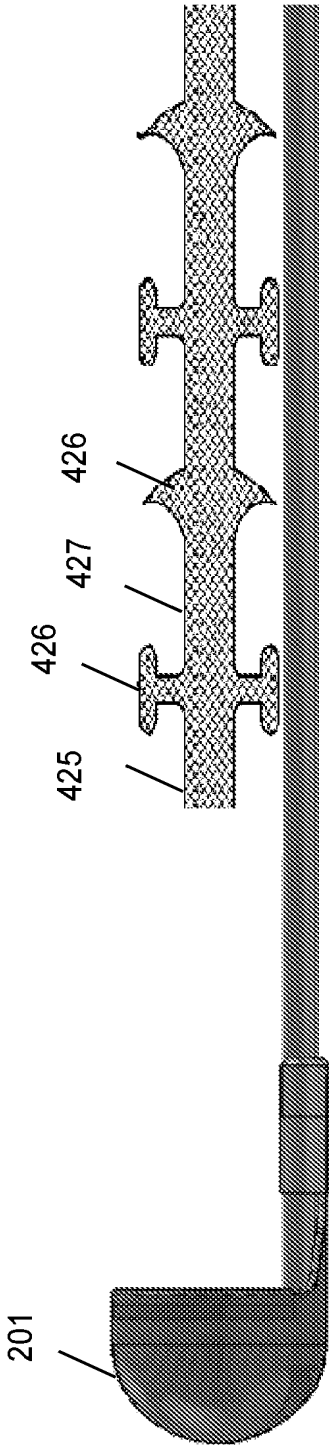


Figure 88G

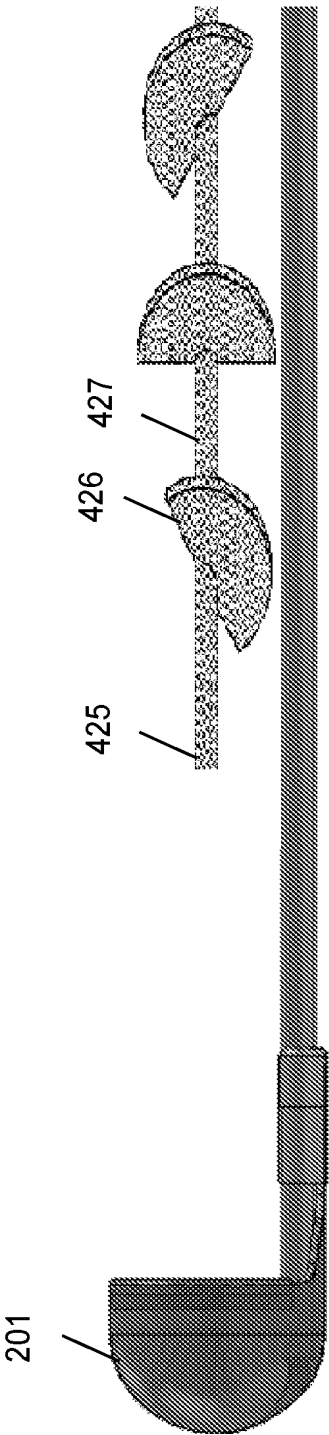


Figure 88H

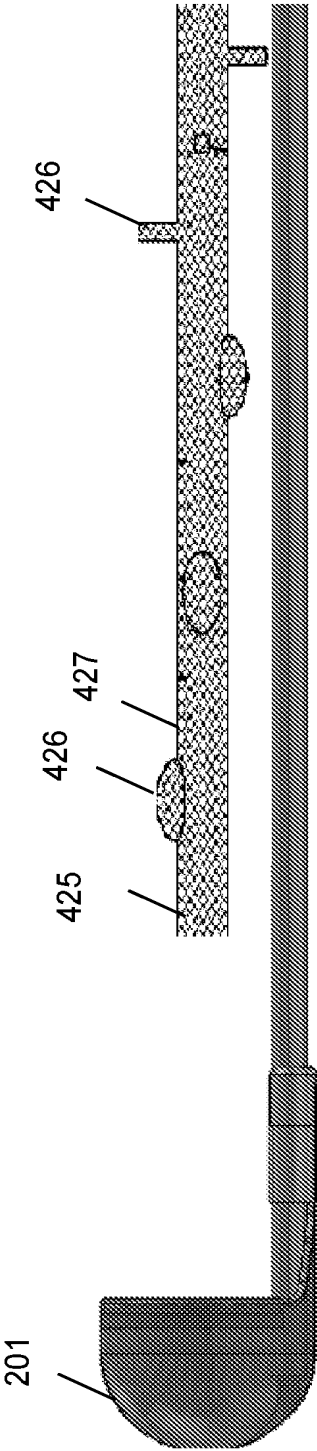


Figure 88l

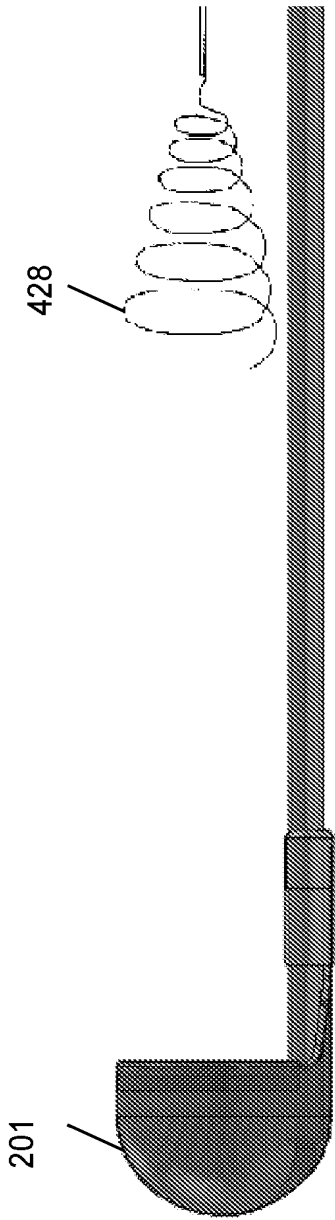


Figure 88J

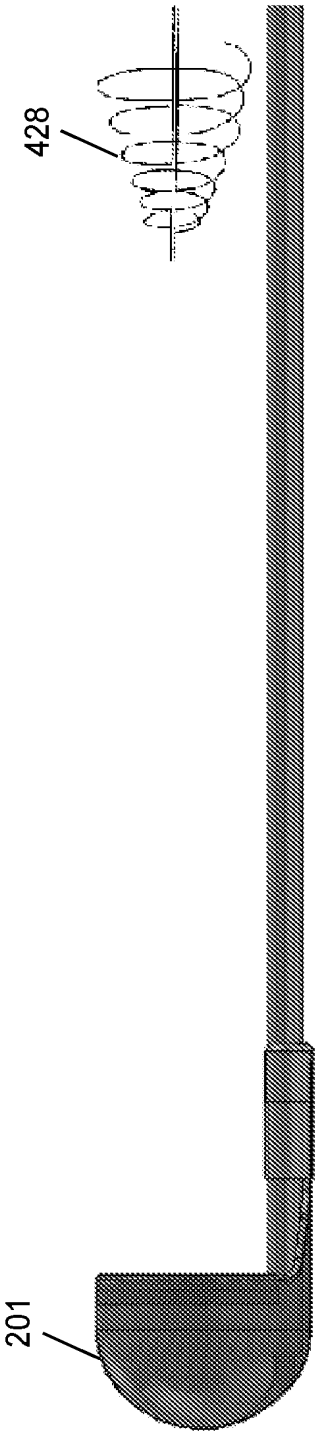


Figure 88K

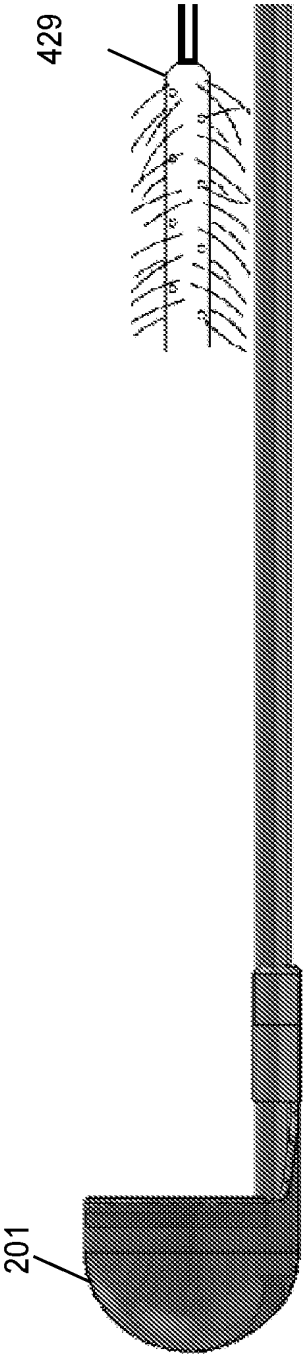


Figure 88L

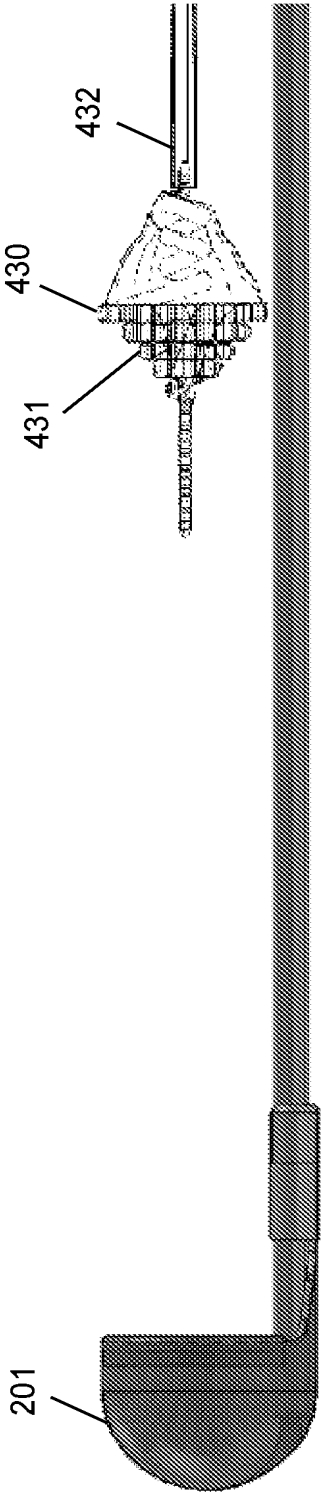


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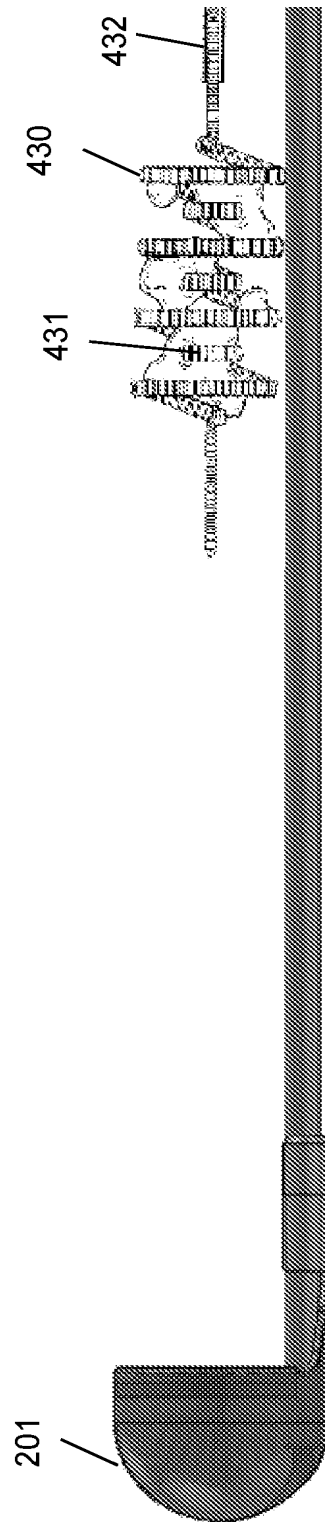


Figure 88N

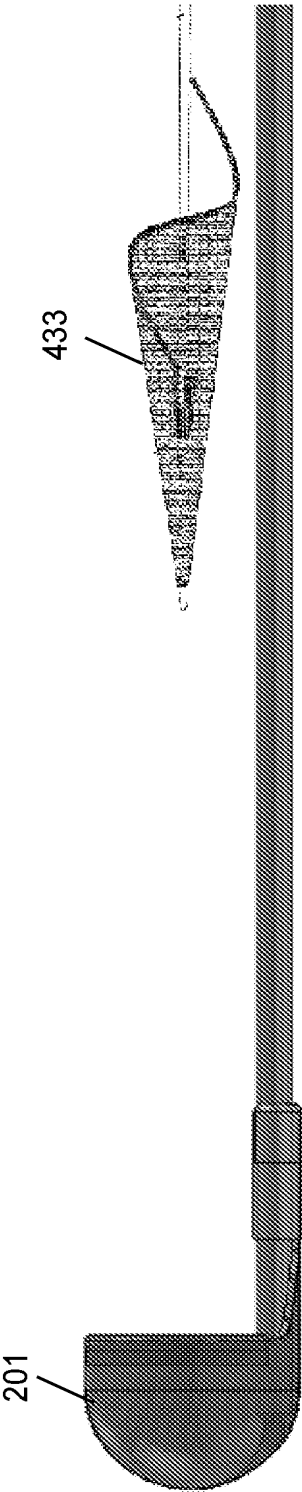


Figure 88O

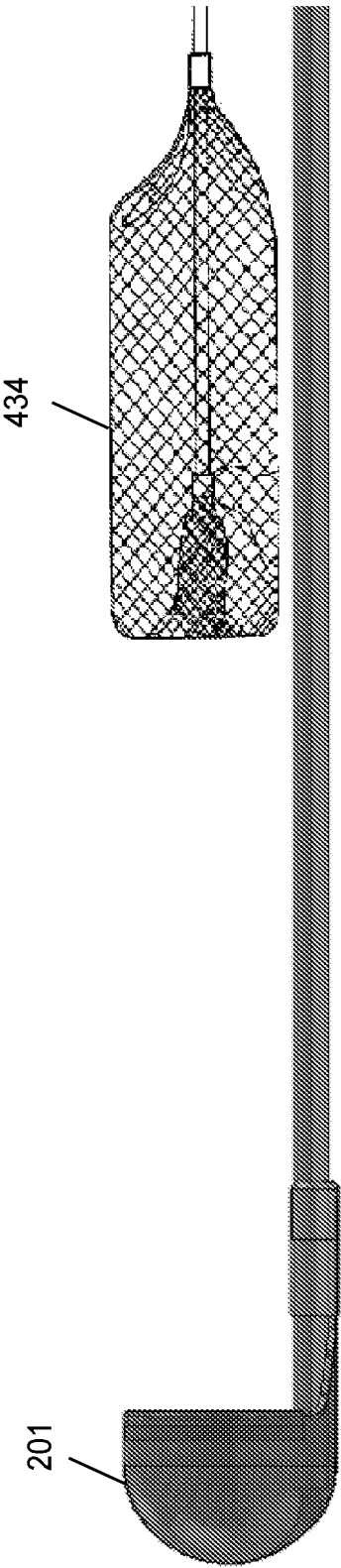


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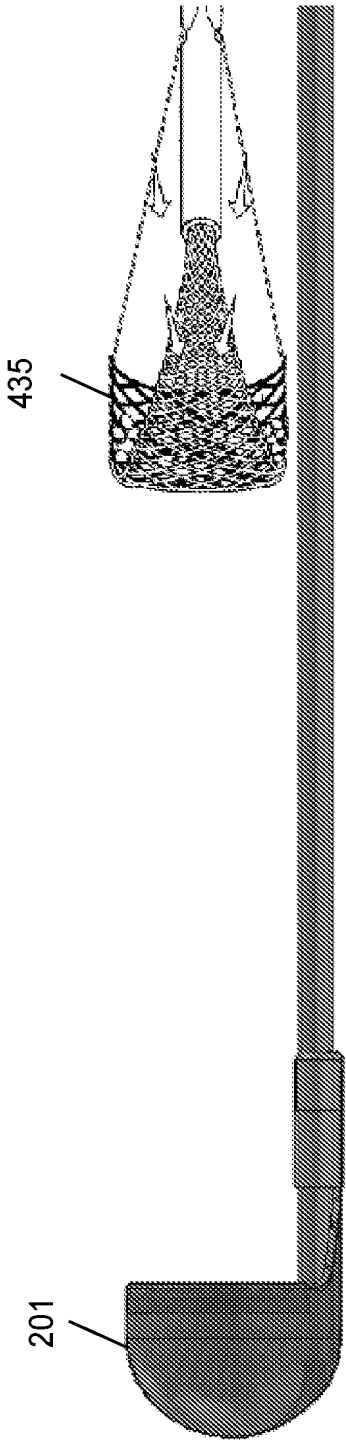


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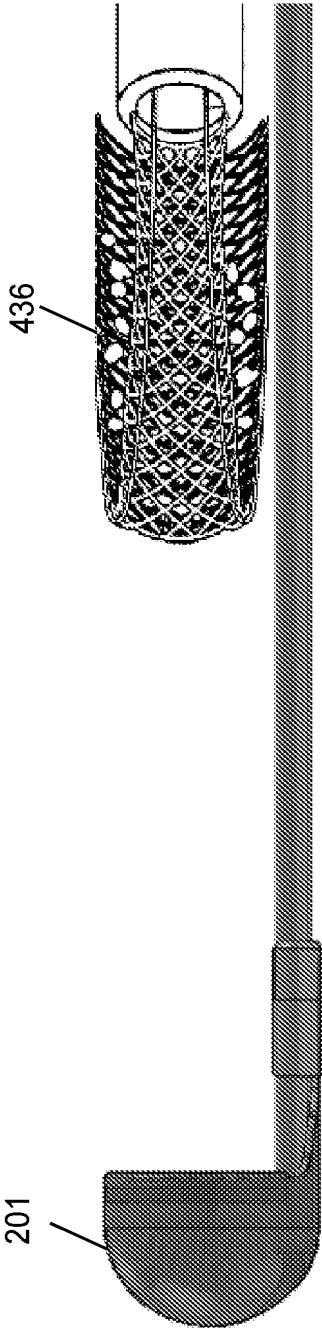
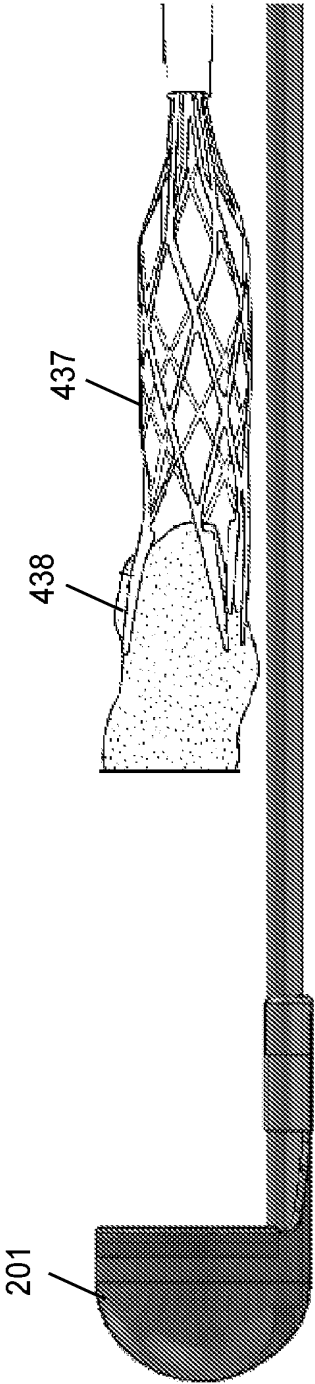
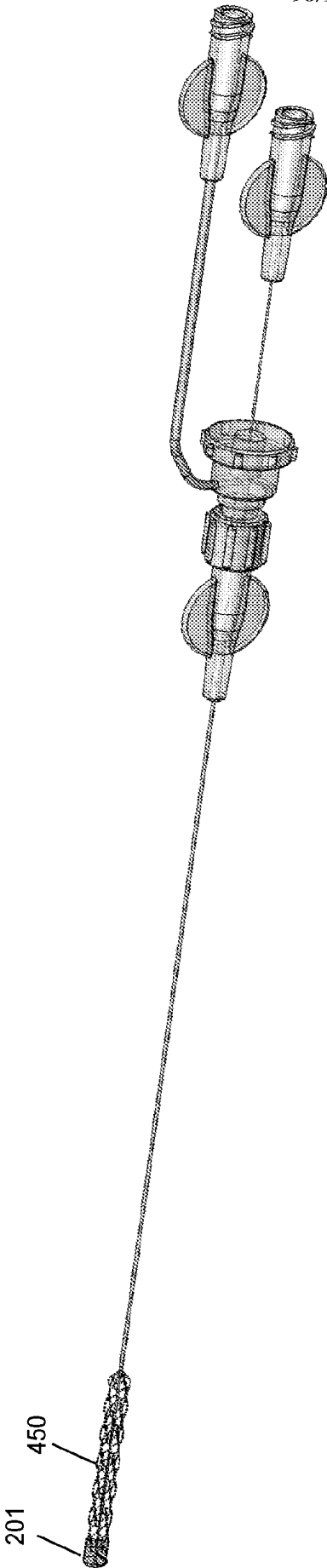


Figure 88R



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Figure 89



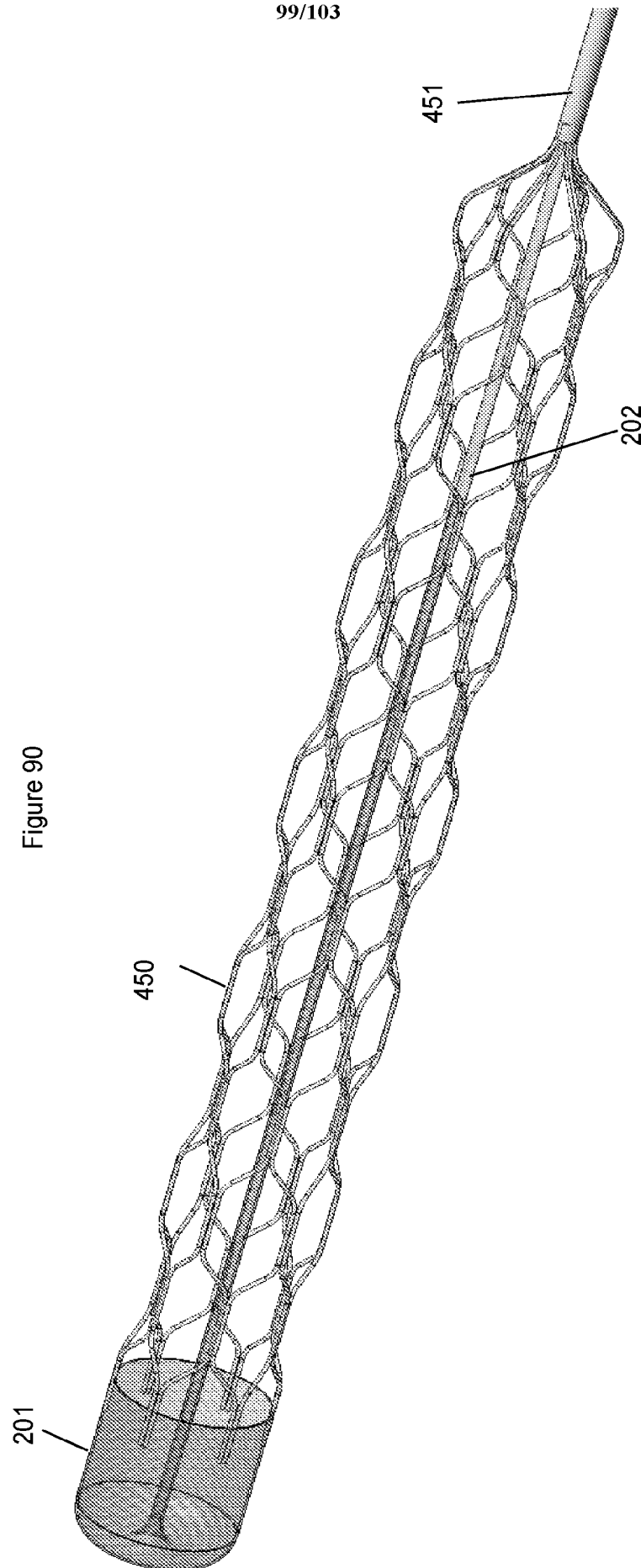


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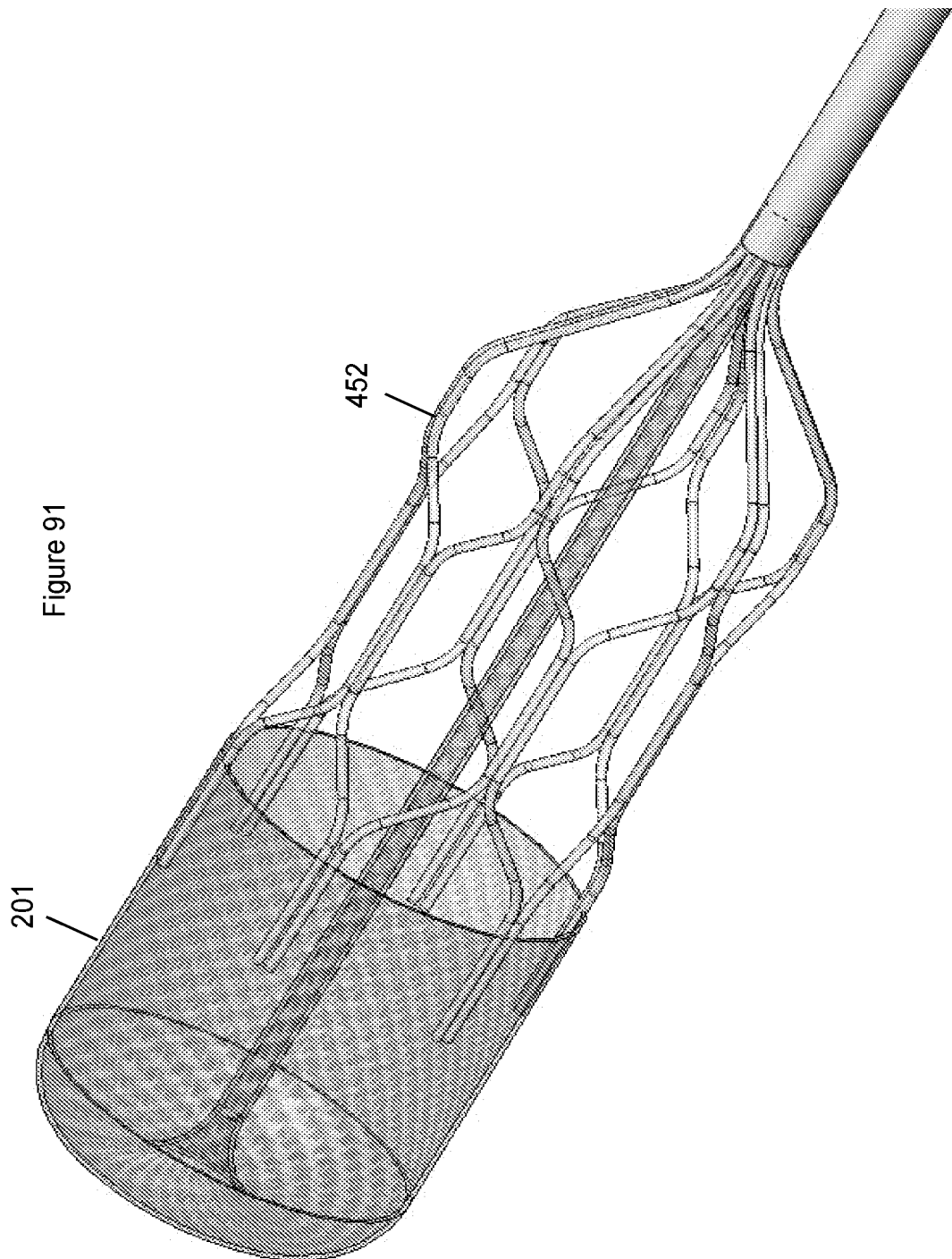


Figure 91

Figure 94

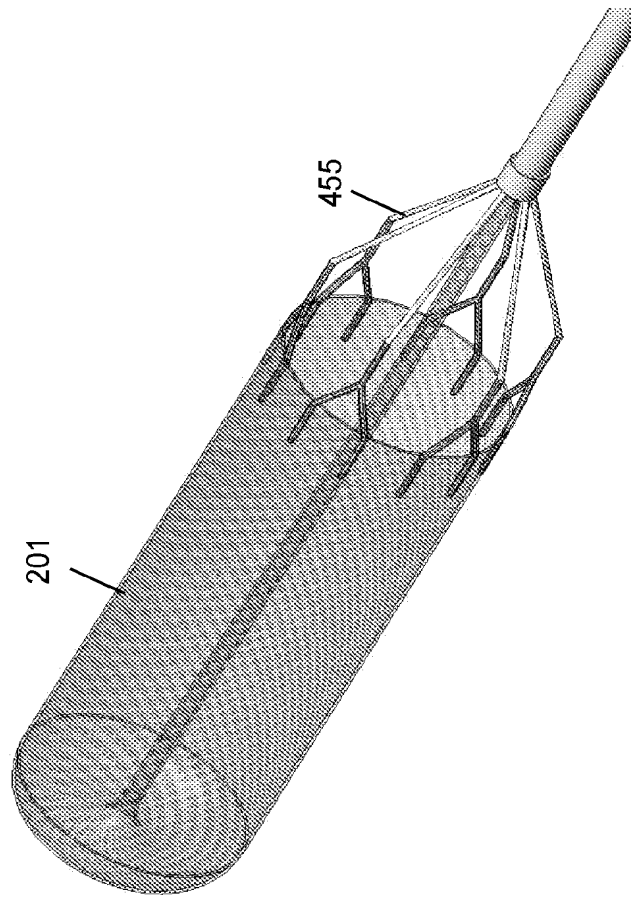


Figure 92

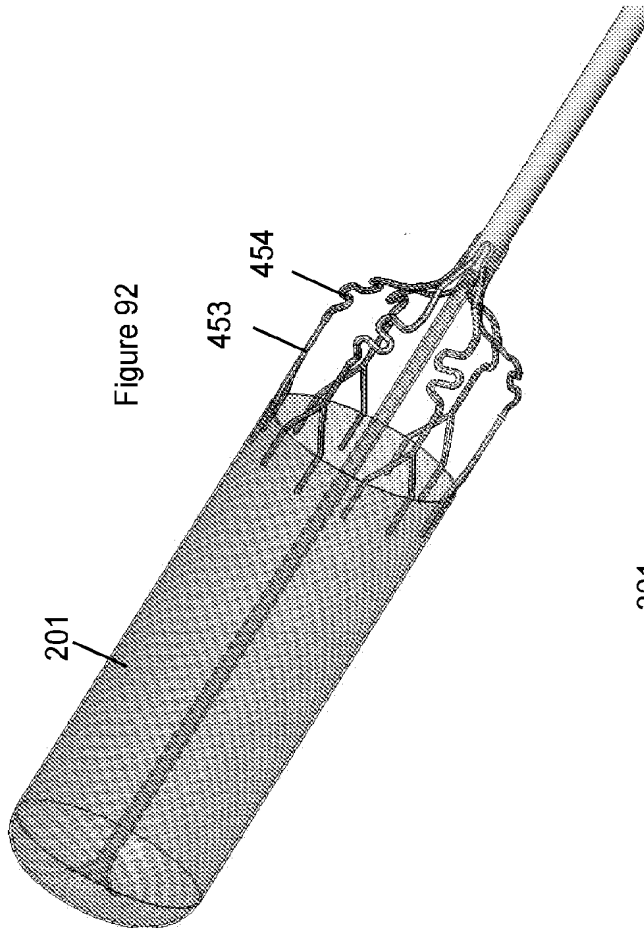


Figure 93

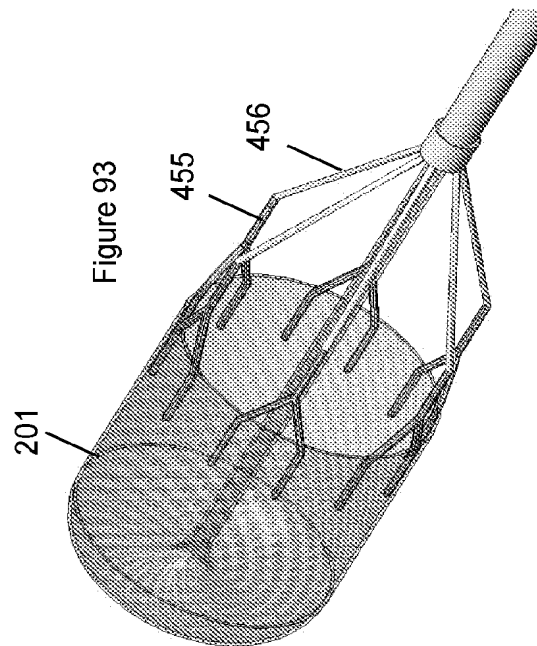
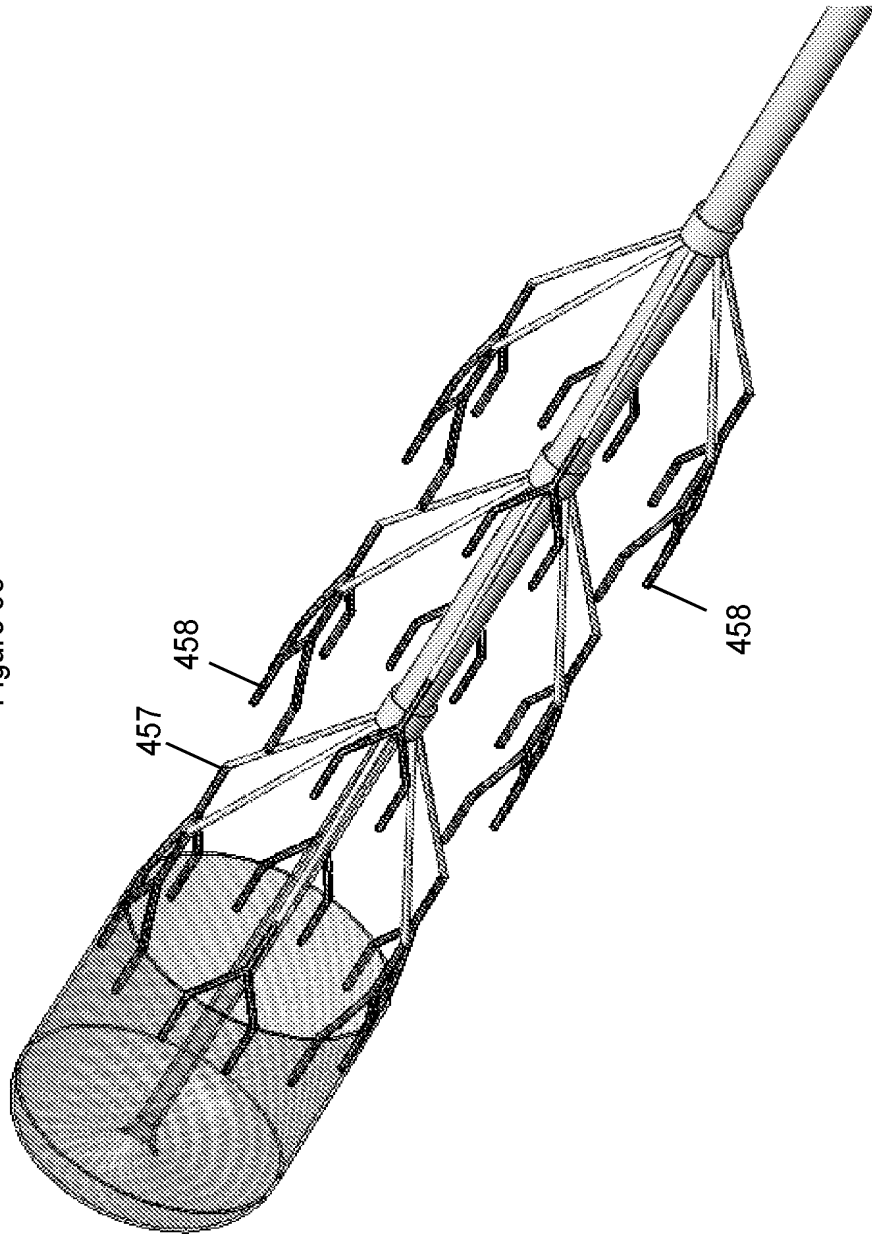
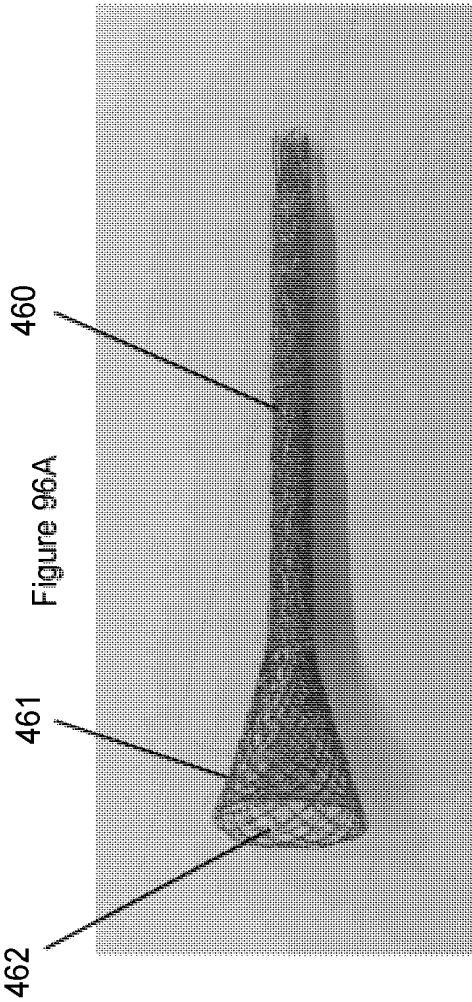
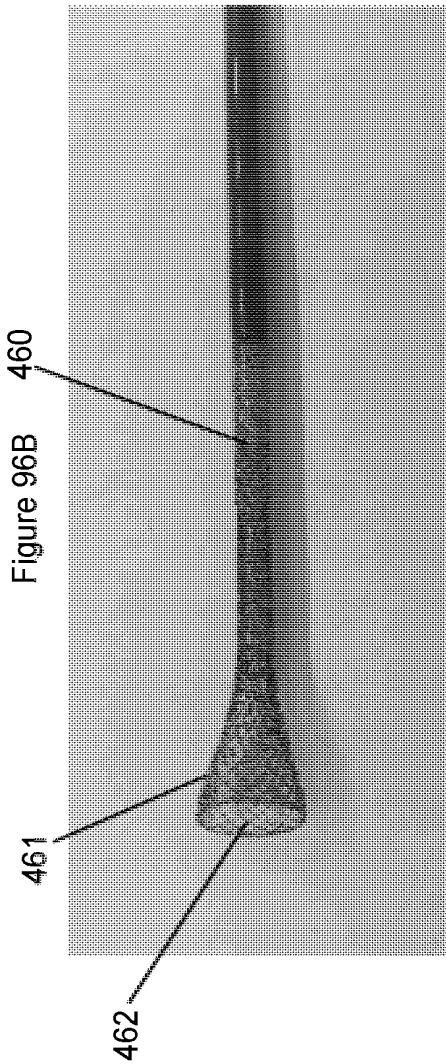


Figure 95





INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 2018/016976

A. CLASSIFICATION OF SUBJECT MATTER				
<i>A61B 17/22 (2006.01)</i>				
According to International Patent Classification (IPC) or to both national classification and IPC				
B. FIELDS SEARCHED				
Minimum documentation searched (classification system followed by classification symbols)				
A61B 17/00, 17/22, 17/221, A61F 2/01				
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched				
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)				
PatSearch (RUPTO internal), Esp@cenet, PAJ, USPTO, Information Retrieval System of FIPS				
C. DOCUMENTS CONSIDERED TO BE RELEVANT				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
X Y A	US 8968330 B2 (INCEPTUS MEDICAL LLC) 03.03.2015, fig. 6E-7B, 9A-9H, col. 3, line 57 - col. 7, line 39	1-4, 6, 7, 9-18, 20, 44 5, 8, 9 21-43		
Y	US 5868708 A (APPLIED MEDICAL RESOURCES CORPORATION) 09.02.1999, fig. 1, 5, 7, 9-11, col. 6, line 10 - col. 9, line 65	5, 8		
Y	US 6221006 B1 (ARTEMIS MEDICAL INC.) 24.04.2001, col. 8, lines 32-37, col. 9, lines 19-26	19		
A	US 2011/0125181 A1 (EAMON BRADY et al.) 26.05.2011	1-44		
☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.				
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27 April 2018 (27.04.2018)		24 May 2018 (24.05.2018)		
Name and mailing address of the ISA/RU: Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37		Authorized officer Y. Leonova Telephone No. (495)531-64-81		

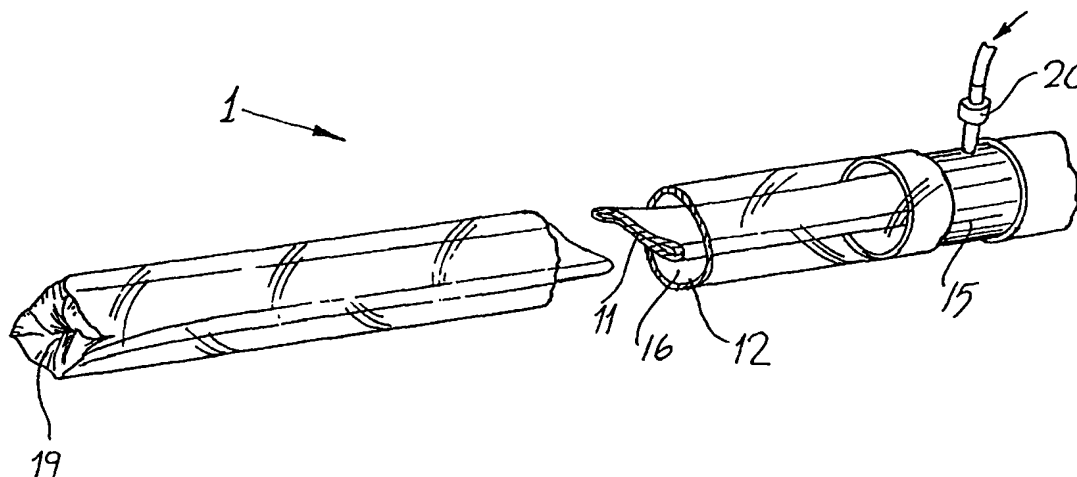
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(71) Applicant (for all designated States except US): ATROPOS LIMITED [IE/IE]; 1 Earlsfort Centre, Hatch Street, Dublin 2 (IE).			
(72) Inventors; and		Published	
(75) Inventors/Applicants (for US only): BONADIO, Frank [US/IE]; 2 Martello Terrace, Bray, Co. Wicklow (IE). YOUNG, Derek, William [IE/IE]; 3 Cloister Way, Carysfort Avenue, Blackrock, County Dublin (IE). REID, Alan [IE/IE]; 7 Kincora Drive, Clontarf, Dublin 3 (IE).		With international search report.	
(74) Agents: O'BRIEN, John, A. et al.; John A O'Brien & Associates, 3rd floor, Duncairn House, 14 Carysfort Avenue, Blackrock, County Dublin (IE).			

(54) Title: A MEDICAL DEVICE COMPRISING AN EVERTABLE SLEEVE



(57) Abstract

A medical device may comprise an introducer (1) for introducing an object such as an instrument through a body opening such as the throat. The device (1) comprises a tubular sleeve (10) of pliable plastics material which is turned axially back on itself to define inner and outer sleeves sections (11, 12). The inner sleeve section (11) defines an inner lumen (19) and the sleeve may be twisted to centralise the lumen. The sleeve is pre-shaped to define a desired non-linear shape. A chamber (16) between the inner and outer sleeve section (11, 12) is inflatable. The device may also be deployed remotely for example, for balloon angioplasty.

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A MEDICAL DEVICE COMPRISING AN EVERTABLE SLEEVE

Introduction

5 The invention relates to a medical device, particularly for use in minimally
invasive and endoluminal surgical and medical techniques. In particular the
invention relates to an introducer for introducing an instrument into the body
through an opening. More specifically, the invention relates to a device to assist
10 in the introduction of endoscopic devices into the lumen of a natural bodily
orifice, in particular the rectum and colon.

The introduction of an instrument or the like through a body opening such as the
throat or rectum is traumatic for the patient and difficult for the medical
practitioner as such openings lead into a complex passageway(s) through which
15 the instruments must be passed. Therefore great skill and experience is required.

Background of the Invention.

20 The practise of gastroenterology has been much improved due to the development
of the fibre-optic endoscope. Modern endoscopes consist of a control section
attached to a long flexible shaft with a steerable tip. The flexible shaft carries
several tubes for light, air, water and suction. In some cases a biopsy channel with
a larger bore to allow therapeutic procedures to be performed is included. Light is
transmitted through non-coherent fibre-optic bundles. Older scopes used coherent
25 fibre-optic bundles for transmission of the image but these are largely obsolete
now and video-endoscopes are the norm. These use fibre-optic bundles for light
transmission only and use a CCD TV camera for image acquisition. The camera
output is then transmitted through wire pairs.

30 Endoscopes use a torque control mechanism that allows the endoscope to be
steered through the passage of interest using control wheels on the handle at the
proximal end. Steering is achieved by turning control knobs on the control section

of the endoscope. There are usually two knobs, one for lateral control and another for vertical control. These control wheels are attached to guide wires that run up through the endoscope and are attached to the tip.

5 An endoscope is typically 100-150 centimetres long and may be inserted into either end of the digestive system. Generally the devices have specific design features adapted to the bodily opening through which the endoscope is inserted. The endoscope is pushed from the bottom and guided through tortuous passages using external manipulation.

10 In the upper gastrointestinal tract the insertion of the device presents relatively little difficulty. This is due to the short length of the upper GI tract and the relatively straight anatomy. Difficulty is encountered when attempting to advance into the proximal end of the small intestine for example to examine the pancreato-
15 duodenal junction.

In the lower GI tract the picture is quite different. The lower GI tract is made up of the rectum and the large intestine or colon. The colon, in a textbook arrangement of its anatomy, extends upwards from the lower right quadrant,
20 traverses the width of the body just below the diaphragm, extends downwards along the left side of the abdomen and then loops in a retrograde manner before linking up with the rectum and the anus. Even with this textbook arrangement, the large intestine is difficult to cannulate with a flexible endoscope due to the flexible nature of the endoscope shaft and the floppy nature of the colon. It is even
25 more difficult with the more realistic lumen anatomies. In some people the sigmoid colon can be very long and is unfixed, except by its mesentery, and so can be extremely difficult to cannulate due to its predisposition to form loops when an endoscope is pushed through it. Some anatomical landmarks, such as the recto-sigmoidal junction, the splenic flexure and the hepatic flexure, are difficult to pass
30 through simply because of their tortuous nature. Problems traversing these areas are exacerbated by looping of the endoscope in the sigmoid colon.

Endoscopy is a difficult technique that can only be mastered after performing many hundreds of examinations. The ability to speedily cannulate the bowel and traverse the entire colon all the way to the caecum is a skill that is only enjoyed by a minority of endoscopists. Published research on the subject of difficulty encountered in endoscopy shows that the procedure fails in up to 15% of cases where failure is defined as inability to reach or visualise the caecum. Up to 35% of cases are considered to be difficult as defined by extended duration of the procedure and experience of pain by the patient. Other research shows that up to 29% of cases are considered to be technically difficult.

Several devices have been described in the prior art to assist in the practise of lower GI endoscopy.

US-A-3805770 describes an endoscope guide and lubricating means comprising a cylindrical spongy member to guide and lubricate the endoscope as it enters the anus. This device however does not address the problems associated with looping of the scope in the sigmoid colon and resulting problems crossing the splenic and hepatic flexures.

US-A-4207872 describes a sleeve device for positioning on the end of an endoscope to assist it in advancing through a body passage. The device has protrusions extending perpendicularly from the sleeve that may be expanded and retracted using fluid pressure. Upon repetitious expansion and retraction of the protrusions using pulsing pressure within the device, the device assists in advancing the scope along the body passage. There is likely to be considerable internal friction between the device and the inner wall of the body passage.

US-A-4321915 describes a device consisting of an everting tube which includes a pressure and evacuation valve to allow eversion and retraction of the tube. The tube is slidably attached to a fibre-optic bundle for vision. Whilst this device allows a means of vision to be advanced up the confines of a body passage it cannot be used with existing endoscopes because of its size. It is proposed for use

in small narrow bore tubes such as the urethra. There is a similar problem with the device disclosed in US-A-4615331. This device consists of an everting tube which has a plurality of folds which telescope open as the everting tube advances.

5 US-A-4676228 describes a device that is removably attached to the front end of an endoscope to assist in pulling the scope through the colon. It consists of two inflatable cuff sections that are alternatively inflated and deflated whilst being moved towards and away from each other. In this way the endoscope is dragged up through the colon in short steps. This procedure is lengthy and complex. In
10 addition, there is considerable friction between the colon and the scope.

US-A-4971033 describes a flexible endoscope with a working channel designed to cause the tube to stiffen when fluid pressure is applied to the channel. The channel takes up space in the endoscope that is more appropriately used for either vision,
15 suction, insufflation or tissue sampling. In addition, an endoscope is stiffened along a particular section or along its entire length which exacerbates the difficulty of passing the endoscope through the floppy sigmoid colon.

US-A-5045070 describes an everting tube for entering body cavities and
20 depolying a tube for administration of drugs or therapy through the tube. The device is designed for introducing a channel attached to the tube and is not designed for introducing a removable endoscope or the like.

WO-A-97/32515 describes a semi-toroidal tube for introducing an endoscope into
25 a body cavity for examination and therapeutic purposes. The device is a tubular endless body that everts at its distal end and inverts at its proximal end when advanced through a duct such as the human colon. WO-A-99/01171 describes a similar device with the addition of corrugations designed to assist in the passage of the endless tube around the anatomy of the colon.

30

US-A-5941815 describes a sigmoid splint device for use in endoscopy. The device is intended to be used to keep the sigmoid colon from looping while the operator is attempting to cross more difficult junctions.

5 In general, such known devices are either difficult to use, cause discomfort to the patient, can only be advanced incrementally, do not cater for complex nature and shape of tortuous body passageways.

10 There is a need for an improved medical device which will address at least some of these problems and which may be especially used as an introducer to navigate the lower gastrointestinal tract with minimum discomfort to the patient.

Statements of Invention

15 According to the invention there is provided a medical device for insertion in a body opening or an incision comprising:

a sleeve of pliable material, the sleeve having a twisted sleeve section to define a reduced lumen section;

20

the sleeve having an outer sleeve section and an inner sleeve section;

a chamber for pressurised fluid defined between the inner and outer sleeve sections;

25

the inner sleeve section defining a lumen to receive an object;

30

the pressurised sleeve being evertable on engagement of an object in the lumen and axial movement of an object relative thereto so that the twisted inner sleeve section is rolled over outwardly to become an outer untwisted sleeve section and the untwisted outer sleeve section is correspondingly rolled over inwardly to become a twisted inner sleeve section.

Preferably the sleeve is turned axially back on itself to define an outer sleeve section and a twisted inner sleeve section.

5 In one embodiment the device the sleeve sections define a continuous endless track which may be advanced by engaging an object in the lumen.

In one embodiment the device includes a guide collar for locating relative to a datum, a sleeve section being movable relative to the collar on engaging an object
10 into the lumen and/or on passage of an object through the lumen. In a preferred arrangement the free ends of the sleeve are joined to the collar.

The device preferably includes an inflation port for inflation of the enclosed chamber between the sleeve sections.

15 In a preferred arrangement the device includes adjustment means for adjusting the twist in the sleeve.

In one embodiment of the invention at least portion of the sleeve has a non linear shape. Usually, the non linearity corresponds to a desired predetermined shape.
20 The non linearity may be in at least two, and typically in three dimensions

In one embodiment the sleeve is biased into the non linear shape.

25 The sleeve may be sculpted or formed into the non linear shape.

In one embodiment the device includes guide means through which the sleeve and/or an object is advanced. Typically, the guide means includes a ring means for placing in a body opening or incision through which the sleeve and/or an
30 object is advanced.

In another embodiment of the invention the device includes a delivery means for delivery of the device to a remote location. In one case, the delivery means is a tube such as a catheter or cannula.

5 In one aspect the device defines a transporter for delivery or retrieval of an object to or from a desired location.

In another aspect the device defines an introducer for introducing an object such as an instrument to a desired location.

10

In a further aspect the device is an expandable element. The expandable element may be a balloon for angioplasty.

Brief Description of Drawings

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The invention will be more clearly understood from the following description thereof given by way of example only, in which :-

20

Fig. 1 is a perspective view from a proximal end of an introducer according to the invention.

Fig. 2 is a perspective view from a distal end of the introducer of Fig. 1;

25

Fig. 3 is a cross sectional view of the introducer in one position of use;

Fig. 4 is a cross sectional view of the introducer in another position;

Fig. 5 is an end view of the introducer;

30

Figs 6 and 7 are diagrammatic view illustrating one method for manufacturing the introducer;

Figs 8 and 9 are side partially cross sectional view of other introducers;

Figs 10 to 14 are cross sectional views illustrating the operation of an expandable medical device according to the invention;

5

Fig. 15 is side, partially cross section view of the device of Figs 10 to 14, in use; and

Fig. 16 is an enlarged view of a detail of Fig. 15.

10

Figs 17 to 25 are diagrams illustrating the principles of operation of the invention.

Fig. 27 is a perspective view of an introducer device in an untwisted configuration;

15

Fig. 28 is a plan view of the device of Fig. 27;

Fig. 29 is a cross sectional view of the line A-A in Fig. 28;

20

Fig. 30 is a perspective view of the introducer device of Fig. 27 in a twisted configuration;

Fig. 31 is a plan view of the device of Fig. 30; and

25

Fig. 32 is a cross sectional view on the line B-B in Fig. 31.

Detailed Description

30

Referring initially to Figs 1 to 7 there is illustrated a medical device according to the invention which in this case is configured as an introducer 1 for introducing an object such as an instrument through a body opening such as the throat or rectum.

5 The device 1 comprises an elongate tubular sleeve 10 of pliable material, especially a suitable biocompatible gas impermeable plastics material which is turned axially back on itself to define an inner sleeve section 11 and an outer sleeve section 12. The sleeve sections 11, 12 are joined in this case via a collar 15, to define an enclosed inflatable chamber 16 therebetween. The inner sleeve
10 section 11 defines an inner lumen 19 and the sleeve is twisted to centralise the lumen 19. An inflation port 20 is provided for inflating the chamber 16 between the inner and outer sleeve sections.

It will be particularly apparent that the device of the invention may be readily
15 advanced through a complex passageway such as the bowel or the like. It may therefore be used for cannulating such a passageway.

Figs 6 and 7 illustrate the twisting of the sleeve 10. The free ends of the sleeve 10 are rotated relative to one another prior to or after final assembly to the collar 15.
20 The twist will be apparent with reference to the points marked X. Such a twist may be provided when the device is in situ and is adjustable in situ.

The present invention provides a device that permits an endoscope or similar instrument to pass easily through the body's natural canals for purposes of
25 performing an endoscopic examination of those canals. The introducer allows the user to easily pass beyond junctions such as the sigmoid colon, splenic and hepatic flexures and other convolutions of the body's inner canals in the upper or lower gastrointestinal tracts. In addition, the device allows pain free cannulation of the body's canals by substantially eliminating friction and rubbing contact between
30 the endoscope and the walls of the canal under examination. Further the device is easy to manufacture and is convenient and simple to use.

Referring to Figs 8 and 9 there are illustrated other devices 50, 51 according to the invention which may be twisted or not. The devices are pre-shaped for a particular use. The devices may be biased to form a desired non linear shape on eversion. In this case the device has sculpted sections 52, 53 to confirm, an
5 eversion to a desired shape. It will be noted that the sculpted section 53 is initially part of the inner sleeve section. On eversion, it become unparalleled into a section of desired shape. The devices may be formed by moulding and/or sculpting to define the desired shape dependent to the passageway to be navigated.

10 The devices address two significant problems in lower GI endoscopy: the problem of friction between the endoscope and the colon and the problem caused difficulty in navigating bends and convolutions in the colon. Such a device would place itself between the colon and the endoscope such that the scope passed through the lumen of the colon without touching the side walls of the colon. Some
15 conventional introducers can address this problem, especially in a straight section of colon, but will have difficulties when the colon is in any way convoluted or has a tight junction or bend. In reality all colons have such a twisted layout. In the case of conventional devices the device may fail to turn at the bend and will simply push up against the side wall of the colon causing pain and possibly
20 damage to the mesentry. In serious cases the wall of the colon may be perforated.

The devices of the invention are predisposed to bend at certain points or gradually slope in a certain direction. In this way the device, for example, can be inserted into the rectum and will be disposed towards following the bend of the sigmoid
25 colon or turn at the splenic flexure as it moves through the colon. The device may be predisposed to bend at more than one point. For example, it could be constructed in such a manner that it would gradually curve through the sigmoid colon and then straighten out to traverse the descending colon. A further turn could be constructed into the device so that it would turn at the splenic flexure.
30 By preshaping the everting tube in this manner it would be possible to plan all the bends and convolutions in a passageway to be navigated.

The device may be used as a transporter for delivery or retrieval of an object. It has the effect of providing a substantially frictionless tunneling action. The device may be used endoluminally. The device may be used for example to provide a soft tissue dissector or an envaginator and may be delivered through a delivery device such as a tubular sleeve, catheter or the like. The device itself may be used in medical procedures such as in the form of a balloon which may be linear or non linear.

Referring to Figs 10 to 16 there is illustrated a device 60 similar to that of Figs 1 to 7 which is deliverable through a tube 6 such as a cannula. A pressure is applied to push the device 61 out through an end opening of the tube 61 as illustrated in Figs 10 to 12. To retract the device a suction force is applied to draw the device 60 back into the tube 61 as illustrated in Figs 13 and 14.

Referring in particular to Figs 15 and 16 there is illustrated one mechanism which may be used to deliver the device 60 through the tube 61 and to remotely control the operation of the device 60. Air is delivered through an air delivery tube 65 extending through the outer tube 61. The air delivery tube 65 has a central outlet 66 for driving the device 60 and one or more entry ports 67 for delivery of inflation air into the air chamber 69 defined by the device 60. In this way the inflation of the device 60 can be readily remotely controlled. The device 60 may

be used, for example for tissue dissection or for delivery/deployment of a balloon angioplasty, stent or the like.

The Twisted Tube

Consider the hollow cylindrical tube shown in Fig. 17. The wall of the cylinder defines a lumen through its centre. Consider a linear element A-B. if the upper edge of the tube is rotated through some angle point A will move to the position

shown in the middle sketch. The element A-B will still define a straight line. The tube will distort into a nominally hour glass shape with a reduced lumen at mid height. The diameter of the lumen at the neck of the tube is dependant on the angle of twist. When the upper edge is rotated through 180° the lumen will close down to zero diameter. At any horizontal plane through a twisted tube the material must be wrinkled and hence under compressive hoop stress. If the height of the tube remains unaltered then the element A-B in a twisted tube, being longer than in a plain tube, must be under tensile axial stress. If the tube is free of axial constraint the overall length of the tube will reduce.

Lumen Diameter vs. Angle of Twist

Fig. 18 a shows the lumen diameter (D_2) as a proportion of the tube diameter (D_1) for angles of twist (E) from 0 to 180 degrees. The lumen diameter is calculated as:

$$D_2 = D_1 \cos(E/2).$$

As can be seen the lumen diameter is independent of the tube length

Elongate object passed through twisted tube

As can be clearly seen from Figs 18a and 18b the angle of twist necessary to collapse the lumen of a tube to the diameter of an elongate object passed therethrough is dependant on the ratio of the tube diameter and the diameter of the elongate object. The angle of twist can be calculated from:

$$\cos^{-1}(E/2) = D_2/D_1$$

Where E = angle of twist

$D1$ = tube diameter

$D2$ = diameter of elongate object

- 5 Although depicted as of circular profile, a tube of sufficiently compliant material will conform to any non recursive profile. For such a profile $D2$ is taken as the smallest diameter which can be inscribed within the profile.

Twin walled pressure vessels under internal pressure

10

Consider a thin walled tube as shown in Fig. 19a. One end of the tube is folded back on itself as shown in Fig. 19b and the free ends conjoined. What is defined is essentially a twin walled tube (or two coaxial tubes conjoined at their ends) with an enclosed volume between the two walls. The introduction of a pressurised fluid into the enclosed volume will cause the outer tube to behave like a pressurised aircraft fuselage, that is it will be subject to tensile axial and hoop stresses. The inner tube will be subject to tensile axial stress and compressive hoop stress. As a result the lumen will collapse in to a nominally duck bill configuration but constrained by the outer tube.

20

Greater control of the lumen can be obtained by the introduction of a twist into the tube. The tube shown in Fig. 20a is twisted as shown in Fig. 20b. One end of the tube is folded back on itself, as shown in Fig. 20c, and the free ends conjoined. As in the previous example this configuration defines two coaxial conical vessels conjoined at their bases and at the apex. However the common apex is not constrained to remain in this configuration. In reality in the inner and outer tubes are free to behave as individual tubes each with half of the original twist and as such the composite tube can better be defined as two coaxial hour glass tubes as shown in Fig. 20d, each containing half the original total twist. As both the inner and outer tubes are necked they each are subject to compressive hoop stresses. The introduction of a pressurised fluid into the enclosed volume produces what is believed to be a novel response.

30

Firstly, consider the outer tube. It is a necked hour glass tube with compressive hoop stresses. The introduction of the pressurised fluid induces tensile hoop stresses, negating the compressive hoop stresses induced by the twist. Since, to remain in its twisted configuration, the tube must have compressive hoop stresses and since the pressurised fluid overcomes these compressive stresses the tube must untwist and take on a nominally cylindrical configuration, see Fig. 20e. Since the inner and outer tubes are conjoined, as the outer tube untwists the inner tube twists more in response. Since the outer tube now has no twist the inner tube must have all the twist. If the original total twist were 180° then the lumen would close totally. Additionally, the material defining the inner tube will be central within the diameter of the outer tube. This configuration will for brevity be called a Cyclops.

Translation of an elongate object through a Cyclops

Consider the arrangement depicted in Fig. 21a. A shaft is passed through a Cyclops with the lumen in mutual contact with the shaft. The outside diameter of the Cyclops is resting in mutual contact with a fixed surface. Consider points of contact A, between the Cyclops and the fixed surface, and B, between the shaft and the lumen of the Cyclops. As the shaft is translated, as shown in Fig. 21b, Point A remains fixed whilst the leading end of the lumen rolls out. Since the Cyclops does not change in overall length the trailing end of outside diameter rolls in as depicted. It will be apparent that the shaft translates to the right twice as far as the Cyclops. This, of course, is exactly the motion of a caterpillar track. From this point of view a Cyclops could be considered as a three dimensional caterpillar track. Since points A and B on the Cyclops do not move relative to their corresponding positions on the shaft and the fixed surface there is no frictional resistance to the translation of the shaft. In Fig. 21c the Cyclops has translated to the right by approximately its own length. The material which had originally formed the inner tube has rolled out to become the outer tube and vice versa. In other words the Cyclops has turned inside out. Since the inner tube of the

Cyclops is in a twisted configuration and since the point B remains in contact with the same point on the shaft the shaft rotates about its axis as depicted by arrow C (in this instance approx. 120°). In order to obtain this translation the resistance required to be overcome is that generated as the leading and trailing ends of the Cyclops deform as they roll out and roll in respectively.

Effects of an introduced member

Assume that the Cyclops in Fig. 22 has a 180° twist and is filled with a fluid under pressure. The lumen is closed by the action of the twist. As the shaft enters the Cyclops the pliable nature of the material of the Cyclops allows it to envelop the leading edge of the shaft as shown in Fig. 22b. As can be seen the effective volume of the Cyclops decreases. There will be a resulting increase of the fluid pressure causing the lumen to exert a greater pressure on the shaft. As the shaft proceeds through the Cyclops, see Fig. 22c, the pressure increases to its maximum. ($P_1V_1=P_2V_2$). If it is not desirable that there be such a pressure increase then the supply of fluid could be controlled by a pressure regulator.

Forces acting on the Lumen due to axial component of pressure

Fig. 23a depicts a Cyclops subject to internal pressure P. A force (F_{axial}) is induced in the Cyclops. Since the cross sectional area of the Cyclops is uniform the system is in force balance. A proportion of this force is taken by the outside cylinder and the remainder is taken by the material which constitutes the lumen. If a shaft, or similar, is pressed against one end of the Cyclops an imbalance is introduced. Consider the material of the inner tube in isolation. Fig. 23b, F represents the proportion of the axial force taken by the inner tube. As with the Cyclops as a whole this is in force balance. When an imposed force (F_{imp}) is applied to one end of the inner tube the net force acting at the left end of the tube is now less than that acting on the right hand end. The system is in an unbalanced situation. The inner tube must therefore translate to the right hand side.

Cyclops as an axial force limiter

Fig. 24a depicts a Cyclops with two independent shafts inserted, one in each end. Shaft B is in contact with a fixed surface. The fluid pressure within the Cyclops causes the lumen material to be maintained in tension. A force F is applied to shaft A, Fig. 24b. This force is transferred to shaft B via the lumen material and is reacted by the fixed surface. Force F exerts a compressive axial force on the lumen material. As force F increases the applied compressive force begins to negate the axial tensile force induced by the pressurised fluid. When force F becomes greater than the initial tensile force the lumen material goes into axial compression. This will cause the lumen material to buckle. The maximum axial force that the inner tube of a Cyclops can transmit is equal to the tensile force induced into the inner sleeve by the pressurised fluid.

Effects of the tube preform shape

Consider the tube preform shown in Fig. 25a. The lower portion defines a circular elbow with an upper section configured as a plain cylinder. If the cylindrical section is inverted as indicated, with or without a twist, and the free ends of the preform conjoined a basic Cyclops is formed. The elbow section must wrinkle up in order to lie within the plain cylinder as shown in Fig. 25b. As previously, the introduction of a pressurised fluid into the enclosed cavity formed will cause the elbow section to collapse forming a closed lumen and the cylindrical section to inflate, see Fig. 25c. The plain cylinder, being on the outside of the structure, will determine the shape of the inflated Cyclops. The Cyclops will be in force balance. If a force is applied to the lower end of the lumen the net force on the lumen will cause the Cyclops to translate. The upper portion of the lumen will roll out and the lower end of the cylindrical wall will roll in, Fig. 25d.

Since the outside wall of the Cyclops is now made up of part of the original plain cylinder and part of the elbow section the inflation pressure will cause the Cyclops to take on the form of this composite profile, the Cyclops will appear to bend as it translates. Figs 25d shows the Cyclops completely inverted. All of the elbow section forms the outer wall and all of the plain cylindrical section forms the inner tube. As such the Cyclops has take on the form of the elbow section. It will be noted that lumen material follows the shortest line between the ends of the Cyclops. For simplicity of illustration the Cyclops has been represented as translating in two space. It will be apparent that if the preform were "sculpted" or moulded such that its axis were three dimensional then as the Cyclops translated the path of translation would follow a three dimensional path. It will also be appreciated that the preform need not be of a regular cross section. Variations in tube diameter along it's length is possible.

Referring to Figs. 26(a) to 26(d) there is illustrated the roll-out or eversion of a pre-shaped device, in this case an introducer device 100. The device 100 is in this case pre-shaped or sculpted to roll-out in a non-linear shape corresponding to a desired predetermined shape. The non linearity may be in two, and in this case three dimensions. The introducer 100 is initially in the shape of a tubular sleeve. On eversion the introducer first turns in one direction (Fig. 26(b)), then in another direction (Fig. 26(c)) and, finally in a still further direction illustrated in Fig. 26(d). Such an arrangement greatly facilitates the navigation of the device along torturous routes.

Referring to Figs. 27 to 32 there is illustrated another introducer device 100 according to the invention which is similar to the devices described above and like parts are identified by the same reference numerals. In particular, the device 100 is similar to and operates in a similar manner to the introducer described above with reference to Figs. 1 to 7. In this case the introducer is adjustable to vary the degree of twist in the elongate tubular sleeve 10 from an untwisted configuration illustrated in Figs. 27 to 29 to a twisted configuration illustrated in Figs. 30 to 32.

The sleeve 10 is attached at one end 101 to a first shaft section 102 and is attached on the other end 103 to a second shaft section 104. The shaft sections 102, 104 have a respective male projection 105 and a complementary female recess 106 which interengage to facilitate relative rotation therebetween. The shaft sections 102, 104 have respective handles formed by knobs 107, 108 to facilitate manipulation to vary the degree of twist. In use, the shaft section 104 may be turned by the knob 108 to any desired extent, for example from the untwisted configuration of Fig. 27 to the twisted configuration of Fig. 30. The variation in the twist may be effected prior to insertion of the device and/or when the device is in situ.

Reference is also made to appropriate alternatives and modifications which are outlined in our parallel applications referenced ATRO1/C, ATRO12/C, ATRO15/C, ATRO16/C, ATRO17/C, the entire contents of which are incorporated herein by reference.

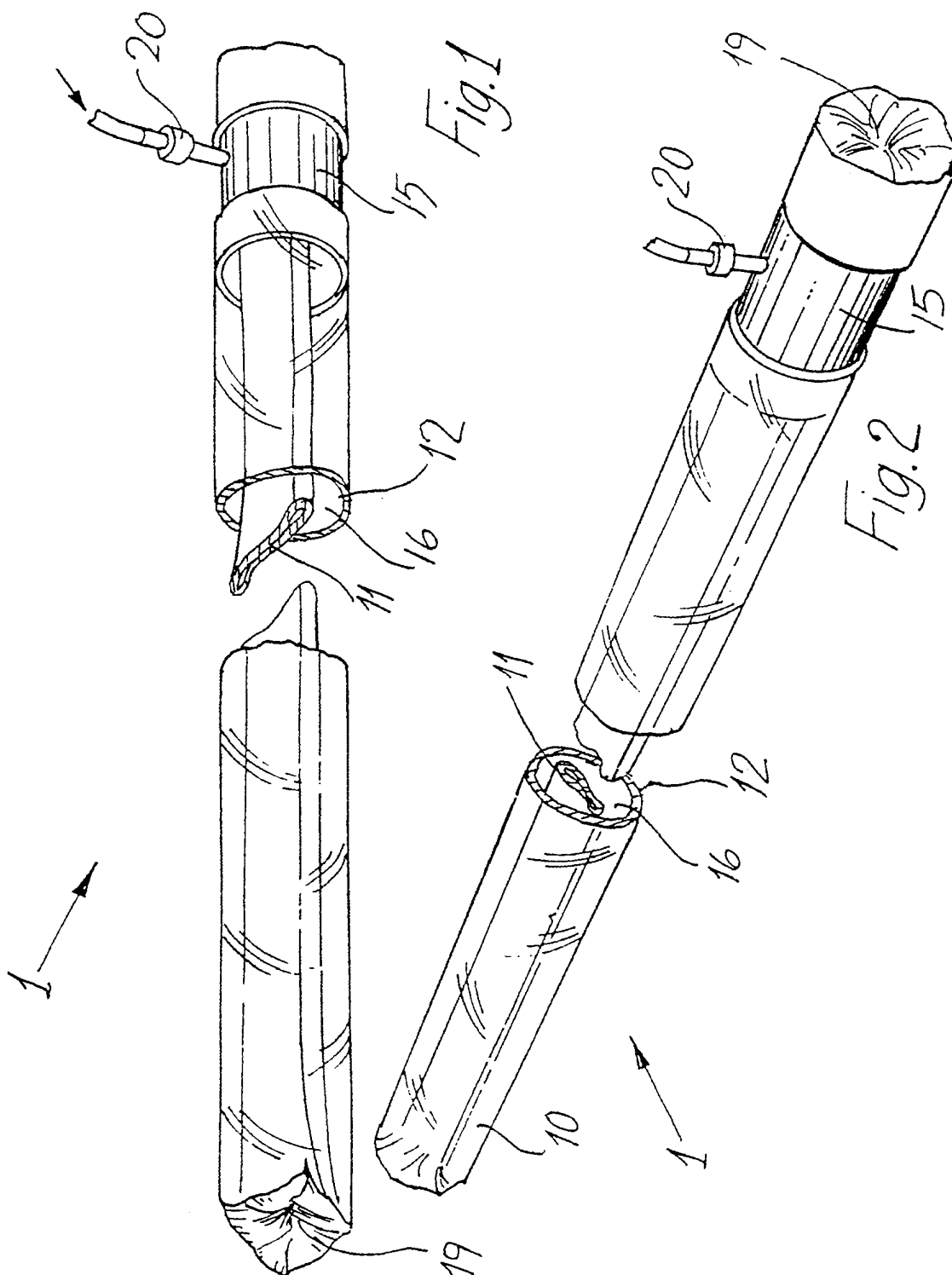
The invention is not limited to the embodiments hereinbefore described which may be varied in detail.

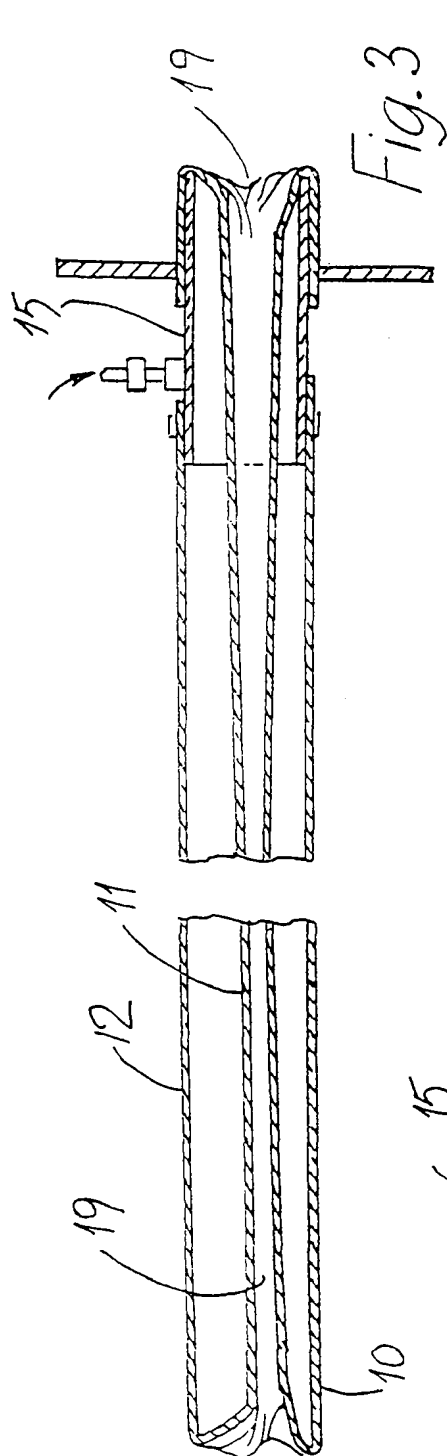
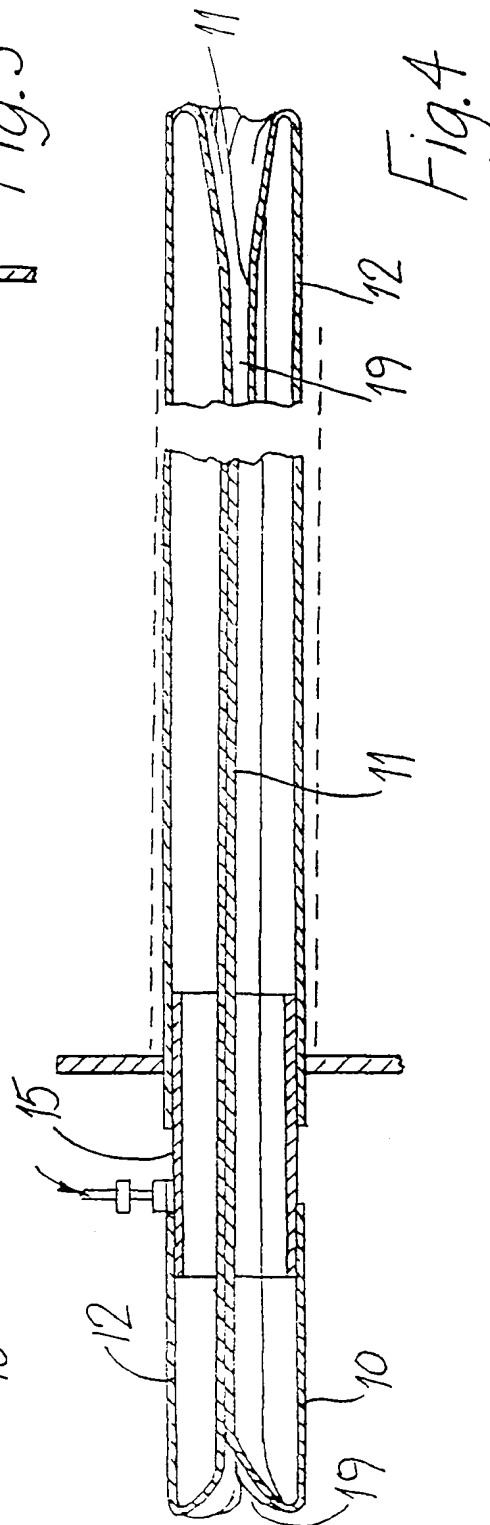
Claims

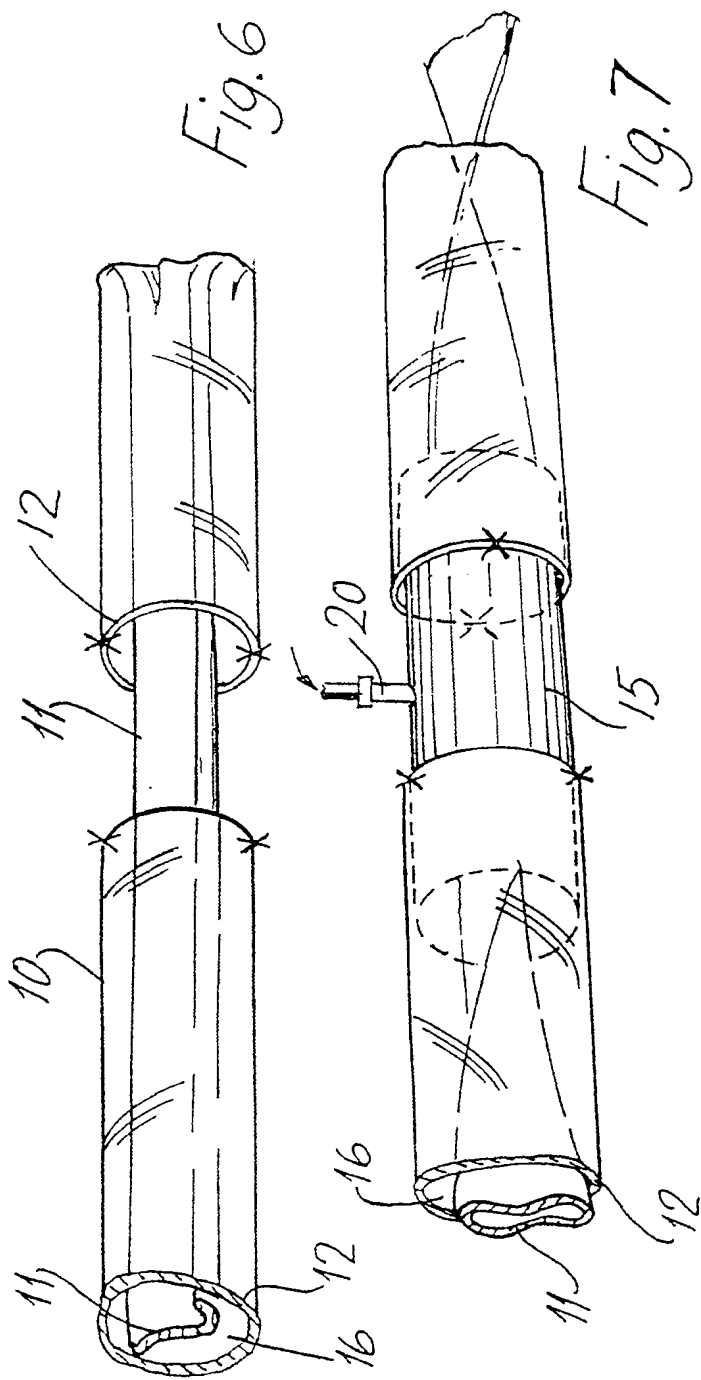
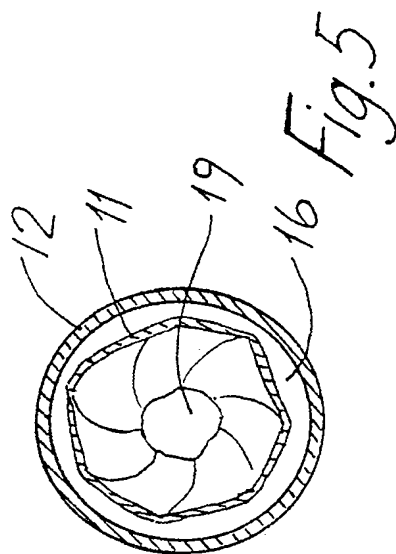
1. A medical device for insertion in a body opening or an incision
5 comprising:
- a sleeve of pliable material, the sleeve having a twisted sleeve
section to define a reduced lumen section;
- 10 the sleeve having an outer sleeve section and an inner sleeve
section;
- a chamber for pressurised fluid defined between the inner and outer
sleeve sections;
- 15 the inner sleeve section defining a lumen to receive an object;
- the pressurised sleeve being evertable on engagement of an object in
the lumen and axial movement of an object relative thereto so that
20 the twisted inner sleeve section is rolled over outwardly to become
an outer untwisted sleeve section and the untwisted outer sleeve
section is correspondingly rolled over inwardly to become a twisted
inner sleeve section.
- 25 2. A device as claimed in claim 1 wherein the sleeve is turned axially back on
itself to define an outer sleeve section and a twisted inner sleeve section.
3. A device as claimed in claim 1 or 2 wherein the sleeve sections define a
continuous endless track which may be advanced by engaging an object in
30 the lumen.

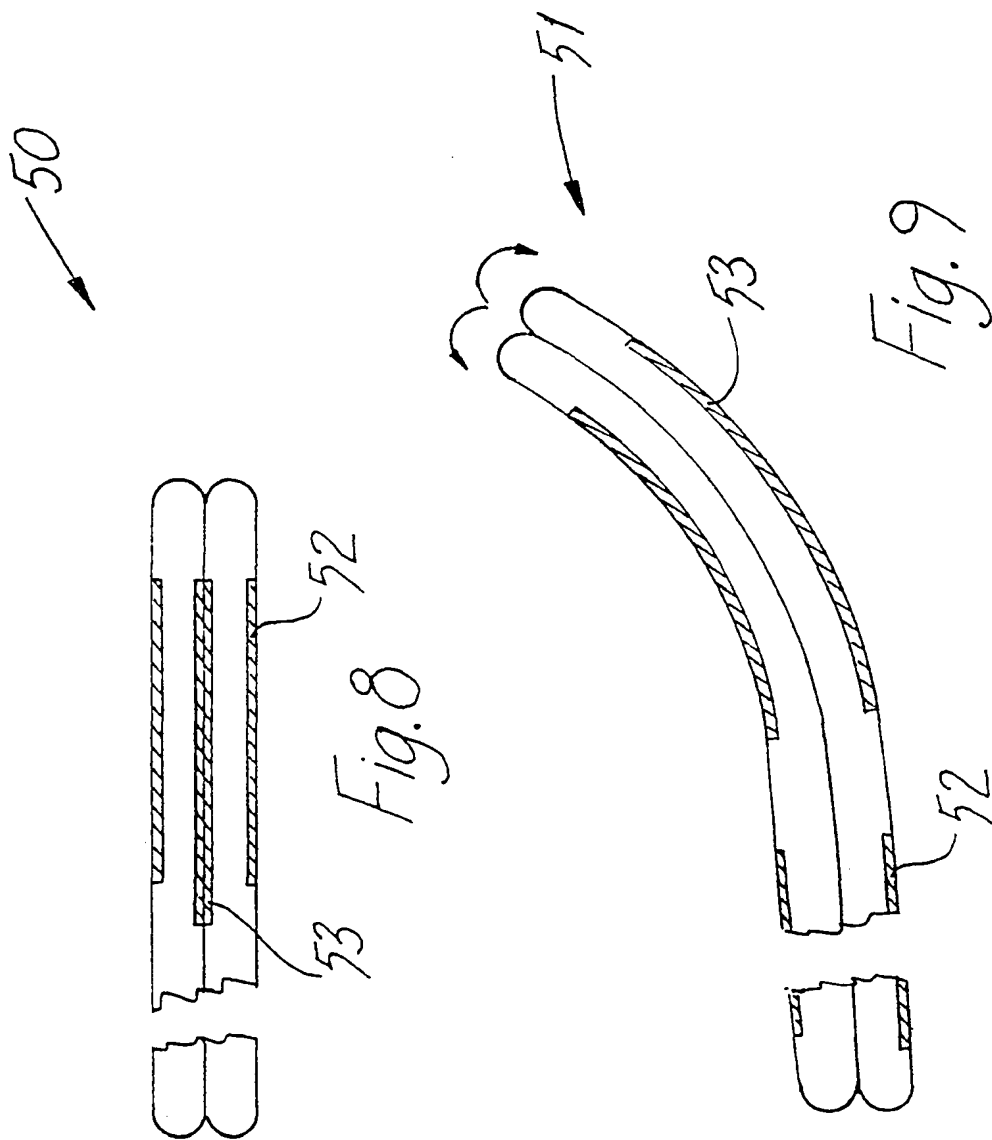
4. A device as claimed in any preceding claim including a guide collar for locating relative to a datum, a sleeve section being movable relative to the collar on engaging an object into the lumen and/or on passage of an object through the lumen.
- 5
5. A device as claimed in claim 4 wherein the free ends of the sleeve are joined to the collar.
6. A device as claimed in any preceding claim including an inflation port for inflation of the enclosed chamber between the sleeve sections.
- 10
7. A device as claimed in any preceding claim including adjustment means for adjusting the twist in the sleeve.
- 15
8. A device as claimed in any preceding claim wherein at least portion of the sleeve has a non linear shape.
9. A device as claimed in claim 8 wherein the non linearity corresponds to a desired predetermined shape.
- 20
10. A device as claimed in claim 8 or 9 wherein the non linearity is on at least two dimensions.
11. A device as claimed in any of claims 8 to 9 wherein the non linearity is in three dimensions.
- 25
12. A device as claimed in any of claims 8 to 11 wherein the sleeve is biased into the non linear shape.
- 30
13. A device as claimed in any of claims 8 to 12 wherein the sleeve is sculpted or formed into the non linear shape.

14. A device as claimed in any preceding claim including guide means through which the sleeve and/or an object is advanced.
- 5 15. A device as claimed in claim 14 wherein the guide means includes a ring means for placing in a body opening or incision through which the sleeve and/or an object is advanced.
16. A device as claimed in any preceding claim including a delivery means for delivery of the device to a remote location.
- 10 17. A device as claimed in claim 16 wherein the delivery means is a tube.
18. A device as claimed in claim 15 or 16 wherein the delivery means is a catheter.
- 15 19. A device as claimed in any preceding claim wherein the device defines a transporter for delivery or retrieval of an object to or from a desired location.
- 20 20. A device as claimed in any preceding claim wherein the device defines an introducer for introducing an object such as an instrument to a desired location.
- 25 21. A device as claimed in any of claims 1 to 18 wherein the device is an expandable element.
22. A device as claimed in claim 21 wherein the expandable element is a balloon for angioplasty.
- 30 23. A medical device substantially as hereinbefore described with reference to the accompanying drawings.









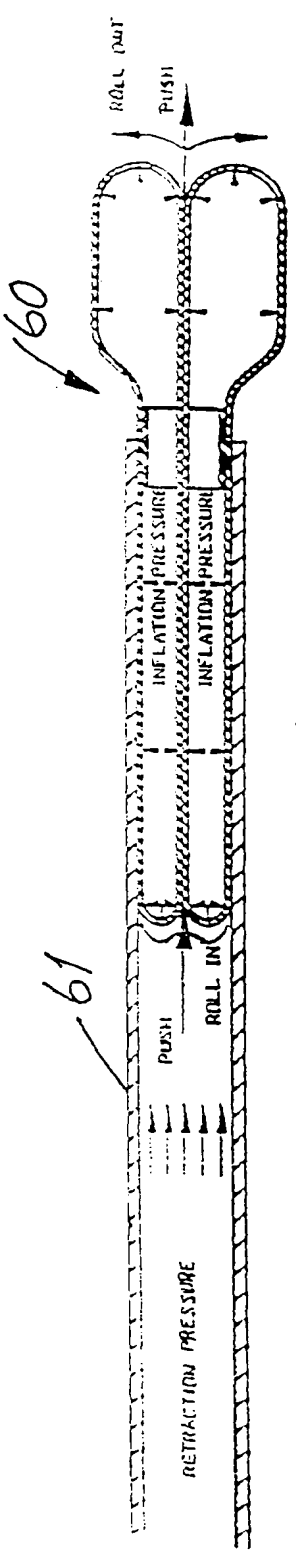


Fig. 10

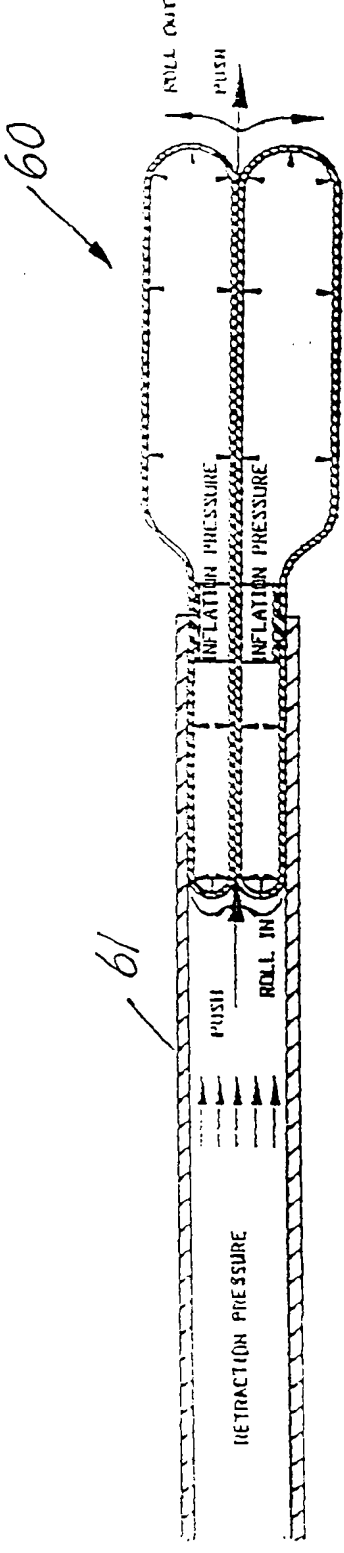


Fig. 11

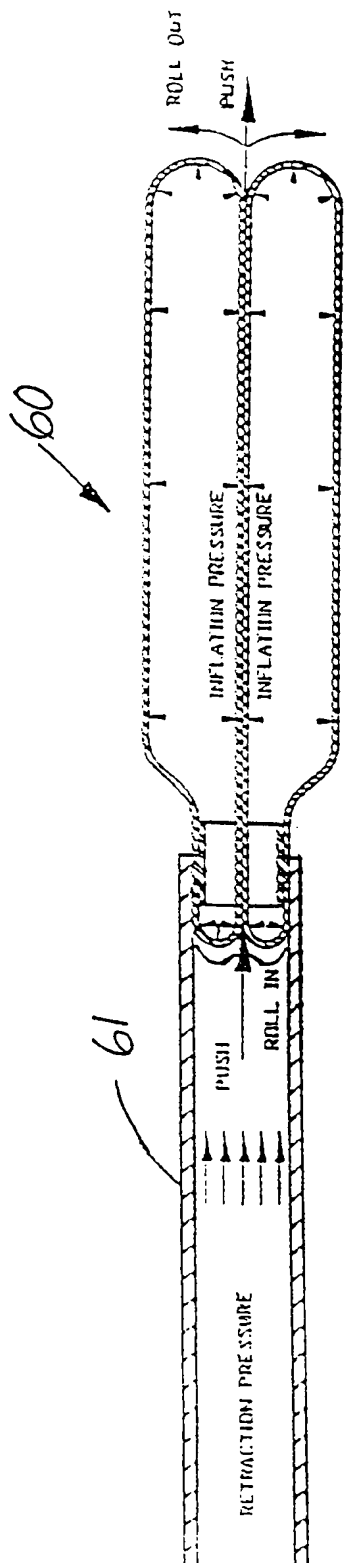


Fig. 12

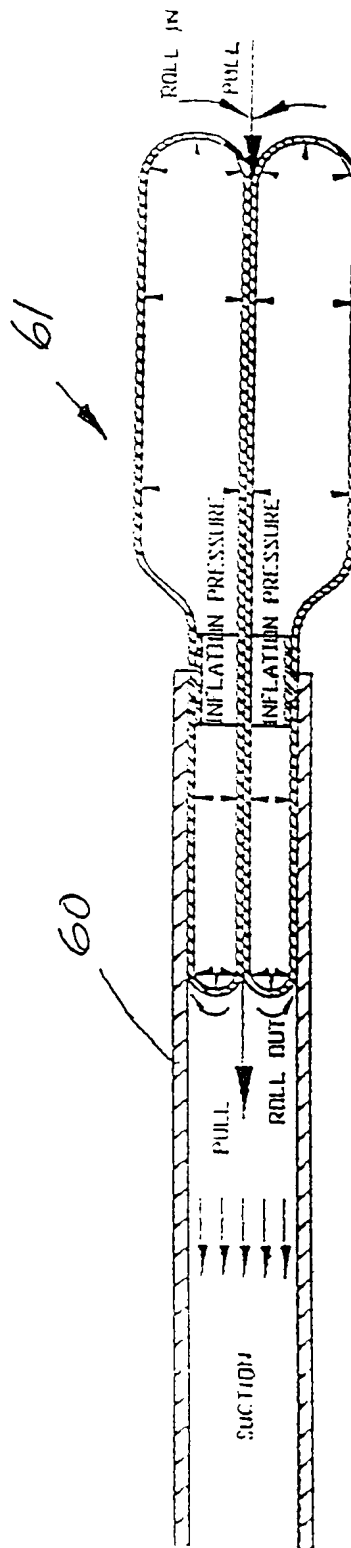


Fig. 13

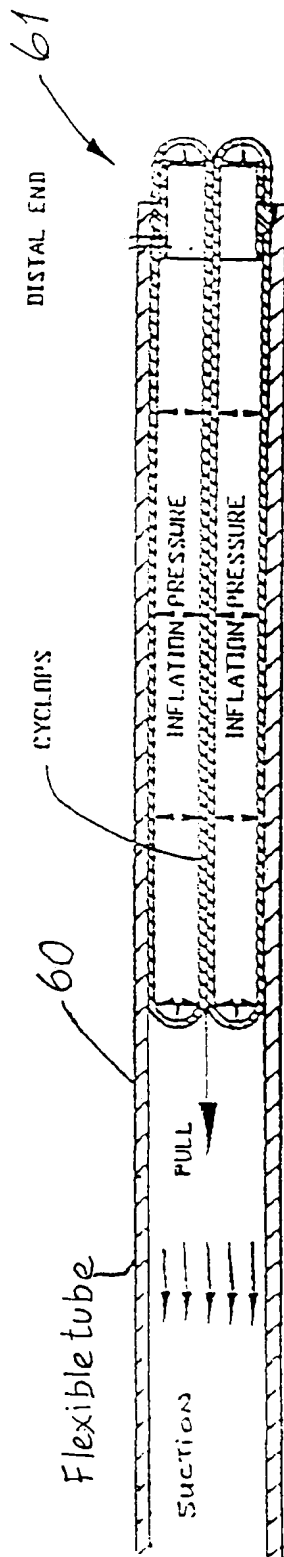


Fig. 14

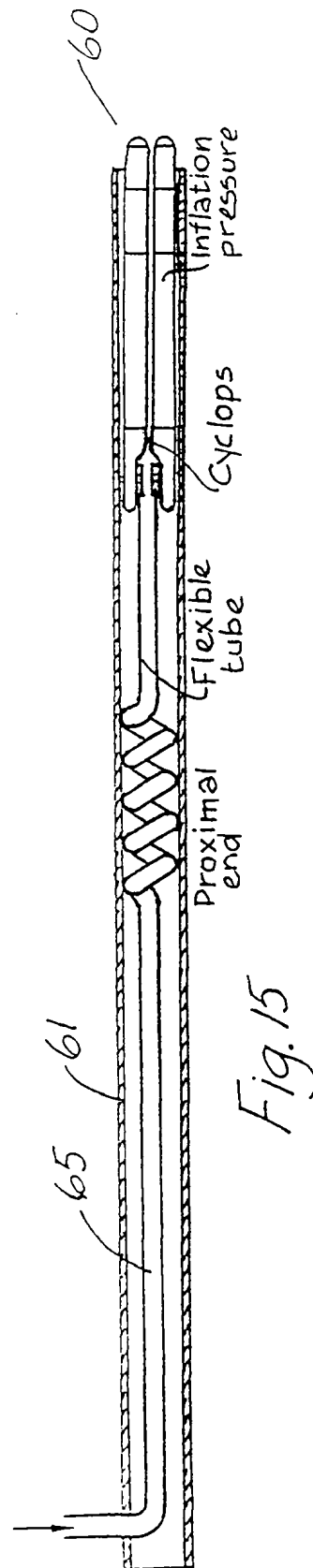


Fig. 15

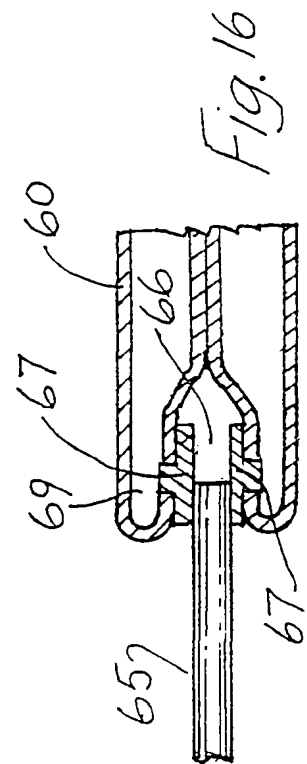


Fig. 16

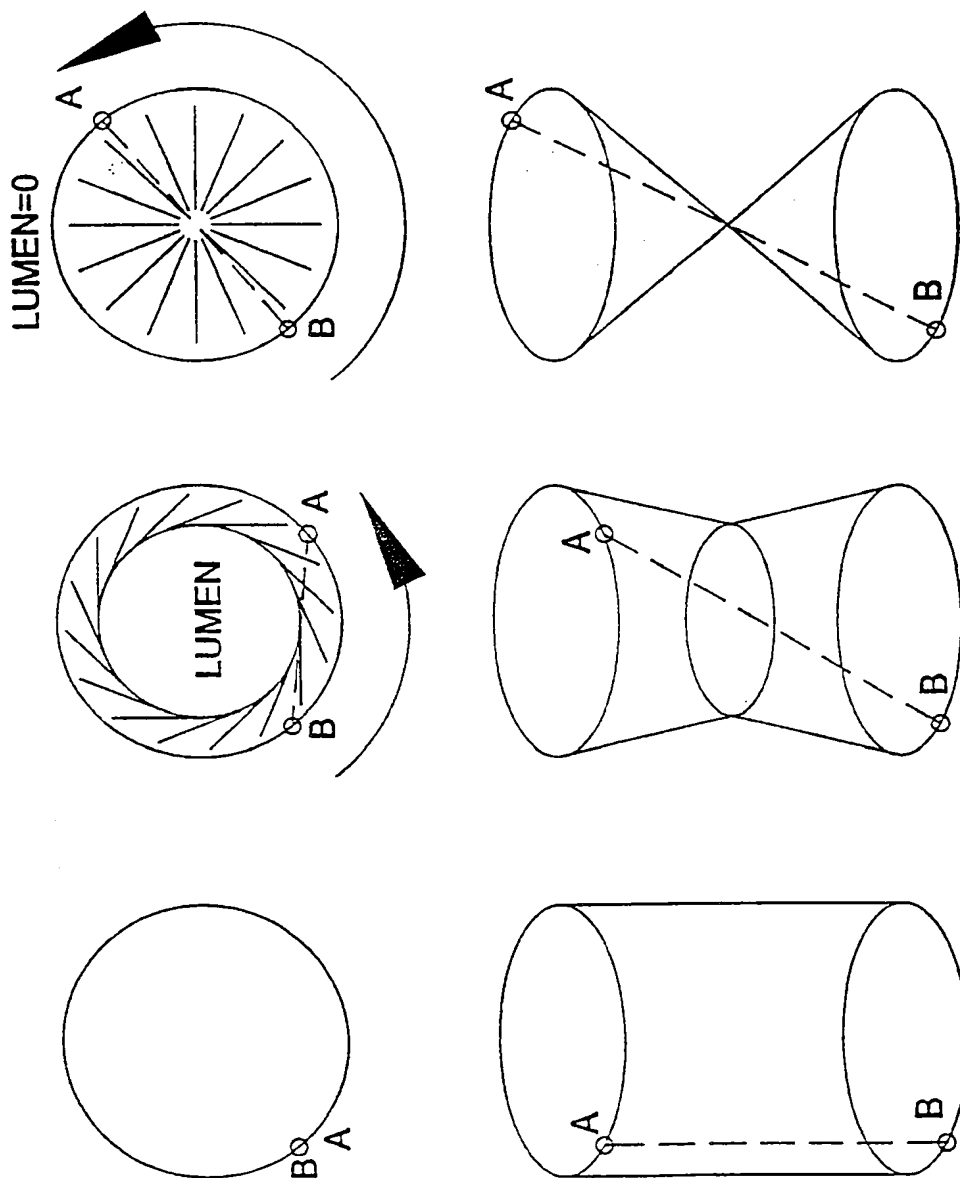


Fig. 17 The Twisted Tube

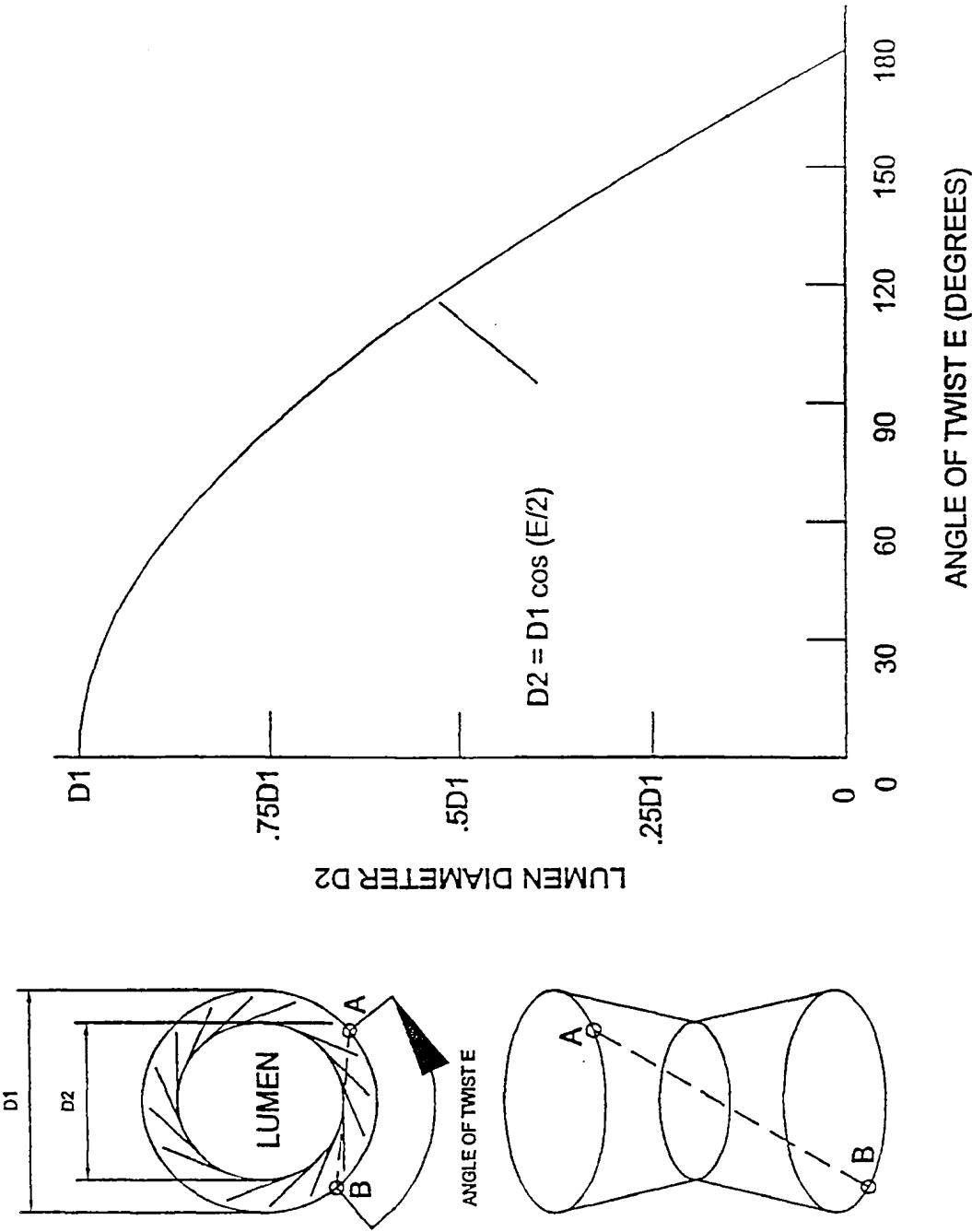


Fig.18a Angle of twist vs lumen

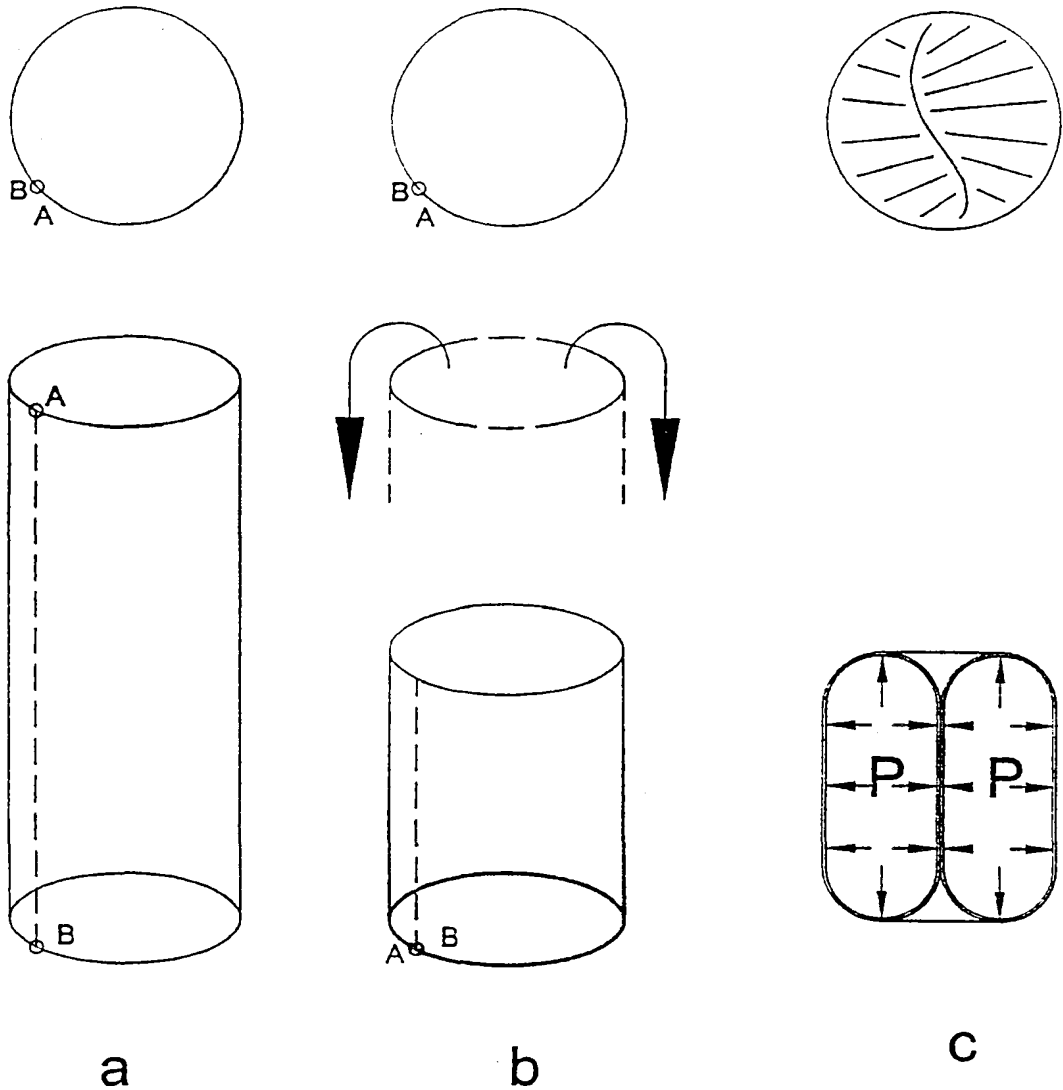


Fig.19 Twin Walled vessel under internal pressure

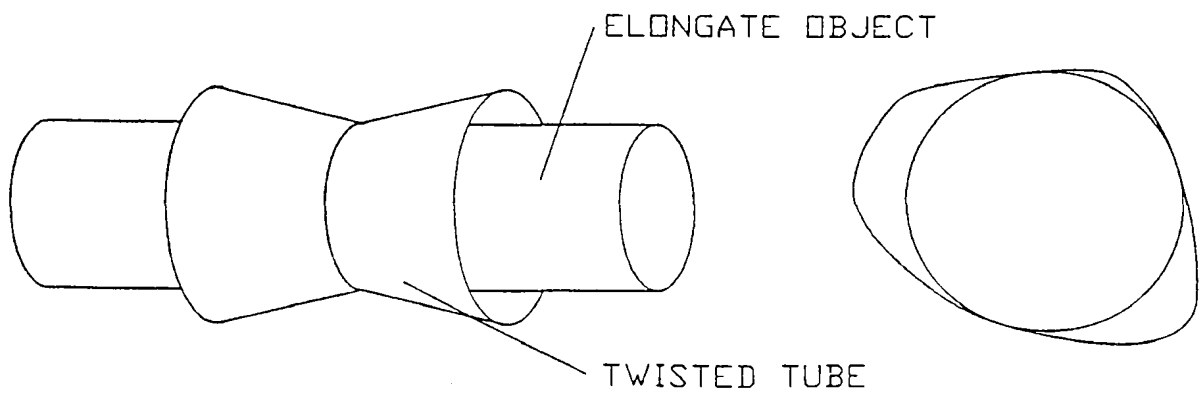


Fig.18b Twisted tube with elongate object passing therethrough

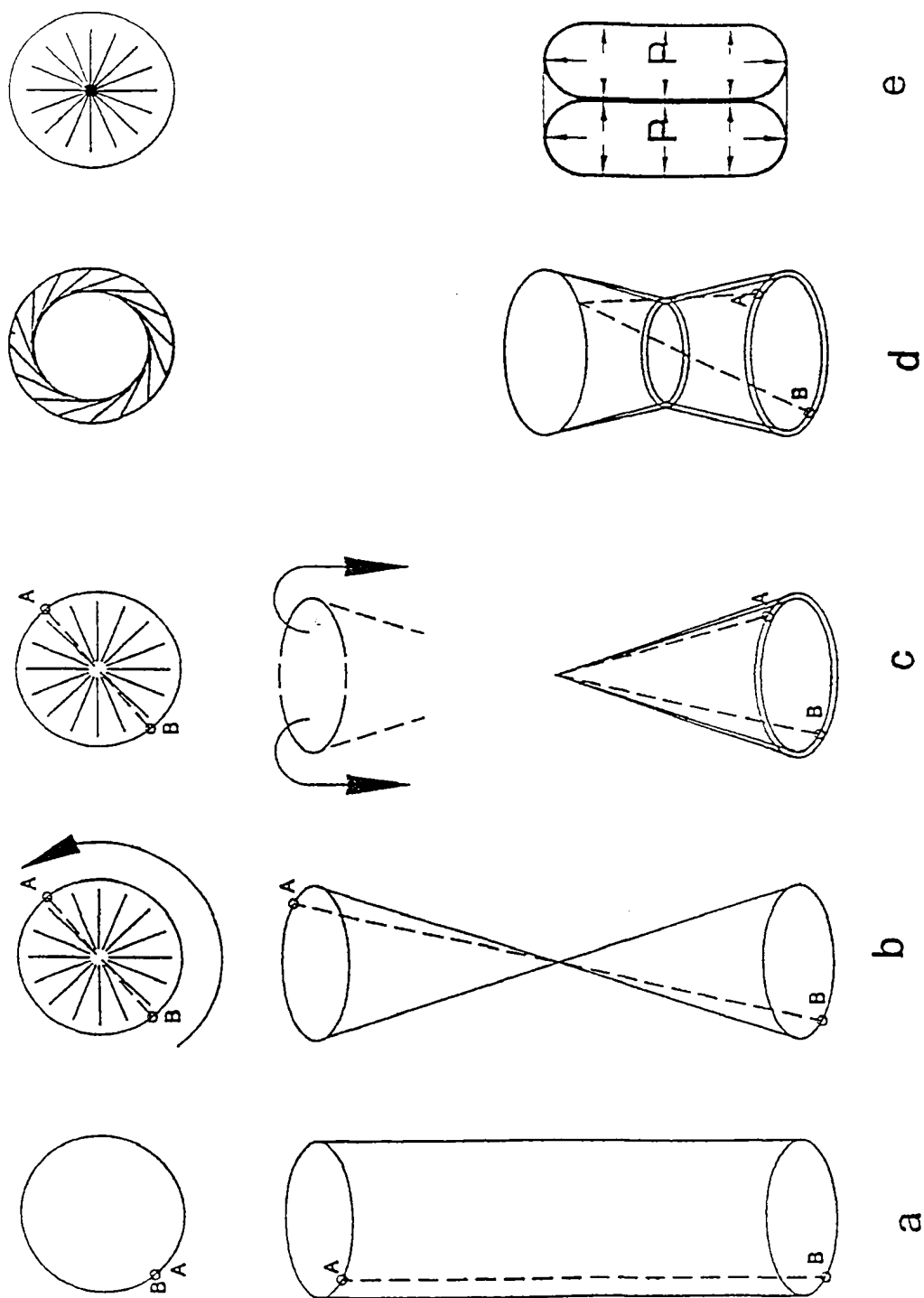


Fig.20 Twin walled tube with twist subject to internal pressure

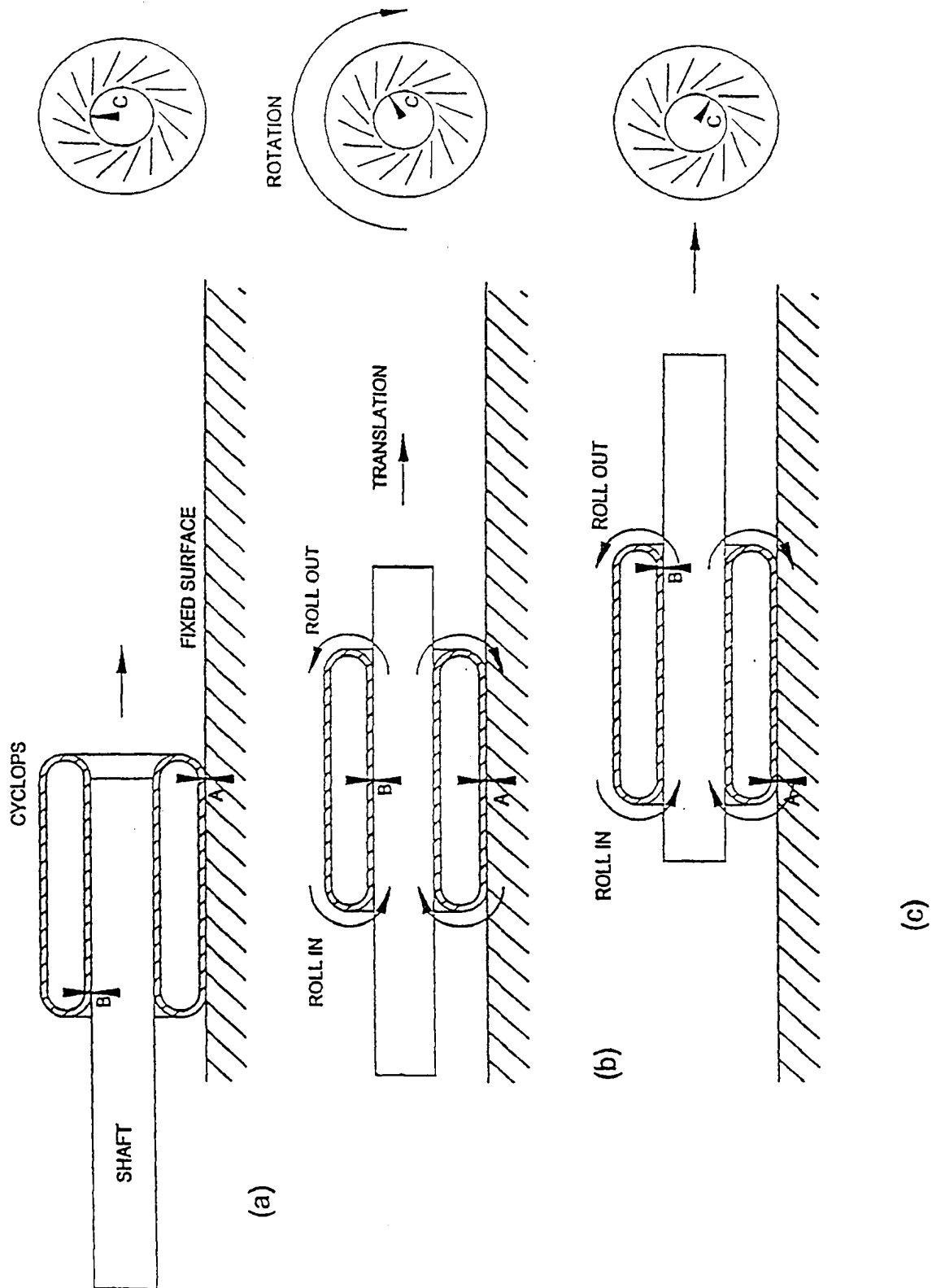


Fig.21 Translation of a shaft within a Cyclops

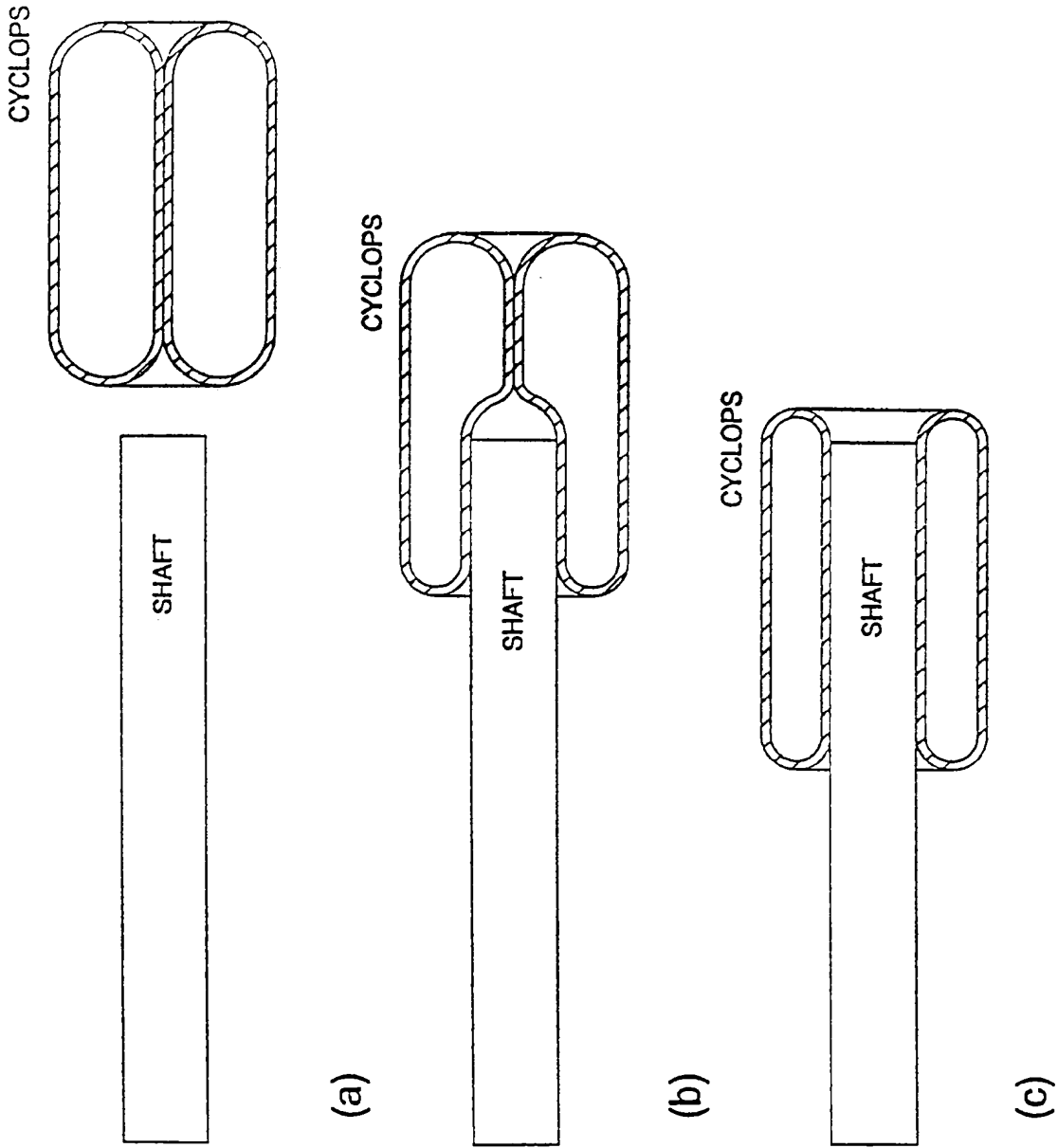


Fig.22 The deformation of a Cyclops as a shaft enters and translates

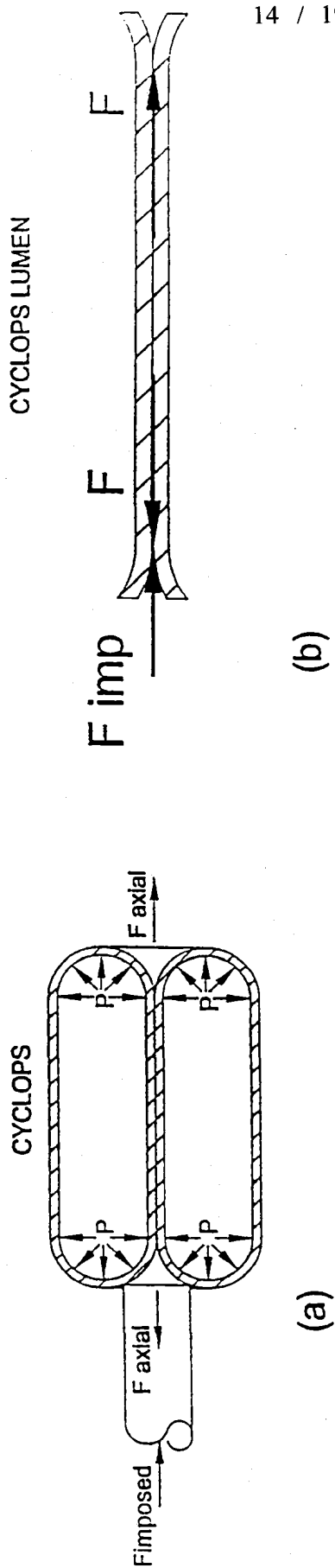
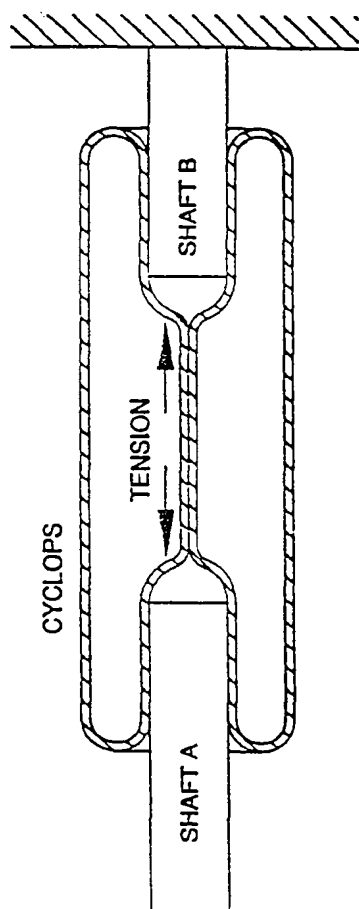
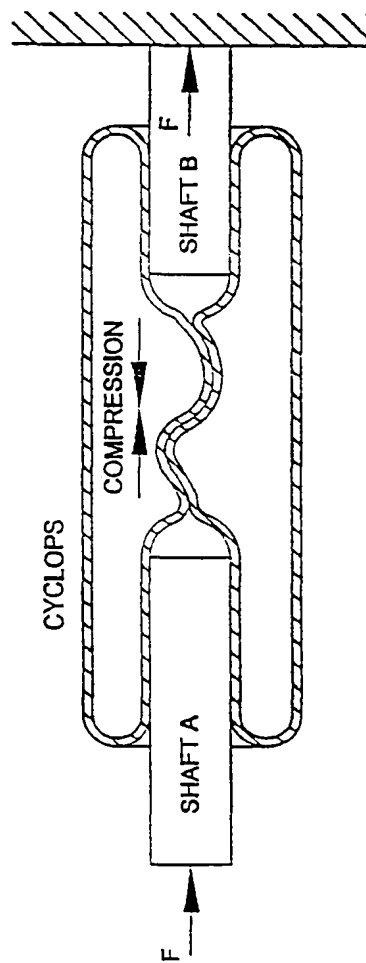


Fig 23 Forces acting on Cyclops lumen due to axial component of pressure



(a)



(b)

Fig.24 Stiffness of Cyclops lumen

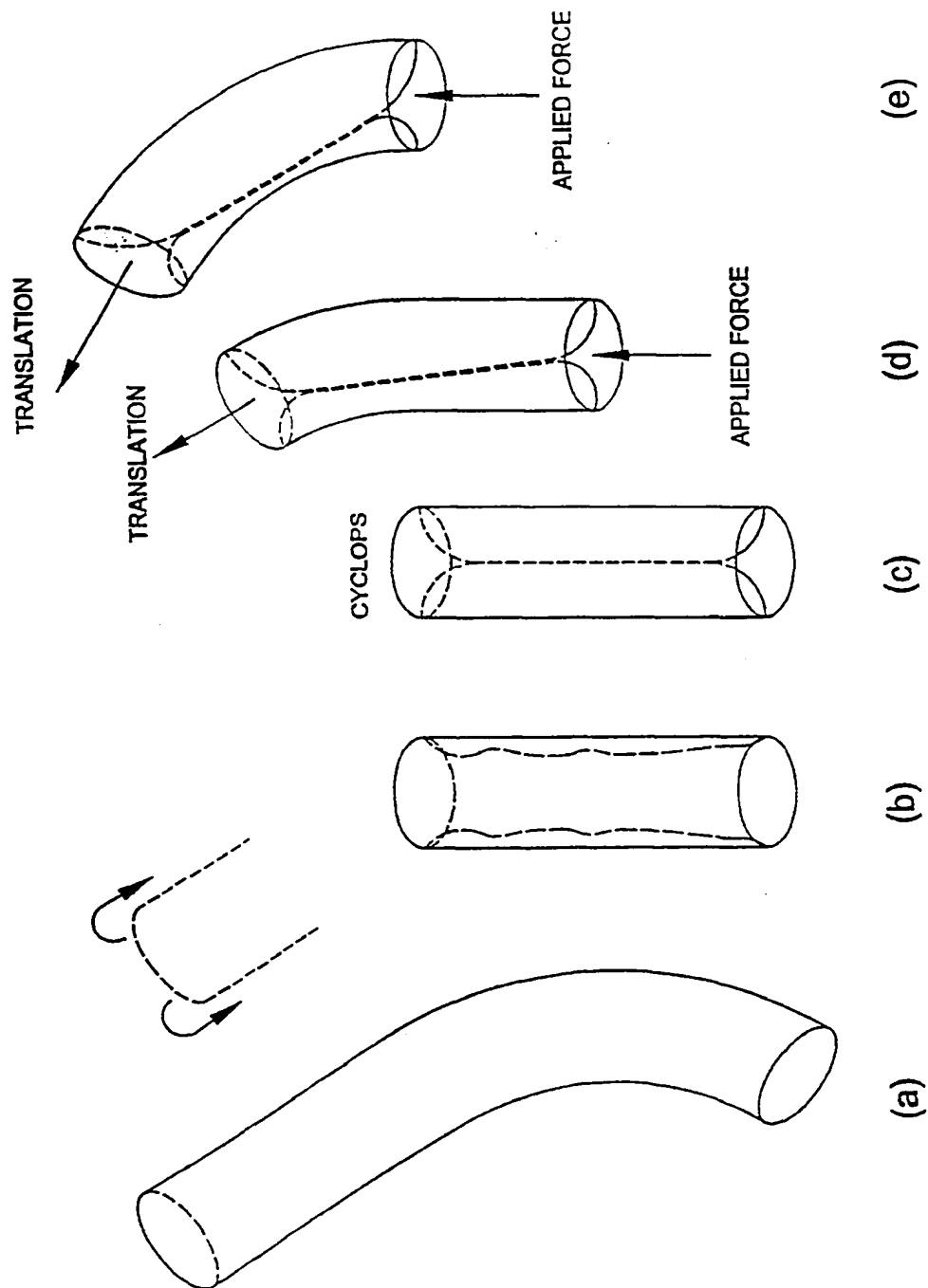
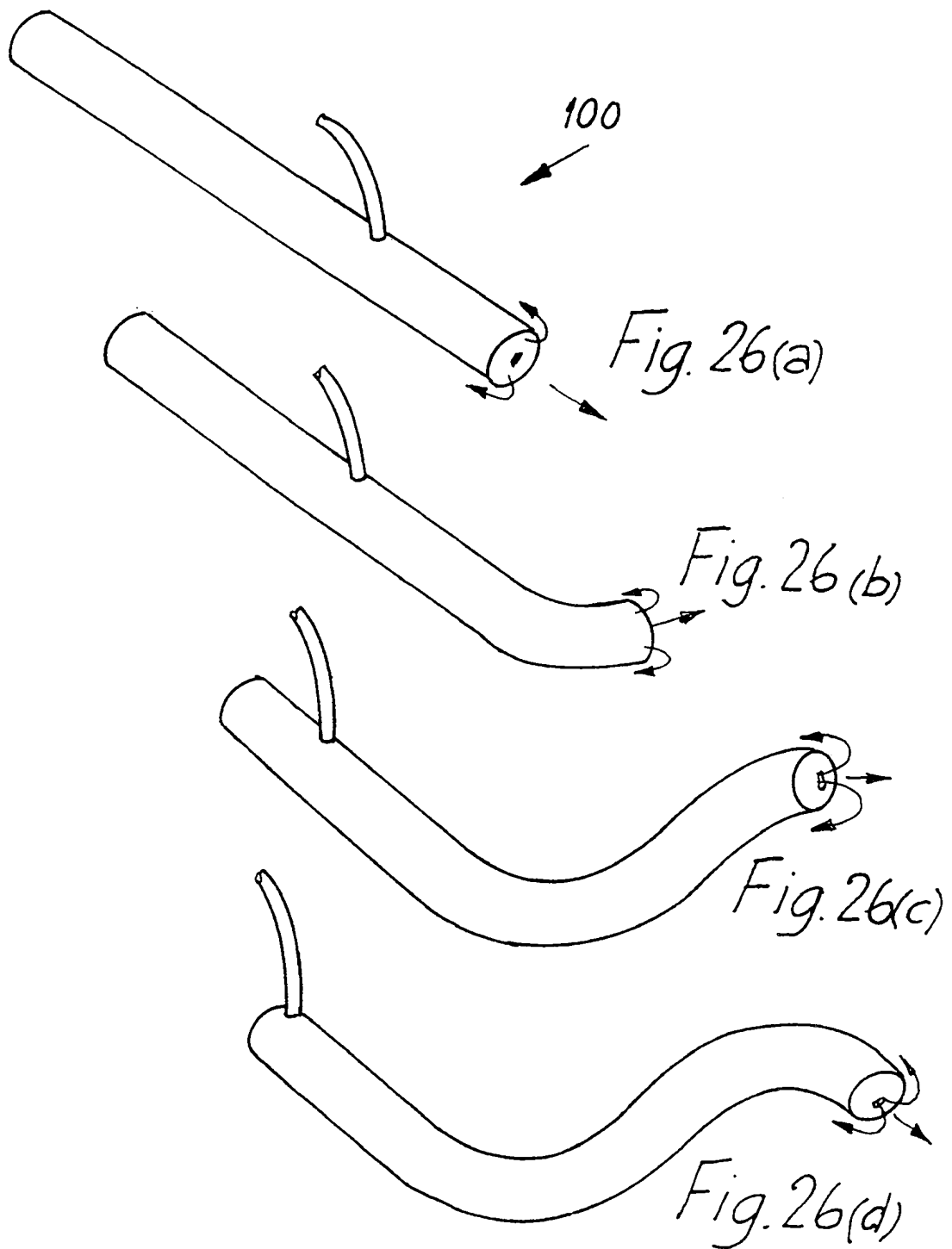
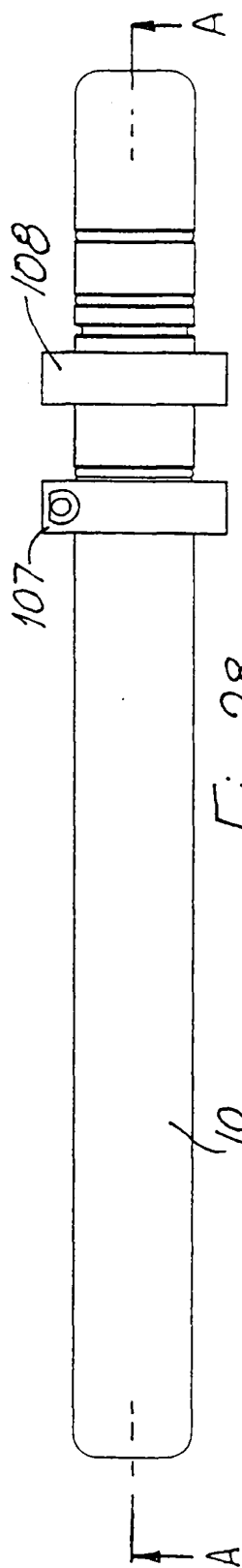
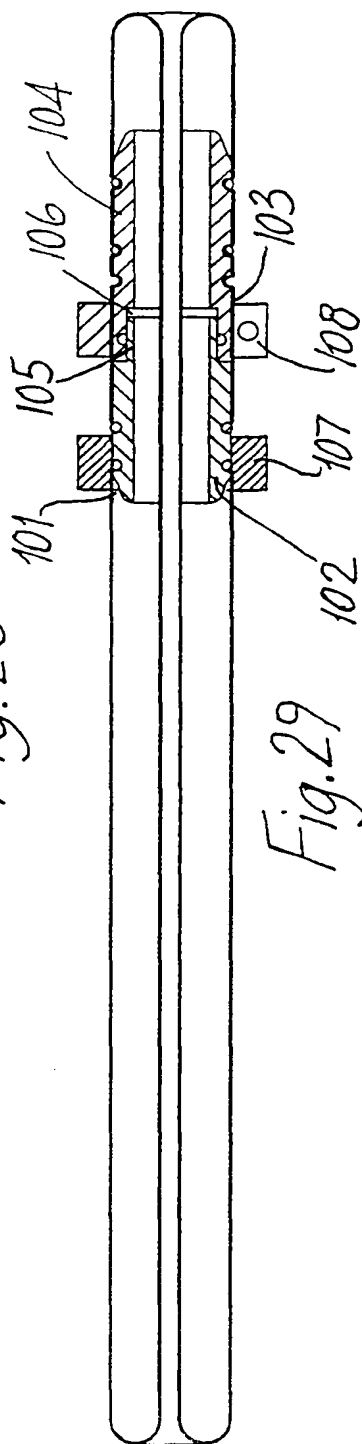
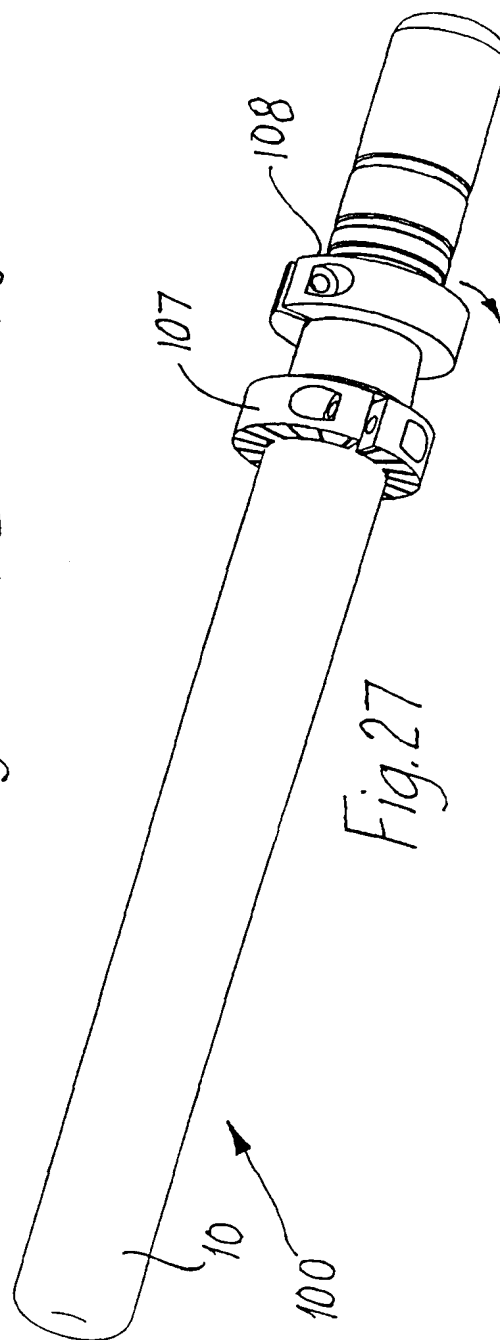
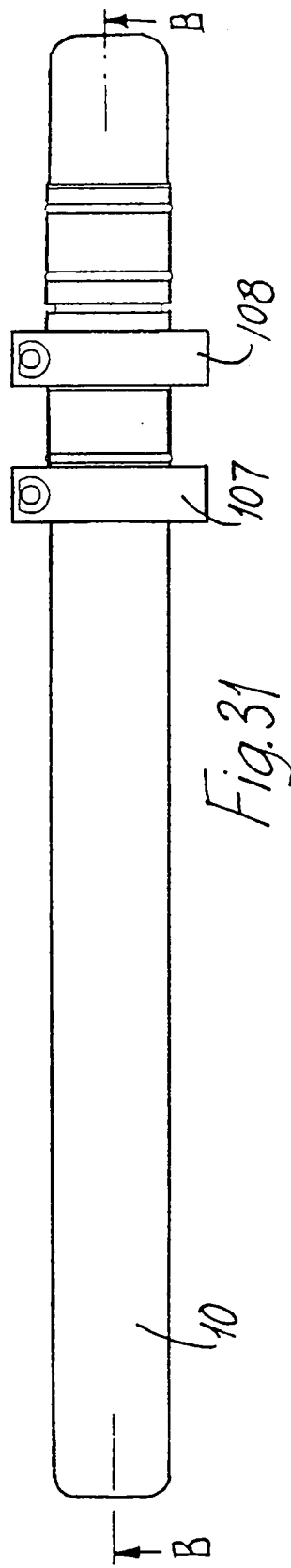
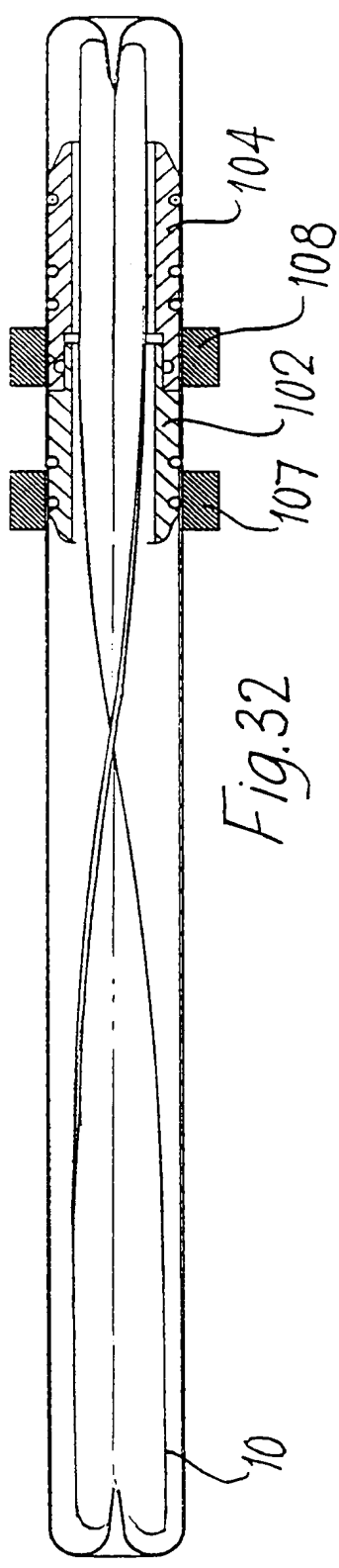
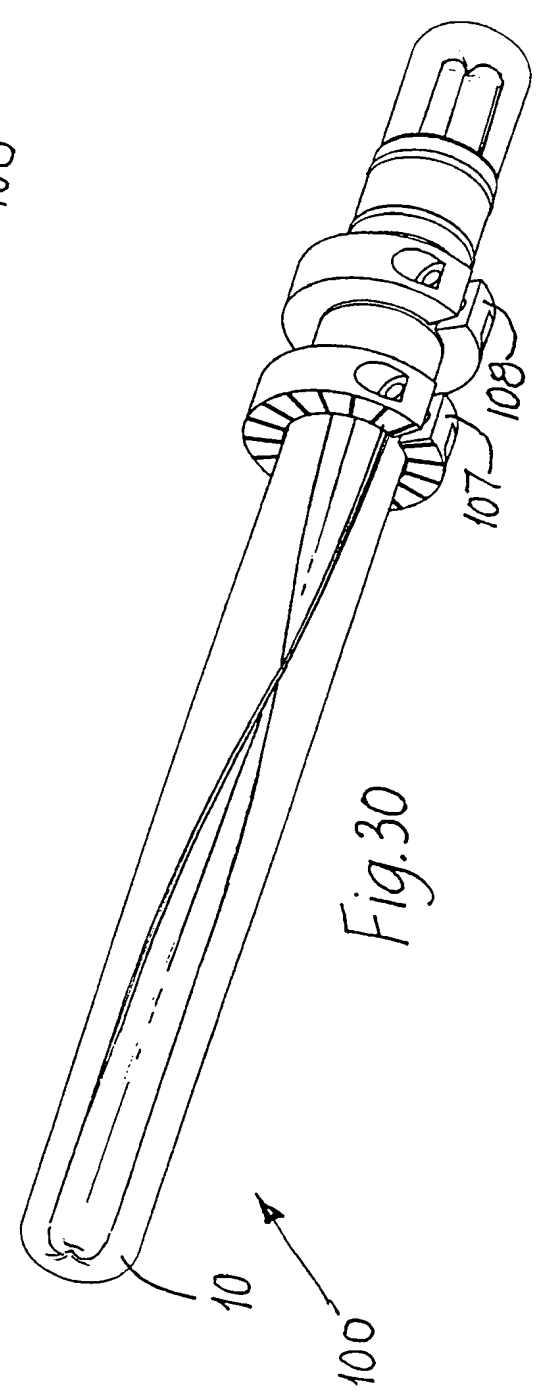


Fig.25 Effects of tube preform shape







INTERNATIONAL SEARCH REPORT

International Application No

PCT/IE 99/00124

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/34 A61M25/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 634 937 A (MOLLENAUER KENNETH H ET AL) 3 June 1997 (1997-06-03) column 10, line 16 - line 50	1
A	US 5 636 645 A (OU HONZEN) 10 June 1997 (1997-06-10) cited in the application column 6, line 34 - line 54	1
A	WO 98 48724 A (CARROLL MAUREEN E ; NIEMANN ALLISON C (US); STAMM EDWARD I JR (US);) 5 November 1998 (1998-11-05) cited in the application figure 68 & US 5 906 577 A	1



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Date of the actual completion of the international search

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Date of mailing of the international search report

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Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

Int'l. Application No.

PCT/IE 99/00124

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>DE 37 39 532 C (ZERBST EKKEHARD) 8 December 1988 (1988-12-08) column 3, line 14 - line 21</p>	1

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IE 99/00124

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 23
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

SEE RULE 6.2(a) PCT
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
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Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IE 99/00124

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5634937	A	03-06-1997	WO 9636283 A		21-11-1996
			US 5964781 A		12-10-1999
US 5636645	A	10-06-1997	NONE		
WO 9848724	A	05-11-1998	US 5906577 A		25-05-1999
			AU 7274698 A		24-11-1998
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Declarations under Rule 4.17:

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- as to applicant's entitlement to apply for and be granted
a patent (Rule 4.17(ii))
- of inventorship (Rule 4.17(iv))

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(54) Title: AN INVERSIBLE TUBULAR MEMBER AND A GRIPPING DEVICE INCLUDING SUCH A MEMBER

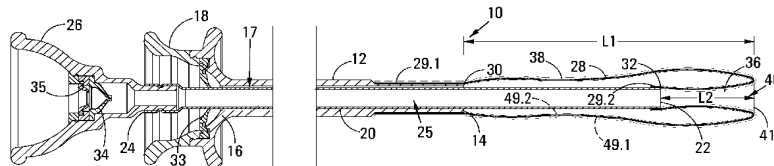


FIG 4

(57) Abstract: This invention relates to a gripping device (10), e.g. a surgical retrieval device. The device includes an inversible tubular member (28), which is composed of interengaged stitches of resiliently flexible filamentary material and which is progressively transformable between an everted condition and an inverted condition. The device includes also actuation means (12,20) carrying the inversible tubular member and operable for effecting progressive inversion and eversion of the inversible tubular member. Through progressive inversion of the inversible tubular member, an object can be gripped thereby.

**AN INVERSIBLE TUBULAR MEMBER AND A GRIPPING DEVICE INCLUDING
SUCH A MEMBER**

5 THIS INVENTION relates to an inversible tubular member and to a gripping device including such a member.

According to a first aspect of the invention there is provided an inversible tubular member which is substantially round in cross-section and progressively transformable
10 between an everted condition and an inverted condition, with a transformation end being defined intermediate an everted length and an inverted length of the inversible tubular member during such transformation and with the inverted length and the everted length defining opposite to the transformation end respectively an inverted end and an everted end of the inversible tubular member, in which:

15 the inversible tubular member is composed of interengaged stitches of resiliently flexible filamentary material;

 with the inversible tubular member at least partially inverted, the inverted length has sufficient stiffness to cause eversion of the inversible tubular member at the transformation end upon axial displacement of the inverted end towards the
20 transformation end, for a length of the inverted length up to X times an average relaxed outer diameter of the inverted length;

$$X \geq 2.0;$$

 with the inversible tubular member at least partially everted, the everted length has sufficient stiffness to cause inversion of the inversible tubular member at the
25 transformation end upon axial displacement of the everted end towards the transformation end, for a length of the everted length up to Y times an average relaxed outer diameter of the inverted length; and

$$Y \geq 2.0.$$

In a particular embodiment of the inversible tubular member of the invention:

with the inversible tubular member at least partially everted, the everted length has sufficient stiffness to cause inversion of the inversible tubular member at the transformation end upon axial displacement of the everted end towards the transformation end, for a length of the everted length up to Z times the average relaxed outer diameter of the inverted length, whilst one half of a sphere of diameter 1.5 times an average relaxed outer diameter of the inverted length is received in the inversible tubular member at the transformation end; and

$$Z \geq 2.0.$$

The applicant has found that, by suitable selection of the filamentary material, pattern of the stitches, and so forth, the following values are achievable:

$$X \geq 5.0 \text{ with the inverted length not restrained against lateral buckling;}$$

$X \geq 30$ with the inverted length restrained against lateral buckling, for example by the everted length;

$$Y \geq 50; \text{ and}$$

$$Z \geq 3.0.$$

In a particular embodiment of the inversible tubular member, it may define in the everted condition a larger outer diameter than in the inverted condition. Preferably, the inner diameter of the inversible tubular member in the everted condition is larger than its outer diameter in the inverted condition. As a result, during inversion and eversion, friction between an inverted length and an everted length of the inversible tubular member will be minimized.

The stitches may be knitted stitches of at least one length of the filamentary material.

The stitches may be plaited stitches, each defining a loop.

The filamentary material may be a monofilament material, for example a polymer such as Nylon. Alternatively, the filamentary material may be a multifilament material, for example stranded stainless steel wiring.

The filamentary material may be a superelastic material.

The filamentary material may be a shape memory material, e.g. Nitinol.

- 5 The inversible tubular member may have a substantially constant cross-section along its length in each of the inverted and everted conditions.

Alternatively, the inversible tubular member may have a variable diameter along its length in each of the inverted and everted conditions. Such a variable diameter may be
10 achieved by varying the stitch size, or the number of stitches per circumferential row, along the length. Alternatively, if the properties of the filamentary material permit, a variable diameter may be achieved by heating, setting, and cooling of the filamentary material. The Applicant believes that such variable diameter may be useful in at least one envisaged application of the inversible tubular member, i.e. grabbing of an object,
15 as is described below.

The filamentary material may be coated in a coating of a different material. The coating may, for example, serve to alter at least one surface property of the filamentary material, for example its coefficient of friction. In the case of the filamentary material
20 being a multifilament material, the coating may serve to bind the filaments of the multifilament material together.

According to a second aspect of the invention there is provided a gripping device including:

- 25 an inversible tubular member which is substantially round in cross-section and progressively transformable between an everted condition and an inverted condition, with a transformation end being defined intermediate an everted length and an inverted length of the inversible tubular member during such transformation and with the inverted length and the everted length defining opposite to the transformation end respectively
30 an inverted end and an everted end of the inversible tubular member, the inversible tubular member being composed of interengaged stitches of resiliently flexible filamentary material; and

actuation means carrying the inversible tubular member and operable for effecting progressive inversion and eversion of the inversible tubular member,

the inversible tubular member defining a transformation end where the progressive inversion and eversion occurs, with such inversion providing for gripping an object in the inversible tubular member.

- 5 The gripping device may be used for gripping an object, as is described below. The inversible tubular member must have rigidity sufficient for performing the method.

10 In the gripping device, the inversible tubular member may be an inversible tubular member, in accordance with the first aspect of the invention. Accordingly, further features of the inversible tubular member of the gripping device may be the same as any of the features of the inversible tubular member of the first aspect of the invention, as described above. Also, it is envisaged that the following relationship may apply in the inversible tubular member, where X and Y are as defined above:

15
$$X \geq Y \geq 5.0$$

20 The applicant envisages that the gripping device of the second aspect of the invention may be used for the retrieval of loose objects from small or deep cavities where other forms of access may be difficult or impossible. It may also be used for gripping objects while they are being manipulated, modified, inspected, dissected, or excised. Typical applications could include capture and manipulation/removal of objects/organs during laparoscopic surgery, capture and removal of objects from natural body orifices, and capture and manipulation/removal of objects in/from pipes or machinery.

25 The gripping device may include a membrane over at least a part of a surface of the inversible tubular member which is an outer surface in the everted condition. Alternatively or additionally, the gripping device may include a membrane over at least a part of a surface of the inversible tubular member which is an inner surface in the everted condition.

30

In a particular embodiment of the gripping device, the actuation means includes:

an outer tubular member defining a distal end, i.e. a front end, and a proximal end, i.e. a rear end, and a longitudinal passage extending between the distal end and the

proximal end, the distal end being peripherally attached to an everted end of the inversible tubular member; and

an inner elongate member received within the passage and defining a distal end and a proximal end, the distal end being peripherally attached to an opposite inverted end of the inversible tubular member,
the outer tubular member and the inner elongate member being slidably displaceable relative to each other to effect the progressive inversion and eversion.

In the said particular embodiment, the actuation means may include:

a first hand grip formation on the proximal end of the outer tubular member; and
a second hand grip formation on the proximal end of the inner elongate member,
the hand grip formations being manually relatively displaceable for effecting the relative sliding displacement of these members.

Still in the said particular embodiment, the inversible tubular member may be retractable into the outer tubular member.

Still in the said particular embodiment, the inner elongate member may be received within the outer tubular member in a snug sliding fit to provide sealing between these members to a required pressure, which is not less than 15 mmHg. Such sealing may be required in certain medical applications of the gripping device, as envisaged by the applicant.

Alternatively, the said particular embodiment may include sealing means, for example a circular sealing ring, sealing between the inner elongate member and the outer tubular member to a required pressure, which is not less than 15 mmHg.

Still in the said particular embodiment, the inner elongate member may define therethrough a longitudinal passage, permitting insertion of an elongate surgical or other instrument through it. This may be required in certain medical applications, for example laparoscopic applications, of the gripping device, as envisaged by the applicant. The inner elongate member may have sealing means sealing the longitudinal passage defined therethrough, the sealing means being configured to permit passage of an elongate surgical or other instrument through it and to seal around the instrument. The

sealing means may, for example, include a duckbill for sealing the longitudinal passage when there is no instrument in the passage and a circular seal for sealing around an instrument when present in the passage.

- 5 Still in the said particular embodiment, the inversible tubular member may be releasable from the outer tubular member and the inner elongate member. In this case, the gripping device may include a first coupling secured to the everted end of the inversible tubular member, the first coupling being releasably engageable with the distal end of the outer tubular member; and a second coupling secured to an end of an inverted length of
10 the inversible tubular member opposite to the transformation end, the second coupling being releasably engageable with the distal end of the inner tubular member. The first and second couplings may be interengageable through relative displacement of the outer tubular member and the inner elongate member.
- 15 Still in the said particular embodiment, the outer tubular member may include a distal end portion that is radially expandable for operatively accommodating therein a length of the inversible tubular member and an object therein where the size of the object requires radial expansion of the end portion. The distal end portion may define therein an arrangement of slits which are angularly spaced about the central axis of the tubular
20 member to provide for the expansion. The distal end portion may be resiliently flexible to provide for the expansion.

According to a third aspect of the invention, there is provided a method of gripping an object, the method including:

- 25 providing an inversible tubular member which is substantially round in cross-section and progressively transformable between an everted condition and an inverted condition with a transformation end being defined intermediate an everted length and an inverted length of the inversible tubular member during such transformation, the inversible tubular member being composed of interengaged stitches of resiliently flexible
30 filamentary material;
- with at least a part of the length of the inversible tubular member in the everted condition, contacting the transformation end of the said part with the object; and
- progressively inverting the said part at the transformation end, thus causing the inversible tubular member to grip the object.

Clearly, in order to perform the method, the inversible tubular member must have sufficient rigidity.

- 5 The inversible tubular member used in the method may be an inversible tubular member, in accordance with the first aspect of the invention.

The method may include at least partially drawing the object into the inversible tubular member by the progressive inverting of the inversible tubular member.

10

The applicant has found that, due to flexibility in the inversible tubular member, the method may be used to grip and draw into the inversible tubular member an object having a size substantially larger than the outer diameter of the said part of the length of the inversible tubular member in the everted condition. The applicant has further found
15 that, by suitably sizing the inversible tubular member, it is able to grip and draw in very fragile objects.

20

According to a fourth aspect of the invention there is provided a method of making an inversible tubular member, in accordance with the first aspect of the invention, the method including forming stitches in a suitable filamentary material and inter-engaging them to define the inversible tubular member.

25

In one possible implementation of the method, both the forming and inter-engaging of the stitches may be performed in a knitting process.

30

In another possible implementation of the method, a series of the stitches may be formed in the filamentary material and thereafter the stitches may be interengaged in a knitting process. The series of stitches may, for example, be formed as a series of loops in the filamentary material by forming the filamentary material into a helix and then flattening the helix.

The knitting process, where applicable, may be performed by means of a knitting spool.

Further features of the invention, in its various aspects, will become apparent from the description below of example embodiments of the invention, with reference to and as illustrated in the accompanying diagrammatic drawings. In the drawings:

5 Figure 1 shows a side/rear three-dimensional view of a first embodiment of a gripping device, in accordance with the invention, including an inversible tubular member, in accordance with the invention;

 Figure 2 shows an enlarged side/front three-dimensional view of a distal end portion of the device of Figure 1;

10 Figure 3 shows a broken side view of the device of Figure 1;

 Figure 4 shows a broken long section of the device of Figure 1;

 Figure 5 shows a detail long section of an end part of the device of Figure 1 and an object gripped thereby;

15 Figure 6 shows a detail of an inverted length of the inversible tubular member of Figure 1;

 Figure 7 shows a detail of an everted length of the inversible tubular member of Figure 1;

 Figure 8 shows a detail illustrating a step in a method, in accordance with the invention, of making the inversible tubular member of Figure 1;

20 Figure 9 shows a detail IX of Figure 8;

 Figure 10 shows a detail long section of an end part of a second embodiment of a gripping device, in accordance with the invention, and an object gripped thereby, the device being for the most part identical to the gripping device of Figure 1;

25 Figure 11 shows a long section of a third embodiment of a gripping device, in accordance with the invention;

 Figure 12 shows a detail XII of Figure 11;

 Figure 13 shows a detail XIII of Figure 12; and

30 Figure 14 shows a three-dimensional view of a fourth embodiment of a gripping device, in accordance with the invention, including an inversible tubular member, in accordance with the invention.

In Figures 1 to 4, a first embodiment of a gripping device, in accordance with the invention, more particularly a laparoscopic surgical retrieval device, is designated generally by the reference numeral 10.

The retrieval device 10 includes:

an outer tubular member 12 defining a distal end 14, a proximal end 16, and a longitudinal passage 17 extending from the distal end 14 to the proximal end 16;

5 a first hand grip formation 18 around the proximal end 16 of the outer tubular member 12;

an elongate inner member in the form of an inner tubular member 20 defining a distal end 22, a proximal end 24, and a longitudinal passage 25 extending from the distal end 22 to the proximal end 24, the inner tubular member 20 being snugly and
10 slidably received through the passage 17 of the outer tubular member 12;

a second hand grip formation 26 on the proximal end 24 of the inner tubular member 20; and

a tubular member 27.

15 The tubular member 27 comprises:

a first length 29.1, secured around the distal end 14 of the outer tubular member 12;

a second length 29.2, secured around the distal end 22 of the inner tubular member 20; and

20 a third length 28, which is an inversible tubular member, in accordance with the invention, and which extends from the length 29.1 to the length 29.2.

The entire tubular member 27 was formed as an inversible tubular member, in accordance with the invention. However, the lengths 29.1 and 29.2 of the tubular
25 member 27 clearly are now restrained and therefore no longer inversible.

The inversible tubular member 28 has:

an everted end 30, secured to the distal end 14 of the outer tubular member 12 via the first length 29.1; and

30 an opposite, inverted end 32, secured to the distal end 22 of the inner tubular member 20 via the second length 29.2.

It is known that in certain laparoscopic procedures, it is required for a surgical retrieval device to seal up to a particular pressure, being a pressure maintained inside a

peritoneal cavity during surgery. Accordingly, the retrieval device 10 includes a seal 33 effectively sealing between the inner tubular member 20 and the outer tubular member 12. The seal 33 seals up to a prescribed pressure, which is not less than 15 mmHg. Alternatively, the inner tubular member 20 may be received sufficiently snugly within the outer tubular member 12 to seal to a prescribed pressure, which is not less than 15 mmHg.

The passage 25 extends also through the hand grip formation 26. The retrieval device 10 includes also, within a widened proximal end of the passage 25, sealing means in the form of a circular seal 35 and a duckbill 34, both capable of sealing up to at least 15 mmHg. Another surgical device may be inserted through the retrieval device 10, particularly through the circular seal 35, the duckbill 34, and the passage 25. The circular seal 35 is for sealing around such a surgical device. The duckbill 34 is for sealing when there is no such surgical device present.

A length 38 of the inversible tubular member 28, having a length L_1 , is in an everted condition and a length 36 of the inversible tubular member 28, having a length L_2 , is in an everted condition. The inverted length 36 defines therein a cavity 40 which forms an extension of the passage 25. At a peripheral boundary between the inverted length 36 and the everted length 38 is defined a transformation end 41 of the inversible tubular member 28. As will be described below, the gripping device 10 is operable to effect progressive inversion and eversion of the inversible tubular member 28 at the transformation end 41, meaning that L_1 and L_2 are variable.

The inversible tubular member 28 has a total length $L = L_1 + L_2$ of about six times a natural or relaxed outer diameter of the inverted length 36. The diameter of the inversible tubular member 28 may be variable along its length when it is entirely everted. In an alternative embodiment (not shown), the diameter of the inversible tubular member may be at least substantially constant along its length when it is entirely everted.

With the inversible tubular member 28 completely everted (not shown), then by relative forward displacement of the hand grip formation 18 and the outer tubular member 12 with respect to the hand grip formation 26 and the inner tubular member 20, the end 30

of the inversible tubular member 28 is linearly relatively displaced towards the transformation end 41 and the inversible tubular member 28 is progressively inverted, i.e. the inverted length 36 and the space or cavity 40 defined therein are progressively extended away from the distal end 22 of the inner tubular member 20. The everted length 38 clearly must have sufficient rigidity to cause such inversion.

With reference particularly to Figure 5, by such inversion, an object 42 can be gripped by means of the inversible tubular member 28 and drawn into the cavity 40. Figure 5 will be referred to again below.

With the inversible tubular member 28 completely inverted (not shown) within the outer tubular member 12, then by relative rearward displacement of the hand grip formation 18 and outer tubular member 12 with respect to the hand grip formation 26 and the inner tubular member 20, the end 32 of the inversible tubular member 28 is linearly relatively displaced towards the transformation end 41 and the inversible tubular member 28 is progressively everted, i.e. the inverted length 36 and the space or cavity 40 defined therein are progressively shortened. The inverted length 36 clearly must have sufficient rigidity to cause such eversion.

With reference now to Figure 6, the inversible tubular member 28 (of which only a small portion is shown) is composed of interengaged plait stitches 43, each including a loop 44, the stitches 43 being made of a resiliently flexible filamentary material in the form of nylon filament 46. The same applies to the entire tubular member 27, of which the inversible tubular member 28 forms a part.

The loops 44 may be formed and interengaged in a knitting process, for example using a knitting spool. Alternatively, a series of the loops 44 may be formed in the nylon filament 46 prior to interengaging the loops in a knitting or similar process. This may be done by forming the filament 46 into a helix and then flattening the helix.

Figure 6 shows the portion of the inversible tubular member 28 in the inverted condition. Figure 7 shows essentially the same portion of the inversible tubular member 28 in the everted condition.

Figures 8 and 9 show a step in a method, in accordance with the invention, for making the inversible tubular member 28. The nylon filament 46 is knitted such as to form circumferential rows, of which three rows 48.1, 48.2, and 48.3 are shown, in a helix pattern. In this case, the rows 48.1 and 48.2 have already been completed and the row 48.3 is being formed. Two loops 44.1 and 44.2 respectively in the rows 48.2 and 48.3 have been interengaged and two loops 44.3 and 44.4 in the respective rows are about to be interengaged. Such stitches are known in relation to, for example, yarn as plaited stitches and therefore do not require further elaboration herein.

At the time of making the inversible tubular member 28, the loops 44 are in the arrangement shown in Figure 6, the loops 44 being on the inside of the inversible tubular member 28. This arrangement corresponds to the inverted condition of the inversible tubular member 28, as referred to herein. This arrangement is referred to below as the "inner loop arrangement".

By everting the inversible tubular member 28 into its everted condition, the loops 44 are transformed into the arrangement shown in Figure 7, in which the loops 44 are on the outside of the inversible tubular member 28. This arrangement is referred to below as the "outer loop arrangement".

The inventor has found in practice that an inversible tubular member such as the inversible tubular member 28 naturally defines in its inverted condition an outer diameter which is smaller than its outer diameter in the everted condition. The bias created in the knitting process as the loops 44 are formed causes adjacent loops to overlap in the inverted condition while they are constrained to a side-by-side arrangement in the everted condition. This creates two stable diameters respectively for the inversible tubular member 28 in the inverted and everted conditions, meaning that there is very low friction and minimal interference between the inverted length 36 and the everted length 38 (see Figure 4).

A possible further explanation of the two diameters is given below:

All of the loops 44, having been constructed as a helical spring either during or before the knitting process, have a tendency to want to return to a stacked, helical arrangement. This results in two forces on the loops:

A force pulling the loops 44 together due to the fact that the apex of the loop is highly flexed and creates a tendency for the loop to attempt to decrease its rate of flexure. As the loop is attached to its neighbouring loops by the roots 31 this effect pulls neighbouring loops together as each attempts to expand; and

A moment around the axis of symmetry of each loop 44 which attempts to return the loops to a parallel arrangement.

In the inner loop arrangement, the root 31 between loops in the next row passes on the inside of the curvature and the loops 44 are therefore not fully constrained in rotation and are able to rotate slightly about their axes. This rotation also allows them to overlap with the loops 44 to either side. As the loops 44 are not restricted from circumferential overlap, the force created by the highly flexed apex of the loops 44 is able to pull the loops 44 together and they partially overlap each other which results in a smaller circumference and, thus results in a smaller diameter.

In the outer arrangement the loops 44 are unable to rotate due to the root 31 of the next row now passing over the loops 44 and following the increased path of the outside of the curvature. This creates an inward force on the loops 44 and they are restricted from rotation and circumferential overlap (at 45 in Figure 7). The moment about their axes further tensions the roots and the side-by-side arrangement now creates a greater circumference and, thus results in a greater diameter.

The loops in the outer loop arrangement are also restricted from longitudinal overlap (at 47 in Figure 7), which increases the longitudinal stiffness and rigidity of the everted length of the inversible tubular member and provides the rigidity required for the everted length to withstand the forces of inversion and ingesting a captured object without crumpling and without the need for alternative support.

Referring now particularly to Figures 1 and 5, in order to use the retrieval device 10 for gripping the object 42, say during a laparoscopic procedure on a person, the hand grip formations 18 and 26 are pushed together until substantially the entire inversible tubular

member 28 is in the everted condition as an extension to the outer tubular member 12. The inversible tubular member 28 and outer tubular member 12 is then at least partially inserted into the body through a standard laparoscopic port. The object 42 is contacted by the transformation end 41 of the inversible tubular member 28. The hand grip
5 formations 18 and 26 are progressively pulled apart so that the inversible tubular member 28 grips the object 42 and draws it into the cavity 40. This is an example of the method of the third aspect of the invention.

10 In the inversible tubular member 28, the loops 44 on the outside of the everted length 38 point in the distal direction. As the loops 44 approach the transformation end 41 during inversion, they do not project past the outer diameter of the inversible tubular member 28. As they pass the end 41, they project inwardly into the cavity 40 and proximally for a short travel distance. This behavior of the loops 44 enhances grip of the loops 44 on the object 42.

15 The applicant has found with the prototype of the retrieval device 10 that the inversible tubular member 28 will stretch sufficiently for ingesting a sphere of a diameter of 1.5 times the average relaxed outer diameter of the inverted length 36. Take a case where the inversible tubular member 28 is halfway inverted when the sphere is halfway into the
20 inversible tubular member 28 at the transformation end 41. In this case, the applicant has found that further inversion occurs at the transformation end 41.

25 Optionally, a membrane 49.1 (shown in broken lines in Figure 4) may be applied over the surface of the inversible tubular member 28 which is an outer surface in the everted condition. Alternatively or additionally, such a membrane 49.2 may be applied over the opposite surface. Such a membrane may, for example, serve to prevent spillage of toxins from tissue removed during a surgical procedure.

30 As was stated above, the diameter of the inversible tubular member 28 may be variable along its length when it is entirely everted. This may be achieved by varying the sizes of the loops, or the number of loops per row, along the length of the inversible tubular member. Alternatively, if the properties of the filamentary material permit, a variable diameter may be achieved by heating, setting, and cooling of the material.

In Figure 10, a second embodiment of a gripping device in the form of a laparoscopic surgical retrieval device, in accordance with the invention, of which only a part is shown, is designated generally by the reference numeral 50.

5 The retrieval device 50 is for the most part identical to the retrieval device 10 of Figures 1 to 9 and therefore like features, where shown, will again be designated by the same reference numerals as before and these features will not be described again. Moreover, the retrieval device 50 differs from the retrieval device 10 only in respect of the orientation of its inversible tubular member 28. In this case, the loops 44 on the outside
10 of the everted length 38 of the length of the inversible tubular member 28 point in the proximal direction.

As the loops 44 approach the transformation end 41 during inversion, they project past the outer diameter of the inversible tubular member 28. As they pass the transformation
15 end 41, they do not project inwardly into the cavity 40. This behavior of the loops 44 means that the transformation end 41 can effectively gather material over an area larger than its outer diameter 28. This feature may also aid gripping and drawing in of an object 52 which tends to break apart.

20 In Figure 11, a third embodiment of a gripping device in the form of a laparoscopic surgical retrieval device, in accordance with the invention, of which only a part is shown, is designated generally by the reference numeral 54.

The retrieval device 54 is for the most part identical to the retrieval device 10 of Figures
25 1 to 9 and therefore like features, where shown, will again be designated by the same reference numerals as before and these features will not be described again.

With reference to Figures 11 to 13 generally, the retrieval device 54 includes:

30 a tubular first coupling 56 to which the everted end 30 of the inversible tubular member 28 is peripherally attached; and

a tubular second coupling 58 to which the inverted end 32 of the inversible tubular member 28 is peripherally attached.

By relative axial displacement, the second coupling 58 fits into the first coupling 56 in a snug fit. These couplings define complementary clip-in formations 60 for retaining the coupling 58 in the coupling 56.

- 5 The coupling 56 defines an outer screw thread 62 complementary to an inner screw thread 64 defined by the distal end of the outer tubular member 12.

The coupling 58 defines an inner screw thread 66 complementary to an outer screw thread 68 defined by the distal end of the inner tubular member 20.

10

The extractor device 54 provides the following operation. With the couplings 56 and 58 engaged respectively with the tubular members 12 and 20 by screwing them in, the device 54 is used similarly to the use of the retrieval device 10 as described above to grip an object in a body of, say, a person. The tubular members 12 and 20 are relatively
15 longitudinally displaced until the object is at least partially within the cavity 40 and the clip-in formations 60 are interengaged. The tubular members 12 and 20 are then unscrewed from the respective couplings 56 and 58, which may require the inversible tubular member 28 to be held by means of another surgical instrument.

- 20 The inversible tubular member 28 has a diameter which may vary substantially along its length to facilitate operative holding of an object received therein.

In Figure 14, a fourth embodiment of a gripping device in the form of a laparoscopic surgical retrieval device, in accordance with the invention, of which only a part is shown,
25 is designated generally by the reference numeral 70.

The retrieval device 70 is for the most part identical to the retrieval device 10 of Figures 1 to 9 and therefore like features, where shown, will again be designated by the same reference numerals as before and these features will not be described again.

30

An outer tubular member 12 of the retrieval device 70 is made of a resiliently flexible material, e.g. polypropylene. It includes an end portion 71 defining therein four elongate slits 72 (only two shown), angularly evenly spaced about its central axis. As such, the end portion 71 is split into four fingers 74 (only three shown). Distal ends of the fingers

74 have an everted end of a tubular member 27, which includes an inversible tubular member 28, secured to their outsides. An opposite end of the inversible tubular member 28 is secured to an inner tubular member (see reference numeral 20 in Figure 4).

5 The inversible tubular member 28 is shown almost entirely in an inverted condition. The fingers 74 are shown resiliently deformed into a flared out or expanded condition and similarly, the inversible tubular member 28 is shown in a radially expanded condition. Such expansion will, in use of the retrieval device 70, be caused by an "oversized" ingested object (not shown) in the inversible tubular member 28.

10

It will be understood that, in an ex-factory condition of the retrieval device 70, the fingers 74 were more closely spaced and defined a circumference substantially the same as that of the remainder of the tubular member 12.

15 Other features and operation of the retrieval device 70 are essentially the same as those of the retrieval device 10 of Figures 1 to 9. Expansion of the end portion 71 merely facilitates ingestion of larger objects than would have been the case with the retrieval device 10.

20 In all of the above examples, the gripping device of the invention was intended for surgical use. It must be appreciated, however, that a similar gripping device may be configured for other uses, for example an industrial use. It may be suitably scaled up or down for a required application. For certain heavier duty applications, the resiliently flexible filamentary material may, for example, be a multifilament material, for example
25 stranded stainless steel wiring or cabling.

It is envisaged that, generally in all practical embodiments of the gripping device of the invention, requirements a), b), and c) below will apply. The numbers in brackets refer to equivalent features of the retrieval device 10 of Figures 1 to 9.

30

a) With the inversible tubular member (28) at least partially inverted, the inverted length (36) must have sufficient stiffness to cause eversion of the inversible tubular member at the transformation end (41) upon axial displacement of the inverted end (32) towards the transformation end, for a length of the inverted length (L2) up to X times an

average relaxed outer diameter of the inverted length, with $X \geq 2.0$. In some possible embodiments, $X \geq 5.0$.

b) With the inversible tubular member (28) at least partially everted, the everted length (38) must have sufficient stiffness to cause inversion of the inversible tubular member at the transformation end (41) upon axial displacement of the everted end (30) towards the transformation end, for a length (L1) of the everted length up to Y times an average relaxed outer diameter of the inverted length, with $Y \geq 2.0$. In some possible embodiments, $Y \geq 5.0$

c) With the inversible tubular member (28) at least partially everted, the everted length (38) must have sufficient stiffness to cause inversion of the inversible tubular member at the transformation end (41) upon axial displacement of the everted end (30) towards the transformation end, for a length (L1) of the everted length up to Z times the average relaxed outer diameter of the inverted length, whilst one half of a sphere of diameter 1.5 times an average relaxed outer diameter of the inverted length is received in the inversible tubular member at the transformation end, with $Z \geq 2.0$.

CLAIMS:

1. A gripping device including:

an inversible tubular member which is substantially round in cross-section and progressively transformable between an everted condition and an inverted condition, with a transformation end being defined intermediate an everted length and an inverted length of the inversible tubular member during such transformation and with the inverted length and the everted length defining opposite to the transformation end respectively an inverted end and an everted end of the inversible tubular member, the inversible tubular member being composed of interengaged stitches of resiliently flexible filamentary material; and

actuation means carrying the inversible tubular member and operable for effecting progressive inversion and eversion of the inversible tubular member, the inversible tubular member defining a transformation end where the progressive inversion and eversion occurs, with such inversion providing for gripping an object in the inversible tubular member.

2. A gripping device as claimed in claim 1, in which:

with the inversible tubular member at least partially inverted, the inverted length has sufficient stiffness to cause eversion of the inversible tubular member at the transformation end upon axial displacement of the inverted end towards the transformation end, for a length of the inverted length up to X times an average relaxed outer diameter of the inverted length;

$X \geq 2.0$;

with the inversible tubular member at least partially everted, the everted length has sufficient stiffness to cause inversion of the inversible tubular member at the transformation end upon axial displacement of the everted end towards the transformation end, for a length of the everted length up to Y times an average relaxed outer diameter of the inverted length; and

$Y \geq 2.0$.

3. A gripping device as claimed in any of the preceding claims, in which:

$X \geq Y \geq 5.0$

4. A gripping device as claimed in any of the preceding claims, in which:

with the inversible tubular member at least partially everted, the everted length has sufficient stiffness to cause inversion of the inversible tubular member at the transformation end upon axial displacement of the everted end towards the transformation end, for a length of the everted length up to Z times the average relaxed outer diameter of the inverted length, whilst one half of a sphere of diameter 1.5 times an average relaxed outer diameter of the inverted length is received in the inversible tubular member at the transformation end; and

$$Z \geq 2.0$$

5. A gripping device as claimed in any of the preceding claims, which defines in the everted condition a larger outer diameter than in the inverted condition.

6. A gripping device as claimed in claim 5, of which the inner diameter in the everted condition is larger than its outer diameter in the inverted condition.

7. A gripping device as claimed in any of the preceding claims, in which the stitches are knitted stitches of at least one length of the filamentary material.

8. A gripping device as claimed in claim 7, in which the stitches are plaited stitches, each defining a loop.

9. A gripping device as claimed in any of the preceding claims, in which the filamentary material is a monofilament material.

10. A gripping device as claimed in any of the preceding claims, in which the filamentary material is a multifilament material.

11. A gripping device as claimed in any of the preceding claims, in which the filamentary material is a superelastic material.

12. A gripping device as claimed in any of the preceding claims, in which the filamentary material is a shape memory material.

13. A gripping device as claimed in any of the preceding claims, in which the inversible tubular member has a variable diameter along its length.

14. A gripping device as claimed in any of the preceding claims, which includes a membrane over at least a part of a surface of the inversible tubular member which is an outer surface in the everted condition.

15. A gripping device as claimed in any of the preceding claims, which includes a membrane over at least a part of a surface of the inversible tubular member which is an inner surface in the everted condition.

16. A gripping device as claimed in any of the preceding claims, in which the actuation means includes:

an outer tubular member defining a distal end, i.e. a front end, and a proximal end, i.e. a rear end, and a longitudinal passage extending between the distal end and the proximal end, the distal end being peripherally attached to an everted end of the inversible tubular member; and

an inner elongate member received within the passage and defining a distal end and a proximal end, the distal end being peripherally attached to an opposite inverted end of the inversible tubular member,

the outer tubular member and the inner elongate member being slidably displaceable relative to each other to effect the progressive inversion and eversion.

17. A gripping device as claimed in claim 16, which includes:

a first hand grip formation on the proximal end of the outer tubular member; and
a second hand grip formation on the proximal end of the inner elongate member,
the hand grip formations being manually relatively displaceable for effecting the relative sliding displacement of these members.

18. A gripping device as claimed in any of claims 16 to 17, in which the inversible tubular member is retractable into the outer tubular member.

19. A gripping device as claimed in any of claims 16 to 18, in which the inner elongate member is received within the outer tubular member in a snug sliding fit to provide

sealing between these members to a required pressure, which is not less than 15 mmHg.

20. A gripping device as claimed in any of claims 16 to 18, which includes sealing means sealing between the inner elongate member and the outer tubular member to a required pressure, which is not less than 15 mmHg.

21. A gripping device as claimed in any of claims 16 to 20, in which the inner elongate member defines therethrough a longitudinal passage, permitting insertion of an elongate surgical or other instrument through it.

22. A gripping device as claimed in claim 21, in which the inner elongate member has sealing means sealing the longitudinal passage defined therethrough, the sealing means being configured to permit passage of an elongate surgical or other instrument through it and to seal around the instrument.

23. A gripping device as claimed in any of claims 16 to 22, in which the invertible tubular member is releasable from the outer tubular member and the inner elongate member.

24. A gripping device as claimed in claim 23, which includes:

a first coupling secured to the everted end of the invertible tubular member, the first coupling being releasably engageable with the distal end of the outer tubular member; and

a second coupling secured to an end of an inverted length of the invertible tubular member opposite to the transformation end, the second coupling being releasably engageable with the distal end of the inner tubular member;

25. A gripping device as claimed in claim 24, in which the first and second couplings are interengageable through relative displacement of the outer tubular member and the inner elongate member.

26. A gripping device as claimed in any of claims 16 to 25, in which the outer tubular member includes a distal end portion that is radially expandable for operatively

accommodating therein a length of the inversible tubular member and an object therein where the size of the object requires radial expansion of the end portion.

27. A gripping device as claimed in claim 26, in which the distal end portion defines therein an arrangement of slits which are angularly spaced about the central axis of the tubular member to provide for the expansion.

28. A gripping device as claimed in any of claims 26 to 27, in which the distal end portion is resiliently flexible to provide for the expansion.

29. An inversible tubular member which is substantially round in cross-section and progressively transformable between an everted condition and an inverted condition, with a transformation end being defined intermediate an everted length and an inverted length of the inversible tubular member during such transformation and with the inverted length and the everted length defining opposite to the transformation end respectively an inverted end and an everted end of the inversible tubular member, in which:

the inversible tubular member is composed of interengaged stitches of resiliently flexible filamentary material;

with the inversible tubular member at least partially inverted, the inverted length has sufficient stiffness to cause eversion of the inversible tubular member at the transformation end upon axial displacement of the inverted end towards the transformation end, for a length of the inverted length up to X times an average relaxed outer diameter of the inverted length;

$X \geq 2.0$;

with the inversible tubular member at least partially everted, the everted length has sufficient stiffness to cause inversion of the inversible tubular member at the transformation end upon axial displacement of the everted end towards the transformation end, for a length of the everted length up to Y times an average relaxed outer diameter of the inverted length; and

$Y \geq 2.0$.

30. An inversible tubular member as claimed in claim 29, in which:

with the inversible tubular member at least partially everted, the everted length has sufficient stiffness to cause inversion of the inversible tubular member at the

transformation end upon axial displacement of the everted end towards the transformation end, for a length of the everted length up to Z times the average relaxed outer diameter of the inverted length, whilst one half of a sphere of diameter 1.5 times an average relaxed outer diameter of the inverted length is received in the inversible tubular member at the transformation end; and

$$Z \geq 2.0.$$

31. An inversible tubular member as claimed in any of claims 29 to 30, which defines in the everted condition a larger outer diameter than in the inverted condition.

32. An inversible tubular member as claimed in claim 31, of which the inner diameter in the everted condition is larger than its outer diameter in the inverted condition.

33. An inversible tubular member as claimed in any of claims 29 to 32, in which the stitches are knitted stitches of at least one length of the filamentary material.

34. An inversible tubular member as claimed in any of claims 29 to 33, in which the stitches are plaited stitches, each defining a loop.

35. An inversible tubular member as claimed in any of claims 29 to 34, in which the filamentary material is a monofilament material.

36. An inversible tubular member as claimed in any of claims 29 to 34, in which the filamentary material is a multifilament material.

37. An inversible tubular member as claimed in any of claims 29 to 36, in which the filamentary material is a superelastic material.

38. An inversible tubular member as claimed in any of claims 29 to 37, in which the filamentary material is a shape memory material.

39. An inversible tubular member as claimed in any of claims 29 to 38, which has a variable diameter along its length in each of the inverted and everted conditions.

40. An inversible tubular member as claimed in claim 39, in which the variable diameter has been achieved by heating, setting, and cooling of the filamentary material.

41. A method of gripping an object, the method including:

5 providing an inversible tubular member which is substantially round in cross-section and progressively transformable between an everted condition and an inverted condition with a transformation end being defined intermediate an everted length and an inverted length of the inversible tubular member during such transformation, the inversible tubular member being composed of interengaged stitches of resiliently flexible
10 filamentary material;

 with at least a part of the length of the inversible tubular member in the everted condition, contacting the transformation end of the said part with the object; and

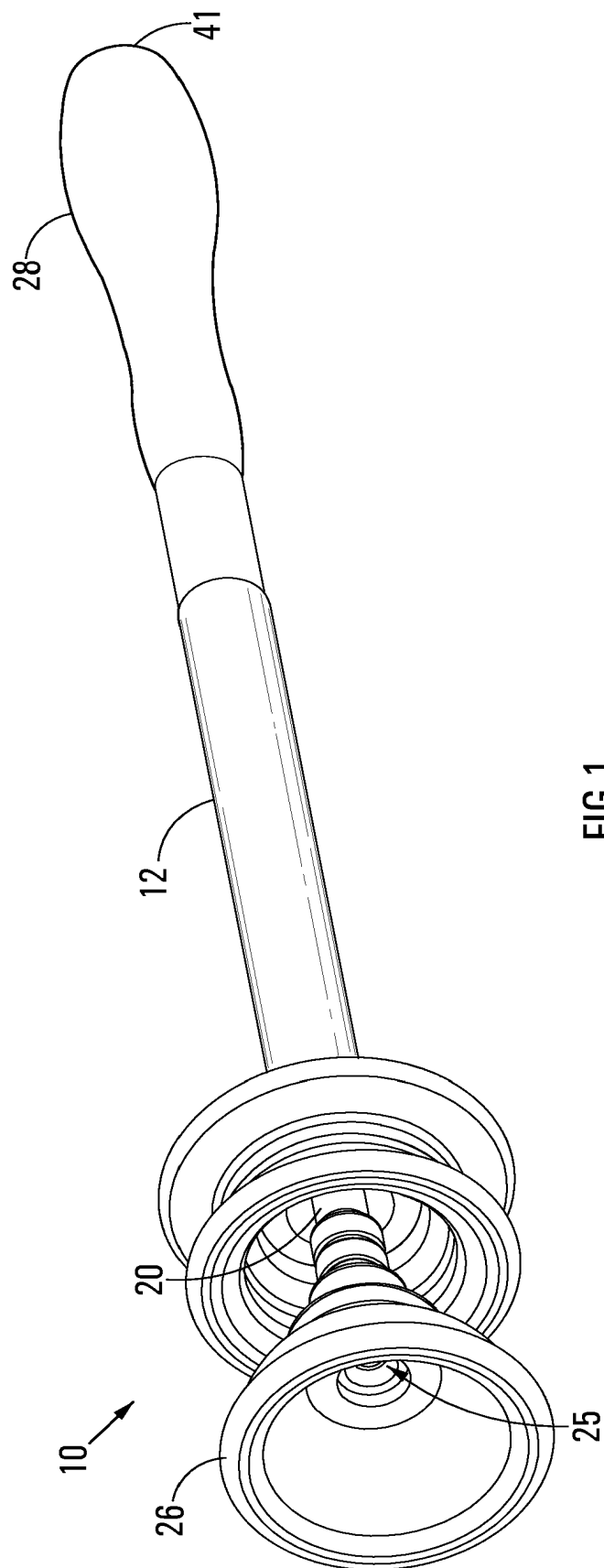
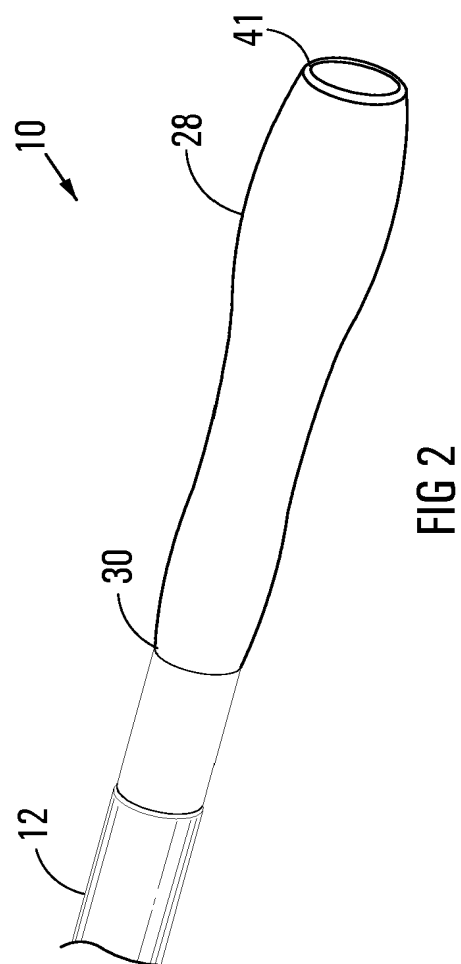
 progressively inverting the said part at the transformation end, thus causing the inversible tubular member to grip the object.

15

42. A method as claimed in claim 41, in which the inversible tubular member is an inversible tubular member as claimed in any of claims 29 to 40.

20

43. A method as claimed in any of claims 41 to 42, which includes at least partially drawing the object into the inversible tubular member by the progressive inverting of the inversible tubular member.



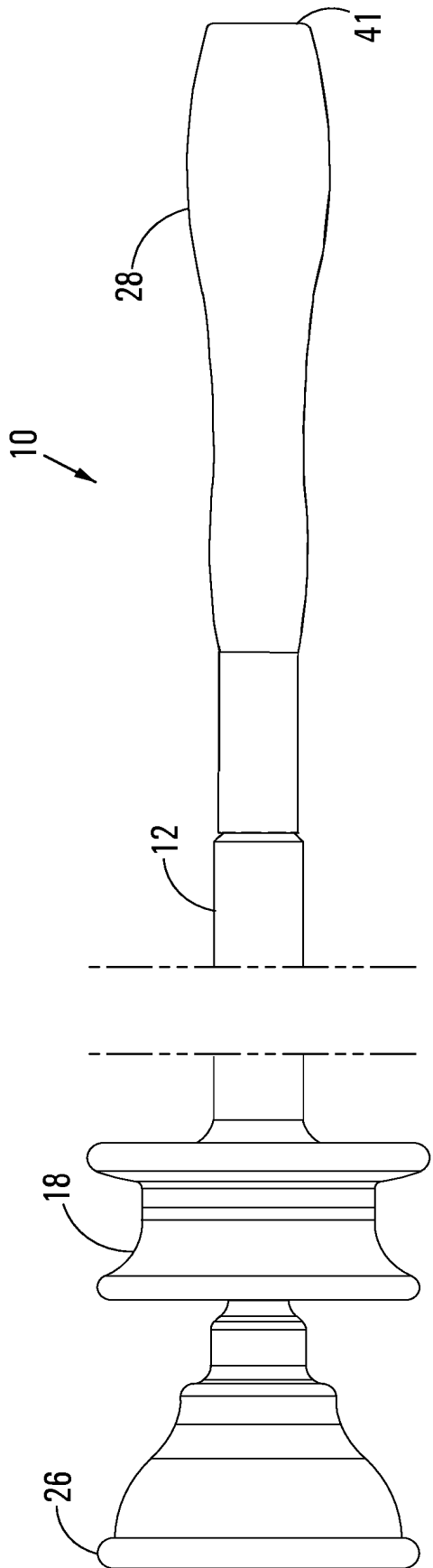


FIG 3

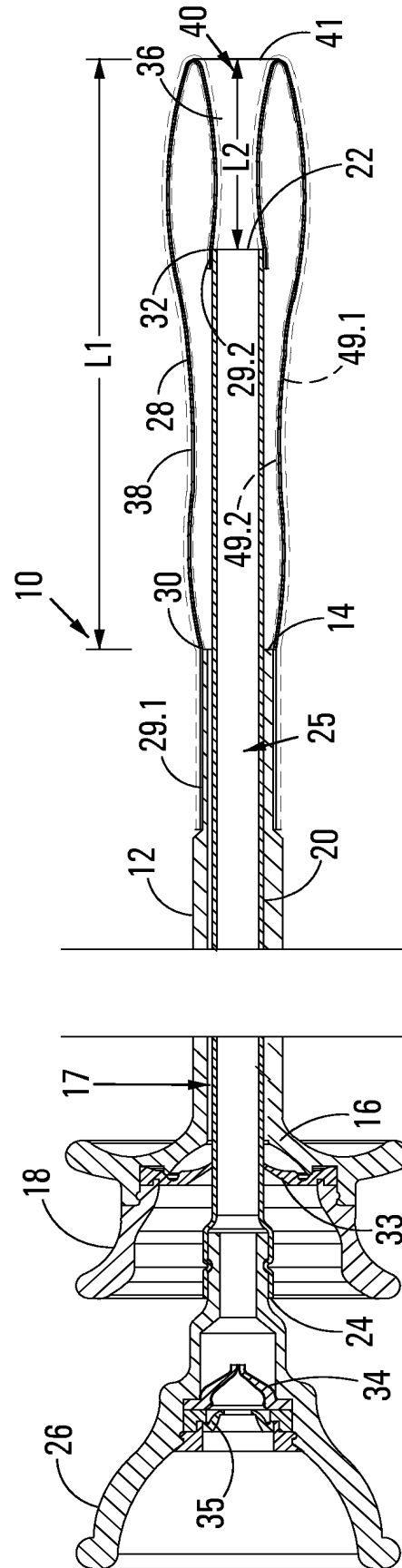


FIG 4

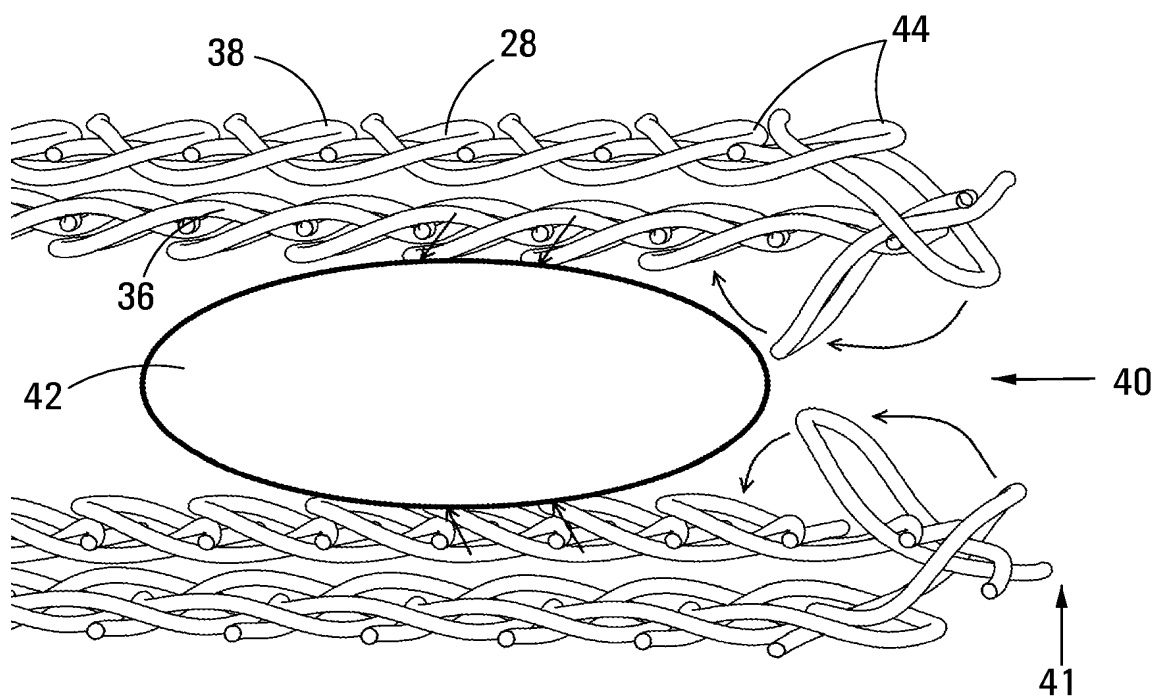


FIG 5

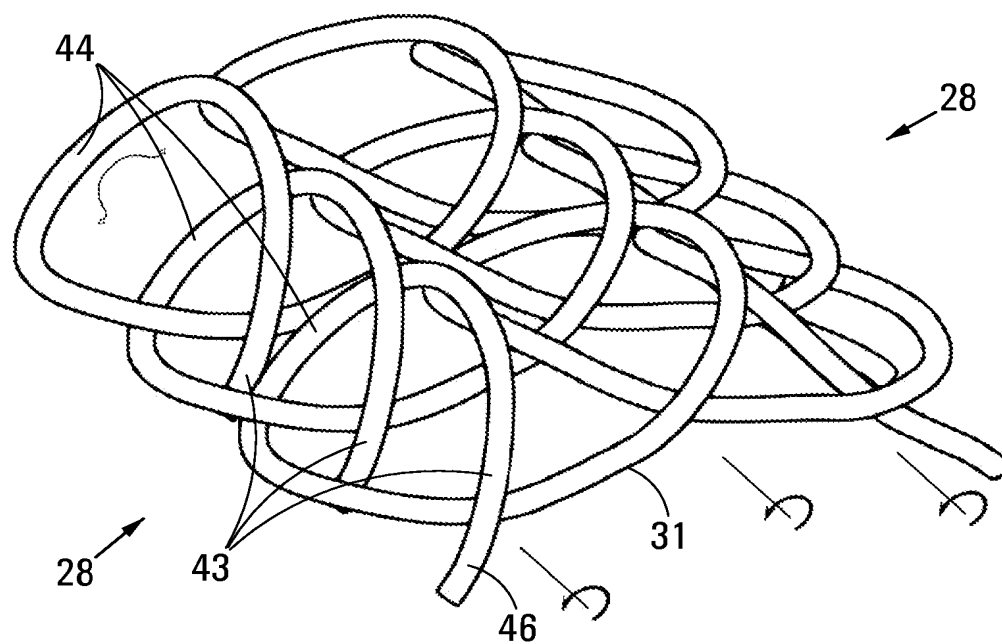


FIG 6

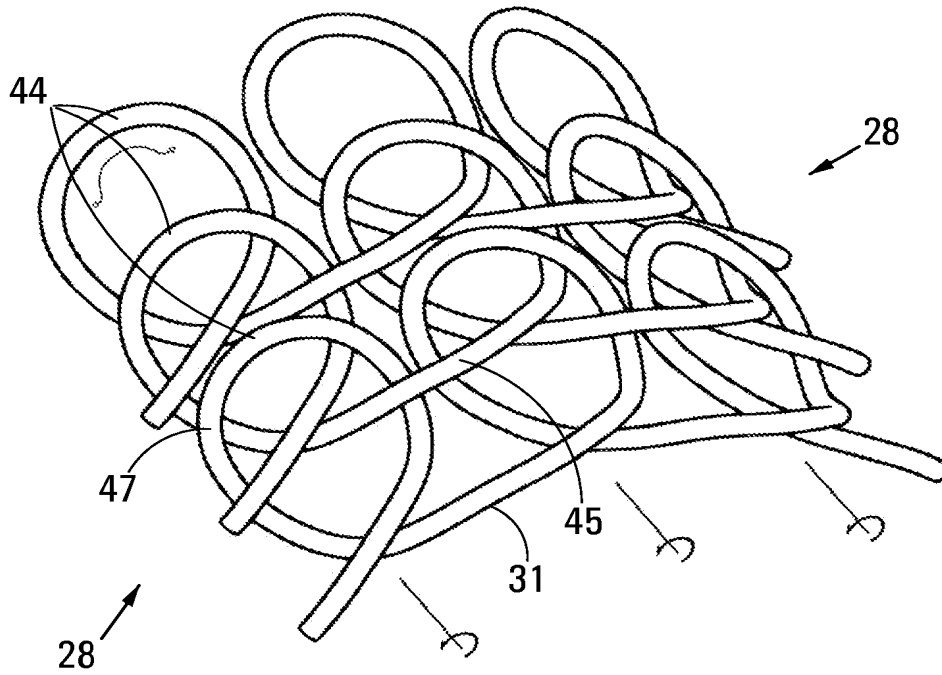


FIG 7

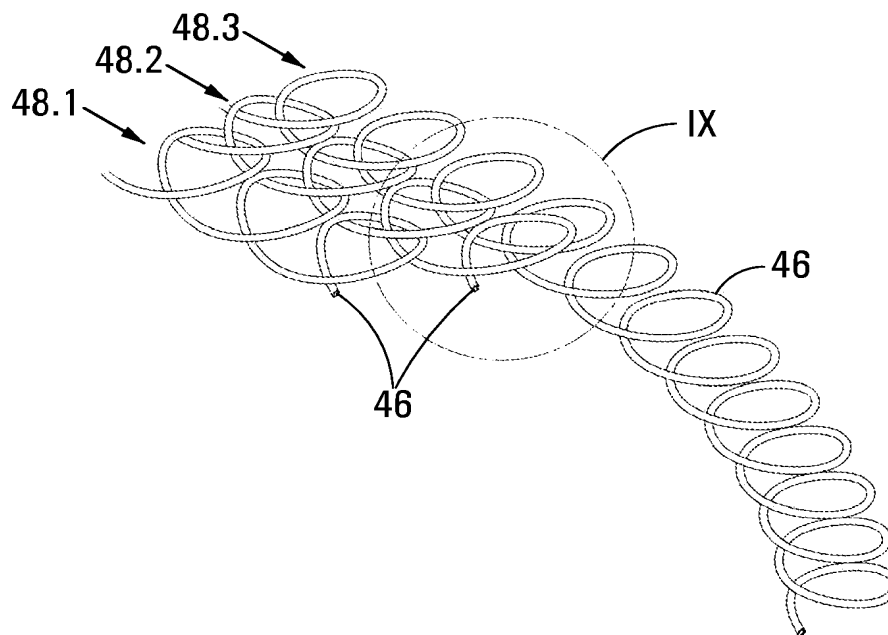


FIG 8

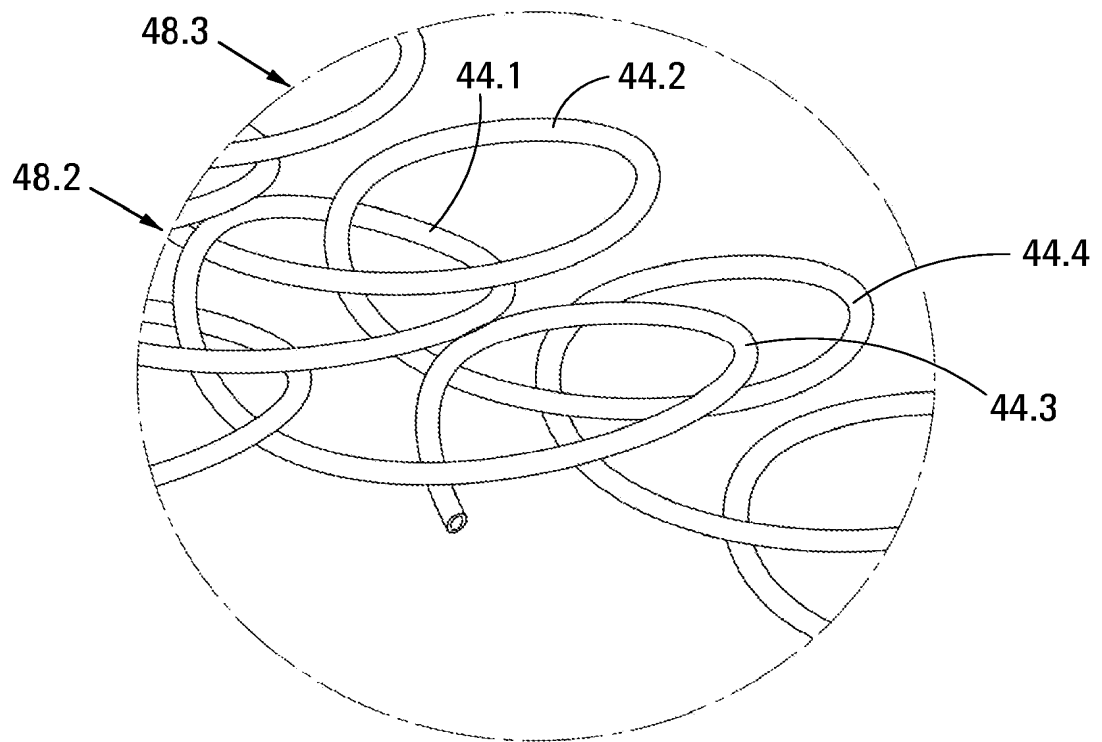


FIG 9

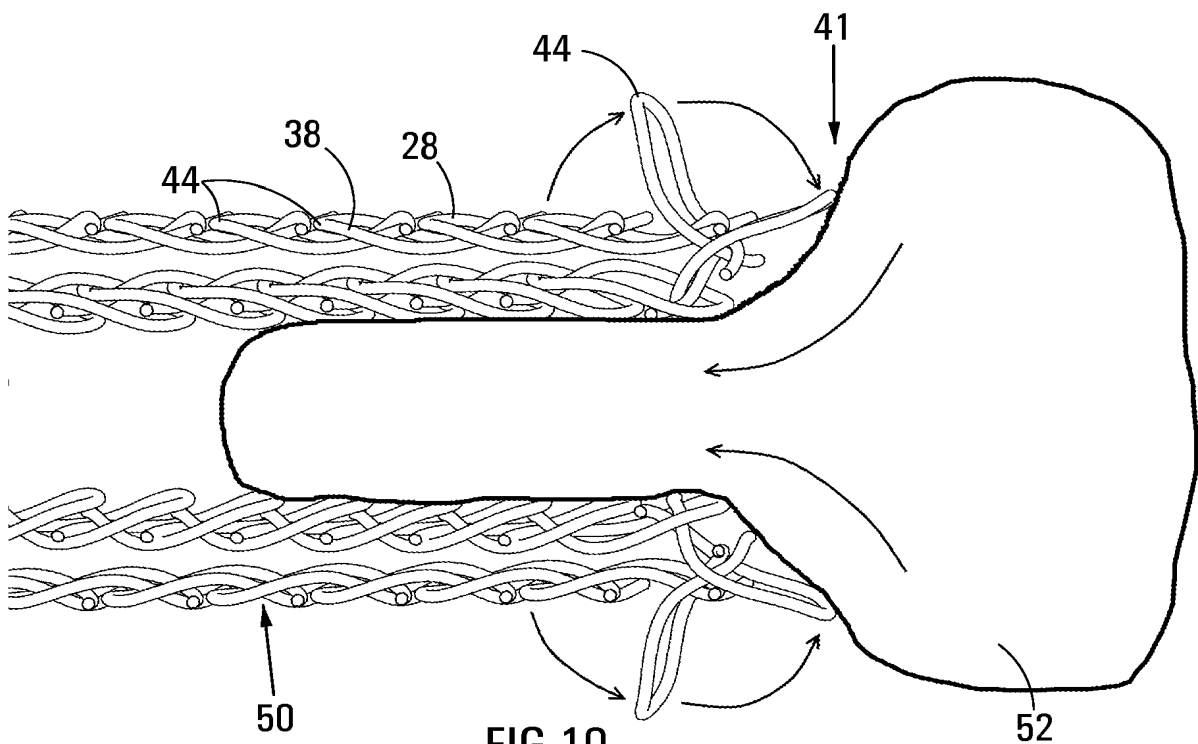
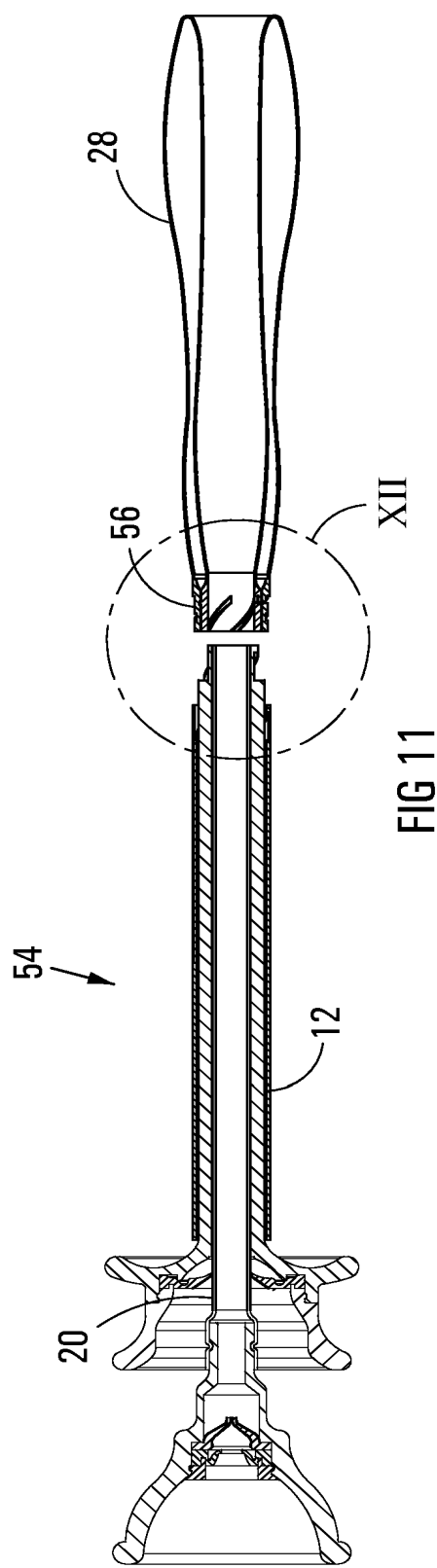
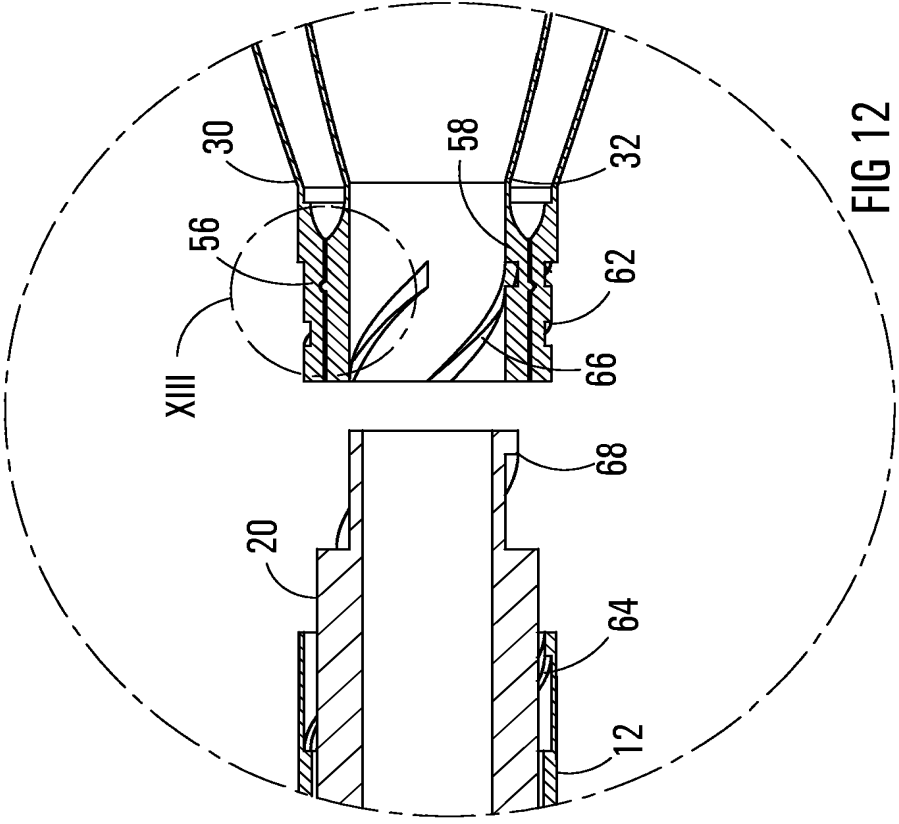
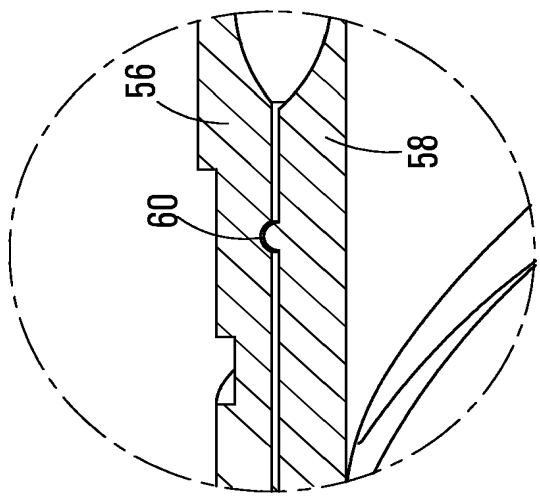


FIG 10



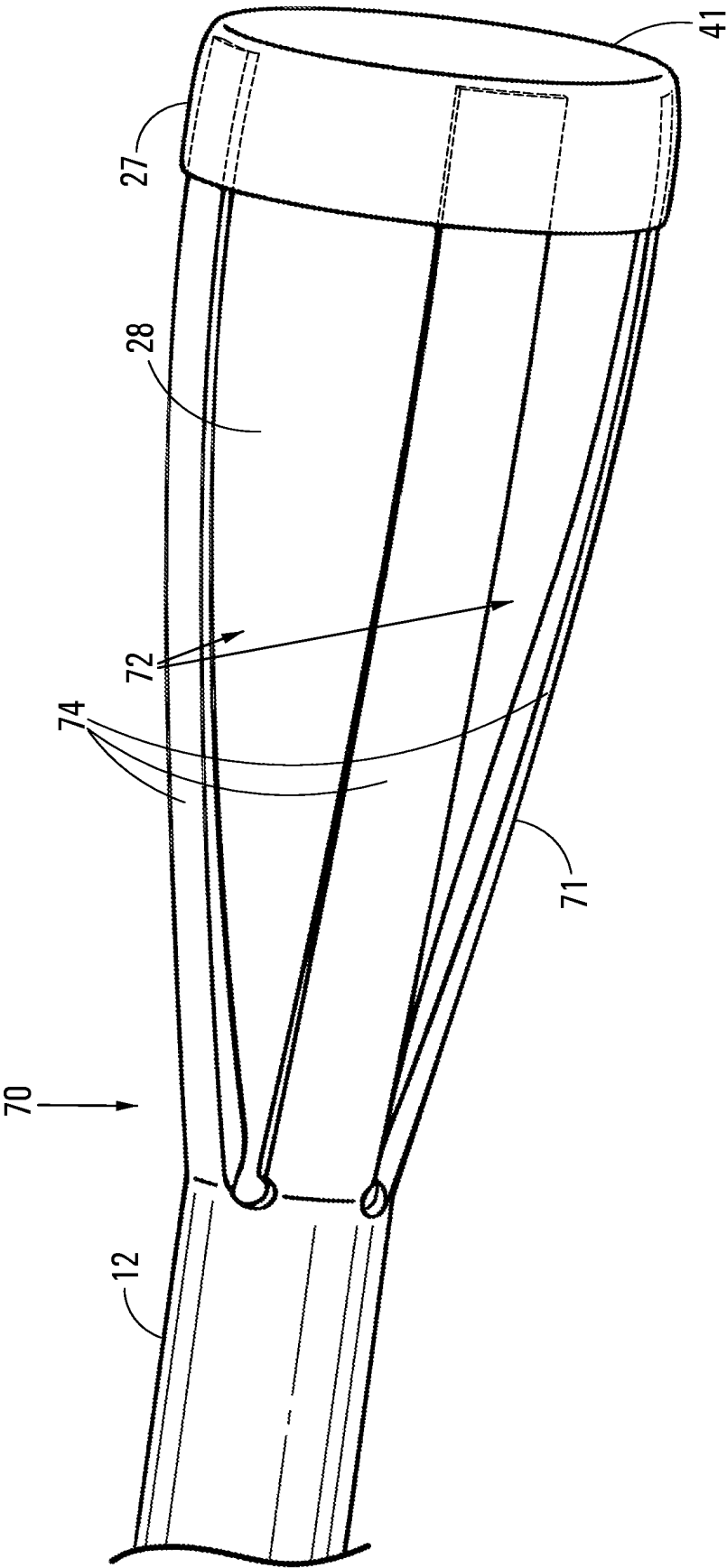


FIG 14

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/054535

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/00 A61B17/22 A61B17/221
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009/086482 A1 (LAZARUS EFFECT INC [US]; MARTIN BRIAN B [US]; FOLLMER BRETT [US]; AGUI) 9 July 2009 (2009-07-09)	1-13,16, 17,21, 29-39
Y	figures 13A,13B paragraph [0159] - paragraph [0162] -----	18
X	US 2010/137846 A1 (DESAI RUPESH [US] ET AL) 3 June 2010 (2010-06-03)	1,7-13, 16,17,21
Y	figures 1-5 ----- US 2010/249815 A1 (JANTZEN ALEXANDRA E [US] ET AL) 30 September 2010 (2010-09-30)	18
	figures 1-5 -----	



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

25 January 2012

Date of mailing of the international search report

20/03/2012

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2011/054535

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 41-43
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☒ Claims Nos.: 40
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-13, 16-18, 21, 29-39

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-13, 16-18, 21, 29-39

A gripping device providing specific ratios of the inverted / everted length and the average relaxed outer diameter of the inverted length for which the respective length has sufficient stiffness to cause eversion / inversion (see claims 2 to 4 and 29), or in which the inversible tubular member is retractable into the outer tubular member (claim 18). These features allow a more secure and complete gripping of objects having a diameter of about the average relaxed outer diameter of the inverted length.

2. claims: 14, 15

A gripping device including a membrane over the inner or outer surface of the inversible tubular member in the the everted condition (claims 14, 15)

3. claims: 19, 20, 22

A gripping device providing a sealing between the an outer tubular member and an inner elongate member of the actuation means, or of the longitudinal passage of the inner elongate member (claims 19, 20, 22) to enable use of the device in laparoscopic procedures.

4. claims: 23-28

A gripping device wherein the inversible tubular member is releasably engageable with the distal ends of the outer tubular member and the inner elongate member (claims 24), or wherein the dital end portion of the outer tubular member is radially expandable (claim 26). Thereby the device is capable to grip objects substantially larger than the outer diameter of the outer tubular member.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 41-43

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

Continuation of Box II.2

Claims Nos.: 40

Present claim 40 relates to a product defined by reference to a process of manufacturing it. In the present context this is considered to lead to a lack of clarity because the claim does not clearly identify the structural features encompassed by the manufacturing steps defined. This makes it impossible to compare the claim to the prior art. As a result, the application does not comply with the requirement of clarity under Article 6 PCT.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2011/054535

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		JP 2011508635 A	17-03-2011
		US 2009299393 A1	03-12-2009
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US 2010137846 A1	03-06-2010	EP 2355717 A1	17-08-2011
		US 2010137846 A1	03-06-2010
		WO 2010065556 A1	10-06-2010

US 2010249815 A1	30-09-2010	NONE	

(12) UK Patent

(19) GB

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(56) Documents Cited:
US 20100249815 A1

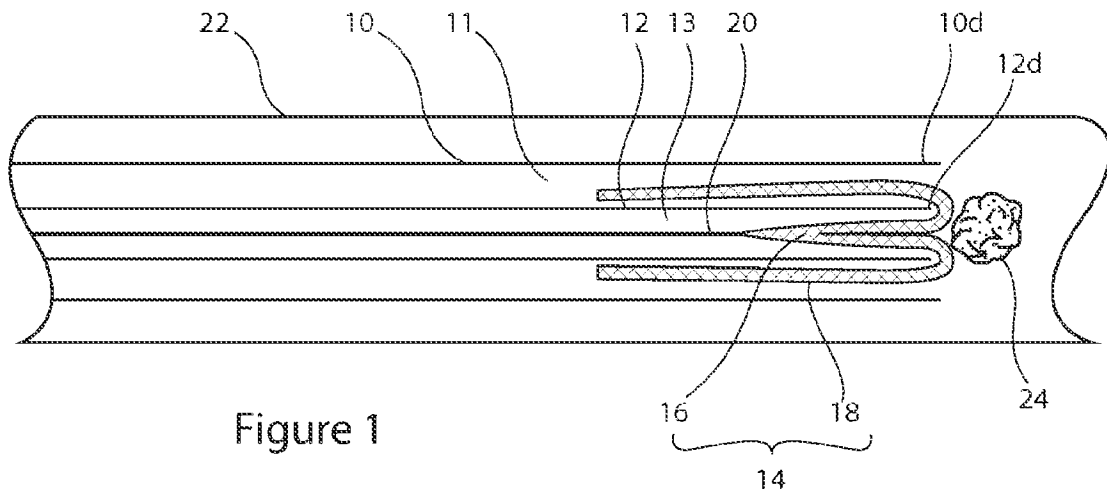
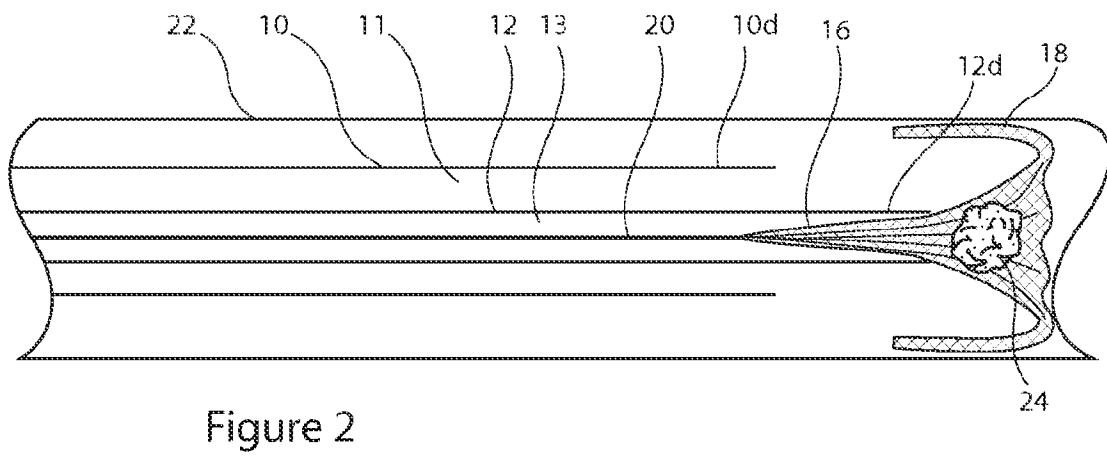
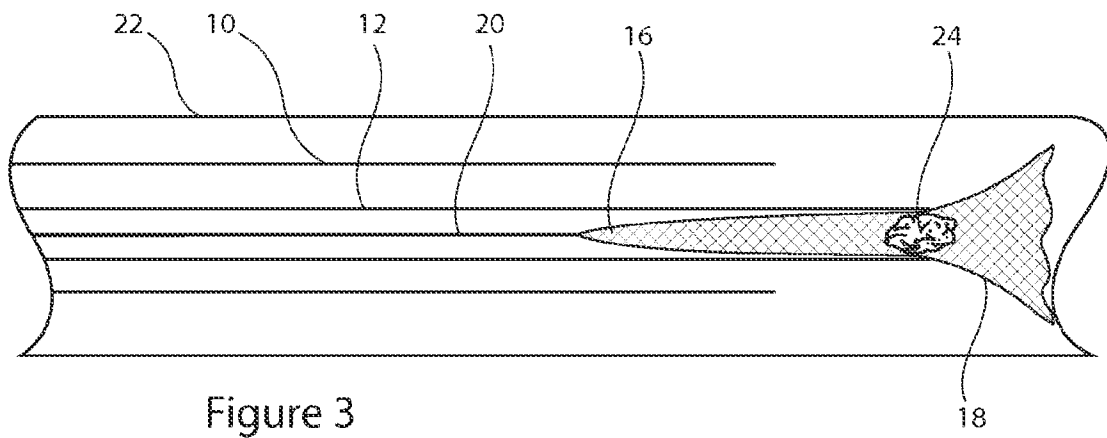
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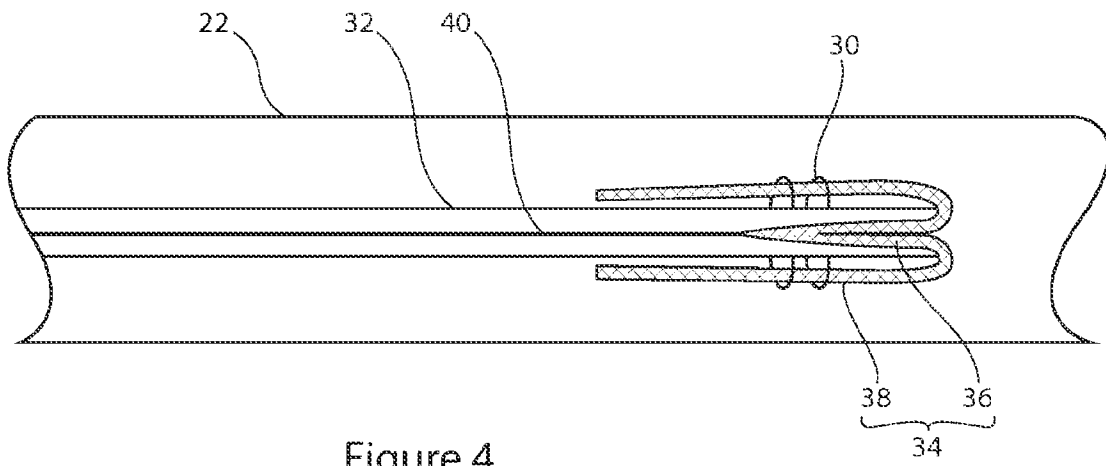
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OBJECT CAPTURE DEVICE

DescriptionTechnical Field

The present invention relates to an object capture device as well as to
5 a method of capturing objects from a body lumen, particularly for the capture of
thrombi in a patient's vasculature.

Background Art

It is known that material may form or build up in vessels of the
10 circulatory system; such material may seriously compromise the health of the
patient. For example, thrombi or blood clots may form and may partially or
completely occlude a blood vessel, decreasing or even completely cutting off
blood flow through the vessel. The thrombus may adhere to the vessel wall or
may be dislodged, becoming free floating in the vessel. A free floating thrombus,
15 also known as an embolus, may travel along a vessel and eventually cause a
blockage in a distant part of the body, such as the heart or the brain, with
potentially lethal consequences.

Various devices are known for capturing and removing thrombi and
other objects from a patient's blood system. Such devices typically involve the
20 use of a plurality of different tools which are deployed in different stages of the
capture and removal procedure. For example, a first medical device may be
introduced to break the thrombus into pieces so as to prevent it from blocking a
vessel. However, breaking the thrombus into pieces can be harmful to the patient
as dislodged parts may travel through the circulatory system and eventually block
25 another vessel elsewhere. In order to avoid this, blocking and/or suction means
are required to ensure that the dislodged parts are safely collected. For example,
a filter may be positioned distal of the thrombus so as to catch the dislodged parts
after the thrombus has been broken up by the first medical device. The material
trapped by the filter can remain in place until removed using yet further apparatus

such as an aspirator. Various prior art thrombus capturing devices are disclosed in US2010/0249815, US 7,621,870, US 2007/0149996 and US 7,780,696.

Disclosure of the Invention

5 The present invention seeks to provide an improved object capture device and method, particularly for removing objects such as thrombi from a patient's vasculature.

 The preferred embodiment provides a single tool for capturing and removing thrombi. This tool can be used in a single stage, thus facilitating the
10 medical procedure quickly and easily. There is also disclosed a method for capturing and removing thrombi. In particular the invention provides a mechanism for pulling a thrombus away from a vessel wall. The device comprises an object collecting member, hereinafter referred to as a basket.

 According to an aspect of the present invention there is provided a
15 medical device for collecting objects from a body vessel, including: a catheter provided with a proximal end, a distal end and a lumen therethrough; an elongate basket provided with a closed first end and an open second end; and an actuator connected to the closed first end of the basket and extending through the lumen of the catheter to the proximal end of the catheter; wherein the catheter and the
20 basket are movable relative to one another between a first configuration in which the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over the first end of the basket, and a second configuration in which the first end of the basket is withdrawn into the catheter and the everted second end is at least
25 partially inverted; and wherein, the medical device is operable so as to relatively move the catheter and the basket from said first configuration to said second configuration, said movement in use causing objects in a body vessel to be drawn into the basket.

 The second end may be constrained in the first position and free from
30 attachment or constraint in the second position.

The actuator may be, for example, a wire, rod or cable, hereinafter referred to as a wire.

In the second configuration at least part of the second end of the basket may be withdrawn into the catheter.

5 Also described is a medical device for collecting objects from a body vessel, including: a catheter provided with a proximal end, a distal end and a lumen therethrough; an elongate basket provided with a first end and a second end; and an actuator connected to the first end of the basket and extending through the lumen of the catheter to the proximal end of the catheter; wherein the catheter and the basket
10 are movable relative to one another between a first configuration in which the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over the first end of the basket, the second end being constrained in position, and a second configuration in which the first end is withdrawn into the catheter and the everted second end is at
15 least partially inverted, the second end being free from constraint; and wherein, the medical device is operable so as to release the second end from constraint, and move the catheter and the basket from said first configuration to said second configuration, said movement in use causing objects in a body vessel to be drawn into the basket.

20 The basket may be provided with a closed first end and an open second end. By providing a basket having a closed first end, the basket is able to pull, as if sucking, an object such as a thrombus into the basket.

Preferably the basket is made of spring steel, or shape memory material such as, for example, Nitinol, hereinafter referred to as shape memory material. Where
25 the remembered shape is a generally tubular basket, on release of the second end of the basket the basket may spring radially outwardly and distally of the catheter to surround a thrombus. By providing a rolling basket which rolls outwardly during its deployment so as to position itself between a thrombus and the vessel wall in which the thrombus lies, the basket may surround

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the thrombus such that when the basket is withdrawn into the catheter the thrombus is withdrawn into the basket.

The everted portion of the basket may scrape against the vessel wall thus dragging any plaque or thrombus adhered thereto into the basket as the basket is reverted or inverted by withdrawal of the member into the catheter. As the basket
5 is withdrawn into the catheter a pulling or suction effect is created, pulling an end of the thrombus or other object or material into the basket and pulling the rest of the thrombus through the vessel towards the catheter so that it too can be captured by the basket. The pulling or suction effect may be best achieved when
10 the basket is positioned up against the object in the vessel before pulling the basket into the catheter.

The actuator may be actuatable so as to draw the basket into the catheter and so move the catheter and the basket from said first configuration to said second configuration. The medical device may be operable so as to advance
15 the catheter over the basket and so move the catheter and the basket from said first configuration to said second configuration. The medical device may be operable so as to advance the catheter over the basket and so as to draw the basket into the catheter. Thus the basket may be withdrawn into the catheter and the catheter may be advanced over the basket at the same time. In use the
20 movement between the catheter and the basket may cause objects in a body lumen to be drawn into the basket.

In the second configuration the first end and substantially the whole of the second end of the basket may be withdrawn into the catheter. If the thrombus is appropriately sized, the basket containing the thrombus may be withdrawn
25 through the catheter lumen and out of the patient.

The thrombus may be broken down in the patient's lumen by a lytic agent, before being removed from the patient. The lytic agent may be delivered to the site of the thrombus through the catheter lumen, or through a lumen external to the catheter, for example through a lumen in an outer sheath.

30 The basket can, in the first configuration, have a first end inside the catheter and second end everted over the distal end of the catheter. In the first

configuration the second end of the basket may extend radially out of the catheter and be everted over the first end of the basket and over the distal end of the catheter.

The basket may be made from wire or filamentary material. The basket
5 may be made from braided material such as braided wire. The braiding of the basket may be tight. In other words the wires may be packed closely together, such that the spaces between the wires, if any, are small. The wires may be tightly braided so as to prevent bodily fluid such as blood from passing through the basket. For example the basket may be similar to that found in a flow diverter.
10 The basket may have an impermeable covering to prevent fluid from passing through the basket.

The basket may be constructed so as to allow fluid to pass through the closed first end of the basket. For example the basket may comprise apertures through which fluid can pass. However, the closed first end of the basket may
15 prevent captured objects, such as fibres from a thrombus, from passing through.

The basket may be sized so as to collect a substantially entire thrombus or other object or material. Thrombi can be very large. As such the second end of the basket may be, for example from approximately 10 mm to 200mm in length.

The medical device may comprise an outer catheter, also known as an
20 outer sheath. The outer sheath may be provided with a proximal and a distal end and a lumen therethrough. The catheter may be disposed within the lumen of the outer catheter, thereby to be configured as an inner catheter. An annular space may be provided between the inner and the outer catheters. Where an outer catheter is provided, the second end of the basket may be located in the annular
25 space between the inner and outer catheters in the first configuration, so as to constrain the second end during delivery.

The inner and outer catheters may be moveable relative to one another so as to release the second end of the basket from between the outer catheter and the inner catheter. The second end of the basket may be free from constraint in
30 the second configuration. The second end of the basket may be free from attachment in both the first and second configurations.

The second end may be attached to the catheter in the first configuration. Such attachment may be with ties. The ties may be releasable using a trigger wire, for example.

Where the basket is made of shape memory material, releasing the second end may allow the basket to assume its memory shape.

Also described is a method of collecting objects from a body vessel, including: providing a medical device comprising a catheter provided with proximal end, a distal end and a lumen therethrough, and an elongate basket provided with a closed first end and an open second end; and an actuator connected to the closed first end of the basket and extending through the lumen of the catheter to the proximal end of the catheter; wherein the catheter and the basket are moveable relative to one another between a first configuration and a second configuration, wherein in the first configuration the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over the first end of the basket, and in the second configuration the first end of the basket is withdrawn into the catheter and the everted second end is at least partially inverted; inserting the medical device into a body vessel; and operating the medical device so as to move the catheter and the basket from said first configuration to said second configuration thereby causing objects in a body vessel to be drawn into the basket.

The method may comprise the step of withdrawing the medical device from the body lumen, the medical device containing objects from the body vessel. In particular the basket may contain objects from the body vessel. The object containing portion of the basket may be contained within the catheter.

Where the medical device comprises an outer sheath, and where the second of the basket is held between the sheath and the inner catheter, the method may comprise the step of withdrawing the outer sheath so as to release the basket. After operating the medical device so as to capture a thrombus or other object or material in the basket, the method may comprise advancing the outer

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sheath distally relative to the catheter and basket, such that the outer sheath surrounds an object containing portion of the basket, before removing the device from the patient's lumen. In this case the object containing portion of the basket may be contained within the outer sheath. Where the second end of the basket is held in the first position by ties, for example, the method may comprise the step of releasing the ties so as to release the basket.

The device described may be in the first configuration whilst tracking through the vasculature. On reaching a location proximate to the thrombus or other object, the site of interest, the device may be activated so as to move to the second configuration.

Also described is a method of collecting objects from a body vessel, including: providing a medical device for collecting objects from a body vessel, the medical device including: a catheter provided with a proximal end, a distal end and a lumen therethrough; an elongate basket provided with a first end and a second end; and a wire connected to the basket and extending through the lumen of the catheter to the proximal end of the catheter; wherein the catheter and the basket are movable relative to one another between a first configuration in which the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over the first end of the basket, the second end being constrained in position, and a second configuration in which the first end is withdrawn into the catheter and the second end is at least partially inverted, the second end being free from constraint; inserting the medical device into a body vessel; and operating the medical device so as to release the second end from constraint, and so as to move the catheter and the basket from said first configuration to said second configuration, such that an object in a body vessel is drawn into the basket.

Brief Description of the Drawings

Embodiments of the present invention are described below, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 shows an embodiment of a medical device for collecting objects from a body lumen, the medical device comprising a catheter and a basket arranged in a first configuration;

Figure 2 shows the medical device of Figure 1 after the outer sheath
5 has been withdrawn from around the basket;

Figure 3 shows the medical device of Figures 1 and 2, the catheter and the basket arranged in the second configuration; and

Figure 4 shows another embodiment of a medical device for collecting objects from a body lumen.

10

Description of the Preferred Embodiments

Referring to Figure 1, there is shown in schematic form an embodiment of a medical device for collecting objects from a body lumen 22. The medical device is shown inside a patient's vessel 22; within which there is also a thrombus
15 24. The medical device comprises an outer catheter 10 disposed concentrically around an inner catheter 12, and an object collecting member 14, hereafter called a basket 14.

The inner 12 and outer 10 catheters are in the form of elongate tubes having proximal (not shown) and distal 10d,12d ends. In use the distal ends
20 10d,12d of the catheters are positioned proximate the thrombus or object or material to be removed and the proximal ends are outside of the patient. The outer catheter 10 comprises a lumen in which the inner catheter 12 is disposed. The catheters are arranged such that an annular gap 11 is provided between the inner 12 and outer 10 catheters. The inner catheter 12 also comprises a lumen
25 13, into which the basket 14 may be withdrawn.

The basket comprises a first end portion 16 and a second end portion 18. The first end portion 16 of the basket 14 is connected to an actuator wire 20. The wire 20 is disposed inside the lumen of the inner catheter 12 and extends through the lumen to an actuating portion of the medical device which in use is
30 external to the patient's body. The first end portion 16 of the basket 14 is, in a first configuration, housed within the lumen of the inner catheter 12. The basket

14 extends, from the first end portion 16, out of the end of the inner catheter 12 and is everted so as to extend backwardly over itself around the inner catheter and inside the outer catheter 10 such that the second end portion 18 of the basket 14 is housed in the annular gap 11 between the inner catheter 12 and the outer catheter 10.

In this case the distal ends of the catheters are aligned with one another and are positioned such that the basket abuts the thrombus 24. The basket surrounds part of the thrombus when it is moved up against the thrombus, giving it a grip on the thrombus and thus aiding withdrawal/pulling of the thrombus into the basket when the device is used.

The basket 14 comprises a braided wire basket made of shape memory material, or of spring steel, for example. Such a basket may be flexible so as to fit around thrombi of various shapes and sizes, and so as to be able to be withdrawn into the narrow lumen of the inner catheter. The braiding of the basket is tight, such that the spaces between the wires, if any, are small. It is not necessary for the basket to allow blood or other fluid to pass through it. The thrombus removal process may be carried out very quickly and as such preventing blood flow through the vessel whilst the procedure is carried out does not harm the patient.

Figure 2 shows the medical device of Figure 1 after the outer catheter 10 has been withdrawn relative to the inner catheter 12. The outer catheter is provided so as to cover the basket and prevent it from springing open during introduction of the device. Once the outer catheter has been withdrawn the second end portion 18 of the basket 14 is no longer constricted and is able to spring open outwardly. The basket opens until it comes into contact with the internal walls of the vessel, scraping along the sides of the lumen so as to surround the thrombus 24. The second end portion 18 of the basket 14 remains everted, backwards over itself, and contacts the sides of the vessel 22.

Figure 3 shows the medical device of Figures 1 and 2 in a second configuration, in which the first end portion 16 of the basket 14 and part of the second end portion 18 are withdrawn into the inner catheter 12 such that the basket 14, and the thrombus 24 inside it, is substantially contained within the

inner lumen 12. The basket 14 can be from 10 to 200mm long, depending on the length and size of the material/thrombus to be captured. The basket 14 is designed to be long enough to trap the entirety of the thrombus. In particular, the everted second portion 18 of the basket 14 is designed to be long enough to trap the entirety of the thrombus. In one mode movement of the basket 14, from the first configuration shown in Figure 1 to the second configuration shown in Figure 3, is actuated by pulling on the actuating element 20. By pulling back on the actuating element 20 the second end portion 18, the open end of the basket, is pulled into the distal end 12d of the inner catheter 12. This action causes the second end portion 18 of the basket to roll inwardly, thus drawing, as if pulling or sucking, the thrombus into the closing basket. The thrombus is thus trapped bit-by-bit in the basket and withdrawn into the inner catheter 12. As a result of the relative movement between the inner catheter 12 and the basket 14 from the first configuration to the second configuration the thrombus 24 is thus drawn into the inner catheter 12, inside the basket 14.

Where the thrombus is small enough to be withdrawn through the lumen of the inner catheter continued retraction of the actuating element 20 allows withdrawal of the basket, in which the thrombus is held, through the lumen 13 of the inner catheter 12. The basket 14 containing the thrombus 24 may thus be completely removed from the patient's vessel through the lumen 13 of the inner catheter 12. As such this embodiment provides a single tool which is used in a single stage to remove the thrombus from a patient's vessel.

Where the thrombus is too large to be pulled into the lumen of the inner catheter, the outer catheter or sheath may be advanced over the thrombus. In this manner the thrombus can be held within the basket and also within the outer catheter so that it can then be removed from the patient.

In some instances, instead of pulling back on the actuator wire 20, the inner catheter 12 may be advanced over the basket 14. This movement from the first configuration to the second configuration will have the same effect of withdrawing the basket 14 into the inner catheter 12.

The apparatus may be operated by advancing the inner catheter 12 over the basket 14 as the actuator wire 20 is basket 14 withdrawn into the catheter 12. A combination of the two movements may be performed together so that as the basket 14 is withdrawn in the catheter 12 the catheter is also advanced over the basket.

5 Figure 4 shows another embodiment of a medical device for collecting objects from a body vessel. The medical device comprises an inner catheter 32, and a basket 34 having first 36 and second 38 end portions.

10 In this device ties 30 are provided to secure the second end portion 38 of the basket 34 in its everted position around the outside of the inner catheter 32. In this embodiment the outer catheter is not required to secure the basket 34 in its first configuration. Trigger wires (not shown) may be used to release the ties 30 so as to enable the basket to open outwardly as a result of its shape memory characteristics, and to be withdrawn into the inner catheter 32. An outer catheter (not shown) may be provided for use in delivery of the medical device to a location adjacent a thrombus inside a vessel.

15 It is to be understood that the different features of the various embodiments described herein can be combined together; as such the features described in the dependent claims may be combined with the embodiments described in each of the independent claims.

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CLAIMS

1. A medical device for collecting objects from a body vessel, including:
a catheter provided with a proximal end, a distal end and a lumen therethrough;
an elongate basket provided with a closed first end and an open second end;
and
an actuator connected to the closed first end of the basket and extending through the lumen of the catheter to the proximal end of the catheter;
wherein the catheter and the basket are movable relative to one another between a first configuration in which the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over at least part of the first end of the basket, and a second configuration in which the first end is withdrawn into the catheter and the everted second end is at least partially inverted; and
wherein, the medical device is operable so as to move the catheter and the basket from said first configuration to said second configuration, said movement in use causing objects in a body vessel to be drawn into the basket.
2. A medical device according to claim 1, wherein the basket is made of shape memory material.
3. A medical device according to claim 1, wherein the basket is made of wire or filamentary material.
4. A medical device according to claim 3, wherein the basket is made of braided wire or filamentary material.
5. A medical device according to claim 4, wherein the wire or filamentary material is tightly braided so as to prevent fluid from passing through the basket.

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6. A medical device according to claim 5, wherein the basket has an impermeable covering.
7. A medical device according to claim 1, wherein the actuator is a wire.
8. A medical device according to claim 1, wherein the basket comprises apertures sized to allow fluid to pass through the closed first end of the basket but prevent the captured objects from passing therethrough.
9. A medical device according to claim 1, wherein the actuator is actuatable so as to draw the basket into the catheter and so move the catheter and the basket from said first configuration to said second configuration.
10. A medical device according to claim 1 wherein, the medical device is operable so as to advance the catheter over the basket and so move the catheter and the basket from said first configuration to said second configuration.
11. A medical device according to claim 1, wherein in the second configuration the first end and substantially the whole of the second end of the basket may be withdrawn into the catheter.
12. A medical device according to claim 1 wherein the basket is from 10 to 200mm in length.
13. A medical device according to claim 1 wherein the second end is constrained in the first position and free from constraint in the second position.
14. A medical device according to claim 1 comprising an outer sheath provided with a proximal and a distal end and a lumen therethrough, wherein the catheter is disposed within the lumen of the outer sheath, thereby to be configured as an inner catheter, an annular space being provided between the inner catheter and the outer

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sheath, and wherein in said first configuration the second end of the basket is located in the annular space between the inner catheter and outer sheath.

15. A medical device according to claim 14 wherein the second end of the basket is free from attachment and wherein the inner catheter and outer sheath are moveable relative to one another so as to release the second end of the basket from between the outer sheath and the inner catheter.

16. A medical device according to claim 13 wherein, the medical device is operable so as to release the second end from constraint.

17. A medical device according to claim 16, wherein the basket is made of shape memory material, said material having a memory shape, and wherein releasing the second end portion allows the basket to assume its memory shape.

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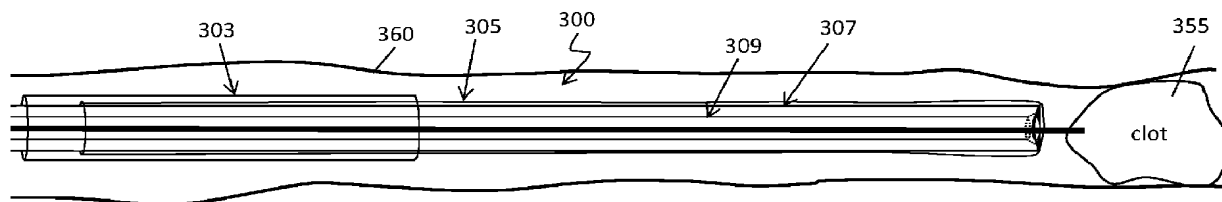


FIG. 3A

(57) Abstract: Mechanical thrombectomy apparatuses including an inverting, rolling conveyor region ("tractor") at the distal end that are configured to grab and remove thrombus material. In particular, described herein are mechanical thrombectomy apparatuses that are adapted to prevent premature deployment of the tractor, e.g., by including a tractor hold (e.g., a housing, a lock, a clamp, etc.) or the like to secure the outer end of the tractor against and/or relative to the elongate inversion support.

PRE-LOADED INVERTING TRACTOR THROMBECTOMY APPARATUSES AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims priority to U.S. provisional patent application no. 62/327,024, filed on April 25, 2016 and titled “DOZER THROMBECTOMY SYSTEM”; U.S. provisional patent application no. 62/345,152, filed on June 3, 2016, and titled “DOZER THROMBECTOMY SYSTEM 2”; and U.S. provisional patent application no. 62/357,677, filed on July 1, 2016, and titled “DOZER THROMBECTOMY SYSTEM 3”.

[0002] This patent application may be related to U.S. patent application no 15/291,015, filed on October 11, 2016, titled “MECHANICAL THROMBECTOMY APPARATUSES AND METHODS”, which is a continuation of U.S. Patent Application No. 15/043,996, filed February 15, 2016, now U.S. 9,463,035, which claims priority to each of the following provisional patent applications: U.S. Provisional Patent Application No. 62/284,300, filed September 28, 2015; U.S. Provisional Patent Application No. 62/284,752, filed October 8, 2015; and U.S. Provisional Patent Application No. 62/245,560, filed October 23, 2015.

[0003] Each of these patents and patent applications is herein incorporated by reference in its entirety.

INCORPORATION BY REFERENCE

[0004] All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

[0005] The apparatuses and methods described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses and methods.

BACKGROUND

[0006] It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue from within a vasculature, such as blood clots, may improve patient conditions and quality of life.

[0007] Many vascular system problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery.

[0008] When a thrombus forms, it may effectively stop the flow of blood through the zone of formation. If the thrombus extends across the interior diameter of an artery, it may cut off the flow of blood through the artery. If one of the coronary arteries is 100% thrombosed, the flow of blood is stopped in that artery, resulting in a shortage of oxygen carrying red blood cells, e.g., to supply the muscle (myocardium) of the heart wall. Such a thrombosis is unnecessary to prevent loss of blood but can be undesirably triggered within an artery by damage to the arterial wall from atherosclerotic disease. Thus, the underlying disease of atherosclerosis may not cause acute oxygen deficiency (ischemia) but can trigger acute ischemia via induced thrombosis. Similarly, thrombosis of one of the carotid arteries can lead to stroke because of insufficient oxygen supply to vital nerve centers in the cranium. Oxygen deficiency reduces or prohibits muscular activity, can cause chest pain (angina pectoris), and can lead to death of myocardium which permanently disables the heart to some extent. If the myocardial cell death is extensive, the heart will be unable to pump sufficient blood to supply the body's life sustaining needs. The extent of ischemia is affected by many factors, including the existence of collateral blood vessels and flow which can provide the necessary oxygen.

[0009] Clinical data indicates that clot removal may be beneficial or even necessary to improve outcomes. For example, in the peripheral vasculature, interventions and procedures can reduce the need for an amputation by 80 percent. The ultimate goal of any modality to treat these conditions of the arterial or venous system is to remove the blockage or restore patency, quickly, safely, and cost effectively. This may be achieved by thrombus dissolution, fragmentation, thrombus aspiration or a combination of these methods.

[00010] Mechanical thrombectomy devices may be particularly advantageous. Depending on the size, location and extent of a clot, it may also be particularly advantageous to

mechanical retrieve and break apart the clot in a manner that is both safe and effective. There is a definite need for a thrombectomy device, and particularly a mechanical thrombectomy device that can be more effective in removing tissue such as clots from within a body. Described herein are apparatuses (devices, systems and kit) and methods of using them that may address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[00011] Described herein are mechanical thrombectomy apparatuses (devices, methods, systems, etc.) that include a distal inverting tube of highly flexible material, referred to herein as a tractor, that is pulled to continuously invert over a distal opening, such as the distal end of a catheter or annulus, in a rolling manner. This rolling can be used, alone or on conjunction with a vacuum or mechanical thrombus (e.g., “clot”) grabber, to grab, capture and remove a clot from a vessel. As mentioned, the tractor may be formed of a material having many openings and may therefore be flexible, and loose, and may be biased so as to flare open within the vessel when deployed. Prior to positioning the apparatus for grabbing the clot, it may be particularly desirable to prevent the tractor from deploying (e.g., sliding axially axially, expanding, etc.) so as to allow accurate tracking within the body as well as to ensure reliable operation of the device. Thus, it may be helpful to pin or hold the tractor, and particularly the end of the tractor that has not been inverted (e.g., within a catheter and/or within the tractor itself) prior to deployment. However, holding or and/or retaining the tractor prior to deployment must be properly balanced. If too much force is required to deploy the tractor, the force may cause the apparatus to kink, collapse, and/or jam. If the tractor can be deployed with too little force may deploy prematurely. Further, since the apparatus is likely to be used in highly tortuous vessels of the body, including arteries such as the internal carotid artery, it must be retained in a manner that does not inhibit overall flexibility of the device, or trigger premature release when navigating through the vessels.

[00012] In general, an inverting tractor apparatus may include a tractor (e.g., tractor region, tractor portion, etc.) comprising a flexible tube of material that inverts as it rolls over itself at a distal end. The inverting/rolling portion may be performed over an annulus that may be separately maneuvered relative to the tractor; the annulus may be part of a catheter (e.g., the distal end of a catheter) or may be attached to a wire or other element having sufficient column strength to prevent the annulus (distal opening) over which the tractor is inverting from being collapsed or pulled proximally as the tractor is rolled.

[00013] In operation, the tractor inverts and may roll back into itself. When an outer catheter is used, the tractor may be drawn into the catheter. The annulus about which the tractor inverts at the distal end region of the apparatus is supported by a structure (e.g., rod, hypotube, catheter) that typically is more rigid (has a much larger column strength) than the tractor. Thus, as the tractor rolls, it produces a conveyor-like motion as a formerly outward-facing tractor region rolls around to become an inward-facing region within the lumen of the tractor and/or within the lumen of the catheter. This conveyor or rolling motion may draw a clot (or other object) from a vessel into the catheter.

[00014] The mechanical thrombectomy apparatuses described herein include pre-loaded inverting tractor thrombectomy apparatuses (e.g., devices, systems, etc.). These apparatuses may be configured to prevent premature release of the tractor. Any of these apparatuses may include, for example, a tractor hold that prevents the end of the tractor that is “outside” of the inner lumen from sliding axially and inverting until deployment. The tractor hold may include a housing, and particularly a housing extends only a slight distance proximally (therefor preventing increasing the stiffness of the apparatus or otherwise inhibiting maneuverability/tracking). The tractor hold may include hydrophobic and/or hydrophilic surfaces, e.g., coatings, on the outside end region of the tractor and/or the outer portion of a catheter over which the tractor rolls; these hydrophobic/hydrophilic surfaces may be arranged in a pattern. Any of the tractor holds described herein may include a releasable attachment, such as an adhesive, a mechanical attachment such as a clamp or interference region or the like. Any of the tractor holds may include a pair of engaging portions, such as a stop or hold (e.g., a tractor hold or stop element on the catheter) and a lock (e.g., a tractor lock, such as a ring on the end region of the tractor).

[00015] As mentioned, any of these apparatuses may include an inverting annulus that may be part of an elongate member having sufficient column strength to resist collapsing or deflecting when the tractor is pulled proximally through the annulus to roll over and invert. The annulus may be the distal end of a catheter, or a portion of a catheter, or it may be a ring or cylindrical region to which an elongate support (e.g., wire, rod, hypotube, or any combination of these, including concentric or sequential arrangements). The annulus is typically a ring-shaped opening (the opening of which may be any shape, including but not limited to round, oval, triangular, square, rectangular, etc.), over which the tractor is inverted, and this annulus is typically connected to an elongate supporting member. The annulus may be integral with the elongate supporting member. The annulus and elongate support member may together be referred to as an elongate inversion support. As mentioned this elongate

inversion support may generically be referred to herein as a catheter, which may include a tube, rod, hypotube, wire, shaft, etc. having an annulus or distal end opening over which the tractor is inverted so that the tractor rolls over the distal end opening (annulus) when an end of the tractor that is more radially positioned in the apparatus is pulled proximally. Also described herein are a variety of elongate inversion supports (e.g., catheters), as the shape (e.g., outer diameter) of the inverting support may affect the retention of the tractor prior to deployment.

[00016] For example, described herein are mechanical thrombectomy apparatuses for removing a clot from a vessel that include: an elongate inversion support (e.g., a catheter) having a proximal end and a distal end and a distal annulus (e.g., distal end opening); a tractor comprising a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter; a puller coupled to first end of the tractor, wherein the puller extends within the catheter to the proximal end of the catheter; and a tractor hold attached to an outer diameter of the catheter proximal to the distal end of the catheter, wherein the tractor hold secures a second end of the tractor that extends over the distal end of the catheter until a force greater than a threshold force is applied by pulling the first of the tractor proximally within the catheter. Any of these apparatuses may include a guidewire lumen extending through the catheter, the puller and the tractor, and configured to pass a guidewire.

[00017] In any of these variations, the tractor hold may be a housing. The housing may be a cylinder that is pinned or closed on one (e.g., the proximal) end, leaving an annular opening for the outermost end of the tractor.

[00018] The tractor hold may not extend to the proximal end of the catheter. For example, the tractor hold may extend proximally along the catheter for less than 10 cm (e.g. for less than 9 cm less than 8 cm, less than 7 cm, less than 6 cm, less than 5 cm, etc.).

[00019] In any of these variations, the tractor hold may compress the tractor against the catheter. Typically, the threshold force for the tractor hold is determined by the force required to deploy the tractor within the lumen, which may depend upon the length of the apparatus, the diameter of the tractor and/or catheter, and the materials of the tractor and elongate inversion support (e.g., catheter). For example, the tractor hold may be configured to hold the second end of the tractor until the threshold force is applied, wherein the threshold force is between 50 g force and 2000 g force (e.g., between 50 g of force and 1700 g of force,

between 50 g of force and 1500 g of force, between 40 g of force and 1000 g of force, between 50 g of force and 500 g of force, between 100g of force and 500 g of force, between 200 g of force and 500 g of force, between 250 g of force and 500 g of force, between 50 g of force and 450 g of force, between 100 g of force and 450 g of force, between 100 g of force and 400 g of force, between 200 g of force and 400 g of force, etc.). The range of force appropriate to the threshold force may be important in proper functioning of the apparatus, particularly when the force is applied by pulling proximally on the puller and/or tractor; too little force for the threshold and the tractor will prematurely deploy; too much force and the apparatus will jam (e.g., by kinking the elongate inversion support).

[00020] In any of the variations described herein, the tractor may be biased to collapse and/or expand. For example, the tractor may be biased to collapse over the catheter outer diameter (e.g., the outer diameter of the elongate inversion support, including the distal end of the catheter); such tractors may also be biased to expand after inverting (e.g., within the catheter) over the distal end opening of the elongate inversion support. This arrangement may cause the tractor to form a distal-facing region that flares, trumpet-like, towards a clot distal to the device, which may help in capturing the clot and also may prevent jamming of the tractor. Alternatively or additionally, some or all of the tractor regions may be configured to expand over the outer diameter of the elongate inversion support.

[00021] The proximal end of the tractor hold may be attached to the catheter. The tractor hold may be fixed, fused, or integrally formed with the catheter.

[00022] In any of these variations, the catheter (elongate inversion support) may include comprises a larger outer diameter region and a smaller outer diameter region that is proximal to the larger outer diameter region; the annulus (distal end opening) may be at the distal end of the elongate inversion support. The the tractor hold may secure the tractor at one or more of: over the smaller outer diameter region, and between the larger outer diameter region and the smaller outer diameter region. The outer diameter of the tractor hold may be flush with the larger outer diameter region. The tractor hold may reside in a narrowing (necked) region of the catheter to avoid forming a larger-diameter region. Any of these elongate inversion supports (e.g., catheters) having regions of different diameter may have a gradual (angled) or rapid (e.g., stepped) transition between the larger outer diameter and the smaller outer diameter.

[00023] The tractor hold may comprise one or more of: a polyether block amide, a polyolefin, a polyethylene, a polypropylene, a polyethylene terephthalate (PET), and a Polytetrafluoroethylene (PTFE).

[00024] The apparatus may include a tractor lock on the second end of the tractor, wherein the tractor lock engages with the tractor hold to secure the tractor lock on a proximal side of the tractor hold until the threshold force is applied by pulling the first of the tractor proximally within the catheter. For example, the tractor lock may be a ring affixed to the end region of the tractor. The tractor lock may be a band configured to slide over the outer diameter of the catheter. The tractor hold may be a projection extending from the outer diameter of the catheter. Either or both the tractor lock and tractor hold may be elastic (e.g., compliant, rubbery, etc.) so that pulling above the threshold deployment force may cause the tractor tractor lock to release from the tractor hold.

[00025] For example, described herein are mechanical thrombectomy apparatuses for removing a clot from a vessel, the apparatus comprising: a catheter having a proximal end and a distal end and a distal end opening, wherein the catheter comprises a larger outer diameter region and a smaller outer diameter region that is proximal to the larger outer diameter region; a tractor comprising a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter; a puller coupled to first end of the tractor, wherein the puller extends within the catheter to the proximal end of the catheter; and a tractor hold on an outer diameter of the catheter proximal to the distal end of the catheter, wherein the tractor hold secures a second end of the tractor that extends over the distal end of the catheter until a force greater than a threshold force is applied by pulling the first of the tractor proximally within the catheter, further wherein the tractor hold secures the tractor at one or more of: over the smaller outer diameter region, and between the larger outer diameter region and the smaller outer diameter region.

[00026] Also described herein are methods of removing a clot using a mechanical thrombectomy apparatus. These methods may include: positioning a distal end of the mechanical thrombectomy apparatus adjacent to a clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter; disengaging a second end of the tractor from a tractor hold that secures the second end of the tractor to an outer diameter of the catheter by applying a first force that is greater than a threshold force (threshold deployment force) to the first end of the tractor; pulling the distal end of the tractor proximally within the catheter to

roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter; and drawing the clot into the catheter with the inverting tractor.

[00027] Disengaging the second end of the tractor from the tractor hold may include disengaging the second end of the tractor from a tractor hold that is attached to an outer diameter of the catheter. For example, disengaging the second end of the tractor from the tractor hold may comprise disengaging the second end of the tractor from a tractor hold that extends proximally along the catheter for less than 10 cm.

[00028] Disengaging the second end of the tractor from the tractor hold may include disengaging the second end of the tractor from a tractor hold that is open at a distal-facing end; a proximal end of the tractor hold may be attached to the outer diameter of the catheter. Disengaging the second end of the tractor from the tractor hold may include disengaging the second end of the tractor from a tractor hold that secures the second end of the tractor over a smaller outer diameter region of the catheter that is distal to a larger outer diameter region of the catheter.

[00029] Disengaging the second end of the tractor from the tractor hold may comprise disengaging the second end of the tractor from a tractor hold that secures the second end of the tractor between a larger outer diameter region of the catheter and a larger outer diameter region of the catheter, wherein the larger diameter outer region is distal to the smaller outer diameter region. Disengaging the second end of the tractor from the tractor hold may comprise disengaging a tractor hold from a tractor lock, wherein the tractor lock is on the second end of the tractor. Disengaging the second end of the tractor from the tractor hold may include compressing either or both the tractor hold and a tractor lock on the second end of the tractor so that the tractor lock moves from a position proximal to the tractor hold to a position that is distal to the tractor hold.

[00030] As mentioned, the deployment threshold may be between 0.5 N and 50 N. For example, disengaging the second end of the tractor from the tractor hold may comprise pulling the first end of the tractor with the first force wherein the threshold force is between 1 N and 20 N.

[00031] In any of the apparatuses described herein the puller to which the tractor is coupled may be configured to extend from the distal end of the apparatus further than the tractor. In any of these apparatuses, the puller may be a tube (inner catheter, hypotube, etc.), and may be inserted into the clot, or may be used to draw a vacuum, apply an agent (e.g., anticoagulant, etc.) or the like. For example, described herein are mechanical thrombectomy apparatuses for removing a clot from a vessel that include: a catheter having a proximal end

and a distal end and a distal end opening; a tractor comprising a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter; a puller having a proximal end and a distal end, wherein the first end of the tractor is coupled to the puller at a region that is proximal to the distal end, further wherein the puller extends within the catheter to the proximal end of the catheter. Any of these apparatuses may include a guidewire lumen extending through the catheter, the puller and the tractor, and configured to pass a guidewire.

[00032] For example, the apparatus may further include a stop between the distal end of the puller and the distal end opening. For example, the apparatus may include a stop on the puller between the distal end of the puller and the first end of the tractor, wherein first end of the tractor is coupled to a sliding ring configured to slide over the puller until it engages the stop. Any of these apparatuses may include a 2 mm or greater distance between the distal end of the puller and the region of the puller to which the first end of the tractor is coupled.

[00033] As mentioned, the proximal end of the puller may be configured to couple to a vacuum source. For example, the proximal end of the puller may include a valve, e.g., a Tuohy-Borst valve/rotating hemostasis valve (RHV).

BRIEF DESCRIPTION OF THE DRAWINGS

[00034] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00035] FIGS. 1A-1H illustrate an example of an apparatus for mechanically removing an object such as a clot from a body region. FIG. 1A shows an example of an elongate inversion support portion of an apparatus, configured as a catheter portion. For example, at least the distal end of the elongate inversion support may be configured as a catheter. FIG. 1B shows an enlarged view of a distal end (opening) of the catheter of the elongate inversion support of FIG. 1A, showing the aperture formed by the distal end opening; FIG. 1C shows an example of a distal tractor region of a flexible tube (tractor tube) extending from a puller (the puller in this example is configured as a catheter. The tractor is shown in a first (e.g., uninverted) configuration) and may be biased open, e.g., by heat setting, to have an outer

diameter that is greater than the inner diameter of the catheter of the elongate inversion support, as shown in FIG. 1D. FIG. 1D shows the same distal tractor region of FIG. 1C with the expandable first end region expanded. This first configuration may be compressed down into the elongate inversion support and the distal end inverted over the catheter portion of the elongate inversion support, as shown in FIG. 1E. In FIG. 1E, the assembled mechanical thrombectomy apparatus with the elongate inversion support and the flexible tube forming the tractor is shown. The tractor extends through the catheter of the elongate inversion support and doubles back over the distal end opening of the catheter and extends over the outer diameter of the catheter. The outer portion of the tractor (extending along the outer diameter of the catheter) may be held in a collapsed configuration (as shown in FIG. 1E), or it may be expanded, as shown in FIG. 1F. Thus, the tractor may be biased so that in the second configuration (inverted over the distal end of the catheter), the tractor has a 'relaxed' outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. FIGS. 1G and 1H illustrate the use of the apparatus of FIGS. 1E and 1F to remove a clot by drawing the flexible tube proximally and/or advancing the catheter distally towards the clot so that the expandable first end region inverts as it is drawn into the distal end of the catheter, pulling the clot into the catheter.

[00036] FIG. 1I illustrates an alternative variation of a tractor and puller. In FIG. 1I, the tractor is shown attached to the distal end of a tapered or narrow puller; the distal end region is tapered, and includes a radiopaque marker at or near the attachment site to the tractor; the tractor may be knitted, braided, woven, etc. Thus, in some variations the distal end region of the puller may have a greater flexibility than the proximal end of the puller. The puller may be hollow (e.g., a catheter or hypotube) or solid (e.g., like a wire).

[00037] FIGS. 2A-2C illustrate a mechanical thrombectomy apparatus deploying prematurely within a vessel.

[00038] FIGS. 3A-3C illustrate a method of operating a mechanical thrombectomy apparatus that includes a tractor hold to prevent premature deployment.

[00039] FIGS. 4A-4C illustrate examples of mechanical thrombectomy apparatuses including a tractor hold that secures the tractor to the outer diameter of the catheter until release.

[00040] FIGS. 5A-5C illustrate examples of mechanical thrombectomy apparatus including a tractor hold as described herein.

[00041] FIG. 6A illustrates a catheter for a mechanical thrombectomy apparatus with an outer diameter that steps up from a first proximal outer diameter to a second, larger distal

outer diameter. FIGS. 6B-6D illustrate the catheter of FIG. 6A as part of different mechanical thrombectomy apparatuses having tractor holds that secure the tractor to the catheter.

[00042] FIG. 7A-7L illustrate examples of different elongate inversion supports for mechanical thrombectomy apparatuses. FIGS. 7A-7B illustrate a catheter portion of an elongate inversion support having both different diameters (e.g., a larger-diameter distal catheter connected to a smaller-diameter proximal region extending longitudinally in the proximal-to-distal axis), and a plurality of openings (e.g., cut-out regions, holes, etc.). FIGS. 7C-7D illustrate a catheter of an elongate inversion support having a plurality of opening formed therethrough. FIGS. 7E-7F illustrate another variation of a catheter of an elongate inversion support having a distal catheter region and an elongate support member formed by skive cutting the catheter. FIGS. 7G-7H illustrate another variation of an elongate inversion support having a distal catheter region and an elongate support member extending from the catheter region. FIGS. 7I-7J illustrate another variation of an elongate inversion support having a plurality of openings along the distal-to-proximal length. FIGS. 7K-7L illustrate another variation of an elongate inversion support having a minimal catheter region at the distal end forming a distal end opening that is connected to an elongate support (e.g., wire, tube, bar, rod, etc.).

[00043] FIGS. 8A-8D illustrate another example of an elongate inversion support that may be used as part of a mechanical thrombectomy apparatus. FIG. 8A shows the elongate inversion support. FIG. 8B shows a variation of the elongate inversion support of FIG. 8A including guide rings for the puller and tractor. FIG. 8C shows the elongate inversion support of FIG. 8B with the tractor and puller attached. FIG. 8D shows a mechanical thrombectomy apparatuses including that shown in FIG. 8C with an additional outer catheter.

[00044] FIGS. 9A-9C illustrate mechanical thrombectomy apparatuses, including apparatuses having pullers that may extend distally of the catheter (FIGS. 9B and 9C).

[00045] FIGS. 10A-10C illustrate an example of a mechanical thrombectomy apparatuses having a tractor hold configured to engage a tractor lock on the tractor.

[00046] FIG. 11A illustrates a method for removing clot using an intermediate catheter (e.g., sleeve) and a vacuum, in which a mechanical thrombectomy apparatus is extended from a distal end of the intermediate catheter to remove a clot.

[00047] FIG. 11B illustrates a method for removing clot using an intermediate catheter (e.g., sleeve) and a vacuum, in which a mechanical thrombectomy apparatus removes a clot that has been drawn into the distal end of the intermediate catheter.

[00048] FIGS. 12A-12C illustrates an example of the operation of a mechanical thrombectomy apparatus with an expandable distal end region (e.g., expandable distal end opening in the elongate inversion support).

DETAILED DESCRIPTION

[00049] In general, described herein are mechanical thrombectomy apparatuses having an inverting tractor region and an elongate inversion support having a distal annulus over which the tractor rolls and inverts over itself. Any of these apparatuses, and methods of using them, may be configured to prevent premature deployment of the tractor. The elongate inversion support may be a catheter having a distal end opening. The tractor may comprise a flexible tube that may be formed of a sheet having openings, or may be a woven, braided, knitted, etc. material such as a fiber. The tractor may extend longitudinally within the elongate inversion support and may and double back (e.g., invert) over the annulus of the elongate inversion support (e.g., the distal end of a catheter) so that it extends along the midline of the apparatus; when the elongate inversion support is a catheter, the tractor may extend within the catheter lumen. The tractor may connect to an inner puller that is typically coupled to an end of the tractor (which may be referred to as the inner end or the distal end) that can be pulled proximally to pull and invert the tractor over the distal end so that it rolls over the distal end, which may capture a clot. The apparatus may include a guidewire lumen extending through the catheter, tractor and/or tractor puller.

[00050] In general, a mechanical thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an elongate inversion support having a distal end and a distal annulus, and a flexible tractor assembly at least partially inverted and configured to roll and invert over the distal annulus of the elongate inversion support.

[00051] In many of the examples described herein, the elongate inversion support is a catheter (or a portion of a catheter at the distal end) and the annulus is formed by the distal end opening of the catheter; the tractor extends within the catheter and doubles back over the distal end of the catheter to extend over the outer diameter of the catheter at the distal end of the catheter, although it may extend proximal for any appropriate distance (including between 1-30 cm, between 2-20 cm, greater than 1 cm, 2 cm, 3 cm, 4 cm, 5 cm, 6 cm, 7 cm, 8 cm, 9 cm, 10 cm, 11 cm, 12 cm, 15 cm, 20 cm, etc.). The end of the tractor within the catheter may be coupled to a pusher (e.g., at a proximate pusher region connected to the distal or inner end of the tractor). The tubular tractor may include an elongate lumen that is configured to allow passage of a guidewire. The tubular tractor may also be configured to slide along the

long axis within the catheter lumen and invert over the distal end opening of the catheter when the proximal end region is pulled proximally. The tractor may be referred to herein as a tractor assembly, tractor portion, tractor tube, or simply a tractor, and is typically positioned and longitudinally slideable within the catheter, and arranged so a portion of the tractor (sometimes referred to as the “distal tractor region” or “distal-facing” tractor region) doubles back over itself.

[00052] For example, FIG. 1A shows one variation of a catheter that may form part of the apparatuses described herein. In this example, the catheter 100 includes a distal end region 103 that includes a distal end 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal tip (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing hardness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1 mm, 0.8 mm, 0.5 mm, 0.3 mm, 0.2 mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00053] For example, FIG. 1A shows one variation of a catheter of an elongate inversion support that may form part of the apparatuses described herein. In this example, the elongate inversion support includes a catheter 100 having a distal end region 103 that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing hardness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1 mm, 0.8 mm, 0.5 mm, 0.3 mm, 0.2 mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00054] In FIG. 1A, the elongate inversion support is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include a elongate inversion support that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like (as will be described in greater detail below in reference to FIGS. 7A-8D) or may be skived. Thus, any of the apparatuses and methods described herein may be adapted for use with an elongate inversion support that is not limited to catheters, including elongate inversion supports that include a portion of a catheter, or that include a ring or other structure forming the annulus at the distal end. In FIG. 1A the catheter 100 of the elongate inversion support may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00055] In some variations the distal end 105 of the elongate inversion support is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in some variations the distal tip (end) may be curved or radiused 109 as shown in FIG. 1B, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[00056] FIG. 1C shows an example of a flexible tractor 144 coupled to a puller 146. In this example to form a pullable tractor assembly 140, the tractor is shown integrated with the puller, forming the assembly. In FIG. 1C, the tractor is a tube of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The tractor is shown extended from the puller in a first configuration. It may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 144 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The puller 146 may typically be a less-expandable (or non-expandable) structure (tube, puller, etc.). In the example shown in FIG. 1C, the tractor 144 is configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first

configuration to a radial diameter that is between 1.1 and 10 times the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained, as shown in FIG. 1D. In FIG. 1D, the tractor of FIG. 1C is shown in an expanded, relaxed, configuration. Thus the expandable tractor may be biased to expand open. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00057] In FIGS. 1C and 1D the tractor and puller have two portions, a tractor 144 and a less expandable (or non-expandable) proximal portion comprising the puller 146. The puller may be a separate region, such as a wire, catheter or hypotube, which is connected to an end region of the tractor (e.g., a flexible mesh, woven, braided, etc.), e.g., the distal end or near the distal end. The inverting region of the tractor, where it rolls and inverts over the distal end opening of the catheter may be referred to as the distal-facing region of the tractor, which may actively grab clot when rolling.

[00058] In FIG. 1E, the flexible tractor of FIG. 1C is shown with the tractor doubled back over itself and over the distal end of the catheter of the elongate inversion support 101. The distal end region is collapsed down, e.g., onto the puller and the elongate inversion support, and may be held collapsed. In this example a tractor hold 188 may be used to hold the tractor collapsed down onto the outer diameter of the elongate inversion support. However, in an unconstrained or deployed configuration, as shown in FIG. 1F, the tractor in this second configuration (e.g., the portion that is inverted over the distal end of the catheter) has an outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. Thus, the tractor 144 may be biased so that it has a relaxed expanded configuration in the first configuration (as shown in FIG. 1C) that is greater than the inner diameter (ID) of the catheter of the elongate inversion support portion of the apparatus and the relaxed expanded configuration of the second configuration (shown in FIG. 1F) inverted over the catheter has an OD that is greater than the OD of the catheter. The tractor is expandable and may be coupled to the puller. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to a push/pull wire or catheter.

[00059] FIGS. 1G and 1H illustrate the removal of a clot using an apparatus such as the apparatus assembled from the components of FIGS. 1A and 1E. In this example the apparatus is configured as a thrombectomy apparatus including a catheter of an elongate inversion support 101 and a flexible tractor that extends over the distal end region of the catheter and doubles-over itself at the distal end of the catheter to invert so that the external

tractor end region is continuous with an inner less-expandable (in this example, less-expandable includes non-expandable) second distal end region 146 (puller) that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The pusher/puller member that may be a rod or other member that is continuous with the distal end region of the tractor. In FIG. 1G the apparatus is shown positioned and deployed within the vessel 160 near a clot 155. The clot may be drawn into the catheter by pulling the tractor 140 proximally into the catheter 101, as indicated by the arrow 180 showing pulling of the inner portion of the flexible tractor (e.g., using a handle, not shown) resulting in rolling the tractor over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled into the catheter, shown by arrows 182. The end of the tractor outside of the catheter may be “loose” relative to the outer wall of the catheter. FIG. 1I illustrates another example of a tractor assembly 154 including a tractor 144 that is coupled to a puller 156. The puller in this example is tapered (having tapering region 161) and may therefore have a different flexibility of the distal end region than the proximal end region. For example the proximal end region may be less flexible than the narrower-diameter distal end region 195 to which the tractor is coupled. The assembly includes a radiopaque marker 165. The tractor may be attached to the puller by any appropriate means. For example, the tractor may be crimped, glued, fused, or otherwise attached to the puller, typically permanently.

[00060] These apparatuses may be highly flexible, both before actuating and during operation. For example, in general, the flexible tractor may not increase the stiffness/flexibility of the catheter, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortuous vessels of the neurovasculature. Described herein are flexible tractor tube portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[00061] In any of the apparatuses described herein, in which the tractor is at least partially inverted over the distal end of the catheter so that the tractor extends on the outer surface of the catheter, the tractor may be releasably coupled to the outer diameter of the catheter to

allow the apparatus to be inserted through a body, including through tortuous vessels in the body, prior to being deployed to remove a clot or other element from the vessel. The tractor may be a braided, woven or knit material tube of material that is inverted over the distal end of the catheter; alternatively the tractor may be formed of a sheet of material that include openings therethrough.

[00062] Any of the apparatuses described herein may be adapted to prevent premature deployment of the tractor, e.g., by including a tractor hold (e.g., a housing, a lock, a clamp, etc.) or the like to secure the outer end of the tractor against and/or relative to the elongate inversion support. For example, a tractor hold may secure the outer end of the tractor against a catheter into which the tractor inverts when pulled proximally by the puller.

[00063] An example of premature deployment is shown in FIGS. 2A-2C. For example, in FIG. 2A, the tractor 200 is guided over a guidewire 205 to a clot 255 (alternatively, the apparatus may be delivered without using a guidewire). In this example, the apparatus includes a tractor 203 that extends over and into a catheter 210. The inner end of the tractor is connected to a puller 207 (shown in this example as an inner catheter). The outer end 211 of the catheter is loose and is shown slightly expanded over the catheter outer diameter. As the apparatus is advanced distally towards the clot, shown in FIG. 2B, the tractor is, by virtue of being deployed, driven into the catheter prematurely, shortening the length of the tractor that is outside of the catheter and available to roll for capture of the clot. Further, the loose outer end of the tractor may interfere with accurate positioning of the apparatus. FIG. 2C illustrates the premature deployment compromising the rolling of the tractor 315. Once the tractor is prematurely deployed, moving it back and forth in the vessel to position it may result in the tractor, which may contact the vessel wall when deployed, folding or tangling, as shown in FIG. 2C.

[00064] In general, the apparatuses described herein are configured to prevent premature movement of the tractor on an outside, e.g., outer diameter, of the catheter during catheter access to a target location.

[00065] Any of the variations described herein may include a tractor hold that includes a sticky, tacky, gummy, or adhesive material on the tractor or between the tractor and the catheter over a portion of the tractor that is held against the outer diameter of the catheter. For example, as illustrated in FIGS. 4A-4C, the apparatus may include a sticky substance, like silicone, impregnated on the end of the tractor that is wrapped over the catheter (e.g., the outer end of the tractor, which may be referred to as the proximal-most end of tractor). The sticky material may impregnated over a small portion of the tractor (e.g., local regions at

or near the proximal end and/or discrete regions, or patterns including spots, bands, etc. along the length of the outer portion of the tractor. The presence of the sticky regions may prevent premature slipping of the tractor (e.g., braid, woven, etc.) with respect to the catheter. For example, a silicone impregnated braid may sit on or over a section of the catheter that is not coated with a hydrophilic coating before the tractor is pulled around distal end opening of the catheter, which may help prevent the tractor from prematurely slipping off or over the catheter. As mentioned, a sticky (e.g., tacky, adhesive, gummy, etc.) region may be present on the entire tractor, on just an inside surface of the tractor (e.g., the surface that faces the catheter when applied over the outer diameter of the catheter), on both inner and outer surface of the tractor, and/or in discrete locations (including patterns) of the portion of the tractor outside of the catheter. For example, the apparatus may include a plurality of regions of sticky material arranged over the length of the proximal end of the tractor. In some variations the sticky material is arranged in a pattern. The material applied may be referred to as sticky with respect to the catheter (e.g., causing temporary and/or releasable attachment between the catheter and the tractor). In some variations, the sticky material may be coated or applied to the outer diameter of the catheter. When arranged in a pattern (e.g., on the tractor and/or OD of the catheter), the pattern of sticky material locations on the tractor (and/or catheter) may be arranged in multiple, non-contiguous locations along the length of the tractor. Patterns may include stripes, spirals, rings, spots, etc.

[00066] Alternatively or additionally, the tractor may be temporarily secured to the outside of the catheter through other methods to provide a temporary attachment of the tractor to the catheter outer diameter (OD). For example, a temporary attachment may be presented between the tractor and the catheter OD such that, when axial tension is applied to the tractor, e.g., by the user pulling the tractor to pull the tractor around catheter tip, the temporary attachment (e.g., a temporary bond, temporary securement, etc.) between the tractor and the catheter OD may be released, allowing the braid to slide relative to the catheter.

Alternatively or in addition to the use of a sticky material between the tractor and the catheter, temporary attachments between the tractor and the OD of catheter may include: hydrophilic coatings on the tractor and/or catheter, and/or spot (including micro-spot) bonding between the catheter and the tractor.

[00067] For example a hydrophilic surface on the tractor (e.g., inner face of the tractor) and/or catheter OD may be applied as a coating. The tractor may be pre-assembled onto the catheter and a hydrophilic/hydrophobic surface may provide a temporary attachment between the catheter and the tractor. A layer of hydrophilic coating (or two adjacent layers) may

secure the tractor to the catheter OD, and may help the apparatus track through a body vessel/lumen to the target location, after which the tractor may be deployed by pulling to separate the surfaces of the tractor and catheter OD, and to allow the tractor to roll over the distal end opening freely so that it may engage with a clot and draw it into the apparatus. In some variations, a hydrophilic coating may be separately applied to the tractor and/or the catheter. For example, the catheter OD and tractor may be separately coated with a hydrophilic coating and then assembled. When the apparatus is assembled (e.g., with the tractor over catheter distal end region, inverted and within the catheter), the coating on both subassemblies (e.g., tractor and catheter) may cold flow together. When the assembly is wetted in the body during catheter access and when approaching the target clot to be removed, the user may pull the tractor proximally (by pulling on the puller attached to the inner end of the tractor) which may slide the tractor with respect to the catheter OD, disengaging the tractor hold.

[00068] Alternatively the tractor hold can be formed by spot- or selectively bonding the tractor to the catheter OD. A spot or micro-bond may be adequate to prevent premature sliding of the tractor relative to the catheter OD during catheter access. For example, a spot bond or a plurality of micro-bonds can be created, e.g., by heat bonding (melting) or applying adhesive to attach the tractor to the catheter OD. The micro bonds can be placed circumferentially at several locations along the length of the braid, continuously along the braid/catheter contact length or in any other pattern, as discussed above.

[00069] FIG. 4A illustrates an example of a thermoplastic polyurethane (TPU) 404 that may be used to temporarily secure the tractor 406 to the outer diameter of the catheter; once in position, the distal end of the catheter (internal to the catheter) may be pulled proximally to break the material (in this example, pellathane) and release the tractor so that it may be rolled distally over the catheter to draw a clot into the catheter. In this example, the frangible (e.g., breakable) material is coated over a region on the catheter and/or tractor (shown here as a braided tractor) that does not include a hydrophilic coating). For example, the frangible material may be applied over a region that is masked (uncoated) from hydrophilic coating.

[00070] In FIGS. 4B and 4C, examples of mechanical thrombectomy apparatuses 400, 400' are shown, each having an outer catheter 409, and a tractor that extends over the distal end region of the catheter, and inverts over the distal end opening (annulus 411) of the catheter, and into the catheter where it connects to a puller 407. In FIG. 4B, the tractor is releasably adhered to the outer diameter of the catheter by a sticky (e.g., hydrophilic) region 414 that engages the outer end of the tractor to a region on the outer diameter of the catheter.

Thus, in order to pull the tractor proximally within the catheter and therefore roll the tractor over and into the distal end opening as described above (and shown, e.g., in FIG. 3C), an initial deployment force threshold (e.g., between 0.5 N and 50 N) may be required. Once the force is applied and the tractor is deployed to axially move distally over the outer surface, roll, invert and into the catheter, the force required to continue rolling may be substantially (e.g., the deployment force threshold may be 1.1x, 1.2x, 1.5x, 1.7x, 2x, 3x, 4x, 5x, 10x, or more the force required to roll the apparatus).

[00071] Similarly, in FIG. 4C, the apparatus may include a plurality of spot attachments 424 at the outer end of the tractor. As mentioned, there spots may be an adhesive attached into (e.g., into the mesh, etc.) of the tractor, or between the tractor and the outer diameter of the catheter. In both FIGS. 4B and 4C, the tractor may be held slightly in tension over the distal end region of the catheter, preventing the tractor from deploying and expanding, including expanding at the distal tip region (forming the trumpet-shaped opening such as shown in FIGS. 2A-2B).

[00072] Alternatively or additionally, any of the apparatuses described herein may include a tractor hold that is configured as a housing or garage for holding the outer end of the tractor, as shown in FIGS. 3A-3C and FIGS. 5A-5C. In these examples the tractor hold extends only partially down the catheter, which may prevent the hold from increasing the flexibility and maneuverability of the apparatus in the lumen. FIGS. 3A-3C illustrate the method of use of a variation of a mechanical thrombectomy apparatus 300 including a tractor hold 303. In this example, the tractor hold is positioned over the catheter, as shown in FIG. 3A, and holds the outer end of the tractor 305 against the outer diameter of the catheter 307. The tractor is connected to the puller 309. The tractor hold may be attached to the catheter (e.g., at a proximal end of the hold) or it may be applied over the catheter (e.g., shrink-wrapped over the catheter and the outer end of the tractor). The apparatus 300 may be guided over a guidewire 319, as shown, or it may be directed to the clot 355 within the vessel 360 without the use of a guidewire.

[00073] Once the distal end of the apparatus is near the clot, as shown in FIG. 3A, a force greater than a deployment threshold force (e.g., the force required to pull the tractor out of the tractor hold 303, leaving the tractor hold behind, and allowing the tractor to roll 382 over the distal end opening of the catheter, as illustrated in FIG. 3C. The apparatus may be advanced distally while pulling the inner end of the tractor proximally with the puller to invert and roll the tractor into the catheter. The tractor may then grab a clot and pull it into the catheter, as shown.

[00074] Similarly, in FIGS. 5A-5C, the apparatus 500 includes a tractor 503 coupled to a puller 507 at an inner end that is within a catheter 509. In this example, the outer end 504 of the tractor is pinned against the outer diameter of the catheter by a tractor hold 501 configured as a garage or housing. The housing may hold the end of the tractor lightly or it may secure it against the catheter more tightly, depending on the desired deployment threshold. In FIG. 5A, the tractor hold is secured to the outer diameter of the catheter by a weld or welds 505. Similarly in FIGS. 5B and 5C the tractor hold is secured by either being shrunk-fit to the outer diameter at the proximal end 515, or by an adhesive or glue 525, respectively.

[00075] In all of the examples shown in FIGS. 3A-3C and 5A-5C, the tractor hold extends only slightly down the length of the catheter, e.g., a few cm (e.g., less than 10 cm, less than 9 cm, less than 8 cm, less than 7 cm, less than 6 cm, less than 5 cm, less than 4 cm, less than 3 cm, etc.).

[00076] In any of the variations described herein, the elongate inversion support may have a different outer diameter along its axial (longitudinal) length. For example, although the catheter shown in FIG. 1A has a uniform diameter along its length, other apparatuses may include a catheter having a larger diameter at the distal end region than at more proximal regions, as shown in FIGS. 6A-8C. For example, in FIG. 6A, the elongate inversion support is a catheter having a larger outer diameter at the distal end than at the proximal end. The transition between the two regions is a step 605. The annular region (distal end opening 607) therefore has the same, larger, outer diameter as the distal end region. FIGS. 6B-6C, illustrates examples in which a tractor is held over the outer diameter and may be secured by a tractor hold. In general, particularly where the tractor is configured to contract down onto the tractor, simply having the transition, and particularly a rapid (including step) transition between a region of larger diameter and a region of smaller diameter, as shown in FIG. 6A, may help secure the tractor over the catheter. In FIG. 6B, the same catheter shown in FIG. 6A has had a tractor 603 attached so that it extends along the distal outer diameter region, inverts over the distal end opening 607, and into the catheter inner lumen, where it is connected to or integral with a puller 609. In FIG. 6B, the outer end of the tractor is held in place with a tractor hold 613; in this example, the tractor hold 613 is one or more arms that hold the tractor against the smaller inner diameter immediately adjacent to the step up to the larger diameter region of the catheter.

[00077] In FIG. 6B, the tractor hold is a narrower catheter 623 that extends proximally; the tractor is held between the distal opening of the tractor hold and the step up to the larger

diameter catheter 601. The outer surfaces of the tractor hold and the catheter 601 may be flush, e.g., having the same height. In FIG. 6B, if the tractor hold extends proximally far enough (e.g., to or beyond the end of the catheter) it may be actively disengaged, reducing or eliminating the deployment threshold force.

[00078] FIG. 6D shows another example of a tractor lock 633, similar to that shown in FIG. 6C, only extending partially proximally down the catheter. In any of these variations the tractor hold may be fixed to the outer diameter or it may be movable (e.g., slideable) relative to the outer diameter of the catheter.

[00079] FIGS. 7A-7L illustrate different variations of catheters that may be used as part of any of the apparatuses described herein. For example, FIG. 7A shows an example of a catheter 700 having a larger-diameter distal end region that also includes a plurality of openings, slots, holes, windows, slits, etc. 709. These openings may provide for delivery of fluid (including drugs) to the site of use, and/or removal of material, e.g., the application of vacuum through the apparatus, particularly useful when used with an intermediate catheter into which the apparatus (e.g., an elongate inversion support, a puller and tractor) is inserted, as will be described in greater detail below. FIG. 7B shows the apparatus of FIG. 7A with an attached puller and tractor.

[00080] FIGS. 7C and 7D illustrate another variation of a catheter that may be used as part of any of the apparatuses described herein, including, as here, catheters that have a plurality of cut-out regions. Similarly, FIGS. 7E and 7F show an example including a catheter having a large proximal skive region, leaving the majority of the outer diameter much smaller than at the distal end region, as shown. In addition, the distal end of the catheter may include openings, slots, cut-out regions, etc. 725. FIG. 7F shows the catheter of FIG. 7E with a tractor 714 coupled on an inner end to a puller 713. The puller is still pulled within the lumen of the catheter. A similar example is shown in FIGS. 7G and 7H, however instead of being skived, the elongate inversion support includes a distal portion formed of a catheter having cut-out regions 725 that is coupled to a rod, pole, wire or (as shown) a hypotube. This hypotube may be used as a guidewire lumen and/or as a channel for a stiffening or support member that may, once the device is positioned, enhance the column strength to allow pulling of the tractor proximally when inverting the tractor to roll.

[00081] FIGS. 7I and 7J illustrate an example of a catheter (FIG. 7I) and an apparatus including the catheter (7J) in which the sides of the catheter have been slotted, which may provide enhanced flexibility while maintaining column strength. An apparatus including the catheter of FIG. 7I is shown in FIG. 7J, also including a tractor and puller.

[00082] FIG. 7K is an example of an elongate inversion support in which the distal end is a cylinder 716, formed, for example, from a very small portion of a catheter. The distal end opening (annulus 707) may be used to invert the tractor, as shown in FIG. 7L. The elongate shaft 717 of the elongate inversion support may be a rod, tube, wire, etc. as described above. An additional outer catheter 726 may be included in any of these apparatuses, as shown in the exemplary apparatus shown in FIG. 7L, which includes the elongate inversion support of FIG. 7K.

[00083] FIGS. 8A-8D also illustrate another example of an elongate inversion support having a distal annulus or aperture 743, shown in this example a ring (e.g., toroid ring) bonded to a hypotube 746 (which may alternatively be a rod, wire, small-diameter catheter, etc.); as mentioned above, a stiffening member may be inserted into the elongate body of the elongate inversion support prior to or during pulling of the tractor proximally through the distal annulus. FIG. 8B shows a similar variations of the elongate inversion support of FIG. 8A, only with a plurality of guides 750 extending down the length of the support into which the tractor puller and/or tractor may be held, as illustrated in FIG. 8C. In this example, the tractor 810 extends over the elongate inversion support and can be pulled proximally by the tractor puller 812. Although the tractor puller is shown as a catheter, in any of the apparatuses described herein, the tractor puller may instead be a wire, hypotube, etc. as mentioned above. FIG. 8D is an apparatus similar to that shown in FIG. 8C with the addition of an outer catheter 809.

RELEASABLE LOCK

[00084] In some variations, the tractor hold and distal end region of the catheter to which it is applied over may be configured as (or may include) a releasable lock, in addition to or instead of the tractor holds described above (e.g., a sticky materials, frangible release, housing, etc.). For example, the catheter may include a tractor hold comprising a friction lock (e.g., bump, protrusion, enlarged diameter, region, O-ring, etc.) on the outer diameter of the catheter that engages with a locking region (e.g., constriction, inward-pointing bump, sticky coating, etc.) on the outer (e.g., proximal) end region of the tractor. The locking region on the outer end portion of the tractor may be proximally beyond the locking region (e.g., friction bump) on the catheter, so that the catheter locking region may be initially held beneath the tractor. When force is applied (e.g., deployment force applied by the user) to pull the tractor region proximally from the inside of the tractor, the force may overcome the locking engagement between the tractor locking region (e.g., constriction, inwardly-facing

protrusion, etc.) and the locking catheter locking region (e.g., friction bump, radial enlargement, O-ring, etc.) and the tractor may be released roll distally over the catheter. See FIGS. 10A-10C for an example of this arrangement. Note that this releasable lock may be used in combination with any of the features described above. In FIG. 10A-10C, the tractor 1007 includes a tractor lock 1006 at the outer end of the tractor. FIG. 10A shows just the tractor and puller 1003. The mechanical thrombectomy apparatus 1000 shown in FIG. 10B also includes a catheter 1011, and the catheter includes a tractor hold 1009. The tractor hold engages with the tractor lock; in FIG. 10B, the tractor hold is a protrusion that holds the tractor lock on the tractor on a proximal side of the tractor hold, until sufficient force is applied above the deployment threshold to deploy the tractor by pulling the tractor lock distally over the tractor hold, allowing the tractor 1007 to deploy and/or expanded, and be rolled over the distal end opening of the catheter, to capture a clot.

[00085] In any of these variations, but particularly the locking variations described herein, the tractor region may be held in tension, although tension is not necessary. Alternatively or additionally, a second outer cover or catheter may be used, or may be absent.

APPARATUSES HAVING DISTAL-EXTENDING PULLERS

[00086] In any of the variations described herein, the puller may extend more distally than the tractor in the apparatus. For example, a pre-assembled apparatus having the distal end of a tractor puller (e.g., catheter, hypotube, wire, etc.) that extends more distally beyond the catheter(s) or the rest of the apparatus may be used to help capture the clot. As mentioned above, any of these variations may include the use of a vacuum, e.g., for aspirating the clot. The vacuum may be applied through the puller. It may be easier to grab onto a clot when using aspiration to initiate the grabbing.

[00087] For example, FIG. 9A illustrates an example of a mechanical thrombectomy apparatus similar to that described above. The tractor 903 is connected to a puller 905 and the tractor extends along the outer diameter 901 of the catheter. In some variations, the tractor may be infused, bonded or laminated with a stiffening element in part to make it less likely that the tractor collapses in diameter when the dozer catheter is pulled and allows for vacuum applied to the applied to the proximal end of the tractor puller 905 to exert force/vacuum on the clot via the distal end of the assembly, as shown in FIGS. 9B and 9C.

[00088] In FIG. 9B, the tractor is coupled to a portion of the tractor puller 905 that is proximal 921 to a distal end of the puller. Thus, as the puller is extended distally, the tip may

extend past the distal end of the catheter, prior to inverting the tractor. FIG. 9B also shows an (optional) tractor hold 917

[00089] In FIG. 9C, the apparatus includes a stop element attached at or near the distal end of the puller 905. A sliding ring 911 on the tractor may be used to allow the puller to slide distally without pulling on the tractor; only when the puller is withdrawn proximally far enough that the stop 909 engages with the sliding ring 911 does the puller pull the tractor proximally, and invert the tractor over the distal end opening of the catheter, rolling the tractor and pulling in any clot material, which may be aided by the application of vacuum 914 through the puller. Thus, this arrangement may allow the user to extend the tractor puller distally at lengths beyond the distal end of the catheter without pulling the tractor distally.

[00090] In any of the variations described herein, including those shown in FIGS. 9A-9C, the apparatus may be coupled to a valve 923 for connection to a vacuum source 914. The vacuum may be connected to the elongate inversion support (e.g., catheter) and/or to the puller, as shown in FIGS. 9A-9C.

[00091] Any of the apparatus variations described herein may include a lubricous coatings such as hydrophilic coatings applied on the OD &/or ID of the tractor, on any and all sections, and/or on the outer or inner diameter of the elongate inversion support (e.g., catheter).

[00092] In general, the apparatuses described herein may allow delivery of a guidewire and/or a smaller catheter through the outer catheter and tractor, which may be useful for both guidewire operation (for clot access) and also for applying optional vacuum. In addition, the tractors described herein may have minimal to no collapsing when they are inverted inside the outer catheter when under axial tension, which may prevent jamming on the catheter distal tip and may reduce the amount and/or volume of clot that can be extracted. Further, any of the tractors described herein may have adequate coarseness to grab the clot, yet still roll smoothly around the distal annulus. Typically, the tractor does not adversely affect catheter tracking, as it may be extremely flexible and slippery.

[00093] As just discussed above, the pre-loaded tractors described herein may not slide with respect to the OD of catheter during vessel access. The tractor may only slide on the OD of catheter when the user pulls the tractor puller.

[00094] In general, the user may advance the elongate inversion support (e.g., catheter) forward while holding the tractor puller fixed, thereby enveloping clot in place rather than pulling clot to catheter. Further, the tractor may be biased (e.g., heat-shaped) to a preferred configuration to help grab clot effectively and roll nicely around the catheter tip. In general,

the distal end of the catheter (tip) may be stiffer than the catheter section just proximal to the tip (to allow rolling of dozer around tip). The tip may include a lubricious coating. The catheter tip may have a radius of $> 0.00025''$, $> 0.00035''$, $> 0.0004''$, $> 0.0004''$, $> 0.00025''$, or $< 0.0005''$ to allow rolling of tractor more easily. For example, the catheter tip hardness may be greater than $> 72D$, and/or may be formed of a polymeric material such as PTFE, nylon, PEEK, stainless steel, etc.

[00095] In some variations, the distal region (e.g., distal 5 cm, 10 cm, etc.) of the catheter allows for tracking through $1/8''$ diameter radius and also has a limited axial compress to $< 10\%$ of the distal catheter length during axial compression loads of, e.g., 100g, 200g, and 300g, etc. when pulling in the dozer and grabbing clot.

[00096] As mentioned above, any of these apparatuses may allow for the delivery of guidewire and/or smaller catheter through aspiration catheter. In general, the tractor may be configured to have a Poisson ratio < 1.5 (e.g., < 1.2 , < 1.1 , etc.) when under tension (this helps prevent the tractor from jamming on catheter tip).

[00097] In any of the variations described herein, the tractor and/or catheter may be radiopaque. For example, a band or region may be radiopaque. The entire tractor may be radiopaque, e.g., NiTi wire filled with PT or Tantalum (DFT wire) may be used to form the tractor. Alternatively, the proximal and/or distal end of the tractor may have radiopaque markers.

[00098] The apparatuses described herein may be used to remove materials such as clots, including to prevent or treat stroke. For example, the apparatuses described herein may be used to track up through the siphon of the carotid artery, which is typically highly tortuous. When pulled, the tractor may roll around the catheter distal end without locking up, while still grabbing clot. As mentioned, any of these apparatuses may also work in combination with a vacuum. The use of a vacuum may be unnecessary, but may be beneficial, particularly when initially engaging the clot with the tractor region and/or the distal end of the catheter. Any of the apparatuses described herein may also be configured to grab a clot in a large variety of vessels, including those ranging from 1.5 mm to 3.5 mm, even when the catheter has approximately the same outer diameter as the inner diameter of the vessel, or where the catheter is otherwise coked in the vessel.

APPARATUSES ADAPTED FOR USE WITH ASPIRATION

[00099] As mentioned, any of the apparatuses described herein may be adapted for use with a vacuum to apply suction (e.g. aspiration) to assist in clot removal. Although the

device may be used without the use of aspiration, in some instances clot removal may be aided by the use of the mechanical atherectomy apparatuses described herein. Furthermore, traditional techniques for removing a clot using aspiration (e.g., using a simple flexible catheter, commonly referred to as an intermediate catheter) may be improved by the use of the mechanical atherectomy apparatuses described herein. Use of aspiration alone often results in clogging of the intermediate (aspiration) catheter and may therefore have trouble removing the entire clot, particularly in the tortuous vessels. Any of the apparatuses described herein may be used with an intermediate catheter, and may be adapted for use with vacuum clot removal technique, including being adapted to permit vacuum to be applied while the apparatus is within the lumen of the intermediate catheter, so that aspiration may still be applied from the distal end of the intermediate catheter and/or the apparatus, as well as permitting aspiration to be applied while the apparatus is extended distally from the intermediate catheter. The applied vacuum may aid in initially gasping or grabbing the thrombus. The vacuum may be applied from the distal end of the apparatus and/or of an intermediate or outer catheter or sleeve that is used with the apparatuses (e.g., elongate inversion support and inverting tractor). Also described herein are apparatuses that are adapted for use with a vacuum, including for use with an intermediate or outer catheter through which the apparatus may be delivered to the clot. The apparatus may grab clot from within the outer catheter, or it may be extended distally out of the intermediate or outer catheter. For example, FIGS. 7A-8D, described above and in additional detail below, are examples of elongate inversion supports that may be used in any of the apparatuses described; these elongate inversion supports may be particularly well suited to applying aspiration from the intermediate catheter.

[000100] FIG. 11A shows an example of a configuration in which an outer/intermediate catheter or sleeve that is highly flexible may be maneuvered, for example with a guidewire, to a distal end of the device. Thus, the intermediate catheter may be maneuvered near, or adjacent to, the thrombus. As in any of these methods of use described herein, imaging (such as fluoroscopy, contrast imaging, etc.) may be used. Once in positioned, the guidewire may be removed or left in place, and the apparatus including the elongate inversion support and inverting tractor may be extended within the intermediate catheter/sleeve. In FIG. 11A, the intermediate catheter 4104 is shown positioned within the vessel 4109 distally. As with any of the illustrations here, in the vessel may be highly tortuous and branching, although for convenience it is shown as straight in the figures. The apparatus 4100 is extended distally through the intermediate catheter, and extends out of the distal opening of the intermediate

catheter to grab the clot 4111, as shown. The puller 4105 may thus be drawn proximally (to the left in the figure) to pull the tractor 4103 from over the catheter portion of the elongate inversion support 4113, so that it inverts and rolls into the lumen of the elongate inversion support, capturing and drawing the clot in with it. The clot may be compressed.

[000101] Thus, this configuration may be referred to as a vessel cleaner. In addition to the rolling of the tractor to grab and pull the clot, the clot may be pulled by a vacuum applied from one or both of the intermediate catheter 4121 and/or the elongate inversion support 4123. Vacuum may be applied, e.g., within the intermediate catheter, before the apparatus is positioned distally (or even within the intermediate catheter at all) or after it has been extended distally from the intermediate catheter. This configuration shown in FIG. 11A may introduce the tractor through outer catheter to the face of clot. As mentioned, the mechanical thrombectomy apparatus may be extended distally from the intermediate catheter either by pushing it out distally and/or by pulling back the intermediate catheter to deploy all or part of the tractor into vessel, as shown. If vacuum is applied through the catheter, the catheter forming the elongate inversion support may be jacketed or sealed to allow aspiration through this catheter.

[000102] Optionally pull vacuum through outer and/or inner and/or puller. As mentioned, thereafter the tractor may be pulled proximally relative to the the elongate inversion support to pull the clot. The intermediate catheter may then be advanced distally and/or the mechanical thrombectomy apparatus may be withdrawn proximally to remove the apparatus once the clot has been removed. Thereafter an angiogram may be taken to confirm that the clot has been removed.

[000103] Alternatively, in FIG. 11B, a clot may be removed using the intermediate catheter to draw a vacuum with the mechanical thrombectomy apparatus within the lumen (e.g., near the distal end, but not extending fully from the distal end) of the intermediate catheter. As described for FIG. 11A, in FIG. 11B the intermediate catheter may be inserted into the vessel (e.g., using a guidewire) so that the distal end is positioned near the clot. Suction may be used to draw the clot into the intermediate catheter either before the mechanical thrombectomy device is inserted or after it has been inserted.

[000104] In FIG. 11B, the elongate inversion support 4113' is particularly well suited for use with a vacuum applied through the intermediate catheter 4104 surrounding the apparatus. For example, in FIG. 11B, the elongate inversion support 4113' include a distal catheter region 4125 that extends just a few cm from the distal end opening in which the clot is drawn. The elongate inversion support then tapers down to an elongate support, which may be

formed by a wire, hypotube or skived region. This configuration may prevent the catheter from blocking the lumen of the intermediate catheter and therefore increasing the resistance of the vacuum before it can reach the open distal end and apply suction to draw the clot. Alternatively or additionally, the outer diameter of the catheter portion of the elongate inversion support may be sized to allow more of the vacuum to pass. For example, the apparatus may be sized such that there is at least about 0.002 inches or greater (e.g., 0.003, 0.004, 0.005, 0.006, etc., inches) between the outer diameter of the catheter and the inner diameter of the intermediate catheter ("outer catheter"). This may also permit unimpeded rolling of the tractor over the distal end opening of the elongate inversion support.

[000105] In operation, the method of removing clot such as shown in FIG. 11B may include pulling at least the tip of a clot into the intermediate catheter through the use of a vacuum 4121. Typically the clot may clog within the intermediate catheter; the mechanical thrombectomy apparatuses described herein may be used to remove the clot from within the intermediate catheter. For example, while maintaining vacuum, the mechanical thrombectomy apparatus may be inserted (or it may be preloaded in intermediate catheter as mentioned) and the tractor puller 4105 may be pulled to pull the clot out of the intermediate catheter and the vessel, compress and/or macerate it and pull it into the apparatus and therefore the intermediate catheter, where it can be withdrawn proximally, e.g., by removing the mechanical thrombectomy apparatus. As mentioned, an angiogram may be taken through intermediate catheter (e.g., leaving it in place in case the mechanical thrombectomy apparatus needs to be re-inserted and used to remove more clot) to confirm clot has been removed.

[000106] As mentioned, a full catheter such as shown in FIG. 11A may block or prevent the vacuum from reaching the distal end of the intermediate vessel. Therefore it may be beneficial to adapt the mechanical thrombectomy apparatus so that it can be used with vacuum within an intermediate catheter or sleeve, as shown in FIG. 11B. This may be achieved as mentioned above, by minimizing the larger-diameter catheter portion of the elongate inversion support forming the distal end opening over which the tractor inverts. Returning now to FIGS. 7A-8D, in FIG. 7A, the elongate inversion support 700 has a distal catheter portion 701 having a larger diameter than the more proximal region 703, and also includes a plurality of openings, holes, gaps, cut-out regions, slots, etc. 709 that may allow the flow of vacuum through the elongate inversion support more easily. The elongate inversion support shown also includes a distal end 707 into which a tractor 711 inverts, as shown in FIG. 7B. IN FIG. 7B, the elongate inversion support is shown transparent so that the puller 713 and tractor within the elongate inversion support is visible.

[000107] Similarly, in FIGS. 7B and 7C, the entire length of the elongate inversion support includes a plurality of cut-out regions 713 which may increase the ability to allow the flow of a vacuum or other fluid within the apparatus, but may still allow the elongate inversion support to provide column strength to resist collapsing up to at least 500 g of compressive longitudinal force applied by, e.g., pulling on the tractor. Similarly, the elongate inversion support of FIGS. 7E and 7F show a skived catheter that also includes openings 709 along its length. The puller and tractor 412 are shown within the elongate inversion support in FIG. 7F. FIGS. 7G and 7H illustrate an example in which rather than a skived portion of the catheter, the distal catheter region of the elongate inversion support is formed by a wire, bar, tube, 721 etc., that is attached to the catheter at the distal end. The catheter may also optionally include openings 709. The elongate inversion support of FIGS. 7I and 7J includes openings 709' along all or much of its length (particularly near the distal end region) as shown.

[000108] Finally, the variation of the elongate inversion support shown in FIG. 7K includes a minimal catheter portion (cylinder 716) that is connected to a wire, bar, tube, hypotube, skived region, etc. 717.

[000109] FIGS. 8A-8D illustrate the operation of a similar minimal elongate inversion support 800. In this example, the apparatus includes a distal aperture 743 bonded securely to a wire, bar, tube, hypotube, skived region, etc. 746 forming an elongate support. The elongate support may be hollow (e.g., may include a lumen for a guidewire) or solid. The elongate support may also include one or more additional support guides 750 as shown in FIG. 8B. These supports may help contain the puller and/or tractor within the elongate inversion support. Any of the elongate inversion supports described herein may include additional support guides. The elongate inversion support of FIG. 8B is shown with a tractor 711 and puller 713 in FIG. 8C. As mentioned, this variation may be particularly well suited for use with an intermediate (e.g., “outer”) catheter, sleeve, or the like 809, as shown in FIG. 8D.

EXPANDABLE DISTAL ENDS

[000110] Any of the mechanical thrombectomy apparatuses described herein may include an elongate inversion support having a distal end that is expandable from a smaller diameter aperture (e.g., distal end opening) to a larger-diameter aperture. This expansion may be performed by pulling the clot within the catheter. For example, FIGS. 12A-12C illustrates the operation of an example of an elongate inversion support configured as a catheter having

an expandable distal end. In this variation the catheter distal end 4401 may include slots or slits 4403 formed or cut, e.g., by laser-cutting, in the distal end of the catheter of the elongate inversion support. The apparatus may be operated as described above, positioning near (e.g., against or adjacent to) a clot, and pulling proximally on the puller to draw the tractor 4405 into the catheter, as shown in FIG. 12B. Although the apparatuses described herein may generally compress a clot greatly, compression may be made easier and/or more efficient by providing a more gradual decrease in radial diameter. As shown in FIG. 12B, when the tractor is rolled over the distal end opening and inverted, the clot may be drawn in along with the tractor. As the large clot 4413 is brought into the distal end opening, the distal end opening may expand and open along the slots or slits 4403, as shown in FIG. 12C, so that the distal end opening flares out. In some variations an elastic sleeve, gasket, ring or cover (not shown in FIG. 12A-12C) may be included at least partially covering the distal end to prevent the edge from catching the tractor. For example, an elastic or stretchable layer may cover the cut distal end so that the distal end may be opened to form an outward flare. In FIG. 12C the outward-flared distal end is shown forming a funnel-shape into which the clot may be pulled. This funnel-shaped opening may help compress the clot so that it may be drawn into the mechanical thrombectomy apparatus.

[000111] In some variations the elongate inversion support may be configured to have, or to assume, a funnel-shape at the distal-facing end. The distal-facing end may always have a funnel-shaped mouth at the distal end opening, or the distal end opening may be configured to assume a funnel shape, as shown in FIGS. 12A-12C. In some variations the distal end of the elongate inversion support is configured to be elastic in a radial direction, but maintain stiffness along the proximal-to-distal axis (in compressive load). For example, the distal end of the elongate inversion support may be configured with strands or rods extending in the proximal-to-distal axis that have a high compressive load strength, but which may separate from each other to enlarge the distal end opening; for example they may be connected by rings in which more distal rings are more elastic/stretchable than more proximal rings.

[000112] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present.

In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[000113] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[000114] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[000115] Although the terms "first" and "second" may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[000116] Throughout this specification and the claims which follow, unless the context requires otherwise, the word “comprise”, and variations such as “comprises” and “comprising” means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term “comprising” will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

[000117] In general, any of the apparatuses and methods described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may alternatively be exclusive, and may be expressed as “consisting of” or alternatively “consisting essentially of” the various components, steps, sub-components or sub-steps.

[000118] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word “about” or “approximately,” even if the term does not expressly appear. The phrase “about” or “approximately” may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For example, if the value “10” is disclosed, then “about 10” is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that “less than or equal to” the value, “greater than or equal to the value” and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value “X” is disclosed the “less than or equal to X” as well as “greater than or equal to X” (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point “10” and a particular data point “15” are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[000119] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[000120] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term “invention” merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

What is claimed is:

1. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:
 - a catheter having a proximal end and a distal end and a distal end opening;
 - a tractor comprising a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter;
 - a puller coupled to the first end of the tractor, wherein the puller extends within the catheter to the proximal end of the catheter; and
 - a tractor hold attached to an outer diameter of the catheter proximal to the distal end of the catheter, wherein the tractor hold secures a second end of the tractor to an outside surface of the catheter until a force greater than a threshold force is applied by pulling the first of the tractor proximally within the catheterwherein the threshold force is between 50 g of force and 500 g of force.
2. The apparatus of claim 1, further comprising a guidewire lumen extending through the catheter, the puller and the tractor, and configured to pass a guidewire.
3. The apparatus of claim 1, further wherein the tractor hold does not extend to the proximal end of the catheter.
4. The apparatus of claim 1, wherein the tractor hold extends proximally along the catheter for less than 10 cm.
5. The apparatus of claim 1, wherein the tractor hold compresses the tractor against the catheter.
6. The apparatus of claim 1, wherein the tractor hold is configured to hold the second end of the tractor until the threshold force is applied, wherein the threshold force is between 200 g of force and 500 g of force.

7. The apparatus of claim 1, wherein tractor is biased to expand beyond an outer diameter of the distal end of the catheter in a first relaxed configuration, further wherein the tractor is biased to expand to a second relaxed configuration having an outer diameter that is greater than an inner diameter of the distal end of the catheter, wherein the tractor converts between the first configuration and the second configuration by inverting.
8. The apparatus of claim 1, wherein a proximal end of the tractor hold is attached to the catheter.
9. The apparatus of claim 1, wherein the catheter comprises a larger outer diameter region and a smaller outer diameter region that is proximal to the larger outer diameter region, further wherein the tractor hold secures the tractor at one or more of: over the smaller outer diameter region, and between the larger outer diameter region and the smaller outer diameter region.
10. The apparatus of claim 9, wherein an outer diameter of the tractor hold is flush with the larger outer diameter region.
11. The apparatus of claim 9, further comprising a stepped transition between the larger outer diameter and the smaller outer diameter.
12. The apparatus of claim 1, wherein the tractor hold comprises one or more of: a polyether block amide, a polyolefin, a polyethylene, a polypropylene, a polyethylene terephthalate (PET), and a Polytetrafluoroethylene (PTFE).
13. The apparatus of claim 1, further comprising a tractor lock on the second end of the tractor, wherein the tractor lock engages with the tractor hold to secure the tractor lock on a proximal side of the tractor hold until the threshold force is applied by pulling the first of the tractor proximally within the catheter.
14. The apparatus of claim 13, wherein the tractor lock comprises a band configured to slide over the outer diameter of the catheter.
15. The apparatus of claim 13, wherein the tractor hold comprises a projection extending from the outer diameter of the catheter.

16. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:
- a catheter having a proximal end and a distal end and a distal end opening, wherein the catheter comprises a larger outer diameter region and a smaller outer diameter region that is proximal to the larger outer diameter region;
 - a tractor comprising a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter;
 - a puller coupled to first end of the tractor, wherein the puller extends within the catheter to the proximal end of the catheter; and
 - a tractor hold on an outer diameter of the catheter proximal to the distal end of the catheter, wherein the tractor hold secures a second end of the tractor that extends over the distal end of the catheter until a force greater than a threshold force is applied by pulling the first of the tractor proximally within the catheter, further wherein the tractor hold secures the tractor at one or more of: over the smaller outer diameter region, and between the larger outer diameter region and the smaller outer diameter region.
17. A method of removing a clot using a mechanical thrombectomy apparatus, the method comprising:
- positioning a distal end of the mechanical thrombectomy apparatus adjacent to the clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter;
 - disengaging a second end of the tractor from a tractor hold that secures the second end of the tractor to an outer diameter of the catheter by applying a first force that is greater than a threshold force to the first end of the tractor;
 - pulling the distal end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter; and
 - drawing the clot into the catheter with the inverting tractor.

18. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises disengaging the second end of the tractor from a tractor hold attached to an outer diameter of the catheter.
19. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises disengaging the second end of the tractor from a tractor hold that extends proximally along the catheter for less than 10 cm.
20. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises disengaging the second end of the tractor from a tractor hold that is open at a distal-facing end and wherein a proximal end of the tractor hold is attached to the outer diameter of the catheter.
21. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises disengaging the second end of the tractor from a tractor hold that secures the second end of the tractor over a smaller outer diameter region of the catheter that is distal to a larger outer diameter region of the catheter.
22. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises disengaging the second end of the tractor from a tractor hold that secures the second end of the tractor between a larger outer diameter region of the catheter and a larger outer diameter region of the catheter, wherein the larger diameter outer region is distal to the smaller outer diameter region.
23. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises disengaging a tractor hold from a tractor lock, wherein the tractor lock is on the second end of the tractor.
24. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises compressing either or both the tractor hold and a tractor lock on the second end of the tractor so that the tractor lock moves from a position proximal to the tractor hold to a position that is distal to the tractor hold.
25. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises pulling the first end of the tractor with the first force wherein the threshold force is between 50 g of force and 500 g of force.

26. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:
- a catheter having a proximal end and a distal end and a distal end opening;
 - a tractor comprising a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter;
 - a puller having a proximal end and a distal end, wherein the first end of the tractor is coupled to the puller at a region that is proximal to the distal end, further wherein the puller extends within the catheter to the proximal end of the catheter;
 - a guidewire lumen extending through the catheter, the puller and the tractor, and configured to pass a guidewire.
27. The apparatus of claim 26, further comprising a stop between the distal end of the puller and the distal end opening.
28. The apparatus of claim 26, further comprising a stop on the puller between the distal end of the puller and the first end of the tractor, wherein first end of the tractor is coupled to a sliding ring configured to slide over the puller until it engages the stop.
29. The apparatus of claim 26, wherein there is 2 mm or greater distance between the distal end of the puller and the region of the puller to which the first end of the tractor is coupled.
30. The apparatus of claim 26, wherein the proximal end of the puller is configured to couple to a vacuum source.
31. The apparatus of claim 26, wherein the proximal end of the puller comprises a Tuohy-Borst valve/rotating hemostasis valve (RHV).

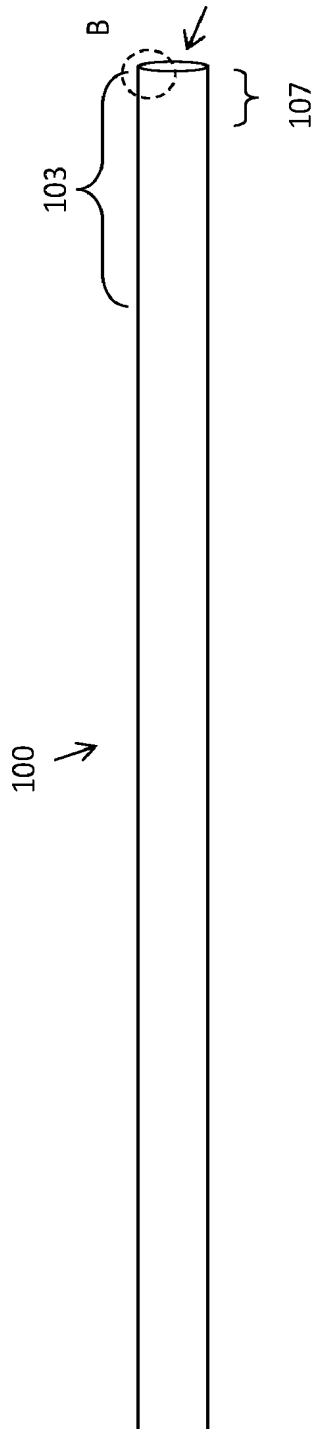


FIG. 1A

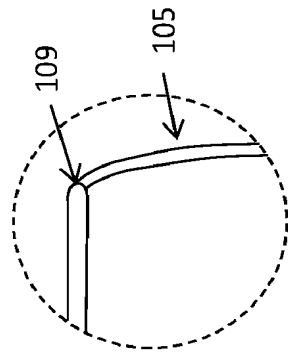


FIG. 1B

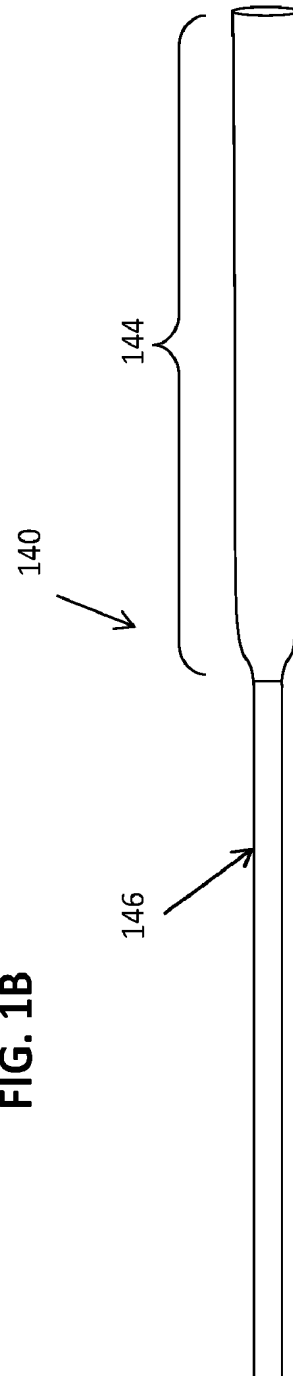


FIG. 1C

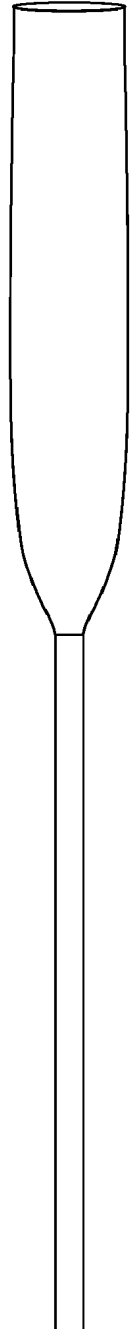


FIG. 1D

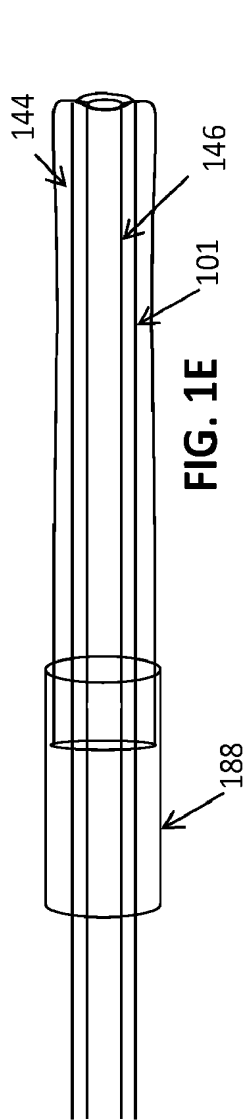


FIG. 1E

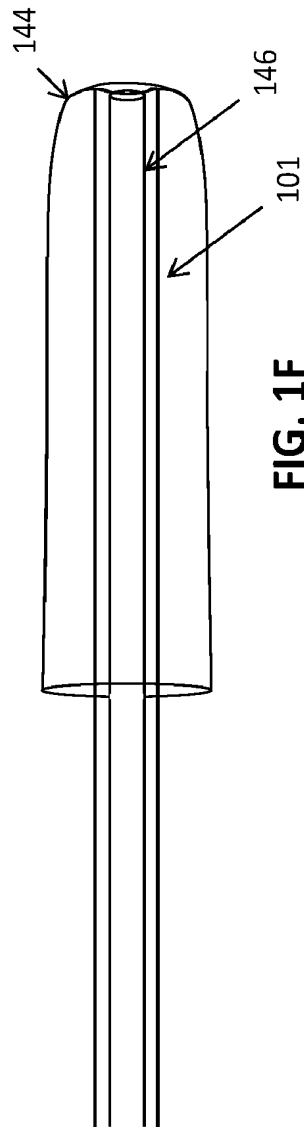


FIG. 1F

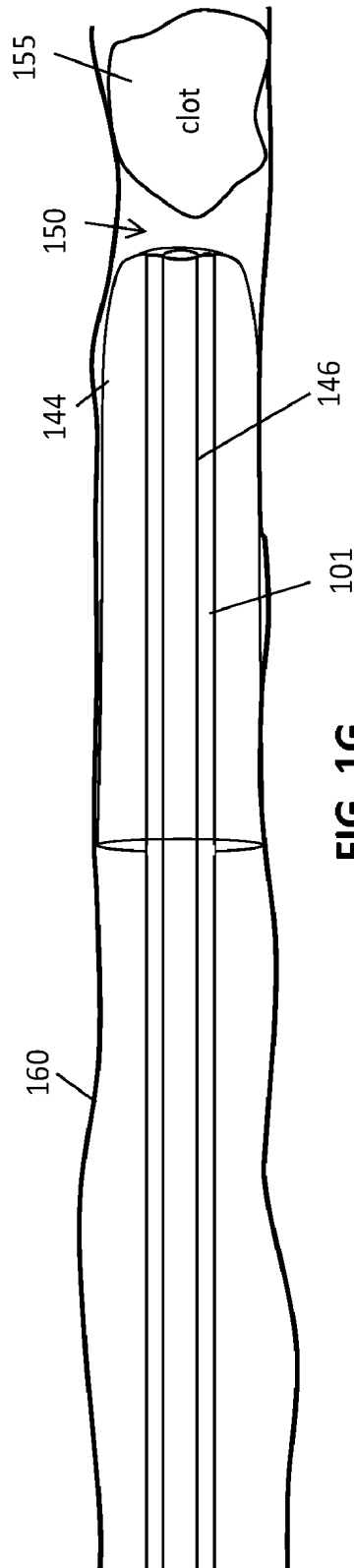


FIG. 1G

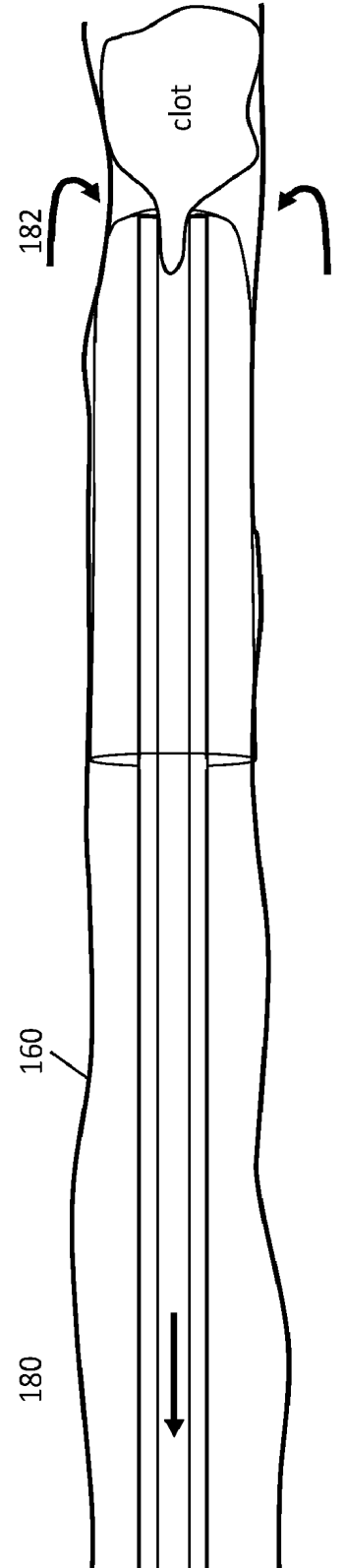


FIG. 1H

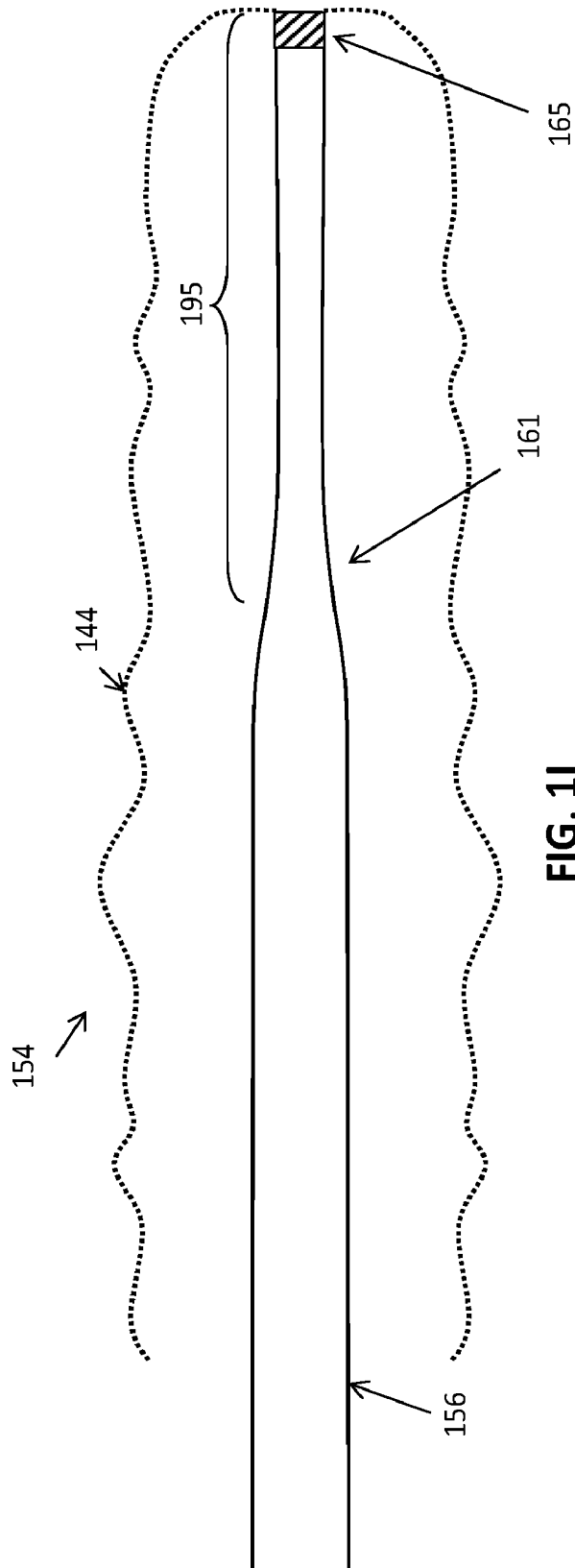


FIG. 1I

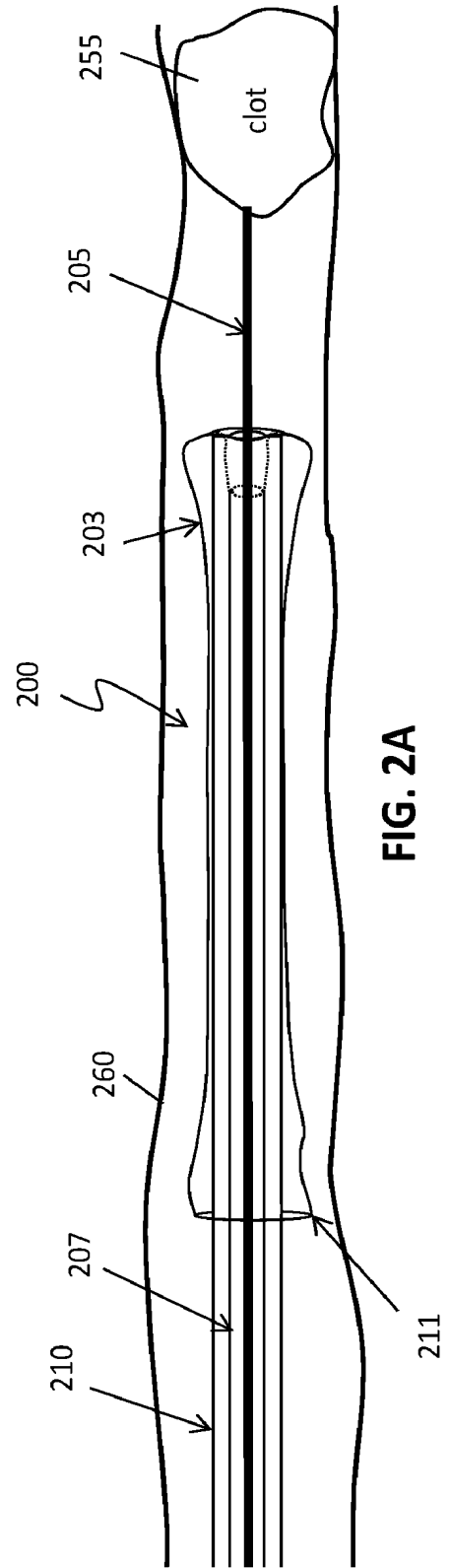


FIG. 2A

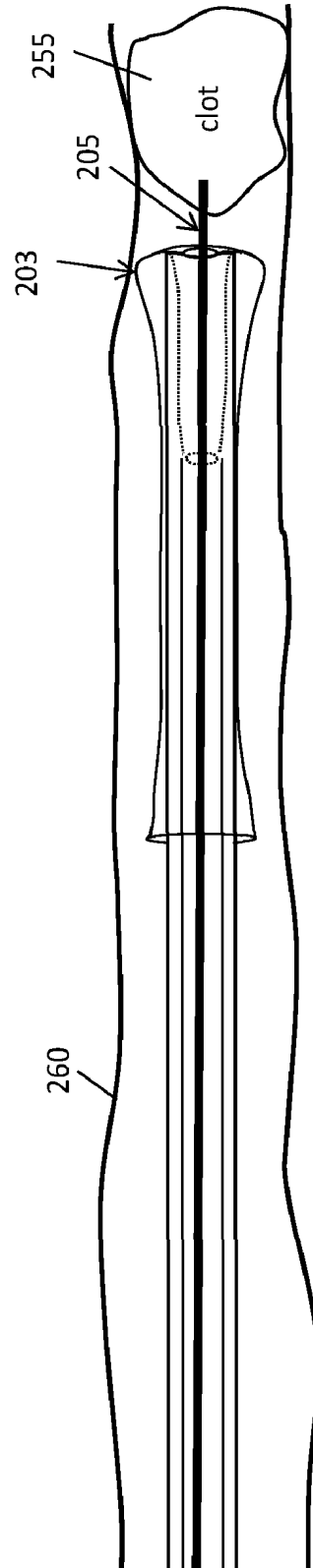


FIG. 2B

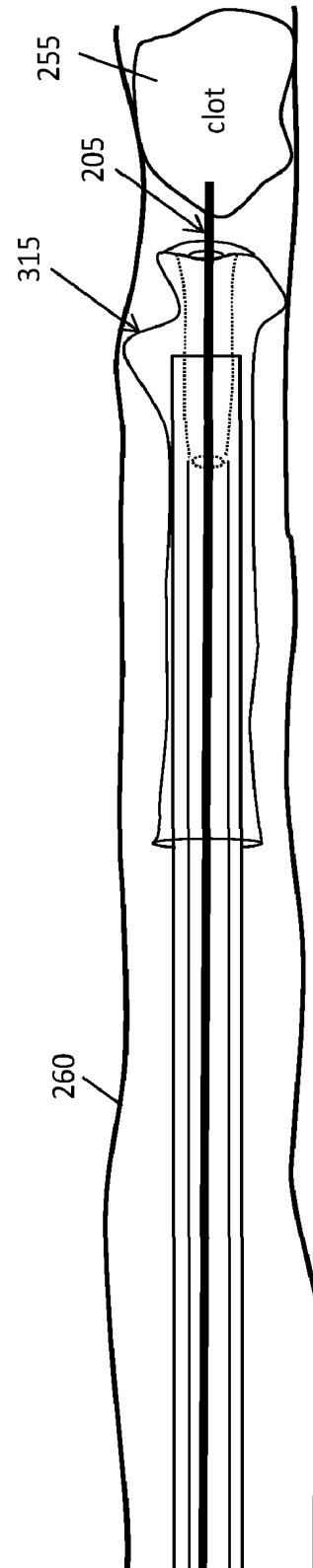


FIG. 2C

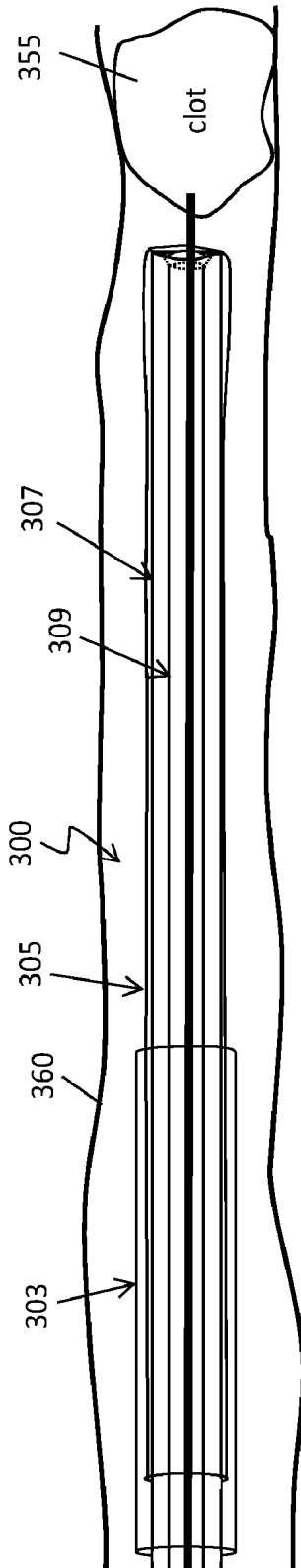


FIG. 3A

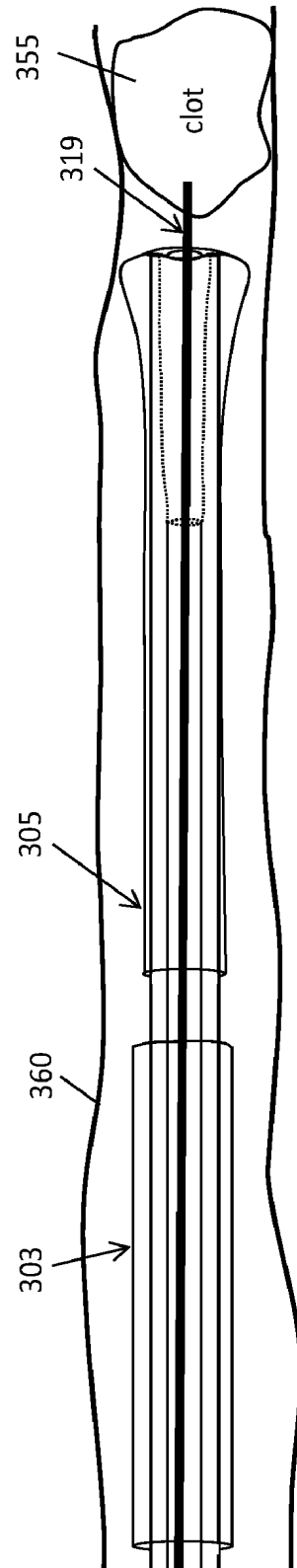


FIG. 3B

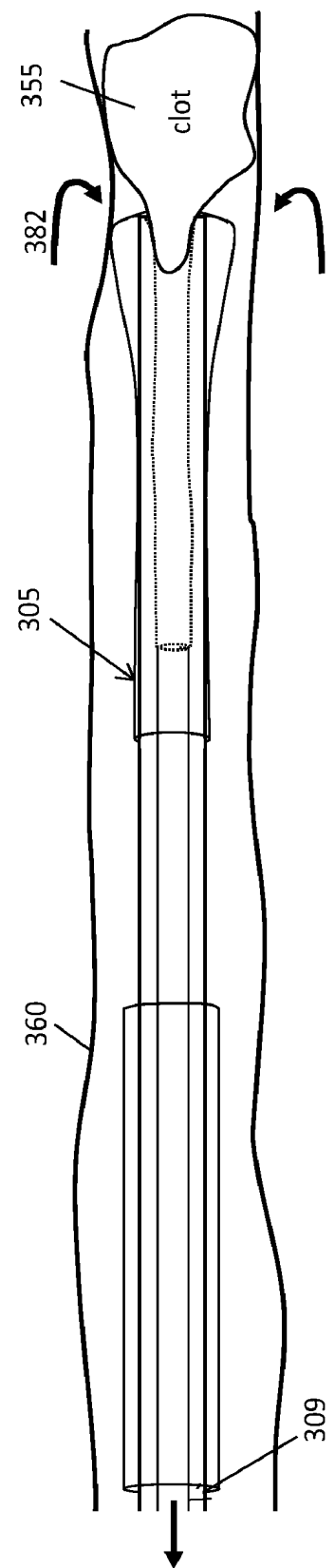


FIG. 3C

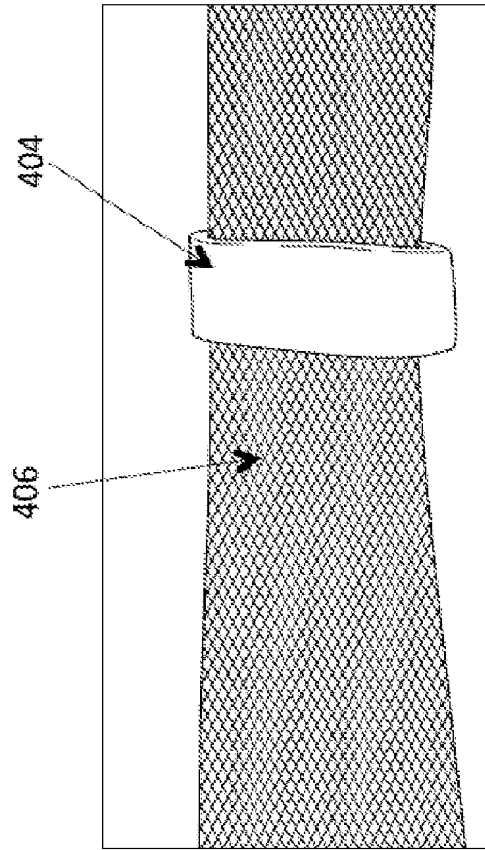


FIG. 4A

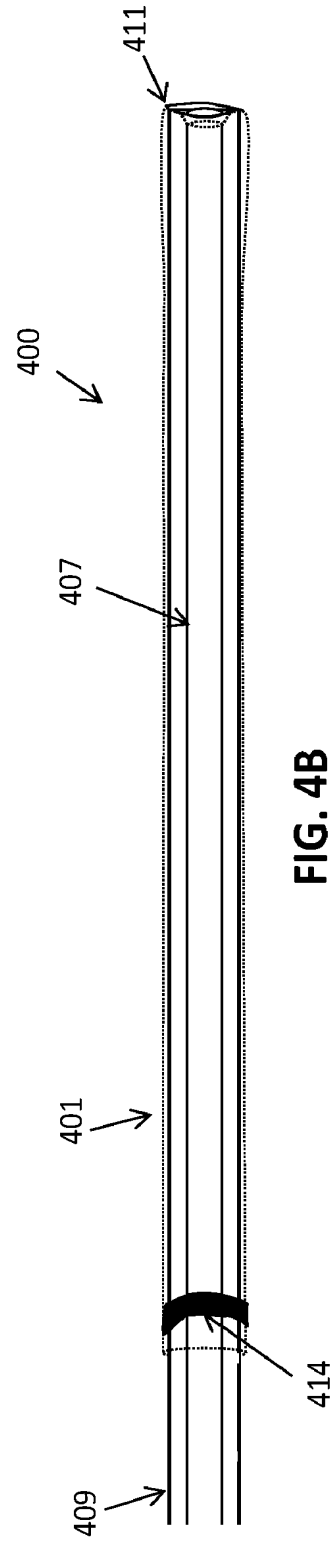


FIG. 4B

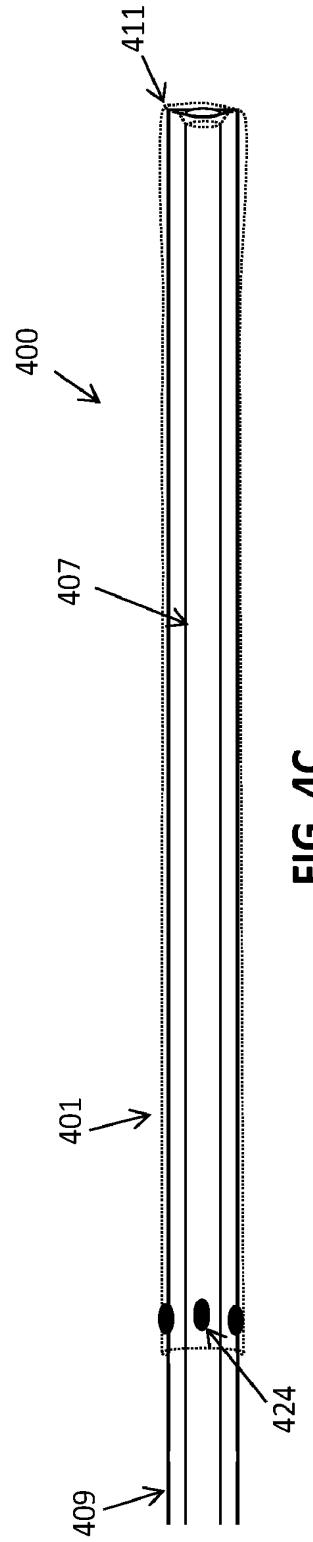
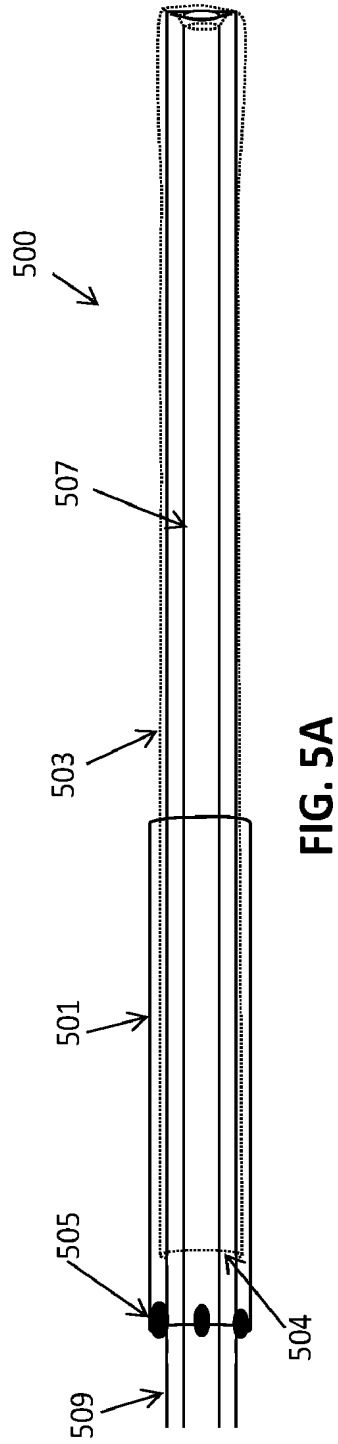
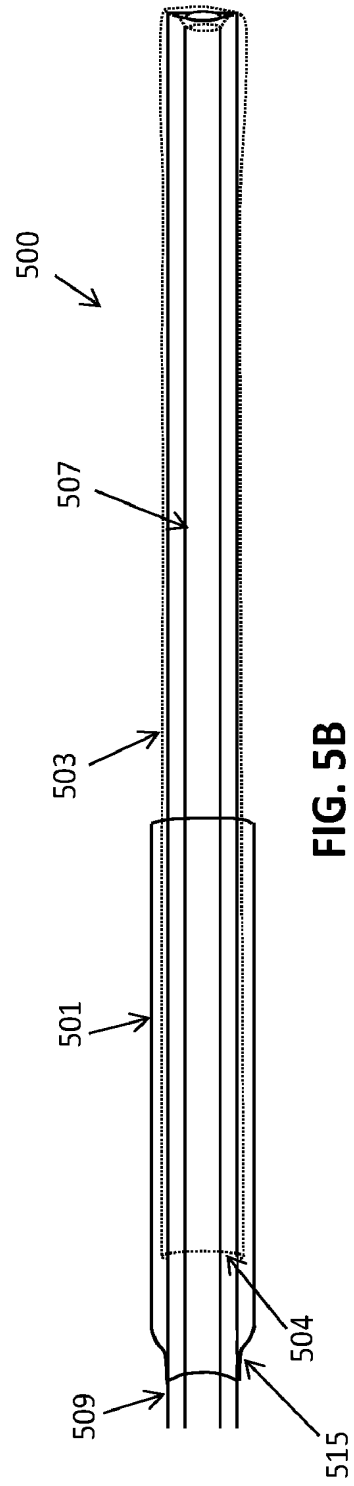
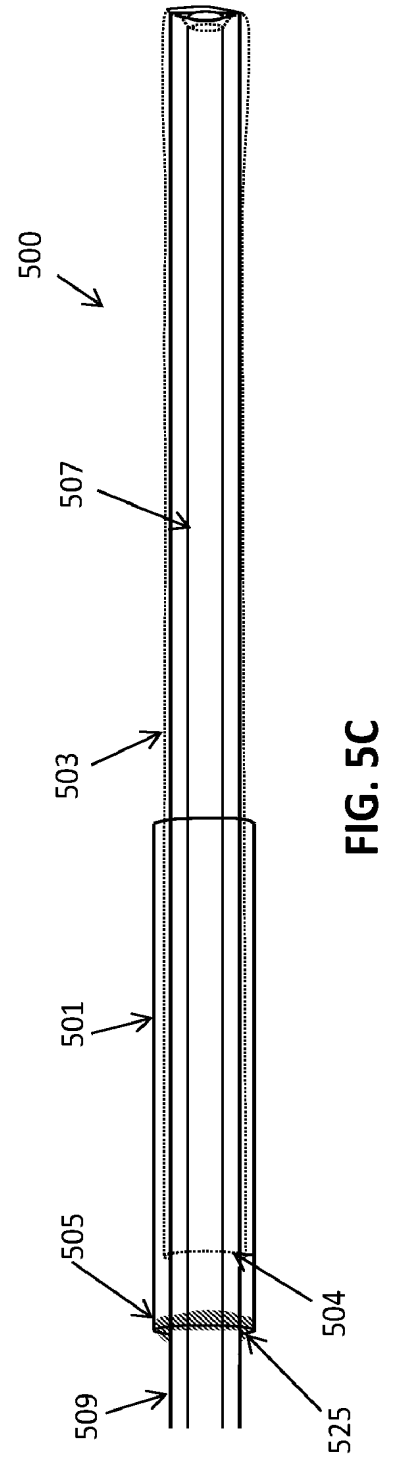


FIG. 4C



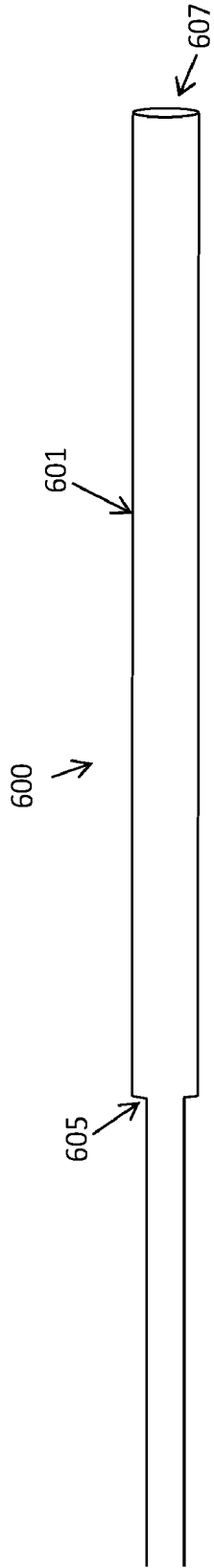


FIG. 6A

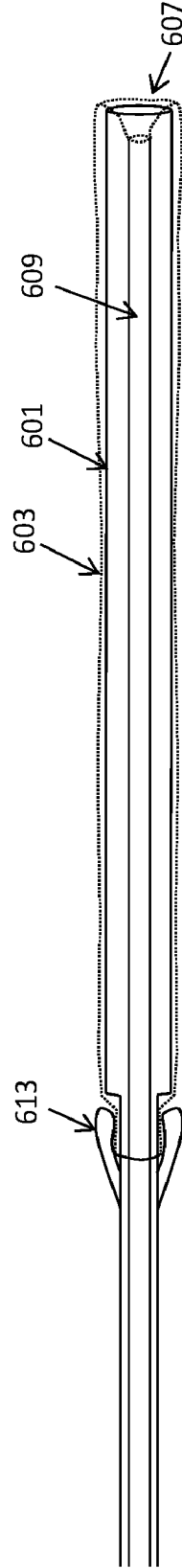


FIG. 6B

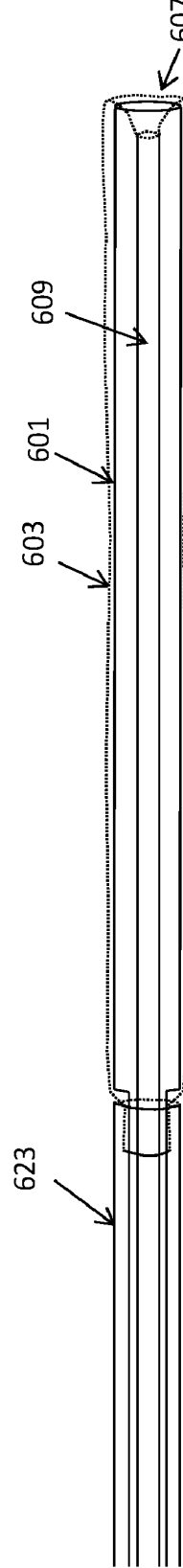


FIG. 6C

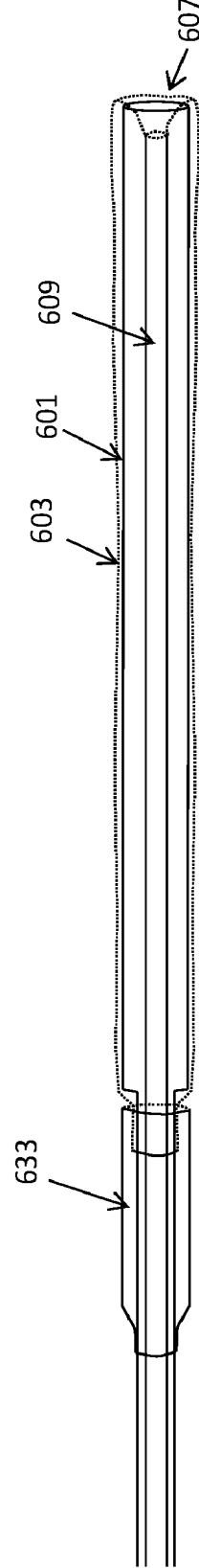
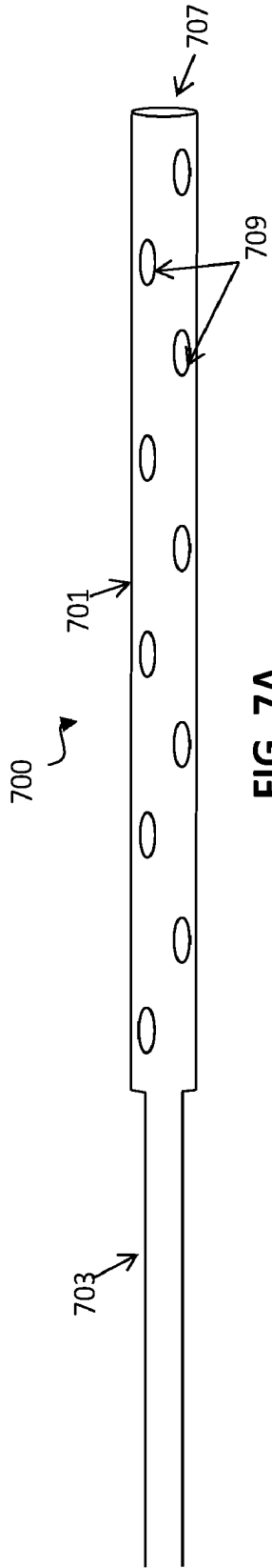
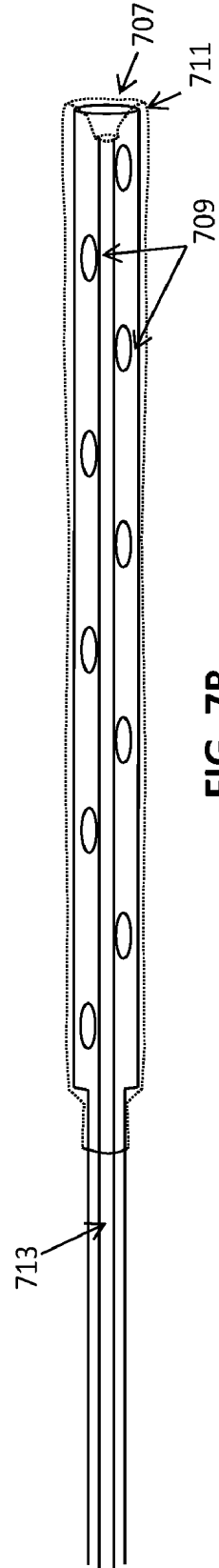
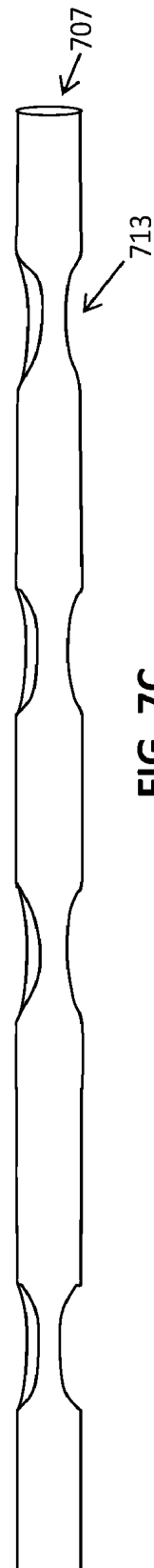
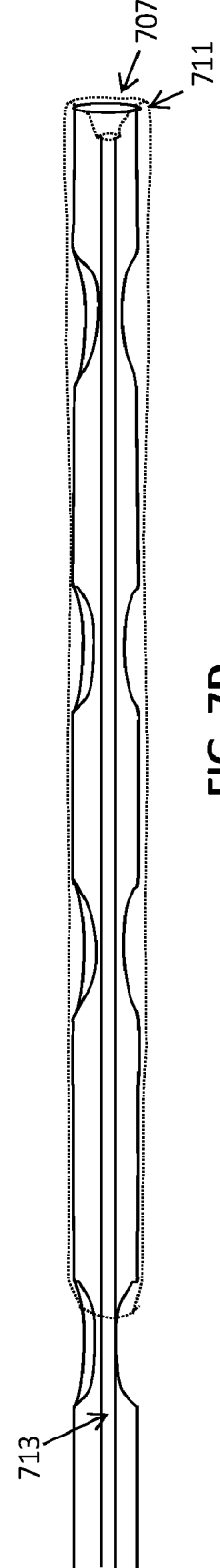
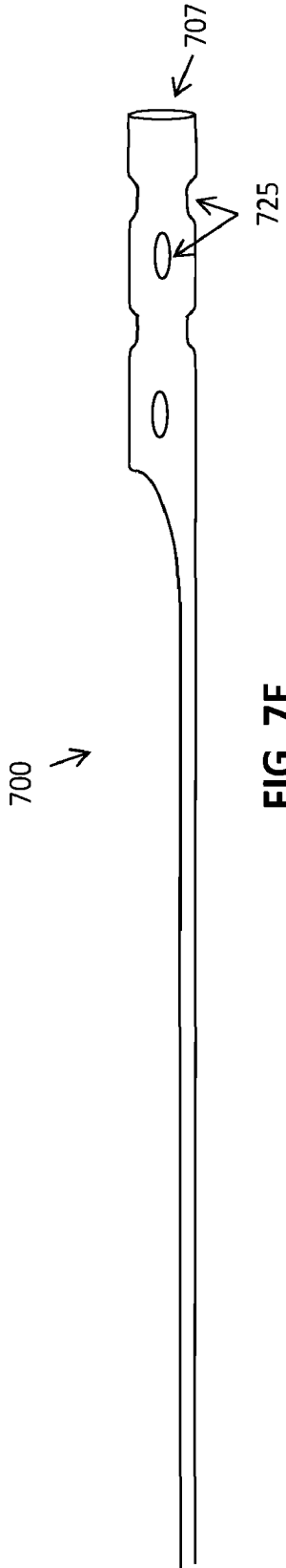
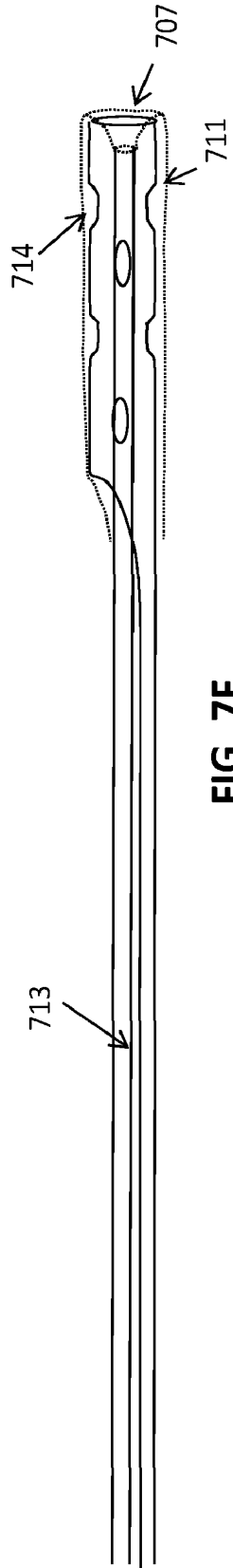
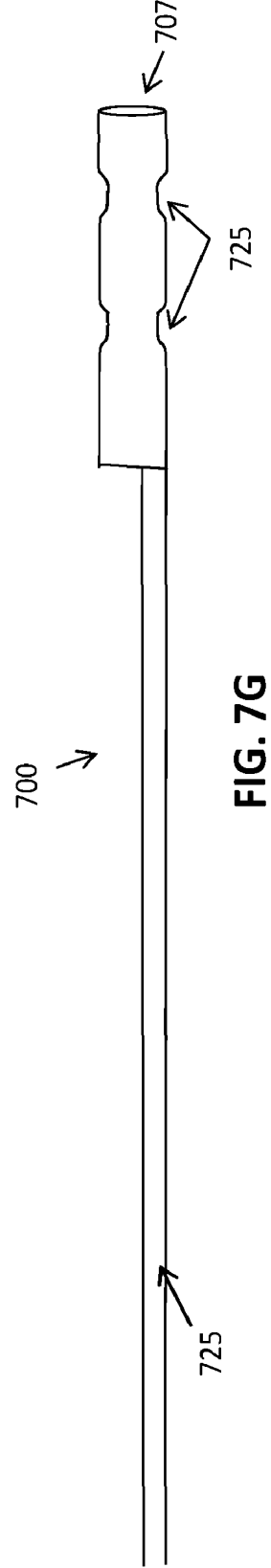
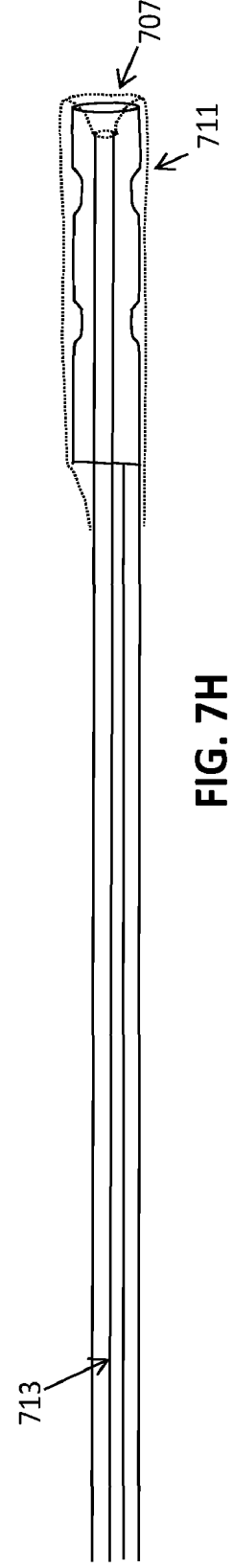
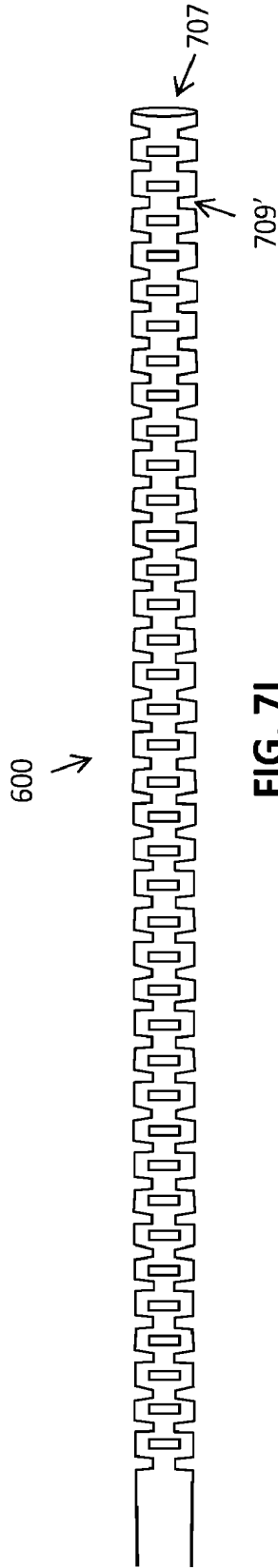
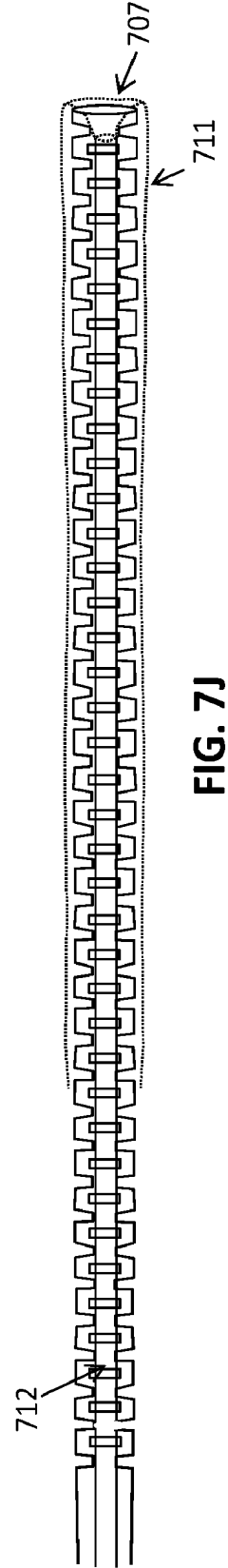
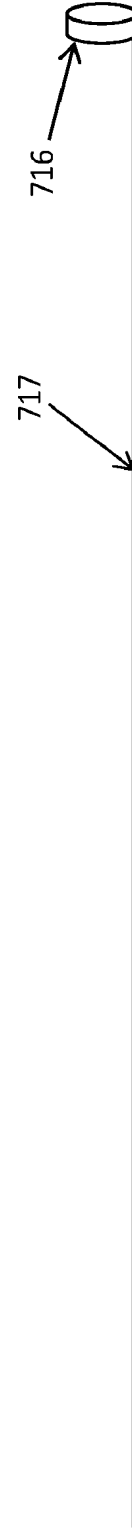
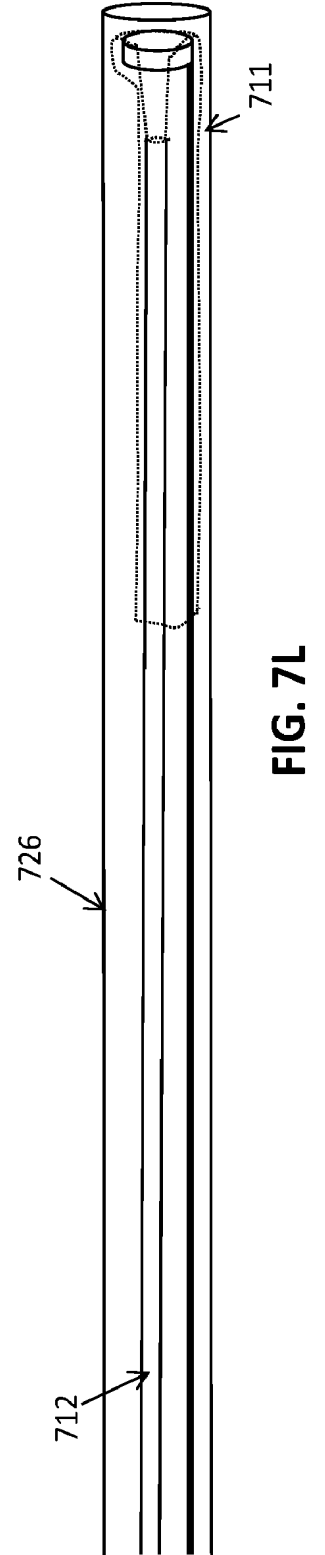


FIG. 6D







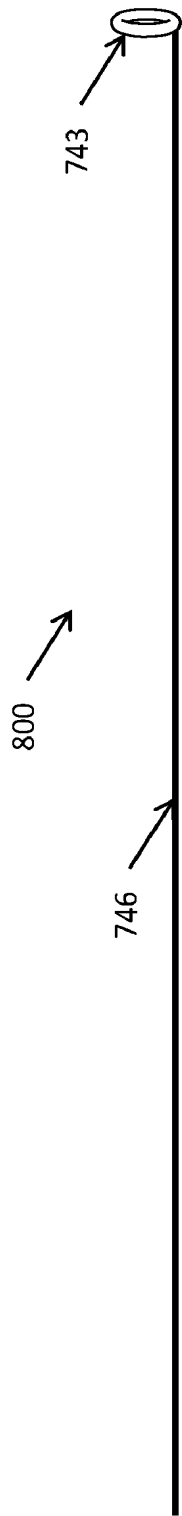


FIG. 8A

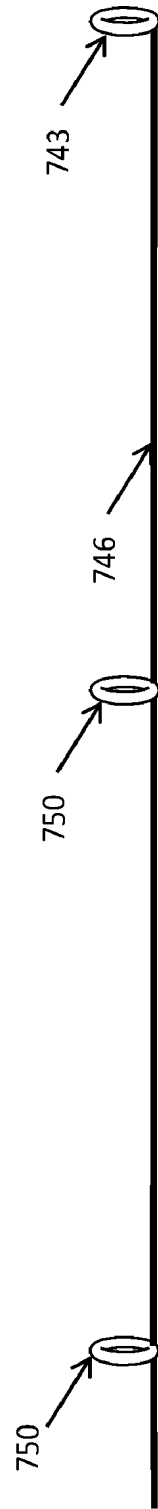


FIG. 8B

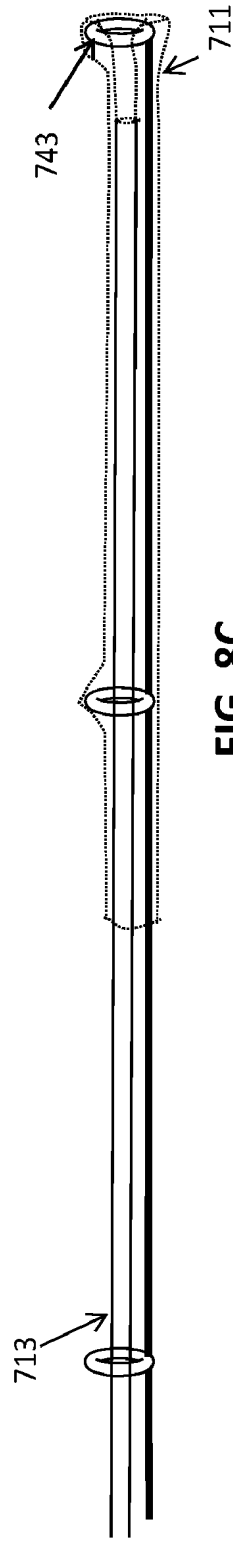


FIG. 8C

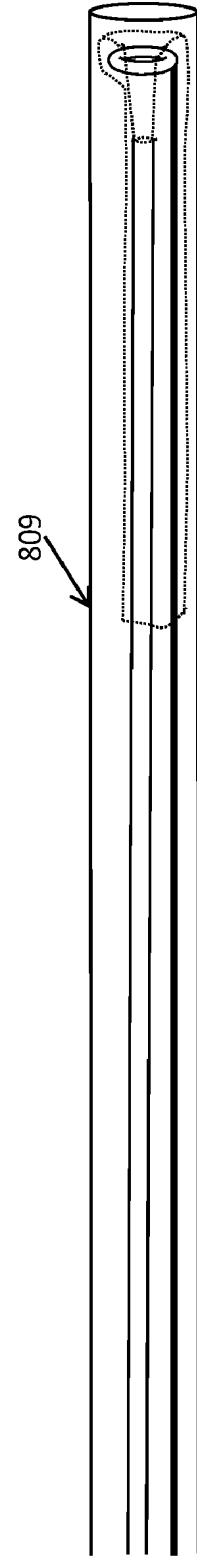


FIG. 8D

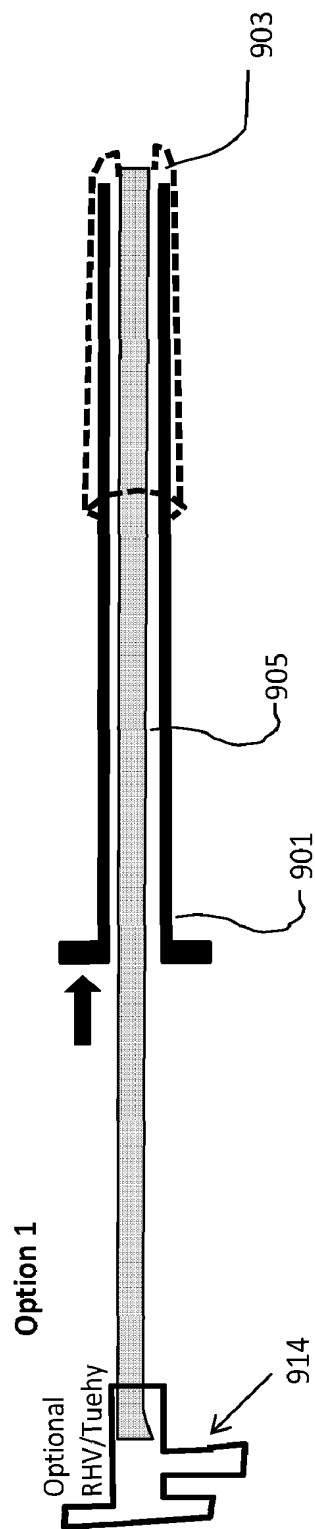


FIG. 9A

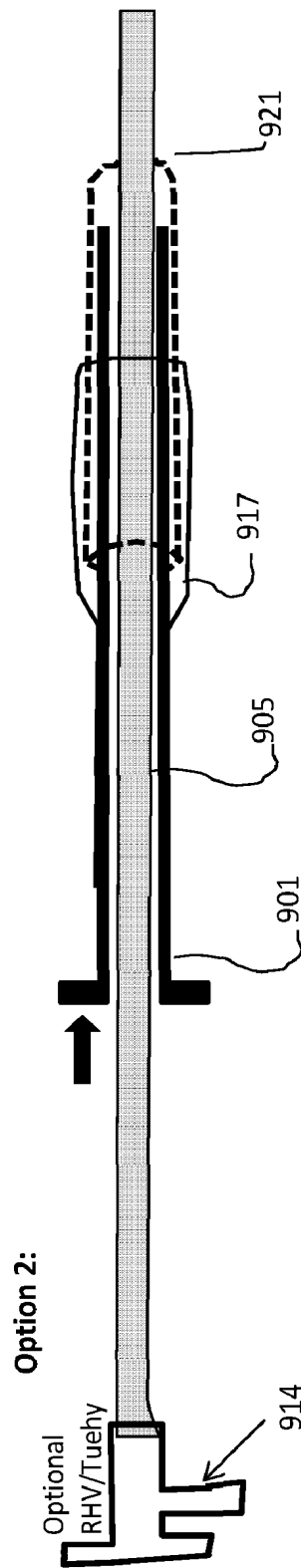


FIG. 9B

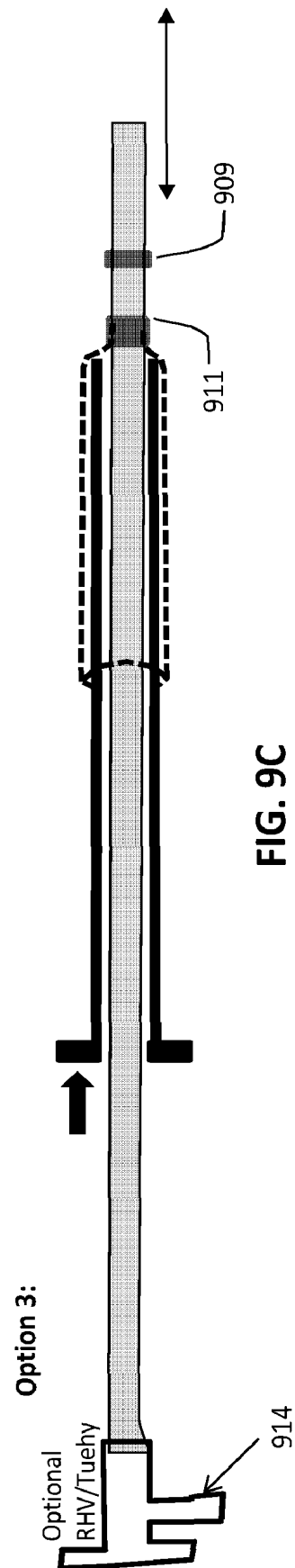


FIG. 9C

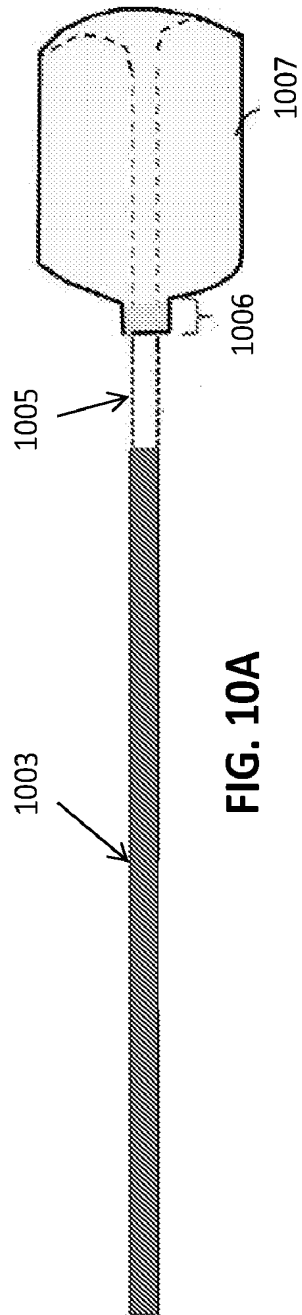


FIG. 10A

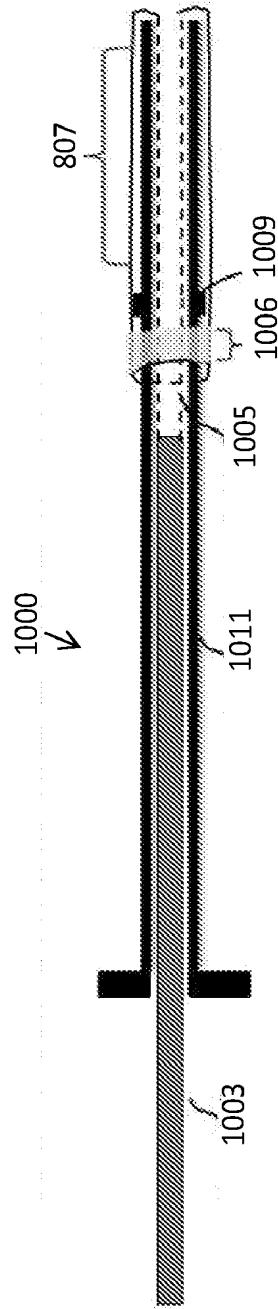


FIG. 10B

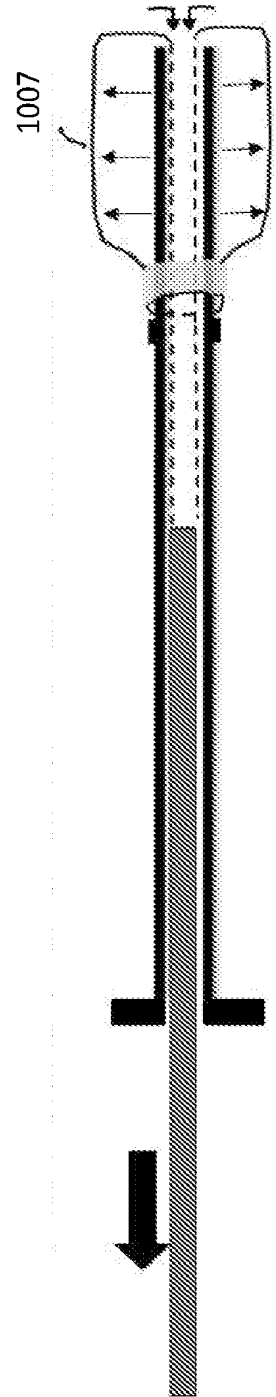
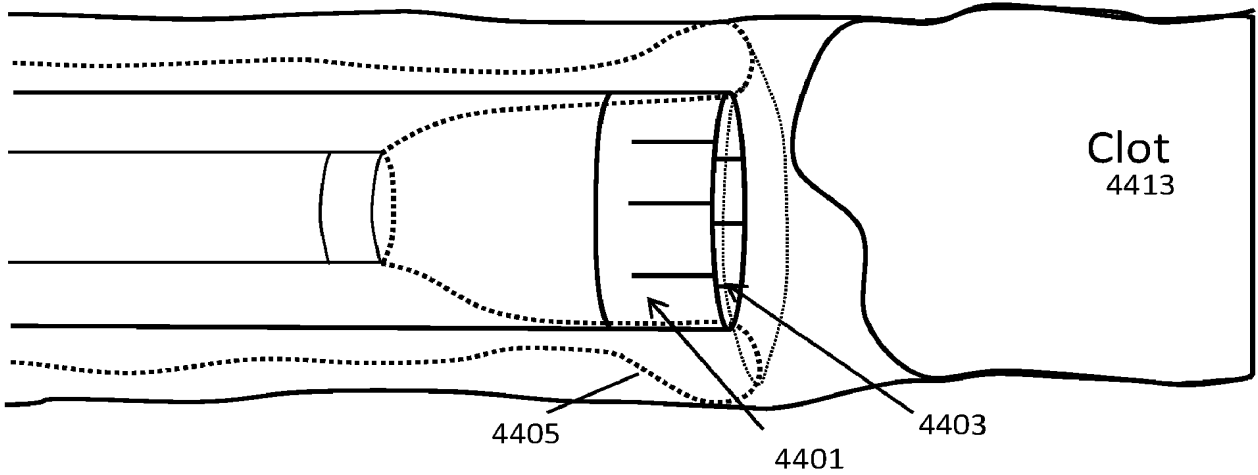
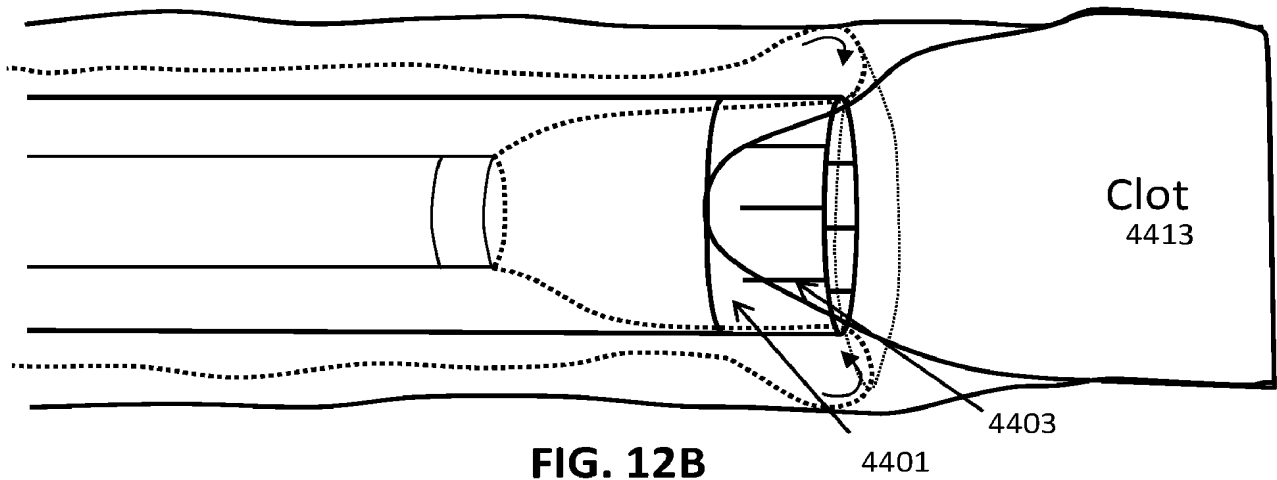
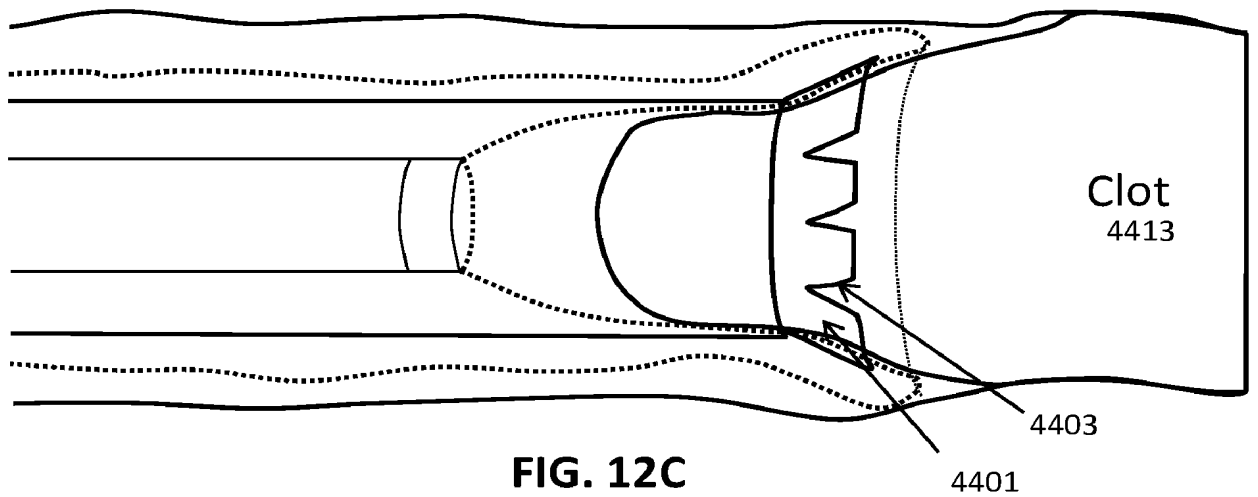


FIG. 10C



A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61B17/22 A61B17/221
 ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; figures page 8, line 12 - page 11, line 16 -----	1,16
A	W0 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19) paragraphs [0152], [0153], [0167] - [0170]; figures 10, 13B -----	1,16



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

29 June 2017

Date of mailing of the international search report

29/08/2017

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040,
 Fax: (+31-70) 340-3016

Authorized officer

Giménez Burgos, R

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 17-25
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-16

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-16

A mechanical thrombectomy apparatus comprising: a catheter, a tractor, a puller and a tractor hold to secure an end of the tractor to an outside surface of the catheter until a force greater than a threshold force is applied by pulling the tractor proximally within the catheter.

2. claims: 26-31

A mechanical thrombectomy apparatus comprising: a catheter, a tractor, a puller and a guide wire lumen extending through the catheter, the puller and the tractor, and configured to pass a guide wire.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 17-25

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
GB 2498349	A	17-07-2013	EP 2802275 A1	19-11-2014
			GB 2498349 A	17-07-2013
			US 2015005781 A1	01-01-2015
			WO 2013106146 A1	18-07-2013

WO 2012009675	A2	19-01-2012	US 2014005712 A1	02-01-2014
			WO 2012009675 A2	19-01-2012



(51) International Patent Classification:

A61B 17/22 (2006.01) A61B 17/221 (2006.01)

(21) International Application Number:

PCT/US2017/050933

(22) International Filing Date:

11 September 2017 (11.09.2017)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/393,460 12 September 2016 (12.09.2016) US

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(72) Inventors: **WALLACE, Michael, P.**; 5849 Corte Margari-
ta, Pleasanton, California 94566 (US). **GREENHALGH,**
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19035 (US).

(74) Agent: **BURSE, David, T.** et al.; Vista IP Law Group LLP,
21760 Stevens Creek Blvd., Suite 100, Cupertino, Califor-
nia 95014 (US).

(81) Designated States (*unless otherwise indicated, for every
kind of national protection available*): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO,

DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,
HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP,
KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME,
MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,
OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA,
SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every
kind of regional protection available*): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: SELF-ROLLING THROMBECTOMY APPARATUSES AND METHODS

(57) Abstract: Self-rolling mechanical atherectomy aka thrombectomy appa-
ratuses for removing a clot from a vessel include a tractor tube portion that rolls
and inverts over itself in a continuous motion, tractor-like, to draw material into
the tractor tube, wherein the tractor tube rolls over itself without requiring any
additional internal support at the distal-facing region of the tractor tube.

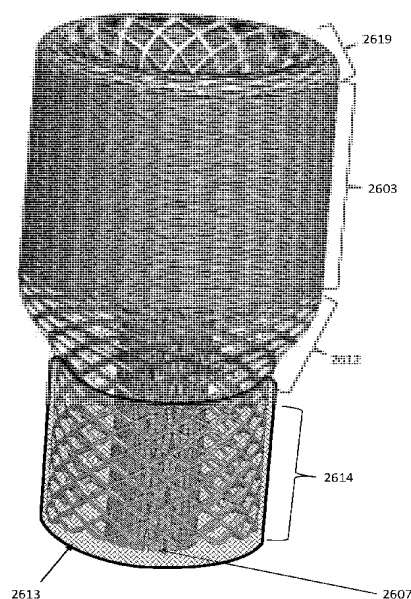


FIG. 26A

SELF-ROLLING THROMBECTOMY APPARATUSES AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims the benefit of priority to U.S. Provisional Patent Application No. 62/393,460, filed September 12, 2016.

5 [0002] The subject matter of this patent application is related to the subject matter disclosed and described in each of U.S. Patent Application No 15/291,015, filed October 11, 2016; U.S. Patent Application No. 15/043,996, filed February 15, 2016, now U.S. 9,463,035, U.S. Patent Application No. 15/496,570, filed April 25, 2017; U.S. Patent Application No. 15/496,668, filed April 25, 2017; U.S. Patent Application No. 15/496,786, filed April 25, 10 2017; U.S. Patent Application No. 15/497,092, filed April 25, 2017; and U.S. Patent Application No. 15/611,546, filed June 1, 2017. Each of the foregoing patents and patent applications is incorporated by reference herein in its entirety.

INCORPORATION BY REFERENCE

15 [0003] All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

20 [0004] The apparatuses and methods described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses and methods.

BACKGROUND

25 [0005] It is often desirable to remove tissue from the body in as minimally invasive a manner as possible, so as not to damage other tissues. For example, removal of tissue from within a patient's vasculature, such as removal of blood clots from veins and arteries, may improve patient conditions and quality of life.

[0006] Many vascular problems stem from insufficient blood flow through blood vessels. One cause of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma 30 such as surgery. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery.

[0007] When a thrombus forms, it may effectively stop the flow of blood through the zone of formation. If the thrombus extends across the interior diameter of an artery, it may cut off the flow of blood through the artery. If a coronary artery is 100% thrombosed, the flow of blood is stopped in that artery, resulting in a shortage of oxygen carrying red blood cells, e.g., to supply the muscle (myocardium) of the heart wall. Such a thrombosis can be triggered within an artery by damage to the arterial wall from atherosclerotic disease. Thus, the underlying disease of atherosclerosis may not cause acute oxygen deficiency (ischemia) but can trigger acute ischemia via induced thrombosis. Similarly, thrombosis of one of the carotid arteries can lead to stroke because of insufficient oxygen supply to the brain. Oxygen deficiency reduces or prohibits muscular activity, can cause chest pain (angina pectoris), and can lead to death of myocardium which permanently disables the heart. If myocardial cell death is extensive, the heart will be unable to pump sufficient blood to supply the body's needs.

[0008] Clinical data indicates that clot removal may be beneficial or even necessary to improve outcomes in such cases. For example, in the peripheral vasculature, interventions and procedures can reduce the need for an amputation by 80 percent. The ultimate goal of any modality to treat these conditions of the arterial or venous system is to remove the blockage or restore patency, quickly, safely, and cost effectively. This may be achieved by thrombus dissolution, fragmentation, thrombus aspiration or a combination of these methods.

[0009] Mechanical thrombectomy devices may be particularly advantageous. Depending on the size, location and extent of a clot, it may also be particularly advantageous to mechanically retrieve and break apart the clot in a manner that is both safe and effective. There is a definite need for a thrombectomy device, and particularly a mechanical thrombectomy device that can be more effective in removing tissue such as clots from within a body. Described herein are systems and apparatuses, and methods of using such systems and apparatuses, that address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[00010] Described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and methods of using and making them.

[00011] In general, described herein are self-rolling mechanical atherectomy apparatuses for removing a clot from a vessel. These atherectomy apparatuses, which may also be referred to as thrombectomy apparatuses, typically include a tractor tube portion that rolls and inverts over itself in a continuous motion, tractor-like, to draw material into the tractor tube.

The apparatuses described herein may be similar to the mechanical atherectomy apparatuses, systems and methods disclosed and described in the above-list of related U.S. patents and applications, which have been incorporated by reference herein in their entirety. However, the self-rolling mechanical atherectomy apparatuses described herein are configured such that the tractor tube (also referred to as a tractor region) rolls and inverts over itself unsupported at the distal-facing end when the inner tractor tube portion is pulled proximally. Specifically, the apparatuses described herein are configured so that the tractor tube rolls and inverts over itself, unsupported, without the need for an internal catheter extending within the inverting tractor tube providing a support or distal end opening to roll over.

[00012] Thus, the tractor tube is inverted over itself to form a distal-facing region at the distal end of the self-rolling mechanical atherectomy apparatus where, in a deployed configuration, the outer tractor tube portion rolls over and into itself, unsupported to become the inner tractor tube portion as the proximal end of the inner tractor tube portion is pulled proximally. At least the distal-most region of the tractor tube (e.g., the region at or near the distal-facing, inverting region of the tractor tube) is unsupported over at least the distal-most 1 or more cm of the apparatus. The tractor tube may be actuated to roll over itself by pulling proximally on the inner tractor tube portion (or an inner tractor puller coupled to the inner tractor tube portion) and/or by pushing distally on a proximal end of the outer tractor tube portion that is braced against an outer tractor pusher. In general, in an expanded configuration, the proximal end of the outer tractor tube portion is braced against a tapered portion of the tractor tube proximal to the outer tractor tube portion.

[00013] The tractor tube may be adapted to allow unsupported rolling over itself having a column strength of the outer tractor tube portion that resists buckling and/or collapse when compressed by pulling proximally on the inner tractor tube portion. As described in greater detail herein, this may be accomplished by one or more of forming the tractor tube from a braided material having a compressed braid angle relative to the proximal-to-distal axis that is greater than 80 degrees (e.g., greater than 85 degrees, greater than 90 degrees, greater than 95 degrees, greater than 100 degrees, between 80-170 degrees, between 90-170 degrees, between 95-170 degrees, etc.); the braid angle of the inner tractor tube portion under tension in the proximal-to-distal axis is typically much less than the compressed braid angle of the outer tractor tube portion in compression, and may be, e.g., less than 90 degrees (e.g., less than 85 degrees, less than 80 degrees, less than 75 degrees, less than 70 degrees, less than 65 degrees, less than 60 degrees, less than 50 degrees, less than 45 degrees, less than 40 degrees, between 90-5 degrees, between 80-5 degrees, between 70-5 degrees, between 65-5 degrees,

between 60-5 degrees, etc.). The compressed outer tractor tube braid angle refers to the braid angle of the outer tractor tube in the deployed (e.g., radially expanded) configuration; pulling the inner tractor tube portion proximally, e.g., by pulling the inner tractor puller, results in a compressive load on the outer tractor tube portion that is continuous but inverted relative to the inner tractor tube portion.

[00014] For example, described herein are self-rolling mechanical atherectomy apparatuses that include: an outer tractor pusher comprising a catheter having a distal end and a distal end opening; a tractor tube comprising an outer tractor tube portion that extends distally in an un-inverted configuration and inverts into itself at a distal-facing region to form an inner tractor tube portion, wherein the tractor tube is configured so that pulling the inner tractor tube portion proximally compresses the outer tractor tube portion so that it has a column strength that resists collapsing, further wherein pulling the inner tractor tube proximally causes a region of the outer tractor tube portion at the distal-facing region to roll over itself, unsupported, and invert into the inner tractor tube portion; and an inner tractor puller coupled to the inner tractor tube portion and extending proximally within the outer tractor pusher.

[00015] In general, the outer tractor pusher may be a catheter, tube, cannula, or the like. During delivery or positioning of the apparatus, the tractor tube, and an inner tractor puller, if included, may be held within the outer tractor pusher in an un-deployed configuration. Prior to clot removal, the tractor tube may be deployed out of the outer tractor pusher portion and the outer tractor pusher portion may be expanded into a deployed configuration that has an outer radial diameter that is greater than the inner radial diameter of the outer tractor pusher. The outer tractor pusher may then be positioned to support or brace the outer tractor tube portion to allow it to roll over and into itself distally when the inner tractor puller is pulled proximally. Alternatively, a separate distal access catheter may be included, and the outer tractor pusher may be held within the distal access catheter along with the tractor tube prior to deployment within the blood vessel.

[00016] In any of these apparatuses, the outer tractor pusher may be coupled to a proximal end of the outer tractor tube portion of the tractor tube. Alternatively, the proximal end of the outer tractor tube portion may be unconnected to the outer tractor pusher.

[00017] As mentioned, the apparatus may include a distal access catheter. The outer tractor pusher, the tractor tube and inner tractor puller may be held within the distal access catheter in an un-deployed configuration, further wherein the tractor tube may be configured to be pushed distally out of the distal access catheter so that the outer tractor tube portion may

expand to a diameter that is greater than an outer diameter of the distal access catheter in a deployed configuration. Alternatively, the outer tractor pusher may be configured as a distal access catheter wherein the tractor tube and inner tractor puller may be held within the outer tractor pusher in an un-deployed configuration, further wherein the tractor tube may be configured to be deployed by being pushed distally out of the outer tractor pusher so that the outer tractor tube portion expands to an outer diameter that is greater than an outer diameter of the outer tractor pusher.

[00018] In any of the self-rolling mechanical atherectomy apparatuses described herein, the tractor tube may be configured so that pulling the inner tractor tube proximally compresses the outer tractor tube portion and the column strength of the outer tractor tube portion resists collapsing up to at least 300g of compression (e.g., at least about 350 g of compression, at least about 400 g of compression, at least about 450 g of compression, at least about 500 g of compression, at least about 550 g of compression, at least about 600 g of compression, at least about 650 g of compression, at least about 700g of compression, etc.).

[00019] In general, the tractor tube comprises a braided or woven material. For example, the tractor tube may be a woven or braided tube, e.g., formed of one or a plurality of filament. The filaments may be monofilaments or bundles of filaments, and may be a polymeric material, a metal material, a natural fiber material, etc. For example, the tractor tube may be formed of between 24-48 filaments. The tractor tube may be formed of a plurality of filaments having a diameter of greater than about 0.003 inches (e.g., greater than 0.0020 inches, greater than 0.0025 inches, greater than 0.0035 inches, greater than 0.0040 inches, greater than 0.0045 inches, greater than 0.0050 inches, etc.).

[00020] In particular, the tractor tube may be configured to resist buckling when rolling over itself based in part on the arrangement of the filaments. For example, the outer tractor tube portion may have a braid angle in a proximal to distal axis (in a compressed configuration) that is between 80 and 170 degrees, and the inner tractor tube portion may have a braid angle in the proximal to distal axis (e.g., under tension) of less than 80 degrees.

[00021] In any of the apparatuses described herein, the proximal end of the outer tractor tube portion may be configured to have a tapered shape when the outer tractor tube portion is expanded radially outward. This tapered region may be shape set into the tractor tube (e.g., when the tractor tube is formed of a shape-settable material, for example, such as a nickel titanium alloy) and/or it may be formed by attaching a retaining structure to the proximal end of the outer tractor tube portion, such as a retaining band, retaining ring, etc., or by attachment to the outer tractor pusher.

[00022] As mentioned, the distal-facing region of the tractor tube may be unsupported, including unsupported over at least 1 cm proximally from the distal-facing region of the tractor tube (e.g., at least 1.5 cm, at least 2 cm, at least 2.5 cm, etc.). Thus, the tractor tube does not roll over a support (such as a catheter) at the distal-facing tractor portion at the distal
5 end of the device.

[00023] In general, the tractor tube may be porous. For example, the tractor tube may have a porosity of 50% or greater (e.g., 55% or greater, 60% or greater, 65% or greater, 70% or greater, 75% or greater, etc.).

[00024] Any of the apparatuses described herein may be used with a guidewire, for placing
10 the apparatus. For example, the inner tractor puller may include an inner lumen configured to pass a guidewire out of a distal end of the apparatus. In general a guidewire may be included as part of the apparatus.

[00025] Any of these apparatuses may include a vacuum source coupled to the tractor tube and configured to apply a vacuum (e.g., aspiration) therethrough. The vacuum source may
15 include a pump.

[00026] For example, a self-rolling mechanical atherectomy apparatus for removing a clot from a vessel may include: an outer tractor pusher comprising a catheter having a distal end and a distal end opening; a tractor tube comprising an outer tractor tube portion that extends distally in an un-inverted configuration and inverts into itself at a distal-facing region to form
20 an inner tractor tube portion, wherein the tractor tube is configured so that pulling the inner tractor tube portion proximally compresses the outer tractor tube portion so that it has a column strength that resists collapsing up to at least 500g of compression and extends inner tractor tube portion, further wherein pulling the inner tractor tube proximally causes a region of the outer tractor tube portion at the distal-facing region to roll over itself, unsupported, and
25 invert into the inner tractor tube portion; and an inner tractor puller coupled to the inner tractor tube portion and extending proximally within the outer tractor pusher.

[00027] Also described herein are methods of removing a clot from a blood vessel using any of the apparatuses described herein. Generally, these methods may include actuating a self-rolling mechanical atherectomy apparatus so that the distal-facing region of the tractor
30 tube is unsupported as the outer tractor tube portion rolls over and into itself and inverts, pulling in any clot or other target material into the tractor tube. The tractor tube is typically configured to roll over itself without support (e.g., be “self-rolling”) from any other structure, e.g., by having a sufficient column strength in the outer tractor tube portion in compression to resist or prevent buckling, bending or collapse, yet be sufficiently flexible that it may bend

and navigate through the often tortious anatomy of the vasculature (and particularly the neurovasculature), and to roll over itself. Various configurations are described herein to achieve this combination of flexibility and column strength, including forming the apparatus with a braided (or woven) tractor tube having a large braid angle in the outer tractor tube portion (under compression) and a relatively smaller braid angle in the inner tractor tube portion (e.g., under tension).

[00028] For example, a method of removing a clot from a blood vessel may include: advancing a distal end of a self-rolling mechanical atherectomy apparatus through the blood vessel to the clot, wherein the self-rolling mechanical atherectomy apparatus comprises a tractor tube, an outer tractor pusher, and an inner tractor puller; pulling an inner tractor puller of the tractor tube proximally to compresses an outer tractor tube portion of the tractor tube, wherein pulling the inner tractor puller proximally causes the outer tractor tube portion at a distal-facing region of the tractor tube to roll over itself, unsupported, and invert into the inner tractor tube portion; and engaging the clot with the tractor tube as it rolls over itself so that the clot is pulled into the tractor tube.

[00029] Any of these methods may include deploying the tractor tube of the self-rolling mechanical atherectomy apparatus so that the outer tractor tube portion of the tractor tube expands to have an outer diameter that is greater than an outer diameter of the outer tractor pusher. Pulling the inner tractor puller may include bracing a distal-facing end of the outer tractor pusher against a tapered face of the tractor tube that is proximal to the outer tractor tube portion. Thus, the tapered face or region of the tractor tube may be pushed against the outer tractor pusher when the tractor tube is attached or un-attached to the outer tractor pusher. When attached to the outer tractor pusher, the tapered face region of the tractor tube may still be driven against the opening of the outer tractor pusher.

[00030] Any of the methods described herein may include advancing a guidewire within the blood vessel to the clot, wherein advancing the self-rolling mechanical atherectomy apparatus comprises advancing the self-rolling mechanical atherectomy apparatus over the guidewire through the blood vessel until the self-rolling mechanical atherectomy apparatus is proximate to the clot.

[00031] Engaging (or “grabbing”) the clot may include advancing the outer tractor pusher distally while pulling the inner tractor puller proximally. Alternatively or additionally, engaging the clot may include advancing the outer tractor pusher distally at a first rate while pulling the inner tractor puller proximally at a second rate that is different (e.g., faster) than the first rate.

[00032] In general, advancing may include advancing the self-rolling mechanical atherectomy apparatus distally with the tractor tube and inner tractor puller within the outer tractor pusher, wherein the tractor tube is in an un-deployed configuration. Once near (e.g., adjacent) the clot or other target, the tractor tube may be deployed from the inner tractor puller and/or distal access catheter.

[00033] Any of these methods may include applying aspiration through the tractor tube.

[00034] Advancing the self-rolling mechanical atherectomy apparatus may include advancing a distal access catheter enclosing the tractor tube, outer tractor pusher and inner tractor puller, wherein the outer tractor tube portion is inverted over the inner tractor puller in an un-deployed configuration within the distal access catheter.

[00035] Pulling the inner tractor puller may include applying up to 500 g of compressive force on the outer tractor tube portion without collapsing the outer tractor tube portion.

[00036] For example, a method of removing a clot from a blood vessel may include: advancing a distal end of a self-rolling mechanical atherectomy apparatus through the blood vessel to the clot, wherein the self-rolling mechanical atherectomy apparatus comprises a tractor tube, an outer tractor pusher, and an inner tractor puller; deploying the tractor tube of the self-rolling mechanical atherectomy apparatus so that an outer tractor tube portion of the tractor tube expands to have an outer diameter that is greater than an outer diameter of the outer tractor pusher, wherein a distal-facing end of the outer is braced against a tapered face of the tractor tube proximal to the outer tractor tube portion, and wherein the outer tractor tube portion inverts over itself at a distal-facing region of the tractor tube and extends proximally within the outer tractor tube portion as an inner tractor tube portion that is coupled to the inner tractor puller; pulling the inner tractor puller proximally to compresses the outer tractor tube portion of the tractor tube, and to cause the outer tractor tube portion of the tractor tube to roll over itself, unsupported, at the distal-facing region and to invert into the inner tractor tube portion; engaging the clot with the tractor tube as it rolls over itself so that the clot is pulled into the tractor tube; and withdrawing the self-rolling mechanical atherectomy holding the clot from the blood vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

[00037] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative

embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00038] FIGS. 1A-1C illustrate an example of an apparatus for mechanically removing an object such as a clot from a body region that include an inverted tube (e.g., “tractor” tube) of material that rolls and inverts over the distal end of an inner catheter. FIG. 1A shows the device, including the tractor tube portion connected to a puller that is within the catheter. The tractor tube may be deployed in a vessel near a clot, as shown in FIG. 1B. To activate this type of mechanical thrombectomy device the end of the tractor tube in the catheter, which is shown connected to a puller also within the catheter, is pulled proximally away from the clot, rolling the tractor tube over the distal end of the catheter and inverting it, as shown in FIG. 1C. The clot may then be drawn into the catheter by the rolling and inverting action of the tractor tube.

[00039] FIG. 2A illustrates one example of a self-rolling mechanical atherectomy apparatus that is configured so that the distal-facing portion of the tractor tube inverts over itself, unsupported, when the internal tube portion of the tractor tube is pulled proximally. In FIG. 2A, the apparatus includes an outer tractor pusher (e.g., catheter, cannula, tube, etc.), a tractor tube that is inverted over itself at a distal-facing portion of the apparatus, and an inner tractor puller (e.g., rod, catheter, cannula, tube, etc.) connected to an inner tractor tube portion of the tractor tube that is inverted relative to the outer tractor tube portion and extends inside of the outer tractor tube portion.

[00040] FIG. 2B shows the apparatus of FIG. 2A within a delivery catheter (e.g., a distal access catheter).

[00041] FIG. 2C is another example of a self-rolling mechanical atherectomy apparatus similar to the one shown in FIG. 2A, in which the end of the outer tractor tube portion of the tractor tube that is on the outside of the inverted tractor tube is attached to the outer tractor pusher.

[00042] FIG. 2D is another example of a self-rolling mechanical atherectomy apparatus similar to the apparatus shown in FIG. 2D, in which the end of the outer tractor tube portion of the tractor tube that is on the outside of the inverted tractor tube is attached to an outer tractor pusher that is internal to an outer (e.g., distal access) catheter, and may be used to push or pull the tractor tube from the proximal end. The outer catheter may be slid distally to protect the tractor portion, or it may be held proximally relative to the outer tractor pusher to help support the proximal end of the outer tractor tube portion of the tractor tube.

[00043] FIGS. 3A and 3B show examples of self-rolling mechanical atherectomy apparatuses. In FIG. 3A, the tractor tube is formed of as a woven structure that is configured to compress with a large braid angle under tension, e.g., when pushing the outer tractor tube portion distally and/or pulling the inner tractor tube portion proximally, and is further configured to have a small braid angle in the inner tractor tube portion. Thus, the tractor tube supports itself so that it may roll over itself and invert at a distal-facing region when either the inner tractor tube portion of the tractor tube is pulled proximally (and the outer tractor tube portion of the tractor tube is held in position or pushed distally), or when the outer tractor tube portion of the tractor tube is pushed distally (and when the inner tractor tube portion is pulled proximally or held in position). The tractor tube rolls over itself at the distal-facing region of the tractor tube and this rolling action may draw material into the inner tractor tube portion. FIG. 3B is similar to FIG. 3A, except that one end of the tractor tube (the region adjacent to the outer tractor tube portion) is constrained within the outer tractor pusher, and the outer tractor pusher pushes or braces against the tapered surface between the constrained region and the outer tractor tube portion.

[00044] FIGS. 4A-4D illustrates the operation of a self-rolling mechanical atherectomy apparatus such as those shown in FIGS. 2A-3. In FIG. 4A, the self-rolling mechanical atherectomy apparatus has a tractor tube is inverted over itself at a distal-facing region, and includes an inner tractor tube portion that is connected to an inner tractor puller. The inner tractor puller shown may be a rod, catheter, or cannula (e.g., hypotube). In this example, the end of the outer tractor tube portion of the tractor tube is connected to an outer tractor pusher (catheter). FIG. 4B illustrates the self-rolling mechanical atherectomy apparatus being actuated to roll and invert the tractor tube over itself, unsupported, at its distal-facing region. In FIG. 4B, the outer tractor tube region has sufficient column strength to prevent buckling, or collapse of the tractor tube under the applied tension. The apparatus is actuated in FIG. 4B by pushing the outer tractor pusher distally (to the right) while holding the inner tractor puller fixed relative to the patient's body (e.g., the vessel). FIG. 4C shows actuation of the self-rolling mechanical atherectomy apparatus of FIG. 4A so that the tractor tube rolls and inverts from the outer tractor tube portion to the inner tractor tube portion at the distal-facing region by holding the outer tractor pusher and pulling proximally on the inner tractor puller. FIG. 4D illustrates actuation of the self-rolling mechanical atherectomy apparatus of FIG. 4A by both pulling the inner tractor tube portion proximally (e.g., by pulling the inner tractor puller proximally) and by pushing the outer tractor tube portion distally (e.g., by pushing the outer tractor pusher distally).

[00045] FIGS. 5A-5D illustrate the use of a self-rolling mechanical atherectomy apparatus such as those shown schematically above, to remove a clot (thrombus) from within a vessel. In FIG. 5A, the apparatus includes an outer catheter (e.g., distal access catheter), a tractor tube having an outer tractor tube portion that inverts at a distal-facing region into an inner tractor tube portion, an inner tractor puller connected at the proximal end of the inner tractor tube portion of the tractor tube, and an outer tractor pusher connected at the proximal end of the outer tractor tube portion of the tractor tube. The apparatus is in a vessel and is maneuvered so that the distal-facing end region of the tractor tube is adjacent to the clot. Once positioned, the outer catheter may be withdrawn, and tension may be applied (e.g., by pushing distally on the outer tractor pusher), expanding the tractor tube within the vessel, as shown in FIG. 5B. The tractor tube may be positioned at or against the clot. Thereafter, the tractor tube may be rolled on itself, unsupported by any internal catheter at the distal-facing end region, as shown in FIG. 5C, by pulling the inner tractor puller proximally and/or pushing the outer tractor pusher distally, drawing the clot into the inner tractor tube portion. This process may be continued until the entire clot is pulled into the inner tractor tube portion, as shown in FIG. 5D. Thereafter the tractor tube, outer tractor pusher and inner tractor puller may be withdrawn back into the distal access catheter and withdrawn from the vessel.

[00046] FIGS. 6A-6D illustrate a method of removing of a clot using a self-rolling mechanical atherectomy apparatus. In FIG. 6A, the apparatus includes a tractor tube having an outer tractor tube portion, distal-facing region where the outer tractor tube portion inverts into an inner tractor tube portion, and an inner tractor puller that is connected to the inner tractor tube portion. The tractor tube and the inner tractor puller are held within a distal access catheter, and the outer tractor tube portion is unattached. The self-rolling mechanical atherectomy apparatus is positioned within a vessel near a clot. In FIG. 6B the outer distal access catheter is withdrawn proximally and/or the inner tractor puller is advanced distally, so that the tractor tube is partially extended from the distal end of the outer distal access catheter and adjacent to the clot. The outer tractor tube portion is placed under tension, e.g., by pulling the inner tractor puller proximally, as shown in FIG. 6B, expanding the outer tractor tube portion so that it is jammed against the distal opening of the outer distal access catheter. As the inner tractor puller is pulled proximally, the tractor tube rolls and inverts at the distal-facing region, drawing the inner tractor tube portion proximally and engaging the clot, as shown in FIG. 6C. The inner tractor tube portion is withdrawn proximally by pulling the

inner tractor puller until the clot is engulfed, as shown in FIG. 6D. The self-rolling mechanical atherectomy apparatus, holding the clot, may then be withdrawn.

[00047] FIG. 7A-7B illustrate possible failure modes for the operation of a self-rolling mechanical atherectomy apparatus. In FIG. 7A, the tractor tube (e.g., the outer tractor tube portion) is shown collapsed when applying tension by pulling the inner tractor puller proximally. In FIG. 7B, the tractor tube (e.g., the outer tractor tube portion) is shown collapsed when applying tension by pushing the outer tractor pusher (e.g., an outer catheter) distally. The configuration of the tractor tube may be configured to avoid this failure mode, including adjusting the braid angle of the outer and/or inner tractor tube portions, the amount of expansion of the tractor in the outer tractor tube portion, the number of strands (or strand equivalents) forming the tractor tube, the minimum length of expanded tractor tube, the material used for the tractor tube, the thickness of the strands or strand equivalents of the tractor tube, the porosity of mesh forming the tractor tube, or combinations of these.

[00048] FIGS. 8A and 8B illustrate another example of a possible failure mode of a self-rolling mechanical atherectomy apparatus. FIG. 8A shows an example of a self-rolling mechanical atherectomy apparatus. FIG. 8B show the apparatus of FIG. 8A when the outer tractor tube portion is placed under tension by advancing the outer catheter (e.g., outer tractor pusher) relative to the inner tractor puller, collapsing the proximal end of the outer tractor pusher portion

[00049] FIG. 9 schematically illustrates a self-rolling mechanical atherectomy apparatus showing examples of internal and external braid angles for the outer tractor tube portion and the inner tractor tube portion, respectively.

[00050] FIG. 10 is an example of the distal-facing region of a self-rolling mechanical atherectomy apparatus.

[00051] FIG. 11 is an example of a self-rolling mechanical atherectomy apparatus including a tractor tube that is inverted over itself, and an inner tractor puller.

[00052] FIG. 12 shows an example of the attachment of an outer tractor tube portion of a tractor tube connected to an outer tractor pusher, showing the braid angle of the outer tractor tube portion.

[00053] FIG. 13 is another example of a distal-facing region of a self-rolling mechanical atherectomy apparatus, similar to that shown in FIG. 10.

[00054] FIGS. 14A-14D show examples of a method of using a self-rolling mechanical atherectomy apparatus having a pre-shaped tractor tube. In FIG. 14A the self-rolling mechanical atherectomy apparatus, which is held within a distal access catheter, is positioned

adjacent to a clot within a blood vessel. Once positioned, distal access catheter is withdrawn, allowing the outer tractor tube portion of the tractor tube to expand, as shown in FIG. 14B. The proximal end of the outer tractor tube portion is tapered, as shown, and may present a face that the distal access catheter, acting as an outer tractor pusher, may push against, as shown in FIG. 14C. The proximal end may be shape-set into this tapered shape, or it may be formed in this shape. Thereafter, the proximal end of the inner tractor tube portion may be pulled proximally to roll the outer tractor tube portion over itself (unsupported) so that it inverts into the inner tractor tube portion, capturing and drawing the clot with it, as shown in FIG. 14D. The inner tractor tube may be pulled fully back into the outer tractor pusher (in this example, the distal access catheter) and withdrawn from the body.

[00055] FIG. 15A illustrates an example of a tractor tube including an outer tractor tube portion that is tapered forming a face that may be braced against an outer tractor pusher. The distal end of an exemplary outer tractor pusher is shown for reference. FIG. 15B is an example of another example of an outer tractor tube portion including a collar (shown as a ring) that forms a tapered shape at the proximal end of the outer tractor tube portion or a tractor tube.

[00056] FIGS. 16A-16C illustrate another example of a self-rolling mechanical atherectomy apparatus in which the proximal end of the outer tractor tube portion of the tractor tube of the apparatus is releasably attached to an outer tractor pusher, e.g., by bonding with a frangible material, mechanical connection, dissolvable connection, etc. In contrast, the proximal end of the inner tractor tube portion of the tractor tube may be permanently bonded to an inner tractor puller, as shown in FIG. 16A. FIG. 16B illustrates the use of the self-rolling mechanical atherectomy apparatus of FIG. 16A to grab and withdraw a clot from a vessel by pulling the inner tractor tube portion of the tractor tube proximally, so that the outer tractor tube portion rolls over itself, unsupported, at the distal-facing region of the tractor tube, and inverts to become more inner tractor tube portion. FIG. 16C illustrates the fully withdrawing the tractor tube into the outer tractor pusher, releasing the end of the tractor tube that is attached to the outer tractor pusher and allowing the entire (now inverted) tractor tube to be withdrawn into the apparatus.

[00057] FIGS. 17A-17D illustrate exemplary tractor tubes formed by cutting (e.g., laser cutting) a tubular material.

[00058] FIGS. 18A-18C illustrate different slotted patterns that may be cut into a tube (or sheet) to form a tractor tube or portion of a tractor tube.

[00059] FIG. 19 is another example of a pattern that may be used to form a tractor tube.

[00060] FIGS. 20A-20B show an example of a pattern that may be use to form a tractor tube. FIG. 20B is an enlarged view of the pattern of FIG. 20A.

[00061] FIGS. 21A-21B show an example of a pattern that may be use to form a tractor tube. FIG. 21B is an enlarged view of the pattern of FIG. 21A.

[00062] FIGS. 22A-22B show an example of a pattern that may be use to form a tractor tube. FIG. 22B is an enlarged view of the pattern of FIG. 22A.

[00063] FIGS. 23A-23B show an example of a pattern that may be use to form a tractor tube. FIG. 23B is an enlarged view of the pattern of FIG. 23A.

[00064] FIGS. 24A-24B show an example of a pattern that may be use to form a tractor tube. FIG. 24B is an enlarged view of the pattern of FIG. 24A.

[00065] FIGS. 25A-25B illustrate tractor regions having different patterns of slots and openings.

[00066] FIG. 26A illustrates another example of a tractor portion of a self-rolling mechanical atherectomy apparatus, showing properties of different regions (“zones”) of the tractor tube in different configurations, including an inner tractor tube portion that stretches in tension, a distal-facing region between the inner tractor tube portion and the outer tractor tube portion, a high column strength outer tractor tube portion, a constrained region at the proximal end of the outer tractor tube portion, and a transition zone between the high column strength outer tractor tube portion and the constrained region.

[00067] FIGS. 26B and 26C illustrate the functional operation of the different regions (“zones”) of the self-rolling mechanical atherectomy apparatus shown in FIG. 26A. Pulling on the inner tractor tube portion (e.g., by pulling on the inner tractor tube portion itself or on an inner tractor puller to which it is attached) causes the outer tractor tube portion closest to the distal-facing region of the tractor tube to roll over itself and invert into the inner tractor tube portion; at least in part because of the high column strength of the outer tractor tube portion and the strength of the transition zone preventing the tractor tube from collapsing (as shown in FIGS. 7A-7B and 8B). FIG. 26B shows a side perspective view, while FIG. 26C shows a sectional view though the self-rolling mechanical atherectomy apparatus of FIG. 26B during operation of the apparatus.

[00068] FIG. 27A shows a top view looking proximally on the distal-facing region of the tractor puller of FIGS. 26A-26C, showing the change in the braid angle from the high column strength (large braid angle) outer tractor tube portion in compression, to the elongated (small braid angle) inner tractor tube portion in extension, when pulling the inner tractor tube portion proximally.

[00069] FIG. 27B shows a bottom view looking distally from the constrained region at the proximal end of the outer tractor tube portion, showing the inside of the distal-facing region of the tractor tube.

[00070] FIG. 28 illustrates a shape outline of a tractor tube of a self-rolling mechanical atherectomy apparatus, showing a funnel shape that may be formed as the tractor tube is rolled over itself, unsupported, at the distal-facing region. The tractor tube may be configured to form this funnel shape; the tractor tube may be a braided, woven, knit, solid, or some combination of these.

DETAILED DESCRIPTION

[00071] In general, described herein are self-rolling mechanical thrombectomy apparatuses having an inverting tractor tube that is configured to roll over and into itself at an unsupported distal-facing region that is at the very distal end of the apparatus, which may be used to capture and remove a blood clot from a blood vessel. These apparatuses may include a tractor tube that comprises a flexible tube that doubles back over (e.g., inverts) over itself so that an outer portion (e.g., an outer tractor tube portion) rolls and inverts, becoming an inner portion (e.g., an inner tractor tube portion) as this inner portion is pulled proximally. The apparatus typically includes an outer tractor pusher that supports and/or pushes the tractor tube just proximal to the proximal end of the outer tractor tube portion. The tractor tube may taper from the outer tractor tube diameter (which is typically larger than the diameter of the outer tractor pusher) to a diameter that is smaller than the inner diameter of the outer tractor pusher. The end of the tractor tube may be attached to the outer tractor pusher or it may be unattached to the outer tractor pusher. Any of these apparatuses may also include an inner tractor puller that is coupled to the other end of the tractor tube (e.g., the end that become the proximal end of the inner tractor tube portion when operating as described herein). Thus, the apparatus may be actuated to cause the tractor tube to roll and invert over itself, unsupported at the distal-most end, by pulling directly on the inner tractor tube portion or by pulling on an inner tractor puller that is coupled to the proximal end of the inner tractor tube portion.

[00072] Thus, in general, the inner tractor tube portion may therefore be pulled proximally to roll and invert the tractor tube over itself, without the need to roll over an annulus at the distal end of an elongate inverting support, since the apparatus may be configured to have a sufficient column strength on the outer portion of the tractor tube (the radially-expanded and longitudinally compressed outer tractor tube portion) to prevent buckling, bending or failure of the tractor tube when compression force (e.g., up to 300 g or more, 350 g or more, 400 g or

more, 500 g, etc.) is applied to the outer tractor tube region by pulling the inner tractor tube region proximally. This is an improvement compared to other mechanical atherectomy apparatuses, including those described and shown in FIGS. 1A-1C, which typically include an elongate support that includes an annulus over which the tractor inverts at the distal end.

5 The support (e.g., catheter) is typically positioned in the distal end region (e.g., the distal-facing tractor tube region) of the apparatus and the tractor tube inverts over it, rather than over itself; such embodiments may therefore require that the support be maneuvered with the tractor, any outer catheter and any inner puller.

[00073] For example, FIGS. 1A-1C shows an example of a mechanical thrombectomy apparatus that is not self-rolling. In this variation, an elongate inversion support is included (shown here as catheter 101) as a part of the mechanical thrombectomy apparatus. In this example, the elongate inversion support catheter 101 has a distal end region 103 that includes a distal end opening. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region may be substantially less soft than the region immediately proximate to it.

[00074] In FIG. 1A, the elongate inversion support (e.g., catheter 101) is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or more of compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force), for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand a higher force (e.g., at least 1500 g of compressive force, at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). The elongate inversion support may not be a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like or may be skived. However, in each of these example, the support extends to the distal end region of the apparatus to provide a supporting surface over which the tractor tube can roll.

[00075] In FIG. 1A the support catheter 101 of the elongate inversion support may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00076] FIG. 1B shows an example of a flexible tractor 144 coupled to a puller 146. In this example to form a pullable tractor assembly 140, the tractor is shown integrated with the puller, forming the assembly, however the support catheter 101 extends between the outer

tractor tube portion and the inner tractor tube portion all the way to the distal-facing tractor portion at the distal-most end of the apparatus. In FIG. 1C, the tractor is a tube of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. In general, it may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 144 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The puller 146 may typically be a less-expandable (or non-expandable) structure (tube, puller, etc.). In the example shown in FIG. 1C, the tractor 144 is configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first configuration to a radial diameter that is between 1.1 and 10 times the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained, as shown in FIG. 1C. In FIG. 1C, the tractor of FIG. 1C is shown in an expanded, relaxed, configuration. Thus the expandable tractor may be biased to expand open. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00077] In FIG. 1C, the flexible tractor of FIG. 1B is shown with the tractor doubled back over itself and over the distal end of the catheter of the elongate inversion support 101. The distal end region is collapsed down, e.g., onto the puller and the elongate inversion support, and may be held collapsed. In this example a tractor hold 188 may be used to hold the tractor collapsed down onto the outer diameter of the elongate inversion support. However, in an unconstrained or deployed configuration the tractor (e.g., the portion that is inverted over the distal end of the catheter) has an outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. Thus, the tractor 144 may be biased so that it has a relaxed expanded configuration in the first configuration (as shown in FIG. 1C) that is greater than the inner diameter (ID) of the catheter of the elongate inversion support portion of the apparatus and the relaxed expanded configuration of the second configuration inverted over the catheter has an OD that is greater than the OD of the catheter. The tractor is expandable and may be coupled to the puller. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to a push/pull wire or catheter.

[00078] FIG. 1C illustrates the removal of a clot using this supported tractor apparatus shown in FIGS. 1A and 1B. In this example the apparatus is configured as a thrombectomy

apparatus including a catheter of an elongate inversion support 101 and a flexible tractor that extends over the distal end region of the catheter and doubles-over itself at the distal end of the catheter to invert so that the external tractor end region is continuous with an inner less-expandable (in this example, less-expandable includes non-expandable) second distal end region 146 (puller) that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The pusher/puller member that may be a rod or other member that is continuous with the distal end region of the tractor.

[00079] However, described herein are self-rolling atherectomy (thrombectomy) apparatuses that do not need to roll over a support such as an elongate inversion support catheter. Instead, these apparatuses are configured to roll over just themselves, unsupported at their distal end. FIGS. 2A-2D illustrate examples of self-rolling thrombectomy apparatuses 200. Any of these apparatuses may include a tractor tube 206 (e.g., having, in a deployed configuration, an outer tractor tube portion 204, an inner tractor tube portion 208, and a distal-facing region 206 at which they invert) that may be configured to prevent collapse when under compression. In FIG. 2A, the apparatus also includes an inner tractor puller 205 coupled to the proximal end of the inner tractor tube portion 208, and an outer tractor pusher 207 which is shown (in this example) unconnected to the tractor tube.

[00080] FIGS. 2B-2D illustrate other variations of the self-rolling atherectomy apparatuses. In FIG. 2B, the apparatus of FIG. 2A is shown in a separate distal access catheter 211. The tractor tube is in an un-deployed configuration, within the distal access catheter; once deployed, the outer tractor tube portion may expand as shown in FIG. 2A. The self-rolling atherectomy apparatus shown in FIG. 2C is similar to that shown in FIG. 2A, however the proximal end of the outer tractor tube 204 is attached 213 to the outer tractor pusher 207. In FIG. 2D, the apparatus of FIG. 2C is shown including both an outer tractor pusher 207 as well as a distal access catheter 211.

[00081] Any of these apparatuses may include a guidewire lumen extending through the tractor tube and/or inner tractor puller that is configured to pass a guidewire.

[00082] Any of these apparatuses may include one or more projections that are configured to enhance engaging and/or maceration of a clot. Engaging the clot may be particularly, but not exclusively, helpful when the tractor is lubricious. It may also be particularly helpful to include projections that are retracted along the length of the tractor adjacent to the outer diameter of the elongate inverting support (e.g., catheter), for example, when positioning the apparatus within a vessel, but extend the projections outward from the tractor when rolling and inverting to grab a clot.

[00083] In many of the examples described herein, the tractor tube and/or inner tractor puller may extend for any appropriate distance (including between 1-100 cm, between 2-100 cm, greater than 1 cm, 2 cm, 3 cm, 4 cm, 5 cm, 6 cm, 7 cm, 8 cm, 9 cm, 10 cm, 11 cm, 12 cm, 15 cm, 20 cm, etc.). Similarly, the outer tractor pusher may extend to the same length or longer. The tractor tube may form an elongate lumen that is configured to allow passage of a guidewire, as mentioned. The tractor tube may also be configured to slide along the long axis within a distal access catheter (and/or an outer tractor pusher) lumen, e.g., during initial placement in the vessel. The tractor tube may therefore be longitudinally slideable within the distal access catheter, and may be arranged so a portion of the tractor tube (the distal –facing tractor region) doubles back over itself within the distal access catheter/outer tractor pusher or after being deployed from the distal access catheter or outer tractor pusher.

[00084] In general the self-rolling mechanical thrombectomy apparatuses described herein may be highly flexible, both before actuating and during operation.

[00085] The self-rolling mechanical thrombectomy apparatuses described herein typically create a rolling cylinder (tractor or tractor tube) that may be used to entrap or ensnare foreign objects from the human body.

[00086] The structure of the tractor tube may be formed from wires, threads, filaments, laser slotted tubing, or the like. The tractor tube may be braided, or may have a braided appearance. See, e.g., FIG. 3. When activated to roll and invert over itself, the tractor tube may produce a center-grabbing effect, similar to conveyor belt. The self-rolling mechanical thrombectomy apparatus may be delivered via a catheter (e.g., distal access catheter and/or outer tractor pusher) to a site of interest (peripheral vessel, neuro vascular, MIS surgical procedure, etc.). When the apparatus is in place, the device may be pushed and/or pulled, as described and illustrated below to activate the tractor tube so that it acts like a grabbing conveyor belt.

[00087] For example, FIG. 3A illustrates an apparatus including a tractor tube 303, outer tractor pusher 305 and inner tractor puller 307. The tractor tube is shown in a deployed configuration. In this example, the tractor tube 303 includes an outer tractor tube portion 309 that is shown in a compressed configuration having a large braid angle (e.g., greater than 150 degrees in this example). The tractor tube 303 also includes an inner tractor tube portion 311 that has a much smaller braid angle (e.g., less than 45 degrees in this example). The portion of the tractor tube proximal to the outer tractor tube portion 309 is a constrained region 313 that may be held (e.g., by shape setting, by a mechanical or structural constraint, such as a ring or catheter, etc.) in an intermediate configuration that is not as radially expanded as the

outer tractor tube portion 309. A tapered region 315 is formed between the constrained region 313 of the tractor tube and the outer tractor tube portion 309 and may act as a bracing surface for an outer tractor pusher 305' (as shown in FIG. 3B). In FIG. 3A, the outer tractor pusher is shown pushing against 317 the end of the constrained region 313 of the tractor tube 303.

5 [00088] In FIG. 3A and 3B, the tractor tube includes a distal-facing region 319 where the tractor tube rolls and inverts over itself. As will be illustrated below (e.g., in FIGS. 26A-26C), when the outer tractor pusher pushes against the end of the tractor tube closest to the outer tractor tube portion and the inner tractor tube portion is pulled proximally, the resulting compressive force compresses the outer tractor tube region 309, resulting in a column
10 strength that prevents buckling and failure of the tractor tube while driving rolling of the outer portion of the tractor tube over and into itself at the distal-facing region 319 of the tractor tube.

[00089] Thus, any of these apparatuses may include a patterned (e.g., braided) tractor tube that may be shape set (e.g., heat set). The inner tractor tube region may be configured to have
15 a lower column strength that allows it to expand to adjust to the clot diameter as it is drawn into the tractor tube.

[00090] FIGS. 4A-4D illustrate examples actuating a self-rolling mechanical atherectomy apparatus. For example, in FIG. 4A, similar to that shown in FIG. 2A-2D, the self-rolling mechanical atherectomy apparatus includes a tractor region (having an expanded/deployed
20 outer tractor region 404 that is continuous with an inner tractor region 408 after rolling and inverting over itself at the distal-facing region. In FIG. 4D the apparatus is shown deployed, with the outer tractor tube portion 404 expanded radially, having an outer diameter that is greater than the inner diameter of the outer tractor pusher 405. The outer tractor pusher is braced against the tapered region 415 proximal to the outer tractor tube region.

25 [00091] FIGS. 4B-4D illustrate alternative methods of actuating the tractor tube so that it rolls over itself and inverts, unsupported, only at the distal end. For example, in FIG. 4B, the outer tractor pusher 405 is pushed distally while the inner tractor puller is held, causing the outer tractor tube portion to roll over itself 431 and invert into the inner tractor tube portion, as shown. Similarly, in FIG. 4C, the tractor tube is actuated by pulling proximally on the
30 inner tractor tube portion while holding the outer tractor pusher in place. FIG. 4D illustrates a combined method including both pushing the outer tractor pusher distally while pulling the inner tractor puller proximally; the two may be operated at different rates or distances. For example, the inner tractor puller may be pulled more proximally than the outer tractor pusher is pushed. In some variations, the entire apparatus may be advanced distally by

pushing the outer tractor pusher distally, while still pulling the inner tractor puller proximally to roll the tractor tube into itself, as shown.

[00092] FIGS. 5A-5D illustrate removal of a clot using a self-rolling mechanical atherectomy apparatus as described herein. In this example, the self-rolling mechanical atherectomy apparatus is a co-axial system including both a distal access catheter 509 and an outer tractor pusher 511, as well as an inner tractor puller 513. The apparatus is deployed in a blood vessel 503. In FIG. 5A, the self-rolling mechanical atherectomy apparatus is shown in an un-deployed configuration in which the tractor tube 505, which is connected at one end 523 to the outer tractor pusher, and at the other (inner) end to the inner tractor puller 513, is in a collapsed configuration within the lumen of the distal access catheter 509. The apparatus is initially positioned adjacent to the clot 519 (FIG. 5A). The distal-facing end 516 of the tractor tube is shown initially inside the distal end of the distal access catheter 509. The tractor tube 505 can either be preloaded in the distal access catheter 509 during access or delivered through the distal access catheter after the distal access catheter is positioned adjacent to the clot. The inner tractor puller can be cannulated (like a catheter) to allow delivery of a guidewire through its self to aid in delivery of the system to the clot. In FIG. 5A, the distal-facing region 516 of the tractor tube is the distal-most end of the assembly. Alternatively the distal-facing region 516 of the tractor tube can be inverted on itself (not shown) prior to delivering the system up to the clot.

[00093] The tractor tube may be made of a braid structure as described above. In this example, when constrained, it may have low braid angles (e.g., between 5 - 90 degrees, between 5-45 degrees, between 5-30 degrees, etc.). After it is released from the distal access catheter and deployed, the braid angle would may be much larger; once compression is applied to the outer tractor tube portion, e.g., by pulling on the inner tractor puller, the braid angle will be much larger (e.g., between 80-170 degrees), while the braid angle in the portion under tension (e.g., the inner tractor tube portion) may be much lower (e.g., less than 90 degrees, less than 80 degrees, less than 70 degrees, etc.). In this context, the braid angle referred to herein may refer to the braid angle relative to the proximal-to-distal axis, and the angle formed between intersecting strands of the mesh forming the tractor tube. This is illustrated below, in FIG. 9.

[00094] In FIG. 5B, the apparatus is shown deployed from the distal access catheter by pulling back on the distal access catheter to release the tractor tube, allowing it to expand radially to an outer diameter that is larger than the inner diameter of both the distal access catheter and the outer tractor pusher. Alternatively or additionally, the tractor tube can be

driven forward out of the distal access catheter, (e.g. and into or towards the clot) rather than pulling back the distal access catheter.

[00095] In FIG. 5C, the inner tractor puller 513 is retracted proximally to cause the tractor tube to invert over and into itself, unsupported at the distal-facing region of the tractor tube, so that it can grab clot and pull the clot into the tractor tube, as shown. The distal facing region of the of tractor tube forms a conical shape as it inverts on its self. By continuing to pull the inner tractor puller or fix the inner tractor puller and push the outer tractor pusher (or some combination of both movements), the conical shape formed on the tractor tube behaves like a conveyor, engaging (i.e., “grabbing”) the clot 519 and pulling it into the tractor tube, engulfing the clot and capturing it, as shown in FIG.5D.

[00096] Pushing the outer tractor pusher and/or pulling the inner tractor puller may be continued until the clot is fully captured. The clot can be removed from the vessel by either withdrawing the entire system, or by pulling the tractor tube into the distal access catheter and then pulling out the tractor tube while leaving the distal access catheter in place. The distal access catheter and or other components (e.g., the inner tractor puller and/or tractor tube) can have vacuum applied during, before and/or after clot engagement by the tractor tube. Alternatively, while pulling the inner tractor puller and pushing the outer tractor pusher, the tractor tube may be withdrawn inside the distal end of the outer tractor pusher with the clot.

[00097] FIGS.6A-6D illustrate the operation of an alternative variation of a self-rolling mechanical atherectomy apparatus, in which the same catheter acts as both the distal access catheter (e.g., delivering the apparatus to the clot) and the outer tractor pusher, e.g., pushing or bracing the tractor tube from the proximal end to allow it to rollover itself distally.

[00098] In FIG. 6A, the apparatus includes a tractor tube 605 that is connected at one end to an inner tractor puller 613; both the tractor tube and the inner tractor puller are held within the outer tractor pusher 611 (acting as a distal access catheter). This configuration may be referred to as a single axial system. The tractor tube is not attached 623 to the outer tractor pusher in this example. In FIG. 6B, the tractor tube may be deployed by pulling back the outer tractor tube (distal access catheter) 611 and allowing the outer tractor tube portion of the tractor tube to expand radially, as shown. The tractor tube 605 can be fully deployed into vessel or the proximal end of the tractor tube can remain in the outer tractor pusher, as shown. The outer tractor pusher braces against the tractor tube at a tapered end before (e.g., just proximal to) the outer tractor tube portion. Alternatively, the tractor tube can be driven

forward into the clot and out of the outer tractor pusher rather than pulled back to deploy the tractor tube in the vessel.

[00099] In FIG. 6C, the inner tractor tube portion is retracted proximally so as to invert the tractor tube over and into itself, thereby engaging the clot 619. The distal-facing region of the tractor tube forms a conical shape as it inverts on itself when pulling the inner tractor puller and/or pushing the outer tractor pusher. By continuing to pull inner tractor puller or holding the inner tractor puller fixed and pushing the outer tractor pusher (or some combination of both movements), the conical shape formed on the tractor tube may act like a conveyor, engaging and pulling the clot into tractor tube (i.e., engulfing and capturing the clot). As shown in FIG. 6D, the clot may be engaged/grabbed and enclosed at least partially, within the tractor tube and removed from patient.

[000100] The self-rolling mechanical atherectomy apparatuses described herein may provide improved clot engagement with lower grabbing forces, and without jamming. As will be described in greater detail below, these apparatuses may be tuned to provide sufficient column strength so that they do not fail during operation, and the forces required to invert the tractor tube are relatively small. The high column stiffness of the expanded tractor tube acts like a catheter-tube, enabling it to be easily advanced forward in a vessel. Finally, these apparatuses can be used with or without aspiration.

[000101] As mentioned above, the self-rolling mechanical atherectomy apparatuses described herein are specifically configured so that the tractor tube portion rolls over itself, unsupported, at its distal end when pulling the inner tractor tube portion proximally and/or pushing the outer tractor tube portion distally. Generally, when pushing and/or pulling a flexible tube that is woven, braided, knitted, or even solid, the tractor tube will bend, buckle or collapse. This is particularly true of flexible tractor tubes that inverted over themselves and biased to expand radially outward in either or both the outer tractor tube configuration and the inner tractor tube configuration). Buckling and collapsing are therefore failure modes for such tractor tube which must be avoided if operating a self-rolling mechanical atherectomy apparatus.

[000102] FIGS. 7A-7B and 8A-8B illustrate these common failure modes. In FIG. 7A, self-rolling mechanical atherectomy apparatus 701 similar to those shown in FIGS. 2A-2D, 3A-3D, 4A-4D, 5A-5D, and 6A-6D are shown buckling or collapsing when either or both the inner tractor tube portion is pulled proximally (e.g., by pulling an inner tractor puller) or the outer tractor tube portion is pushed proximally (e.g., by pushing an outer tractor pusher). In FIG. 7A, a distal access catheter 709 is configured as an outer tractor pusher because a

tapered portion 712 of the tractor tube that is proximal to the outer tractor tube portion 703 of the tractor tube 705 is pushed against the distal opening face 710 of the distal access catheter when the outer tractor pusher (distal access catheter 709) is pushed distally while holding the inner tractor puller 711 fixed relative to the vessel wall as indicated (or alternatively pulling it proximally). In this example, although the outer tractor tube portion 703 may be rolling over itself, unsupported, at its distal end (distal facing end 719), the outer tractor tube portion 803 in the expanded configuration (e.g., not constrained within the distal access catheter) does not have sufficient column strength to prevent the outer tractor tube portion from compressing and buckling. One or more outer tractor tube regions buckle 721, 721', collapsing under the compressive force on the outer tractor tube portion. In some variations, the tractor tube will roll slightly, as shown in FIG. 7A; alternatively, the tractor tube will not roll at all, but will immediately collapse or buckle.

[000103] In FIG. 7A, the force required to roll and invert at the distal end is greater than the force that will cause the expanded outer tractor tube region to buckle; as a result, the outer tractor tube buckles. Once the tractor tube 705 begins to buckle or collapse, it will no longer roll over the distal end region, may lead to further collapse. In addition, the force required to advance the increasingly collapsed tractor tube distally by pushing the outer tractor pusher/distal access catheter may increase substantially.

[000104] A similar failure may occur when pulling the inner tractor tube region proximally, as illustrated in FIG. 7B. In FIG. 7B, a distal access catheter 709 is braced against the distal opening face of the distal access catheter and the inner tractor tube portion 707 is pulled proximally, by pulling on the inner tractor puller 711. The outer tractor tube portion 703 is in the expanded configuration (e.g., not constrained within the distal access catheter). Because the tractor tube 705 is unsupported at the distal-facing end 719, pulling on the inner tractor tube portion 707 compresses the outer tractor portion 705. In this case, as in FIG. 7A, the compressive force is greater than column strength of the outer tractor tube portion. Typically, the force applied to actuate the devices described herein may be up to a maximum of about 400 g of force, (e.g., 300 g of force, 350 g of force, 400 g of force, 450 g of force, 500 g of force, 550 g of force, 600 g of force, etc.), particularly in neurovascular applications. When the applied actuating force, which becomes the applied compressive force, is greater than the column strength of the outer tractor tube portion, the outer tractor tube portion buckles 731, 731' as shown in FIG. 7B.

[000105] Thus, in general, for any of the apparatuses described herein to operate, they must be configured so that the column strength of the expanded outer tractor tube portion, which

may be a braided or woven material, is greater than at least the maximum force in the range of forces used to actuate the apparatus so that the tractor tube rolls and inverts over itself, unsupported, at its distal-facing end region. For example, the apparatuses described herein may be configured so that the outer tractor tube portion has a column strength that is

5 sufficient to resist buckling or collapse under a compressive force of least about 500 g.

[000106] In addition to the column strength of the outer tractor tube under compression, which may lead to buckling or collapse around the longitudinal length of the apparatus, as shown in FIGS. 7A-7B, FIGS. 8A-8B illustrate another failure mode causing collapse at the proximal end of the outer tractor tube portion, which may occur when the proximal tapered

10 portion of the expanded tractor tube buckles against the outer tractor pusher/distal access catheter.

[000107] For example, in FIG. 8A, a self-rolling mechanical atherectomy apparatus 801 is shown in an expanded or deployed configuration. The tractor tube 805 includes an outer tractor tube region 803 that is expanded out of the distal end of the distal access catheter. The tractor tube includes a proximal tapered region 812 that is braced against the distal end opening 810 of the distal access catheter 809. The apparatus also includes an inner tractor puller 811 that is connected to an end of the tractor tube 805; when the tractor tube rolls and inverts over itself at the distal-facing end 819, the inner tractor puller 811 will be attached to the proximal end of the inner tractor tube region. FIG. 8A shows the apparatus prior to

15 actuating by either or both pulling the inner tractor puller and/or pushing the outer tractor pusher (in this configuration, the distal access catheter).

[000108] In FIG. 8B, upon actuating the apparatus, e.g., by either or both pulling or pushing, the tapered region 812 at the proximal end of the outer tractor tube portion 803, against which the distal end opening 810 of the outer tractor pusher 809 pushes or braces

25 collapses, folding the proximal end of the outer tractor tube portion over the distal access catheter. In this example, the relative weakness of the proximal tapered region between the expanded outer tractor tube portion and the distal end opening of the outer tractor pusher/distal access catheter causes this tapered region to fail, so that the tractor tube rolls over 841 the open end 810 of the distal access catheter (and therefore over itself proximally),

30 rather than rolling over itself distally at the distal-facing opening 819.

[000109] As illustrated by FIGS. 7A-7B and 8B-8B, the apparatus, and particularly the tractor tube, should preferably be configured so that the column strength of the expanded outer tractor tube portion is greater than the maximum applied compressive force (e.g.,

actuating force), and the strength of the tapered region should resist the force applied by the outer tractor pusher.

[000110] Thus, a functional self-rolling mechanical atherectomy apparatus for removing a clot from a vessel should be configured to avoid at least these failure modes. Specifically a self-rolling mechanical atherectomy apparatus should have a tractor tube with a sufficient column strength in an expanded outer tractor tube portion so as to resist a compressive force of greater than at least some minimum threshold (e.g., 400 g of force, 500 g of force, 600 g of force, etc.). Alternatively or additionally, the tractor tube should have a tapered region proximal to the expanded outer tractor tube portion that is configured to resist the distally directed force applied by the outer tractor pusher.

[000111] Described herein are configurations and parameters for forming a tractor tube meeting these criterion. For example, the tractor tube may be formed of a material (and particularly a mesh, e.g., braided or woven material) having a braid angle in the expanded tractor tube, when compressed by pushing and/or pulling, in a proximal-to-distal axis that is between about 80 and about 170 degrees. The inner tractor tube portion may have a braid angle in the proximal to distal axis under tension of less than 80 degrees (e.g., less than 75 degrees, less than 70 degrees, less than 65 degrees, less than 60 degrees, less than 50 degrees, less than 45 degrees, less than 40 degrees, less than 35 degrees, etc.). In addition, the amount of expansion of the outer tractor tube portion may be between +/- about 30% of the outer diameter of the outer tractor pusher. In addition, for woven or braided configurations, the number of strands (or strand equivalents) may be at least 12 (e.g., 12 or more, 16 or more, 18 or more, 24 or more, 36 or more, 40 or more, 50 or more, 60 or more, 72 or more, etc.). The expanded tractor tube may also be configured to have a minimum length (e.g., of 0.7 cm or greater, e.g., 0.8 cm or greater, 0.9 cm or greater, 1 cm or greater, 1.2 cm or greater, etc.). For example, the unsupported tractor tube length may be ≥ 1 cm. When the tractor tube is formed of a woven or braided material, the material used for the tractor tube may be a monofilament or a collection of filaments. The tractor tube may also include a number of pores (e.g., cells) formed by the strands; the porosity of the mesh may be, for example, 70% or less (e.g., 65% or less, 60% or less, 55% or less, 50% or less, 45% or less, etc.) and in particular, 60% or less.

[000112] In general, the applicants have found that, for braided or woven tractor tubes having the following ranges of parameters, a self-rolling (e.g., unsupported) tractor tube apparatus will not kink or collapse or otherwise fail as described in FIGS. 7A and 7B and 8A-8B: the tractor tube may be formed of a least 10 strands and have a distal-to-proximal facing

braid angle for the expanded configuration of the outer tractor tube portion of between about 80 and about 170 degrees, a distal-to-proximal facing braid angle of the tensioned inner tractor tube portion that is always less than the braid angle of the expanded outer tractor tube portion and is about 80 degrees or less, further wherein the outer tractor tube portion of the tractor tube is configured to expand to between about +/- 30% of the outer diameter of the outer tractor pusher. Such tractor tubes may have sufficient column strength to resist collapsing when actuated (e.g., with at least 500 g of force) and under compression so as to roll over the distal-facing end of the tractor tube, unsupported.

[000113] For example, it may be preferable that, for braided or woven tractor tubes, the tractor tube is formed of a least 10 strands of materials (more preferably at least 12 strands of material, still more preferably at least 16 strands of material), where the strands have a thickness of about 0.003 inches or greater. The fibers forming the tractor tube may have a distal-to-proximal facing braid angle of between about 80 and about 170 degrees in the expanded outer tractor tube portion under compression and a braid angle in a distal-to-proximal direction of the tensioned inner tractor tube portion that is less than the braid angle of the expanded outer tractor tube portion and is 80 degrees or less. The outer tractor tube portion of the tractor tube may be configured to expand to within +/- about 30% of the outer diameter of the outer tractor pusher. The length of the tractor tube may be at least 1 cm or more.

[000114] Thus, in any of the apparatuses described herein, the tractor tube may be flexible enough to be pushed through a catheter located in the tortuous neuro vasculature anatomy. The tractor may be delivered partially inverted (e.g., rolled on itself) to the clot face through a catheter. The distal-facing end of the tractor tube is generally unsupported (e.g., the tractor tube does not roll over and against the distal opening of a catheter or other support). The unsupported outer tubular length of the tractor tube may be of adequate length when in its axial compressed form to grab typical clot lengths seen in stroke patients (e.g., 1 cm or greater) in a single pass/pull. Typically, the outer tractor tube portion rolls around the distal-facing end of the tractor tube when the distal-facing end of the tractor tube is adjacent and may be in contact (e.g., jammed up against) a clot. The user may then drive the outer tube distally by (or while) pulling the inner tractor puller, and therefore the inner tractor tube portion, proximally, and either supporting or pushing the outer tractor pusher distally. The axial pushing forces on the tractor tube generate an axial compressive load on the expanded outer tractor tube portion and, as long as the column strength is greater than the compressive load, and as long as the strength of the tapered region against the outer tractor pusher is

sufficient, the tractor tube will roll over itself, unsupported, without kinking, collapsing or otherwise failing. Thus, the flexible tractor tubes described herein are configured to have sufficient axially columnar stiffness that when axially compressive forces are applied, the outer tractor tube portion rolls and inverts rather than bunch, buckle, accordion or collapse.

5 [000115] In general, the outer tractor tube portion may be configured so that the maximum expansion relative to the outer diameter of the outer tractor pusher that it is supported against is sized appropriately so device doesn't jam in vessel when pushed & axially compressed, or collapse as shown in FIG. 8B. If the expanded outer diameter (OD) of the outer tractor tube portion is too big, the tractor tube may lock in the vessel when being pushed, rather than
10 advancing in the vessel or driving the rolling/inverting action. Similarly, if the tractor tube OD is too small, the tractor tube may not be large enough to grab the clot sufficiently (e.g., it may core out center of clot only, leaving some of the clot behind or requiring additional removal steps. Thus, in general, the tractor tube may be configured so that it does not over-expand, e.g., due to compressive forces are applied by user to the tractor tube.

15 [000116] In any of the apparatuses described herein, the tractor tube may have sufficient coarseness at its rolling tip to engage and grab a clot. For example, when the tractor tube rolls over the distal end of the apparatus, the inner tractor tube portion may maintain an adequate inner diameter (ID) to leave room for clot. Thus, the inner tractor tube portion may also be configured to expand radially outwards somewhat, rather than collapse onto itself when
20 pulled and tensioned proximally. For example, the inner tractor tube portion may be biased radially outwards to have an inner diameter that is 30% or more of the inner diameter of the expanded outer tractor tube portion (e.g., 35% or more, 45% or more, 50% or more, 55% or more, 60% or more, etc.). The tractor tube may generally be porous, which may provide additional coarseness. For example, it may be beneficial to have a porous structure that has
25 relatively small pores (e.g., small enough to capture all the clot when inverting/rolling), and a sufficient number of pores (e.g., less than 70%, less than 65%, less than 60%, less than 55%, less than 50%, etc. porosity).

[000117] Any of the apparatuses described herein can be used in combination with vacuum/aspiration. For example a vacuum may be applied through the inner tractor puller
30 and/or the tractor tube. Further, any of the apparatuses described herein may be configured so that they are visible under fluoroscopy; in particular, the tractor tube or a portion of the tractor tube may be configured so that it is visible under fluoroscopy.

[000118] FIG. 9 shows one example of a self-rolling thrombectomy apparatus with a braided tractor tube that is configured to provide sufficient column strength in the outer

tractor tube portion when compressed to as to prevent failure by kinking, bending, collapsing or otherwise failing. In FIG. 9, the apparatus includes a distal access catheter 909, an outer tractor pusher 913, and a braided tractor tube 905. The braided tractor tube has an expanded, outer tractor tube portion 903, a tapered portion 912 proximal to the outer tractor tube portion, and an inner tractor tube portion 907 that is connected to an inner tractor puller 911. The tractor tube 905 inverts over itself so that the outer tractor tube portion rolls and inverts to become the inner tractor tube portion at the distal-facing end region 919.

[000119] In FIG. 9, an exemplary distal-to-proximal facing braid angle 909 (Φ_1) for the outer tractor tube portion is illustrated. This Φ_1 angle may be between 80 degrees and 170 degrees, but is more preferably > 90 degrees. In the example shown in FIG. 9, it is between 110 degrees and 160 degrees. FIG. 10 shows an example of a distal-facing end region 1019 of a prototype tractor tube that is configured as described above, including having a distal-to-proximal facing angle (Φ_1) 1015 of between 80 degrees and 70 degrees; in this example, the Φ_1 angle is approximately 130 degrees. Returning to FIG. 9, the outer tractor tube portion in the expanded state has a high braid angle, jammed braid state, and max diameter that provide a high resistance to axial compressive force (e.g., column strength in compression), which makes it easy to advance/push braid structure forward, as well as resisting kinking and failure of the tractor tube. In FIG. 9, the distal-to-proximal braid angle of the inverted, inner tractor tube region 911 (shown as Φ_2) is typically much smaller than Φ_1 , and may be, e.g., less than 90 degrees (e.g., less than 80 degrees, less than 70 degrees, less than 60 degrees, etc.). In FIG. 10, the distal-to-proximal facing braid angle of the inner tractor tube portion 1007 (Φ_2) is also shown, and in this example is about 35 degrees. The low braid angle of the inner tube region is formed as the braid collapses to a small diameter when the tractor tube rolls around distal-facing end, and inverts inside the larger outer tractor tube portion. In FIG. 10, the braided tractor tube is formed of 24 strands ("24 end") of 0.0005" x 0.0010" NiTi ribbon that is braided to have a maximum OD (when axially compressed of 2.5mm).

[000120] FIGS. 11, 12 and 13 illustrate other examples of tractor tubes that may be used as part of a rolling mechanical atherectomy apparatus as described. In FIG. 11, the tractor tube 1105 is shown inverted over itself. The outer tractor tube portion is expanded to a large braid angle. As described and shown above, the braid angle is the distal-to-proximal facing angle formed between intersecting strands of the braid. In FIG. 11 and FIG. 12, the braid angle is greater than 120 degrees for the fully expanded outer tractor tube portion 1103. The inner tractor tube portion is not easily visible in FIG. 11. The proximal end of the outer tractor tube portion is tapered, and has a smaller braid angle as it tapers down (e.g., the tapering braid

angle goes from the expanded outer tractor tube portion braid angle of >120 degrees to approximately 90 degrees where it is attached to the outer surface of the outer tractor pusher 1113. The tractor tube in FIG. 11 is formed of a braided Nickel titanium (NiTi) material. In FIG. 12 a similar tractor tube is shown, including a braid angle (distal-to-proximal facing) of the expanded outer tractor tube portion 1203 that is approximately 150 degrees. The tapered region 1212 proximal to the outer tractor tube portion transitions to a smaller braid angle (e.g., between about 100 and 70 degrees), where it is attached to the outer tractor pusher 1213. FIG. 13 shows a distal-facing end of a tractor tube of a self-rolling apparatus that is unsupported. The distal-facing end 1319 of the tractor tube shown illustrates the inverted, rolling end of the tractor tube. The tractor tube does not enclose or surround a support element (e.g., catheter, loop, etc.) at or near the distal-facing end that is rolling.

[000121] FIGS. 14A-14D illustrate an alternative to the “clot grabbing” tractor tube in which the region of the tractor tube that is proximal to the expanded outer tractor tube portion is shape set into a taper in the relaxed, otherwise expanded, configuration. For example, in FIG. 14A, the apparatus is configured as a single-axis system within a vessel 1402. In operation, the apparatus is delivered within the vessel 1402 through a distal access catheter 1409. A guidewire may also be used to position the apparatus. In FIG. 14A, the apparatus is compressed within the distal access catheter and slid or otherwise driven through the vessel to the clot 1455. The tractor tube 1405 is compressed, but is pre-rolled around itself with a distal-facing end region at the distal end of the device that may be positioned in proximity to the clot 1455 in the vessel. The inner tractor tube portion is attached to an inner tractor puller 1411. In this single axial system shown, the distal access catheter 1409 also acts as the outer tractor pusher once the tractor is pushed out of the catheter and expanded, as shown in FIG. 14B.

[000122] In FIG. 14B, the distal access catheter may be withdrawn proximally and/or the rest of the apparatus may be pushed distally, allowing the distal access catheter to release and deploy the apparatus so that the outer tractor tube portion 1403 can expand to a diameter that is within +/- 30% of the outer diameter of the distal access catheter/outer tractor pusher 1409. In this example, the distal access catheter is withdrawn proximally past the outer, proximal end of the tractor tube portion, showing that this end of the tractor tube is pre-set to a tapered shape 1412. Thus, in FIG. 13C, the distal access catheter (outer tractor pusher) may be advanced distally back over this tapered region, to either drive the outer tractor tube portion distally or to brace against the tapered portion and hold the outer tractor tube portion in position while pulling the inner tractor tube portion proximally, as shown. Thus, in FIG. 14C,

the distal-facing region of the tractor tube forms a conical shape as it inverts on itself when the inner tractor puller is pulled proximally and/or the outer tractor pusher (distal access catheter) is pushed distally. By continuing to pull inner tractor puller and/or hold the inner tractor puller and push the outer tractor pusher (or some combination of both movements), the conical shape formed on the tractor tube behaves like a conveyor, thereby “grabbing” the clot and pulling the clot into tractor tube (e.g., engulfing the clot/capturing the clot). Once the tractor tube is inverted, it (along with the captured clot) can be pulled into the distal access catheter, as shown in FIG. 14D. In FIG. 14D, the inner tractor puller can be fully retracted and the tractor tube can be removed from the patient out of the distal access catheter.

[000123] FIGS. 15A and 15B illustrate variations for forming the pre-set tapered regions of the tractor tube proximal to the expanded outer tractor tube portions. In FIG. 15A, the tapered proximal region 1512 is shown with a rolled distal-facing end region 1532. In this example, the maximum outer diameter is within a predefined range of the outer diameter of the outer tractor pusher catheter 1513 is within a predefined percentage (e.g., between about +/- 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, etc. of the outer diameter of the distal access catheter 1513). The tapered distal region 1512 may be formed by shape setting to the tapered shape. Alternatively, as shown in FIG. 15B, the apparatus may include a limiter, such as a ring, neck, band, etc. 1552 that limits the expansion of the tractor tube portion.

[000124] For example, in FIG. 15B, the proximal end of the tractor tube 1505 on the outside of the tractor tube includes a polymer and/or metal ring 1552 or bulking agent to increase the effective wall thickness of the proximal end of the tractor tube, making it easier for the distal end opening of the distal access catheter to engage with this proximal end of the tractor tube, and may also support and allow for easier pushing of the construct, and/or prevent the failure mode shown in FIG. 8B, above. This can be achieved by bonding, fusing or integrating a separate element into the proximal end of the tractor tube (e.g., stent, O ring, beading of glue/adhesive, fusing or melting a polymer ring or by inverting the braid so the braid is doubled up on the proximal end, making the wall thickness thicker). Alternatively or additionally, the ends of the braid at this proximal end may be left open and even purposely frayed to provide filaments that would easily catch on the distal end of the distal access catheter when trying to push the tractor tube distally.

[000125] In general, the self-rolling apparatuses described herein may have a jammed braid angle on the outside of the tractor tube (e.g., a maximum diameter of the braid). The braid's maximum diameter during axially compression may be slightly smaller and/or larger than the vessel ID (e.g., it may have the same OD, > 5% bigger, >10% bigger, <5 % smaller, <10%

smaller, < 20% smaller, < 30% smaller, etc.). This may facilitate the structure advancing when pushed forward. Examples of high braid angles range from 80-170deg, or by an increment within that range by 10 deg or more. For example, a tractor tube for an M1 vessel (e.g., 2-2.5mmID) may have 36 braid ends of 0.001" NiTi wire formed onto a 2mm mandrel at max braid angle. This tractor tube may be annealed to this shape on the 2mm mandrel. In another example, a tractor tube may be formed for an M1 vessel (e.g., 2-2.5mmID), from 48 braid ends of 0.0005" by 0.001" of flat wire onto a 2.5 mm mandrel, at max angle. In another example, a tractor tube for an M1 vessel (e.g., 2-2.5mmID) may have a braid of 48 ends of 0.0005" by 0.001" flat NiTi wire onto a 2.5 mm mandrel, near max angle, that is removed from mandrel, and slid over a larger mandrel of 2.75mm (e.g., to increase braid angle to a jammed braid angle). In another example, for a larger vessel (e.g., 3-3.5 mm ID), a braid having 72 ends of 0.0005" by 0.001" of flat NiTi wire may be formed onto a 3 mm mandrel, near max angle, removed from the mandrel, and slid over a larger mandrel of 3.5 mm (to increase braid angle to a jammed braid angle). For much larger vessels (e.g., 5 -8mm) a 72 ends 0.002"-0.003" NiTi wire, having a max braid angle on 5-8 mm mandrel may be formed.

[000126] In general, the tractor tube may be formed of flat wires; this may help create a grabbing edge when the braid rolls. In addition, radiopaque wires can be mixed into the pattern for visibility under flouro (e.g., platinum, platinum iridium, DFT wire, gold, marker bands or beads, etc.). Any of these apparatuses can be delivered pre-loaded inside the distal access catheter and/or separately (e.g., using a secondary catheter after the distal access catheter is in position) delivered.

[000127] Any of the tractor tubes may be coated with a flexible material like urethane, silicone or other elastic element. A coating can be throughout the entire tractor tube length and/or thickness or partially on the length, e.g., just on one surface (such as inside or outside of the structure). In one embodiment, the tractor tube surface that touches ID of the distal access catheter wall when rolled around the catheter tip may not have a coating (as this surface touches the clot), while the other surfaces may have a coating or lamination. These coatings may cover all the interstices of the structure so aspiration/vacuum could be applied through the inner tractor puller and/or the distal access catheter to get a vacuum force to the clot. The coating could also include a hydrophilic coating to help make the CGS more lubricous for rolling on itself.

[000128] In any of the apparatuses described herein, the proximal end of tractor tube may be temporarily attached to the distal end of the outer tractor pusher (in some variations, the distal access catheter). For example, a temporary bond or connection between the end of the

tractor tube and the outer tractor pusher may allow the tractor tube to push and maybe pull the tractor tube distally and proximally; however, when the tractor tube is fully inverted, the tractor tube may be released from the distal end of the outer tractor pusher, allowing the user to pull out both elements separately (e.g., the outer tractor pusher and the tractor tube). FIGS. 16A-16C illustrate one example of this. In FIG. 16A, the apparatus includes a distal access catheter 1609 that has been withdrawn over a separate outer tractor pusher 1613 within the blood vessel 1602. The outer tractor pusher is temporarily attached 1633 (e.g., by a frangible bond or connection that is fused, adhesive and/or a mechanical connection) to an end of the tractor tube 1605, and particularly the end that is proximal to the outer tractor tube portion, which is shown expanded in this example. The opposite end of the tractor tube is permanently attached 1631 to the distal end of an inner tractor puller 1611. The apparatus is shown deployed within the vessel adjacent to a clot 1619.

[000129] In FIG. 16B, the inner tractor puller may be withdrawn proximally as describe above to grab the clot and withdraw it into the tractor tube as it is rolled from the outer tractor tube portion into the inner tractor tube portion. Once the entire outer tractor tube portion has been rolled and inverted into itself, the connection to the outer tractor pusher may be broken, as shown in FIG. 16C, so that the entire tractor tube may be withdrawn into the outer tractor pusher and distal access catheter, as shown.

[000130] FIGS. 26A-26C and 27A-27B illustrate examples tractor tubes that are formed from slotted tubes (e.g. tubes formed with slot or openings cut through them). The same general properties described above for woven/braided tractor tubes may be applied to rolled/cut or otherwise formed tractor tubes. For example, in FIG. 26A, the tractor tube may be formed of a tube of material into which slots and pores (windows) through the tube have been laser cut. The material may initial be a sheet of solid (e.g., nickel titanium) material. In FIG. 26A, the tractor tube includes a distal-facing region 2619 is the rolling zone of the tractor tube, the region where the outer tractor tube portion 2603 rolls and inverts to become the inner tractor tube portion 2607. The cuts in the sheet of material form quadrilaterals arranged with a “braid angle” (in this variation, a cut angle) that converts from the very large braid angle in the compressed outer tractor tube portion 2603 to a much smaller braid angle in the inner tractor tube region.

[000131] The expanded outer tractor tube region 2603 shows that the angles of the pores (the braid angle) arranged in the proximal-to-distal axis have an angle of between 80-170 degrees, as described above. In This example, the angle is approximately 165 degrees. The cut-out pores are approximately diamond shapes and the entire circumference is cut with

these shapes, forming a larger diameter, flexible cylindrical column structure that has a very high column strength. Just proximal to the expanded outer tractor tube region 2603 is a tapered region 2612 that is a transition zone between a smaller diameter region that is constrained to have a smaller diameter (e.g., by the outer tractor pusher and/or the distal access catheter). The length (along the distal-to-proximal axis) of this tapering transition region 2612 may be approximately 0.25x to 2x the diameter (outer diameter) of the outer tractor tube region 2603.

[000132] As mentioned, the constrained region 2614 may be constrained so that it cannot expand radially (unlike the expanded outer tractor tube region), and may also be held to the outer tractor pusher by a releasable bond, as described above in FIGS. 16A-16D. This region may be held within the outer tractor pusher 2613.

[000133] FIG. 26B illustrates the rolling movement of the variation shown in FIG. 26A when the inner tractor tube portion 2607 is pulled proximally 2651. In this example, pulling the inner tractor tube portion proximally results in the elongation and tension on the inner tractor tube portion, putting compression (by the forced pulling down 2653 from the inner tractor tube portion, and the opposing force 2655 from the outer tractor pusher 2613) on the outer tractor tube portion 2603. The compressive force as well as the biasing force from the tractor tube maintains the expansion 2657 of the outer tractor tube portion. Pulling the inner tractor tube proximally and holding the outer tractor pusher (or pushing it distally) results in rolling 2659 of the distal-facing region of the tractor tube, causing it to collapse and fold back onto itself, as shown. The outer diameter of the outer tractor tube portion is therefore compressed to a minimum axial (distal-to-proximal) length, and a jammed maximum diameter, as shown. The constrained region 2614 is held within the outer tractor pusher 2613 by the constraining force 2661 against the inner diameter of the outer tractor pusher. The outer tractor pusher also applies a force 2665 against the tapered region 2612.

[000134] The sectional view of FIG. 26C provides additional detail, showing the transition between the outer tractor tube portion 2603 and the inner tractor tube portion 2607. As shown, the outer regions of the tractor tube (e.g., the constrained region, the tapered region and the outer tractor tube portion 2603) are all in compression while the inner regions (e.g., the inverting region and the inner tractor tube portion 2607) are in tension, causing rolling of the tractor tube.

[000135] FIGS. 27A-27B show views looking down the long axis of the tractor tube from the distal end and the proximal ends, respectively. In FIG., 26C, the transition in the cut angles ("braid angles") between the outer tractor tube portion and the inner tractor tube

portion at the distal-facing region of the tractor is apparent. FIG. 28 is a transparent view of a tractor tube showing the regions discussed above. In FIG. 28, the tractor tube includes the distal-facing region 2819 which forms a funnel-shape 2841 as it transitions from the expanded outer tractor tube portion 2803 to the inner tractor tube portion 2807. The inner
5 funnel region could be formed/shaped and/or laser cut to be more similar in diameter to the ID of the outer tube, as described above. Thus, the inner tractor tube diameter could be biased to expand to a particular diameter (e.g., a fraction of the constrained tractor tube region, such as 30%, 40%, 45%, 50%, 60%, 65%, 70%, 80%, etc., or a fraction of the unconstrained outer tractor tube portion, etc.). In FIG. 28, the shape outline also shows the constrained region
10 2814, and a tapered region 2812 that is proximal to the expanded outer tractor tube region 2803. As already mentioned above, the tractor tubes may be formed from braid, knit, fabric tube, polymer extrusion, etc.

[000136] For example, any of the tractor tubes described herein may be formed from a laser-cut tube material. Examples of slotted laser cut tubes forming a tractor are provided
15 herein, including those shown in FIGS. 17A-25B. The starting tubes may be flexible or rigid. For example, a soft flexible tube, strip, or roll of material such as ePTFE or a dense fabric (e.g., knit or weave or braid) may be used. Flexible tubes may provide tractors and/or combinations of tractors and catheters that allow tracking of the apparatus to the treatment site even in tortuous vessels. Tracking allows pushing of the apparatus through tortuous
20 vessels of small caliber over long distances from their introduction site to the human body, over length that can exceed 1 meter in some uses. A flexible tube (pre-laser cutting to form the tractor) may have a softness resulting in a low radial crush force, such as a micro-porous, polymer based tube. The tube may be processed (e.g., by cutting or any of the other techniques mentioned herein) to provide flexibility (e.g., the ability to pull the tractor into
25 catheter, invert, and expand over catheter outer diameter) and/or to create a textured/porous surface that may aid in engaging/grabbing a clot (e.g., emboli) and may provide free spaces (voids) that may help store and/or masticate emboli, making them easier to store within the apparatus and transport. Prior to forming into the tractors the sheets or tubes (e.g., films, rolls, etc.) may have a smooth surface. Patterns may be formed into the sheet or tube to form the
30 tractor. For example, laser slot patterns may be formed in the material to increase macro-surface roughness. Holes, slots, edges, divots, and bumps may be formed on the material. In addition to helping grab and hold emboli, such holes or slots may create free space in the tube wall to cut the clot and/or carry it away. The patterns used to form any of the tractors described herein may have a shorter strut length to strut width ratios. Short, wider struts may

create tractors that are stiffer and may grab clot better. In combination with strut length to width, in some variations, thicker walls may be preferred. Thicker slotted walls may create stiffer struts and more aggressive surface texture to grab clots. Furthermore, thicker walls may enhance clot storage capacity within the slot gaps.

5 [000137] In some variations, it may be beneficial to provide slot designs which do not foreshorten. For example, if the slotted tube design is pulled axial (e.g., down its length), the tube diameter may not decrease. A decreasing diameter slotted tube may grab the outside of the catheter and cleat, increasing drag force when the tube is pulled.

[000138] In variations in which the initial tube or sheet of material used to form the tractor
10 tube is relatively rigid (e.g., formed of a material such as Steel, Nitinol, Polyester, PTFE, Nylon, etc.), the initial tube stiffness/hardness may enhance the clot-grabbing ability when the tractor is slotted properly, to allow both increased flexibility, expansion and rolling. For example, a rigid tube may include slot designs that focuses in catheter tracking and creates a flexibly bending tractor with minimal foreshortening, that is able to be pulled into a catheter
15 (inverting) structure. As with the more flexible starting tubes discussed above, tractors formed of more rigid starting materials may grab and transfer a clot, and the number of slots and/or voids may be increased to increase clot grabbing and/or carrying capacity. A slotted tube forming a tractor may include surface grabbing features, such as channels/corrugations (e.g. any of the microstructures such as those shown in FIGS. 12A-12I above. More rigid
20 tubes may create harder or stiffer slotted tractors. For example, when struts are formed into the tractor (e.g., by cutting, etc.), the slot strut length to strut width may be greater than with less rigid starting materials, and may be a function of the rigid tubes elastic modulus. Higher elasticity materials (e.g., Niti, PET, PTFE) may have strut length to width ratios from 10 to 100. Stiffer materials (e.g., steel, MP35N) may have a length to width ratio greater than 50.
25 The wall thickness to strut width ratio for elastic materials may be, for example, between 0.5 to 10. For stiffer materials, the wall thickness to strut width ratio may be, for example, between 0.25 to 5.

[000139] As mentioned, any of the apparatuses described herein may include a tractor region that is non-foreshortening. The foreshortening of the tractor may depend at least in
30 part on the slot designs for non-woven, non-braided, non-knitted designs (e.g., tractors that are not formed of a strand or strands of material). FIGS. 17A-17D illustrate an example of non-foreshortening design. Also, for both flexible and rigid starting tubes forming a non-woven tractor, the tube inner diameter can be slightly bigger than catheter tube outer diameter pre-slotting. Slotted tube designs which foreshorten may reach their smallest diameter limit

when tensioned axially. If the tube is sized to be slightly larger than the catheter outer diameter, then it may jam (preventing any foreshortening) before it cleats to the catheter outer diameter. Tractor regions formed of an initially rigid material may grab clot more efficiently than tractors having an equivalent thickness but formed of a more flexible material, although
5 more flexible materials may deform as a function of stiffness.

[000140] FIGS. 17A-17D illustrate an example of tractors that are formed by cutting slots and/or windows into tubes of material. In FIGS. 17A-17D, an initially soft material (e.g., ePTFE) was formed by a subtractive manufacturing technique to form, slots, pores and textures in the soft flexible tube. In FIGS. 17A-17D, a 3mm ID ePTFE tube (configured to be
10 used with a 2.9mm OD catheter) was made to be highly flexible and have some level of column stiffness and radial/hoop stiffness by laser-cutting slot patterns into the tube wall to create textures and bend zones which impart clot grabbing and rolling. The ePTFE itself is highly lubricous. Addition of a lubricant (e.g., hydrophilic coating) may improve tracking and rolling. Lubricant can be applied to ID and OD or to either separately. FIG. 17A shows a first
15 pattern 1701, having minimal cuts to create a smooth rolling of the tractor around the catheter 1703 portion of the apparatus.

[000141] A second exemplary pattern is shown in FIG. 17B. In this example, the apparatus slightly larger cut-out regions 1709 (removed by laser cutting in this example), which may create better clot grabbing properties and more clot holding capacity. In FIG. 17B, the ePTFE
20 tube forming the tractor region is slotted on the outside of the catheter. Note that the porosity (14 holes around the circumference) may help grab and hold clot. In both FIG. 17A and 17B, the laser pattern may foreshorten, but may jam before it grips/cleats the catheter outer surface.

[000142] Another example of a tractor was made from a 2.9 mm OD ePTFE tube
25 (configured for use with a 3 mm ID catheter). This example was made to be highly flexible and have some level of column stiffness and radial/hoop stiffness by laser-cutting slot patterns into the tube wall in a pattern to create textures and configured to include bend zones which impart clot grabbing and rolling. Similarly, a tractor may be made of, e.g., a 2.9mm OD PET woven fabric tube (for use with a 3mm ID catheter). The tractor may be formed of
30 30 Denier PET multi-filaments, 0.003" thickness. The resulting tractor may be configured to be soft and have some level of column stiffness and radial/hoop stiffness by laser cutting slot patterns into the tube wall in a patterns providing texture and bend zones which may impart clot grabbing and rolling. As with ePTFE, the PET material may itself be lubricous although

additional lubricant may be added to improve tracking and rolling. Lubricant can be applied to ID and OD or to either separately.

[000143] An example of a tractor made from a somewhat rigid starting material was formed from a nickel titanium (NiTi) tube having a 3mm OD (which may be used with, e.g., a 2.9 mm ID catheter). The wall thickness in these examples was between 0.001" and 0.002". Laser slot patterns were cut into the tube wall in various patterns to create textures and purpose-designed bend zones which may help impart clot grabbing and rolling. A lubricant may be applied, e.g., as a coating, to the ID and OD or to either separately. A first pattern similar to that shown in FIG. 17A was made by minimal laser cutting to create a smooth rolling tractor, with a strut length to width ratio between 25-50. A second pattern having larger slots/openings (similar to that shown in FIG. 17B) was formed by laser cutting. These patterns may foreshorten, but typically minimize or stop foreshortening before the tractor grips/cleats the catheter outer surface (which may result in jamming). The Niti design has the additional benefits of radiopacity, thermal shaping and super elasticity.

[000144] Any of these designs or patterns may for projections that may extend from the rolling distal-facing and inverting portion of the tractor, as discussed above. Such projection may be cut out as "teeth" or elongate members. The regions forming the projections may be sharp, e.g., pointy and/or cutting. Sharp projections may be chew and cut a mature clot. These projections regions may be short or long, may extend in one or more directions (e.g., forward or backward or bidirectional), and may be scoop-shaped (e.g., paddle-shaped). The number of projections may be selected based on the desired coarseness, e.g., the number of projections, the size (length/width/thickness), etc. The projections may change density down their length. For example, the laser pattern can be designed to allow tractor rolling (e.g., long struts) more easily initially, then have grabbing teeth at higher density; alternatively the tractor may be configured for greater initially grabbing, having a pattern with more and/or larger projections initially (distally) then transitioning to more slits (and flexibility) toward the proximal end, which may make it easier to pull. Further, the distribution of projections can be uniform around the tube perimeter and/or non-uniform (e.g., forming a spiral pattern, distributed in patches, having open areas, etc.).

[000145] Any of the tractors described herein may include a marker or makers (e.g., radiopaque markers, such as gold, Pt, etc.). When forming the tractor from a tube or sheet, the tubes may be cut, then shaped to have any profile, such as straight, rolled over the tip, flaring at the proximal end, etc. Any of the microstructure described herein may be included or formed, as mentioned above, e.g., wells on the struts may help carry and grab clot.

Tractors formed of tubes from which material was removed (or sheets formed into tubes) may be configured to have less cleating of the tractor onto the outer diameter of the clot, preventing jamming, particularly compared to woven or braided or knitted materials. However any of the slotted tube tractor configurations described herein may be used with,

5 e.g., in combination with, a braid or knit or polymer sleeve, including either in parallel or in series. In general, any of these tractors may be formed as multi-layers, particular these slotted tube tractors.

[000146] For example, a tractor portion of an apparatus may be formed by removing material from a Nitinol tube that is slightly smaller than the inner diameter of the catheter that it will be used with, or it may be made from a tube that is slightly larger than the outer diameter of the catheters. The tube may be cut with a pattern that increase the coarseness of the outer surface (e.g., to include projections such as struts/scoops/teeth). For example a 0.001" tube wall thickness or smaller may be used.

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[000147] FIGS. 17C and 17D illustrate an example of a tractor region cut from paper. In FIG. 17C a rigid paper tube was cut to include slots and the distal end expanded, as shown. It may be inverted over itself and used as a tractor region. This paper prototype was prepared to illustrate the effectiveness of this pattern. Similarly, FIG. 17D is an example of a prototype tractor region.

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[000148] FIGS. 18A-18C illustrate examples of patterns that may be formed into a flat sheet or tubular member to form a tractor (e.g., slotted tractor). Similar to those shown in FIGS. 17A-17D. In FIG. 18A, the pattern may be cut to form the tractor. White regions 1801 may represent or form struts, while the lines indicate slots 1803 from which material is removed. This pattern is one of many resulting in a flexible tube having stout struts. FIG. 18B shows a similar example having a higher density of slots forming thinner struts and potentially higher porosity, which may result in a larger clot-carrying capacity. FIG. 18C illustrates an example of a pattern having curves that may produce a slightly more bendable (flexible in bending stiffness) slotted tractor. In FIGS. 18A-18C, the pattern is oriented so that the distal direction of the tractor formed by the pattern is at the right or left of the pattern shown (e.g., the tube is oriented right and left, relative to the figures, so that the tube is formed by rolling up from the bottom of the figure).

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[000149] FIG. 19 is an example of a pattern that may be formed into a tube as part of a tractor having a plurality of both slots 1903 and cut-out regions 1901 (holes). Another example of a pattern having a plurality of cut-out holes 2001 formed into it is shown in FIGS. 20A and 20B. FIG. 20B shows an enlarged view.

[000150] An example of a pattern having a plurality of projections is shown in FIGS. 21A-24B. For example in FIGS. 21A and 21B, the pattern includes a plurality of slots 2101 and cut-out regions that leave a projecting strut or tooth 2105 behind. In these examples, the tooth 2105 is pointed and oriented to the left of the page, which may be the distal end direction of the tractor. (e.g., the left side of the image may correspond to the distal end of the tractor); thus when the pattern is formed into a tubular body to form the tractor, and the tractor is inverted over itself (e.g., rolling over the distal end opening of a catheter) the plurality of pointed projections 2105 may extend out of the tractor, and may help grab and draw clot into the catheter.

[000151] Similarly, the pattern shown in FIGS. 22A-22B illustrate another example include a slot 2201, a projection 2203 and a cut-out portion 2205. As in FIGS. 21A and 21B, the projection may extend out of the plane of the tubular tractor (shown here as the plane of the paper, even when rolled up to form the tractor region). FIG. 23A, and enlarged view of FIG. 24B, shows another example of a pattern for a tractor that is similar to that shown in FIG. 21A-21B, but with smaller projecting regions. In this example, the projections 2305 are sharp, and open into an opening 2303 connected to a slot 2301. The pattern shown in FIGS. 24A-24B is similar to that shown in FIG. 23A-23B but with additional openings (cut out regions 2407) which may increase the carrying capacity (e.g., clot carrying capacity) of the tractor region.

[000152] FIGS. 25A-25B are examples of laser-cut tube prototypes of tractor regions. In FIG. 25B the tractor region is inverted over the distal end opening of the catheter.

[000153] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[000154] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[000155] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[000156] Although the terms "first" and "second" may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[000157] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising" means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term "comprising" will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

[000158] In general, any of the apparatuses and methods described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may alternatively be exclusive, and may be expressed as “consisting of” or alternatively “consisting essentially of” the various components, steps, sub-components or sub-steps.

5 [000159] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or "approximately," even if the term does not expressly appear. The phrase “about” or “approximately” may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or
10 positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For
15 example, if the value "10" is disclosed, then "about 10" is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that "less than or equal to" the value, "greater than or equal to the value" and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value "X" is disclosed the "less than or
20 equal to X" as well as "greater than or equal to X" (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point “10” and a particular data point “15” are disclosed, it is understood that greater than, greater than or
25 equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[000160] Although various illustrative embodiments are described above, any of a number
30 of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments

and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[000161] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term “invention” merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

1. A self-rolling mechanical atherectomy apparatus for removing a clot from a vessel, comprising:

5 an outer tractor pusher comprising a catheter having a distal end and a distal end opening;

 a tractor tube comprising an outer tractor tube portion that extends distally in an un-inverted configuration and inverts into itself at a distal-facing region to form an inner tractor tube portion, wherein the tractor tube is configured such that pulling the inner tractor tube
10 portion proximally (i) compresses the outer tractor tube portion into a configuration having a column strength that resists collapsing, and (ii) causes a region of the outer tractor tube portion at the distal-facing region to roll over itself, unsupported, and invert into the inner tractor tube portion; and

 an inner tractor puller coupled to the inner tractor tube portion and extending
15 proximally within the outer tractor pusher.

2. The apparatus of claim 1, wherein the outer tractor pusher is coupled to a proximal end of the outer tractor tube portion of the tractor tube.

20 3. The apparatus of claim 1, further comprising a distal access catheter, wherein the outer tractor pusher, the tractor tube, and inner tractor puller are held within the distal access catheter in an un-deployed configuration, and wherein the tractor tube is configured to be deployed by being pushed distally out of the distal access catheter so that the outer tractor tube portion expands to a diameter that is greater than an outer diameter of the distal access
25 catheter in a deployed configuration.

 4. The apparatus of claim 1, wherein the outer tractor pusher is configured as a distal access catheter in which the tractor tube and inner tractor puller are held within the outer tractor pusher in an un-deployed configuration, and wherein the tractor tube is configured to
30 be deployed by being pushed distally out of the outer tractor pusher so that the outer tractor tube portion expands to an outer diameter that is greater than an outer diameter of the outer tractor pusher.

5. The apparatus of claim 1, wherein the tractor tube is configured so that pulling the inner tractor tube proximally compresses the outer tractor tube portion into a configuration in which the column strength of the outer tractor tube portion resists collapsing up to at least 500g of compression.

5

6. The apparatus of claim 1, wherein the outer tractor tube portion of the tractor tube is configured to expand to between about +/- 30% of an outer diameter of the outer tractor pusher.

10

7. The apparatus of claim 1, wherein the tractor tube comprises a braided material.

8. The apparatus of claim 7, wherein the outer tractor tube portion has a braid angle in a proximal to distal axis in a compressed configuration that is between 80 and 170 degrees, and the inner tractor tube portion has a braid angle in the proximal to distal axis under tension of less than 80 degrees.

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9. The apparatus of claim 1, wherein the tractor tube is formed of between 24-48 filaments.

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10. The apparatus of claim 1, wherein the tractor tube is formed of a plurality of filaments, each having a diameter of greater than 0.003 inches.

11. The apparatus of claim 1, wherein the proximal end of the outer tractor tube portion is configured to have a tapered shape when the outer tractor tube portion is expanded radially outward.

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12. The apparatus of claim 1, wherein the distal-facing region of the tractor tube is unsupported over at least 1 cm proximally from the distal-facing region of the tractor tube.

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13. The apparatus of claim 1, wherein the tractor tube has a porosity of 60% or greater.

14. The apparatus of claim 1, wherein the inner tractor puller comprises an inner lumen configured to pass a guidewire out of a distal end of the apparatus.

15. The apparatus of claim 1, further comprising a vacuum source coupled to the tractor tube and configured to apply a vacuum therethrough.

5 16. A self-rolling mechanical atherectomy apparatus for removing a clot from a vessel, comprising:

 an outer tractor pusher comprising a catheter having a distal end and a distal end opening;

 a tractor tube comprising an outer tractor tube portion that extends distally in an un-
10 inverted configuration and inverts into itself at a distal-facing region to form an inner tractor tube portion, wherein the tractor tube is configured so that pulling the inner tractor tube portion proximally (i) compresses the outer tractor tube portion into a configuration having a column strength that resists collapsing up to at least 500g of compression and extends inner tractor tube portion, and (ii) causes a region of the outer tractor tube portion at the distal-
15 facing region to roll over itself, unsupported, and invert into the inner tractor tube portion; and

 an inner tractor puller coupled to the inner tractor tube portion and extending proximally within the outer tractor pusher.

20 17. The apparatus of claim 16, wherein the outer tractor pusher is coupled to a proximal end of the outer tractor tube portion of the tractor tube.

 18. The apparatus of claim 16, further comprising a distal access catheter, wherein the outer tractor pusher, the tractor tube, and inner tractor puller are held within the distal access
25 catheter in an un-deployed configuration, and wherein the tractor tube is configured to be deployed by being pushed distally out of the distal access catheter so that the outer tractor tube portion expands to a diameter that is greater than an outer diameter of the distal access catheter in a deployed configuration.

30 19. The apparatus of claim 16, wherein the outer tractor pusher is configured as a distal access catheter in which the tractor tube and inner tractor puller are held within the outer tractor pusher in an un-deployed configuration, and wherein the tractor tube is configured to be deployed by being pushed distally out of the outer tractor pusher so that the

outer tractor tube portion expands to an outer diameter that is greater than an outer diameter of the outer tractor pusher.

20. The apparatus of claim 16, wherein the tractor tube comprises a braided material.

5

21. The apparatus of claim 20, wherein the outer tractor tube portion has a braid angle in a proximal to distal axis in a compressed configuration that is between 80 and 170 degrees, and the inner tractor tube portion has a braid angle in the proximal to distal axis under tension of less than 80 degrees.

10

22. The apparatus of claim 16, wherein the outer tractor tube portion of the tractor tube is configured to expand to between about +/- 30% of an outer diameter of the outer tractor pusher.

15

23. The apparatus of claim 16, wherein the tractor tube is formed of between 24-48 filaments.

24. The apparatus of claim 16, wherein the tractor tube is formed of a plurality of filaments, each having a diameter of greater than 0.003 inches.

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25. The apparatus of claim 16, wherein the proximal end of the outer tractor tube portion is configured to have a tapered shape when the outer tractor tube portion is expanded radially outward.

25

26. The apparatus of claim 16, wherein the distal-facing region of the tractor tube is unsupported over at least 1 cm proximally from the distal-facing region of the tractor tube.

27. The apparatus of claim 16, wherein the tractor tube has a porosity of 60% or greater.

30

28. The apparatus of claim 16, wherein the inner tractor puller comprises an inner lumen configured to pass a guidewire out of a distal end of the apparatus.

29. The apparatus of claim 16, further comprising a vacuum source coupled to the tractor tube and configured to apply a vacuum therethrough.

30. A self-rolling mechanical atherectomy apparatus for removing a clot from a vessel, comprising:

an outer tractor pusher comprising a catheter having a distal end and a distal end opening;

a tractor tube formed from 10 or more strands, the tractor tube comprising an outer tractor tube portion that extends distally in an un-inverted configuration and inverts into itself at a distal-facing region to form an inner tractor tube portion, wherein the tractor tube is configured such that pulling the inner tractor tube portion proximally (i) compresses the outer tractor tube portion into a configuration having a column strength that resists collapsing, and (ii) causes a region of the outer tractor tube portion at the distal-facing region to roll over itself, unsupported, and invert into the inner tractor tube portion,

wherein the outer tractor tube portion has an expanded configuration with a distal-to-proximal facing braid angle for the expanded configuration of between about 80 and about 170 degrees; and wherein the outer tractor tube portion of the tractor tube is configured to expand to between about +/- 30% of an outer diameter of the outer tractor pusher; and

an inner tractor puller coupled to the inner tractor tube portion and extending proximally within the outer tractor pusher.

31. A method of removing a clot from a blood vessel, comprising:

advancing a distal end of a self-rolling mechanical atherectomy apparatus through the blood vessel to the clot, wherein the self-rolling mechanical atherectomy apparatus comprises a tractor tube, an outer tractor pusher, and an inner tractor puller;

pulling an inner tractor puller of the tractor tube proximally to compresses an outer tractor tube portion of the tractor tube, wherein pulling the inner tractor puller proximally causes the outer tractor tube portion at a distal-facing region of the tractor tube to roll over itself, unsupported, and invert into the inner tractor tube portion; and

engaging the clot with the tractor tube as it rolls over itself so that the clot is pulled into the tractor tube.

32. The method of claim 31, further comprising deploying the tractor tube of the self-rolling mechanical atherectomy apparatus so that the outer tractor tube portion of the tractor

tube expands to have an outer diameter that is greater than an outer diameter of the outer tractor pusher.

33. The method of claim 31, wherein pulling the inner tractor puller comprises
5 bracing a distal-facing end of the outer tractor pusher against a tapered face of the tractor tube that is proximal to the outer tractor tube portion.

34. The method of claim 31, further comprising advancing a guidewire within the
blood vessel to the clot, wherein advancing the self-rolling mechanical atherectomy apparatus
10 comprises advancing the self-rolling mechanical atherectomy apparatus over the guidewire through the blood vessel until the self-rolling mechanical atherectomy apparatus is proximate to the clot.

35. The method of claim 31, wherein engaging the clot comprises advancing the outer
15 tractor pusher distally while pulling the inner tractor puller proximally.

36. The method of claim 31, wherein engaging the clot comprises advancing the outer
tractor pusher distally at a first rate while pulling the inner tractor puller proximally at a
second rate that is faster than the first rate.

20

37. The method of claim 31, wherein advancing the distal end of the self-rolling
mechanical atherectomy apparatus comprises advancing the self-rolling mechanical
atherectomy apparatus distally with the tractor tube and inner tractor puller within the outer
tractor pusher, wherein the tractor tube is in an un-deployed configuration.

25

38. The method of claim 31, further comprising applying aspiration through the
tractor tube.

39. The method of claim 31, further wherein advancing the distal end of the self-
rolling mechanical atherectomy apparatus comprises advancing a distal access catheter
30 enclosing the tractor tube, outer tractor pusher and inner tractor puller, wherein the outer tractor tube portion is inverted over the inner tractor puller in an un-deployed configuration within the distal access catheter.

40. The method of claim 31, wherein pulling the inner tractor puller comprises applying up to 500 g of compressive force on the outer tractor tube portion without collapsing the outer tractor tube portion.

5 41. A method of removing a clot from a blood vessel, comprising:

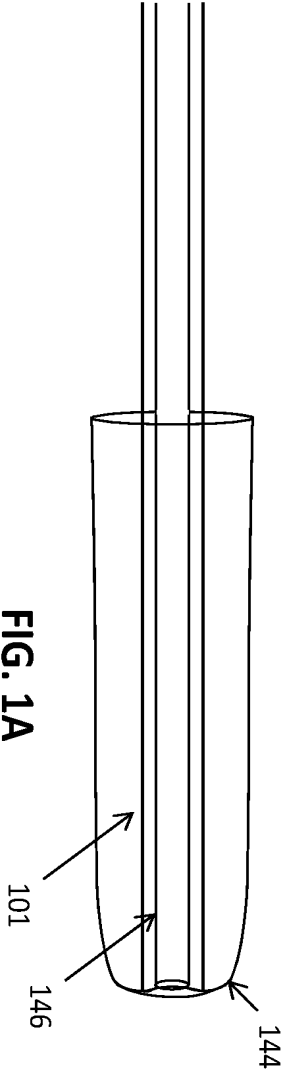
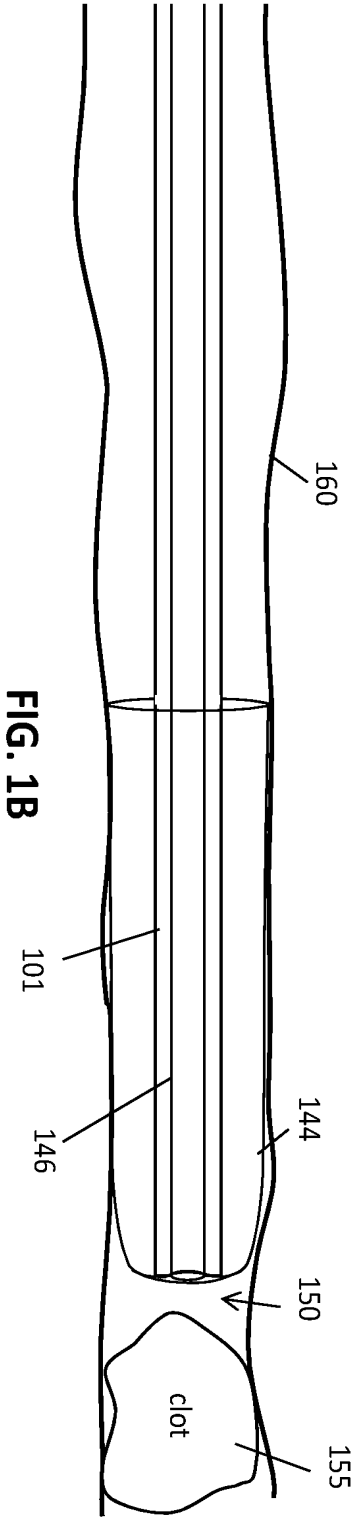
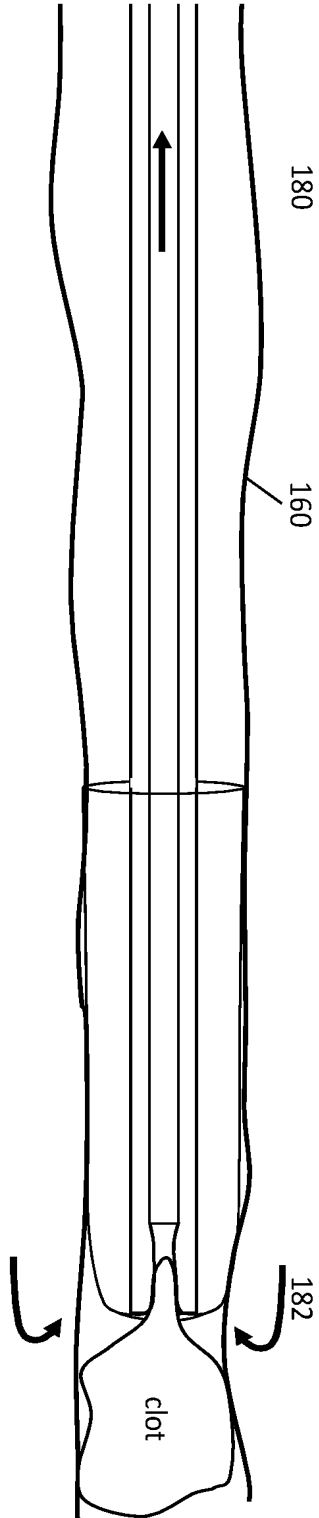
 advancing a distal end of a self-rolling mechanical atherectomy apparatus through the blood vessel to the clot, wherein the self-rolling mechanical atherectomy apparatus comprises a tractor tube, an outer tractor pusher, and an inner tractor puller;

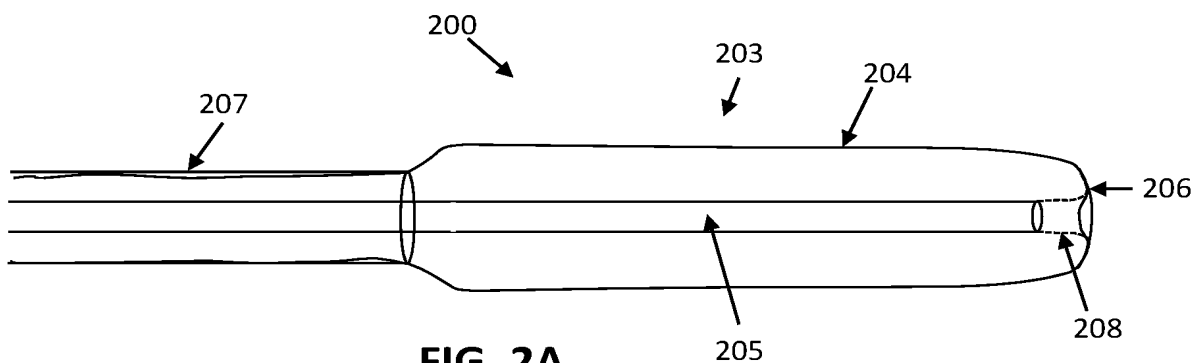
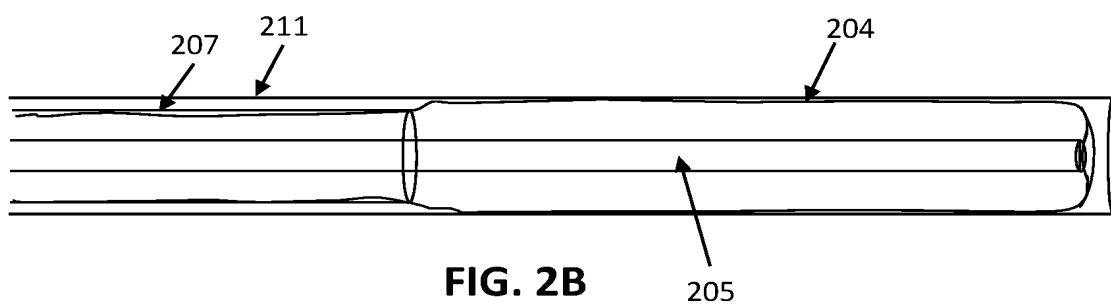
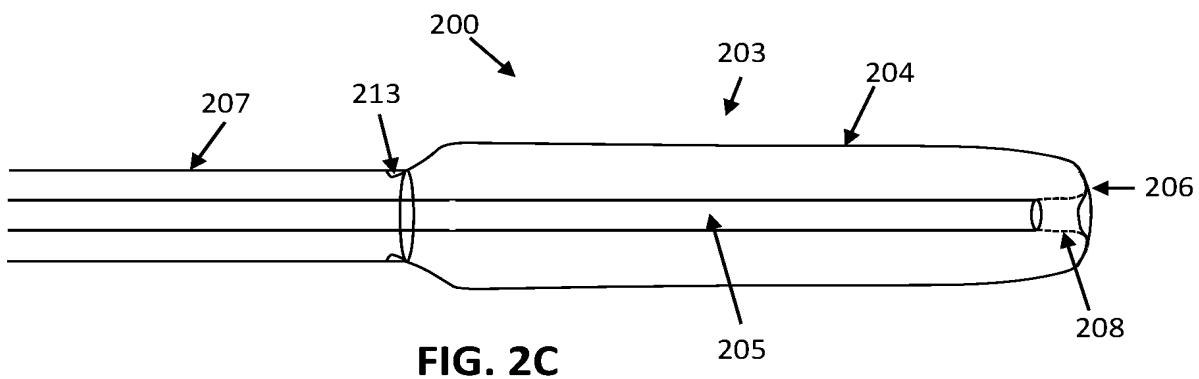
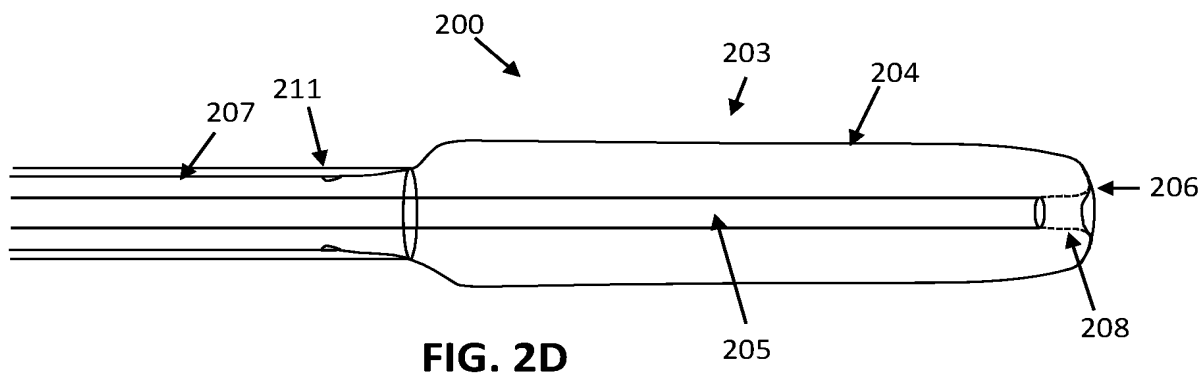
 deploying the tractor tube of the self-rolling mechanical atherectomy apparatus so that
10 an outer tractor tube portion of the tractor tube expands to have an outer diameter that is greater than an outer diameter of the outer tractor pusher, wherein a distal-facing end of the outer is braced against a tapered face of the tractor tube proximal to the outer tractor tube portion, and wherein the outer tractor tube portion inverts over itself at a distal-facing region of the tractor tube and extends proximally within the outer tractor tube portion as an inner
15 tractor tube portion that is coupled to the inner tractor puller;

 pulling the inner tractor puller proximally to compresses the outer tractor tube portion of the tractor tube, and to cause the outer tractor tube portion of the tractor tube to roll over itself, unsupported, at the distal-facing region and to invert into the inner tractor tube portion;

 engaging the clot with the tractor tube as it rolls over itself so that the clot is pulled
20 into the tractor tube; and

 withdrawing the self-rolling mechanical atherectomy holding the clot from the blood vessel.





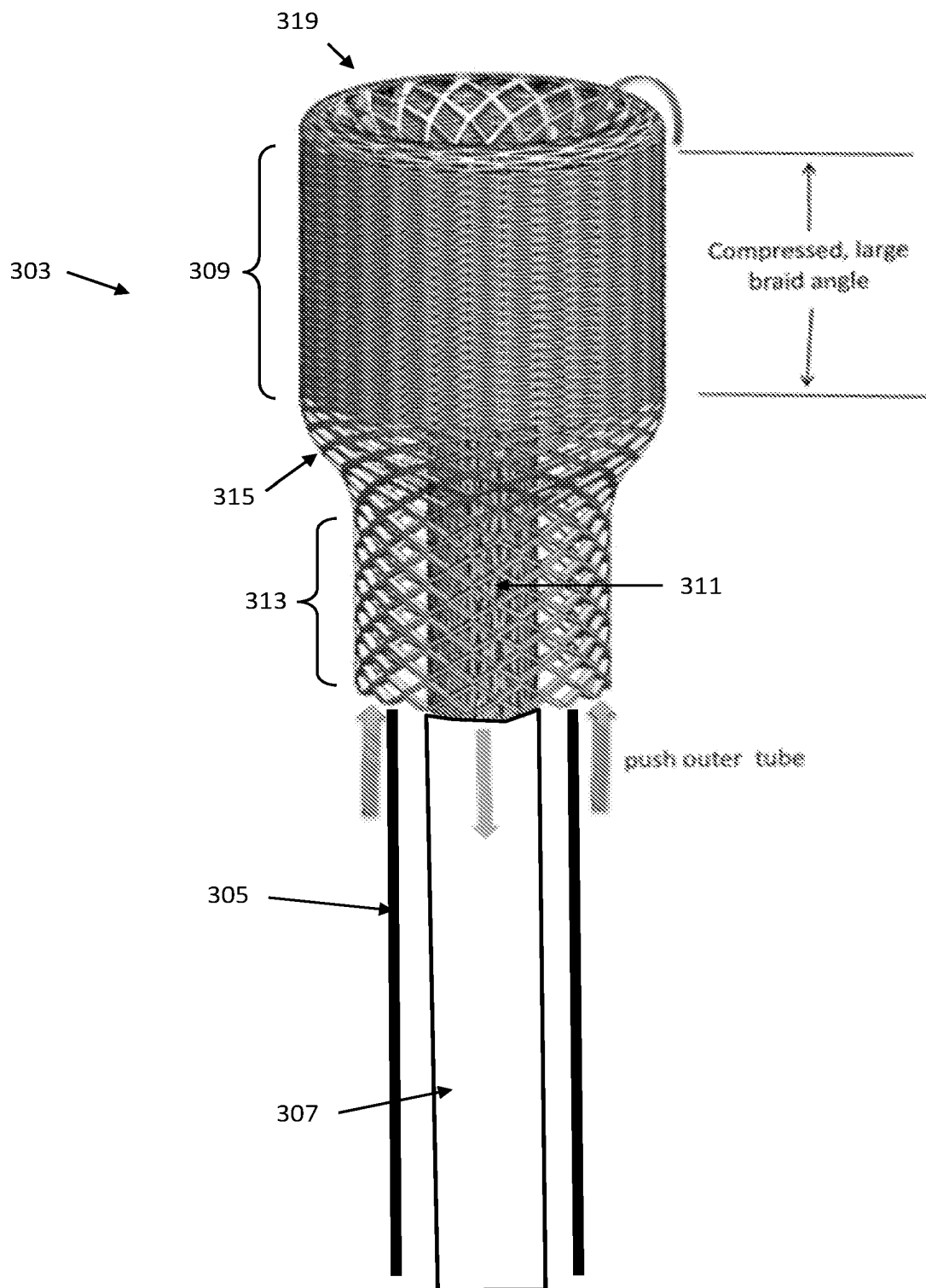
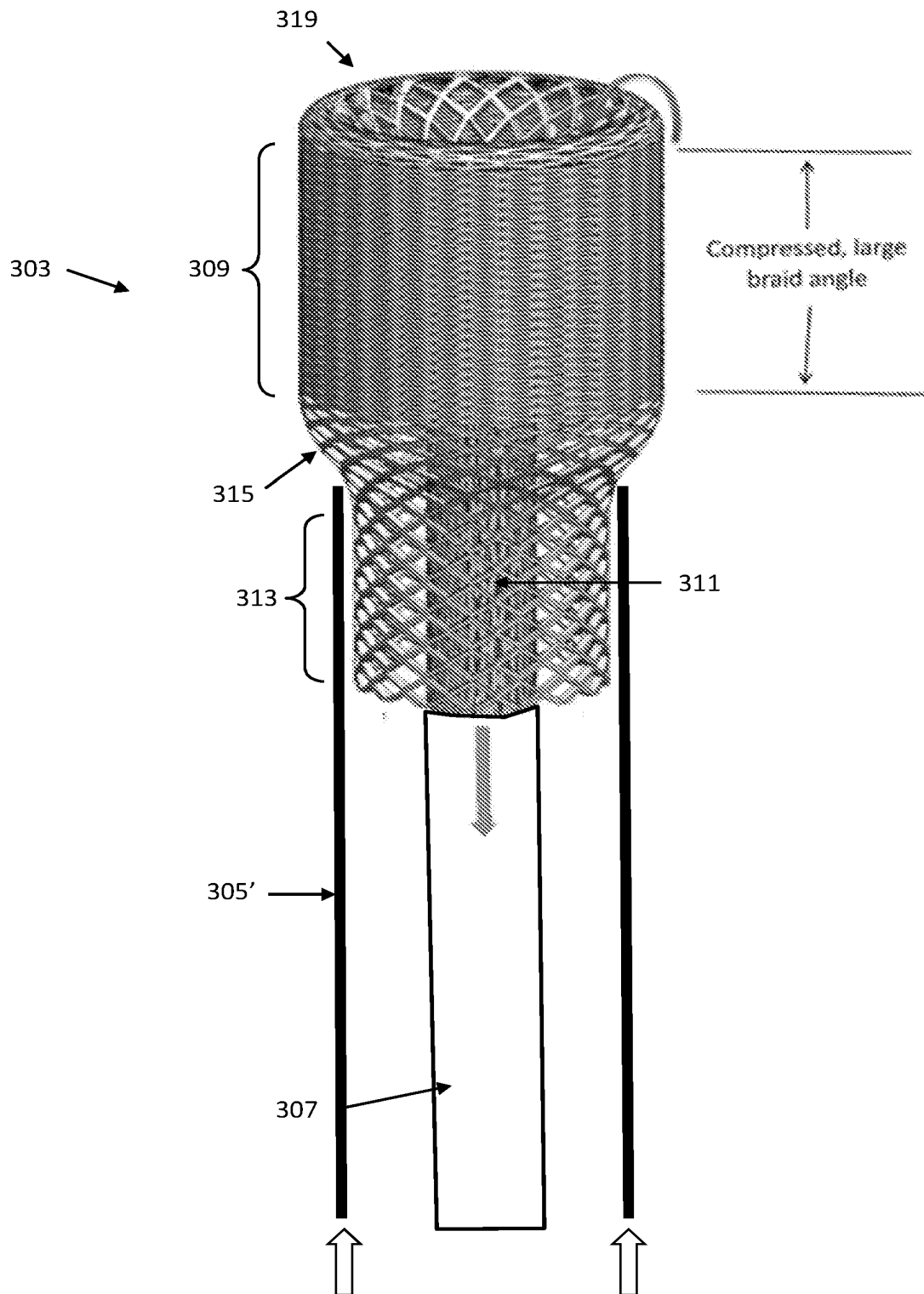


FIG. 3A

**FIG. 3B**

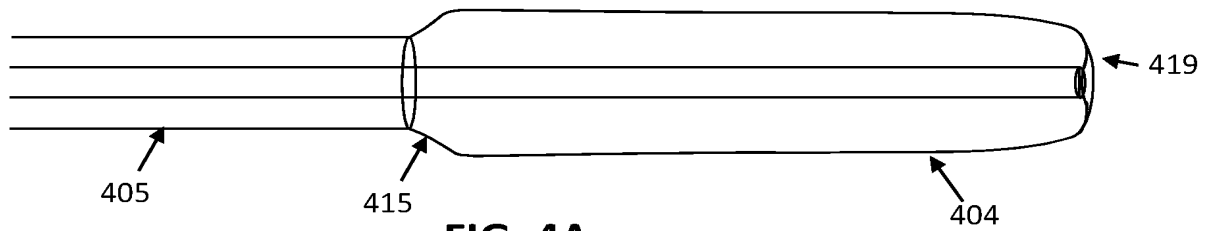


FIG. 4A

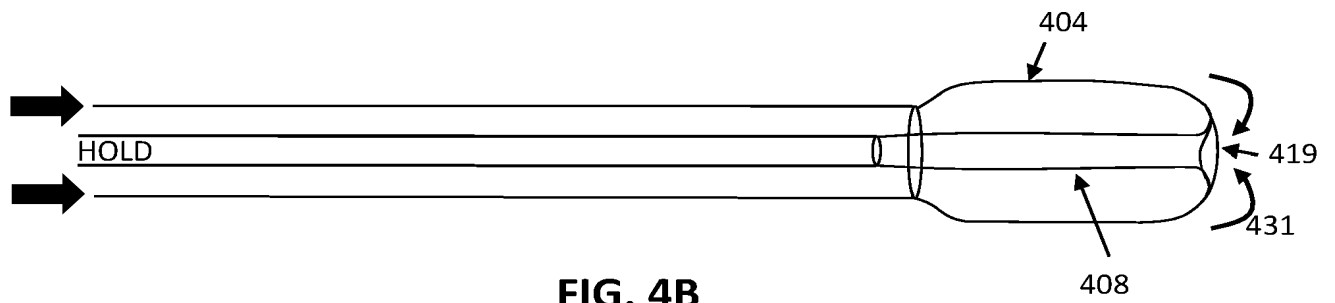


FIG. 4B

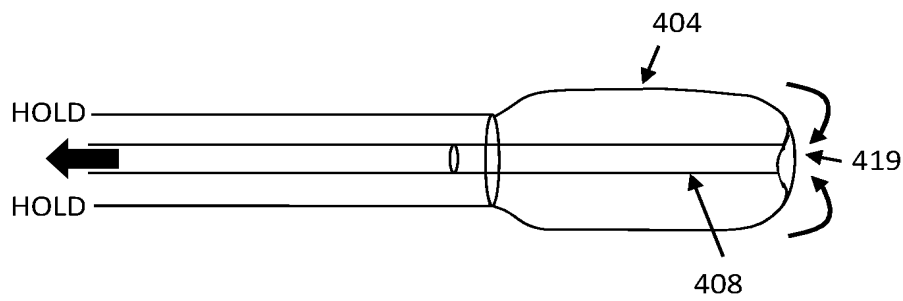


FIG. 4C

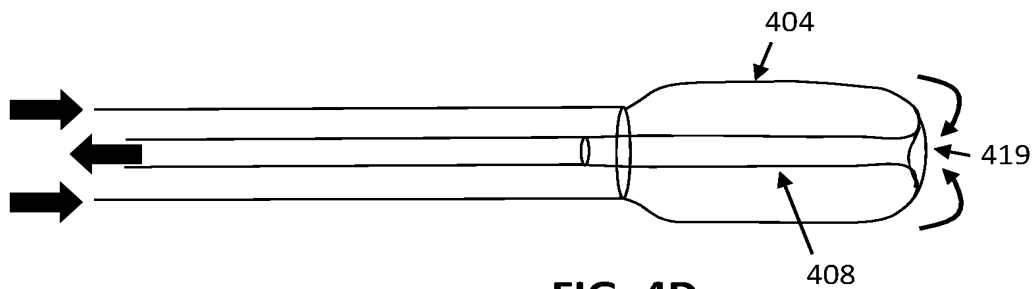
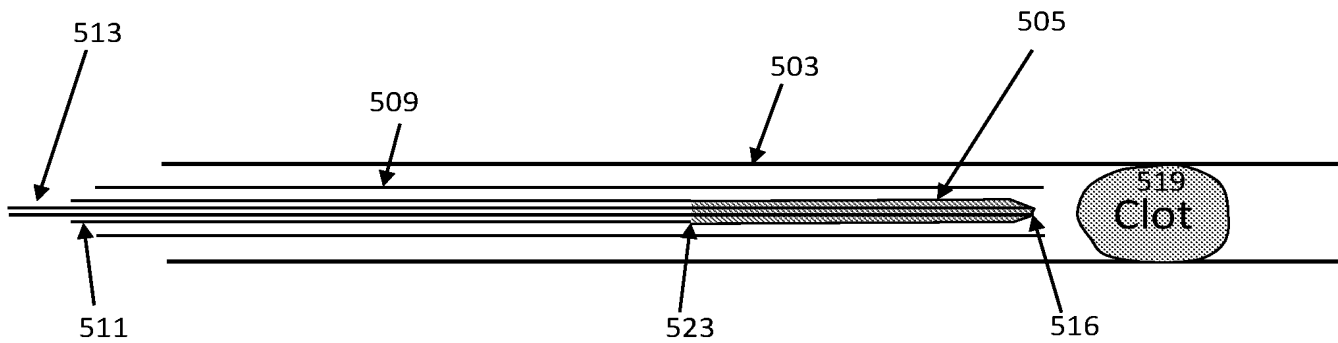
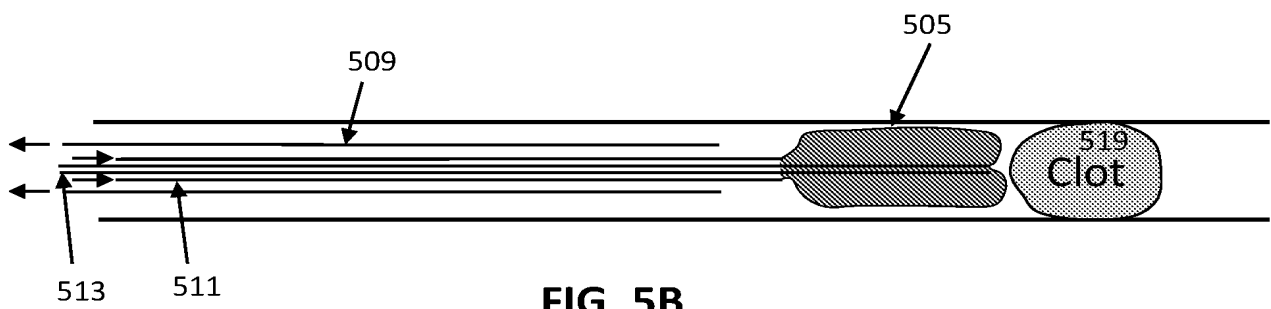
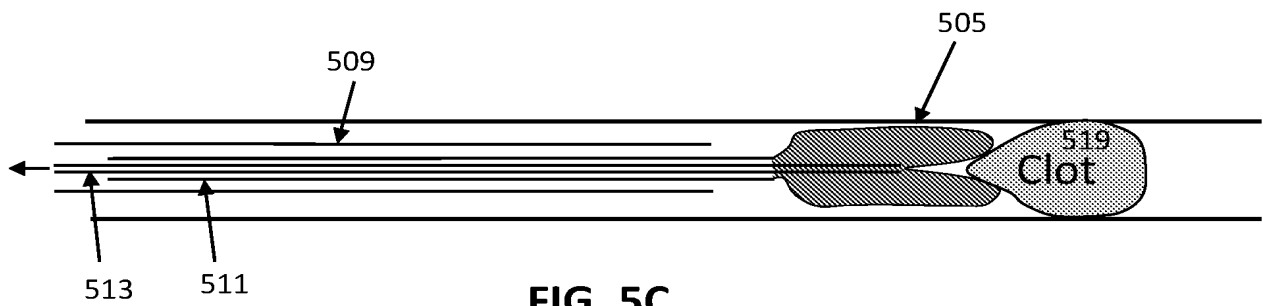


FIG. 4D

**FIG. 5A****FIG. 5B****FIG. 5C****FIG. 5D**

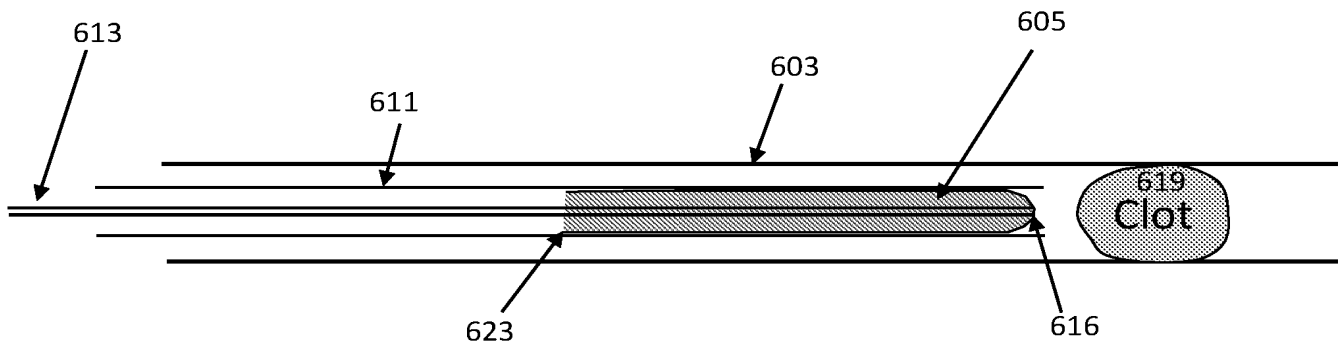


FIG. 6A

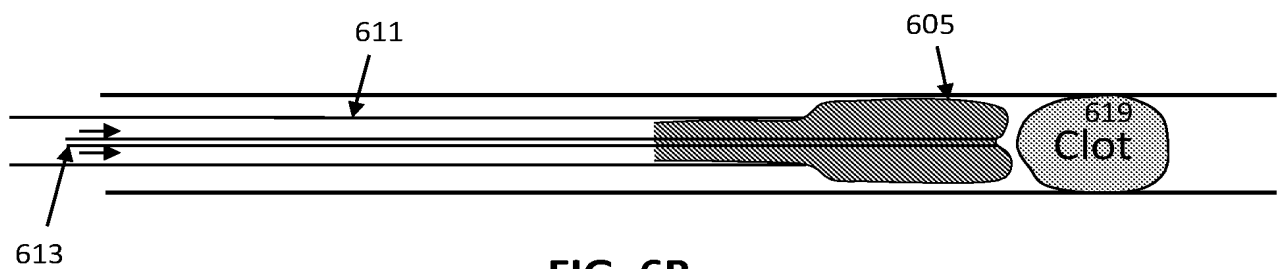


FIG. 6B

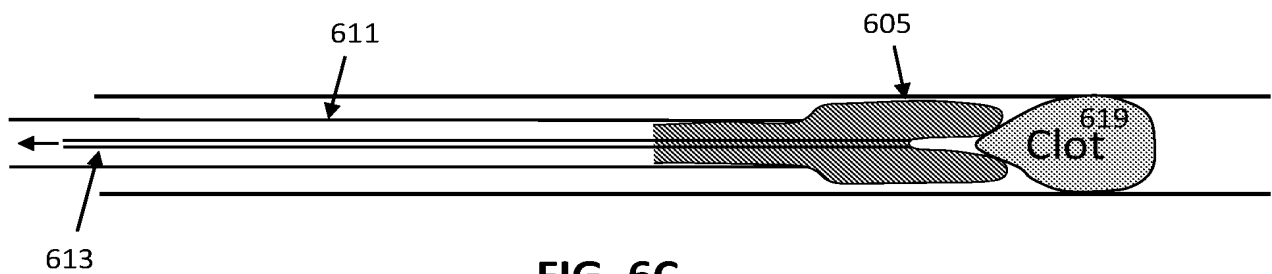


FIG. 6C

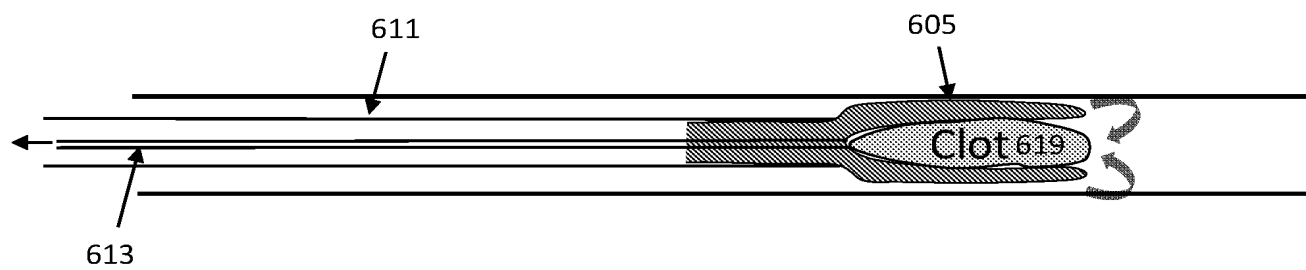


FIG. 6D

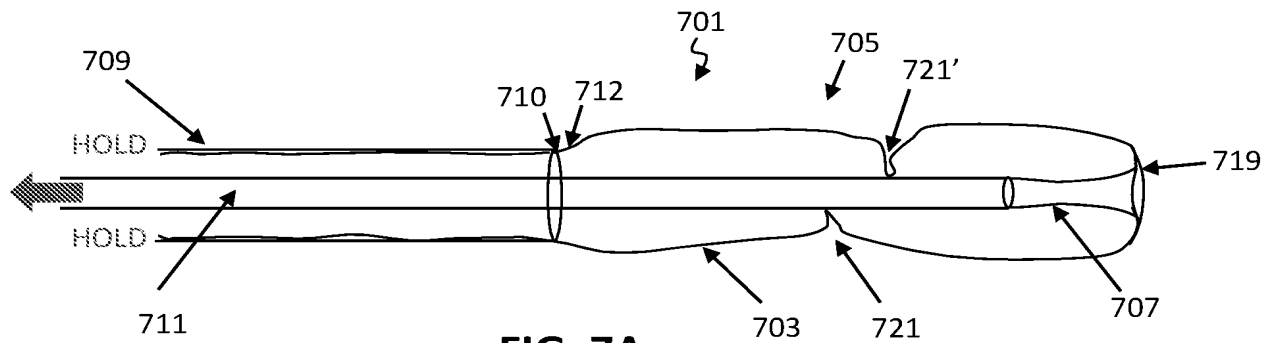


FIG. 7A

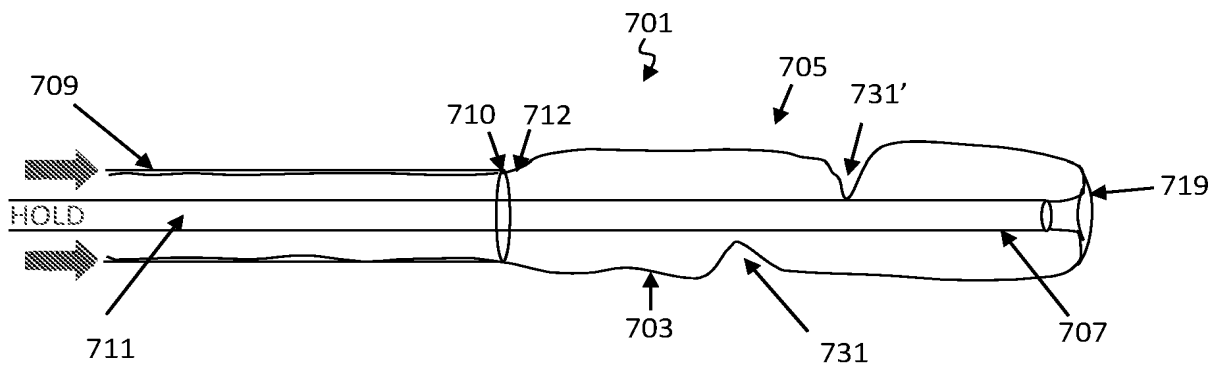


FIG. 7B

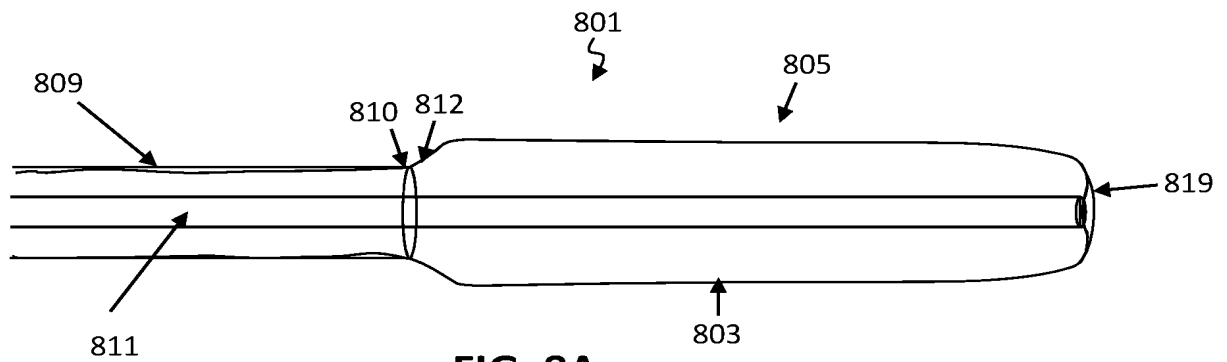


FIG. 8A

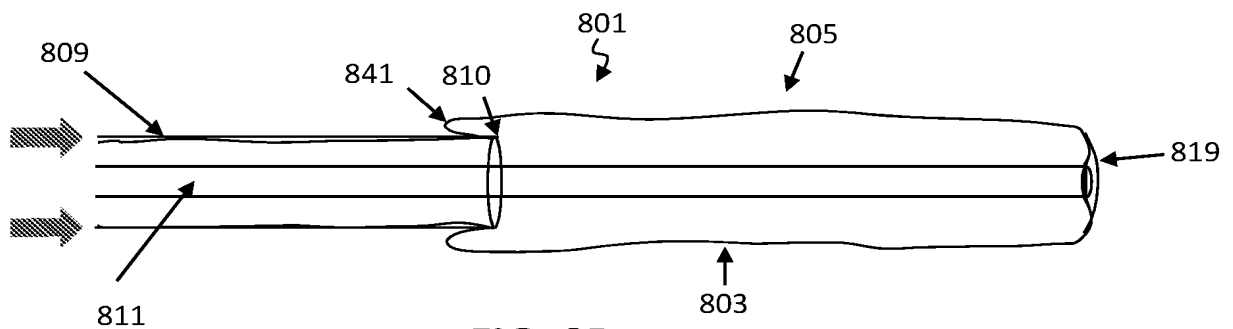


FIG. 8B

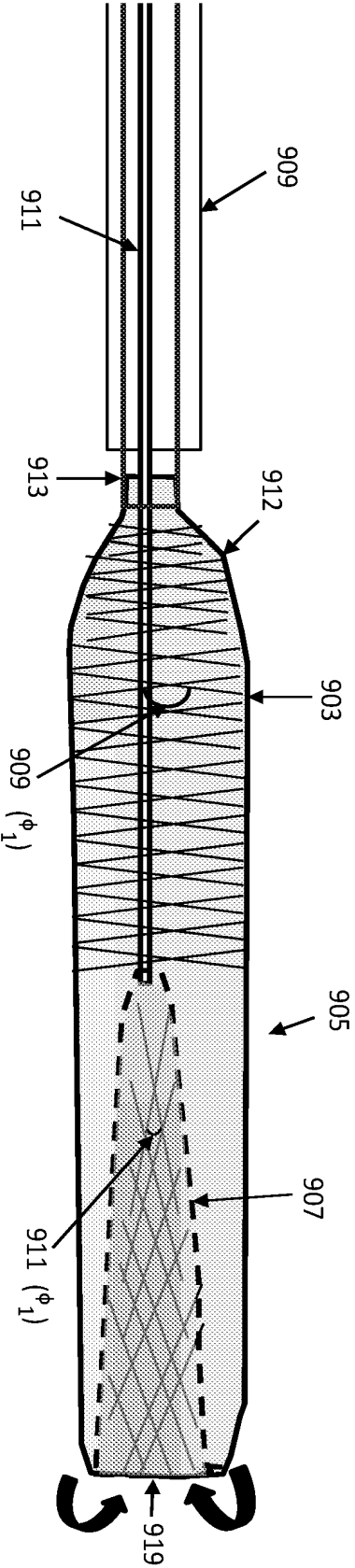


FIG. 9

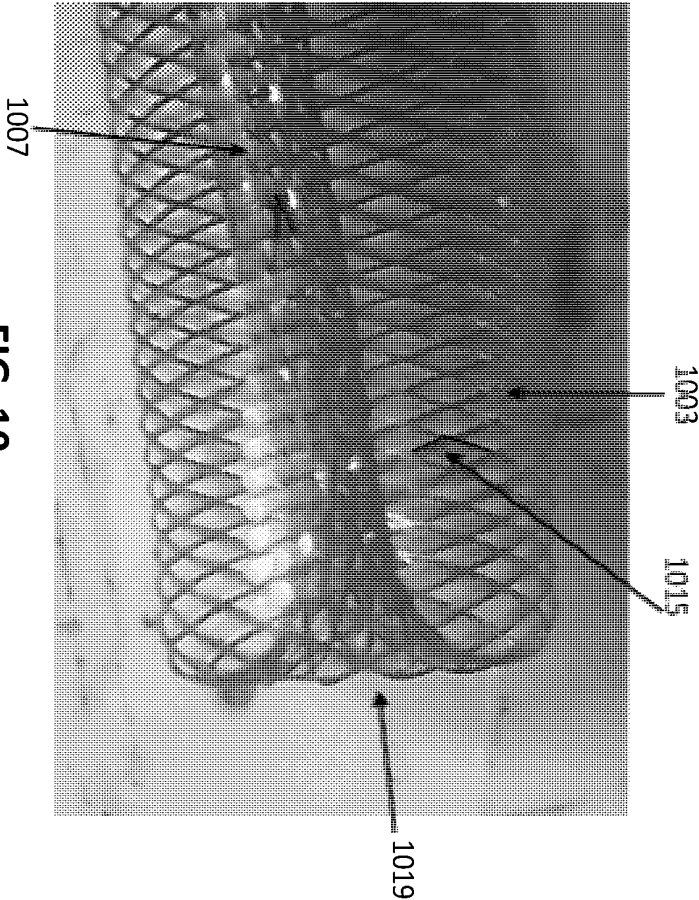
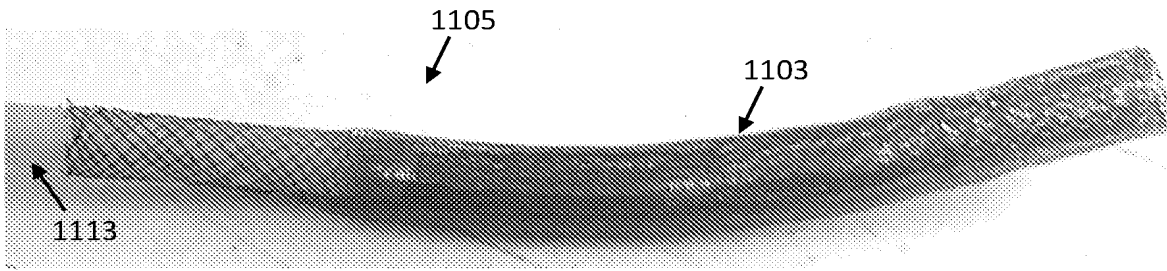
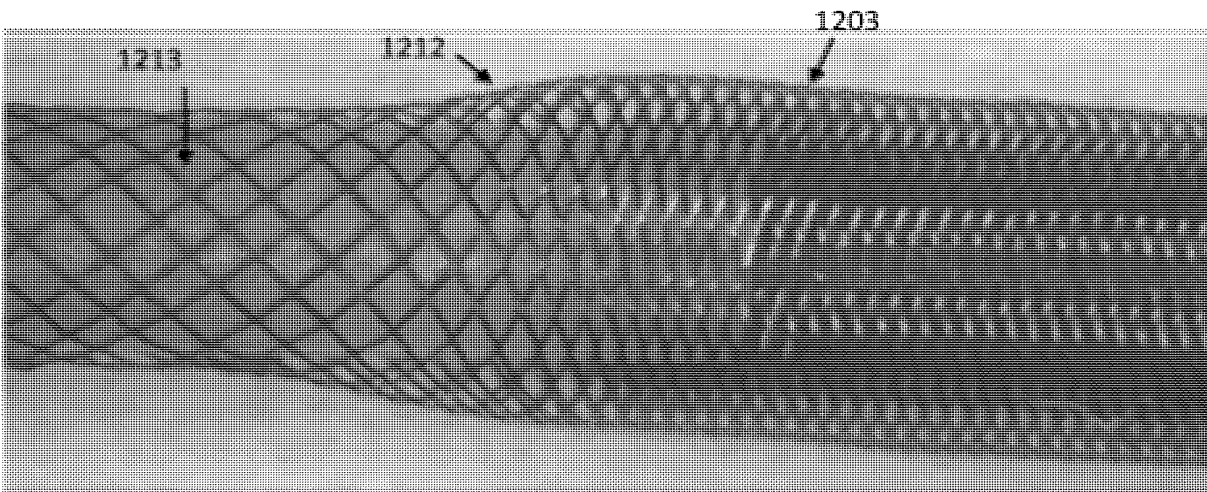
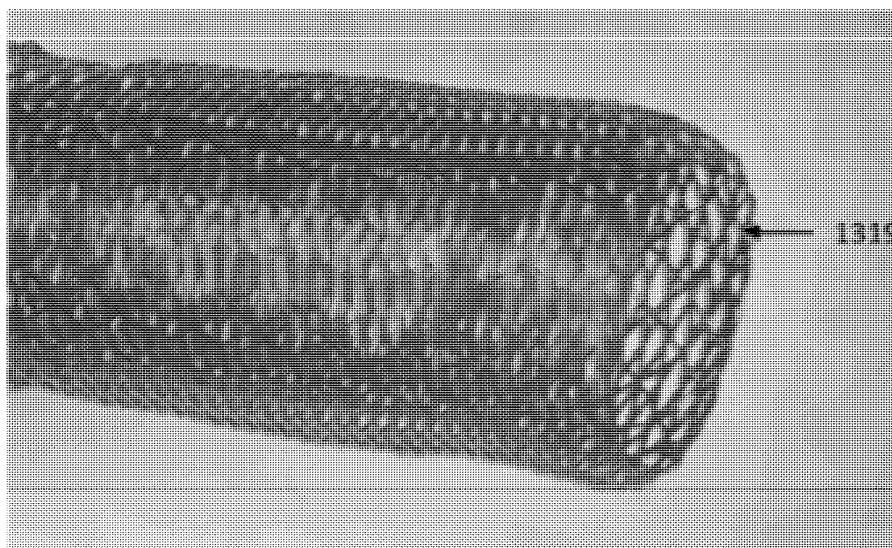
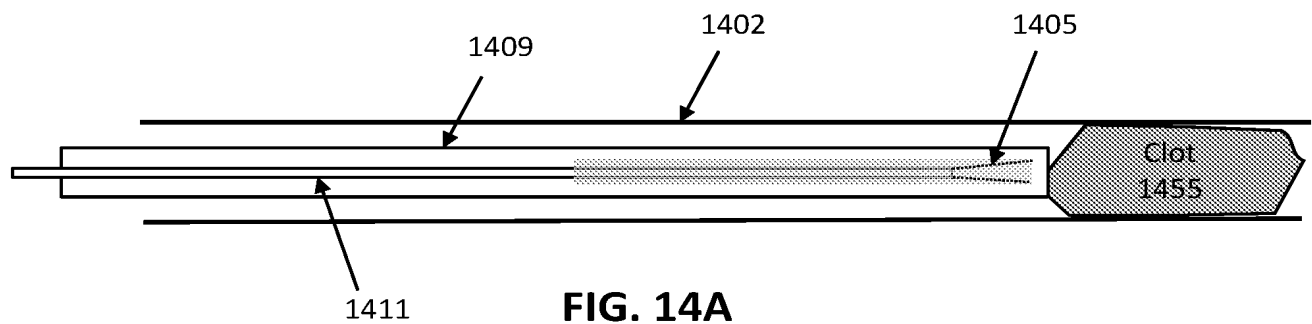
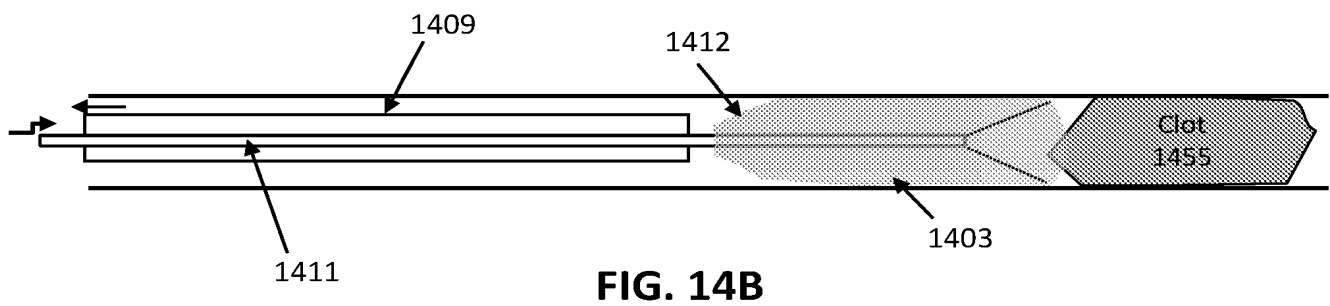
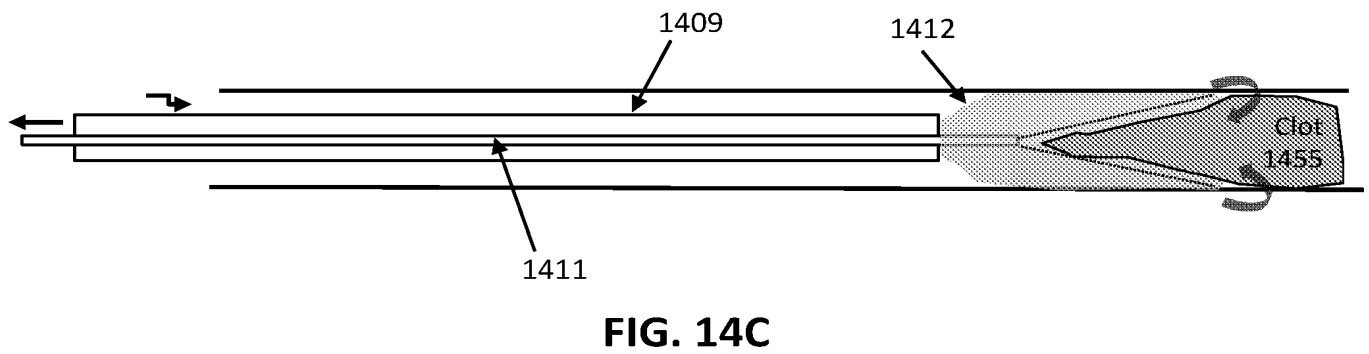
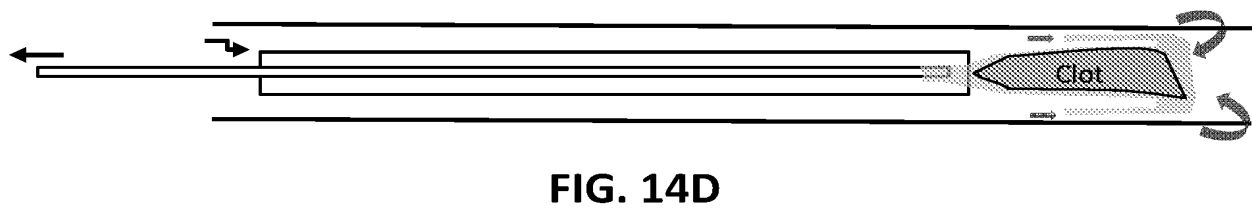


FIG. 10

**FIG. 11****FIG. 12****FIG. 13**



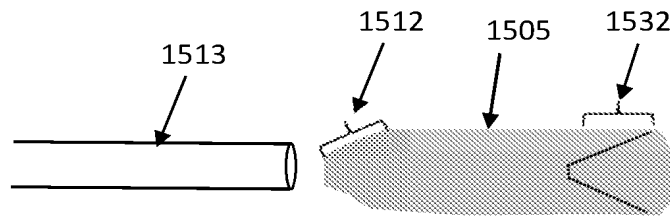


FIG. 15A

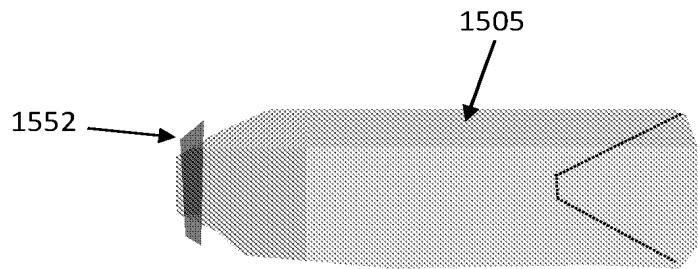


FIG. 15B

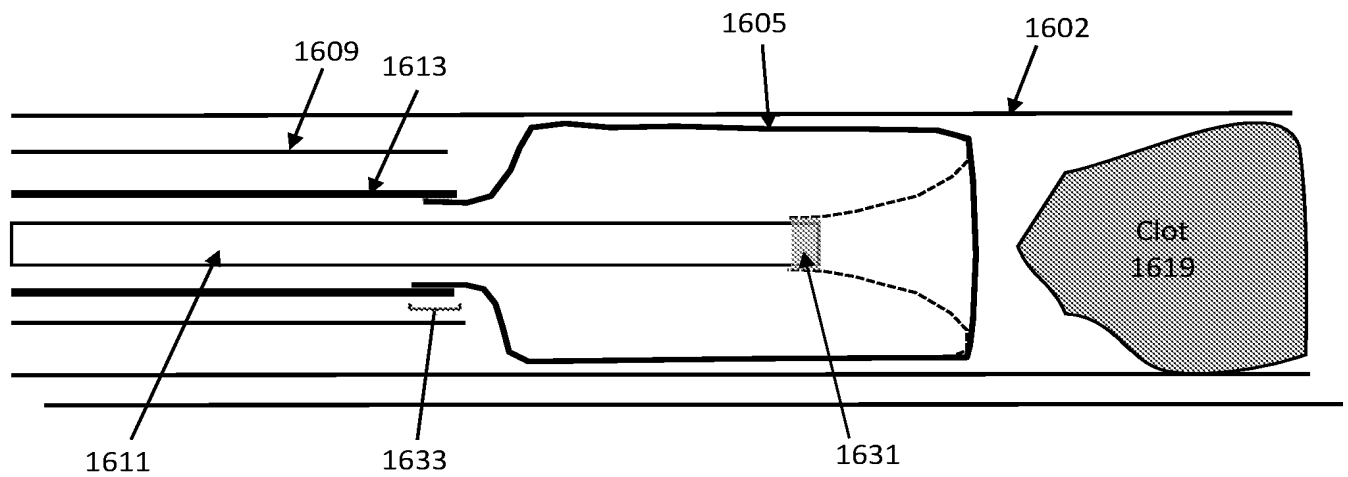


FIG. 16A

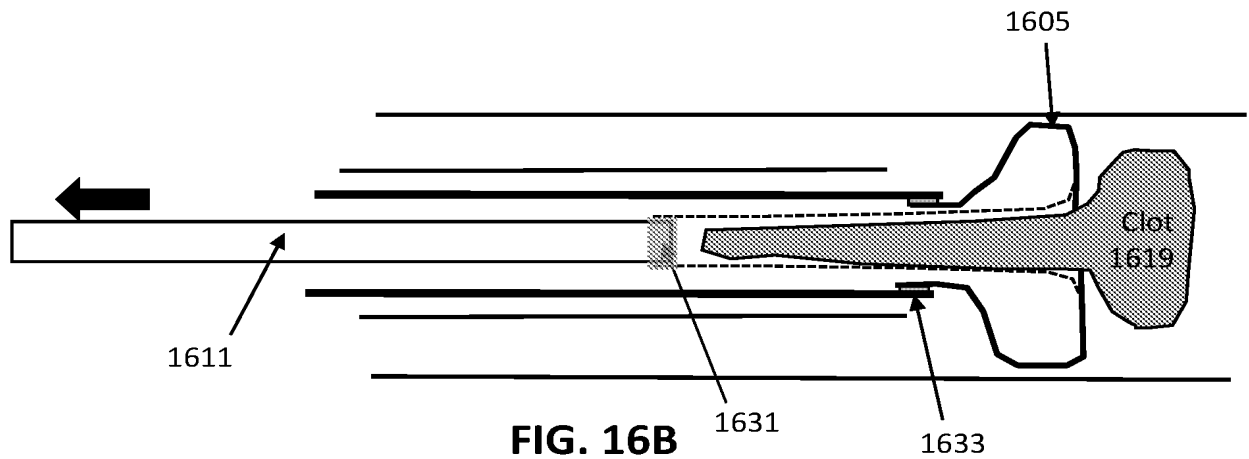


FIG. 16B

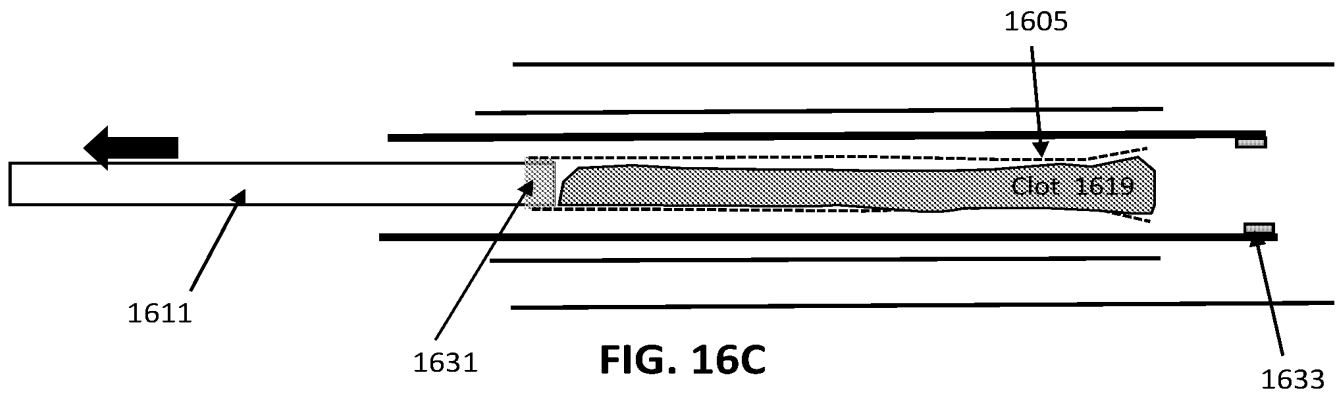
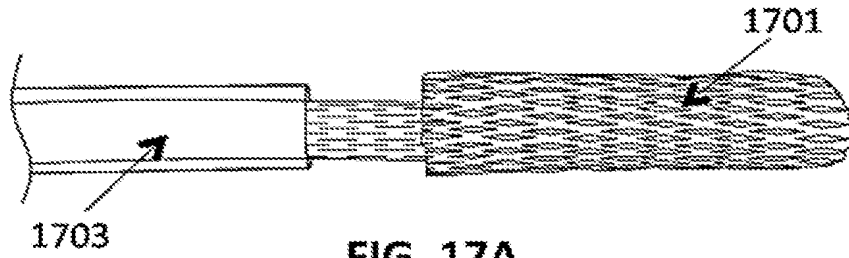
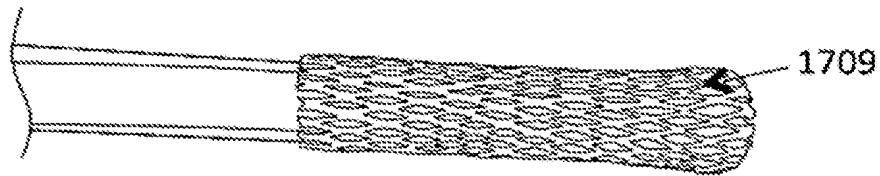
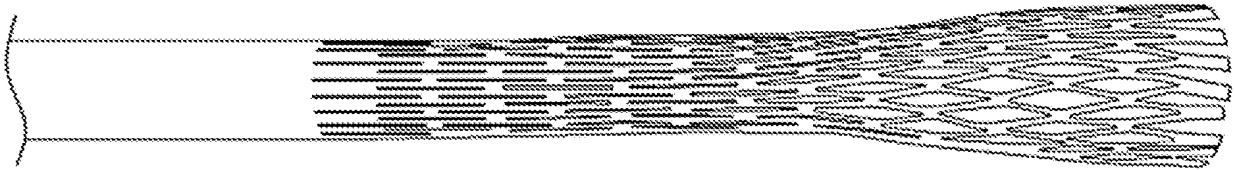
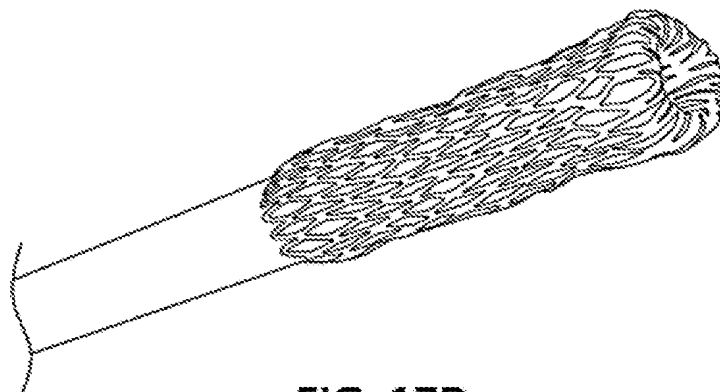
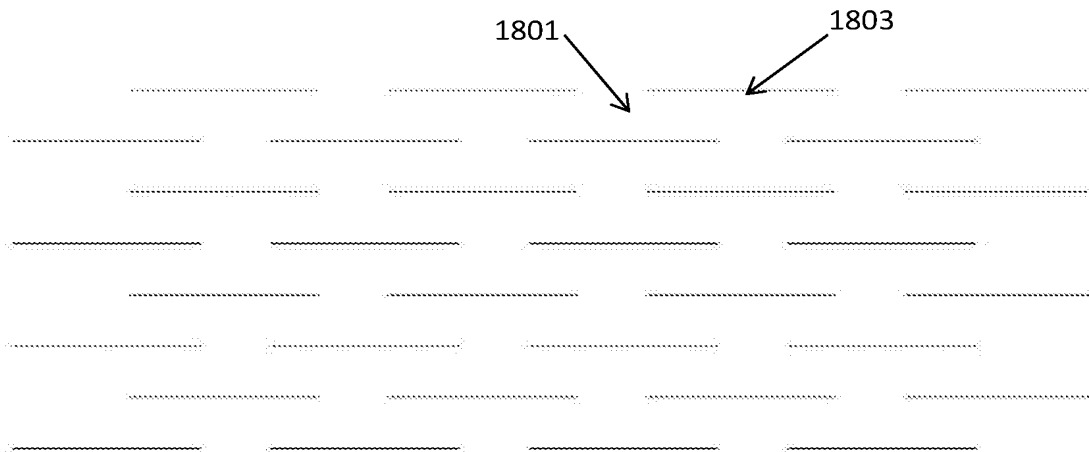
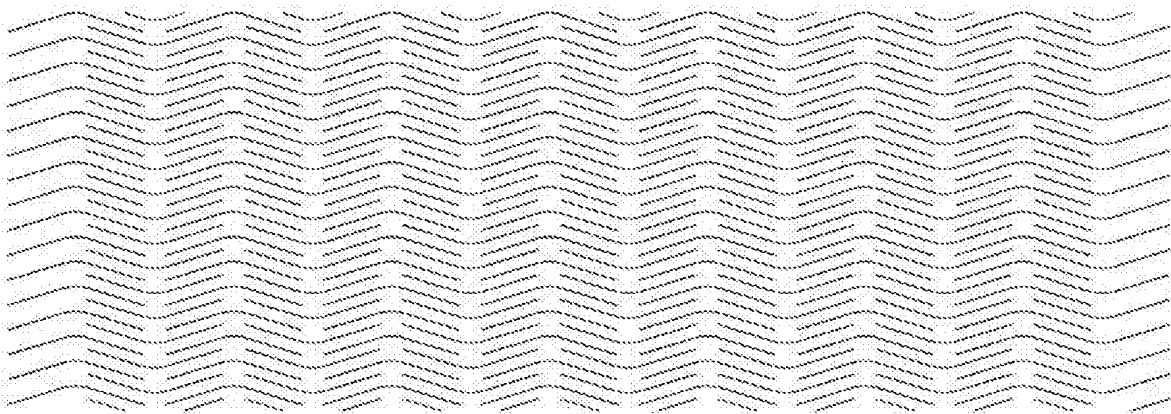


FIG. 16C



**FIG. 18A****FIG. 18B****FIG. 18C**

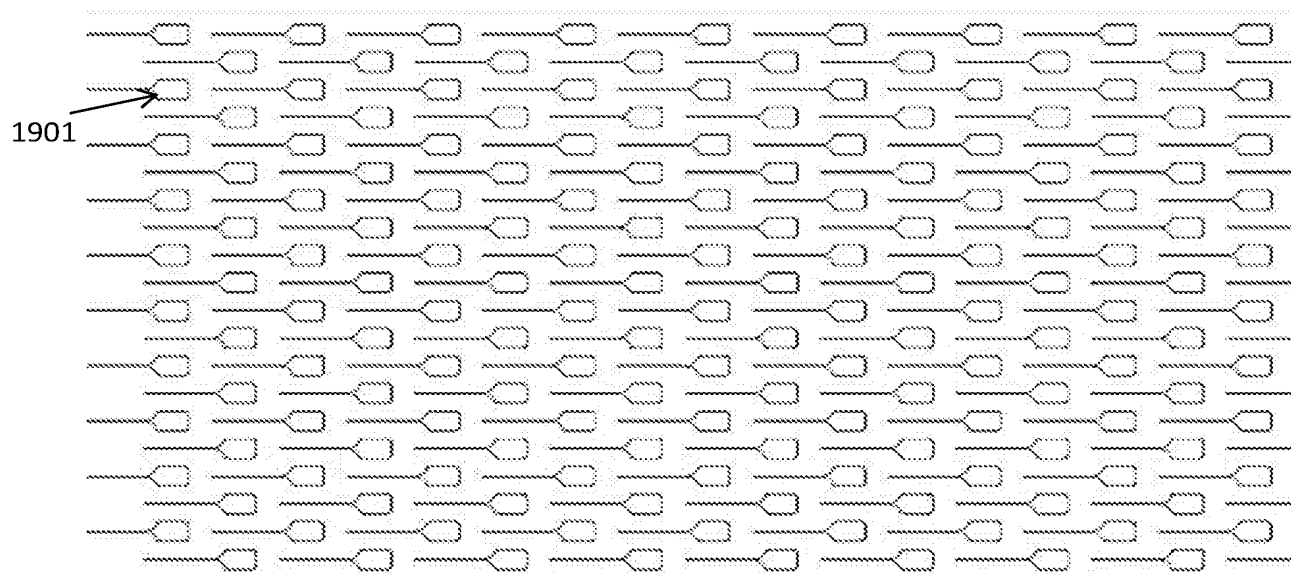


FIG. 19

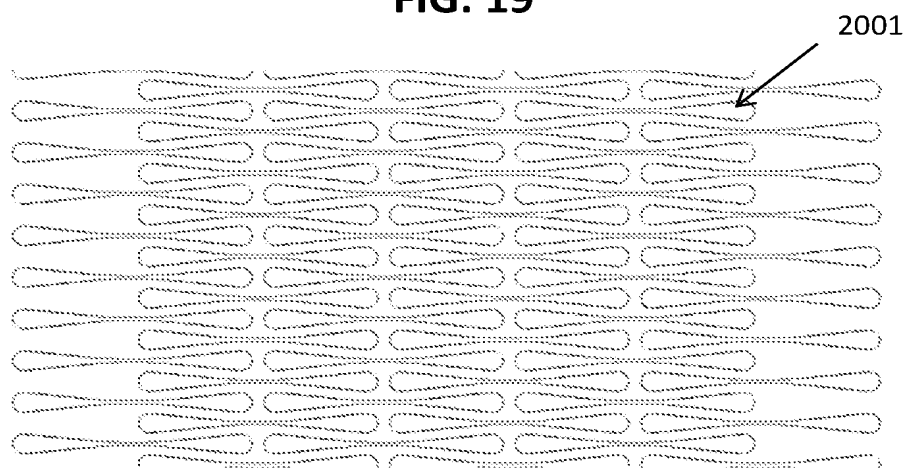


FIG. 20A

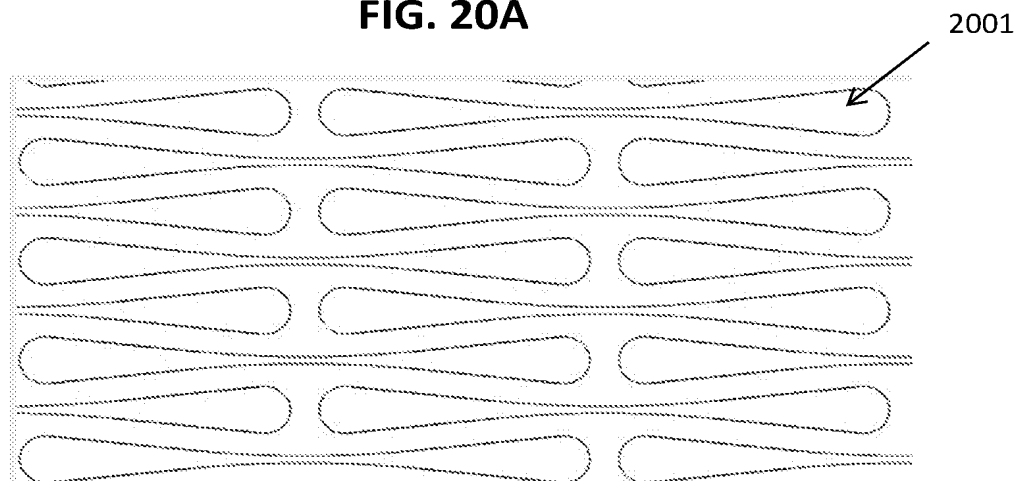


FIG. 20B

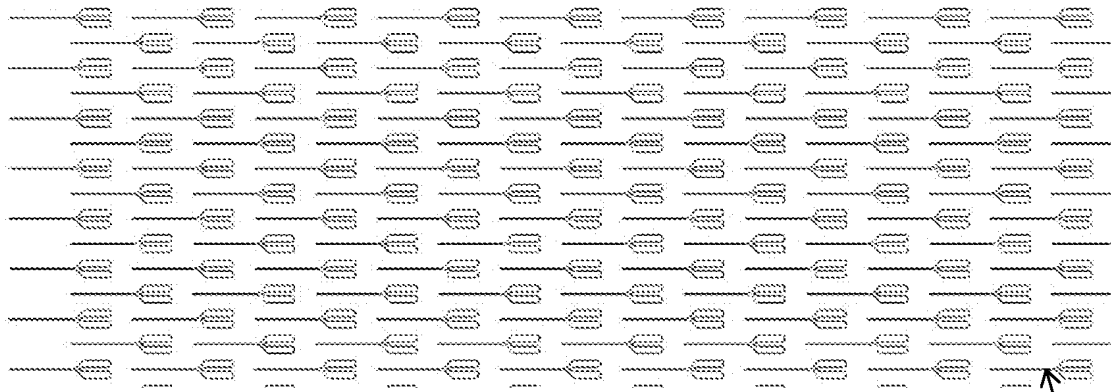


FIG. 21A

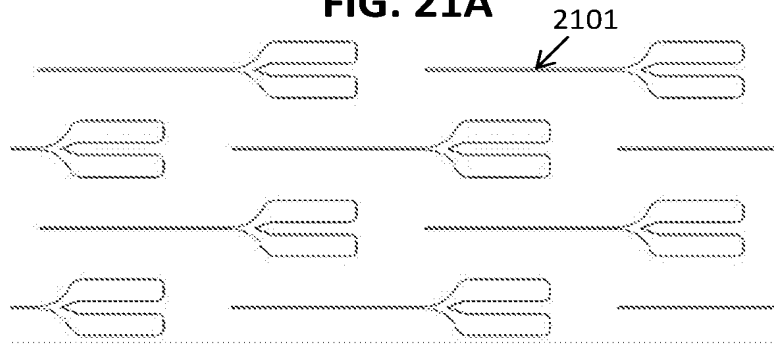


FIG. 21B

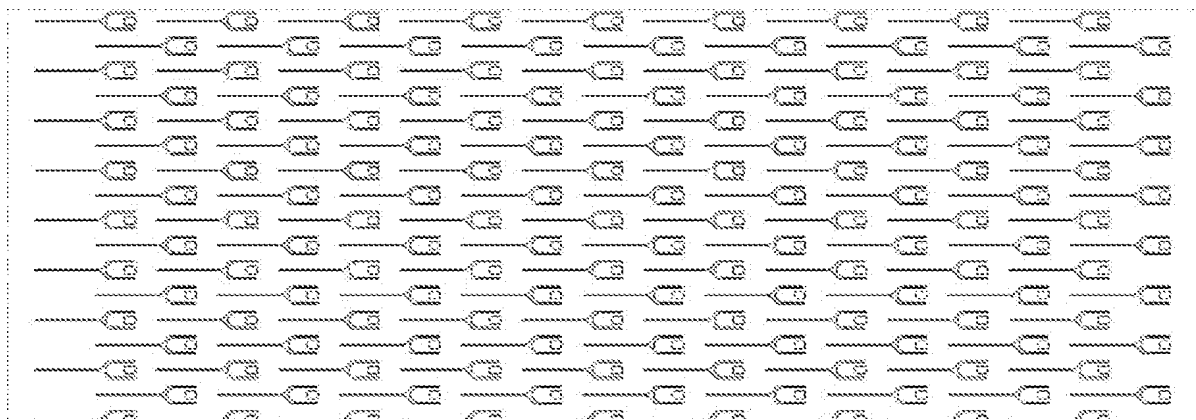


FIG. 22A

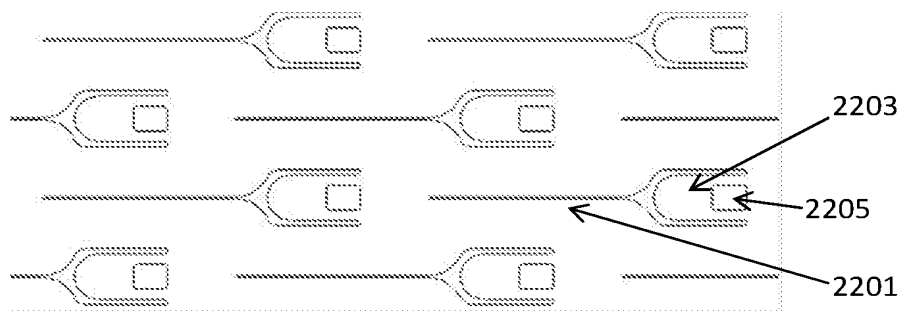


FIG. 22B

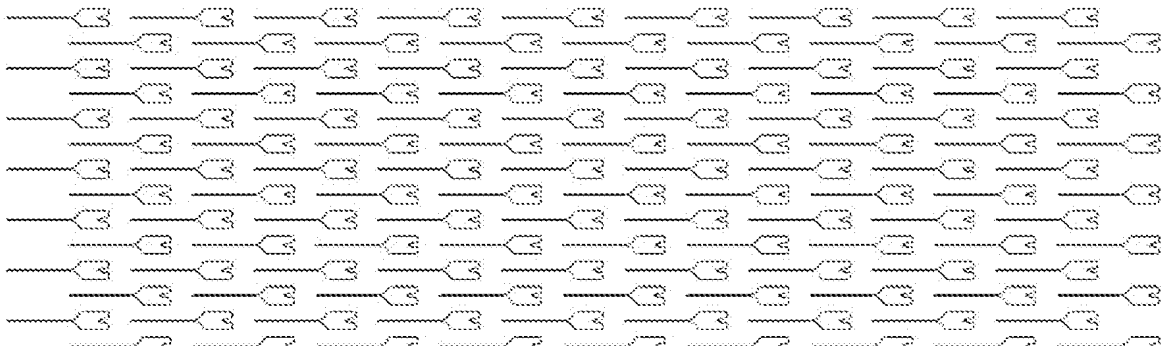


FIG. 23A

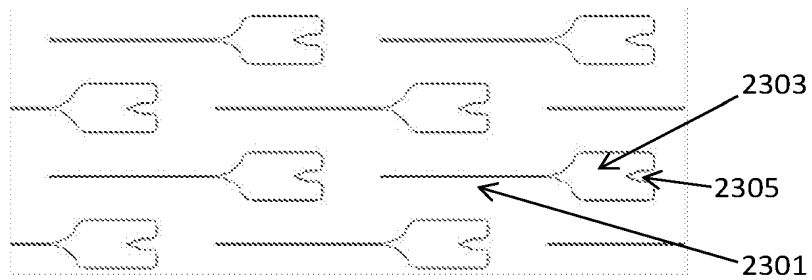


FIG. 23B

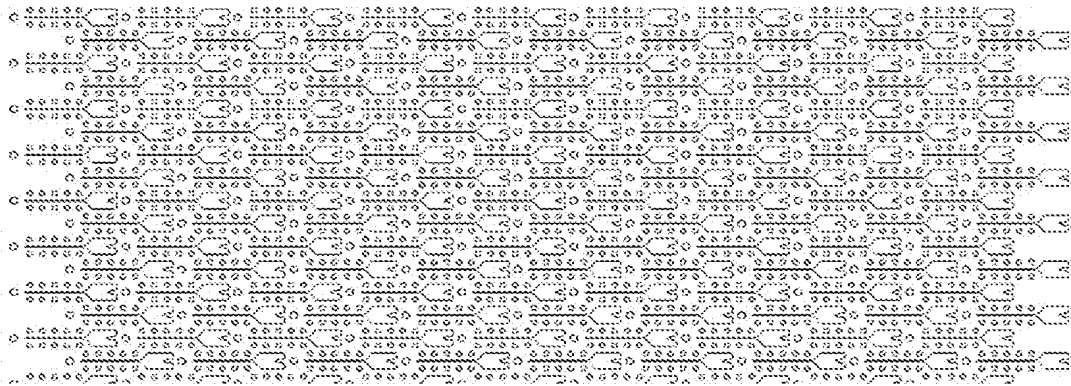


FIG. 24A

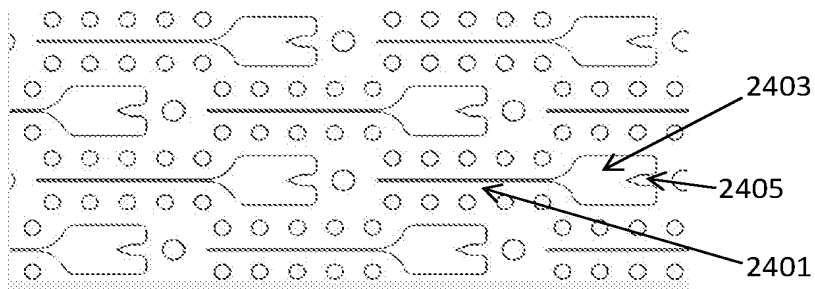


FIG. 24B

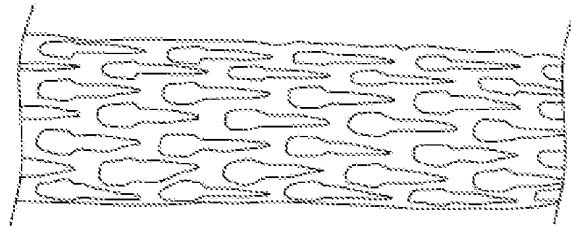


FIG. 25A

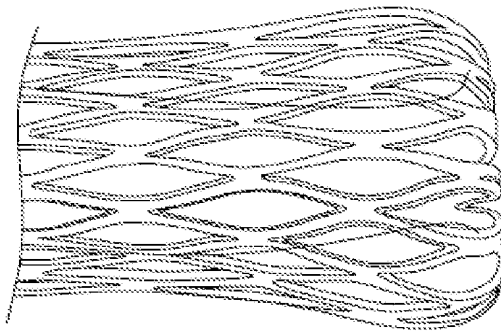
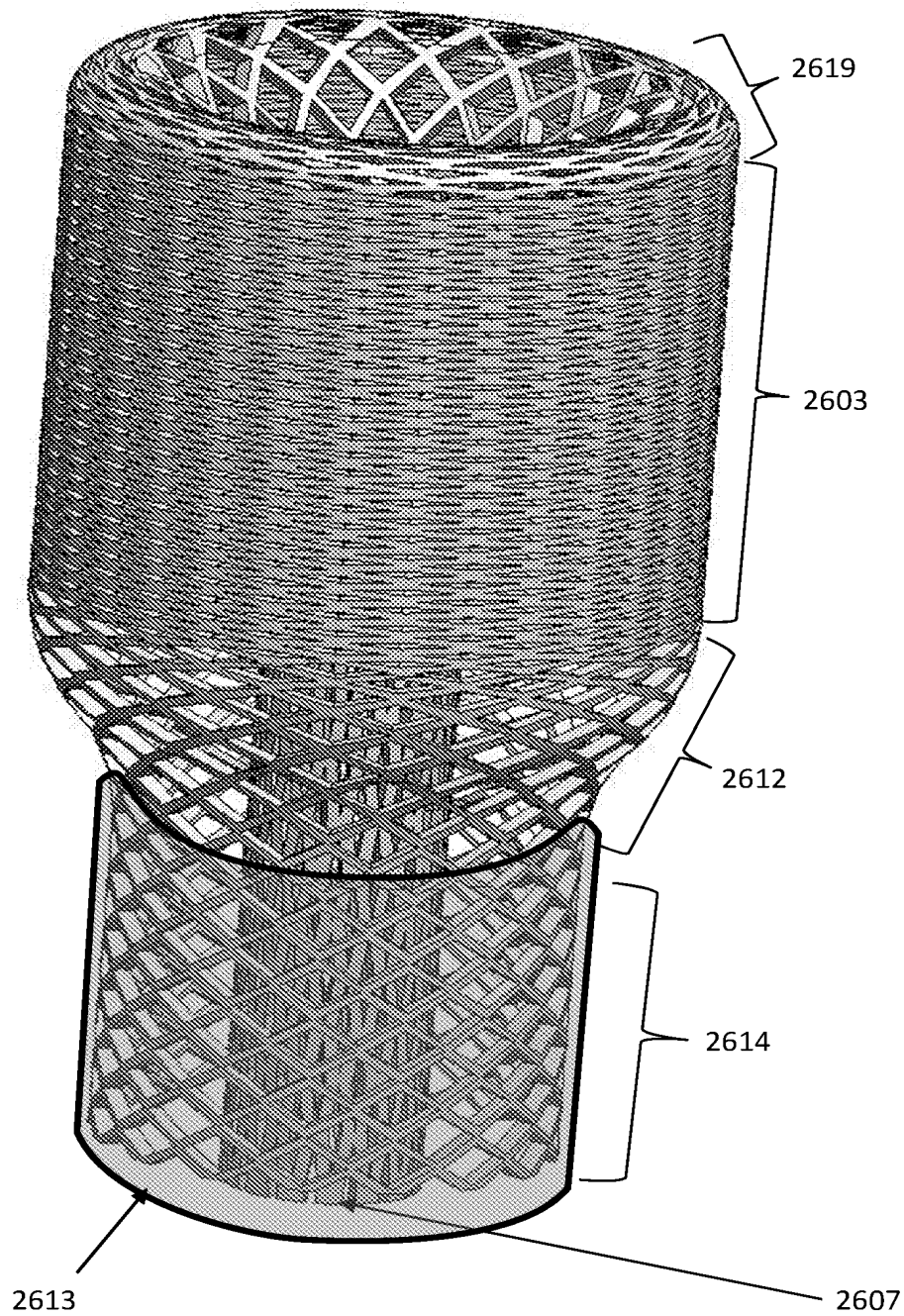


FIG. 25B

**FIG. 26A**

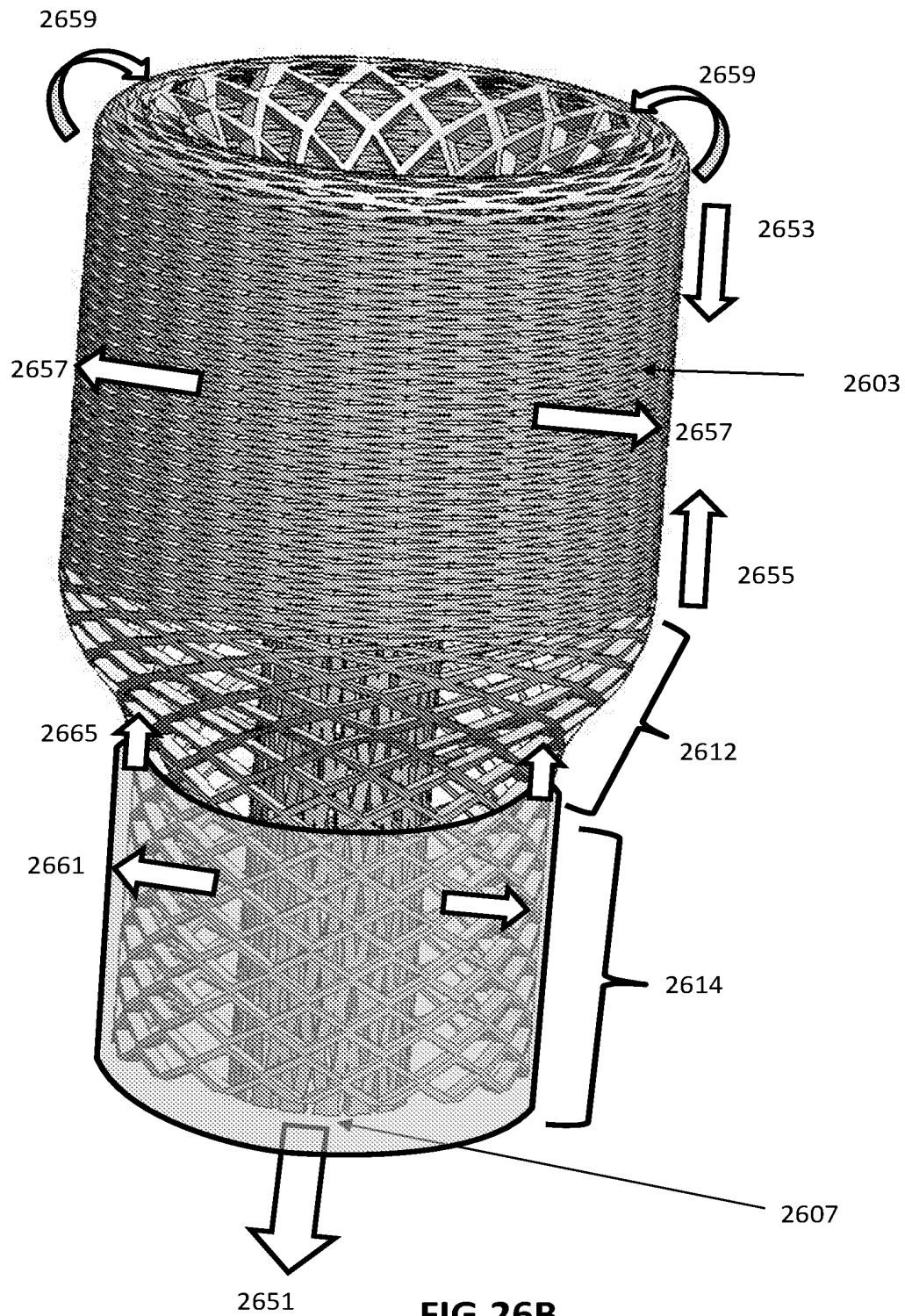


FIG. 26B

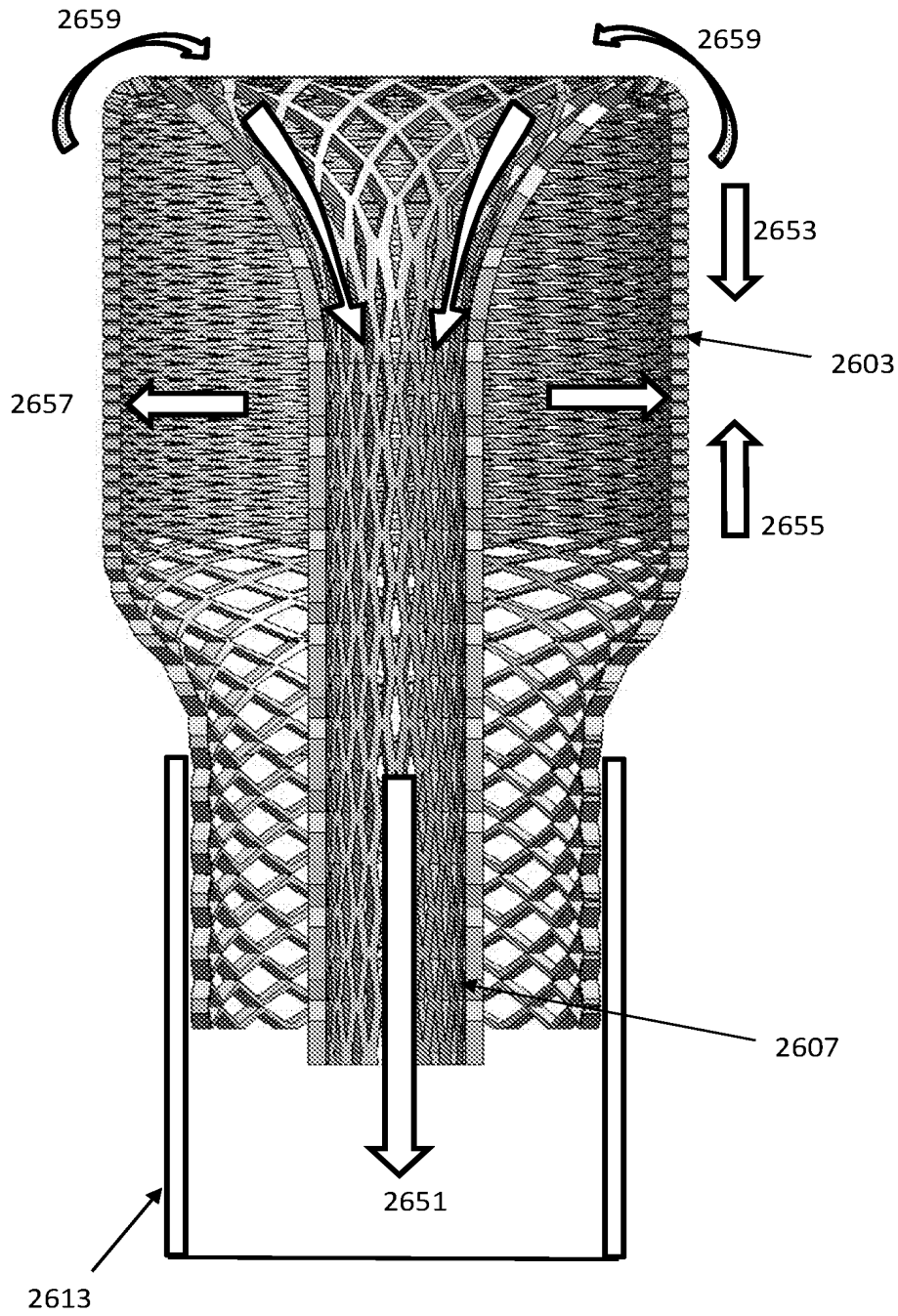


FIG. 26C

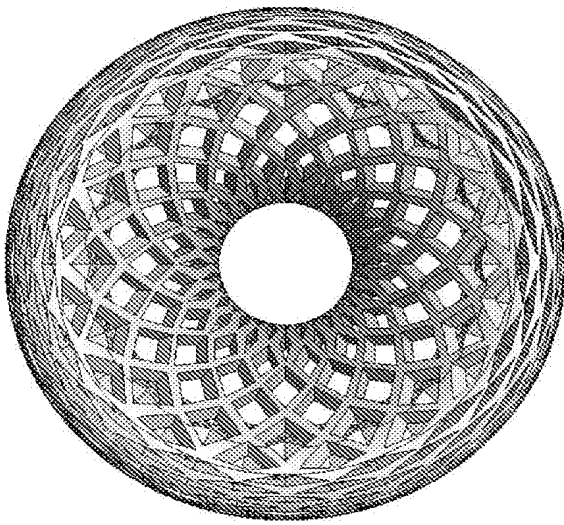


FIG. 27A

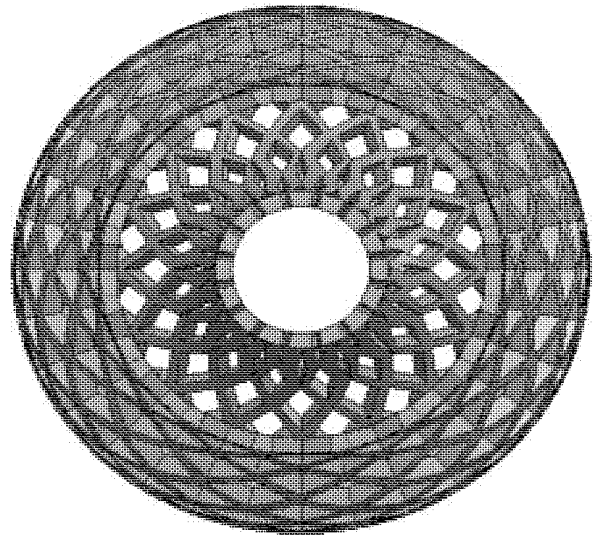


FIG. 27B

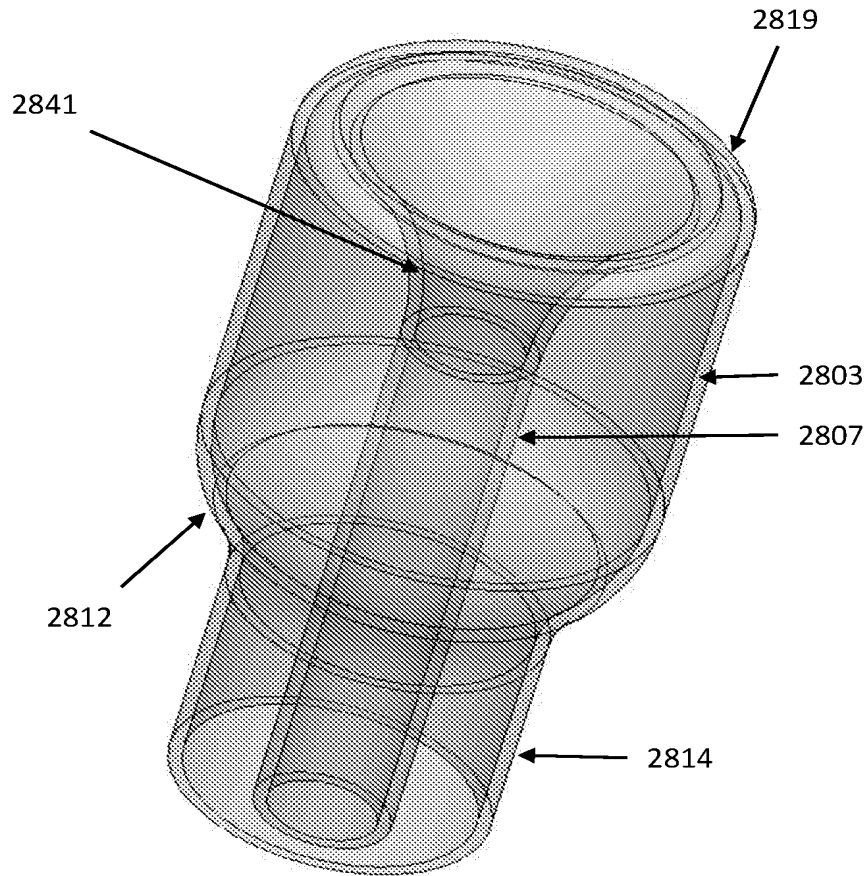


FIG. 28

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/050933

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/22 A61B17/221
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19)	1-14, 16-28,30
Y	paragraphs [0008], [0077], [0161], [0167] - [0170], [0172]; figures 10, 13B -----	15,29
Y	US 2010/249815 A1 (JANTZEN ET AL.) 30 September 2010 (2010-09-30) paragraphs [0026], [0027], [0030]; figures 1,2 -----	15,29
A	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; claims; figures page 8, line 12 - page 11, line 16 ----- -/--	1,16,30



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

26 October 2017

Date of mailing of the international search report

10/11/2017

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Giménez Burgos, R

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/050933

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2012/049652 A1 (ENDO GROWTH (PROPRIETARY) LTD) 19 April 2012 (2012-04-19) page 8, line 32 - page 15, line 26; figures 4-10 -----	1,16,30
A	US 4 863 440 A (CHIN) 5 September 1989 (1989-09-05) abstract; figures -----	1,16,30

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/050933

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 31-41
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2017/050933

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2012009675 A2	19-01-2012	US 2014005712 A1 WO 2012009675 A2	02-01-2014 19-01-2012
US 2010249815 A1	30-09-2010	NONE	
GB 2498349 A	17-07-2013	EP 2802275 A1 GB 2498349 A US 2015005781 A1 WO 2013106146 A1	19-11-2014 17-07-2013 01-01-2015 18-07-2013
WO 2012049652 A1	19-04-2012	US 2013226196 A1 WO 2012049652 A1 ZA 201302264 B	29-08-2013 19-04-2012 30-04-2014
US 4863440 A	05-09-1989	CA 1326198 C DE 3686408 D1 DE 3686408 T2 EP 0227583 A2 JP 2529838 B2 JP S62170260 A US 4863440 A	18-01-1994 17-09-1992 21-01-1993 01-07-1987 04-09-1996 27-07-1987 05-09-1989



(51) International Patent Classification:
A61B 17/221 (2006.01)

(21) International Application Number:
PCT/US2018/040937

(22) International Filing Date:
05 July 2018 (05.07.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/529,386 06 July 2017 (06.07.2017) US

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(US).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,
HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP,
KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME,
MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,
OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA,
SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

(54) Title: INVERTING THROMBECTOMY APPARATUSES AND METHODS

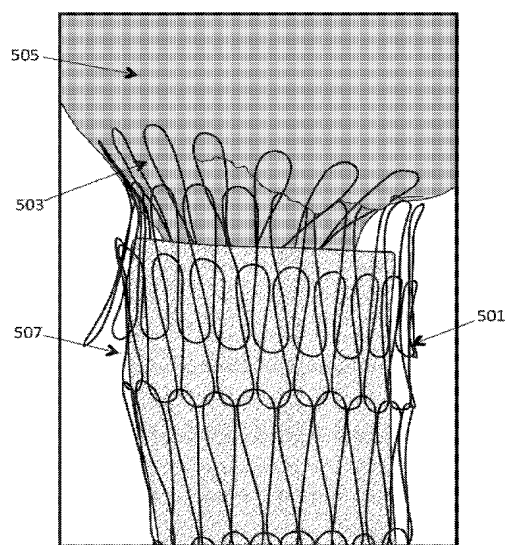


FIG. 5

(57) Abstract: A mechanical thrombectomy apparatus for removing a clot from a vessel includes an elongate inversion support catheter having a distal end opening, an elongate puller extending within the support catheter, and a knitted tractor tube (501) extending over an outer surface of the support catheter, inverting into the distal end opening of the support catheter, and attached to the elongate puller at a first end within the support catheter, wherein the portion of the knitted tractor tube extending over the support catheter comprises a wire forming a helical spiral of alternating teardrop shaped-links (503) each having a rounded apex, wherein each link is connected to two adjacent links so that the apex of each link is on an outward-fac- ing surface of the tractor tube, wherein the links flare outward from an outer wall of the support catheter when the puller is pulled proximally within the support catheter.

Published:

- *with international search report (Art. 21(3))*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

INVERTING THROMBECTOMY APPARATUSES AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims priority to U.S. provisional patent application no. 62/529,386, filed July 6, 2017, the content of which is herein incorporated by reference in its entirety.

INCORPORATION BY REFERENCE

[0002] All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

[0003] The apparatuses and methods disclosed and described herein relate to mechanical removal of objects from within a body lumen, such as a blood vessel. In particular, disclosed and described herein are mechanical thrombectomy apparatuses and methods of using same.

BACKGROUND

[0004] Many vascular problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery. It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue, such as blood clots, from within a patient's vasculature may improve patient conditions and quality of life.

[0005] When a thrombus forms, it may effectively stop the flow of blood through the zone of formation. If the thrombus extends across the interior diameter of an artery, it may cut off the flow of blood through the artery. If one of the coronary arteries is 100% thrombosed, the flow of blood is stopped in that artery, resulting in a shortage of oxygen

carrying red blood cells, e.g., to supply the muscle (myocardium) of the heart wall. Such a thrombosis is unnecessary to prevent loss of blood but can be undesirably triggered within an artery by damage to the arterial wall from atherosclerotic disease. Thus, the underlying disease of atherosclerosis may not cause acute oxygen deficiency (ischemia) but can trigger acute ischemia via induced thrombosis. Similarly, thrombosis of one of the carotid arteries can lead to stroke because of insufficient oxygen supply to vital nerve centers in the cranium. Oxygen deficiency reduces or prohibits muscular activity, can cause chest pain (angina pectoris), and can lead to death of myocardium which permanently disables the heart to some extent. If the myocardial cell death is extensive, the heart will be unable to pump sufficient blood to supply the body's life sustaining needs. The extent of ischemia is affected by many factors, including the existence of collateral blood vessels and flow which can provide the necessary oxygen.

[0006] Clinical data indicates that clot removal may be beneficial or even necessary to improve outcomes. For example, in the peripheral vasculature, interventions and procedures can reduce the need for an amputation by as much as 80 percent. The ultimate goal of any modality to treat these conditions of the arterial or venous system is to remove the blockage or restore patency, quickly, safely, and cost effectively. This may be achieved by thrombus dissolution, fragmentation, thrombus aspiration or a combination of these methods.

[0007] Depending on the size, location and extent of a clot, it may be particularly advantageous to employ a mechanical thrombectomy device to remove the clot in a manner that is both safe and effective. Described herein are mechanical thrombectomy apparatuses (devices, systems and kit) and methods of using and making such apparatuses that may address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[0008] Disclosed and described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and methods of using and making them. In particular, described herein are mechanical thrombectomy apparatuses having improved rolling/inverting which may be particularly well adapted for removing large and hard clots, and/or difficult to grasp clots, from within a vessel. The disclosed and described apparatuses may include a low-friction (or friction-reducing) sleeve, one or more adaptations (e.g., chamfers, etc.) in the elongate inversion support catheter for pulling in larger clots, and knitted tractor tubes having woven links that are optimized for grabbing and compressing large clots without jamming. Also disclosed and described herein are mechanical thrombectomy apparatuses that may be

reusable. In particular, disclosed and described herein are mechanical thrombectomy apparatuses that include an elongate inversion support catheter over which the tractor (also referred to herein as a tractor tube, or an inverting tube) may be pulled to invert; these inversion support catheters may be configured so that they have a high degree of flexibility, but also a very high column strength.

[0009] For example, in some variations, the mechanical thrombectomy apparatuses disclosed and described herein are inverting tractor thrombectomy apparatuses that includes a tractor tube (e.g., tractor tube, inverting tube, etc.) comprising a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support. In some variations this tractor tube may be knitted, and may be configured (e.g., sized, oriented, etc.) to roll smoothly over the distal end opening of the elongate inversion support catheter.

[00010] The elongate inversion support typically comprises a catheter having a distal end opening into which the tractor inverts. The flexible tractor inverts and rolls back into itself and may be drawn into the elongate inversion support in a conveyor-like motion; the outward-facing region rolls around to become an inward-facing region, e.g., within the lumen of the elongate inversion support. The rolling motion may thus draw a clot or other object within a vessel into the elongate inversion support.

[00011] A knitted tractor tube may be configured to roll into the distal end opening of the elongate inversion support catheter without jamming by being oriented in an inverted knit, so that the adjacent rows of links are connected with the loops interlocking so that when the tube is inverted into itself, the loops are free to swing outward from the tube and are not held in place. For example, the loops of the knit are configured so that they pass under/over then over/under two loops of the adjacent rows. This arrangement may be configured as an “inverted knit” as most knitting machines will produce a tube that is woven in an over/under than under/over pattern.

[00012] For example, disclosed and described herein are mechanical thrombectomy apparatuses for removing a clot from a vessel, the apparatus may include: an elongate inversion support catheter having a distal end and a distal end opening; an elongate puller extending within the elongate inversion support catheter; and a knitted tractor tube extending over an outer surface of the elongate inversion support catheter, inverting into the distal end opening of the elongate inversion support catheter, and attached to the elongate puller at a first end within the elongate inversion support catheter, wherein the portion of the knitted tractor tube extending over the outer surface of the elongate inversion support catheter comprises a wire (e.g. a single wire or multiple wires) forming a helical spiral of alternating

(e.g., alternating extending proximally to distally and distally to proximally) teardrop-shaped links each having a rounded apex, wherein each link is connected to two adjacent links so that the apex of each link is on an outward-facing surface of the tractor tube, wherein the links flare outward from an outer wall of the elongate inversion support catheter when the puller is pulled proximally within the elongate inversion support catheter.

[00013] Any of these apparatuses may include a lubricious liner sleeve extending from within the elongate inversion support catheter and over the distal end opening of the elongate inversion support catheter. The pull force required to roll the knitted tractor tube over the distal end of the elongate inversion support catheter and into the elongate inversion support catheter may be less than about 250 g of force (e.g., less than about 225 g of force, less than about 215 g of force, less than about 200 g of force, less than about 190 g of force, less than about 175 g of force, less than about 150 g of force, less than about 125 g of force, less than about 100 g of force, etc.), e.g., by pulling the puller proximally to pull the tractor tube proximally into the inversion support catheter so that it rolls over and against the distal end opening of the inversion support catheter.

[00014] The lubricious liner may be, for example, a PTFE liner wrapping around the open distal end of the elongate inversion support catheter.

[00015] The knitted tractor tube may be formed of an alloy of nickel titanium.

[00016] In any of the apparatuses disclosed and described herein may be configured to easily roll over the distal end of the inversion support catheter while still extending outward to grab and pull the clot. For example, the links may have a length of L , and a grab width of W when flaring outward from the outer wall of the elongate inversion support catheter when the puller is pulled proximally, wherein W is between 30-90% of L (e.g., between 45% and 85%, of L , between 50% and 81%, etc.). The distal open end of the elongate inversion support catheter may be tapered, instead or in addition to using a lubricious sleeve.

[00017] The knitted tractor tube may include a second end (e.g., the proximal end that is pulled distally) that is unattached and free to slide over the outer surface of the elongate inversion support catheter. The second end may include a stop that is configured to prevent the second end from inverting over the distal end of the elongate inversion support catheter.

[00018] For example, disclosed and described herein are mechanical thrombectomy apparatuses for removing a clot from a vessel, the apparatus comprising: an elongate inversion support catheter having a distal end and a tapered or rounded distal end opening; an elongate puller extending within the elongate inversion support catheter; and a knitted tractor tube extending over an outer surface of the elongate inversion support catheter, inverting into

the distal end opening of the elongate inversion support catheter, and attached to the elongate puller at a first end within the elongate inversion support catheter, wherein the portion of the knitted tractor tube extending over the outer surface of the elongate inversion support catheter comprises a wire forming a helical spiral of alternating teardrop shaped-links each having a rounded apex, wherein each link is connected to two adjacent links so that the apex of each link is on an outward-facing surface of the tractor tube, wherein the links flare outward from an outer wall of the elongate inversion support catheter when the puller is pulled proximally within the elongate inversion support catheter, further wherein the links have a length of L , and a grab width of W when flaring outward from the outer wall of the elongate inversion support catheter when the puller is pulled proximally, wherein W is between 30-90% of L .

[00019] Also disclosed and described herein are methods of removing a clot from a vessel using an apparatus (e.g., device or system) such as those described above. For example, a method of removing a clot from a vessel may include: positioning the distal-facing end of the apparatus adjacent to the clot, and pulling the first end of a knitted tractor tube proximally (e.g., by pulling proximally on a puller attached to the tractor tube), so that the portion of the knitted tractor tube extending over the outer surface of the elongate inversion support catheter that forms a helical spiral of alternating teardrop-shaped links each having a rounded apex, wherein each link is connected to two adjacent links so that the apex of each link is on an outward-facing surface of the tractor tube, roll over the distal end of the device and invert so that the links flare outward from an outer wall of the elongate inversion support catheter when the puller is pulled proximally. The teardrop shaped arms may roll by seesawing over the open distal end of the inversion support catheter and swing outward with a lever arm force may grasp the clot and pull it into the device.

[00020] Also disclosed and described herein are mechanical thrombectomy apparatuses for removing a clot from a vessel that include: an elongate slotted inversion support catheter having a distal end and a distal end opening, wherein the elongate inversion support catheter comprises a spiral pattern having a plurality of slots arranged approximately transversely to a long axis of the elongate slotted inversion support catheter, wherein the slots have an open diameter of about 0.001 inches or less and wherein there are between 2 and 4 slots per circumferential turn of the spiral pattern; and a tractor tube extending over an outer surface of the elongate inversion support catheter, inverting into the distal end opening of the elongate inversion support catheter; wherein the tractor tube is configured to invert over the distal end opening of the elongate inversion support catheter when pulled proximally into the elongate inversion support catheter.

[00021] In any of these apparatuses a second region of the elongate slotted inversion support catheter may be included and may comprise a second spiral pattern having a second plurality of slots arranged approximately transversely to the long axis of the elongate slotted inversion support catheter, wherein the second plurality of slots have an open diameter of about 0.001 inches or more and wherein there are between 2 and 4 slots per circumferential turn of the spiral pattern. The second region may be adjacent to the first region and may be distally of the first region. Alternatively, the second region may be proximal to the first region.

[00022] Any of these apparatuses may include a puller that extends within the elongate inversion support catheter to which a first end of the tractor tube is attached.

[00023] In any of the apparatuses disclosed and described herein, there may be between 2 and 3 slots per circumferential turn (e.g., on average 2.5 slots). The spiral pattern may be helically arranged around the circumference of the elongate slotted inversion support catheter. The slotted inversion support catheter may be heat set into a compressed configuration so that the slots form closed cells in a relaxed configuration. The slots may extend between about 50 and 98% of each circumferential turn of the spiral pattern. In some variations, at least 1 mm of the distal end of the slotted inversion support catheter comprises the spiral pattern.

[00024] The spiral pattern may be configured so that at least 80% of a length of the slots contact and are supported by an opposite side of the slots when the elongate slotted inversion support catheter is longitudinally compressed. E.g., at least 85%, at least 90%, at least 95%, etc.). The slots may be rectangular. The elongate slotted inversion support catheter has a catheter compression yield force of greater than about 1000 g. The elongate slotted inversion support catheter may be one or both of: a nickel titanium alloy and stainless steel.

[00025] For example, a mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate slotted inversion support catheter having a distal end and a distal end opening, a first region of the elongate inversion support catheter comprising a plurality of slots arranged approximately transversely to a long axis of the elongate slotted inversion support catheter, wherein the slots have an open diameter of about 0.001 inches or less and wherein there are between 2 and 4 slots per circumferential turn about the long axis; a second region of the elongate slotted inversion support catheter comprises a second plurality of slots arranged approximately transversely to the long axis of the elongate slotted inversion support catheter, wherein the second plurality of slots have an open diameter of about 0.001 inches or more and wherein there are between 2 and 4 slots per circumferential

turn about the long axis; a tractor tube extending over an outer surface of the elongate inversion support catheter, inverting into the distal end opening of the elongate inversion support catheter; and a puller within the elongate slotted inversion support catheter, wherein a first end of the tractor tube is attached to the puller; wherein the tractor tube is configured to invert over the distal end opening of the elongate inversion support catheter when pulled proximally into the elongate inversion support catheter.

[00026] Also disclosed and described herein are methods of removing a clot from a vessel using any of these apparatuses, including an apparatus having an elongate slotted inversion support catheter having a distal end and a distal end opening, a first region of the elongate inversion support catheter comprising a plurality of slots arranged approximately transversely to a long axis of the elongate slotted inversion support catheter, wherein the slots have an open diameter of about 0.001 inches or less and wherein there are between 2 and 4 slots per circumferential turn about the long axis; a second region of the elongate slotted inversion support catheter comprises a second plurality of slots arranged approximately transversely to the long axis of the elongate slotted inversion support catheter, wherein the second plurality of slots have an open diameter of about 0.001 inches or more and wherein there are between 2 and 4 slots per circumferential turn about the long axis; a tractor tube extending over an outer surface of the elongate inversion support catheter. The method may include guiding the elongate slotted inversion support catheter through the patient's tortuous vasculature by bending the second region more than the first region, e.g., by pushing it over a guidewire, etc.

BRIEF DESCRIPTION OF THE DRAWINGS

[00027] The various features and aspects of the inventions disclosed and described herein are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the disclosed and described apparatuses and methods will be obtained by reference to the following detailed description when read with the accompanying drawings, of which:

[00028] FIGS. 1A-1H illustrate an example of an apparatus for mechanically removing an object such as a clot from a body region. FIG. 1A shows an example of an elongate inversion support catheter portion of an apparatus. At least the distal end of the elongate inversion support is configured as a catheter. FIG. 1B shows an enlarged view of a partial section of a distal end (opening) of the catheter of the elongate inversion support of FIG. 1A, showing the aperture formed by the distal end opening; FIG. 1C shows an example of a flexible tractor tube attached over a puller (the puller in this example is configured as a catheter). The tractor

is shown in a first configuration. In some variations, the flexible tractor tube may be biased open, e.g., by heat setting, to have an outer diameter that is greater than the inner diameter of the catheter of the elongate inversion support, as shown in FIG. 1D. FIG. 1D shows the same distal tractor region of FIG. 1C with the expandable first end region expanded. This first configuration may be compressed down into the elongate inversion support and the distal end inverted over the catheter portion of the elongate inversion support, as shown in FIG. 1E. In FIG. 1E, the assembled mechanical thrombectomy apparatus includes an elongate inversion support catheter having a distal end and a distal end opening; the elongate puller extends within the elongate inversion support catheter and a flexible tractor tube is connected at one end to the elongate puller. The flexible tractor tube and puller may be extended through the elongate inversion support catheter, including extended out of the distal end (e.g., by pulling the elongate inversion support catheter proximally and/or by pushing the elongate puller distally). The flexible tractor tube may initially be held in a collapsed first configuration (as shown in FIG. 1E) for positioning within a vessel; it may be deployed and expanded, as shown in FIG. 1F, with the elongate inversion support catheter positioned between the flexible tractor tube and the elongate puller. The flexible tractor tube may be biased so that in the second configuration (inverted over the distal end of the catheter), the tractor has a 'relaxed' outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support.

[00029] FIGS. 1G and 1H illustrate the use of an apparatus such as the one shown in FIGS. 1E and 1F to remove a clot by drawing the flexible tractor tube proximally and/or advancing the catheter distally towards the clot so that the expandable first end region inverts as it is drawn into the distal end of the catheter, pulling the clot into the catheter.

[00030] FIG. 1I illustrates an alternative variation of a tractor and puller. In FIG. 1I, the tractor is shown attached to the distal end of a tapered or narrow puller; the distal end region is tapered, and includes a radiopaque marker at or near the attachment site to the tractor; the tractor may be knitted, braided, woven, etc. Thus, in some variations the distal end region of the puller may have a greater flexibility than the proximal end of the puller. The puller may be hollow (e.g., a catheter or hypotube) or solid (e.g., like a wire).

[00031] FIG. 2A illustrates a first mechanical thrombectomy apparatus and method of using it to remove a clot. In FIG. 2A, the apparatus includes a lubricious liner that is inverted over the distal end opening of the elongate inversion support catheter. FIG. 3 is a flowchart illustrating the method shown in FIG. 2A.

[00032] FIG. 2B is the mechanical thrombectomy apparatus of FIG. 2A, and an alternative method of using it to remove a clot. In this example, the outer catheter (“intermediate catheter”) is only partially withdrawn so that the distal end of the tractor tube (shown as a knit tractor tube) is still held in place against the outer wall of the elongate inversion support catheter portion by the intermediate catheter.

[00033] FIG. 3 is a schematic illustrating a method of operating a mechanical thrombectomy apparatus such as the one shown in FIG. 2A.

[00034] FIG. 4A is an example of a large (e.g., 3mm) and hard clot into a smaller ID catheter (e.g., 0.045 ID catheter of 1.2 mm opening diameter). FIG. 4B illustrates the normal forces on the inner and distal ends of the elongate inversion support catheter wall. The use of a low-friction material, such as a Teflon sleeve, extending around the distal end opening of the elongate inversion support catheter portion may prevent jamming and aid in compacting the hard clot.

[00035] FIG. 5 illustrates a knit tractor tube that may also aid in pulling a large-diameter clot into an elongate inversion support catheter. In FIG. 5, the loops forming the knit are interlocked, but may swing outward as the knit is rolled over the distal end opening of the elongate inversion support catheter, which may knead and/or masticate the clot, aiding in pulling it into the elongate inversion support catheter.

[00036] FIG. 6A illustrates an elongate inversion support catheter of a mechanical atherectomy apparatus including a low-friction liner (e.g., a PTFE liner) extended around the catheter tip to reduce pull friction.

[00037] FIG. 6B illustrates a modified tip for an elongate inversion support catheter, having a chamfer on the inner radius of the catheter to reduce pulling forces.

[00038] FIGS. 7A and 7B show an example of a knit tractor tube that undesirably includes regions where adjacent links of the knit include triple crossover points, e.g., as shown in greater detail in FIG 7B. Typically, when the diameter of the knitted tractor tube is greater than the outer diameter of the elongate inversion support catheter such that the adjacent links form triple cross-over points, as shown in FIG. 7B, the resulting tractor tube may roll move less smoothly (and/or may jam) over the distal end opening of the elongate inversion support catheter. In contrast, FIG. 7C and 7C shows an example of a knitted tractor tube having only double overlaps, which may more desirably roll over the elongate inversion support catheter. In FIG. 7D, an enlarged view of the links of the woven tractor tube is shown.

[00039] FIG. 7E and 7F illustrates a non-inverted knitted tube that is less desirable, as it may jam or prevent smooth rolling, despite having links that are the same dimension (and

formed of the same materials) as the inverted knit shown in FIG. 7C and 7D. FIG 7F is an enlarged view of FIG. 7E.

[00040] FIG. 8A is a side view of a distal end of a elongate inversion support catheter with a knitted tractor tube rolling into the distal end opening, illustrating tuning of the length, L, of the woven links to achieve a desired grab width, W, e.g., between 30-90% of L, for grabbing a clot with a woven tractor as described herein. FIG. 8B is an end-on view of the apparatus of FIG. 8A.

[00041] FIGS. 9A-9C illustrate an example of a mechanical thrombectomy apparatus that is configured as a reusable apparatus. In FIG. 9A, the apparatus includes a distal tractor stop/grip portion that prevents the tractor tube from inverting fully into the elongate inversion support catheter. Once the clot is pulled into the elongate inversion support catheter as shown in FIG. 9B, the apparatus may be removed from the body, and the clot ejected, e.g., by sliding the tractor tube along the outer diameter of the elongate inversion support catheter, as shown in FIG. 9C. The apparatus may then be re-used.

[00042] FIGS. 10A-10C illustrate variations of mechanical thrombectomy that may have improved tracking, e.g., within a vessel (e.g., lumen) and/or within the lumen of a catheter, such as an intermediate catheter. FIG. 10A show an example in which the elongate puller is adapted to include a nose region at the distal end, including a bumper. The distal nose region/bumper may extend out from the elongate inversion support catheter until the target location, near the clot, has been reached, and then retracted proximally to roll the tractor tube into the elongate inversion support catheter. FIG. 10B is another example in which the puller (e.g. pull wire or pull catheter) is slidable within a collar coupled to the tractor tube, but further includes an engagement region at or near the distal end of the puller that engages the collar and allows the puller to pull the tractor tube proximally in the elongate inversion support catheter to roll the tractor tube into the elongate inversion support catheter. FIG. 10C is another example in which the puller is a pull wire having a collar region near the distal end through which a guidewire may pass.

[00043] FIGS. 11A-11B illustrate another example of a mechanical thrombectomy that may have improved tracking, pulling of a clot and/or inverting of the tractor tube over the elongate inversion support catheter. FIG. 11A shows a puller (which may be solid or cannulated) having a distal tip region that includes a plurality of flanges or edges extending therefrom. In FIG. 11A the distal tip includes a plurality of cup-like members extending from therefrom. FIG. 11B shows another example of a puller in which the distal end includes a plurality of projections extending proximally. In FIG. 11B, the projections may be fringe or

fibers extending from the outer surface of the distal end of the puller, which may be tapered or cylindrical.

[00044] FIG. 11C shows an example of a distal tip of a puller configured to include a helical protrusion spiraling around the distal end.

[00045] FIG. 11D is an example of a distal end of a puller configured to have a stepped profile. In FIG. 11D, the stepped profile includes a plurality of (e.g., 5) different sized cones connected and arranged from larger (proximal) to smaller (distal). The cones may be separate or solid and fused together.

[00046] FIG. 12 is an example of an internal carotid artery, which has a tortuous vascular path. This path may be divided up in to sub-regions, and a model of this path may be used to examine tracking of any of the apparatuses disclosed and described herein.

[00047] FIGS. 13A to 13C illustrate exemplary rectangular slots that may be formed in any of the inversion support catheters described herein. FIG. 13A shows a slot that is in a neutral configuration, prior to heat setting in a collapsed or expanded configuration. In FIG. 13A, the slot has a width at the ends (w_1) that is approximately the same as the width in a middle region between the ends (w_2). In FIG. 13B, the slot has been compressed (e.g., by applying a longitudinal compression force on the catheter into which the slot is cut and heat setting in the compressed state) so that the width of the middle region (w_2) is less than the width of the end regions, which are not compressible (w_1). FIG. 13C shows a first open configuration, in which the slot has been pulled (e.g., by pulling a catheter in which the slot is formed in the longitudinal direction) to form an open configuration, in which the middle region has a diameter (w_2) that is greater than the diameter of the end regions (w_1).

[00048] FIG. 14A shows three examples of inversion support catheters having a slotted pattern of cuts. FIG. 14B is an enlarged view of one of the inversion support catheters of FIG. 14A.

[00049] FIG. 14C describes a pattern used to form slotted inversion support catheter such as the ones shown in FIG. 14A.

[00050] FIG. 15 illustrates bending of a slotted inversion support catheter having a distal end region with a combination of open-cell and closed-cell slots cut into the distal ends; in this example, only two open-cell regions are included in the distal end region.

[00051] FIGS. 16A-16F illustrate increasing compression force applied to an exemplary slotted catheter, showing minimal compression/kinking. FIG. 16G shows the distal end of the device shown in FIGS. 16A-16F.

[00052] FIGS. 17A-17B illustrate another example of a slotted inversion support catheter undergoing 400 g of compression, showing kinking and shortening of the catheter. FIGS. 17C-17D illustrate a second example of a slotted inversion support catheter undergoing 400 g (FIG. 17C) and 300g (FIG. 17D) of compression; this example also kinked/shortened. FIG. 17D, shown for comparison, is the slotted inversion support catheter shown and described in FIG. 16A-16F, which did not substantially kink or shorten under 400g of compression. FIG. 17E illustrates another example of a slotted inversion support catheter similar to that shown in FIG. 16G, above.

[00053] FIGS. 18A-18E illustrates examples of slotted inversion support catheters having proximal regions with close-cell slots and distal regions with open-cell cut out regions (including slots).

[00054] FIG. 19A illustrates an example of an approximately rectangular slot in an open-cell (left) and closed-cell (right) configuration. FIG. 19B illustrates an example of a lobed slot (e.g., centrally tapered, hourglass-shaped, barbell-shaped) slot in an open-cell and closed-cell configuration. In FIG. 19B, even the closed-cell configuration remains open at the ends, as shown. FIG. 19C provides exemplary dimensions of the slots shown in FIGS. 19A and 19B.

[00055] FIGS. 20A-20C illustrate examples of bi-lobed slots (e.g., centrally tapered, hourglass-shaped, barbell-shaped) similar to that shown in FIG. 19B.

[00056] FIGS. 21A-21C illustrate another example of a slotted catheter having a brick-like pattern of aligned slots. FIG. 21A shows the repeating cut-out pattern that may be applied to a catheter (e.g., nitinol catheter tube). FIG 21B shows a side view of the slotted catheter. FIG. 21C shows a perspective view of the slotted catheter.

[00057] FIGS. 22A-22C illustrate another example of a slotted catheter having a spiral-like pattern of aligned slots. FIG. 22A shows the repeating cut-out pattern that may be applied to a catheter (e.g., nitinol catheter tube). FIG 22B shows a side view of the slotted catheter. FIG. 22C shows a perspective view of the slotted catheter.

[00058] FIGS. 23A-23C illustrate another example of a slotted catheter having a dog bone pattern of aligned slots. FIG. 23A shows the repeating cut-out pattern that may be applied to a catheter (e.g., nitinol catheter tube). FIG 23B shows a side view of the slotted catheter. FIG. 23C shows a perspective view of the slotted catheter.

[00059] FIGS. 24A-24C illustrate slotted catheters having different slot patterns along their length. FIG. 24A shows an alternating spiral/brick pattern. FIG. 24B shows an alternating spiral/dog bone pattern. FIG. 24C show a pattern of spiral/brick/spiral/dog bone/spiral, which may also alternate.

[00060] FIGS. 25A-25C illustrate an example of a slotted catheter having a continuous spiral slot cut into the catheter body. FIG. 25A shows the cut (slot) pattern including a notched, “bump” region that is spaced so as to align with a series of notched bumps in the long axis of the catheter, when cut in the spiral pattern, as illustrated in FIGS. 25B and 25C. In FIG. 25B a side view of the catheter is shown. FIGS. 25C shows a side perspective view of the catheter of FIGS. 25A-25C. Although three longitudinal lines of aligned bumps are shown circumferentially spaced in FIGS. 25B-25C; any number of aligned bumps (e.g., greater than 2, between 1 and 60, etc.) etc.) may be formed by the spiral cut.

[00061] FIG. 26 illustrates one example of an elongate slotted inversion support catheter of a mechanical thrombectomy apparatus for removing a clot from a vessel formed of both a stainless steel (laser cut) and NiTi (nickel titanium) that has been shape-set.

[00062] FIG. 27 illustrates a method of joining two regions of an elongate slotted inversion support catheter that are formed of different materials (e.g., stainless steel and nickel titanium).

[00063] FIG. 28 is an example illustrating the tracking (bending) of a distal end region of an elongate slotted inversion support catheter.

[00064] FIG. 29A illustrates an example of a traditional catheter exposed to a high compression force (e.g., when pulling a guidewire through the distal end of the apparatus), showing buckling along the length.

[00065] FIG. 29B is another example illustrating an apparatus configured as described herein, e.g., using a specifically configured elongate slotted inversion support catheter having a region of the elongate inversion support catheter comprising a plurality of slots arranged approximately transversely to a long axis of the elongate slotted inversion support catheter, wherein there are between 2 and 4 slots per circumferential turn about the long axis.

DETAILED DESCRIPTION

[00066] In general, disclosed and described herein are mechanical thrombectomy apparatuses having an inverting flexible tractor tube that is configured to invert over an elongate inversion support catheter. One end of the tractor tube may be coupled to a puller (e.g., pull wire, pull catheter, etc.). In particular, disclosed and described herein are apparatuses including one or more adaptations to prevent jamming and/or roll smoothly, particularly when pulling a large and/or hard clot.

[00067] In general, a mechanical thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an elongate inversion support catheter having a distal end and a distal annulus (distal end opening), and a flexible tractor assembly including a flexible tractor tube coupled to an elongate puller. The flexible tractor tube is configured to roll and invert over the distal end opening of the elongate inverting support catheter.

[00068] In many of the examples disclosed and described herein, the tractor assembly is configured to extend within the elongate inversion support catheter when deployed. Any of these apparatuses may switch between a delivery configuration, e.g., in which the entire tractor assembly may be held within the elongate inversion support catheter prior to deployment, and a deployed configuration, e.g., in which the elongate inversion support catheter is positioned between the flexible tractor tube and the elongate pusher to support the flexible tractor tube as it is pulled into the elongate inversion support catheter distal end opening to roll and invert into the elongate inversion support catheter. In particular, the methods and apparatuses may be configured so that the transition between the delivery configuration and the deployed configuration is robust. For example, as will be described in greater detail herein, any of the apparatuses and methods disclosed and described herein may include an annular bias that enhances the ability of the elongate inversion support catheter to be inserted between the flexible tractor tube and the elongate puller.

[00069] FIGS. 1A to 1I illustrate various components of a mechanical thrombectomy apparatus that may include any of the features disclosed and described herein. For example, FIG. 1A shows a catheter (e.g., an elongate inversion support catheter) that may form part of the apparatuses disclosed and described herein. In this example, the elongate inversion support catheter includes a catheter body 100 having a distal end region 103 that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing harness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x)

has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00070] In FIG. 1A, the elongate inversion support catheter is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses disclosed and described herein may include an elongate inversion support catheter that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like. In FIG. 1A the catheter 100 of the elongate inversion support catheter may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00071] In some variations the distal end 105 of the elongate inversion support is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in some variations the distal tip (end) may be curved or radiused 109 as shown in FIG. 1B, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[00072] FIG. 1C shows an example of a flexible tractor tube 144 coupled to an elongate puller 146, forming a pullable tractor assembly 140. In this example, the tractor tube is shown integrated with the puller and extending back over the puller, forming the assembly. The opposite end of the flexible tractor tube 147 is open and free (e.g., not connected to the puller or catheter). As will be described in greater detail below, this open, free, end may be adapted to be expanded and held open, e.g., by shape setting back on itself and/or by including an annular bias, to enhance deployment and positioning of the catheter between the flexible tractor tube and the puller. In FIG. 1C, the tractor tube is formed of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The tractor is shown extended from the puller in a first configuration. It may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 144 may be sufficiently soft and

flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The puller 146 may typically be a less-expandable (or non-expandable) structure (tube, puller, etc.). For example, the tractor 144 may be configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first configuration to a radial diameter that is between 1.1 and 10 times (e.g., between 1.1x and 5x, between 1.1x and 4x, etc.) the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained. In FIG. 1D, the tractor tube has a larger expanded diameter than the variation shown in FIG. 1C in a relaxed configuration. In any of these variations, the expandable tractor may be biased to expand open. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00073] In FIGS. 1C and 1D the tractor and puller have two portions, a tractor tube 144 and a less expandable (or non-expandable) proximal portion comprising the elongate puller 146. The puller may be a separate region, such as a wire, catheter or hypotube, which is connected to an end region of the tractor (e.g., a flexible mesh, woven, braided, etc.), e.g., the distal end or near the distal end. The inverting region of the tractor, where it rolls and inverts over the distal end opening of the catheter may be referred to as the distal-facing region of the tractor, which may actively grab clot when rolling.

[00074] In FIG. 1E, the tractor assembly (flexible tractor tube 144 and puller 146 of FIG. 1D) are shown within an elongate inversion support catheter 100. The tractor is collapsed down 101, e.g., onto the puller, and may be held collapsed within the elongate inversion support catheter. Thus, FIG. 1E shows the pre-deployment (e.g., delivery) configuration. The tractor assembly may be axially movable (slidable) within the catheter so that it can be positioned within the catheter and within the vessel.

[00075] FIG. 1F shows a fully deployed apparatus. In FIG. 1F, the tractor tube is in an unconstrained or deployed configuration, and the elongate inversion support catheter is positioned between the tractor tube and the puller so that the tractor tube can be pulled proximally by pulling on the puller and rolling the tractor tube into the elongate inversion support catheter so that it inverts. In FIG. 1F, the tractor in this deployed configuration (e.g., the portion that is inverted over the distal end of the catheter) has an outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. Thus, the tractor 144 may be biased so that it has a relaxed expanded configuration with a diameter that is greater than the outer diameter (OD) of the elongate inversion support catheter; in addition, as will be described in relation to FIGS. 1G and 1H, below, the tractor tube may also be

configured (e.g., by heat setting, etc.) so that when the tractor tube is inverted and pulled into the elongate inversion support catheter, the outer diameter of the inverted tractor tube has an outer diameter that is greater than 0.5x (e.g., greater than 0.6x, greater than 0.7x, greater than 0.75x, greater than 0.8x, greater than 0.9x, greater than 1x, etc.) the inner diameter (ID) of the elongate inversion support catheter. This combination of an un-inverted diameter of the tractor tube of greater than the diameter of the OD of the elongate inversion support catheter and an inverted diameter of the tractor tube of greater than 0.7x the ID of the elongate inversion support catheter is surprisingly helpful for preventing jamming of the apparatus, both when deploying the apparatus and when rolling the tractor over the distal end opening of the elongate inversion support catheter to grab a clot. The tractor may be expandable and may be coupled to the puller as shown. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to elongate puller (e.g., a push/pull wire or catheter).

[00076] FIGS. 1G and 1H illustrate the removal of a clot using an apparatus such as the apparatus components of FIGS. 1A and 1E. The apparatus 10 is shown in a deployed state. In this example the thrombectomy apparatus 10 is configured as a thrombectomy apparatus including an elongate inversion support catheter 100 and a flexible tractor tube 144 that extends over the distal end region of the catheter and doubles-over itself at the distal end of the catheter to invert so that the external tractor end region is continuous with an inner, less-expandable (in this example, less-expandable includes non-expandable) second distal end region 146 (puller) that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The pusher/puller member that may be a rod or other member that is continuous with the distal end region of the tractor. In FIG. 1G the apparatus is shown positioned and deployed within the vessel 160 near a clot 155. The clot may be drawn into the catheter by pulling the tractor 140 proximally into the catheter 101, as indicated by the arrow 180 showing pulling of the inner portion of the flexible tractor (e.g., using a handle, not shown) resulting in rolling the tractor over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled into the catheter, shown by arrows 182. The end of the tractor outside of the catheter may be “loose” relative to the outer wall of the catheter. FIG. 1H illustrates another example of a tractor assembly 154 including a tractor tube 144 that is coupled to a puller 156. The puller in this example is tapered (having tapering region 161) and may therefore have a different flexibility of the distal end region than the proximal end region. For example, the proximal end region may be less flexible than the narrower-diameter distal end region 195 to which the tractor is

coupled. The assembly includes a radiopaque marker 165. The tractor may be attached to the puller by any appropriate means. For example, the tractor may be crimped, glued, fused, or otherwise attached to the puller, typically permanently.

[00077] In general, the mechanical thrombectomy apparatuses disclosed and described herein may be highly flexible, both before actuating and during operation. For example, the flexible tractor may not increase the stiffness/flexibility of the catheter of the elongate inversion support, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortuous vessels of the neuro-vasculature. Disclosed and described herein are flexible tractor tube portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, disclosed and described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[00078] The tractors may be woven, braided and/or knitted materials. For woven and braided materials, which may include a plurality of fibers that are woven or braided to form the inverting tube, these structures may be tuned to prevent jamming and/or to reduce the force necessary to pull the tractor and invert over the catheter tip. For example, the mechanical atherectomy apparatus may include a braid-type tractor that can roll freely around the tip of catheter even in a tortuous anatomy and when grabbing clot by tuning one or more of the braid structure; minimizing the braid angle; including a hydrophilic coating on the distal aspect of the catheter outer diameter (OD) or the inner diameter (ID) of the braid (e.g., tractor); including a radiused wall on the catheter; and/or increasing the stiffness of the distal tip region relative to adjacent proximal regions. Alternatively, it may be advantages to have a hydrophilic coating on 1, 3, 5, 10, or 15 cm of the distal ID or the entire catheter ID. This may even enhance aspiration of the clot without a tractor element.

[00079] As mentioned, the tractor (e.g., braided, woven, knitted, etc.) may be configured to collapse down into the inner diameter (ID) of the catheter as little as possible. For example, the tractor may collapse to an ID that is greater than, equal to, or within 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter inner diameter (ID)/Catheter Tip OD, since, when the tractor is being pulled around catheter tip it may create axial tension on the tractor (e.g., braid, knit, etc.) that can inadvertently cause the tractor to jam on the catheter tip. When

tractor is pulled around catheter tip, the tractor is being pulled in the axial orientation creating axial tension on tractor structure as the tractor is being pulled through the catheter ID. By having the tractor elements jam at an ID greater than or equal to 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter ID (or in some variations, OD), when being axially tensioned, the tractor is less likely to grab/synch down onto the catheter tip, helping the braid roll around the catheter tip with less axial force applied by the user. If less axial force is required by the user to pull the tractor structure around the tip then the catheter tip is less likely to buckle or deflect when retracting the tractor. It may be advantageous to minimize the chance the catheter tip will buckle. The tractor can be tuned to "jam" at a specific ID by controlling any of the following variables and in any combination: selecting a specific number of braid ends, selecting the size/diameter of the braid ends; selecting the braid material (e.g., multifilament or monofilament); heat setting the bias on the braid (e.g., braid diameter); and selecting a braid pattern, e.g., 1x2, 1x1 or any other pattern.

[00080] The braid angle may be minimized to prevent locking up of the rolling of the tractor over the catheter end opening. Typically, the lower the braid angle (e.g., 45 degrees or less, 40 degrees or less, 35 degrees or less, 30 degrees or less, 25 degrees or less, 20 degrees or less, etc.) the less likely it is to have the braid cross over points catch on the catheter tip.

[00081] In any of the variations disclosed and described herein, the catheter and/or a surface of the tractor may be coated to enhance rolling over the distal end region of the catheter. It may be helpful to have a hydrophilic coating on the distal aspect of the catheter OD or the ID of the tractor so the tractor can more easily slide over the catheter's distal end and around the tip of the catheter when pulled through the inside of the catheter.

[00082] The radius wall of the catheter tip may be chosen/set to within a range that allows sliding. For example, it may be helpful for the tip of the catheter to have the largest radius possible but at least 0.0025" radius wall on the catheter, ideally approximately 0.005" radius wall.

[00083] The stiffness of the distal of the catheter may be sufficiently stiff to prevent collapse as the tractor is pulled; it may also be lubricious (e.g., by a coating or material property). The distal most section of the catheter tip (e.g., the last 5mm) may be fabricated of a material which is stiff enough and lubricious enough so the distal tip of the catheter does not collapse or buckle inwardward when the braid structure is rolling around the catheter tip. Thus, the distal tip may have a stiffness that is greater than the more proximal region at the distal end of the catheter.

[00084] It may be helpful or desirable to have pores in the tractor. A lack of gaps or small pore size may limit the ability of the braid to grab clot. Alternatively, or additionally, it may be desirable to form a braid structure with texture. One example is to braid two or more different diameter braid ends into the same structure: the difference in braid end diameters will help form a texture to the braid structures outer surface, aiding the grabbing of the clot when rolling the braid-dozer around the catheter tip.

[00085] As an alternative (or in addition) the tractor may be configured to lock so it does not compress in diameter during axial load by adding a coating, laminate or adhesive to the braid at a desired diameter. Adding a thin coating, laminate or adhesive can inhibit the braid elements from sliding with respect to each other, thereby locking the braid to a specific diameter. The coating can be applied while leaving the majority of the pores and pore area substantially open. Examples of thin coatings include urethanes and silicones with and without hydrophilic coatings and hydrophilic coatings with no tie layer.

[00086] Reducing the sliding friction of tractor to outer catheter wall, improving tractor to tip rolling, and/or enhancing tractor to inner catheter sliding may also be achieved by including a sliding skin or sleeve. For example, a thin (e.g., ultrathin) sleeve may be used. The sleeve would be made from low friction polymer (e.g., PET, PE, PP, PTFE, ePTFE, Pebax, urethanes) by braiding, knitting, weaving, extrusion, melt blown, melt spinning, etc. The sleeve could be made from laser slotted tubing, chemical etching, micro machining. The sleeve could be also coated with a lubricious coating such as a hydrophilic coating. Lubricious coatings can be located on the outside and/or inside surfaces. The sleeve may be placed between the dozer element and the catheter wall and attached to the puller element. The sleeve may be less than 0.002" thick, ideally, less than 0.001" wall thickness. The sleeve may decouple the tractor clot grabbing system from the catheter wall, tip rolling and inner catheter dragging friction. The sleeve could be totally free from the tractor, connected to the tractor in discrete locations or connected fully to the tractor. This may allow the tractor to be designed to grab clot (larger wires: 0.001" to 0.002" for neuro, and 0.002" to 0.007" for other applications) and the skin to be minimized in thickness and structure to reduce friction and skin bending stiffness.

[00087] In any of the apparatuses disclosed and described herein, the catheter (e.g., the inversion support catheter) may be covered with a jacket along all or a part of its length. This jacket may be highly elastic, and may include a single layer or multiple layers. The jacket may have a single durometer (e.g., stiffness) or multiple durometers along its length; for example the jacket durometer may be less stiff near the distal end of the catheter. The jacket

may be formed of any appropriate material, including urethane (e.g., Teflon 20A to 93A, e.g., 80-85A), PEBAX (e.g., 25A to 72D), silicone, nylon, etc. In any of these variations the jacket may be continuous or formed along with a sleeve such as described above, that transitions from the inside of the catheter and around this distal end opening and along the outer surface of the catheter. The jacket may be integrally formed and/or fused to the sleeve. The sleeve may also be referred to as a liner. As mentioned, the sleeve may be a lubricious material, such as PTFE, FEP, HDPE, Polypropylene, and/or other polymers, particularly those with modifier such as siloxane modifiers. The jacket may be bonded to the sleeve/liner (e.g., through the cut frame of the catheter, such as a slotted catheter).

[00088] In some variations, the tractor region may be formed of with a mixed or hybrid structure, combining one or more of interwoven or knitted braid polymer filaments with metallic filaments. The mixed structure (hybrid structure) may leverage both metallic elements interwoven with low friction polymer elements. The metallic filaments may create stiffness elements that may grip/grab a clot. The polymer filaments may aid in grabbing clot but may provide surface friction reduction to the outer catheter wall, the catheter tip and the inner catheter wall once around the tip.

[00089] Any of the apparatuses disclosed and described herein may include a tractor having a hydrophilic/lubricous coating on the inside surface, e.g., for braided/knitted tractors, on the inside surface (contacting the outer and inner diameter of the catheter) of the braid/knit, which is in contact with the outside of the catheter. Examples of lubricous coatings include hydrophilic coatings (e.g., hydrogels) and hydrophobic coatings (e.g., fluorine coating such as PTFE & FEP, parylene, silicone, siloxane (silicone additive) added to various polymers including pebax to make any material more lubricious, Polyethylene, polypropylene, FEP)

[00090] As mentioned above, any of these apparatuses may include a distal tip that is less rigid (e.g., 'softer') than the more proximal regions of the distal tip. This may be achieved by having a structural supporting member reinforcing the distal tip, or by modifying the material forming the distal tip.

[00091] Any of the tractors disclosed and described herein may include a marker or markers (e.g., radiopaque markers, such as gold, Pt, etc.).

[00092] Any of the apparatuses disclosed and described herein may include a lubricious sleeve within the distal end of the elongate inversion support catheter to enhance rolling of the tractor tube, and particularly a knitted tractor tube into the distal end of the elongate inversion support catheter. For example, FIG. 1A illustrates a first example of a mechanical

thrombectomy apparatus including a lubricious liner 211 that wraps over the distal end of the elongate inversion support catheter 201. In this example, the inverted knitted tractor tube 203 rolls over the distal end of the elongate inversion support catheter and is attached at one end to a puller 207 (shown as a pull wire in this example). Pulling proximally on the puller rolls the tractor tube into the elongate inversion support catheter's distal end opening and pulls the clot 219 into the elongate inversion support catheter. The apparatus may include or may be operated with a guide catheter 205, so that the inner elongate inversion support catheter may be extended distally out of the guide catheter. In some variations, the guide catheter may be used to releasably secure the outer portion of the tractor tube 203 against the outer surface (outer diameter) of the elongate inversion support catheter 201 and may be retracted fully (as shown in FIG. 2A) or partially (as shown in FIG. 2B) when operating the apparatus to grab and/or remove a clot 219.

[00093] FIG. 3 schematically illustrates a method of removing a clot using an apparatus including a lubricious sleeve inverting over the distal end of the elongate inversion support catheter, similar to that shown in FIG. 2A. In FIG. 3, the method may include generally delivering a guide (or “intermediate”) catheter to the face of a clot 301. This step may be optionally performed with the mechanical thrombectomy apparatus (e.g., the elongate inversion support catheter and tractor tube pre-loaded, e.g., near the distal end of the delivery catheter). Thereafter, the thrombectomy catheter may be delivered thru guide (intermediate) catheter 303 so that the elongate inversion support catheter is near the face of the clot. Once in position, the tractor may be deployed; for example, while applying some push force on the elongate inversion support catheter, the guide (intermediate) catheter may be retracted to un-sheath the tractor tube 305. This may result in the arrangement shown in FIG. 2A, for example. Optionally, aspiration may be applied through the elongate inversion support catheter (and/or the puller in variations of the puller having an inner lumen) before retracting the guide (intermediate) catheter. Aspiration may therefore be optionally through elongate inversion support catheter (and/or the intermediate catheter). Thereafter, the puller connected at one end to the tractor tube may be pulled proximally, preferably while putting forward an advancing force on the elongate inversion support catheter, to grab and remove the clot from the vessel 309.

[00094] Alternatively, as shown in FIG. 2B, the guide (intermediate) catheter 205 may be only partially withdrawn over the elongate inversion support catheter 201 so the distal end of the knitted tractor tube 203 is still contained inside the intermediate catheter. This configuration may provide additional support for the elongate inversion support catheter

when engulfing the clot with the knit tractor tube, so it is less likely to buckle or snake when it is exposed to the related compressive loads.

[00095] This configuration may also, because of the additional outside support of the intermediate catheter, allow the user to more easily advance the elongate inversion support catheter forward in the vessel as the trailing edge of the clot is engulfed. The intermediate catheter can cover 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, etc., of the tractor length on the outside of the catheter. Or the intermediate catheter can be positioned less than 1 cm, 2 cm, 3 cm, 4 cm, 5 cm, 10 cm, etc. back from the distal tip of the elongate inversion support catheter.

[00096] The lubricious liner wrapping around the elongate inversion support catheter tip may be any appropriate liner. The liner typically wraps from an outer surface of the elongate inversion support catheter over to an inner surface of the elongate inversion support catheter. This may be in addition to or instead of a coating and/or shaped distal end region of the elongate inversion support catheter.

[00097] FIGS. 6A and 6B illustrate another example of a lubricious liner. For example, in FIG. 6A the lubricious liner 601 is a PTFE liner wrapping around the open distal end of the elongate inversion support catheter 603. A tractor tube (a nickel titanium knitted tractor 605) is shown inverting into the end and over the PTFE liner 601. One end of the tractor tube is connected to a puller 609 and may be drawn proximally to pull in a clot 607.

[00098] Alternatively, or additionally, the elongate inversion support catheter may be shaped to reduce the pull force need to to invert the tractor tube into the elongate inversion support catheter. For example, FIG. 6B shows an elongate inversion support catheter 613 distal end opening may be shaped (e.g., chamfered 645) to reduce the pull force/friction.

[00099] In general, larger (e.g., clots having a diameter greater than 2x the diameter of the elongate inversion support catheter) and/or hard clots may be more difficult to compress and pull into a mechanical thrombectomy apparatus. Surprisingly, the apparatuses and methods disclosed and described herein may be used to draw even larger and hard clots into the apparatus.

[000100] A hard clot typically may take a significant compressive load in order to compress the clot and engulf it in a smaller ID elongate inversion support catheter. As mentioned, hard clot may require a significant compressive load to compress the clot, generating a relatively high normal force to the distal & inner end of the catheter wall. The low friction surface (including sleeves) disclosed and described herein may help reduce the load to pull in clot to less than 300 g of force, when measured from the pull force required to pull the tractor

grabbing the clot into the elongate inversion support catheter (e.g., less than or equal to 300 g, less than or equal to 250g, less than or equal to 200 g, etc.). FIG. 4A and 4B illustrate the compression of a large-diameter (compared to the diameter of the elongate inversion support catheter) clot into an apparatus as disclosed and described herein. FIG. 4A shows a 3mm clot being pulled into a 0.045 ID catheter (having a diameter of 1.22 mm). In FIG. 4B, the arrows 403 show normal forces generated at the inner opening edge of the elongate inversion support catheter.

[000101] As mentioned above, any of the apparatuses disclosed and described herein may preferably include knitted tractor tubes. The orientation (e.g., “inside out”) as well as the shape-set of the knit may be selected to prevent jamming, reduce the pull force necessary to invert the tractor into the elongate inversion support catheter, and may help knead, compress, and/or drive the clot into the opening of the elongate inversion support catheter. For example, FIG. 5 illustrates an example of a knitted tractor 501 being pulled to invert into an elongate inversion support catheter 507. The knit is formed by knitting single strand of wire (though multiple strands of one or more filaments, weaves, braids, etc. may be used) to form a plurality of rows of loops 503 that are interconnected. The loops may be pulled and inverted into the distal end opening of the elongate inversion support catheter so that, when in the inverted knit configuration, they flare outward and push the clot 505 into the elongate inversion support catheter. In FIG. 5 the clot is a large-diameter clot (>2x the diameter of the elongate inversion support catheter) and the knit tractor is shown flaring out to whip in front of the elongate inversion support catheter tip to knead the clot into catheter.

[000102] FIGS. 7A-7F illustrate an example of knitted tractor tubes. FIGS. 7A (and the enlarged view 7B) illustrate a first variation of a knitted tractor tube having a knit pattern that is less optimal, as the diameter of the knitted tractor tube is sufficiently large so that there are triple crossover points between the wire (e.g., strand, fiber, filament, etc.) forming the knit. Such “triple overlap” regions 705 may result in a thickness or OD of the tractor tube that is undesirably large. Thus, it may be better to size and/or shape set the knitted tractor tube to prevent or minimize these triple overlap regions in the links forming the knit (e.g., having less than 10% triple overlaps, <9%, <8%, <7%, <6%, <5%, <4%, etc.). FIGS. 7C (and the enlarged region shown in FIG. 7D) illustrate a more optimized variation of a knitted tractor tube showing only double overlaps 707.

[000103] As mentioned above, it is also desirable to use a knitted tractor tube pattern in which the orientation of the knit is inverted (as compared to most commercially available knitted tubes), so that the links, when the tractor tube is inverted over the distal end opening

of an elongate inversion support catheter and pulled into the elongate inversion support catheter, the links flair outward. Thus, the orientation of the knit may be configured so that the apex (tip) of the loops in each row are on the outside face of the elongate inversion support catheter over which the tractor tube is inverting, compared to the adjacent pair of links that each link loop is connected to. This inverted knit configuration is shown in FIG. 7C and 7D. For example, in FIG. 7D the link 703 is formed of a filament (e.g., nitinol, polymeric material, etc.) that is knitted into a pattern of adjacent links that are interconnected (e.g., as the double crossover points 707, 707'). The knitted tractor tube is shown over an elongate inversion support catheter 709, so that the outward-facing surface of the knitted tractor tube includes all of the apexes 711 of each link. These links are therefore arranged to pass under then over a first adjacent link, then over and under a second adjacent link, as shown in FIG. 7D, leaving the apex region on the outward-facing side of this "inverted" knit configuration. In contrast, FIGS. 7E (and enlarged view 7F) show a non-inverted knit configuration, in which each link 713 includes an apex 721 that is instead underneath (on the side facing the elongate inversion support catheter, not shown). Each loop in this example is formed of a filament that is woven in an over-under and then under-over pattern relative to adjacent links of the knit. The non-inverted knitted tube shown in FIGS. 7E and 7F is constrained when inverting over an elongate inversion support catheter, so that it cannot swing outward relative to the distal end of the elongate inversion support catheter, by the adjacent links. As a result, the pulling force of the tractor tube is surprisingly higher, and the clot-grabbing of the tractor may also be greatly reduced.

[000104] FIG. 8A shows an example of an inverted knit tractor tube rolling over the distal end opening of an elongate inversion support catheter. In any of these variations, the knitted pattern may be optimized so that the stitch length (L) may be tuned to get a desired grab width (W) increase that is greater than elongate inversion support catheter outer diameter (OD). This larger grab width may aid in grabbing a clot with the apparatus. In FIG. 8A, the length of each knitted link (L) is shown, as is the width (W) that the link ends outwards when inverting into the itself and the elongate inversion support catheter. Typically, it has been found to be desirable to have a width (W) of between about 30-90% of length (L). The exact dimension of the width (W) may depend on the tension in the knit used to pull in the clot (e.g., the greater the tension, the smaller the W dimension), and the flexibility of the filaments used in the knit structure (e.g., the softer the filament used to form the knit, the smaller the W). The knit can be tuned through both the design and the processing so when it is tensioned at loads between 100-500 grams (g), the structure may have a limited elongation (e.g., <15%,

<12%, <10%, etc.0). When the knit structure is in this non-compliant/semi-compliant form the OD & ID of the knitted tractor tube may also be stable (e.g., having a <20%, less than 15%, less than 12%, less than 10%, etc. diameter change) under loads between 100-500 g. In this non-complaint/semi compliant form, the knit OD may be greater than the thrombectomy catheter, but less than the vessel OD. In other variations, the knit OD may be greater than the catheter OD, and the knit is rolled around and less than 5%, %10%, 20%, 30%, 40%, 50%, 60%, 70%, 80% of the same catheter OD.

[000105] Also disclosed and described herein are reusable mechanical thrombectomy apparatuses. For example, FIGS. 9A-9C illustrate one reusable mechanical thrombectomy apparatus and method of use. In FIG. 9A, the apparatus includes a tractor tube (shown here as a knitted tractor tube 903). One end of the tractor tube is coupled to a puller 909 within the inner diameter of the elongate inversion support catheter 905. The puller in this example is configured as a hollow tube, which may allow passing of a guidewire and/or vacuum. The other end of the tractor is coupled to a distal tractor stop forming a finger grip 901 that is configured to slide over the outer surface of the elongate inversion support catheter. The finger grip may be sized for ease in grabbing manually and sliding proximally to “reload” the apparatus, as described below.

[000106] In FIG. 9A, the apparatus may be positioned near the clot 911, and the puller drawn proximally to invert and roll the tractor tube 903 into the elongate inversion support catheter 905, while advancing distally, and thereby pull the clot 911 into the elongate inversion support catheter (shown by arrow. 917). Once grabbed, either fully or partially, as shown in FIG. 9B, the apparatus may be withdrawn from the vessel, the clot may be removed, as shown in FIG. 9C, by pulling the outer portion of the tractor tube proximally. The tractor tube is prevented from completely inverting into the elongate inversion support catheter by a distal stop 907 on the elongate inversion support catheter. For example, in FIG. 9C, the outer portion of the tractor tube may be manually pulled proximally 915 by sliding the distal tractor stop/grip 901 proximally, ejecting the compressed clot 911 from inside the apparatus. The device may then be rinsed and re-used to remove additional clot(s).

[000107] Any of the apparatuses disclosed and described herein may be adapted to enhance tracking with an intermediate catheter and/or a lumen of a vessel. To assist the mechanical thrombectomy apparatus in tracking inside an intermediate catheter or tracking directly inside a native vessel (e.g., in which the puller, tractor tube and elongate inversion support catheter must track inside the distal end of an intermediate catheter), it may be beneficial to allow the puller to extend distally relative to the elongate inversion support catheter without disrupting

the tractor tube. For example, FIG. 10A illustrates one example of a mechanical thrombectomy apparatus including a tractor tube 1003, elongate inversion support catheter 1005 and puller 1007, which is shown within an intermediate catheter 1010. In this variation, the distal end of the puller is configured to include a bumper region 1009 that can extend distally out past the distal end of the elongate inversion support catheter 1005. This nose element (“bumper”) 1009 may be a constant stiffness or variable stiffness structure. For example, the distal end may be the softest section and the section most proximal to the distal end of the catheter may be less soft, and/or possible tuned to be of similar stiffness to the distal end of the elongate inversion support catheter. The tractor tube may be coupled proximal to the distal end, which may extend, e.g., approximately 1 cm, as shown.

[000108] In this example, the distal nose of the pull wire may be solid or cannulated (as shown). A cannulated nose may allow for guidewire access and also for aspiration through the intermediate catheter to allow vacuum forces to reach any clot or any other targeted element located in the body or vessel.

[000109] In use, the user may approach the clot within the lumen of the vessel with the nose region of the puller extended from the elongate inversion support catheter or extended within the elongate inversion support catheter. Once near the clot the nose region may be retracted inside the elongate inversion support catheter. Next the user may optionally pull a vacuum through the elongate inversion support catheter to engage the clot into the tip of the elongate inversion support catheter. Then, while slightly advancing the intermediate catheter, the tractor tube may be pulled proximally into the elongate inversion support catheter by pulling proximally on the puller.

[000110] FIG. 10B illustrates another example of a mechanical thrombectomy apparatus having a puller (elongate puller 1027) which is configured to freely extend distally relative to the tractor tube, but when pulled proximally may engage with the tractor tube 1003 at one end to pull it proximally into the elongate inversion support catheter 1005. A portion (e.g., at or near a distal end region of the puller) may include one or more engagement regions (e.g., bumps, projections, etc.) that may engage with an annular ring or collar to pull the tractor tube proximally so that it may invert into the elongate inversion support catheter and therefore pull clot into the apparatus. In FIG. 10A, the puller can be extended beyond the tip of the elongate inversion support catheter at the user’s preference when advancing the system to the clot. The male bump or other grabbing mechanism will engage on the proximal end of the tractor to pull in the clot.

[000111] FIG. 10C illustrates another variation, in which the puller 1047 is configured to pass a guidewire and maybe extended or retracted using the guidewire 1055. In FIG. 10C, the construction that allows a guidewire to track through its lumen to aid in tracking within the vessel. For example, in FIG. 10C the puller includes a guidewire channel at the distal end region to which the tractor tube is attached.

[000112] In general, any of the mechanical thrombectomy apparatuses may include a modified puller that may enhance trackability, clot grabbing and/or pulling of the tractor tube into the elongate inversion support catheter. In addition to the examples shown and described in FIGS. 10A-10C, FIGS. 11A-11D show puller apparatuses that have a distal region adapted to include one or more projections.

[000113] The puller tips shown in FIG. 11A-11D may enhance the trackability of the apparatus (e.g., the elongate inversion support catheter and/or tractor tube and/or puller) through tortuous anatomy, including the lumen of the vessel and/or an intermediate catheter. For example, FIG. 11A shows an apparatus including a tractor tube 1103, an elongate inversion support catheter 1105, and a puller 1107. In this example, the apparatus is used within an intermediate catheter 1110. The distal end 1109 of the puller 1107 is tapered and includes a plurality of projections 1115 extending away from the tapered distal end of the outer surface of the puller. In this example, the projections are configured as cups 1115 that have proximal-facing edges. The projections of this distal tip region may be used to grab and/or hook onto a clot when deployed; the puller may be advanced distally as described above and projected either by itself or over a pullwire into a clot 1127, as shown in FIG. 11A. When retracting the puller, the distal tip may pull the clot to the distal opening of the elongate inversion support catheter and/or it may advance the elongate inversion support catheter and tractor towards the clot. Any of these puller embodiments may be used with or without aspiration (e.g., through the elongate inversion support catheter, intermediate catheter and/or puller). Thus, in FIG. 11A, the distal end is configured as a cup-shaped male feature. The puller distal end region may be solid or cannulated and may be tapered (as shown in FIGS. 11A-11D) or non-tapered (e.g., cylindrical). In FIG. 11A, each projection (“cup”) extends all or partially around the entire tip and more distal projections may have smaller diameters.

[000114] Another example of a puller having a plurality of projections is shown in FIG. 11B. In FIG. 11B, the projections are configured as fibers or fingers extending proud (and may be angled proximally) from the outer surface of the distal tip of the puller 1107'. In any of these examples, the puller (including the distal tip region of the puller 1107') may be solid or cannulated. In FIG. 11B, the distal tip region of the puller includes one or more sets of

projections 1125 (e.g., fingers or fibers) directed proximally. The projections may be constructed from an open-end braid feature. The projections may be configured (oriented and/or soft enough) to slide into the clot when extending distally, but when retracing the puller proximally the projections may flare out and help anchor the tip of the puller the clot, as shown in FIGS. 11A and 11B. Optionally the projections may also engage with the tractor tube when pulled proximally and/or distally and may help pull the tractor and clot back through the elongate inversion support catheter.

[000115] FIGS. 11C and 11D illustrate alternative variations of puller tips including protrusions. In FIG. 11C, the puller tip 1135 includes one or more helical projections 1137 extending proud of the outer surface of the puller and extending around the puller. In some variations the projections are formed of a wire wrapped around the distal tip of the puller; the wire forms the male projection. FIG. 11D shows another example of a distal tip region 1145 having a stepped profile forming projections from the distal end of the puller. In this example, the distal end is formed by a plurality (e.g., two, three, four, five, six, etc.) of cones that are arranged in progressively smaller sizes extending distally (forming a tapered tip region). The cones may be solid or cannulated. The tip may be formed of a plurality of connected elements or may be a unitary (or fused) element.

INVERSION SUPPORT CATHETERS

[000116] As discussed above, any of the apparatuses disclosed and described herein may include an elongate inversion support catheter having a distal end and a distal end opening, in addition a tractor tube (e.g., a knitted tractor tube). In operation, the tractor tube extends over an outer surface of the elongate inversion support catheter, and inverts into the distal end opening of the elongate inversion support catheter when the end of the tractor tube is pulled into the inversion support catheter, for example, by pulling on the elongate puller coupled to a first end of the tractor tube that is within the inversion support catheter. Thus, as mentioned above, the inversion support catheter must have a sufficient column strength so that it does not buckle or collapse as the tractor tube is pulled into the distal end of the inversion support catheter, even when pulling a hard clot.

[000117] The inversion support catheter may be configured so that it does not collapse (e.g., buckle) when 500 g or less of compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force), particularly when the apparatus is configured for neurovascular applications. For peripheral vascular applications, the elongate inversion support catheter may be selected or configured to withstand at least 1500 g of

compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In addition, the inversion support catheters disclosed and described herein may be configured so that they do not foreshorten substantially when the tractor tube is pulled over the distal end (e.g., do not foreshorten by more than 2%, 3%, 4%, 5%, 6%, 7%, 8%, 9%, 10%, etc.).

[000118] It may also be desirable that the inversion support catheters maintain sufficient column strength even when tracked or tracking through highly tortuous anatomical regions. FIG. 12 is an example of a tortuous neuroanatomical region, showing a drawing of the internal carotid artery, which includes multiple regions (labeled as regions 1, 2, 3, 4 and 5 in FIG. 12). The inversion support catheters disclosed and described herein may have sufficient column strength and may have a structure configured to resist buckling and compression when pulling a tractor tube so that it rolls into the distal end opening of the inversion support catheter (often applying up to 500g of force or more in compression), yet still be sufficiently flexible to track through such tortuous regions of the vasculature including regions 1-5 of an internal carotid artery such as the example shown in FIG. 12.

[000119] A number of inversion support catheter designs have been examined by the applicants. Many of the inversion support catheters tested, even those having cut-out regions that enhance flexibility, and those with support structures to enhance column strength (e.g., withstanding up to 500 g or more of compression force), do not have both a sufficient column strength to resist buckling/compression and a sufficient flexibility to navigate a region having a tortuosity equivalent to that in a model internal carotid artery, such as the one shown in FIG. 12. Disclosed and described herein are inversion support catheters configured to meet these criteria. In particular, disclosed and described herein are inversion support catheters having a plurality of slots (“slotted inversion support catheters”) in which the slots are configured to provide both column strength and flexibility. Slots are typically formed substantially transverse to the long axis of the catheter, wherein substantially transverse includes e.g., +/- a few degrees off transverse (e.g., +/- 2 degrees, +/- 3 degrees, +/- 4 degrees, +/- 5 degrees +/- 7 degrees, +/- 10 degrees, +/- 12 degrees, etc.). The slots may be cuts through the catheter that extend approximately transverse to the length of the inversion support catheter (at a pitch of between +/- a few degrees, e.g., a pitch of between 0.05 to 0, etc.). The slots may extend, for example, between 60 and 180 degrees (e.g., between 90 and 180 degrees, between 100 and 170 degrees, between 110 and 160 degrees, between 120 and 150 degrees, etc.) around the circumference of the inversion support catheter.

[000120] In some of the variations disclosed and described herein, the slots are formed, e.g., by laser cutting, rectangular cut-out regions. The slots may be configured as compressed slots, e.g., by heat-setting the catheter or a portion of the catheter into a longitudinally compressed state. In the compressed state, the slots be configured so that the ends of the slots, which are not typically compressible, have a fixed width, and the region between the ends of the slots is compressed so that the width of this region is less than the width of the ends of the slots. See, e.g., FIGS. 13A-13C. For example, In FIG. 13A a “neutral” slot is shown cut through a catheter, and typically curving around the radius of the catheter. The slot shown in FIG. 13A has end regions 1301, 1305 of the slot that each have a width (w_1) that is approximately the same width as the middle region 1303 between the ends (w_2). For example, the width may be between 0.01 and 0.0001 inches (e.g., between 0.005 and 0.0001, between 0.001 and 0.0001, etc.). The neutral slot shown in FIG. 13A may be compressed, e.g., by applying a compressive force on the long axis of the catheter and heat-setting the catheter in the compressed configuration. This may form a compressed slot, also referred to herein as a “closed” slot or “closed cell” slot. In FIG. 13B a closed rectangular slot is shown, having edge regions that have a width (w_1) that is substantially the same as in the neutral position, however the middle region 1303 between the ends 1301, 1305 has a width (w_2) that is less than the width at the ends of the slot (e.g., $w_2 < w_1$, e.g., $w_2 < 95\% w_1$, $w_2 < 90\% w_1$, $w_2 < 85\% w_1$, etc.).

[000121] The slot may also be opened, as shown in FIG. 13C. In some variations, the slot is opened by applying a tension (e.g., by pulling) force on all or a portion of the elongate length of the catheter into which the slot is formed, and heat-setting the slot in the resulting expanded configuration. In FIG. 13C the middle region 1303 of the slot has been expanded to have a width (w_2) that is greater than the width (w_2) of the end regions 1301, 1305. This may be referred to an an open or open cell configuration for the slot. For example, in an open configuration of a rectangular slot, $w_2 > w_1$. In some variations, in which w_2 is much larger than w_1 (e.g., $w_2 \gg w_1$, e.g., w_2 is greater than about $2x w_1$, w_2 is greater than about $2.5x w_1$, w_2 is greater than about $3x w_1$, w_2 is greater than about $4x w_1$, w_2 is greater than about $5x w_1$, etc.) these slots may be referred to as super-open slots.

[000122] Any of the inversion support catheters disclosed and described herein may be configured so that the distribution of slots is non-uniform along the length of the catheter. For example, the distal end region of a slotted inversion support catheters (e.g., the distal most region of the catheter between 1-50 mm from the distal end, e.g., between 2-30 mm, between 2-20 mm, between 2-10 mm, etc.) may include open-cell slots (all or some open-cell slots.

The portion of the catheter proximal to this distal end may include closed cell or normal slots. In some variations, the catheter may include both open-cell and closed-cell slots arranged around and along the distal end region. The percentage of open-cell slots may be, e.g., between 0.1%-80% of the total number of slots in the distal end region (e.g., between 0.1% to 70%, between 0.1% to 60%, between 0.1% to 50%, between 0.1% to 40%, between 0.1% to 30%, between 0.1% to 20%, between 0.1% to 10%, between 0.1% to 5%, etc.).

[000123] As will be described in greater detail herein, in some variations, the catheter, and particularly the distal end region, may include super open-cell slots. In particular, the percentage of super open-cell slots to other open-cell slots and closed-cell slots may be less than 50% (e.g., less than 40%, less than 30%, less than 20%, less than 10%, less than 5%, less than 1%, less than 0.5%, etc.). As mentioned, other slots may be closed-cell slots and/or may have different dimensions. The region of the inversion support catheter proximal to the distal end region may have a slotted configuration of closed-cell slots.

[000124] It is hypothesized that closed-cell slots may help provide column strength to an inversion support catheter, since the adjacent walls of the slot are not able to compress much. However, closed-cell slots are less flexible than slots in the neutral configuration or in the open (or super open) configurations described above. Towards this end, variations of catheters having a proximal region that included primarily or exclusively closed-cell slots with a distal end region (e.g., distal 1-50 mm) that was primarily or exclusively open-cell slots were initially examined.

[000125] For example, FIG. 14A illustrates three examples of inversion support catheters, 1401, 1402, 1403. These inversion support catheters have a slotted pattern of cuts (formed by laser cutting). The inversion support catheters were laser cutting a length of NiTi tubing. The entire length of the laser-cut catheter was then compressed and heat set to close the cells formed by the laser cutting. The cut-out regions (e.g., cells) were then compressed so that the separation of the opposite sides of the cut-out region transverse to the length of the catheter had a separation of less than 95% of the original cut-out diameter (e.g., if the original cut-out diameters is 0.001", the compressed configuration is 0.0001") over at least a portion of the slot (e.g., a middle region of the slot).

[000126] Catheters having compressed cut-out regions such as this may show good column strength (e.g., resisting up to 500 g of compression force without bucking), however, they generally were not capable of tracking a tortuous model of the vasculature such as shown in FIG. 12, and typically failed to track further than the first (1) or second (2) regions of the model.

[000127] To improve tracking, catheters having compressed cut-out regions such as those shown in FIGS. 14A were re-heat set at their distal ends while applying a stretching force. Expanding just the distal end region (e.g., the distal 12mm, distal 15 mm, distal 20 mm, distal 30 mm, distal 40 mm, distal 50 mm, etc.) to have larger-diameter gaps (open-cell slots) was performed on all three of the catheters shown in FIG. 14A. In FIG. 14A, the middle 1402 and right devices 1403 were each first compressed and heat-set in a compressed configuration and then the distal ends were expanded to have a uniform stretching and separation of the gaps in the slotted cells, forming open-celled slots in this distal end region. The slots shown have a middle width between the ends of the slots that is the same or slightly larger than the width of the end regions (e.g., the width of the middle region of the slot is between about 100.5% and 120% of the width of the end regions of the slot). These devices 1402, 1403 performed better than catheters having just closed-cell slots, and were able to track slightly further (e.g., to the second (2) or third (3) regions in the internal carotid model show in FIG. 13).

[000128] For example, FIGS. 16A-16F illustrate a slotted inversion support catheter first formed to have uniformly closed-cell slots by heat-setting in a longitudinally compressed configuration, and then heat-setting the distal end region in a stretched (e.g., the distal 2 cm) configuration. The apparatus was then jacketed by lamination of a jacket material over the catheter. As shown in FIGS. 16A-16F, such devices had a column strength that was sufficiently high to avoid significant kinking. Although a slight bend occurred beginning at 100g of compression (FIG. 16B), this bend did not increase significantly even up to 500g of compression (FIG. 16F). FIG. 16G shows a slightly enlarged view of the distal end region of the catheter.

[000129] FIGS. 17A-17C illustrate, for comparison, other slotted catheters (e.g., catheters having cut-out regions) that kinked in compression. For example, FIG. 17A (shown enlarged in the inset FIG. 17B) is an example of a first catheter having slots cut therein (neutral slot configuration), showing substantial kinking and compression when 400 g of compression was applied. Similarly, FIG. 17C (with an enlarged view of the slots shown in FIG. 17D) shows another example of a catheter having somewhat large, open-cell slots along the length of the catheter; this catheter also showed a great deal of kinking and compression. FIG. 17E is another example of a catheter of FIGS. 16A-16G), repeated here to show a side-by-side comparison.

[000130] During the process of stretching the distal end of catheters that had been heat-set in a compressed configuration, some catheters (see, e.g., the catheter 1401 on the left in FIG. 14A, shown in greater detail in FIG. 14B), were inadvertently expanded so that apparent

“defects” 1409 were formed in a small minority of some of the cells, forming super open-celled slots. These defects resulted in a subset of slots/cells that were opened to a greater degree than other slots, which were either not opened (remained closed cell, having a maximum width of the middle region that is less than the maximum width of the end regions), were neutral (in which the width of the middle region is approximately the same as the width of the end regions), or were only slightly opened by the stretching process, forming open-cell slots (e.g., slots having a maximum width of the inner region that is between 1x and 1.5x the diameter of the end regions, e.g., between 1x and 2x, between 1x and 2.5x, between 1x and 3x). Surprisingly, catheters having these “defect” regions (super open-cell regions having a maximum width of the middle region that is greater than 1.5x the width of the end regions, e.g., greater than 2x, greater than 2.5x, greater than 3x, etc.) had a greater column strength (e.g., less buckling at an applied, e.g., 500 g, compression force) and better tracking. Such devices were able to track through the model of tortuous vasculature, such as the internal carotid model shown in FIG. 12, completely, e.g., to region (5) or beyond.

[000131] FIG. 15 illustrates an example of one such device including these introduced “defects” in the distal end region of the catheter. The defects in this example are formed in a subset of cells formed by cutting the slots in the distal end region of the catheter. These defects may be referred to as super open-cell slots (compared to the other closed cell and/or open-cell slots in the distal end region) in which the separation between long and opposite sides of the slot are separated by greater than 1.5x the separation of the majority of the closed cell slots in the distal end region. For example, the maximum separation between the opposite long side of the open cell configuration may be greater than 1.5x, greater than 2x, greater than 2.5x, greater than 3x, greater than 3.5x, greater than 4x, greater than 4.5x, greater than 5x, etc. the maximum separation between the opposite long side of the closed-cell slots at the ends of the rectangular slot. The super open-cell (defect) slots may be distributed within the distal end region and may be present or absent from the proximal region (which may also include slots).

[000132] For example, the distal end region of the elongate inversion support catheter may include at least two types of slots cut generally transverse to the length of the elongate inversion support catheter through the wall of the elongate inversion support catheter, based on the size of the gap between opposite walls of the slots, including open-cell slots and super open-cell slots (and/or closed-cell slots or neutral slots). The slots may extend around the circumference of the catheter so that there are between 4 and 1 slots per rotation of the catheter (e.g., between 2 and 3, approximately 2.5, etc.). The opposite walls of the slot may

be the walls that are transverse or approximately transverse to the long axis of the catheter. The closed cell slots may have a maximum separation between the opposite walls of c inches (e.g., c may be, for example, 0.0001 inches, 0.0002 inches, 0.0005 inches, 0.001 inches, etc.). The open-cell slots and may have a maximum separation between the opposite walls of o inches, where o is between $1x$ and $1.5x$ the width of the ends of the slot w_1 (e.g., o is between $1x$ and $1.5x w_1$, e.g., o is between $1x$ and $2x w_1$, o is between $1x$ and $2.5x w_1$, o is between $1x$ and $3x w_1$, etc.). The super open-cell slots may have a maximum diameter o that is greater than $1.5x w_1$, greater than $2x w_1$, greater than $2.5x w_1$, greater than $3x w_1$, greater than $4x w_1$, greater than $5x w_1$, greater than $6x w_1$, greater than $7x w_1$, greater than $8x w_1$, greater than $10x w_1$, etc. The distribution of super open cell slots to other slots may be uniform or non-uniform, including random. The majority of the slots in the distal end region may be closed and/or open-cell slots, particularly compared to super open-cell slots. For example, there may be between 0.001% and 20% super open-cell slots in the distal end region (e.g., between 0.001% and 10%, between 0.001% and 5%, between 0.01% and 5%, between 0.1% and 5%, etc., between 0.001% and 1%, etc.). For example, there may be between 0.5 and 20 super open-cell slots for every cm length of catheter (e.g., between 1 and 20, between 0.5 and 15, between 0.5 and 10, between 1 and 10, etc.). The super open-cell slots may be oriented at different radial positions around the catheter.

[000133] FIG. 14C illustrates an exemplary laser cut pattern for an inversion support catheter such as the ones shown in FIG. 14A. As mentioned above, a length of NiTi tubing may be cut (e.g., laser cut) to form slots, and these slots may be compression heat set along the entire length of the catheter to form closed-cell slots. The catheter may then be re-heat set with the distal end region stretched, to form open-cell slots. In some variations, a small number of these slots may also be formed as super open-cell slots. In FIG. 14C, a variety of pitches are shown (e.g., between 0 and 0.01) for the slots.

[000134] FIG. 15 illustrates an example of an inversion support catheter in which the distal 5 mm of the catheter were treated (by stretching and heat setting) to introduce two “defects” (super open-cell regions) 1509. Although the majority of the slots in the distal end remained simply open-cell slots, these super open-cell slots (which have a maximum width of greater than $1.5x$ the width of the ends of the rectangular/oval slot) greatly enhanced the flexibility and tracking of the catheter; the exemplary catheter in FIG. 15 also had a column strength sufficient so that little or no kinking resulted even when applying up to 500 g of compressive force, as may be applied when rolling a tractor tube into the catheter to capture a hard and/or large clot.

[000135] In any of the apparatuses disclosed and described herein, distal end region (e.g., the distal 1-50 mm, distal 2-10 mm, etc.) may have open-celled slots (and/or super open-cell slots) compared the more proximal regions, which may be formed of closed cell slots. For example, FIGS. 18A-18E illustrate examples of inversion support catheters having a combination of open cell and closed cell cut-out regions. In FIG. 18A, the distal end region includes open cells, which may be configured as described above. In FIG. 18A, the majority or all of the distal end region include open-celled slots, compared to the proximal region which are closed-cell slots. In FIG. 18B, a percentage of the cut-out slots are open-celled, but not all (e.g., between 0.1% and 80%, etc.) of the slots are open-cell slots. In FIG. 18C, the distal end region includes slots that are tapered in the middle (e.g., “hourglass” slots) so that each slot includes open-celled and closed-cell regions; the proximal region is shown as all closed-cell slots. Such bi-lobed slots (also referred to as hourglass, barbell and/or dog bone slots) may also have improved tracking and compression strength, comparable to the device having super open-cell slots discussed above; these will be described in greater detail below.

[000136] In FIG. 18D the distal end region includes an open coil configuration. In FIG. 18E, the distal coil region is referred to as “closed coil” as the adjacent coils are spaced (over at least a portion of their length) very close together. Although FIGS. 18A-18E show catheters having a stark transition from the proximal and distal end regions, in some variations the transition may be more gradual, so that the device transitions gradually from close cell (proximal) to open-cell (distal) cut-out regions.

[000137] FIGS. 19A and 19B illustrate open and closed cell configurations of cut-out regions that may be formed by heat-setting the catheter in compression. In FIG. 19A, a rectangular slot is cut from the catheter as described above in an open configuration, having a separation between the opposite long walls of the slot that is z_1 wide (shown on left) in the closed configuration (under compression) the slot may be heat-set to have a diameter over the middle (x_2) region that is z_2 wide. The edge region of the slot (e.g., regions x_1 and x_3) may be nearly incompressible near their edges and may therefore remain separated. As described in FIG. 19C, the design of FIG. 19A may have dimensions in the closed cell configuration so that x_2 is between about 5% of x_1 and 95% of x_1 . For example, in the compressed, close-cell configuration, the compressed region x_2 may be the middle 1% to 90% of the total length (x) of the slot. Similarly, the separation z_2 between in the long walls of the slot in the compressed configuration may be less than or equal to 95% of the original separation, z_1 . For example, if the original separation (z_1) is 0.001 inches, the compressed separation (z_2) may be

approximately 0.0001 inches. Generally, the open cell separation may be between, for example, 0.0005 inches and 0.010 inches.

[000138] The centrally-tapered slots (hourglass configuration) shown in FIG. 19B in the open-cell and closed-cell configurations may include larger width regions (y_1) on either side of the slot, separated by a narrow region z_1 . The lengths of the wider regions (x_1 , x_3) and the intervening narrower region (x_2) may add up to the total length of the slot, x . In the closed cell configuration, the separation of the wider regions (y_1) may remain approximately the same, while the middle region, z_2 , may be much smaller than the original, open-cell width, z_1 . As exemplified in FIG. 19C, the configuration of FIG. 19B, may have a closed cell configuration in which the closed cell width z_2 is less than or equal to 90% of the original open-cell width z_1 . The narrower region is typically centered (but may be offset) within the slot, and may include the middle 5%-95% of the slot. For example, an hourglass-cut slot such as the one shown in FIG. 19B may have an open-cell maximum width of between 0.0005 inches and 0.010 inches at the wide regions on either end and a narrower central region that is between about 10% and 50% of the width of the wider ends (y_1).

[000139] FIGS. 20A-20C illustrate alternative configuration of slots that may be cut into the catheter having a centrally-tapered (e.g., hourglass- or barbell- shape) configuration. These configurations typically include an open cell region even in the compressed configuration.

[000140] FIGS. 21A-21C illustrate additional slotted catheter designs having regions of closed and open sections that may be formed by cutting or patterning, without requiring heat setting. Alternatively, or additionally, heat setting may be used. In FIG. 21A, the cut pattern 2101 is shown, with slots arranged in an overlapping pattern (a brick stacked pattern). FIG. 21B shows a side view, showing the pattern of alternating slots arranged adjacently along the length of the catheter so that there are columns of high-compression strength in the noon 2103, 3 o'clock 2103', 6 o'clock 2103'', and 9 o'clock 2103''' positions radially around the circumference of the slotted catheter (or the slotted portion of the catheter). FIG. 21C shows a side perspective view of the slotted catheter. Other overlapping patterns may be used, including patterns in which high-support regions 2103, 2103', 2103'', 2103''' line up along the long length of the catheter in more or fewer than the 4 radial locations shown in FIG. 21A-21C (e.g., in the noon, 4 o'clock, 8 o'clock position, etc.). In some variations the overlapping pattern creates a spiral or helical pattern of high-support regions along the length of the catheter. As mentioned, this pattern may also be compressed and heat-set in a closed-cell configuration. Further cells can be open-cell or closed-cell in different regions along the length of the catheter.

[000141] Another example of a slotted catheter design is shown in FIG. 22A-22C. FIG. 22A shows the cut pattern 2201 comprising a narrow spiral cut pattern. The open-cell spiral design pattern may be shaped (e.g., by applying compression and/or pulling longitudinal force and shape-setting) to be open-cell or closed-cell along the entire length of along portions of the length of the catheter. In FIGS. 22A-22C, the spiral pattern includes aligned overlapping/adjacent regions so that there are five columns of higher-support regions down the elongate length of the catheter. FIG. 22B shows a side view, and FIG. 22C shows a side perspective view.

[000142] FIGS. 23A-23C illustrate another variation of a slotted catheter pattern design. In this example, the slotted pattern is a dog bone pattern, as shown in FIG. 23A. Each cut-out slot has a distal end region with a large width between the opposite sides, and a narrow connection region, with a much smaller width between the opposite sides. The narrow-width regions may be aligned in adjacent slots along the length of the catheter, as shown in FIGS. 23B and 23C. In this example, this alignment of the narrow regions in the middle of the slot (similar to the “closed-cell rectangular slots described above) result in four columns of high-compression strength in the noon 2303, three o’clock 2303’, six o’clock 2303’’ and nine o’clock 2303’’’ positions radially around the circumference of the slotted catheter (or the slotted portion of the catheter). In this example, each cell has preferred close contact region. As mentioned above, the cells (or regions of the cells along the length of the catheter) can be compressed or stretched and heat-set in an open-cell or closed-cell configuration.

[000143] In addition to mixing regions of closed-cell and open-cell slots along the length of the catheter, any of these catheters may also include a mixture of the different patterns disclosed and described herein. For example, FIG. 24A shows an example in which the spiral pattern 2403 of FIGS. 22A-22C is shown adjacent to a region of the brick pattern 2405 of FIG. 21A-21C, which is also adjacent to another region of the spiral pattern. Similarly, FIG. 24B shows alternating spiral patterns 2403 and barbell patterns 2407 such as that shown in FIG. 23A-23C. FIG. 24C shows alternating patterns of spiral 2403, brick 2405, spiral 2403, barbell/dog bone 2407, etc. In any of these catheters, including those of FIGS. 21A-24C, regions along the length may be compressed and/or stretched to form open-cell and closed-cell slots as well.

[000144] FIGS. 25A-25C illustrate a continuous spiral-cut slotted pattern 2501 in which a slot includes plurality of narrowed regions (bumps, detents, necks, etc.) in the slot and aligned along the longitudinal axis of the catheter to form lines 2503’, 2503’’, 2503’’’ extending in the long, longitudinal axis of the catheter. As with the embodiments described

above, these lines may increase the column strength while the larger-width cut-out regions between them may enhance flexibility. In FIG. 25A, the cut pattern 2501 is shown. As mentioned, the cut pattern may be continuous, and may spiral around and through the catheter (compare to the discrete patterns of FIGS. 21A-24C, which also spiral around the catheter at a very low pitch). FIG. 25B shows a side view, including the three lines of aligned narrowed regions. Although three lines are shown, a greater or lower number of narrowed regions may be included (e.g., one or more, two or more, three or more, four or more, 2 to 60, 2 to 50, 2 to 40, 2 to 30, 2 to 25, 2 to 20, 2 to 19, etc.), and spaced so that they align to form longitudinally-extending lines. The lines may be parallel with the longitudinal axis of the catheter. In some variations, the lines may spiral around the catheter with a pitch of less than 15 degrees (e.g., less than 14 degrees, less than 12 degrees, less than 10 degrees, less than 8 degrees, less than 6 degrees, less than 5 degrees, etc.). As with the variations shown in any of FIGS. 14A to 24C, the variation shown in FIGS. 25A-25C may be used in order to achieve a high degree of flexibility and column stiffness when pulling a tractor tube into the catheter, as described above, particularly when this pattern is included on the distal end of the catheter (e.g., the distal 30 cm, the distal 25 cm, the distal 20 cm, the distal 15 cm, the distal 20 cm, etc.).

[000145] FIG. 26 illustrates another example of an apparatus including an elongate inversion support catheter comprising a plurality of slots that are arranged approximately transversely to a long axis of the elongate slotted inversion support catheter. In this example, the apparatus includes a first region of the slotted inversion support catheter that has a “crushed spiral” arrangement in which the spiral shape for the slots is formed by cutting (e.g., laser cutting) slots around the circumference, applying a compressive force along the length and heat setting it to hold the compressed format. Adjacent to this first (distal region) is a second region forming a stretch of “crushed brick” configuration in which the slots have an open diameter of about 0.001 inches or more and wherein there are between 2 and 4 slots per circumferential turn about the long axis, and the region has been compressed (compressively loaded) then heat treated to retain the compressed form. Finally, in FIG. 26, a third slotted region is proximal to the second one is shown. In this third embodiment the third one is an “open brick” configuration in which the slots cut transversely to the long axis of the elongate slotted inversion support catheter, have an open diameter of about 0.001 inches or more and wherein there are between 2 and 4 slots per circumferential turn about the long axis. Any combination of slotted regions (spirals, bricks, open, closed) may be used, in any order of particular interest. Also shown in FIG. 26 is an example of a ring of metal (e.g. shape

memory alloy, such as TiNi, or stainless steel, etc. In FIG. 26, the catheter has an ID of 0.048" and an outer diameter (OD) of about 0.062". The catheter is formed of two separate laser-cut hypotubes that have been joined together as shown in FIG. 27 (showing a stainless-steel member interlocking with a nitinol at dovetail joints; a coating or sleeve (e.g., a lamination such as with Tecoflex 80A and Pebax) may be used to secure them together without substantially modifying the flexibility of the catheter. The length of the nitinol catheter cut to form the distal end of the catheter may be approximately 65cm (e.g., between 40 cm and 100 cm, between 45cm and 90cm, between 55 cm and 85, etc.). The length of the stainless steel (SS) catheter cut to form the distal end of the catheter may be approximately 100 cm (e.g., between 50 cm and 150 cm, between 75 cm and 120 cm, between 95 cm and 105 cm, etc.). The regions of the catheter be treated to have a yield compression strength of greater than ~1000grm.

[000146] FIG. 28 illustrates an example of a catheter, e.g., an elongate inversion support catheter, such as the one shown in FIG. 26, comprising a plurality of slots arranged approximately transversely to a long axis of the elongate slotted inversion support catheter, wherein the slots have an open diameter of about 0.001 inches or less and wherein there are between 2 and 4 slots per circumferential turn about the long axis. FIG. 28, the catheter is shown making a tight turn of 2.8 mm diameter, showing good tracking which may be reflected in the body. Similarly, FIGS. 29A and 29B illustrate an example of a comparison between bending of a traditional support catheter and an elongate inversion support catheter (comprising a plurality of slots arranged approximately transversely to a long axis) as disclosed and described herein. In FIG. 29A, the traditional catheter shows buckling and ultimately fails. In contrast, in FIG. 29B the same applied force (e.g., compressive force) does not cause the device (the elongate inversion support catheter. Thus, the improved elongated inversion support catheter handles high compressive loads without snaking/accordioning/buckling when ingesting hard clot.

[000147] The methods and apparatuses disclosed and described herein may be used with all or some portions of the mechanical clot removal devices shown in each of: U.S. app. no. 15/291,015, filed on 10/11/2016 ("Mechanical Thrombectomy Apparatuses and Methods"); U.S. app. no. 15/496570, filed on 4/25/2017 ("Anti-Jamming and Macerating Thrombectomy Apparatuses and methods"), U.S. app. no. 15/496668, filed on 4/25/2017 ("Pre-loaded inverting tractor Thrombectomy Apparatuses and methods"); U.S. app. no. 15/496,786, filed on 4/25/2017 ("Methods for Advancing Inverting Mechanical Thrombectomy Apparatuses IN The Vasculature"); U.S. app. no. 15/497,092, filed on 4/25/2017 ("Clot-Engulfing

Mechanical Thrombectomy Apparatuses and methods of use”); and U.S. app. no. 15/611546, filed on 6/1/2017 (“Inverting Thrombectomy Apparatuses And Methods”).

[000148] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[000149] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the various inventions disclosed and described herein. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the term "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[000150] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially

relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[000151] Although the terms "first" and "second" may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed herein could be termed a second feature/element, and similarly, a second feature/element discussed herein could be termed a first feature/element without departing from the teachings of the disclosed and described embodiments.

[000152] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising" means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term "comprising" will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

[000153] In general, any of the apparatuses and methods disclosed and described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may alternatively be exclusive and may be expressed as "consisting of" or alternatively "consisting essentially of" the various components, steps, sub-components or sub-steps.

[000154] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or "approximately," even if the term does not expressly appear. The phrase "about" or "approximately" may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value unless the context indicates otherwise. For example, if the value "10" is disclosed, then "about 10" is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that "less than or equal to" the value, "greater than or equal to the value" and possible ranges between values are also disclosed, as appropriately

understood by the skilled artisan. For example, if the value "X" is disclosed the "less than or equal to X" as well as "greater than or equal to X" (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point "10" and a particular data point "15" are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[000155] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the disclosed inventions, which are defined by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the inventions as they are set forth in the claims.

[000156] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, as many are, in fact, disclosed. Thus, although specific embodiments have been illustrated and disclosed and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of the various embodiments disclosed and described herein, as well as further embodiments not specifically disclosed and/or described herein, will be apparent to those of skill in the art upon reviewing the above description in conjunction with the accompanying drawings.

CLAIMS

What is claimed is:

1. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

an elongate inversion support catheter having a distal end and a distal end opening;

an elongate puller extending within the elongate inversion support catheter; and

a knitted tractor tube extending over an outer surface of the elongate inversion support catheter, inverting into the distal end opening of the elongate inversion support catheter, and attached to the elongate puller at a first end within the elongate inversion support catheter,

wherein the portion of the knitted tractor tube extending over the outer surface of the elongate inversion support catheter comprises a wire forming a helical spiral of alternating teardrop shaped-links each having a rounded apex, wherein each link is connected to two adjacent links so that the apex of each link is on an outward-facing surface of the tractor tube, wherein the links flare outward from an outer wall of the elongate inversion support catheter when the puller is pulled proximally within the elongate inversion support catheter.

2. The apparatus of claim 1, further comprising a lubricious liner sleeve extending from within the elongate inversion support catheter and over the distal end opening of the elongate inversion support catheter.

3. The apparatus of claim 2, wherein the pull force required to roll the knitted tractor tube over the distal end of the elongate inversion support catheter and into the elongate inversion support catheter is less than about 250 g of force.

4. The apparatus of claim 2, wherein the lubricious liner comprises a PTFE liner wrapping around the open distal end of the elongate inversion support catheter.

5. The apparatus of claim 1, wherein the knitted tractor tube is formed of an alloy of nickel titanium.

6. The apparatus of claim 1, wherein the links have a length of L , and a grab width of W when flaring outward from the outer wall of the elongate inversion support catheter when the puller is pulled proximally, wherein W is between 30-90% of L .

7. The apparatus of claim 1, wherein the distal open end of the elongate inversion support catheter is tapered.

8. The apparatus of claim 1, further comprising a second end of the knitted tractor tube is unattached and free to slide over the outer surface of the elongate inversion support catheter.

9. The apparatus of claim 8, further comprising a stop on the second end configured to prevent the second end from inverting over the distal end of the elongate inversion support catheter.

10. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

- an elongate inversion support catheter having a distal end and a tapered or rounded distal end opening;

- an elongate puller extending within the elongate inversion support catheter; and

- a knitted tractor tube extending over an outer surface of the elongate inversion support catheter, inverting into the distal end opening of the elongate inversion support catheter, and attached to the elongate puller at a first end within the elongate inversion support catheter,

- wherein the portion of the knitted tractor tube extending over the outer surface of the elongate inversion support catheter comprises a wire forming a helical spiral of alternating teardrop shaped-links each having a rounded apex, wherein each link is connected to two adjacent links so that the apex of each link is on an outward-facing surface of the tractor tube, wherein the links flare outward from an outer wall of the elongate inversion support catheter when the puller is pulled proximally within the elongate inversion support catheter, and

- wherein the links have a length of L , and a grab width of W when flaring outward from the outer wall of the elongate inversion support catheter when the puller is pulled proximally, wherein W is between 30-90% of L .

11. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

- an elongate slotted inversion support catheter having a distal end and a distal end opening, wherein the elongate inversion support catheter comprises a spiral pattern having a plurality of slots arranged approximately transversely to a long axis of the elongate slotted

inversion support catheter, wherein the slots have an open diameter of about 0.001 inches or less and wherein there are between 2 and 4 slots per circumferential turn of the spiral pattern; and

a tractor tube extending over an outer surface of the elongate inversion support catheter, inverting into the distal end opening of the elongate inversion support catheter,

wherein the tractor tube is configured to invert over the distal end opening of the elongate inversion support catheter when pulled proximally into the elongate inversion support catheter.

12. The apparatus of claim 11, wherein a second region of the elongate slotted inversion support catheter comprises a second spiral pattern having a second plurality of slots arranged approximately transversely to the long axis of the elongate slotted inversion support catheter, wherein the second plurality of slots have an open diameter of about 0.001 inches or more and wherein there are between 2 and 4 slots per circumferential turn of the spiral pattern.

13. The apparatus of claim 11, further comprising a puller extending within the elongate inversion support catheter to which a first end of the tractor tube is attached.

14. The apparatus of claim 11, wherein there are between 2 and 3 slots per circumferential turn.

15. The apparatus of claim 11, wherein the spiral pattern is helically arranged around the circumference of the elongate slotted inversion support catheter.

16. The apparatus of claim 11, further wherein the slotted inversion support catheter is heat set into a compressed configuration so that the slots form closed cells in a relaxed configuration.

17. The apparatus of claim 11, further wherein the slots extend between about 50 and 98% of each circumferential turn of the spiral pattern.

18. The apparatus of claim 11, further wherein at least 1 mm of the distal end of the slotted inversion support catheter comprises the spiral pattern.

19. The apparatus of claim 11, wherein the spiral pattern is configured so that at least 80% of a length of the slots contact and are supported by an opposite side of the slots when the elongate slotted inversion support catheter is longitudinally compressed.

20. The apparatus of claim 11, wherein elongate slotted inversion support catheter has a catheter compression yield force of greater than about 1000 g.

21. The apparatus of claim 11, wherein the elongate slotted inversion support catheter is one or both of: a nickel titanium alloy and stainless steel.

22. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

- an elongate slotted inversion support catheter having a distal end and a distal end opening, wherein

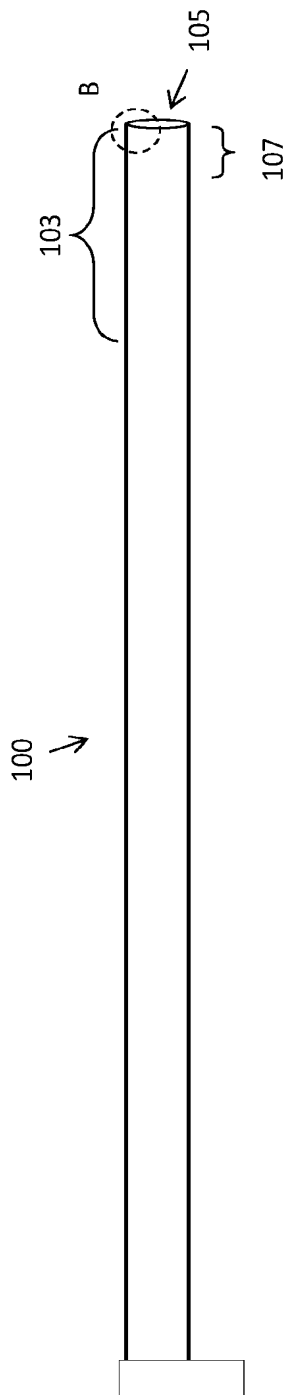
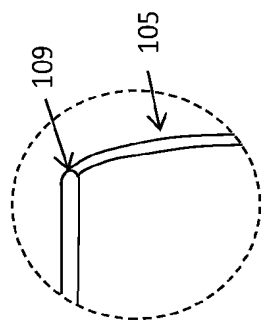
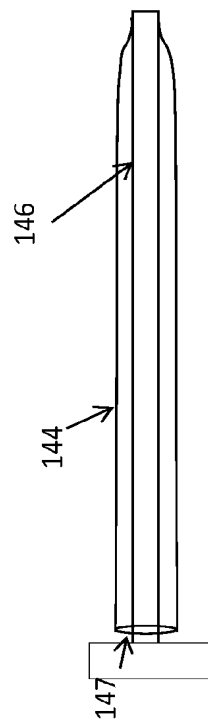
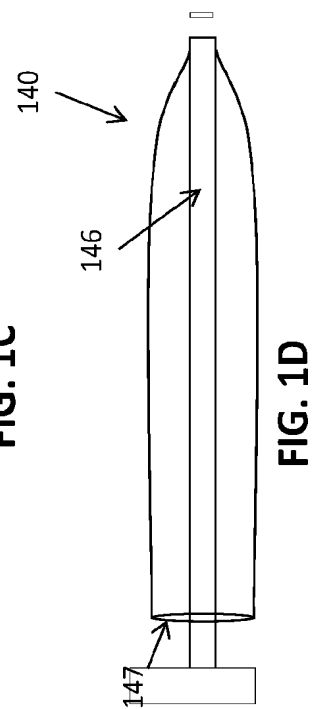
- a first region of the elongate inversion support catheter comprises a plurality of slots arranged approximately transversely to a long axis of the elongate slotted inversion support catheter, wherein the slots have an open diameter of about 0.001 inches or less, and wherein there are between 2 and 4 slots per circumferential turn about the long axis, and

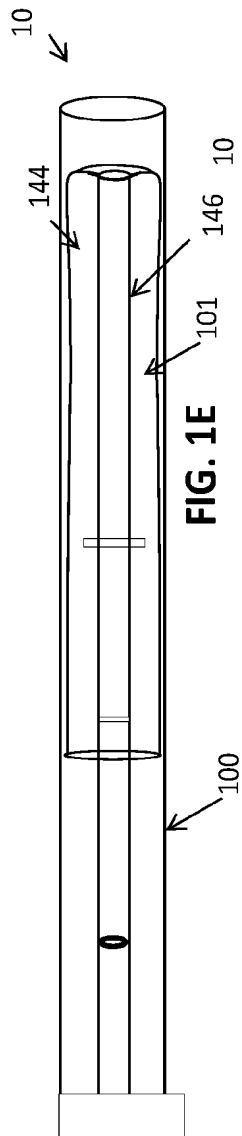
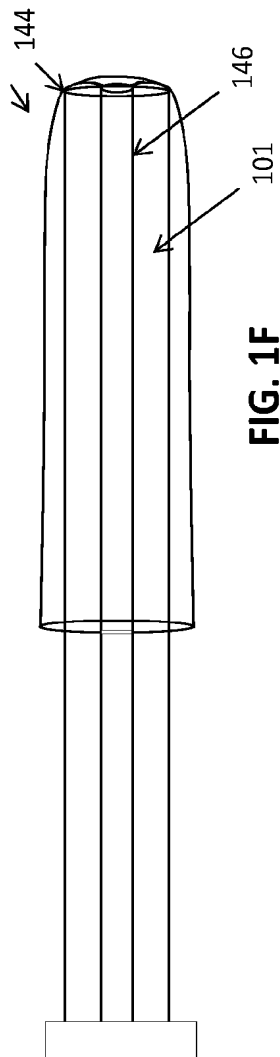
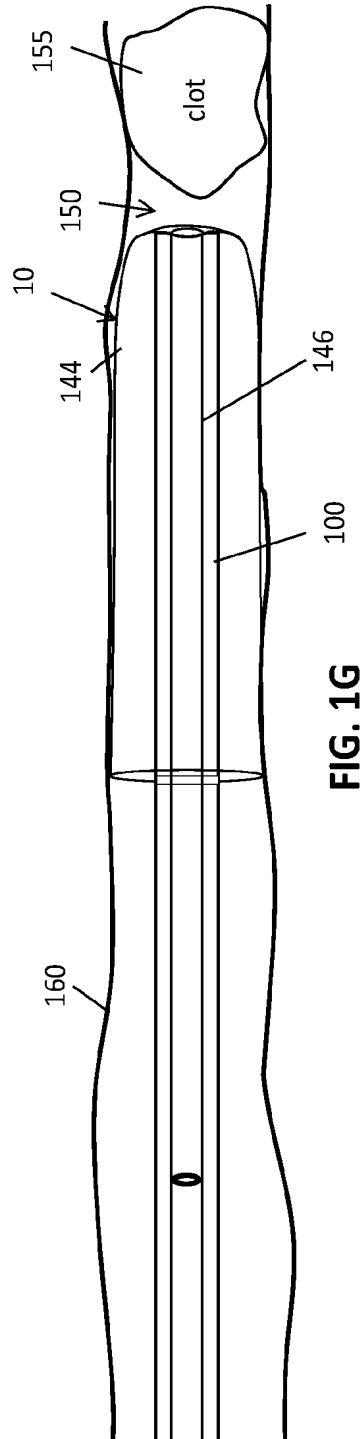
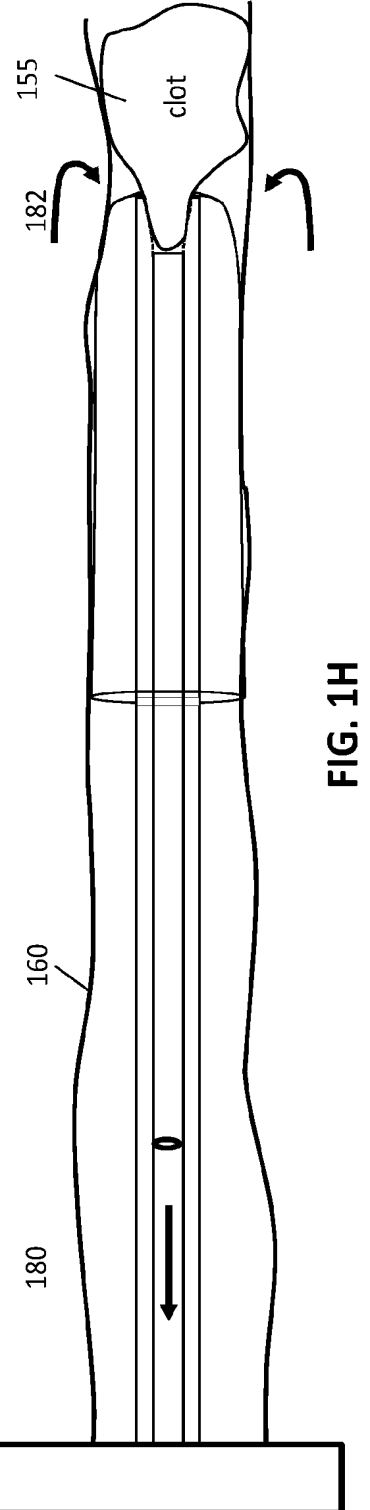
- a second region of the elongate slotted inversion support catheter comprises a second plurality of slots arranged approximately transversely to the long axis of the elongate slotted inversion support catheter, wherein the second plurality of slots have an open diameter of about 0.001 inches or more and wherein there are between 2 and 4 slots per circumferential turn about the long axis;

- a tractor tube extending over an outer surface of the elongate inversion support catheter, inverting into the distal end opening of the elongate inversion support catheter; and

- a puller within the elongate slotted inversion support catheter, wherein a first end of the tractor tube is attached to the puller,

- wherein the tractor tube is configured to invert over the distal end opening of the elongate inversion support catheter when pulled proximally into the elongate inversion support catheter.





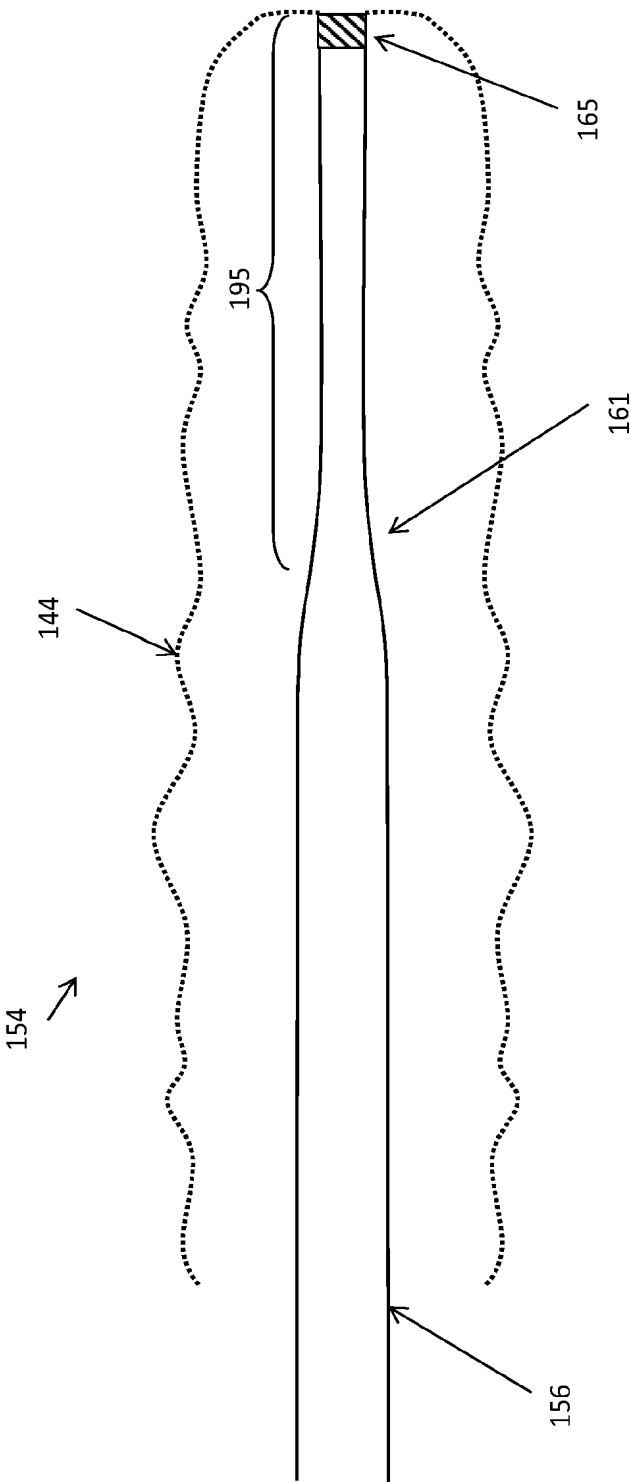
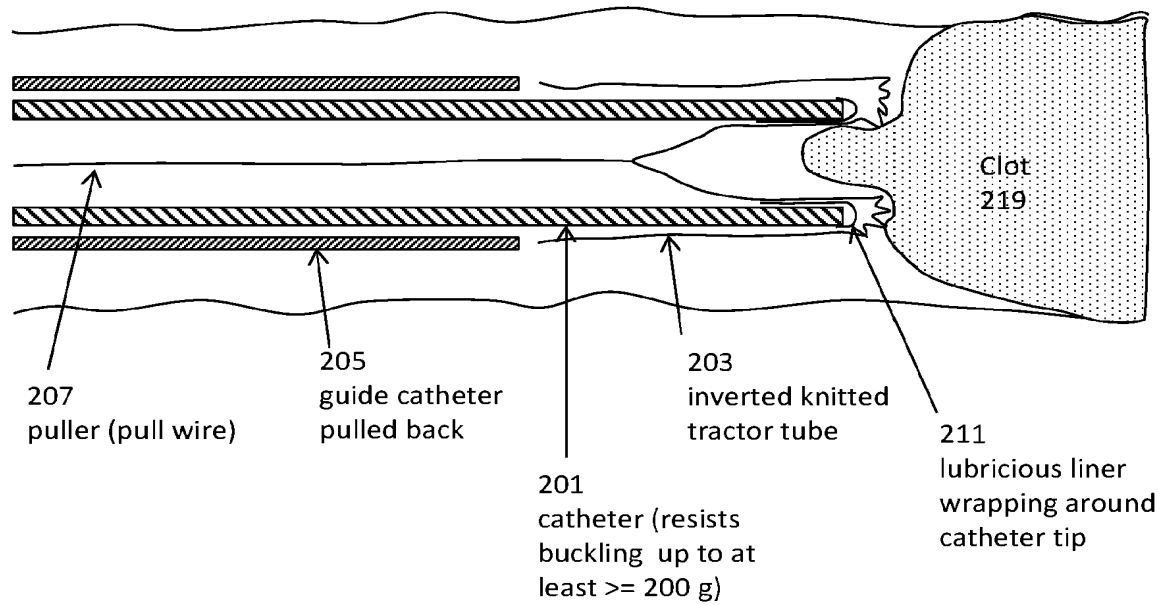
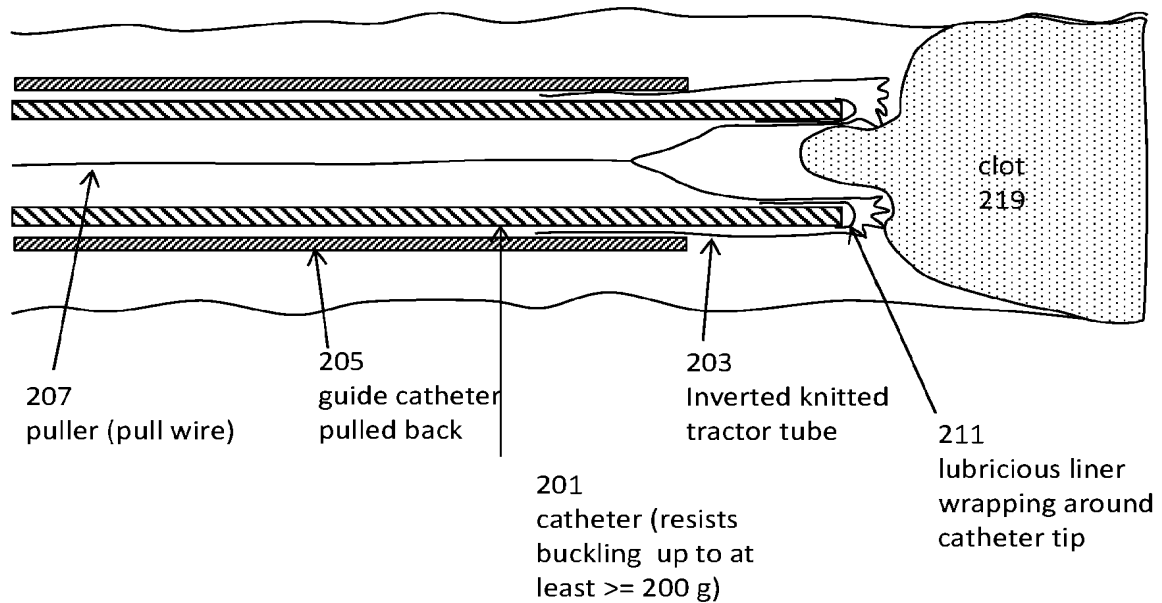
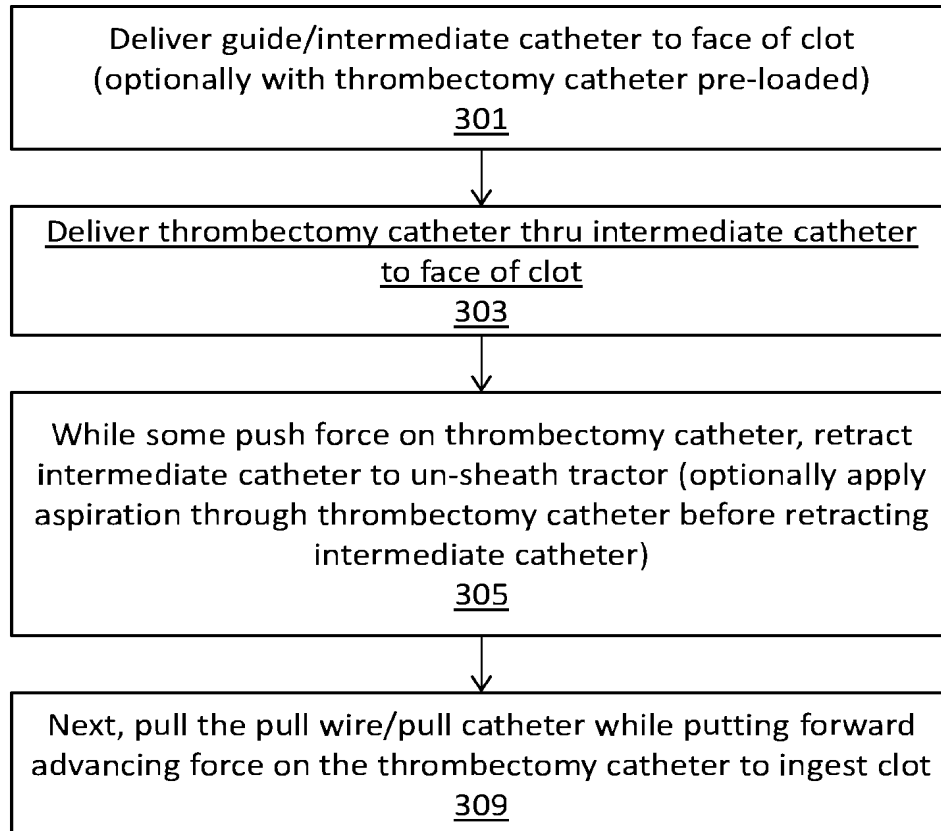


FIG. 1I

**FIG. 2A****FIG. 2B**

**FIG. 3**

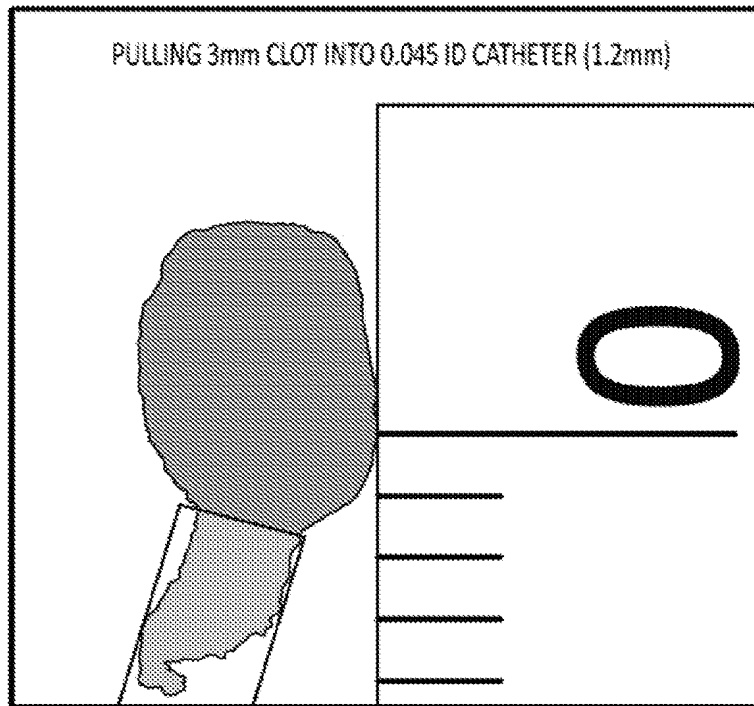


FIG. 4A

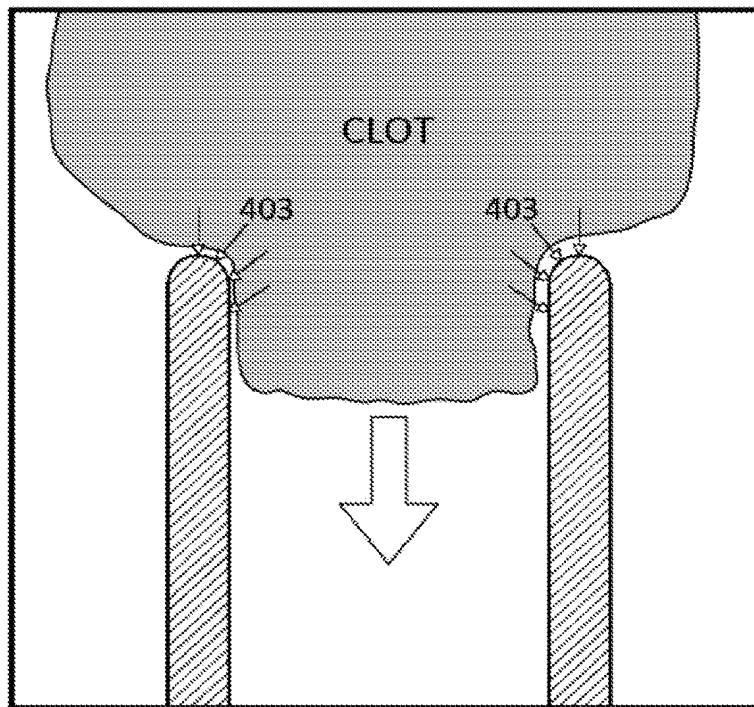


FIG. 4B

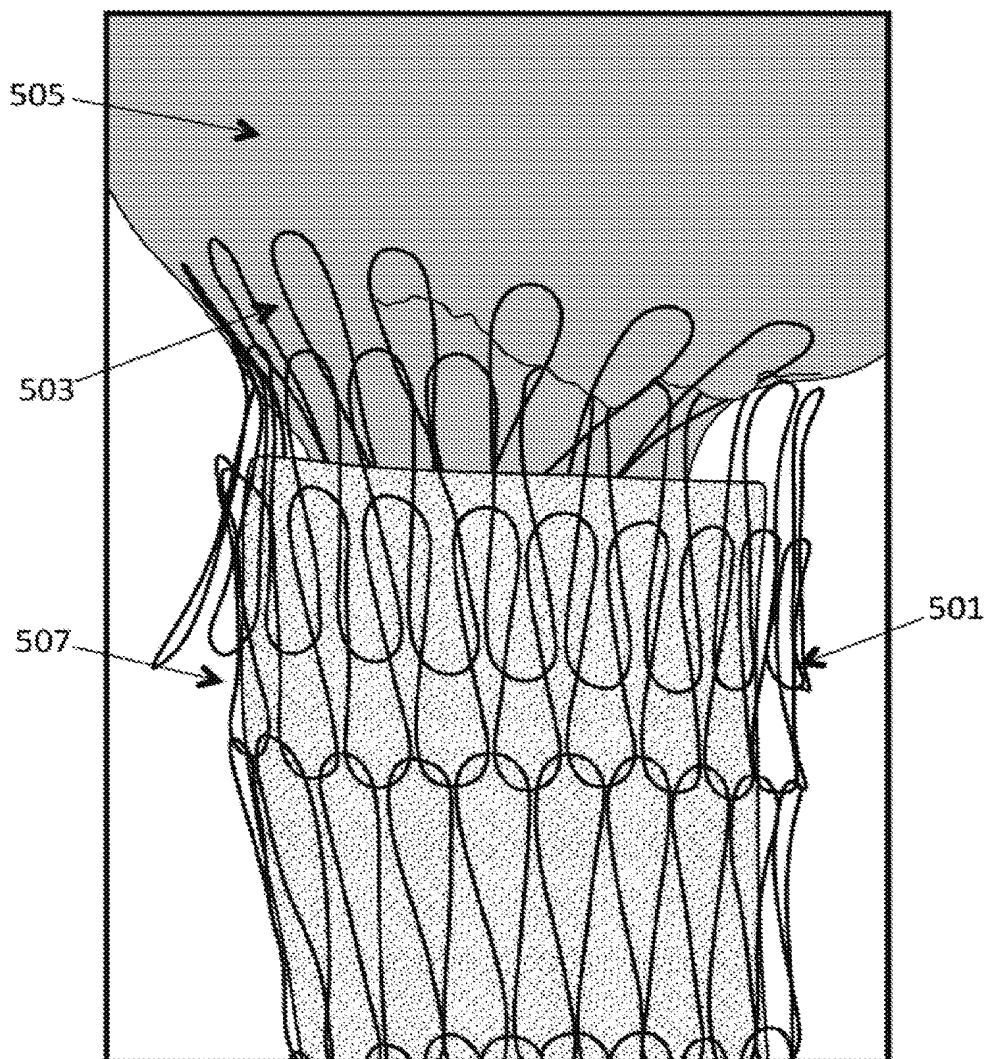


FIG. 5

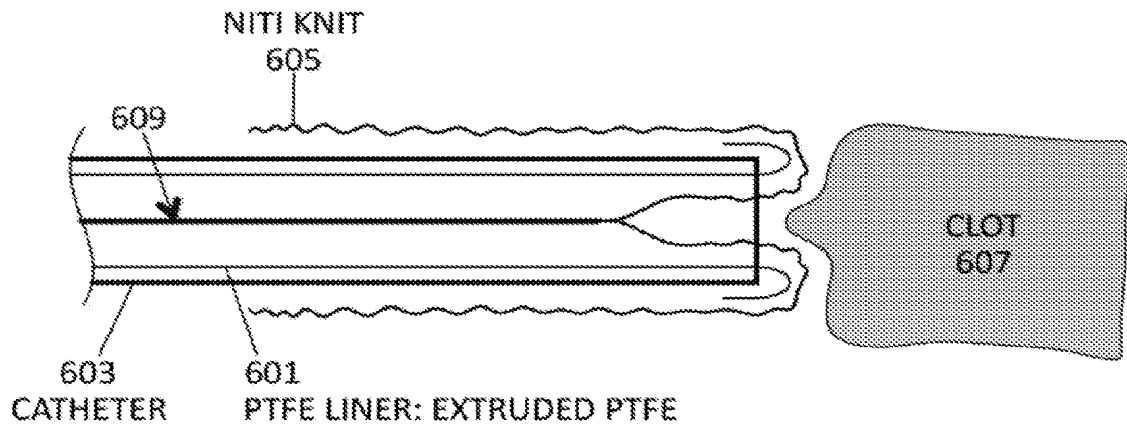


FIG. 6A

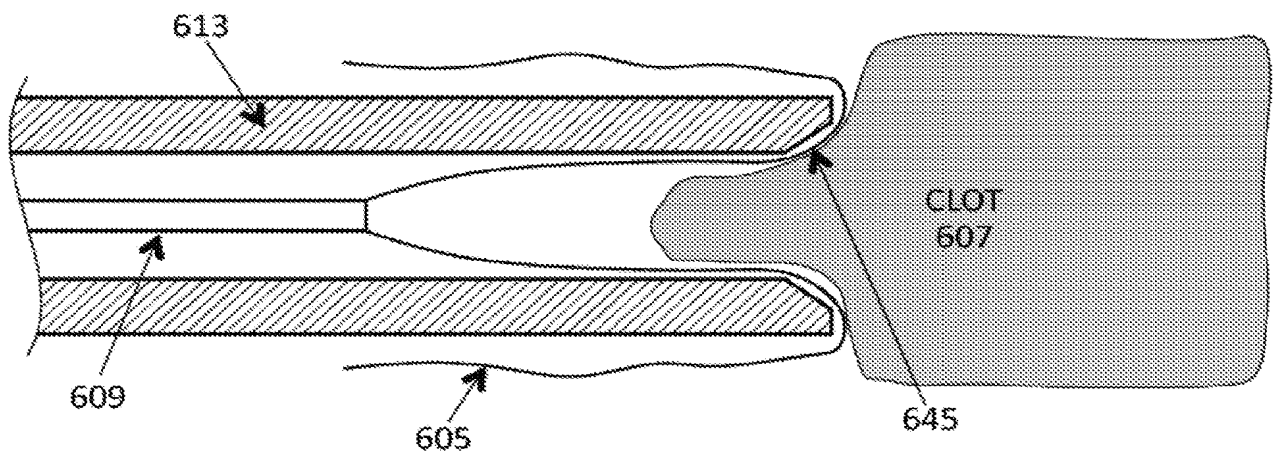


FIG. 6B

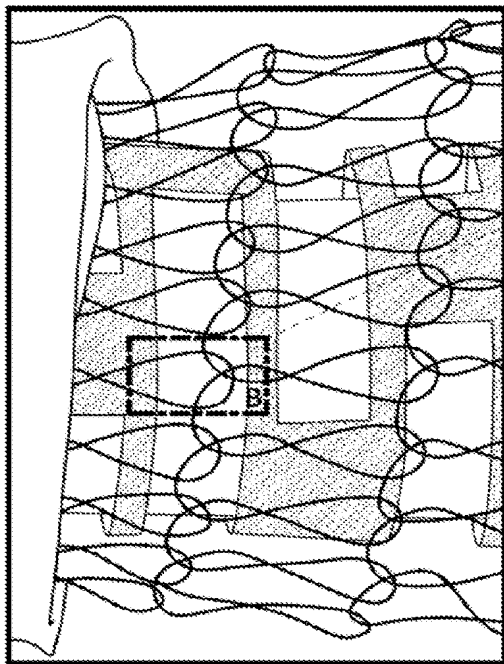


FIG. 7A

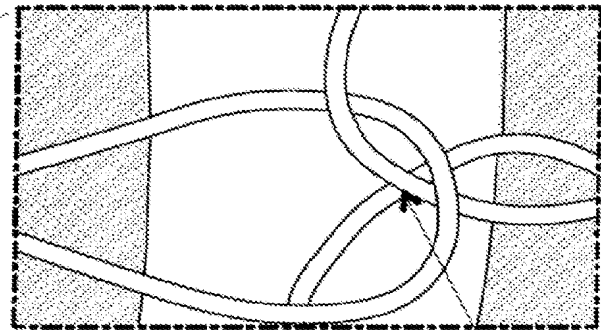


FIG. 7B

705

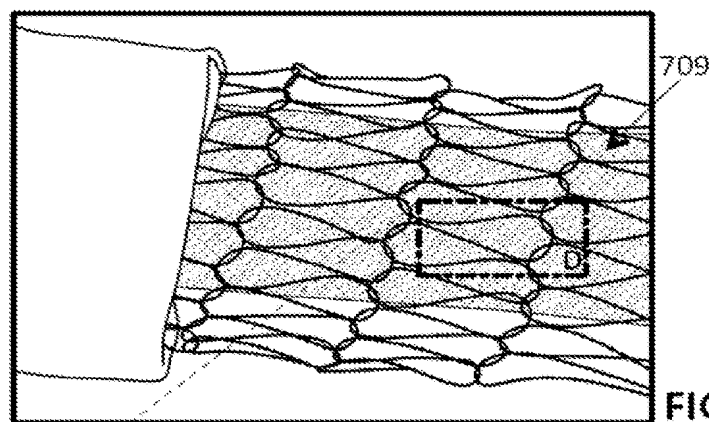


FIG. 7C

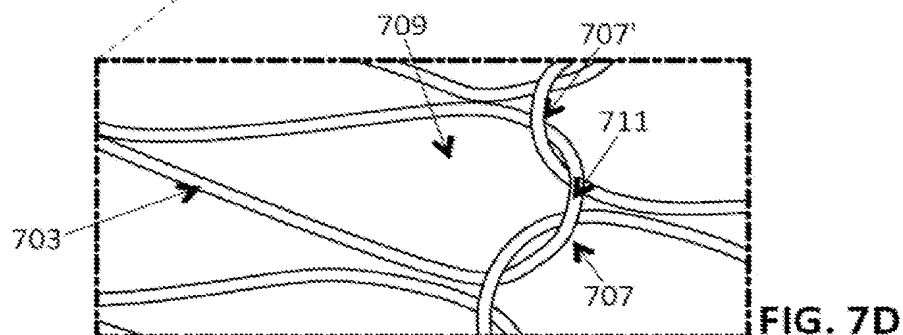


FIG. 7D

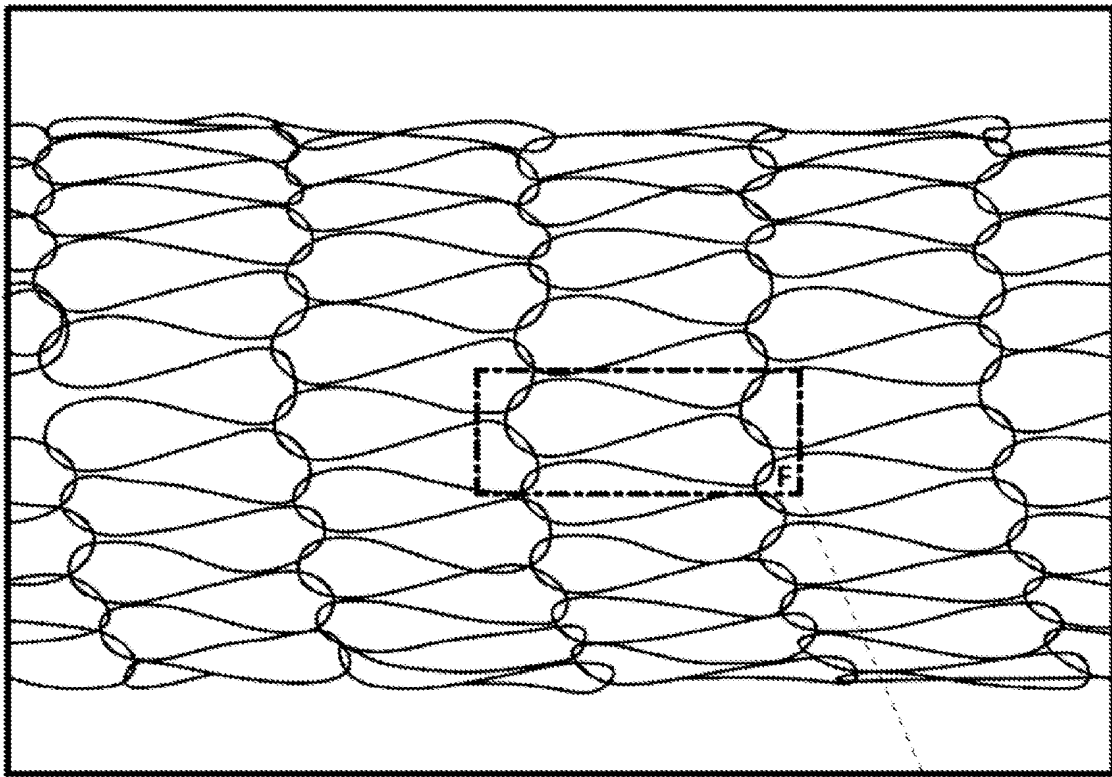


FIG. 7E

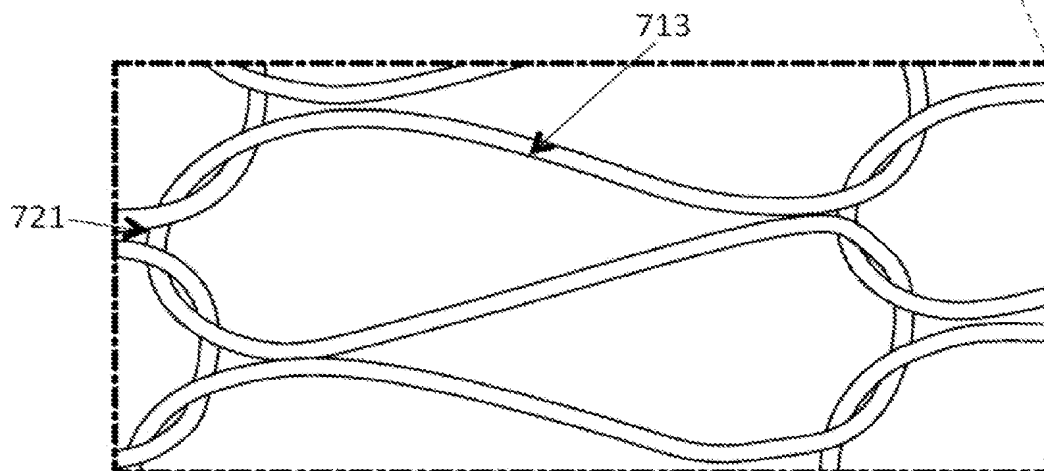


FIG. 7F

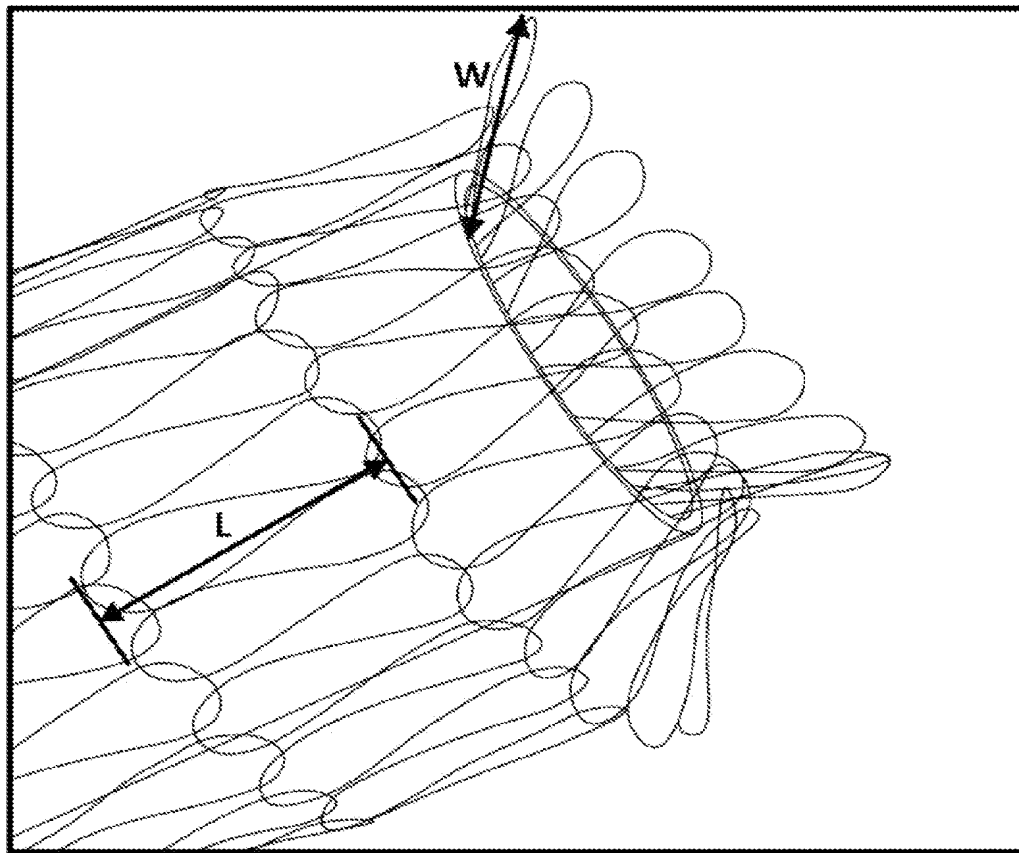


FIG. 8A

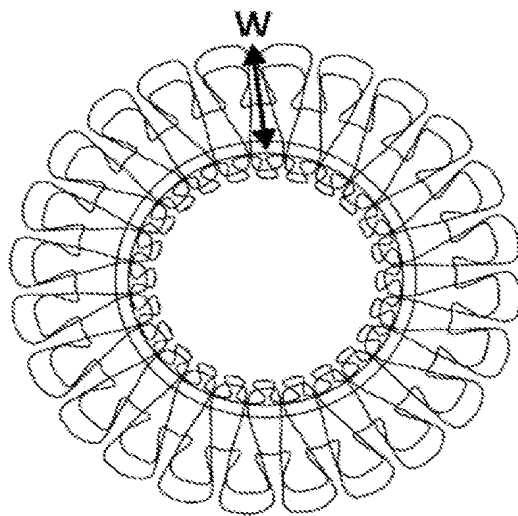


FIG. 8B

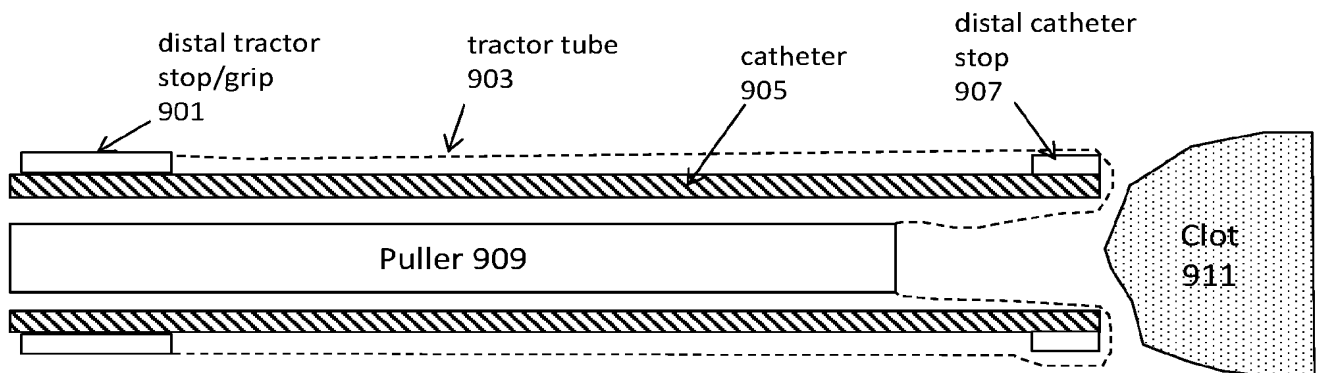


FIG. 9A

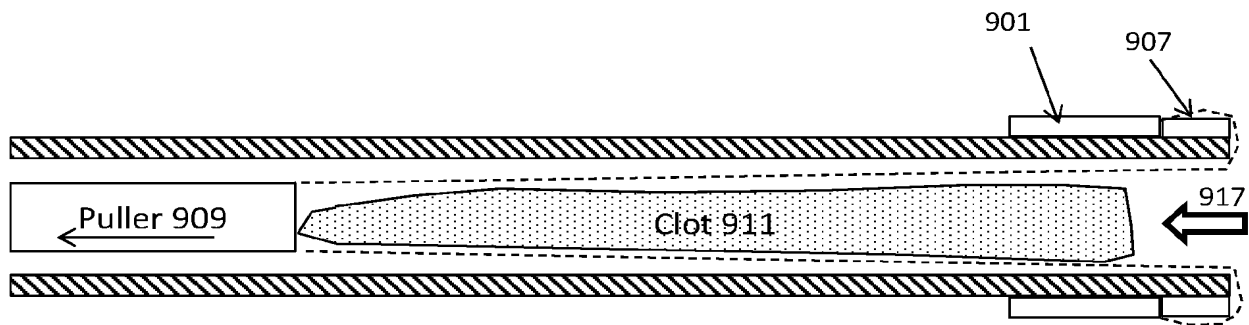


FIG. 9B

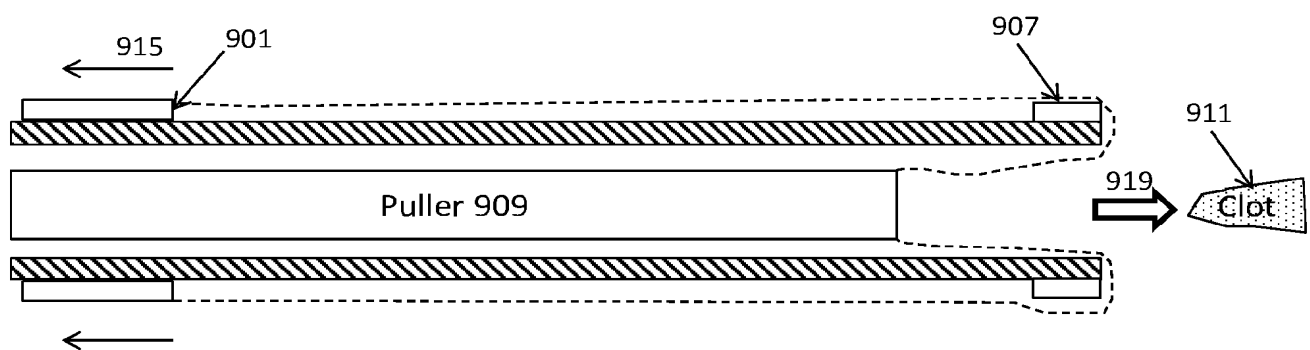
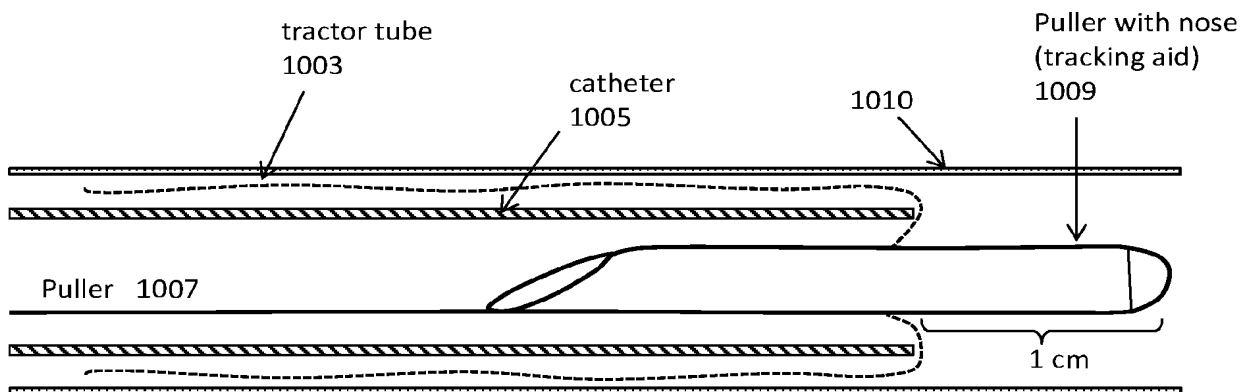
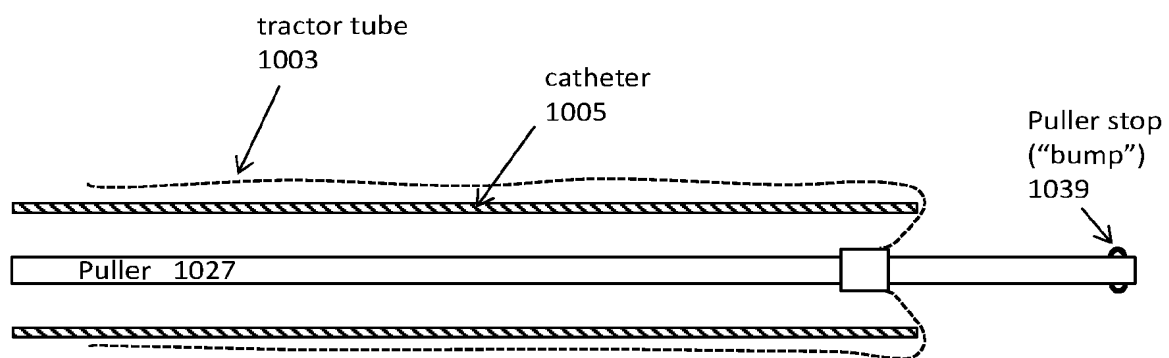
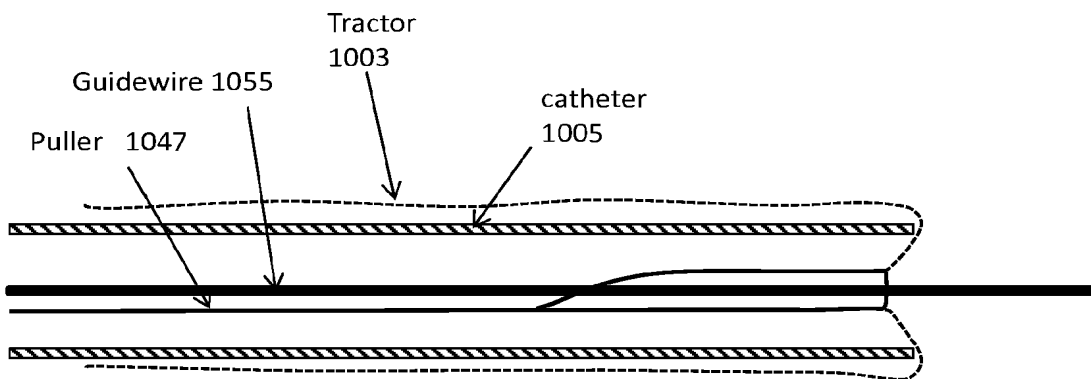
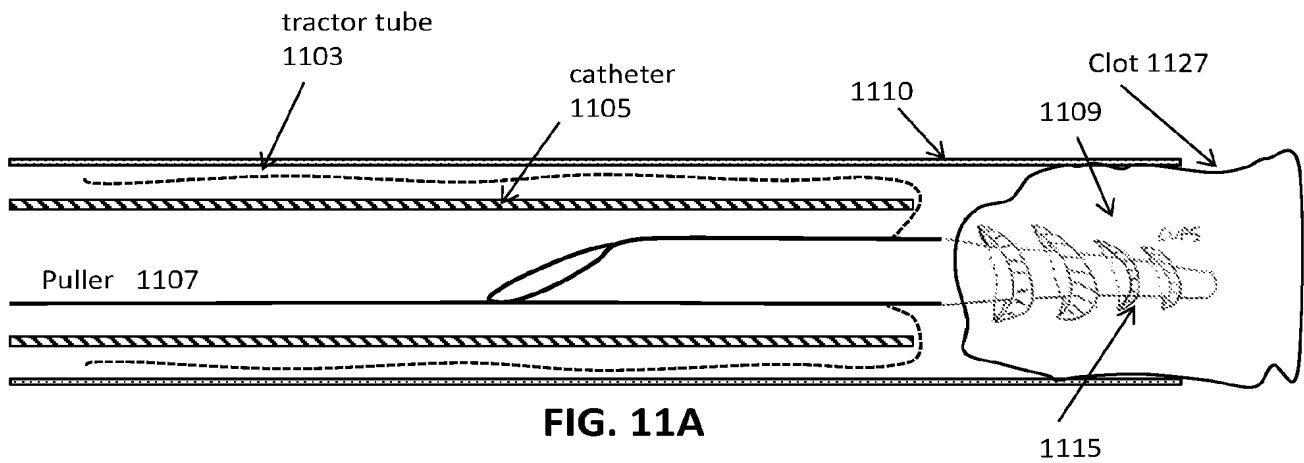
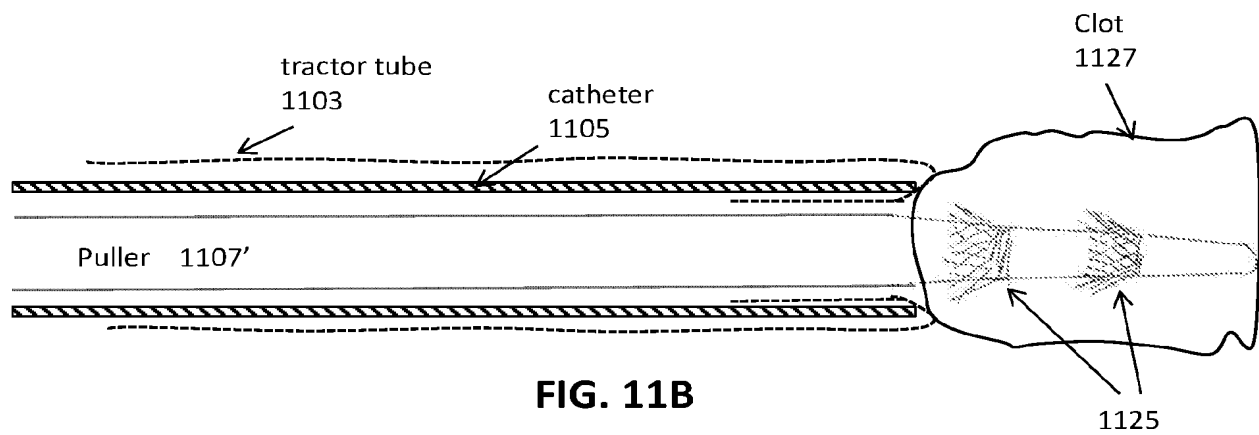
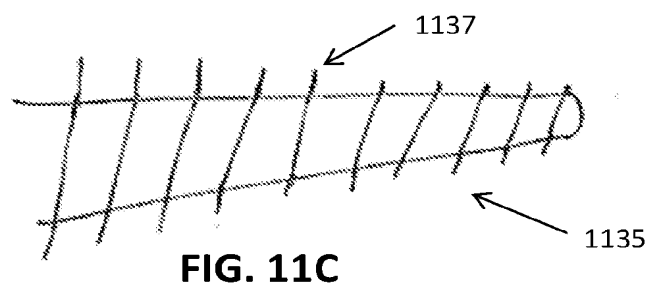
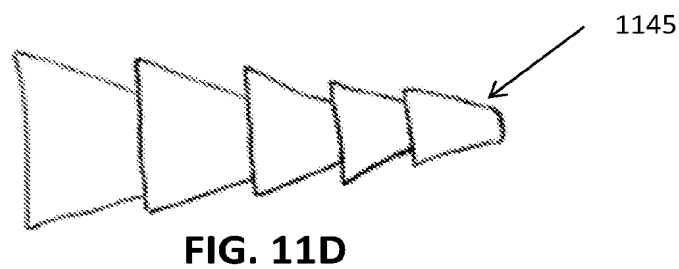


FIG. 9C

**FIG. 10A****FIG. 10B****FIG. 10C**



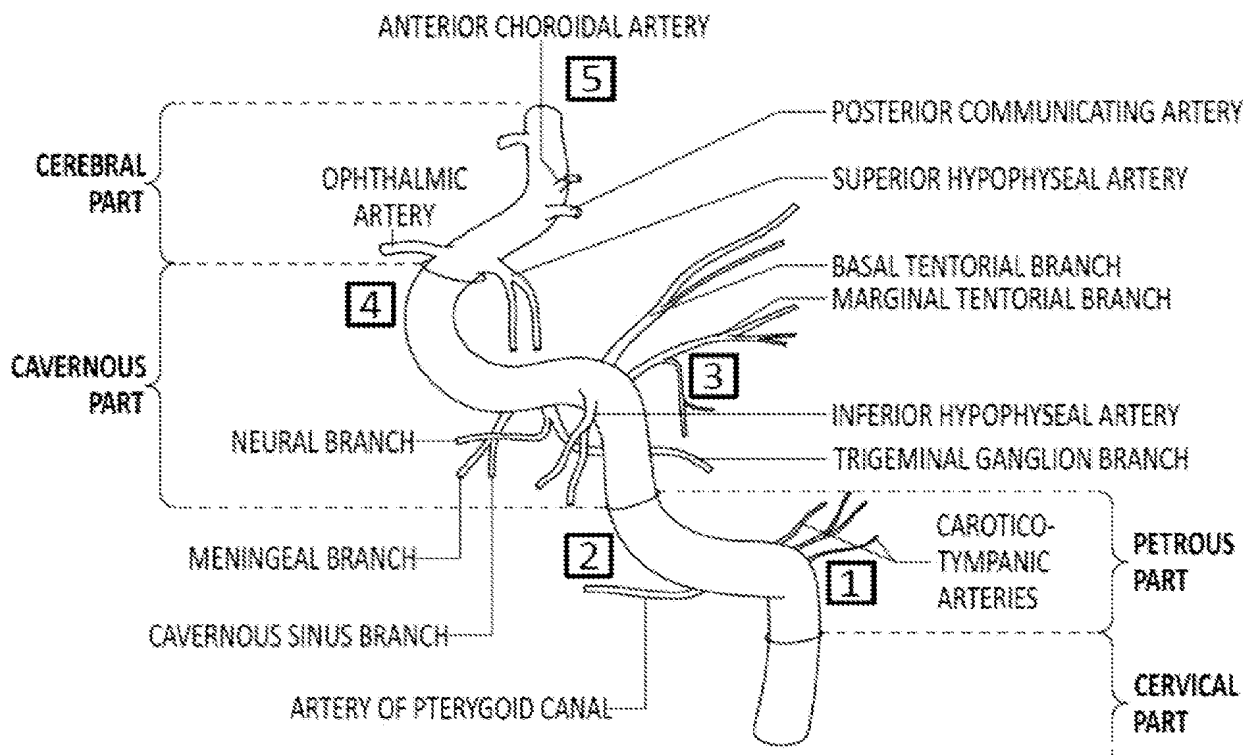


FIG. 12

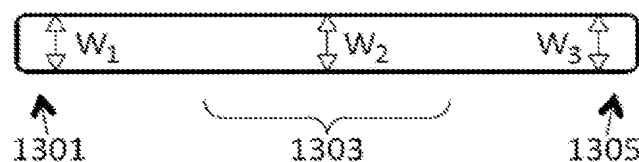


FIG. 13A

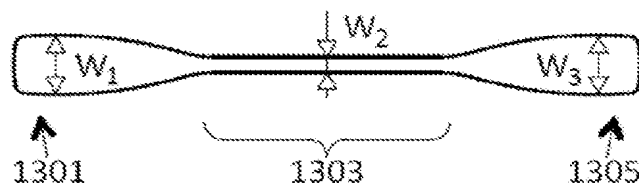


FIG. 13B

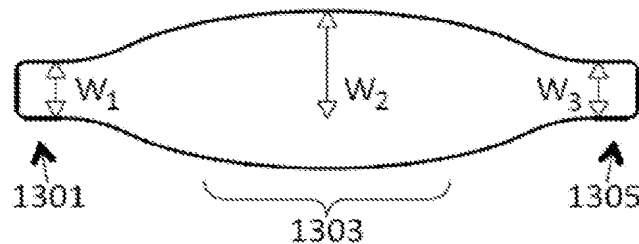


FIG. 13C

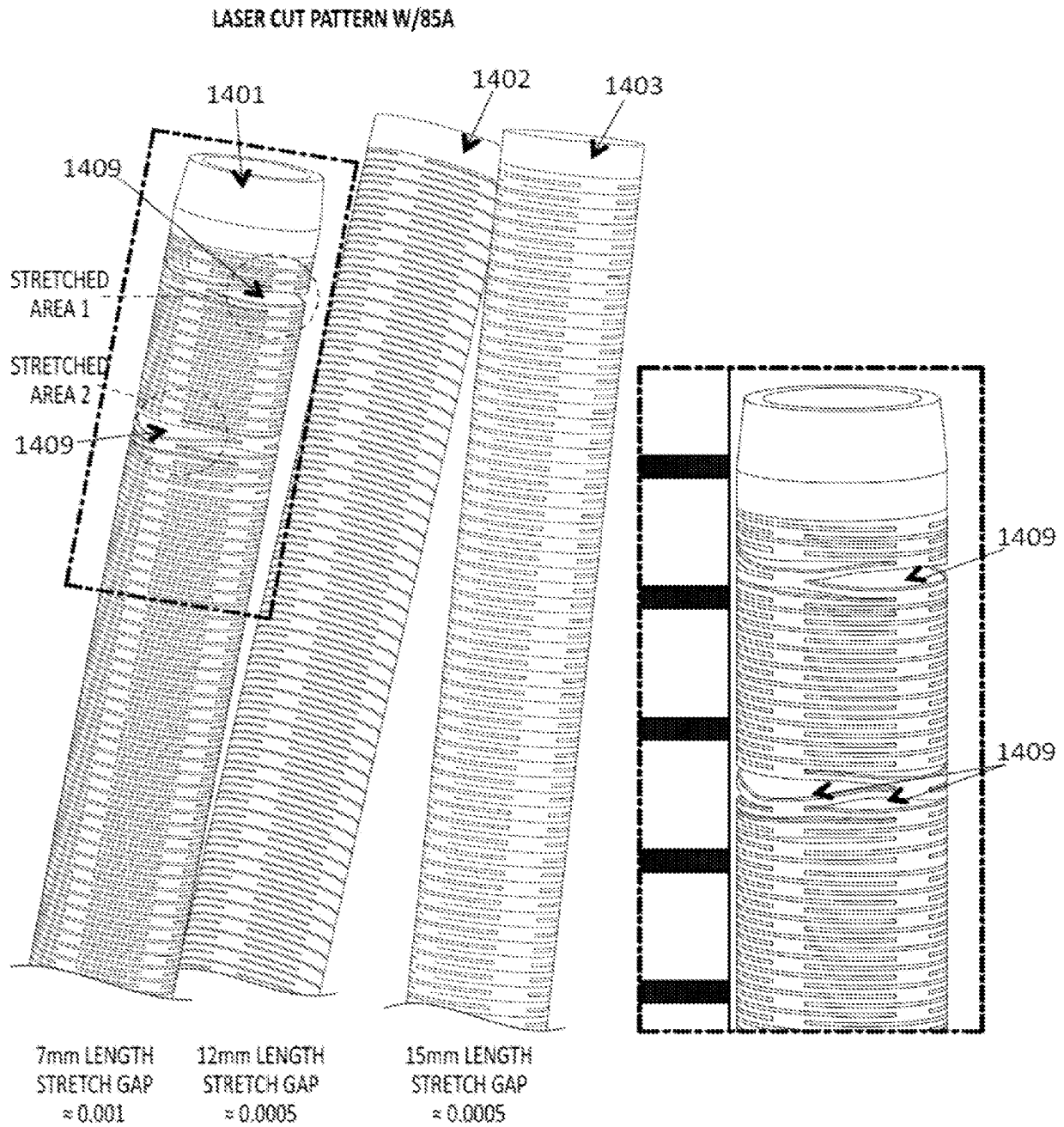


FIG. 14A

FIG. 14B

HYPOTUBE DESIGN									
TUBING MATERIAL: NITINOL				TUBING SIZE: .057x.052					
CUTS PER ROTATION: 2.5				CUT ANGLE: 121		UNCUT ANGLE: 23			
ZONE	1	2	3	4	5	6	7	8	9
PITCH	0	0.003	0.0035	0.004	0.0045	0.005	0.008	0.01	0.013
LENGTH	0.025	2	8	4	4	6	3	2	26

FIG. 14C

DESIGN W/ 80A
(WHERE THE DISTAL 5MM IS STRETCHED 8MM + TWO DEFECTS)

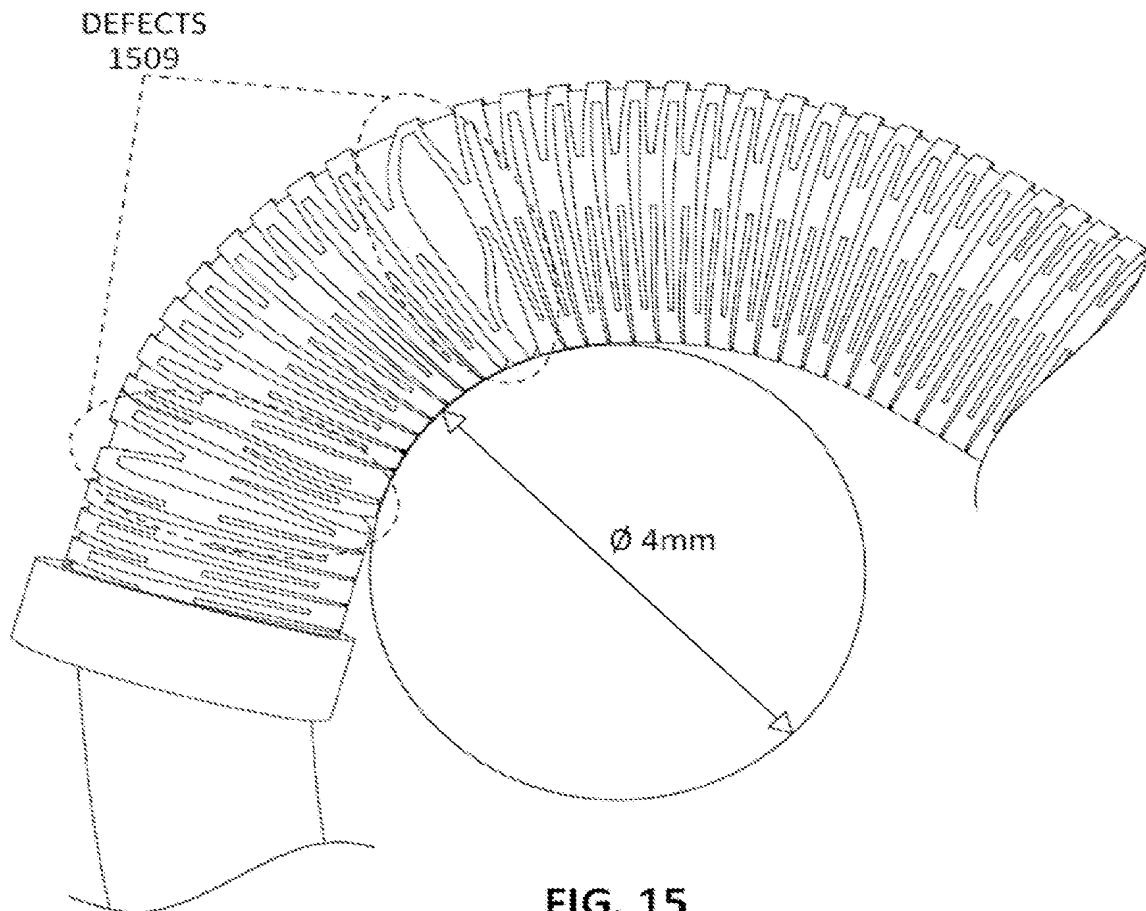
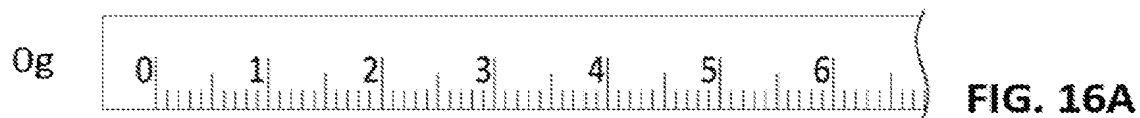
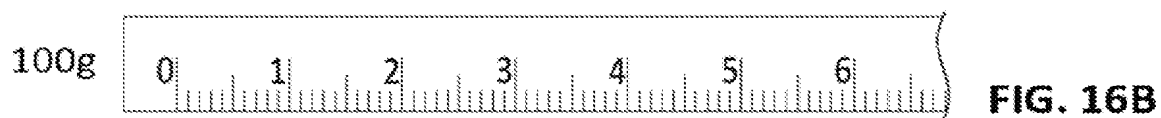
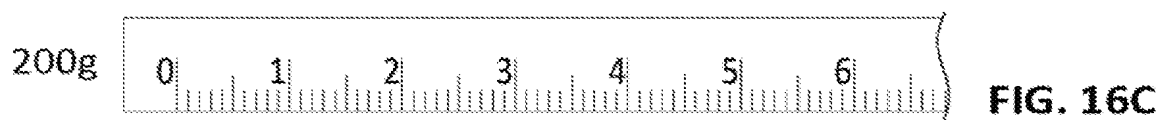
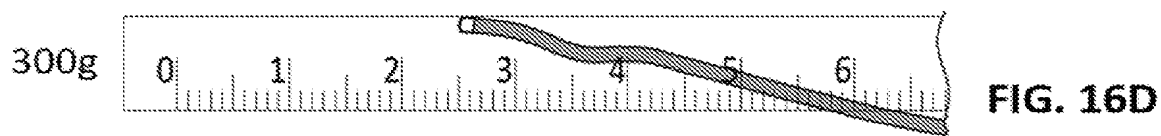
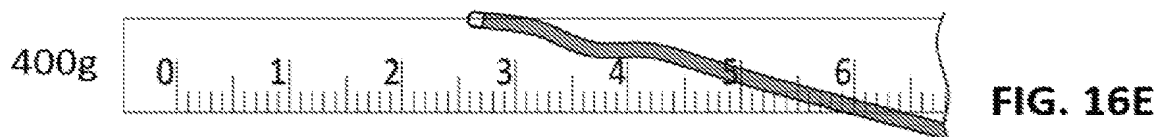
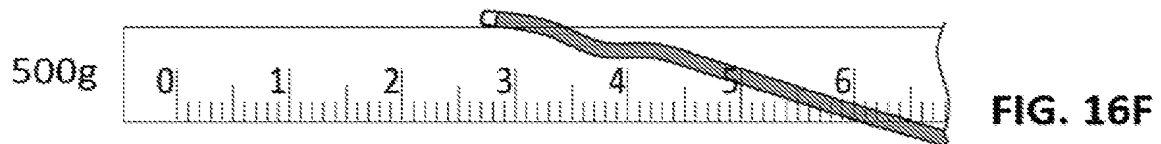
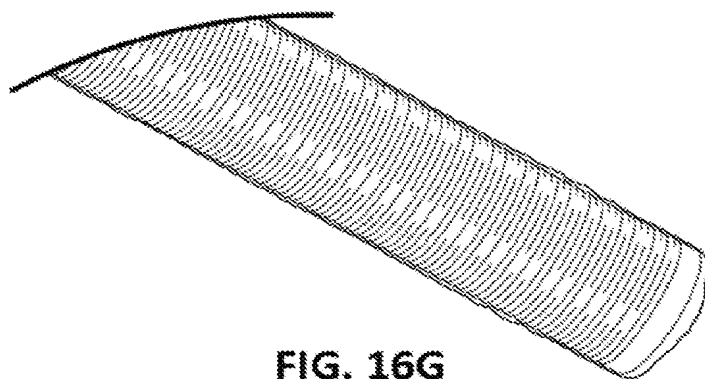


FIG. 15



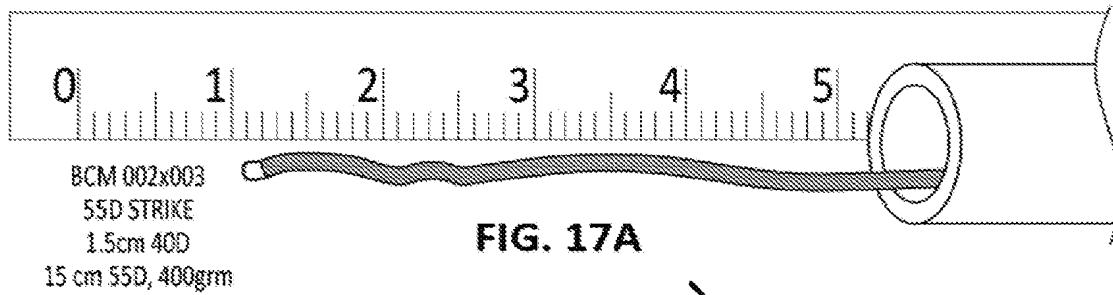
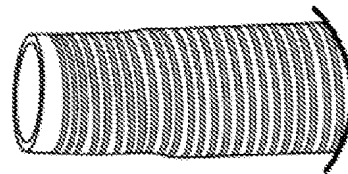
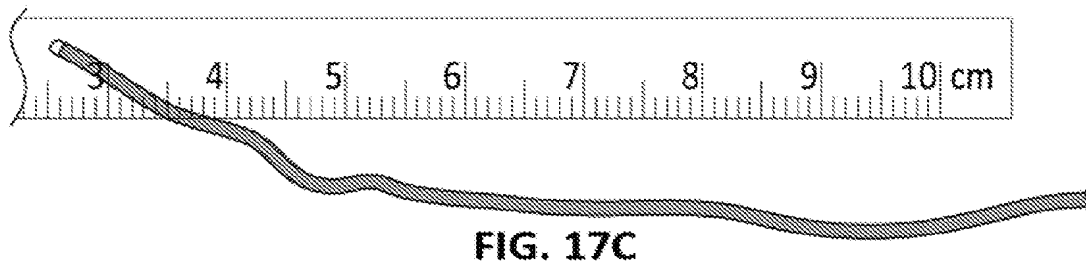
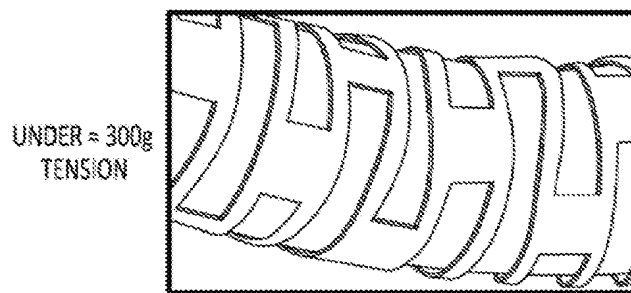
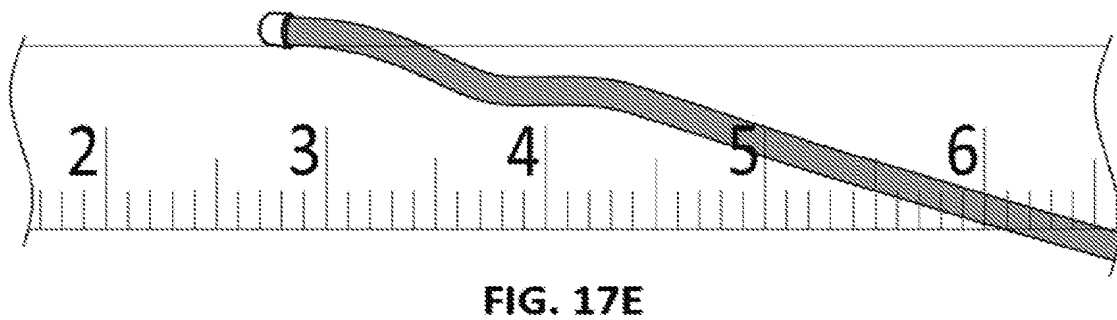


FIG. 17B



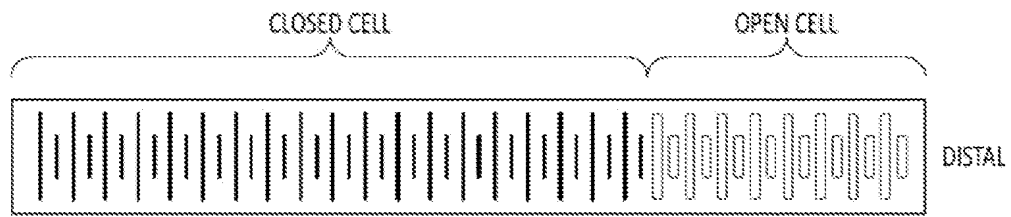


FIG. 18A

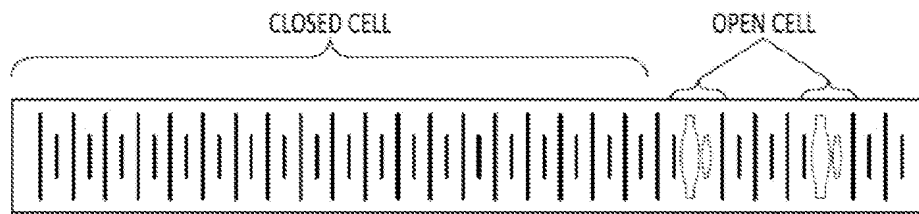


FIG. 18B

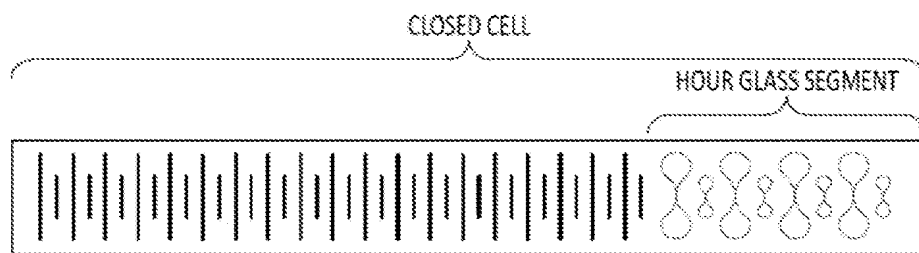


FIG. 18C

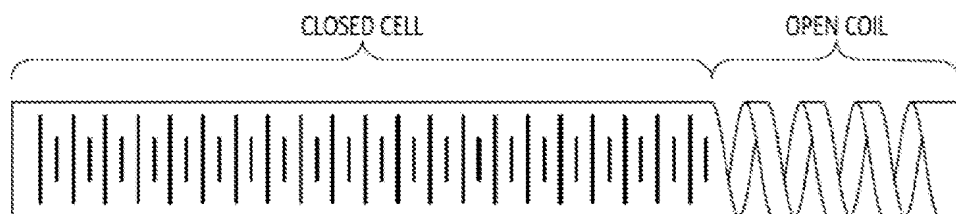


FIG. 18D

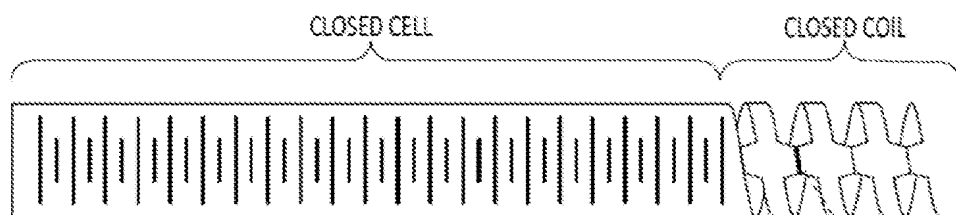
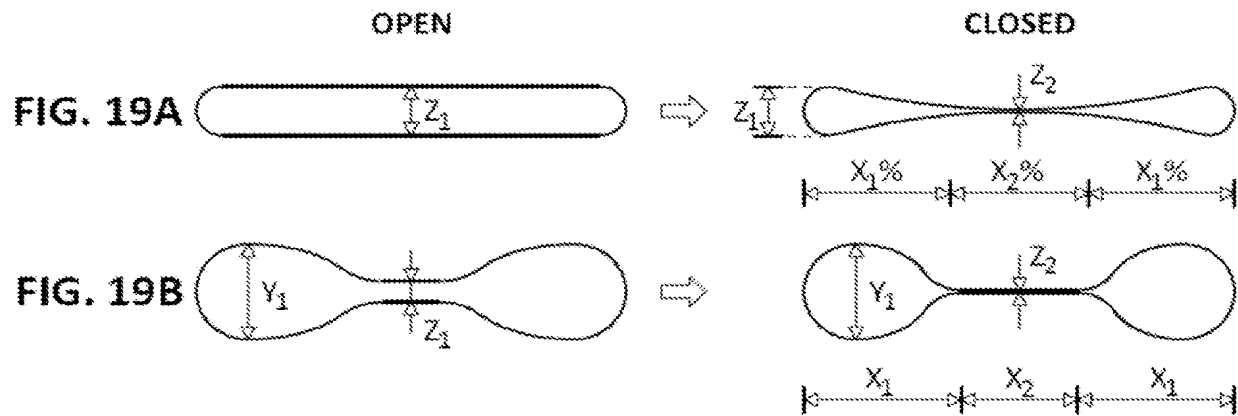


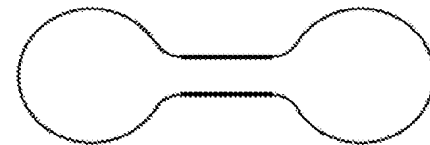
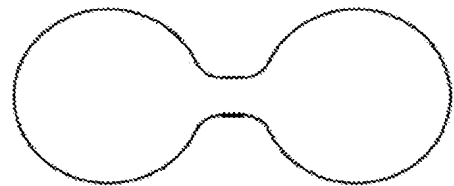
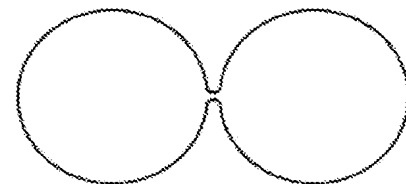
FIG. 18E

"X"
 - RANGES FROM 1 - 50mm
 - PREFERRED 2 - 10mm OR 2 - 5mm

CONTACT POINT
 X



A DESIGN	
— "CLOSED CELL"	<ul style="list-style-type: none"> • $5\% X_1 \leq X_2\% \leq 95\% X_1$ • $\emptyset \leq Z_2\% \leq 95\% Z_1$ ex $Z_1 = .001"$ ex $Z_2 = .0001"$
— "OPEN CELL"	<ul style="list-style-type: none"> • $.0005" \leq Z_1 \leq .010"$ ex $Z_1 = .001"$
B DESIGN	
— "CLOSED CELL"	<ul style="list-style-type: none"> • $5\% X_1 \leq X_2\% \leq 95\% X_1$ • $\emptyset \leq Z_2\% \leq 90\% Z_1$
— "OPEN CELL"	<ul style="list-style-type: none"> • $.0005" \leq Y_1 \leq .010"$ • $10\% Y_1 \leq Z_1 \leq 500 Y_1$ • $5\% X_1 \leq X_2 \leq 95\% X_1$

FIG. 19C**FIG. 20A****FIG. 20B****FIG. 20C**

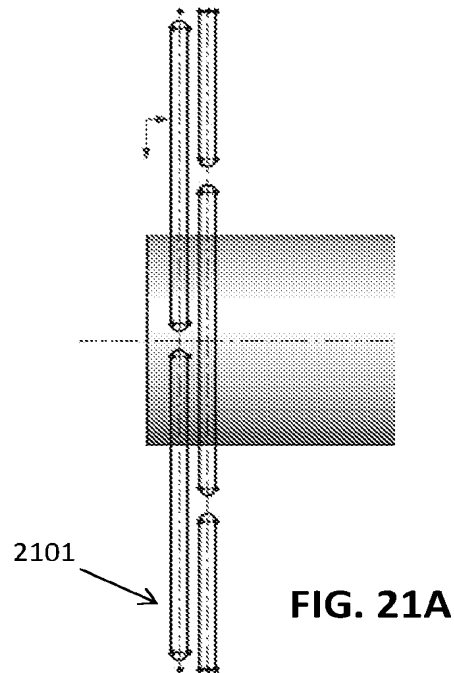
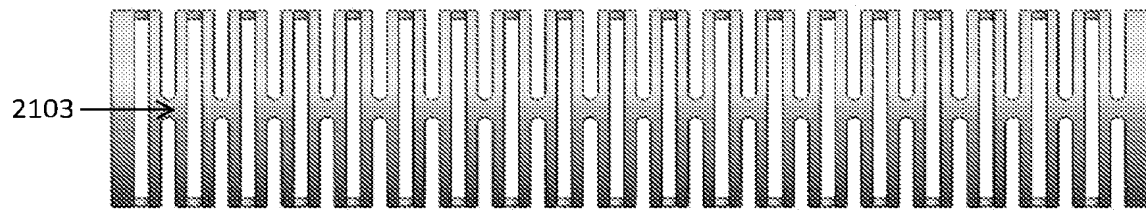


FIG. 21B

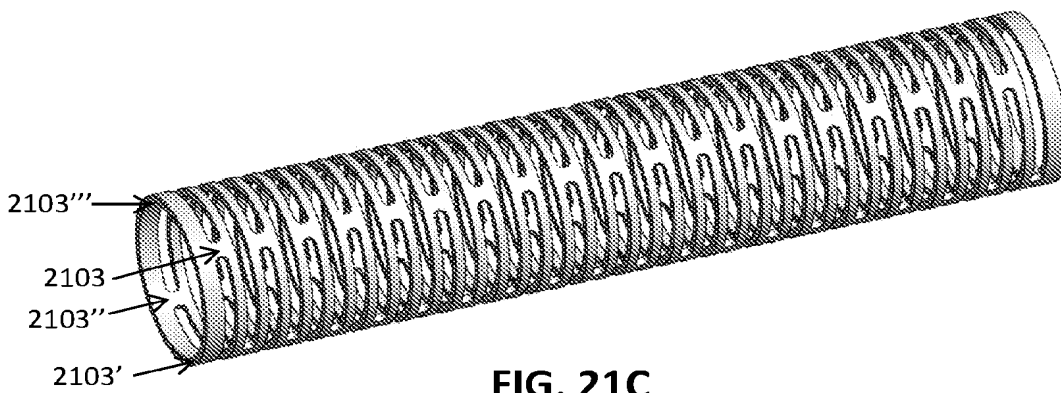


FIG. 21C

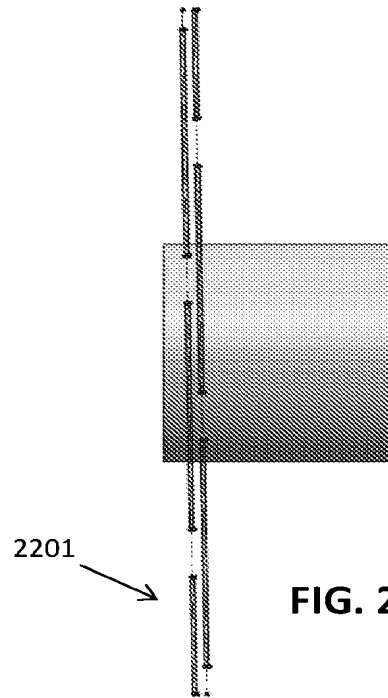


FIG. 22A

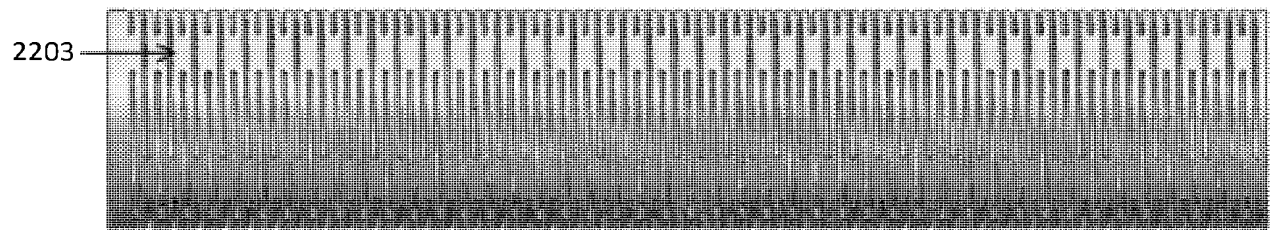


FIG. 22B

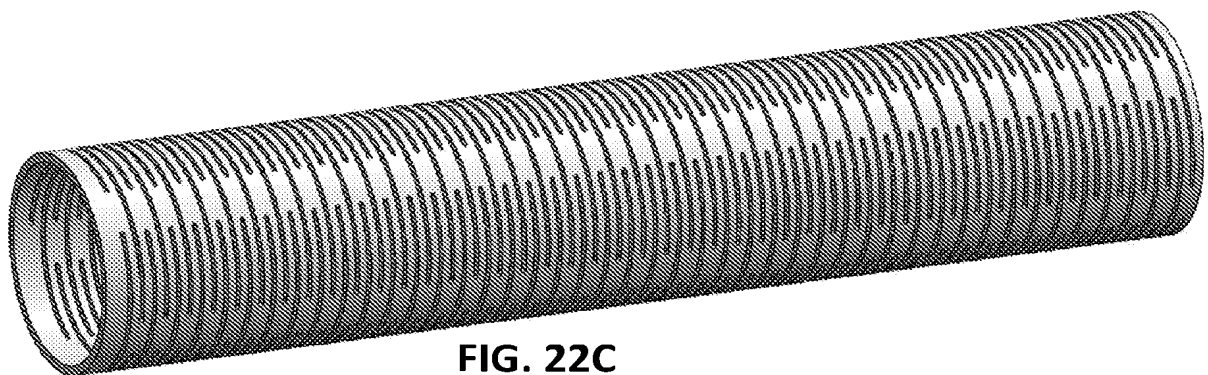


FIG. 22C

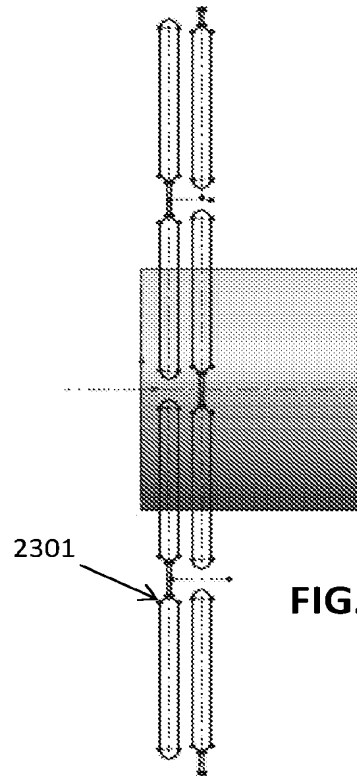


FIG. 23A

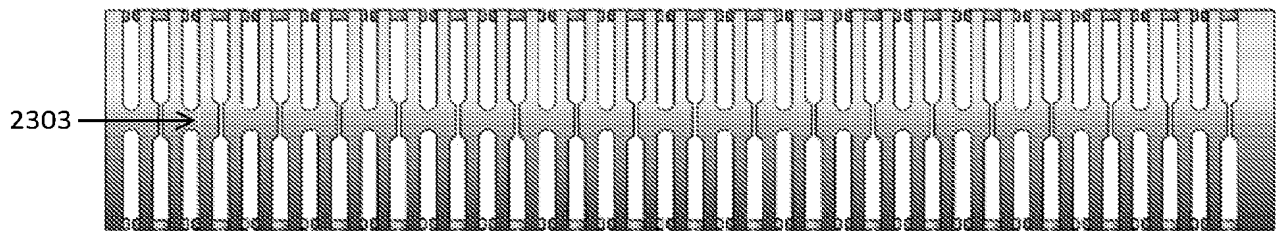


FIG. 23B

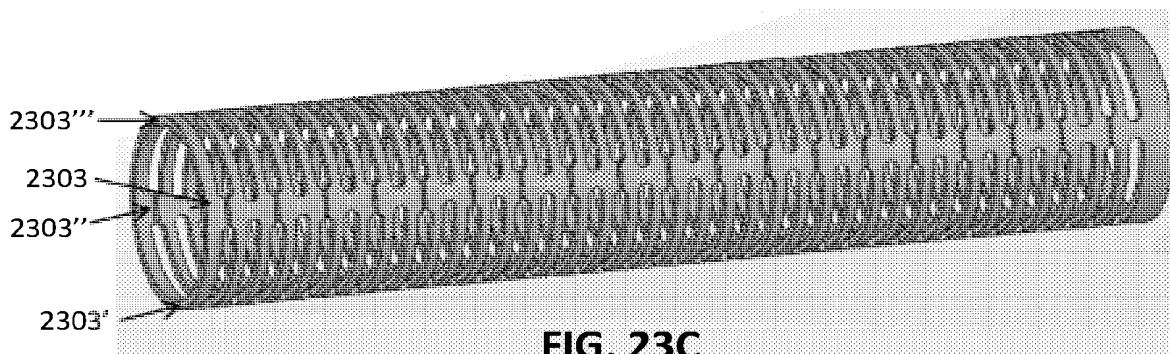


FIG. 23C

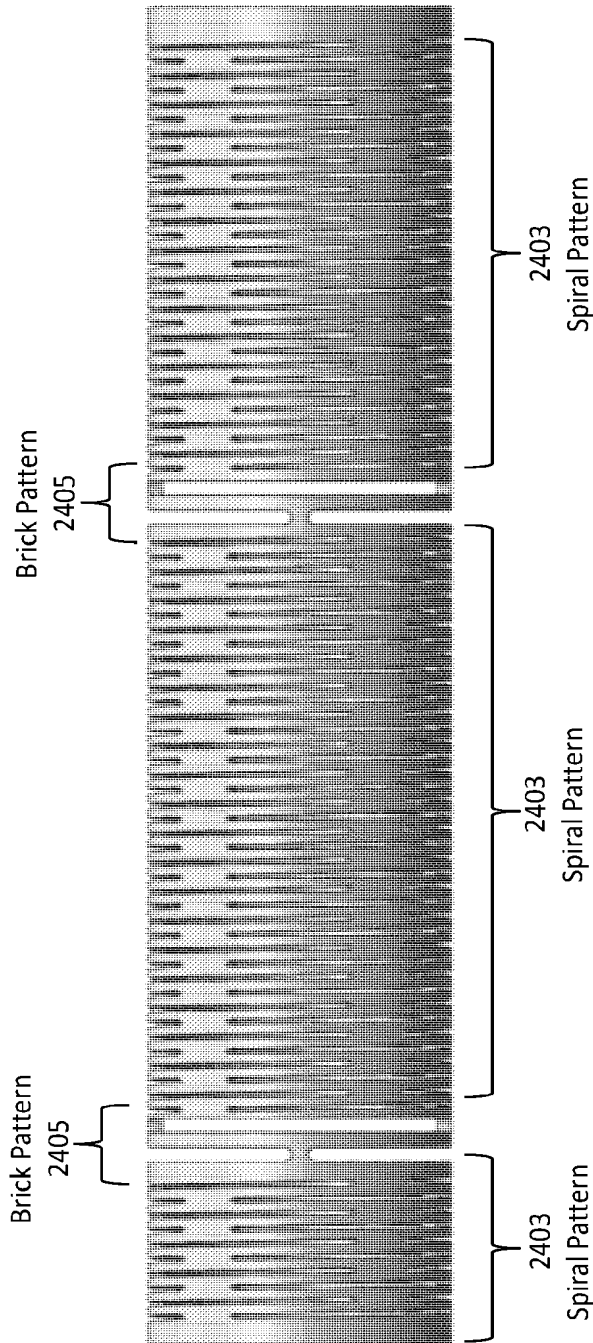


FIG. 24A

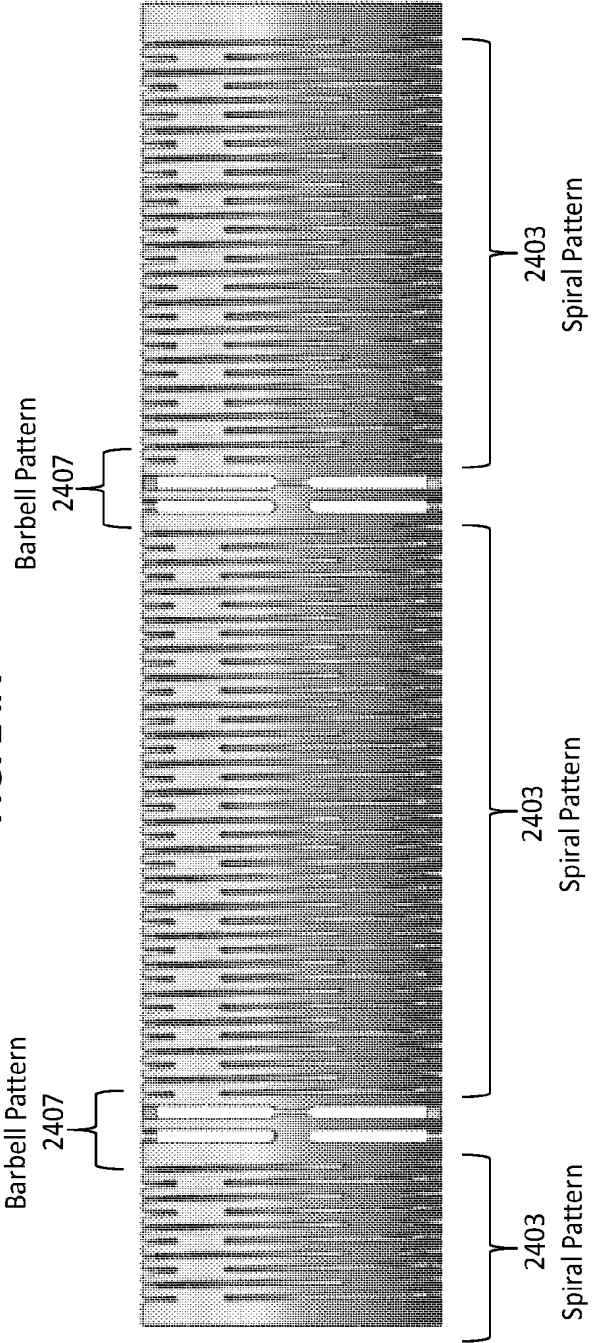


FIG. 24B

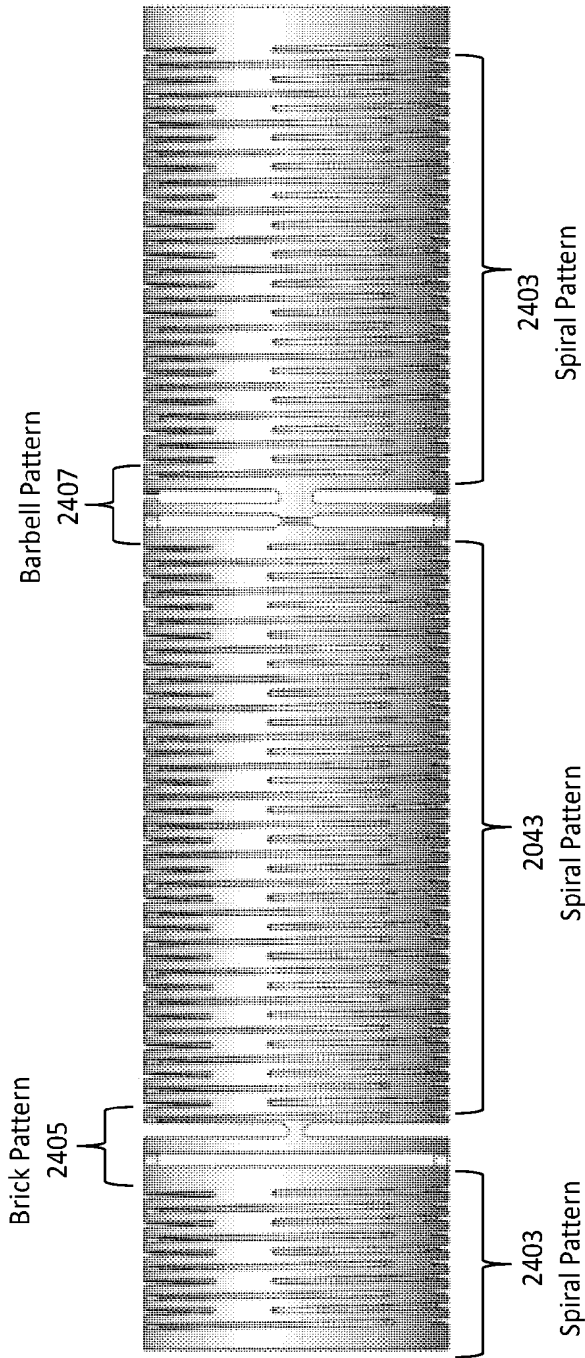


FIG. 24C

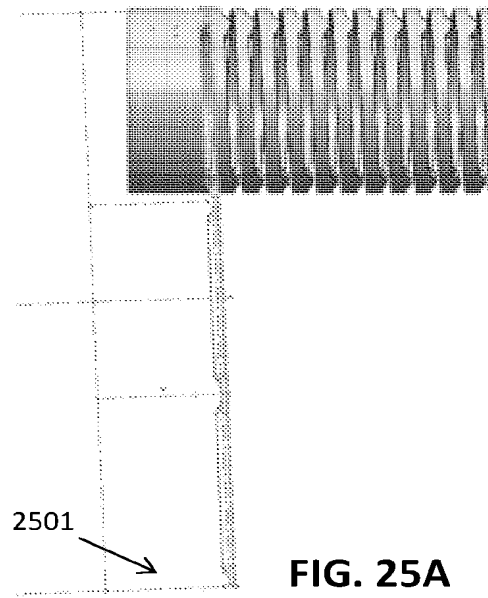


FIG. 25A

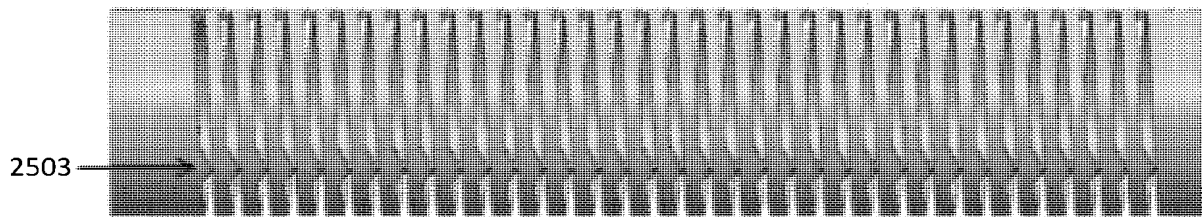


FIG. 25B

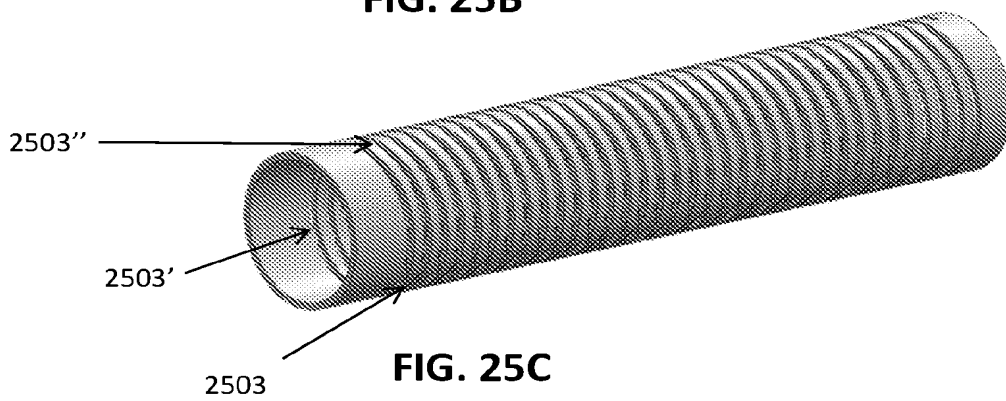


FIG. 25C

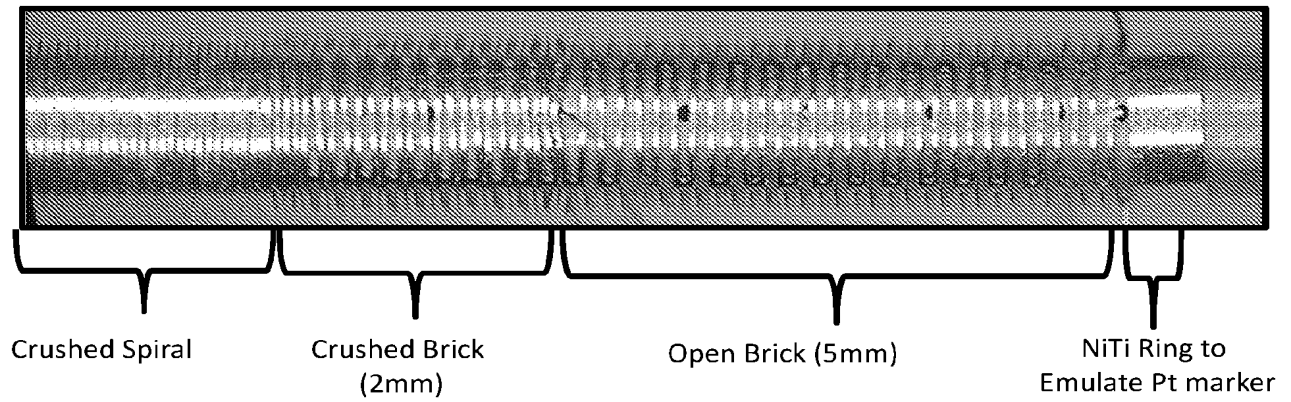


FIG. 26

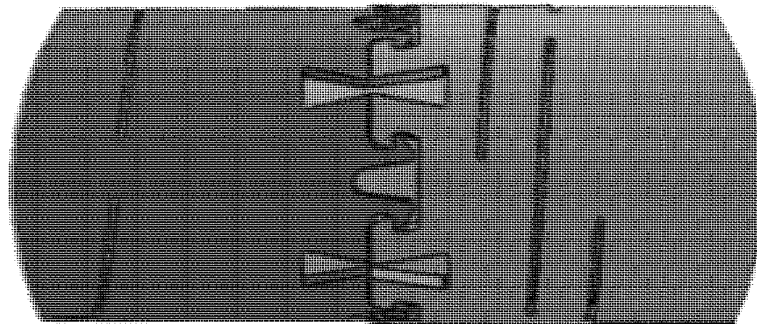


FIG. 27

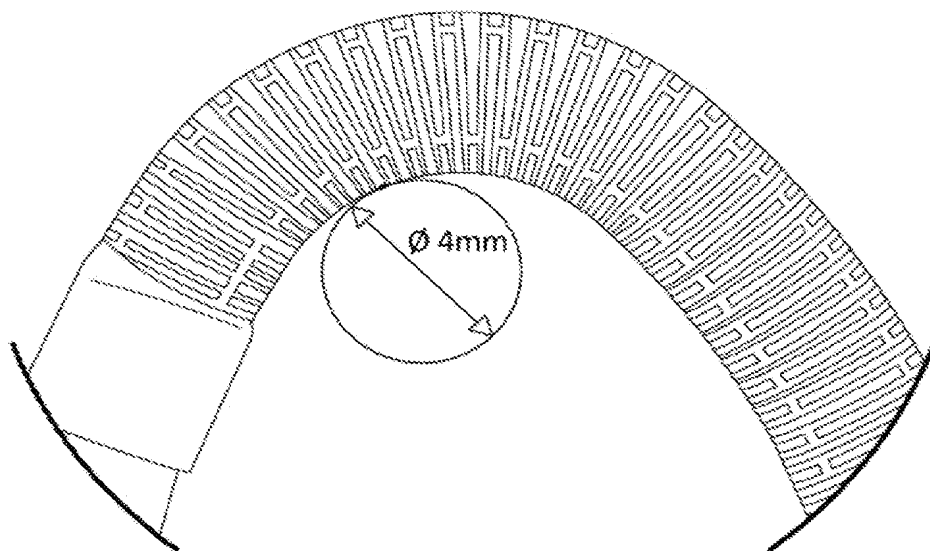
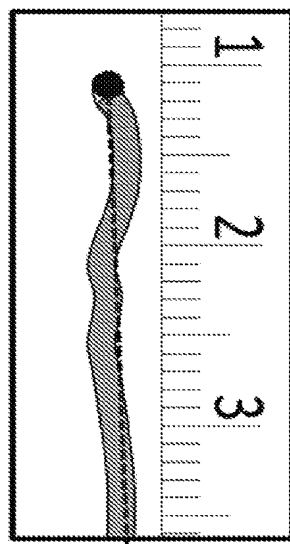


FIG. 28

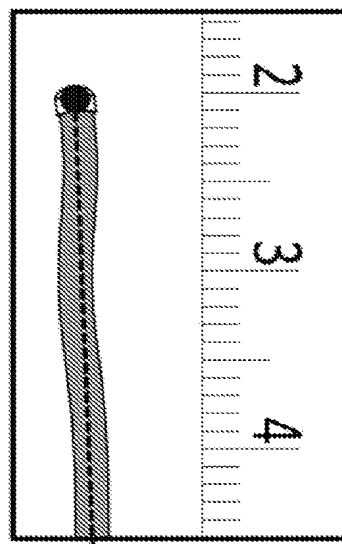
TRADITIONAL CATHETER
BUCKLES & FAILS



100g

FIG. 29A

880 CATHETER
NO BUCKLING



500g

FIG. 29B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/040937

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/040937

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/221
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2017/086864 A1 (GREENHALGH E SKOTT [US] ET AL) 30 March 2017 (2017-03-30) paragraph [0021]; figures 1-6 paragraph [0064] paragraph [0121] - paragraph [0125] paragraph [0164]	1-22
Y	----- US 2013/226196 A1 (SMITH JAMES [ZA]) 29 August 2013 (2013-08-29) paragraph [0112] - paragraph [0114]; figures 4, 10	1-10
A	----- US 2010/249815 A1 (JANTZEN ALEXANDRA E [US] ET AL) 30 September 2010 (2010-09-30) abstract; figures 1, 2 ----- -/--	1,10



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

25 October 2018

Date of mailing of the international search report

14/11/2018

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Moers, Roelof

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/040937

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2016/074627 A1 (COTTONE ROBERT J [US]) 17 March 2016 (2016-03-17) paragraph [0095] - paragraph [0100]; figures 7A-8D -----	11-22
A	AU 2015 210 338 A1 (SHIFAMED HOLDINGS LLC) 27 August 2015 (2015-08-27) paragraph [0087] - paragraph [0092]; figures 3-7b -----	11-22
A	US 2005/177132 A1 (LENTZ DAVID J [US] ET AL) 11 August 2005 (2005-08-11) paragraph [0027]; figures 1-7 -----	11,22

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2018/040937

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2017086864 A1	30-03-2017	CN 108348319 A EP 3355829 A1 JP 2018529495 A US 9463035 B1 US 2017086864 A1 WO 2017058280 A1	31-07-2018 08-08-2018 11-10-2018 11-10-2016 30-03-2017 06-04-2017
US 2013226196 A1	29-08-2013	US 2013226196 A1 WO 2012049652 A1 ZA 201302264 B	29-08-2013 19-04-2012 30-04-2014
US 2010249815 A1	30-09-2010	NONE	
US 2016074627 A1	17-03-2016	CN 107148289 A EP 3194003 A1 JP 2017532104 A US 2016074627 A1 WO 2016044211 A1	08-09-2017 26-07-2017 02-11-2017 17-03-2016 24-03-2016
AU 2015210338 A1	27-08-2015	AU 2015210338 A1 AU 2018203003 A1	27-08-2015 17-05-2018
US 2005177132 A1	11-08-2005	EP 1768732 A2 US 2005177132 A1 US 2010100073 A1 WO 2006009588 A2	04-04-2007 11-08-2005 22-04-2010 26-01-2006

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-10

Thrombectomy apparatus having knitted tractor tube.

2. claims: 11-22

Thrombectomy apparatus having slotted inversion support catheter.



(51) International Patent Classification:

A61B 17/221 (2006.01) A61M 1/00 (2006.01)
A61B 17/34 (2006.01)

(21) International Application Number:

PCT/US2018/059607

(22) International Filing Date:

07 November 2018 (07.11.2018)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/583,803 09 November 2017 (09.11.2017) US
62/664,822 30 April 2018 (30.04.2018) US

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Ct., Union City, California 94587 (US). **GREENHALGH,**
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19035 (US).

(74) Agent: **BURSE, David, T.** et al.; Vista IP Law Group LLP,
2160 Lundy Avenue, Suite 230, San Jose, California 95131
(US).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,
HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP,
KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME,
MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,

OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA,
SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every

kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments (Rule 48.2(h))

(54) Title: INVERTING THROMBECTOMY APPARATUSES HAVING ENHANCED TRACKING

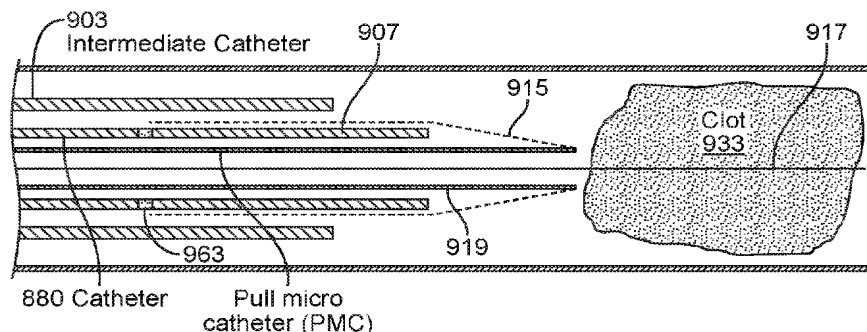


FIG. 9A

(57) Abstract: Mechanical thrombectomy apparatuses, and particularly knitted rolling tube mechanical thrombectomy apparatuses configured to have improved tracking for delivery through tortuous vessels are described herein.

INVERTING THROMBECTOMY APPARATUSES HAVING ENHANCED TRACKING

FIELD

[0001] The apparatuses and methods described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses and methods.

BACKGROUND

[0002] Many vascular problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery. It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue, such as blood clots, from within a patient's vasculature may improve patient quality of life.

[0003] Mechanical thrombectomy devices may be particularly advantageous. There is a definite need for thrombectomy devices, and particularly a mechanical thrombectomy devices that can be easily and accurately delivered through the, often tortuous, anatomy in the peripheral and central vasculature, then reliably deployed to remove clot material. Described herein are apparatuses (devices, systems and kit) and methods of using them that may address the needs and problems discussed above.

SUMMARY

[0004] Described herein are inverting tractor mechanical thrombectomy apparatuses (devices, systems, etc.) and methods of using and making them.

[0005] In particular, described herein are inverting tractor mechanical thrombectomy apparatuses that are configured to have improved tracking within even the most tortuous vessels of the anatomy. These inverting tractor mechanical thrombectomy apparatuses may be referred to herein as mechanical thrombectomy apparatuses. The method and apparatuses described herein may include the use of a deliver catheter (e.g., "intermediate catheter") that

is pre-loaded with the mechanical thrombectomy apparatus in a specific arrangement that provides enhances tracking, and methods of using them to reach, and remove, clot.

[0006] Also described herein are adaptations to mechanical thrombectomy apparatuses that allow them to remove particularly large clots without breaking or disrupting the clot, even if the rolling tractor portion of the mechanical thrombectomy apparatus is not able to pull additional clot into the apparatus.

[0007] Typically, the mechanical thrombectomy apparatuses described herein are inverting thrombectomy apparatuses (also referred to herein as inverting tractor thrombectomy apparatuses and inverting tube thrombectomy apparatuses) that include a flexible tube (e.g., tractor tube, tractor region, tractor portion, etc.) and an elongate inversion support catheter. The tractor tube generally comprises a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support. The flexible tube may be formed of a knitted material, and may be configured (e.g., sized, oriented, etc.) to roll smoothly over the distal end opening of the elongate inversion support catheter.

[0008] The flexible tube may be configured so that it is doubly biased, in order to prevent jamming and to grab and compress relatively large clots as it rolls and inverts into the elongate inversion support catheter at the distal end opening of the elongate inversion support catheter; the flexible tube may be biased so that it has an expanded (e.g., relaxed) un-inverted configuration having an outer diameter that is approximately the same or slightly larger than the inner diameter of the elongate inversion support catheter, which may be referred to as a second configuration of the flexible tube. The flexible tube may also be further biased so that it has an expanded (e.g., relaxed) inverted configuration (which may be referred to as a first configuration) having an inner and outer diameter that is larger than the outer diameter of the elongate inversion support catheter. The inner diameter in this first configuration may be greater than 1.2x (e.g., between 1.2x and 10x, between 1.2x and 8x, between 1.2x and 6x, between 1.2x and 5x, between 1.2x and 3x, etc.) the outer diameter of the inversion support catheter. Thus, when the flexible tube is placed in and over the distal end of the inversion support catheter, a first (inner) portion of the tractor tube is within the distal end of the elongate inversion support catheter in the un-inverted configuration and it is biased to expand towards (and in some configuration against) the inner diameter of the inversion support catheter; the region of the flexible tube that is inverted over the distal end opening of the inversion support catheter and extends proximally down the outside of the inversion support catheter is in an inverted configuration in which the inner diameter of the flexible tube is biased to be larger than the outer diameter of the inversion support catheter. This double-

biased configuration may be a result of the weave pattern (e.g., knitting), and/or a shape setting of the material forming the tractor tube, which may be a shape memory material. As a result, the inverting portion of the flexible tube, where it rolls and inverts over itself at the distal end of the inversion support catheter may be prevented from collapsing on itself as the tractor tube is rolled and pulled into the inversion support catheter. In some variations this configuration may also result in a somewhat flattened (e.g., and in some cases “trumpet shaped”) distal end face that is rolling over the distal end opening of the elongate inversion support catheter. The trumpet-shaped distal end may have a teardrop-shaped cross-section. In some variations, the distal end face of the flexible tube may be T-shaped.

[0009] Also described herein are variations in which the first configuration of the flexible tube on the outside of the inversion support catheter (which may be referred to herein as an elongate inversion support catheter) may be flush or nearly flush with the outer diameter of the inversion support catheter, e.g., within 50%, 40%, 30%, 20%, etc. of the outer diameter of the inversion support catheter.

[00010] The flexible tube may be coupled to a puller that is within the lumen of the inversion support. The puller may be a wire, filament, rod or more preferably a catheter or tube (and may be referred to herein as a pull micro catheter or “PMC” for convenience). A guidewire may be passed through the flexible tube, and therefore through the inversion support and the tractor tube. As will be described herein, this may be used for positioning.

[00011] The inversion support catheter may be configured as a catheter having a distal end opening into which the tractor inverts. The flexible tube may invert and rolls back into itself and may be drawn into the inversion support in a conveyor-like motion; the outward-facing region rolls around to become an inward-facing region, e.g., within the lumen of the inversion support catheter. The rolling motion may thus draw a clot or other object within a vessel into the inversion support. The inversion support catheter may be shaped or configured to have a sufficient column strength to withstand the compressive pulling force of the flexible tube as it is drawn (and rolled, inverting) into the distal end of the inversion support catheter. The inversion support catheter may be slotted (e.g., may include a plurality of slots or openings) to provide increased flexibility as well as column strength. However, as will be described herein, many inversion support catheters may become less flexible (e.g., more rigid) when a compressive force is applied to the flexible tube, either as a result of pulling the flexible tube proximally, either from within the inversion support catheter, or from the outside of the inversion support catheter as the flexible tube brushes against the vessel and/or a delivery catheter when being driven distally towards a clot.

[00012] Thus, described herein are mechanical inverting thrombectomy apparatuses that are adapted to enhance tracking as the apparatus is positioned within the vessel by pushing it distally away from an insertion point into the body to the site of the thrombus. These apparatuses and methods may include pre-loading the apparatus within an intermediate catheter in a particular configuration allowing it to track more easily, as well as variations in which the flexible tube is held within the inversion support catheter and deployed near the clot. Finally, described herein are apparatus in which the flexible tube (e.g., mesh, weave, knit) to limit or prevent the application of a compressive force on the inversion support catheter that may otherwise reduce flexibility and maneuverability of the inversion support catheter.

[00013] Also described herein are apparatuses for removing extensive clots, even when the flexible tube portion of the apparatus has been completely inverted, without breaking the clot and risking release of the clot back into the bloodstream where it could cause further harm.

[00014] For example, described herein are apparatuses that use one or more vacuum sources that may be applied either or both when initially contacting a clot and/or when removing the clot after being completely or partially engulfed by the flexible tube (tractor) portion of the apparatuses described herein. For example, the inverting tube apparatus (e.g., a mechanical thrombectomy apparatus) is configured to be inserted through a vessel such as a blood vessel, artery, etc., until a distal end, or a distal-most end, of the inverting tube apparatus is proximate to a clot. The clot may be immediately adjacent to the end of the apparatus, or it may be within a few cm (e.g., within 1 cm, within 2 cm, within 3 cm, within 4 cm, etc.). This may be detected by visualization, such as fluoroscopy. Thus, the apparatuses described herein may include one or more markers for visualization. Contrast may be used to visualize the clot and/or may be released from the apparatus. The apparatus may be deployed in a pre-loaded/pre-assembled configuration, as will be described in more detail below.

[00015] The flexible tube may be knitted and/or the apparatus may be configured with the opening into the vacuum lumen (e.g., through the puller catheter) at the distal-most end of the device, so that the flexible tube extends behind (proximal) the distal-facing end of the puller catheter. For example, the method of removing a clot from a vessel may include: advancing an inverting tube apparatus through a vessel until a distal end of the inverting tube apparatus is proximate to a clot, wherein the inverting tube apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller catheter within a lumen of the elongate support catheter, and a knitted tube having a first end coupled at a distal end region of the puller catheter, wherein knitted tube inverts over a distal

end of the inversion support catheter and extends proximally between the intermediate catheter and the inversion support catheter, further wherein the knitted tube comprises a filament that is knitted to form a plurality of interlocking loop stitches; advancing the puller catheter distally so that a distal face of puller catheter extends distally from the inverting tube apparatus further than the knitted tube; applying a vacuum through the puller catheter to engage the clot with the distal face of the puller catheter; and pulling the puller catheter proximally to roll the knitted tube over a distal end of the inversion support catheter so that the knitted tube inverts over the distal end of the inversion support catheter, captures the clot, and pulls the clot proximally into the inversion support catheter.

[00016] A large clot may be a clot that is typically longer than the capacity of the apparatus to hold within the flexible tube. This is described in greater detail herein, but may be, e.g., a 12:1 ratio (where, for every 12 cm of, e.g., woven, flexible tube, 1 cm of length of clot may be contained within the woven flexible tube). In general, large clots may have a large diameter and/or a long length. Longer clots may include clots having a length that is about 0.5 m or longer (e.g., about 1 cm or longer, about 2 cm or longer, about 3 cm or longer, about 4 cm or longer, about 5 cm or longer, etc.).

[00017] With respect to removing larger clots, the second end may reach the distal end of the inversion support catheter while a portion of the clot extends distally from the inversion support catheter so that at least a portion of the clot extends out of the flexible tube. The second end of the flexible tube may be prevented (stopped) from inverting over the end of the inversion support catheter, or it may be inverted and flipped (e.g., by advancing the intermediate catheter) in a non-traumatic way that prevents or limits the risk of breaking/tearing/disrupting the clot.

[00018] In any of these variations, suction may be applied through the inverting tube apparatus (e.g., through the intermediate catheter and/or the inversion support catheter) when withdrawing the inversion support catheter and puller with the clot attached proximally into the intermediate catheter.

[00019] The second end of the flexible tube may comprise a cuff that is less flexible than a region of the tube adjacent to the cuff. As will be described in more detail below, the cuff may be formed as a material attached to or applied onto/over the end of the flexible tube. For example, the second end of the flexible tube may comprise a cuff formed of a polymeric material applied onto/over the knitted tube. The cuff may be slit or cut (e.g., all or partially along its length) to provide some flexibility when pulling over or around the end of the tube. For example, the cuff may include longitudinal slits along its length. The cuff may have a

durometer that is greater than the durometer of the flexible tube (e.g., knitted tube). The cuff, in some variations, is thicker than the flexible tube. In any of the variations described herein, the cuff may be radiopaque (e.g., by including a radiopaque material, such as platinum) on or within the cuff.

[00020] As mentioned, the apparatus may be configured so that the end (e.g., the second end) of the flexible tube may be prevented from inverting and rolling over the distal end of the inversion support catheter by simply pulling proximally on the puller. Thus, in any of these variations, the intermediate catheter may be configured to push the cuff over the distal end of the inversion support catheter when the intermediate catheter is advanced distally past the cuff

[00021] Specifically described herein are apparatuses using flexible knitted tubes (tractors) as part of any of the mechanical thrombectomy apparatuses described herein. For example, the knitted flexible tubes may be configured to have stitch lengths that assist in capturing of clot within the vessel, even where the vessel has a larger inner diameter than the outer diameter of the flexible tube in an expanded configuration outside of the inversion support catheter. In particular, apparatuses in which the stitch length is within a range of lengths that may be set by the dimension of the vessel (e.g., blood vessel, artery, peripheral vessel, etc.) and/or the outer diameter of the inversion support catheter. For example, a stitch length may be between about 0.5mm and 10 mm and/or may be selected based on the dimension of the vessel into which the apparatus is to be operated to remove a clot.

[00022] For example, described herein are method of removing a clot from a vessel having an inner diameter (ID), the method comprising: advancing an inverting tube apparatus through the vessel until a distal end of the inverting tube apparatus is proximate to a clot, wherein the inverting tube apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller within a lumen of the support catheter, and a knitted tube having a first end coupled at a distal end region of the puller and a second end, wherein the knitted tube extends between the intermediate catheter and the inversion support catheter; further wherein the knitted tube comprises a filament knitted to form a plurality of interlocking loop stitches, wherein each loop stitch has a stitch length that is between the difference of 25% of the ID and one half the outer diameter (OD) of the inversion support catheter and 65% of the ID and one half of the OD of the inversion support catheter; pulling the puller proximally to roll the knitted tube over the distal end of the inversion support catheter so that the knitted tube inverts over a distal end of the inversion

support catheter driving the loop stitches outward, captures the clot, and pulls the clot proximally into the inversion support catheter.

[00023] Any of these methods may be used in particular with apparatuses in which the flexible tube is configured to remain relative snug on the inversion support catheter (e.g., within 50% (e.g., 40%, 30%, 25%, 20%, 15%, 10%, etc.) of the outer diameter of the inversion support catheter in the expanded (unconstrained) first configuration. In general, these apparatuses may expand at or near the distal-facing ends of the flexible tube, where the tube is inverting over itself, but may not be expanded at more proximal regions. This may form the T-shaped, Y-shaped, and/or trumpet-shaped distal end faces of the flexible tubes described herein. For example, in some variations, the knitted tube extends over the inversion support catheter with an inner diameter that is within 20% of the OD the inversion support catheter.

[00024] The second end of the knitted tube may comprise a cuff that is less flexible than a region of the knitted tube adjacent to the cuff, as described above and further herein. Alternatively, or additionally, the knitted tube may be shape-set to have a narrower region at the second end region (near the second end) of the flexible tube.

[00025] As mentioned above, in general, each loop stitch may have a stitch length that is between the difference of 25% of the ID and one half the outer diameter (OD) of the inversion support catheter and 65% of the ID and one half of the OD of the inversion support catheter. For example, each loop stitch may have a stitch length that is between the difference of 30% of the ID and one half the OD of the inversion support catheter and 60% of the ID and one half of the OD of the inversion support catheter (e.g., between the difference of 35% of the ID and one half the OD of the inversion support catheter and 50% of the ID and one half of the OD of the inversion support catheter, between the difference of 40% of the ID and one half the OD of the inversion support catheter and 45% of the ID and one half of the OD of the inversion support catheter, between the difference of 25% of the ID and one half the OD of the inversion support catheter and 45% of the ID and one half of the OD of the inversion support catheter, etc.). The stitch length may refer to the longitudinal (in the proximal-to-distal axis, which may curve or bend) of the knitted tube. The knitted tube may be formed of one or more filaments (or filament bundles) that are knitted into the tube to form interlocking links (loop stitches). The filament material may be relatively stiff, such as a wire, e.g., Nitinol wire, that when knitted has a material flexibility. The knit may be coated with a material (e.g., a lubricious material, etc.). Examples of knits are illustrated in, e.g.,

U.S. app. no. 15/496,570, filed on 4/25/2017 (“Anti-Jamming and Macerating Thrombectomy Apparatuses and methods”), previously incorporated by reference in its entirety.

[00026] For example, an inverting tube apparatus for removing a clot from a vessel may include: an intermediate catheter; an inversion support catheter within a lumen of the intermediate catheter; a puller within a lumen of the elongate support catheter; and a knitted tube extending over the inversion support catheter, the knitted tube having a first end coupled at a distal end region of the puller and a second end that is free, wherein the knitted tube is configured to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the knitted tube rolls and inverts over a distal end of the inversion support catheter; further wherein the knitted tube comprises a filament knitted to form a plurality of interlocking loop stitches, wherein each loop stitch has a stitch length that is between 0.5mm and 10mm.

[00027] As mentioned, the knitted tube may extend over the inversion support catheter with an inner diameter that is within 20% (e.g., within about 10%, 15%, 20%, 25%, 30%, 40%, etc.) of the outer diameter of the inversion support catheter (e.g., relatively snugly to or against the inversion support catheter). The second end of the knitted tube may comprise a cuff that is less flexible than a region of the knitted tube adjacent to the cuff.

[00028] Any of the methods and apparatuses described herein may include an expanded flexible tube portion that expands outward less than the diameter of the vessel over much (e.g., greater than about 50%, about 60%, about 70%, about 75%, about 80%, about 90%, etc.) of its length while having an expanded second end region that has a much smaller diameter near this second end region (e.g., having a diameter that is within about 10%, 15%, 20%, 25%, 30%, 40%, etc. of the inversion support catheter). This configuration may allow even larger-diameter clots (e.g., from the peripheral vasculature) to be engulfed and safely removed with apparatuses having a much narrower diameter than the vessels in which the clots are located.

[00029] For example, described herein are inverting tube apparatus for removing a clot from a vessel, the apparatus comprising: an inversion support catheter; a puller within a lumen of the inversion support catheter; and a knitted tube extending over the inversion support catheter in a first configuration, the knitted tube having a first end coupled to a distal end region of the puller, and a second end that is free to move relative to the inversion support catheter, wherein the knitted tube is configured to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the knitted tube rolls and inverts over a distal end of the inversion support catheter into a second configuration within the inversion

support catheter; further wherein the knitted tube in the first configuration has an expanded outer diameter that is between 0.5 mm and 12 mm for a first region of the knitted tube that is adjacent to the first end, and the knitted tube in the second configuration has an inner diameter that is greater than 30% of an inner diameter of the inversion support catheter, and wherein a second region of the knitted tube adjacent to the second end has an expanded outer diameter that is less than the expanded outer diameter of the region of the knitted tube adjacent to the first end and within 20% of an outer diameter of the inversion support catheter.

[00030] As mentioned, the knitted tube in the first configuration may have an expanded outer diameter (unconstrained) that is between 0.5 mm and 12 mm; in some variations this expanded outer diameter is between 0.5 mm and 15 mm, e.g., between about 0.5 mm and about 14 mm, between about 0.5 mm and about 13 mm, between about 0.5 mm and about 11 mm, between about 0.5 mm and about 10 mm, between about 0.5 mm and about 9 mm, between about 0.5 mm and about 8 mm, between about 3 mm and about 15 mm, between about 4 mm and about 15 mm, between about 5 mm and about 15 mm, between about 3 mm and about 12 mm, between about 4 mm and about 12 mm, between about 5 mm and about 12 mm, between about 3 mm and about 10 mm, between about 4 mm and about 10 mm, between about 5 mm and about 10 mm, etc.

[00031] Any of the apparatuses described herein may include a cuff at the second end, wherein the cuff has a stiffness that is greater than a region of the knitted tube adjacent to the cuff. Alternatively, or additionally, any of these apparatuses may include a stop configured to limit the travel of the knitted tube so that the second end does not roll and invert over the distal end of the inversion support catheter.

[00032] The knitted tube may be shape set so that the first configuration has the outer diameter between, e.g., 0.5 mm and 10 mm for the region of the knitted tube adjacent to the first end, and the knitted tube in the second configuration has an inner diameter that is greater than, e.g., about 30 % (e.g., about 40%, about 50%, about 60%, etc.) of the inner diameter of the inversion support catheter.

[00033] The first region of the knitted tube (having the larger expanded diameter) may be any appropriate length (e.g., at least about 0.5 cm, about 1 cm, about 2 cm, about 3 cm, about 4 cm, about 5 cm, about 6 cm, about 7 cm, about 8 cm, about 9 cm, about 10 cm, etc.). Similarly, the second region (having the narrower expanded diameter) may be any appropriate length (e.g., at least about 0.5 cm, about 1 cm, about 2 cm, about 3 cm, about 4 cm, about 5 cm, etc.).

[00034] The knitted tube may comprise a filament knitted to form a plurality of interlocking loop stitches, wherein each loop stitch has a stitch length that is between a predetermined range (e.g., between about 0.5mm and 8 mm, about 0.5 to 10 mm, about 0.5 mm to 12 mm, about 0.5 to 14 mm, etc.). This may permit, for example, at a region of the knitted tube that is inverting from the first configuration to the second configuration, a subset of the plurality of loop stitches forming the knitted tube may extend proud from the long axis of the knitted tube by between 0.5 mm and 10 mm (e.g., between about 0.3 mm and about 8 mm, between about 0.5 mm and about 8 mm, between about 0.5 mm and about 7 mm, between about 0.5 mm and about 6 mm, greater than about 1 mm, greater than about 2 mm, greater than about 3 mm, greater than about 4 mm, greater than about 5 mm, etc.) as the knitted tube inverts.

[00035] Any of these apparatuses may include an intermediate catheter having a lumen as described herein. The inversion support catheter may be within the lumen of the intermediate support catheter and may be extended distally from the intermediate catheter to deploy the knitted tube so that the flexible tube may expand into the first configuration.

[00036] As mentioned, described herein are methods for removing a clot from a vessel a larger diameter (and therefore a larger clot diameter) than even the expanded flexible tube of the apparatus. For example, described herein are methods of removing a clot from a vessel having an inner diameter (ID) comprising: advancing an inverting tube apparatus through the vessel until a distal end of the inverting tube apparatus is proximate to a clot, wherein the inverting tube apparatus comprises an inversion support catheter, a puller within a lumen of the support catheter, and a knitted tube having a first end coupled to a distal end region of the puller, and a second end that is free to move relative to the inserting support catheter, wherein the knitted tube comprises a filament knitted to form a plurality of interlocking loop stitches, wherein each loop stitch has a stitch length; expanding the knitted tube to a first configuration along an outer surface of the inverting tube catheter to an outer diameter that between 10% and 80% of an inner diameter of the vessel for a first region of the knitted tube that is adjacent to the first end, wherein the knitted tube has a second configuration within the inverting tube catheter having an inner diameter that is greater than 30% of an inner diameter of the inversion support catheter, and wherein a second region of the knitted tube adjacent to the second end has an expanded outer diameter that is less than the expanded outer diameter of the first configuration; pulling the puller proximally within the inversion support catheter to roll the knitted tube over the distal end of the inversion support catheter so that the knitted tube inverts over a distal end of the inversion support catheter, driving the loop stitches

outward from the knitted tube by between 0.5 and 10 mm; capturing the clot with the knitted tube; and pulling the clot proximally into the inversion support catheter.

[00037] Expanding of the flexible tube (e.g., knitted tube) may comprise exposing the knitted tube from out of an intermediate catheter, wherein the inversion support catheter is within a lumen of the intermediate support catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[00038] The features and aspects of the various embodiments of the disclosed inventions are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00039] FIG. 1A illustrates one example of a delivery catheter (“intermediate catheter” or I.C.) that may be used with a mechanical thrombectomy apparatus as described herein.

[00040] FIGS. 1B-1C2 illustrate components of a mechanical (e.g., inverting tractor) thrombectomy apparatus; FIG. 1B shows an example of an elongate inversion support catheter that is configured to include a plurality of slots (shown here as transverse slots) arranged along the catheter in order to enhance flexibility of the elongate inversion support catheter while providing sufficient column strength to resist buckling as the tractor tube is drawn proximally to invert. The slot pattern of FIG. 1B is intended as a single example only. Other slot/cut-out patterns may be used. FIGS. 1C1 and 1C2 show a tractor tube inverted (e.g., in an inverted configuration) over a puller; in FIG. 1C1 the puller is a puller catheter (PMC) while in FIG. 1C2 the puller is a guidewire. The tractor tube is shown schematically and may be a knitted, woven, or braided material.

[00041] FIGS. 2A-2C illustrate the operation of an inverting tractor mechanical thrombectomy apparatus as described above. FIG. 2A shows the assembled apparatus in which the tractor tube is coupled to the puller and within the elongate inversion catheter with the tractor tube inverting over the distal end of the elongate inversion catheter. FIG. 2B shows the apparatus of FIG. 2A delivered within a vessel near a clot. FIG. 2C shows the operation of the apparatus to withdraw the clot by pulling proximally on the tractor tube from within the elongate inversion support catheter so that the tractor tube is pulled to roll over and evert from the inverted configuration on the outside of the distal end of the elongate inversion support catheter into the un-inverted configuration within the elongate inversion support catheter, pulling the clot with it.

[00042] FIG. 2D illustrates an example of a tortious path that the inverting tractor mechanical thrombectomy apparatus may have to navigate in order to reach the clot.

[00043] FIG. 3A is an example of a preloaded assembly of an inverting tractor mechanical thrombectomy apparatus within an intermediate catheter that may be used as described in order to deliver an inverting tractor mechanical thrombectomy apparatus through a tortious vessel to a deployment location. In this example, the elongate inversion support catheter is held within the intermediate catheter (and may be locked in position) until deployed, while the pusher (e.g., PMC) and tractor are partially extending distally. A guidewire may also be used. FIG. 3B shows a prototype assembly (pre-assembled) similar to that shown in FIG. 3A.

[00044] FIG. 4A is another example of a preloaded assembly of an inverting tractor mechanical thrombectomy apparatus within an intermediate catheter that may be used as described in order to deliver an inverting tractor mechanical thrombectomy apparatus through a tortious vessel to a deployment location. In this example, the elongate inversion support catheter is extended from the intermediate catheter, and extends distally along with the puller (PCM). FIG. 4B shows a prototype assembly (pre-assembled) similar to that shown in FIG. 4A. FIG. 4C shows an example of a preloaded assembly such as the one shown in FIG. 4A and 4B navigating through a model of a tortious vessel. FIG. 4D is another example of a prototype pre-assembled assembly (inverting tractor mechanical thrombectomy apparatus) such as the one shown in FIG. 4A.

[00045] FIG. 5A is another example of a preloaded assembly of an inverting tractor mechanical thrombectomy apparatus within an intermediate catheter that may be used to deliver an inverting tractor mechanical thrombectomy apparatus through a tortious vessel to a deployment location. In this example, the elongate inversion support catheter, and the tractor tube are held within the intermediate catheter, and the distal end (extending beyond the attachment to the tractor tube) of the puller extends distally. FIG. 5B shows a prototype assembly (pre-assembled) similar to that shown in FIG. 5A.

[00046] FIG. 6 is an example of a non-over-the-wire variation of an inverting tractor mechanical thrombectomy apparatus in which the puller is a guidewire, similar to the variation shown in FIG. 2C2.

[00047] FIGS. 7A-7C illustrate one example of an inverting tractor mechanical thrombectomy apparatus in which the apparatus is configured for delivery of the tractor tube within the elongate inversion support catheter so that it may later be deployed (as illustrated in FIGS. 7A-7C) to move the tractor tube portion so that it is inverted over the elongate inversion support catheter distal end.

[00048] FIGS. 8A-8C illustrate another method of deploying an inverting tractor mechanical thrombectomy apparatus (where the apparatus is configured for delivery of the tractor tube within the elongate inversion support catheter) so that the tractor tube portion is inverted over the elongate inversion support catheter distal end when at the deployment region near the clot. In both FIGS. 7A-7C and 8A-8C, withdrawing the tractor tube into the elongate inversion support catheter may prevent it from applying a compressive force on the elongate inversion support catheter as it is deployed through the vessel, either with an intermediate catheter or without an intermediate catheter.

[00049] FIGS. 9A-9K illustrate one method of delivering and deploying an inverting tractor mechanical thrombectomy apparatus pre-loaded into an intermediate catheter such as the one shown in FIGS. 3A-3B. Similar methods may be employed to deliver the pre-loaded variations shown in FIGS. 4A and 5A.

[00050] FIGS. 10A-10D illustrate another example of a method of delivering and deploying an inverting tractor mechanical thrombectomy apparatus pre-loaded into an intermediate catheter such as the one shown in FIGS. 3A-3B.

[00051] FIGS. 11A-11C illustrate a method of using an inverting tractor mechanical thrombectomy apparatus to remove clot after the tractor tube portion of the inverting tractor mechanical thrombectomy apparatus has been completely withdrawn into the elongate inversion support catheter.

[00052] FIG. 12A illustrates an inverting tractor mechanical thrombectomy apparatus configured to prevent the tractor tube from retracting fully into the elongate inversion support catheter. In FIG. 12A the tractor tube has a distal end region that is non-compliant and configured so that it cannot invert over the distal end of the elongate inversion support catheter.

[00053] FIG. 12B shows an example of a cuff on the distal end of an inverted flexible tube.

[00054] FIGS. 13A shows a knitted tractor tube extending in an inverted configuration over the outside of a distal end of an elongate inversion support catheter. FIG. 13B shows the knitted tractor of FIG. 13A applying compressive force to the elongate inversion support catheter when the apparatus is advanced distally. FIG. 13C illustrates an inverting tractor mechanical thrombectomy apparatus configured to hold the knitted tractor tube in a compressed state (in which the transversely arranged, or approximately transversely arranged loops forming the knit overlap over more than 20% of their longitudinal length).

[00055] FIGS. 14A-14D illustrate examples of inverting tractor mechanical thrombectomy apparatuses (e.g., elongate inversion support catheter portions) including a stop that is configured to hold the knitted tractor tube in a compressed configuration. In FIG. 14A a polymer stop is shown. In FIG. 14B a Nitinol braid stop has exposed filaments (“fingers”) that prevent proximal sliding of the tractor tube. FIG. 14C shows another example of a Nitinol braid stop has exposed filaments (“fingers”) that prevent proximal sliding of the tractor tube. FIG. 14D shows a Nitinol knit segment configured as a stop to prevent proximal sliding of the tractor tube during delivery.

[00056] FIGS. 15A-15G illustrate examples of finger-like stop elements similar to those shown in FIGS. 14B-14C. The distally-directed prongs, filaments or fingers of the stops shown may be placed anywhere along the length of the outer surface of the elongate inversion support catheter to prevent compression of the knitted tractor tube during delivery and deployment.

[00057] FIGS. 15H is another example of a stop on the outer surface of an elongate inversion support catheter having distally-facing prongs that prevent proximal movement of a woven tractor tube, in order to prevent compressive forces on the elongate inversion support catheter.

[00058] FIGS. 16A and 16B illustrate examples of annular housings (“garages”) for the tractor tube on the outer surface of an elongate inversion support catheter that may also maintain the tractor tube in a compressed configuration on an outer surface of the apparatus, preventing it from applying compressive force on the distal end of the elongate inversion support catheter. In FIG. 16A, a 48-end braid forms an annular garage for holding the end of the tractor tube so that it remains in a compressed configuration along the outer surface of the elongate inversion support catheter. In FIG. 16B, the apparatus includes a 10 mm long braided region (similar to that shown in FIG. 15A, housing the end of the knitted tractor tube and preventing it from extending proximally and applying compressive forces on the distal end of the elongate inversion support catheter.

[00059] FIG. 17 is an example of one variation of an elongate inversion support catheter having a high column strength in compression, but a high flexibility when not under compression. In FIG. 17, the elongate inversion support catheter includes a plurality of slots or cut-out regions arranged approximately transverse to the elongate length (e.g., long axis). Any of these devices may also include a marker (e.g., platinum, or other radiopaque material) allowing visualization of the distal end region of the elongate inversion support catheter.

[00060] FIGS. 18A-18J illustrate a method of removing a clot from a vessel as described herein, in which a vacuum (suction) may be applied through the puller to make and confirm initial contact with the clot. In FIG. 18A, the apparatus is distally advanced over a guidewire adjacent to the clot. The apparatus may initially be in a tracking configuration as shown and discussed, in which the outer (inversion support) catheter is retracted into the lumen of the intermediate catheter while the puller (puller catheter) with the attached flexible tube extending proximally from the distal end, is tracked over the guidewire. In FIG. 18B, the apparatus is changed to a clot-grabbing configuration in which the inversion support catheter is extended towards the distal end of the apparatus, though still proximal to the puller distal end. The intermediate catheter may also optionally be withdrawn proximally, as shown in FIG. 18C, which in some variations (not shown in FIG. 18A-18J) may allow the flexible tube to expand outwards. FIG. 18C1 shows an example of a prototype device corresponding to FIG. 18C. Once in position, suction may be applied through the puller catheter, as shown in FIG. 18D. This focal suction may be applied while advancing the apparatus distally to engage the clot, as shown in FIG. 18E. The guidewire may be left in place or optionally removed (as shown in FIGS. 18D-18E). Once engaged with the clot at the distal end of the puller, which may be detected by observing the flow and/or pressure through the puller from the suction, the puller may be drawn proximally and/or the inversion support catheter may be moved distally so that the flexible tube rolls over the distal end opening of the inversion support catheter. In FIG. 18F approximately 30% of the clot has been drawn into the inversion support catheter by rolling the flexible tube; in FIG. 18G, more, but not all (e.g., approximately 70%) of the clot has been ingested, though a substantial amount of clot remains outside of the inversion support catheter and flexible tube. The vacuum may be left on, or it may be turned off while pulling the puller proximally to engulf/grab the clot. Heavy arrows indicate movement of the components of the apparatus, such as the intermediate catheter, which may be advanced distally, the inversion support catheter, which may also be advanced distally, and the puller, which may be withdrawn proximally. These motions may be coordinated by the handle (not shown) and/or performed manually by the user. Once the flexible tube has reached the distal end of the inversion support catheter, it may stop or be stopped, to prevent it from rolling over the distal end. In FIG. 18A-18J the second end of the flexible tube includes a cuff that may prevent the flexible tube from rolling over the distal end when pulling proximally on the puller, as shown in FIG. 18H. In FIG. 18I, the intermediate catheter is shown advancing distally beyond the cuff and distal end of the intermediate support catheter, which inverts the cuff over and against the clot without breaking or

disrupting the clot. A vacuum (suction) through the intermediate catheter is also shown being applied (by the small arrows). As shown in FIG. 18J, the flexible tube, puller and inversion support catheter are then drawn proximally into the intermediate catheter along with the un-engulfed portion of the clot, either by driving the intermediate catheter distally over them, and/or by pulling the inversion support catheter (which may be pulled with the puller) proximally.

[00061] FIG. 19 illustrates an example of a mechanical thrombectomy apparatus having a knitted flexible tube that is configured to operate even in larger-diameter vessels (having proportionally larger-diameter clots) by configuring the stitch length of the knitted tube to help grab larger-diameter clots.

[00062] FIG. 20A illustrates a larger-diameter clot (e.g., shown in the top as a 15 mm OD, 5 cm long clot) that was captured using a narrower-diameter mechanical thrombectomy apparatus having a knitted flexible tube portion (shown having an expanded outer diameter of 5 cm with an 8F inversion support catheter). The removed clot is shown on the bottom above the ruler.

[00063] FIG. 20B shows a side view of a distal end region of a similar mechanical thrombectomy apparatus having a knitted flexible tube that inverts into a 3 mm inversion support catheter. The knitted flexible tube has a 6 mm expanded first configuration, but may remove clots having an outer diameter much larger (e.g., a 15 mm outer diameter clot, as shown in FIG. 20A).

[00064] FIG. 21A illustrates an example of a relationship between the length of flexible tube required for a mechanical thrombectomy apparatus as described herein in order to completely engulf (“eat”) a clot having an outer diameter of 15 mm and a length of 5 cm. In this example, the flexible tube is a knitted or woven tube formed of heat-set 0.01 inch NiTi wire.

[00065] FIG. 21B shows example of the distal ends of mechanical thrombectomy apparatus tested in FIG. 21A, showing variations with 8 mm expanded outer diameter, 5 mm expanded outer diameter, and 3 mm outer diameter, as well as an 8 French (8F) inversion support catheter.

[00066] FIG. 22A shows another example of a cuff that may be at the second end of a flexible tube of a mechanical thrombectomy apparatus. In FIG. 22A, the cuff includes a plurality of slits that may engage with the intermediate catheter (IC) when it is driven distally past the cuff to drive the cuff to invert over the distal end of an inversion support catheter, as shown in FIG. 18I, controllably preventing inversion when pulling the puller, but allowing

inversion without disrupting the clot when advancing the intermediate catheter, as illustrated in FIG. 22B, showing inversion of the cuff after driving the intermediate catheter distally.

[00067] FIGS. 23A-23B illustrate example of the proximal end of a mechanical thrombectomy apparatus, showing the components of the apparatus (e.g., guidewire, inner/inversion support catheter, puller, and intermediate catheter). FIG. 23B shows another example, of a proximal end of the mechanical thrombectomy apparatus showing manual controls, including vacuum attachment ports, for the different regions.

[00068] FIGS. 24A-24B illustrate another example of a set of proximal end controls for a mechanical thrombectomy apparatus. In FIG. 24A the apparatus control region is shown in a first puller position (prior to pulling the clot in). In FIG. 24B the apparatus control region is shown after pulling the clot (showing the puller hub extended proximally).

[00069] FIG. 25 illustrate an example of a mechanical thrombectomy apparatus in which the flexible tube is configured to cut tissue as it rolls into the inversion support catheter. In this example, the flexible tube is a knitted tube that includes sharp cutting edges that may be used to cut through tissue.

[00070] FIGS. 26A-26B illustrate two exemplary side perspective views of mechanical thrombectomy apparatuses. In FIG. 26A, similar to that shown in FIGS. 18A-18J, the apparatus include a flexible (e.g., knitted) tube that is attached at the first end to a puller catheter and is configured to expand within the inversion support catheter to an outer diameter that is greater than 40% (shown here, it's greater than 90%) of the inner diameter of the inversion support catheter, driving the region of the flexible tube within the inversion support catheter against the walls, even when unloaded by clot. The other region (un-inverted) of the flexible tube along the outer diameter of inversion support catheter is shown as snug with the inversion support catheter in the un-constrained configuration. This results in the Y-shaped distal profile, for the inverting flexible tube, which may help grab even larger diameter clots.

[00071] FIG. 26B illustrates another example of a mechanical thrombectomy apparatus in which the expanded outer profile of the flexible tube is expanded beyond the outer diameter of the inversion support catheter near the first end where it attaches to the puller, but the second end, that is freely sliding over the inversion support catheter, has a much smaller (nearly snug) expanded diameter. This region may also or alternatively include a cuff as described herein.

[00072] FIGS. 27A-27C illustrate operation of a mechanical thrombectomy apparatus having a cuff on one end of the flexible tube.

[00073] FIGS. 28A-28C illustrate one example of a mechanical thrombectomy apparatus that includes a cuff retainer that may aid in re-sheathing the apparatus into an intermediate catheter.

[00074] FIGS. 29A-29C illustrate another example of a mechanical thrombectomy apparatus that includes a cuff retainer.

[00075] FIGS. 30A-30C illustrate another example of a mechanical thrombectomy apparatus that includes a cuff retainer.

[00076] FIGS. 31A-31C illustrate another example of a mechanical thrombectomy apparatus that includes a cuff retainer (configured as a stop).

[00077] FIGS. 32A-32F illustrate examples of mechanical thrombectomy apparatus including a cuff that is adapted at the proximal-facing end to aid in re-sheathing into an intermediate catheter. FIGS. 32A-32C illustrate cuffs having a tapered proximal end region. FIGS. 32D and 32E illustrate cuffs having angled proximal-facing sides. FIG. 32F is an example of a cuff having a proximal stent-like region.

[00078] FIGS. 33A-33E illustrate one example of a re-loading mechanical thrombectomy apparatus in which a single-use sub-assembly (including the puller, cuff and flexible tube) can be withdrawn and a new sub-assembly inserted.

[00079] FIGS. 34A-34C illustrate operation of a re-usable/reloadable mechanical thrombectomy apparatus.

[00080] FIG. 35 schematically illustrates one example of an ejection apparatus that may be used to assist in ejecting captured clot material and/or reloading of a mechanical thrombectomy apparatus.

DETAILED DESCRIPTION

[00081] In general, described herein are inverting tractor mechanical thrombectomy apparatus having a tractor tube, configured as an inverting flexible tractor tube that may be pulled proximally to invert over and into the distal end of an elongate inversion support catheter. An end of the tractor tube may be coupled to a puller (e.g., pull wire, pull catheter, etc.) to provide the proximal pulling force. In particular, described herein are apparatuses and methods of using them that improve or enhance tracking of the apparatus from a patient insertion side (e.g., a femoral region or elsewhere) through a tortuous vessel, to a deployment site where the apparatus may be deployed to mechanically remove a clot by rolling the tractor tube into the elongate inversion support catheter and grabbing the clot.

[00082] In general, the apparatus may be adapted to improve tracking by preventing stiffening or loss of flexibility of the elongate inversion support catheter that may otherwise occur when the tractor tube, which may extend along a substantial distance proximally from the distal open end of the elongate inversion support catheter, applies a compressive force on the elongate inversion support catheter. This may occur, for example, when the apparatus is deployed through the vessel and/or through an intermediate catheter. Although the outer surface of the elongate inversion support catheter, and/or the outer surface of the tractor tube may be lubricated to reduce friction, the distal movement of the apparatus may still result in a drag force on a portion of the tractor tube that is on the outside surface of the elongate inversion support catheter. The resulting drag force is transferred to the distal end of the elongate inversion support catheter, resulting in a compressive force on the elongate inversion support catheter. An example of this is illustrated in FIG. 13B, described in greater detail below.

[00083] This issue may be exacerbated when the apparatus includes an elongate inversion support catheter that is configured to have both a high column strength (resisting compression) and an increased flexibility, e.g., by including one or more cut-outs, slots, etc. arranged down the length of the elongate inversion support catheter. For example, metal tubes (e.g., Nitinol tubes, etc.) having transversely arranged slots cut into them along the length of the elongate inversion support catheter may have a high column strength, while remaining sufficiently flexible (at least in an unloaded/un-tensioned configuration).

[00084] In general, an inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an elongate inversion support catheter (such as those mentioned above), having a distal end and a distal annulus (distal end opening), and a flexible tractor assembly including a flexible tractor tube coupled to an elongate puller within the elongate inversion support catheter. The flexible tractor tube is configured to roll and invert over the distal end opening of the elongate inversion support catheter. Knitted tractor tubes are of particular interest and described herein, although it should be understood that other tractor tubes, e.g., woven, braided, etc., may be used.

[00085] Tracking of any of the inverting tractor mechanical thrombectomy apparatus described herein may include an intermediate catheter (I.C.) as a delivery catheter along with a guidewire. For example, FIG. 1A illustrates an example of a typical intermediate catheter 101 that may be used. Note that in some variations, as will be illustrated below, an intermediate catheter is not needed or used and the inverting tractor mechanical

thrombectomy apparatus may be delivered to the deployment site near the clot to be removed without the need for an intermediate catheter.

[00086] FIG. 1B illustrates one example of an elongate inversion support catheter. In this example, the elongate inversion support catheter 103 is formed of a normally high column-strength material (such as a metal, e.g. Nitinol) having a number of openings (e.g., cut-out regions) or slots along the length to provide enhanced flexibility. The distal end of the elongate inversion support catheter is open 105. Either the entire length or a portion of the length may be cut/slotted as described. The elongate inversion support catheter includes a catheter body having a distal end region that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 05 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing hardness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00087] In FIG. 1B, the elongate inversion support catheter is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of compressive force is applied (e.g., able to withstand at least about 500g, at least about 700 g, at least about 600 g, at least about 500 g, at least about 400 g, at least about 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include an elongate inversion support catheter that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like. In FIG. 1B the catheter 103 of the elongate inversion support catheter may be any appropriate

type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00088] In some variations the distal end 105 of the elongate inversion support catheter is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in some variations the distal tip (end) may be curved or radiused, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[00089] FIG. 1C1 shows an example of a flexible tractor tube 111 coupled to an elongate puller 113, forming a pullable tractor assembly 140. In this example, the tractor tube 111 is shown integrated with the puller 113 and extending back over the puller. The puller in this example is a catheter (e.g. a micro catheter, also referred to herein as a PMC or pull micro catheter). In this example, the opposite end of the flexible tractor tube 111 is open and free (e.g., not connected to the puller or catheter, e.g. elongate inversion support catheter). As will be described in greater detail below, this open, free, end may be adapted to be expanded and held open, e.g., by shape setting back on itself and/or by including an annular bias, to enhance deployment and positioning of the catheter between the flexible tractor tube and the puller. In FIGS. 1C1 and 1C2, the tractor tube is formed of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The tractor 111 is shown extended from the puller in a first configuration. It may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 111 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The tractor 111 may be configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first configuration to a radial diameter that is between 1.1 and 10 times (e.g., between 1.1x and 5x, between 1.1x and 4x, etc.) the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained. In FIG. 1C2, the tractor tube 111 is shown coupled to a guidewire (non-hollow structure) 115. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00090] FIG. 2A illustrates an example of an inverting tractor mechanical thrombectomy apparatus 200 deployed. In FIG. 2B the inverting tractor mechanical thrombectomy apparatus is shown deployed near a clot 209. In the deployed configuration the puller 201 (shown here as a puller micro catheter) is held within the elongate inversion support catheter so that the

flexile tractor tube 203 extends from the end of the puller and expands toward the inner radius of the elongate inversion support catheter 207; at the distal end opening of the elongate inversion support catheter the tractor tube inverts over itself and extends proximally in an inverted configuration over the distal end of the elongate inversion support catheter. As shown in FIG. 2C, by pulling the puller proximally, the tractor tube rolls and everts over the distal end opening of the elongate inversion support catheter, drawing the adjacent clot into the elongate inversion support catheter, as shown.

[00091] FIG. 2A the elongate inversion support catheter is positioned between the tractor tube and the puller so that the tractor tube can be pulled proximally by pulling on the puller and rolling the tractor tube into the elongate inversion support catheter so that it inverts. The portion of the tractor tube that is inverted over the distal end of the elongate inversion support catheter has an outer diameter that is greater than the outer diameter of the elongate inversion support catheter. The tractor is biased so that it has a relaxed expanded configuration with a diameter that is greater than the outer diameter (OD) of the elongate inversion support catheter; in addition, the tractor tube may also be configured (e.g., by heat setting, etc.) so that when the tractor tube is everted and rolled over the distal end opening into the elongate inversion support catheter, the outer diameter of the tractor tube within the elongate inversion support catheter has an outer diameter that is greater than the inner diameter of the elongate inversion support catheter (e.g., greater than 0.1x, 0.5x 0.6x, 0.7x, 0.75x, 0.8x, 0.9x, 1x, etc. the inner diameter, ID, of the elongate inversion support catheter. This combination of an uninverted diameter of the tractor tube of greater than the diameter of the OD of the elongate inversion support catheter and an inverted diameter of the tractor tube of greater than 0.7x the ID of the elongate inversion support catheter is surprisingly helpful for preventing jamming of the apparatus, both when deploying the apparatus and when rolling the tractor over the distal end opening of the elongate inversion support catheter to grab a clot. The tractor may be expandable and may be coupled to the puller as shown. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to elongate puller (e.g., a push/pull wire or catheter).

[00092] In FIG. 2C the clot may be drawn into the elongate inversion support catheter by pulling the tractor proximally into the distal end of the elongate inversion support catheter, as indicated by the arrows 211, 211' showing pulling of the inner portion of the flexible tractor, resulting in rolling the tractor over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled into the catheter, shown

by arrows. The end of the tractor outside of the catheter may be “loose” relative to the outer wall of the catheter.

[00093] In general the mechanical thrombectomy apparatuses described herein may be highly flexible, both before actuating and during operation. For example, the flexible tractor may not increase the stiffness/flexibility of the catheter or the elongate inversion support, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortuous vessels of the neurovasculature. Described herein are flexible tractor tube portions that increase the stiffness of the last “y” cm (e.g., the distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[00094] The tractors may be woven, braided and/or knitted materials. For woven and braided materials, which may include a plurality of fibers that are woven or braided to form the inverting tube, these structures may be tuned to prevent jamming and/or to reduce the force necessary to pull the tractor and invert over the catheter tip. For example, the mechanical atherectomy apparatus may include a braid-type tractor that can roll freely around the tip of catheter even in a tortuous anatomy and when grabbing clot by tuning one or more of the braid structure; minimizing the braid angle; including a hydrophilic coating on the distal aspect of the catheter outer diameter (OD) or the inner diameter (ID) of the braid (e.g., tractor); including a radiused wall on the catheter; and/or increasing the stiffness of the distal tip region relative to adjacent proximal regions. Alternatively, it may be advantages to have a hydrophilic coating on 1, 3, 5, 10, or 15 cm of the distal ID or the entire catheter ID. This may even enhance aspiration of the clot without a tractor element.

[00095] As mentioned, the tractor (e.g., braided, woven, knitted, etc.) may be configured to collapse down into the inner diameter (ID) of the catheter as little as possible. For example the tractor may collapse to an ID that is greater than, equal to, or within 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter inner diameter (ID)/Catheter Tip OD, since, when the tractor is being pulled around catheter tip it may create axial tension on the tractor (e.g., braid, knit, etc.) that can inadvertently cause the tractor to jam on the catheter tip. When tractor is pulled around catheter tip, the tractor is being pulled in the axial orientation creating

axial tension on tractor structure as the tractor is being pulled through the catheter ID. By having the tractor elements jam at an ID greater than or equal to 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter ID (or in some variations, OD), when being axially tensioned, the tractor is less likely to grab/synch down onto the catheter tip, helping the braid roll around the catheter tip with less axial force applied by the user. If less axial force is required by the user to pull the tractor structure around the tip then the catheter tip is less likely to buckle or deflect when retracting the tractor. It may be advantageous to minimize the chance the catheter tip will buckle. The tractor can be tuned to "jam" at a specific ID by controlling any of the following variables and in any combination: selecting a specific number of braid ends, selecting the size/diameter of the braid ends; selecting the braid material (e.g., multifilament or monofilament); heat setting the bias on the braid (e.g., braid diameter); and selecting a braid pattern, e.g., 1x2, 1x1 or any other pattern.

[00096] The braid angle may be minimized to prevent locking up of the rolling of the tractor over the catheter end opening. Typically, the lower the braid angle (e.g., 45 degrees or less, 40 degrees or less, 35 degrees or less, 30 degrees or less, 25 degrees or less, 20 degrees or less, etc.) the less likely it is to have the braid cross over points catch on the catheter tip.

[00097] In any of the variations described herein, the catheter and/or a surface of the tractor may be coated to enhance rolling over the distal end region of the catheter. It may be helpful to have a hydrophilic coating on the distal aspect of the catheter OD or the ID of the tractor so the tractor can more easily slide over the catheters distal end and around the tip of the catheter when pulled through the inside of the catheter.

[00098] The radius wall of the catheter tip may be chosen/set to within a range that allows sliding. For example, it may be helpful for the tip of the catheter to have the largest radius possible but at least 0.025" radius wall on the catheter, ideally approximately 0.05" radius wall.

[00099] The stiffness of the distal of the elongate inversion support catheter may be sufficiently stiff to prevent collapse as the tractor is pulled; it may also be lubricious (e.g., by a coating or material property). The distal most section of the elongate inversion support catheter tip (e.g., the last 5mm) may be fabricated of a material which is stiff enough and lubricious enough so the distal tip of the catheter does not collapse or buckle inward ward when the braid structure is rolling around the catheter tip. Thus, the distal tip may have a stiffness that is greater than the more proximal region at the distal end of the catheter.

[000100] It may be helpful or desirable to have pores in the tractor. A lack of gaps or small pore size may limit the ability of the braid to grab clot. Alternatively or additionally, it may

be desirable to form a braid structure with texture. One example is to braid two or more different diameter braid ends into the same structure: the difference in braid end diameters will help form a texture to the braid structures outer surface, aiding the grabbing of the clot when rolling the braid-dozer around the catheter tip.

[000101] As an alternative (or in addition) the tractor may be configured to lock so it does not compress in diameter during axial load by adding a coating, laminate or adhesive to the braid at a desired diameter. Adding a thin coating, laminate or adhesive can inhibit the braid elements from sliding with respect to each other, thereby locking the braid to a specific diameter. The coating can be applied while leaving the majority of the pores and pore area substantially open. Examples of thin coatings include urethanes and silicones with and without hydrophilic coatings and hydrophilic coatings with no tie layer.

[000102] As mentioned above, any of the apparatuses described herein may be configured to provide enhance delivery of the apparatus though the tortious anatomy of the vessels in order to deploy the apparatuses near the clot. For example, FIG. 2D illustrates an example of a tortious path 250 that may be navigated by the apparatuses (including in particular the apparatuses that are pre-loaded into an intermediate/delivery catheter).

[000103] PRELOADED APPARATUSES

[000104] One solution to the problem with tracking of the inverting mechanical thrombectomy apparatuses such as those described herein, and particularly those having a high flexibility, high column strength elongate inversion support catheter (which may stiffen when placed under even relatively small compressive forces from their distal end by the tractor tube) is to preload the inverting mechanical thrombectomy apparatuses within an intermediate catheter so that a portion of the inverting mechanical thrombectomy apparatus is protected within the body of the intermediate catheter, while the rest of the intermediate catheter portion is advanced over and/or along (with) a guidewire. For example, FIG. 3A illustrate one example of a pre-loaded inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy. In this example, the apparatus may include an intermediate catheter 303 having a distal end 305. The intermediate catheter (I.C.) may be considered part of the inverting mechanical thrombectomy apparatus, although in other variations it may be considered a separate component that is used with the inverting mechanical thrombectomy apparatus. The apparatus also includes an elongate inversion support catheter 307 (also referred to as push catheter “880 Device” in FIG. 3) within the lumen of the intermediate catheter. The elongate inversion support catheter 307 has a distal end 311 and a distal end opening. The apparatus

also includes a puller 319 extending distally within the elongate inversion support catheter and a flexible tractor tube 315 extending proximally from a distal end region of the puller. The puller extends from the distal end of the intermediate catheter and the distal end opening of the elongate inversion support catheter.

[000105] In the pre-assembled configuration shown in FIG. 3A, the elongate inversion support catheter is held within the lumen of the intermediate catheter so that the distal end opening of the elongate inversion support catheter is proximal to the distal end opening of the intermediate catheter by a first distance 325. This distance may be between about 1mm and about 10 cm (e.g., between about 2 mm and about 10 mm, between about 2 mm and about 20 mm, between about 2mm and about 30 mm, etc.). The elongate inversion support catheter may be fixed in position relative to the intermediate catheter, so that as the two catheters move together, until released. For example, the proximal ends of the intermediate catheter and the elongate inversion support catheter may be removably coupled.

[000106] The tractor tube in the pre-assembled apparatus of FIG. 3 extends between the elongate inversion support catheter and the intermediate catheter for some second distance along the length 323 of the elongate inversion support catheter. Securing the end of the tractor tube between the I.C. and the distal end of the elongate inversion support catheter may help both hold it in place, so that it may be held in compression, as will be described in greater detail below, which may also help prevent it from applying compressive force to the distal end of the elongate inversion support catheter. For example, the second length 323 may be between about 1 mm and about 50 cm (e.g., between about 5 cm and about 10 cm, between about 1 cm and about 20 cm, between about 1 cm and about 10 cm, between about 2 cm and about 20 cm, between about 2 cm and about 10 cm, etc.).

[000107] The portion of the tractor tube 315 and puller 319 (e.g., pull micro catheter, or pmc) in this pre-loaded example may extend distally and ride over the guidewire 317. The tractor tube and puller may also be longitudinally fixed relative to the intermediate catheter 303 (e.g., by releasably locking, e.g., at the distal end region) or they may be somewhat longitudinally slideable (and, in some variations, prevented from exceeding a range of, e.g., between about 1 mm and 20 cm from the distal end opening 305 of the intermediate catheter 303).

[000108] In practice, the portion 327 of the tractor tube 315 that extends outside of the intermediate catheter 303 may be between about 1 mm and about 20 cm (e.g., between about 1 cm and about 7cm, between about 1 cm and about 10 cm, between about 1 cm and about 15 cm, between about 2 cm and about 10 cm, between about 2 cm and about 7 cm, etc.). As

mentioned, this distance may be fixed (e.g., by fixing the puller with respect to the push catheter and/or I.C.), or variable. In any of these variations, the puller may extend some distance 329 beyond the distal attachment site for the flexible tractor tube, or the tractor tube may be attached at the distal end of the puller. The distance from the attachment site of the tractor tube and the distal end of the puller may be between about 0 mm and about 10 cm, for example (e.g., between about 1 mm and about 10 cm, between about 1 mm and about 5 cm, etc.).

[000109] In variations in which the pre-loaded apparatus is configured with the puller (and therefore the tractor tube) and/or the elongate inversion support catheter fixed relative to the intermediate catheter for delivery of the apparatus to the clot (e.g., adjacent to the clot), once in the deployment location, the elongate inversion support catheter and/or puller may be unlocked so that they may move independently of the intermediate catheter. In some variations, the elongate inversion support catheter may be unlocked first, so that it can be advanced distally into the tractor tube and over the puller; once the distal end of the elongate inversion support catheter is near the attachment site for the tractor tube on the puller, the puller may be also be released (manually or automatically).

[000110] FIG. 3B illustrates another example of a pre-loaded apparatus (pre-loaded inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy). In FIG 3B, the tractor tube is a knit 355 that is bonded to the puller near a distal end region, described in FIG. 3A. The distal end region of the puller (pmc) 337 extends from the intermediate catheter 343. The opposite end 345 of the tractor tube, approximately 1 cm) is held between the intermediate catheter and the elongate inversion support catheter 341, which is entirely within the intermediate catheter. Exemplary dimensions are shown by the ruler above the prototype device.

[000111] Another variation of a pre-loaded inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy is shown in FIGS. 4A-4D. In FIG. 4A, the apparatus contains the same elements shown in FIG. 3A, but they are arranged and interact in a different manner. For example, the pre-loaded apparatus includes an intermediate catheter 403 with an open distal end 405, an inner elongate inversion support catheter 307, a tractor tube 415 and a puller 419. In FIG. 4A, the tractor tube is connected to a distal end region of the puller (e.g., within a fixed distance 425 of the distal end of the puller, e.g., between about 0mm and 10 cm (e.g., about 1 mm to about 10 mm, etc.) as in the example in FIG. 3A. The opposite end of the tractor tube is held between the intermediate catheter 403 and the elongate inversion support catheter 407, as in

FIG. 3A. For example, between about 1 mm and about 50 cm of tractor tube (e.g., between about 5 cm and about 10 cm, between about 1 cm and about 12 cm, etc.) may be between the intermediate catheter and the elongate inversion support catheter; the tractor tube may be held loosely, or it may be held so that the distal end of the tractor tube on the outside of the elongate inversion support catheter is compressed, it from being pulled distally by friction from the vessel walls, resulting in compressive forces on the distal end of the elongate inversion support catheter.

[000112] In FIG. 4A, the elongate inversion support catheter is secured in position relative to the puller so that the distal end opening of the elongate inversion support catheter is near the attachment site for the tractor tube on the puller. For example, the distance between the elongate inversion support catheter distal end opening and the attachment site for the tractor tube 429 may be between about 0 mm and about 10 cm (e.g., between about 0 mm and about 1 mm, between about 0 mm and about 2 mm, between about 1 mm and about 5 mm, between about 1 mm and about 3 mm, etc.). As discussed above for FIG. 3A, the puller, elongate inversion support catheter and intermediate catheter may be releasably locked together so that they move together. The portion of the puller from the attachment site of the tractor tube to the distal end of the puller 425 may, as described for FIG. 3A, above, be between about 0 mm and about 10 cm (e.g., between about 0 mm and about 7 mm, between about 0 mm and about 5mm, etc.).

[000113] In operation, the pre-assembled apparatus shown in FIG. 4A may advance distally (e.g., over a guidewire) towards a clot in a vessel with the slightly more flexible distal end portion consisting of a distal portion of the puller, tractor and elongate inversion support catheter extending distally from the distal opening of the intermediate catheter by a distance 427 that may be, for example,, between about 1 cm and 20 cm (e.g., between about 2 cm and about 7 cm, between about 1 cm and 10 cm, between about 2 cm and about 7.5 cm, etc.). This presents a more flexible distal end region that tapers slightly over the guidewire, allowing the apparatus to navigate tortuous vessels, including those having branches. Once the distal end of the apparatus is within the deployment region, near (e.g., adjacent to) the clot to be removed, the apparatus may be deployed by removing the coupling between the intermediate catheter, puller and elongate inversion support catheter, and allowing the intermediate catheter to be withdrawn at least slightly, and for the elongate inversion support catheter to be advanced while withdrawing the tractor tube proximally to roll the tractor tube so that it everts over the distal end opening of the elongate inversion support catheter.

[000114] FIG. 4B illustrates an example of distal end of a prototype pre-assembled apparatus similar to that shown in FIG. 4A. In FIG. 4B the apparatus is shown over a guidewire 417 with the elongate inversion support catheter 407 near the attachment site 433 for the tractor tube onto the distal end region of the puller; a distal end region of the puller 431 extends from the tractor tube attachment site to the distal end opening of the puller.

[000115] FIG. 4C illustrates tracing of an apparatus 460 such as the one shown in FIG. 4B through a tortuous model of a blood vessel 455; the flexible distal end leads the device in tracking and navigating through the vessel. FIG. 4D illustrates another example of a distal end region of a pre-loaded inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel, also showing exemplary dimensions. In FIG. 4D, the apparatus is threaded over a movable guidewire 417, and shows a knitted tractor tube 415' that is attached to the distal end region of a puller 419; an elongate inversion support catheter 407' is between the tractor and the puller, as mentioned above. This is pre-loaded into an intermediate catheter 403'.

[000116] Another example of a pre-loaded inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortuous anatomy. In FIG. 5A, unlike the variations shown in FIG. 3A and 4A, both the elongate inversion support catheter 507 and the tractor tube 515 are held (e.g., releasably locked) within the intermediate catheter 503. This may prevent the tractor tube from pushing against the vessel wall during tracking, and therefore prevent compressive force on the elongate inversion support catheter that may otherwise result in it stiffening. In this example, a portion 509 of the puller 519 may extend distally out of the intermediate catheter, e.g., between about 0 mm to about 30 cm (e.g., between about 0.5 cm to about 20 cm, between about 1 cm to about 15 cm, between about 1 cm to about 10 cm, between about 1 cm and about 5 cm, etc.). The attachment site of the tractor tube to the puller may be at or near the distal opening of the intermediate catheter, or it may be offset by some predetermined distance 507 (or within a range of distances, e.g., between about 0 mm to about 10 cm, such as between about 1 cm to about 8 cm, between about 0 cm to about 2 cm, etc.). Similarly, the elongate inversion support catheter may be preloaded near the attachment site for the tractor tube to the puller (e.g., with a distance 505 of between about 0 mm to about 20 cm, preferably between about 0 mm and 10 mm). The entire length of the tractor tube 503 may be any appropriate length, e.g., between about 1 cm and about 60 cm (e.g., between about 5 cm and about 30cm, between about 5 cm and about 10 cm, etc.).

[000117] In operation, the apparatus shown in FIG. 5A may be deployed over a guidewire (with the component parts all removably secured together, e.g., at a proximal handle) and advanced distally until it is near the clot. In any of these examples, the guidewire may penetrate the clot or it may stop short of the clot. Thereafter, the intermediate catheter may be withdrawn proximally and/or the elongate inversion support catheter advanced distally so that the tractor tube is everted from over the distal end opening of the elongate inversion support catheter and into the elongate inversion support catheter. Pulling the puller proximally may continue to roll the tractor tube, while advancing the elongate inversion support catheter to pull the clot into the elongate inversion support catheter as the tractor tube everts.

[000118] FIG. 5B illustrates another example of the pre-loaded inverting tractor mechanical thrombectomy apparatus shown in FIG. 5A. IN this example, only the distal end of the puller 519' (referred to herein as the pull micro catheter or PMC), while the tractor tube attached more proximally to the PMC remains in the intermediate catheter (I.C.) 503'. In this example, the puller 519' rides over the guidewire 517, and has a length that is about 2 and 5 cm.

[000119] The examples shown in FIGS. 3A-5B shown above include a puller that is configured as a puller micro catheter than may be driven over a guidewire. Any of the variations described herein may instead by configured so that the puller is a guidewire, as shown in the example in FIG. 6. In this example the puller 619 is a guidewire and the tractor tube 615 is attached at one end to the puller. IN this example, the tractor is attached to the distal end of the puller, but it may be attached more proximally, as described above. The elongate inversion support catheter 607 is interposed between the puller and the tractor tube, and may be extended distally so that the tractor tube rolls over the distal end opening of the elongate inversion support catheter when pulling the puller to capture and remove a clot. In the variations shown in FIG. 6, the puller does not necessarily need to be a movable (i.e., longitudinally slideable) pull wire, but may be a fixed wire.

[000120] As an alternative to the pre-assembled configurations described in FIGS. 3A-5B described above, any of the apparatuses described herein may also or alternatively be configured to be deployed through an intermediate catheter that is first deployed (e.g., using a guidewire and one or more internal catheters), and left in place; the inverting tractor mechanical thrombectomy apparatus may then be delivered through the intermediate catheter.

[000121] Some variations an inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy are configured for delivery and deployment to remove a clot without needing an intermediate catheter. For example, in some variations all, or most of, the tractor tube is withdrawn into

the elongate inversion support catheter portion of the apparatus. Thus, the outer surface of the apparatus is the outer surface of the elongate inversion support catheter, which may be smooth, and/or lubricated, and therefore less likely than the tractor tube to provoke a compressive force on the distal end region that would otherwise stiffen the elongate inversion support catheter and prevent it from navigating a tortuous vessel. For example, FIGS. 7A-7C show a first example of an inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortuous anatomy that is configured to deliver the apparatus to the deployment site near the clot with the tractor withdrawn nearly fully into the elongate inversion support catheter.

[000122] In FIG. 7A, the inverting tractor mechanical thrombectomy apparatus does not include (or require) the use of an intermediate catheter, though one may be used with it (not shown). The apparatus includes an outer elongate inversion support catheter 707 that includes a stop 704 at or near the distal end. This stop 704 may be a lip, flange, protrusion, or the like, and may provide a larger diameter region that engages with a complimentary stop 816 on the end of the tractor tube 715. The opposite end of the tractor tube is connected to a puller (puller micro catheter 719) similar to the variations described above. When delivered to the clot region of a vessel the puller is withdrawn (preferably loosely, to avoid compressive forces on the elongate inversion support catheter), so that the tractor tube is withdrawn into the elongate inversion support catheter except for small portion at the distal end that is prevented from rolling into the elongate inversion support catheter by the stop on the tractor tube engaging with the stop on the elongate inversion support catheter. The apparatus may be driven over a guidewire 717, as shown, until it is proximate to the clot. FIGS. 7B and 7C illustrate a two-step method for deploying the apparatus that may be used. In This example, the apparatus may be deployed by advancing the puller distally (e.g., “pushing” the puller 775), as shown in FIG. 7B. Thus, the tractor portion will be inverted over itself, ahead of the distal end of the elongate inversion support catheter. Thereafter, as shown in FIG. 7C, the elongate inversion support catheter may be advanced distally into the pocket 777 formed by the inverted tractor tube. The apparatus is then ready for the puller to be pulled proximally to roll the tractor tube back into the elongate inversion support catheter so that it may capture a clot, and may therefore be positioned against or adjacent to the clot.

[000123] FIGS. 8A-8C show an alternative method of deploying the apparatus shown in FIG. 7A. FIG. 8A is similar to FIG. 7A, showing delivery of the apparatus to the clot over a guidewire 717. The apparatus includes the tractor tube 715 and elongate inversion support catheter 707, which include a stop on one or both of the elongate inversion support catheter

and/or tractor tube to engage the distal end of the elongate inversion support catheter with the end of the tractor tube. The apparatus may be delivered with the tractor tube retracted so that it does not tension the elongate inversion support catheter. As shown in FIGS. 8B and 8C, once near the clot, the tractor tube may be repositioned outside of the elongate inversion support catheter so that it can be rolled and used to capture a clot. In FIG. 8B, the elongate inversion support catheter is pulled proximally 851; since the distal end of the elongate inversion support catheter is engaged with the tractor tube to prevent it from sliding off of the end of the elongate inversion support catheter, when the elongate inversion support catheter is pulled proximally while holding the puller in place (or advancing it distally), the tractor tube will extend out of the elongate inversion support catheter and invert, as shown. Thereafter, as shown in FIG. 8C, the elongate inversion support catheter may be advanced distally between the fold formed by the inverted tractor tube, and the entire apparatus advanced distally back to the clot 833, as shown. Once proximate the clot, the puller may be pulled proximally to capture the clot and remove it.

[000124] FIGS. 9A-9K illustrate one method of removing a clot using a preloaded assembly of an inverting tractor mechanical thrombectomy apparatus within an intermediate catheter, such as the variation shown in FIG. 3A. In general, a method of using any of the preloaded assemblies of inverting tractor mechanical thrombectomy apparatuses described herein (e.g., in FIGS. 3A-5B), may be delivered over a wire, through a guide catheter (or a sheath or balloon guide catheter) to a clot fact, e.g., proximate the clot. The tractor tube may then be aligned so that it warps around and over the distal end of the elongate inversion support catheter and rolls into (everts) the elongate inversion support catheter. Once in positioned (against the face of the clot), the elongate inversion support catheter may be pushed distally while pulling proximally on the puller to ingest the clot, until the full length of the tractor tube is pulled proximally and rolled into the elongate inversion support catheter, unless the apparatus includes a stop to prevent it from entering the elongate inversion support catheter. Aspiration may be applied through the elongate inversion support catheter and/or the puller (when a puller micro catheter is used) to ensure that the clot remains in contact with the distal end of the elongate inversion support catheter and tractor. The intermediate catheter may then be advanced to the distal end of the elongate inversion support catheter (and aspiration may be applied through the intermediate catheter. The elongate inversion support catheter may be withdrawn proximally through the intermediate catheter while applying aspiration, which may both ease retraction of the apparatus within the intermediate catheter and may remove any residual clot portions.

[000125] For example, in FIG. 9A, the apparatus has been delivered to the region adjacent to the clot and deployed out of the intermediate catheter 903. The elongate inversion support catheter 907 and puller 919 are advanced together distally to the clot 933 face over a guidewire 917. The elongate inversion support catheter includes a marking 963 that is visible under, for example, fluoroscopy or other imaging modality. In FIGS. 9A-9K this marking on the elongate inversion support catheter is a band. In FIG. 9B, the elongate inversion support catheter is advanced distally while simultaneously or sequentially pulling the puller proximally so that the tractor tube is rolled over the distal end opening of the elongate inversion support catheter and extends slightly within the elongate inversion support catheter (shown biased against the inner diameter of the elongate inversion support catheter). The tractor extending out of the elongate inversion support catheter is pushed against the clot face. In FIG. 9B, the guidewire has been left in place; alternatively, as shown in FIG. 9C, the guidewire may be removed. Alternatively, or additionally, the intermediate catheter 903 may be withdrawn proximally, which may fully unsheath the tractor, including the distal end of the tractor. This may permit the tractor tube to roll freely over the distal end of the elongate inversion support catheter. The intermediate catheter may be locked to the elongate inversion support catheter, so that the two catheters move together while drawing the puller proximally to roll the tractor tube over the elongate inversion support catheter, as shown in FIG. 9D. In this example, aspiration (e.g., vacuum) may also be applied, e.g., from within the puller and/or elongate inversion support catheter, which may help the rolling tractor to engage with the apparatus, even before rolling the tractor into the elongate inversion support catheter by withdrawing the puller proximally.

[000126] As shown in FIG. 9E, the puller 919 (PMC) may be drawn proximally while the elongate inversion support catheter 907 is advanced towards/into the clot. As previously mentioned, the intermediate catheter 903 may optionally be advanced with the elongate inversion support catheter (e.g., the two may be coupled together for this portion of the method. This step may be continued to ingest the clot. FIG. 9F shows the clot 30% ingested while still rolling the tractor tube into the elongate inversion support catheter (e.g., by pulling on the puller and/or pushing on the elongate inversion support catheter). FIG. 9G shows the clot 80% ingested and rolling into the elongate inversion support catheter. By FIG. 9H, the tractor tube has been fully withdrawn into the elongate inversion support catheter. In this example, the marker 963 on the elongate inversion support catheter aligns with either a marker on the puller or the puller itself (if it is visible under imaging). FIG. 17 shows another example of an elongate inversion support catheter (slotted 1709 to have a high column

strength and high flexibility) in which the distal end region 1707 is marked with a platinum material to make it visible when imaging (e.g., with fluoroscopy). In FIGS. 9A-9H, the entire clot (100%) is captured by the tractor tube within the elongate inversion support catheter once the entire tractor tube has been rolled into the elongate inversion support catheter. However, this is not necessarily the case, as will be described below, in some variations additional clot may be drawn into the elongate inversion support catheter and/or the intermediate catheter by applying a combination of mechanical action (e.g., pulling the clot with the portion captured by the tractor and suction. For example, FIG. 9I shows the (optional) use of aspiration through the intermediate catheter (and in some cases, the elongate inversion support catheter). The aspiration may be left on while withdrawing the apparatus proximally, as shown in FIG. 9J. As mentioned, this may remove any remaining clot. Alternatively, or additionally a second apparatus may be installed through the intermediate catheter and delivered to the deployment site (with the intermediate catheter left in position. Finally, as shown in FIG. 9K, an angiogram may be performed through the intermediate catheter to confirm that the vessel is opened. If not, additional procedures (e.g., another preloaded assembly of an inverting tractor mechanical thrombectomy apparatus may be inserted and used to remove clot) may be performed.

[000127] In general, when deploying any of the inverting tractor mechanical thrombectomy apparatuses described herein, and in particular, the pre-loaded inverting tractor mechanical thrombectomy apparatuses, the deployment may include the general steps described below. These steps may be customized as indicated herein. First, obtaining access with sheath to the patient's common carotid or ICA. Inject contrast through the sheath to image the vessel. Before, during or shortly after, on the back table (e.g., where the proximal end of the mechanical thrombectomy apparatus is held/prepared), flush the intermediate catheter (I.C.) and connect it to a first rotating hemostatic valve (RHV A), then introduce the elongate inversion support catheter ("880 Device"), puller and tractor through RHV A, e.g., using a peel-away sheath. The elongate inversion support catheter may then be positioned relative to the I.C., e.g., within about 1 cm proximal to the tip of the I.C., as shown in FIG. 3A, and locked in position relative to the I.C. RHV A may then be tightened. A second RHV (e.g., RHV B) may be coupled to the pusher and flushed, and RHV A may be flushed as well. Flush lines may be connected. A guide wire may be loaded through the apparatus. The puller may be locked in position (e.g., as shown in FIG. 3A, extending approximately 1 cm or more from the distal end opening of the I.C.) for tracking.

[000128] The apparatus may then be tracked to the desired location (e.g., near the clot). Once in position, the apparatus may be used to perform the thrombectomy. For example, RHV A and B may be loosened. The coupling between the elongate inversion support catheter and the I.C. may be released, as may any coupling between the puller and the I.C. and/or elongate inversion support catheter. The elongate inversion support catheter may be advanced over the puller until its distal end meets the distal connection between the tractor tube and the puller. The I.C. may be pulled back to unsheath the tractor tube. The elongate inversion support catheter and I.C. may again be locked in position relative to each other. RHV A may be tightened, and the elongate inversion support catheter may be advanced to the clot face (possible with aspiration through the puller). With a slight pressure forward (distally) on the pusher (and/or I.C.), the puller may be pulled slowing proximally to ingest the clot. Alignment markers on the elongate inversion support catheter and the tractor (e.g., a region at the end of the tractor tube on the outside of the elongate inversion support catheter, or a region of the puller) may be monitored to indicate when the tractor tube is completely inverted into the elongate inversion support catheter, and the user may stop pulling proximally on the puller. RHV A may be loosened and the IC may be advanced, with aspiration, over the elongate inversion support catheter, which may remove any excess clot or pieces of clot. The elongate inversion support catheter, puller and tractor may then be withdrawn proximally through the I.C. The I.C. may remain in position and contrast applied to again image through the vessel and a TICI score determined.

[000129] Another example of the operation of a pre-loaded assembly of an inverting tractor mechanical thrombectomy apparatus is shown in FIGS. 10A-10D. For example, in FIG. 10A, the pre-assembled apparatus is similar to that shown in FIG. 3A, above. The apparatus includes an intermediate catheter 1003 that entirely houses the elongate inversion support catheter 1007 during the tracking through the tortuous vessel 1081. A puller (pull micro catheter 1019) passes through the elongate inversion support catheter, and include a tractor tube (shown as a knit tractor tube 1015) extends from an attachment site 1008 approximately 2 mm proximal to the distal end of the puller. The opposite end of the tractor tube is held between the elongate inversion support catheter and the intermediate catheter (within the intermediate catheter). In FIG. 10A, the guidewire 1017 has been inserted distally to and through a clot 1033, and the pre-loaded assembly of the inverting tractor mechanical thrombectomy apparatus is locked (e.g., so that the puller extends distally a predetermined distance and the elongate inversion support catheter is locked relative to the intermediate catheter) and advanced distally over the guide wire until it reaches the clot face.

[000130] In FIG. 10B, the puller distal end is adjacent to the clot face, and the puller may be locked in position (e.g., at the handle) while the elongate inversion support catheter is unlocked from the intermediate catheter and advanced distally over the puller and between the gap formed by the tractor tube. In this example, as the elongate inversion support catheter is advanced distally, the tractor tube may compress to a compressed/jammed state, particularly when a knit material is used, before the elongate inversion support catheter slides within its inner diameter. In FIG. 10C, the elongate inversion support catheter is advanced distally 1068 over the puller (and under the tractor tube) until the distal end of the elongate inversion support catheter is aligned with the clot, as shown. Finally, as shown in FIG. 10D, the puller may be pulled proximally 1091 while the elongate inversion support catheter is pushed distally 1093 to roll the tractor into the elongate inversion support catheter and capture the clot 1033.

[000131] As discussed above, in some variations the tractor tube may be completely rolled into the elongate inversion support catheter before a clot has been completely removed. In such cases, it may be helpful to ensure that the clot is not ripped or fragmented during the process. In order to prevent this, the apparatus may be adapted to limit the movement of the puller and/or the tractor, in addition to (or instead of) using the vacuum and intermediate catheter, as described above. FIGS. 11A-11C illustrate an example in which the clot is too long for the tractor tube apparatus to fully engulf. In FIG. 11A, similar to FIG. 9H, the clot has been captured by the tractor tube 915, which is shown fully retracted into the elongate inversion support catheter 907. The user may detect that the tractor tube has been fully retracted because either the puller 919 may be limited to prevent it moving further proximally when the tractor tube is fully retracted into the elongate inversion support catheter. Alternatively, or additionally, the tractor tube may include a first marker 963 that may align with a marker on the puller 965 when the tractor tube is fully retracted, as shown in FIG. 11A. Unlike FIG. 9H, however, in this example, the clot has not been fully captured, and some of it remains outside of the tractor and elongate inversion support catheter.

[000132] If the clot is not fully captured by the apparatus, there is a risk that continuing to pull on the clot may disrupt it, e.g., cutting it into fragments. To avoid this, the apparatus may be configured to prevent the user from continuing to apply force to the clot once the tractor has been fully deployed. As mentioned, the user may be instructed to stop drawing the puller proximally once one or more markers indicate that the tractor tube has been retracted to a predetermined position. In particular, it may be beneficial to prevent the tractor tube from fully inverting over the tractor tube, as described in FIG. 12A, below.

[000133] In some variations, the apparatus may include a stop (e.g., in a handle region) preventing or limiting the puller to prevent it from extending beyond a predefined limit. For example, the limiter or puller stop may be configured as a physical stop on the puller portion of a handle that limits the travel of the puller.

[000134] FIGS. 11B-11C illustrate a method for handling this situation without tearing (and risk harming the patient). In FIG. 11B the elongate inversion support catheter is stopped from advancing any further distally, and instead the intermediate catheter may be advanced distally (with or without aspiration through the intermediate catheter). In FIG. 11C, the clot, including the portion outside of the elongate inversion support catheter, has been fully captured within the intermediate catheter, as shown.

[000135] FIG. 12A illustrates another example of a configuration of the apparatus (and in particular the tractor tube) in which the distal end of the tractor tube is configured with a non-compliant material 1205 (e.g., a cuff) so that it cannot flip or roll over the distal end of the elongate inversion support catheter. This may prevent the user from pulling the tractor all the way around the catheter. In some variations, the cuff is configured to permit the tractor tube to flip over the distal end of the elongate inversion support catheter. For example, a cuff on the outer end of the tractor tube may include one or more slits (e.g., between one and 20 slits or slots) extending along its length configured to permit it to flip and invert, but providing an increase in the stiffness of the tractor tube. In any of these variations, the cuff on the outer end of the tractor tube may include a marker (e.g., radiopaque material); for example, the cuff may be a polymer including a platinum or other radiopaque material suspended in it. FIG. 12B illustrates an example of a cuff 1205' at one end of a flexible tube ('tractor') 1207 that has been inverted over the inversion support catheter 1209.

[000136] As mentioned above, any of these apparatuses may include one or more features that may be used to improve tracking, and in particular, by preventing the elongate inversion support catheter from stiffening. This may be a problem with the high column-strength, highly flexible elongate inversion support catheters that include one or more slot or cut-out regions along their length. One feature that may be included, discussed above, is the use of configurations in which the tractor tube, and particularly knitted tractor tubes, are delivered in a compressed state, rather than a stretched state. As mentioned above, pinning one end of the tractor tube in the intermediate catheter may be configured to do this in some of the preloaded configurations described above. FIGS. 13A-16B illustrate other variations. For example, FIG. 13A shows a knitted tractor tube 1315 over an elongate inversion support catheter 1307 that is stretched. The woven links are connected end-to-end (forming a helical winding pattern

around the elongate inversion support catheter). FIG. 13B illustrates the resulting compressive load on the catheter tip in this configuration; friction loads on the knit during tracking may pull on the distal end of the elongate inversion support catheter, causing it to stiffen in compression. However, such compressive loads may be lessened or eliminated by using a woven material held in a compressed configuration, as shown in FIG. 13C. In this example, the interlocking loops forming the weave are overlapping in a compressed state.

[000137] This compressed state may be maintained by pinning, securing or holding one or more ends or lengths of the tractor tube in place when the tractor tube is compressed. Any appropriate mechanism for holding the compression may be used. For example, the apparatus may include a stop or lock to engage with one or more regions of the tractor tube and hold it in a compressed configuration during tracking. FIGS. 14A-14D illustrate variations of structures (stops) that may be used to hold the woven tractor tube on the outside of the elongate inversion support catheter in a longitudinally compressed state. In FIG. 14A, the elongate inversion support catheter includes a polymeric lip, ridge or rim (stop) 1401 that may secure one end of the woven tractor tube against the elongate inversion support catheter with the tractor tube in compression. Distal force may be applied to pull the tractor tube out of the stop (not shown). FIG. 14B shows a Nitinol (NiTi) braid 1403 that holds the knitted tractor tube in compression along the length of the elongate inversion support catheter. FIGS. 14C shows a similar NiTi braids with exposed ends that engage with the knit of the tractor. FIG. 14D a NiTi knit segment also includes projections that engage with the knit, as shown.

[000138] FIGS. 14A-14G show similar finger-like elements that may be used to engage with the knit (the loops formed by the knit) of the tractor. In FIG. 15A, the loose ends of the woven material form short “fingers” that are exposed and engage with the knitted tractor, as shown in FIG. 15B. In FIG. 15C, a similar construction having longer “fingers” of loose ends is shown, and FIG. 15D shows the fingers engaging with the knitted tractor tube. FIG. 15E shows “fingers” formed by the loose ends of the weave located approximately 1 cm from the tip of the elongate inversion support catheter, and FIG. 15F shows these elements engaging the knitted tractor tube. FIG. 15G is another example of a set of fingers formed of projecting metal wires that may be used to removably hold the tractor tube against the elongate inversion support catheter in compression. FIG. 15H shows an example of a variation formed by a metal wire having very long “fingers”, engaged with a knitted tractor tube, holding it in compression.

[000139] Alternatively, or additionally, any of these apparatuses may include a housing or garage that may be used to hold the knitted tractor tube in compression. For example, FIG.

16A and 16B illustrate one example of this configuration, in which a housing ('garage') region 1602 formed of a 48-end braided material, is used to hold the knitted tractor tube 1604 in a compressed state at one of its ends on the elongate inversion support catheter. FIG. 16B shows a similar example of a elongate inversion support catheter having a 10 mm long 'garage' region made of a braided material 1608.

REMOVAL OF LARGE CLOTS

[000140] Any of the mechanical thrombectomy apparatuses described herein may be adapted to remove large clots. In general, a large clot may be large in either or both diameter (outer diameter) and length, and may be large relative to the mechanical thrombectomy apparatus. For example, the clot may have a diameter that is larger than the diameter of the apparatus (e.g., larger than the expanded diameter of the flexible tube which captures the clot). Thus, the apparatus may be configured to capture and compress the clot so that it may be withdrawn from the lumen of the vessel, into the lumen of the intermediate catheter and/or inversion support catheter. The apparatus may also be configured to capture and remove clots that are longer than the ability of the flexible tube to hold.

[000141] In general, FIGS. 18A-18J show a method of removing a clot 1815 from a vessel 1815 as described herein, in which a vacuum (suction) may be applied through the puller to make and confirm initial contact with the clot. For example, FIGS. 18A-18B illustrate an example of an apparatus that is preloaded and configured to both track to the clot and to remove the large-diameter clot 1815. For example, in FIG. 18A, the apparatus (mechanical thrombectomy apparatus or inverting tube apparatus) includes an intermediate catheter (IC) 1801, an inversion support catheter ("outer catheter") 1803 within a lumen of the intermediate catheter, a puller (shown as a puller catheter) 1805 within a lumen of the inversion support catheter, and a flexible tube (e.g., knit tube) 1809 extending over the inversion support catheter. The flexible tube has a first end 1826 coupled at a distal end region of the puller and a second end 1824 comprising a cuff 1825 that is less flexible than a region of the flexible tube adjacent to the cuff, wherein the flexible tube is configured to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the flexible tube rolls and inverts over a distal end of the inversion support catheter 1823. The apparatus is shown over a guidewire 1807. In this example, multiple regions include markers that may be visualized, e.g., under fluoroscopy. For example, the end of the inversion support catheter includes a marker 1823, as does the distal end of the puller 1826. The puller may

also include an intermediate marker 1821, shown aligned with the cuff 1825; the cuff also includes a marker. The assembly is shown within the vessel 1813.

[000142] The apparatus may be distally advanced over the guidewire and positioned adjacent to the clot 1815. The apparatus may initially be pre-loaded in a tracking configuration, in which the outer (inversion support) catheter 1803 is retracted into the lumen of the intermediate catheter 1801 while the puller (puller catheter 1805) with the attached flexible tube 1809 extending proximally from the distal end 1826, is moved distally to track over the guidewire. In FIG. 18B, the apparatus is adjusted into a clot-grabbing configuration in which the inversion support catheter 1803 is extended distally towards the distal end of the apparatus, although it is still positioned proximal to the puller distal end 1827. The intermediate catheter 1801 may also optionally be withdrawn proximally, as shown in FIG. 18C, which in some variations may allow the flexible tube to expand outwards (see, e.g., FIG. 26B).

[000143] FIG. 18C1 shows an example of a prototype device corresponding to the apparatus configured as shown in FIG. 18C. In this example the flexible tube is a woven flexible tube 1809 that is shown extending distally from the distal end face 1827 of the puller. The puller is shown over a guidewire 1807.

[000144] Once the apparatus is in position near the clot, suction may be applied through the puller catheter, as shown in FIG. 18D. This focal suction (aspiration) 1840 may be applied while advancing the apparatus distally to engage the clot, as shown in FIG. 18E. In some variations, the guidewire is left in place (not shown) or it may be optionally removed (as shown in FIGS. 18D-18E). Once the distal-facing end of the puller is engaged with the clot, as shown in FIG. 18E, connection to the clot may be detected by observing the flow and/or pressure through the puller from the suction 1840'. Thereafter, the puller may be drawn proximally and/or the inversion support catheter may be moved distally so that the flexible tube rolls over the distal end opening of the inversion support catheter (these motions are shown by the large arrows). In FIG. 18F, approximately 30% of the clot has been drawn into the inversion support catheter by rolling 1866 the flexible tube. In FIG. 18G, more, but not all (e.g., approximately 70%) of the clot has been ingested, though a substantial amount of clot remains outside of the inversion support catheter and flexible tube. The vacuum may be left on, or it may be turned off while pulling the puller proximally to engulf/grab the clot. Heavy arrows indicate movement of the components of the apparatus, such as the intermediate catheter, which may be advanced distally, the inversion support catheter, which may also be advanced distally, and the puller, which may be withdrawn proximally. These motions may

be coordinated by the handle (not shown) and/or performed manually by the user. Once the flexible tube has reached the distal end of the inversion support catheter, it may stop or be stopped, to prevent it from rolling over the distal end. Rolling of the second end of the flexible tube over the inversion support catheter distal end may cut or break the clot off, which may be highly undesirable, as it may potentially release the clot, resulting in complications, and/or may require additional removal steps.

[000145] In FIG. 18A-18J the second end of the flexible tube includes a cuff 1825 that may prevent the flexible tube from rolling over the distal end when pulling proximally on the puller, as shown in FIG. 18H. In FIG. 18I, the intermediate catheter is shown advancing distally beyond the cuff and the distal end of the intermediate support catheter. In this configuration (as also described in FIGS. 22A-22B) the motion of the intermediate catheter 1801 may invert the cuff 1825 over the distal end of the inversion support catheter 1803 and against the clot 1815 without breaking or disrupting the clot. A vacuum (suction) may be applied through the intermediate catheter is also shown in FIG. 18I (by the small arrows). In FIG. 18J, the flexible tube, puller and inversion support catheter are then drawn proximally into the intermediate catheter along with the un-engulfed portion of the clot, either by driving the intermediate catheter distally over them, and/or by pulling the inversion support catheter (which may be pulled with the puller) proximally.

[000146] Thus, in the example shown in FIGS. 18A-18J, a larger clot, both in diameter and in length, may be removed by the apparatus.

[000147] FIG. 19 illustrates another example of an apparatus that is configured or adapted to have a smaller diameter (outer diameter) than the vessel and the clot but may be capable of grabbing and removing larger clots (e.g., clots having an outer diameter that are more than 1.5x, more than 2x, more than 2.5x, etc.) the outer diameter of the flexible tube capturing the clot.

[000148] In FIG. 19, the apparatus includes a flexible tube that is configured as a knit tube. In this example the region of the knit tube 1901 on the outside of the inversion support catheter 1903 hugs the outer diameter (OD) of the inversion support catheter. In order to maximize the ingesting efficiency/power of the knit when used to capture larger clots, the stitch length of the knit may be tuned to the diameter of the vessel in which the apparatus is to be used. For example, in general, the stitch length 1905 is the lateral extent of a loop formed by the knit. In general, the outer diameter 1909 of the inversion support catheter may be known, and the inner diameter of the vessel (which may be equivalent to the outer diameter of the clot) may also be known or approximated (e.g. from fluoroscopy). Thus, the user, such

as a surgeon or physician, may select the appropriate flexible tube (e.g., knit) based on the selected size. For example, in FIG. 19, twice the knit or stitch length (knit/stitch length) plus the outer diameter of the inversion support catheter may be approximately equal to the ~Vessel ID in order to maximize power/efficiency when grabbing and/or removing clot. The woven stitches may act as fingers or extensions that swing around the distal end opening of the inversion support catheter 1907, as shown in FIG. 19. Thus, for vessel inner diameters of between set ranges, the knit/stitch length may be determined. In general, the knitted tube may comprise a filament knitted to form a plurality of interlocking loop stitches, wherein each loop stitch has a stitch length that is between the difference of 25% of the ID and one half the outer diameter (OD) of the inversion support catheter and 65% of the ID and one half of the OD of the inversion support catheter. For example, twice the knit/stitch length plus the inversion support catheter OD may be equal to a range of vessel inner diameters (IDs), such as between about 90%-110% of the vessel ID, between about 80-100% of the vessel ID, between about 60-100% of the vessel ID, between about 50-100% of the Vessel ID, between about 30-100% of the vessel ID, between about 20-100% of the vessel ID, between about 10-100% of the vessel ID, and/or between about 50-130% of the vessel ID.

[000149] In practice for most neurovascular and/or peripheral vascular applications, the knit/stitch length may be between about 0.5 mm and about 10 mm (e.g., about 0.5 mm, between about 0.1 to 0.5mm, about 1. mm, between about 0.5 – 1. mm, about 1.5mm, between about 1. -1.5mm, about 2. mm, between about 1.5 – 2. mm, about 2.5 mm, between about 2. - 2.5 mm, about 3. mm, between about 3. – 3.5 mm, between about 0.5mm – 10mm (e.g., by any 0.5 mm increment), etc.

[000150] In general, the apparatuses described herein may compress a clot. For example, FIG. 20A illustrates an example of a clot 2005 shown within the bottle on the top of the figure that is 5 cm long and has an outer diameter of about 15 mm. A portion of an inverting mechanical thrombectomy apparatus is shown in the middle of FIG. 20A, showing an inverting support catheter that is an 8 French (8F) catheter 2003 over which a flexible tube, formed of a knit material 2001, has been arranged, including coupling to one end of a puller (not shown). The flexible (knitted) tube in this example is biased to expand in an uploaded state to an outer diameter that is much greater than the outer diameter of the inverting support catheter. This apparatus was used to remove the clot 2005, which resulted in compressing the clot 2007, as shown in FIG. 20A, bottom.

[000151] Another example of an apparatus for removing clot is shown in FIG. 20B, showing a 10 mm diameter clot 2005' being grabbed and engulfed by a flexible tube 2001'

having an expanded outer diameter of 5 mm extending over a 3 mm outer diameter inversion support catheter.

[000152] In general, the amount of clot that may be contained (e.g., “eaten”) by the rolling and inverting devices described herein in a single pass may be a function of the diameter of the clot, the length of the flexible tube, the structure of the flexible tube (e.g., woven, knitted, etc.) and most importantly, the expanded outer diameter of the flexible tube. For example, FIG.S 21A and 21B illustrate the relationship. In FIG. 21A, the graph shows the length of the flexible tube (e.g., length of the woven tube, L, needed to fully engulf a clot of 15 mm diameter and 5 cm length. In general, the results show that for compressible clots, the length of the flexible tube necessary to fully engulf a 5 cm length of 15 mm diameter clot (depending on the type of clot, including its compressibility) may be between about 6. mm and about 60 mm. Thus, as a rough rule of thumb, as much as a 12:1 ratio of flexible tube to clot may be necessary at this exemplary dimension of a clot. FIG. 21 B illustrates example of different apparatuses 2105 used to generate the data shown in FIG. 21A.

[000153] In general, the knit expands to a larger diameter than the outer diameter of the catheter once the apparatus is delivered to a clot site when the vessel ID is much larger than the catheter OD. Furthermore, the flexible tube (e.g., knit tube) may expand to a larger diameter than the catheter once it is delivered to clot site, particularly when the vessel ID is much larger than the catheter OD. This is illustrated, e.g., in FIG. 20B. Typically, to maximize the efficiency/power of the flexible tube to ingest a clot, when the catheter is much smaller than the vessel ID/clot OD, it may be helpful to have an expanded outer diameter of the flexible tube such that it is at least 10% (e.g., at least 20%, 30%, 40%, 50%, 60%, 70%, 80%, etc. of the Vessel ID, or any range between any two of these percentages). For example, it may be preferable for the expanded flexible tube to have at least 30% of the vessel ID. Further, as mentioned above, the expanded diameter of the flexible tube may be at least about 30%, 50%, 100%, 150%, 200%, 250%, 300%, 400%, 500%, 600%, etc. of the catheter OD (or any range between any of these two percentages).

[000154] As shown in FIG. 19, and discussed above, the extension of the loop stitches in flexible tubes that are knitted (forming “fingers” on the knit, or protrusion that roll and extend beyond the expanded OD of the rest of the flexible tube) may further help grab and remove clot. These extensions for an apparatus such as shown in FIG. 19 (or 26A) may be between about 0.5mm – 10mm (e.g., between any two value in this range, typically by 0.5 mm increments, including any range between any such increments).

[000155] FIGS. 22A and 22B illustrate an example of a cuff as discussed above. In the example shown in FIGS. 22A and 22B, the cuff 2201 is made of (or includes) a radiopaque polymer filling the cuff at the second end of knit tube. This may allow it to be seen under fluoroscopy, and may also prevent unraveling of the knitted tube. In FIG. 22A, the cuff includes a plurality of lateral slits 2205 (e.g., four are shown, though 3, 4, 5, 6, 7 or more slits may be used). These slits may allow the cuff to flip over inversion support catheter, e.g., when driven by an intermediate catheter 2203, as shown in FIG. 22B. In this example, the cuff may be formed of a polymer such (e.g., as Pebax 45D + 80% tungsten filled). The cuff may have a wall thickness of less than about 0.025 inches when laminated on knit, and may have a length of between 1 and 3 loop stitches (e.g., about 1.5 knit stitches long).

[000156] FIGS. 23A-23B and 24A-24B illustrate examples of a proximal end of a mechanical thrombectomy apparatus, showing components of the apparatus (e.g., guidewire 2305, inner/inversion support catheter 2307, puller 2309, and intermediate catheter 2311. FIG. 23B shows another example, of a proximal end of the mechanical thrombectomy apparatus showing manual controls, including vacuum attachment ports (RHVs) 2317, 2319, for the different regions, as well as the puller hub 2321 at the proximal end.

[000157] FIGS. 24A-24B illustrate another example of a set of proximal end controls for a mechanical thrombectomy apparatus. In FIG. 24A the apparatus control region is shown in a first puller position (prior to pulling the clot in), and includes the inner (e.g., puller) rotating hemostat valve (RHV) 2417, outer (intermediate catheter) rotating hemostat valve (RHV) 2419, as well as the puller hub 2421. One or more stop elements 2423, 2423' may be included on the puller to prevent it from pulling and completely inverting the flexible tube over the distal end of the inversion support catheter, as described above; flush ports 2432, 2433 are also shown. In FIG. 24B the apparatus control region is shown after pulling the clot (showing the puller hub extended proximally).

[000158] FIG. 25 illustrate an example of a mechanical thrombectomy apparatus in which the flexible tube 2505 is configured to cut tissue as it rolls into the inversion support catheter. In this example, the flexible tube is a knitted tube that includes sharp cutting edges that may be used to cut through tissue. The apparatus may be used over a guidewire to prevent the cutter from dissecting the vessel wall.

[000159] FIGS. 26A-26B illustrate two exemplary side perspective views of mechanical thrombectomy apparatuses. In FIG. 26A, similar to that shown in FIGS. 18A-18J, the apparatus include a flexible (e.g., knitted) tube 2601 that is attached at the first end to a puller catheter 2603 and is configured to expand within the inversion support catheter to an outer

diameter that is greater than 40% (shown here as greater than 90%) of the inner diameter of the inversion support catheter 2605, driving the region of the flexible tube within the inversion support catheter against the walls, even when unloaded by clot. The other region (un-inverted) of the flexible tube along the outer diameter of inversion support catheter is shown as snug with the inversion support catheter in the un-constrained configuration. This results in the Y-shaped distal profile 2609, for the inverting flexible tube, which may help grab even larger diameter clots.

[000160] FIG. 26B illustrates another example of a mechanical thrombectomy apparatus in which the expanded outer profile of the flexible tube 2601' is expanded beyond the outer diameter of the inversion support catheter 2605 near the first end where it attaches to the puller 2603, but the second end 2621, that is freely sliding over the inversion support catheter, has a much smaller (nearly snug) expanded diameter. This region may also or alternatively include a cuff as described herein.

Re-sheathing the tractor

[000161] Any of the inverting tube apparatuses described herein may be configured so that the inverting tube apparatus may be retracted (e.g., re-sheathed) into an intermediate catheter. In particular, any of the inverting tube apparatuses that include a cuff at one end (e.g., at the distal end) of the inverting flexible tube may be re-sheathed into the intermediate catheter after deployment, including after capturing all or a portion of a clot. FIGS. 27A-27C illustrates operation of an inverting tube apparatus having a cuff on one end of the flexible tube. As shown in FIG. 27A, the inverting tube apparatus includes an inversion support catheter 2707, a puller 2705 within a lumen of the inversion support catheter, and a flexible tube 2709 extending over the inversion support catheter that is coupled at a first (e.g., proximal) end to the puller, and is configured to roll and invert over the open distal end of the flexible inversion support catheter. In some examples, the flexible tube 2709 may be a woven or knit material. A second end (e.g., distal) end of the flexible tube 2709 may include a cuff 2711 that is less flexible than the region of the flexible tube adjacent 2715 to the cuff. In FIG. 27A, the apparatus is shown in a deployed or partially deployed configuration, in which the flexible tube 2709 and inversion support catheter has been extended out of the distal end of an intermediate catheter 2713, also referred to as a sheath). As discussed above, the apparatus may be delivered to the clot and deployed from out of the intermediate support catheter, including using a guidewire (not shown).

[000162] As shown in FIG. 27B, the flexible tube 2709 is configured to be pulled proximally into the inversion support catheter 2707 by pulling 2715 the puller 2705 proximally so that the flexible tube rolls 2719 and inverts over a distal end of the inversion support catheter; the cuff 2711 may slide along the outside surface of the inversion support catheter. As the device is deployed, the distal end 2714 of the cuff 2711 extends further from the distal end 2715 of the intermediate catheter (sheath 2713), which may have a distal end face that faces the deployed cuff 2711, see

[000163] At any point, either before or after flexible tube has completely, or mostly completely, withdrawn and inverted into the inversion support catheter, the apparatus, and in particular the inversion support catheter, flexible tube, cuff, and any captured clot material, may be withdrawn or re-sheathed back into the intermediate catheter 2713. However, in some cases, including (but not limited to) variations having a cuff 2711 at the second (e.g., distal) end of the flexible and inverting tube 2709 may make it difficult to re-insert the cuff back into the intermediate catheter, as illustrated in FIG. 27C.

[000164] In FIG. 27C, the distal face or end 2717 of the intermediate catheter 2713 is shown catching on the distal end 2714 of the cuff 2711 when attempting to re-sheath the sub-assembly including the cuff 2711, flexible tube 2709 and inversion support catheter 2707 back into the intermediate catheter 2713. Although in some variations this may be desirable, as it may help push the cuff and end of the flexible inverting tube off of the end of the inversion support catheter (which it may further envelop and/or cut the clot, as described above in relation to FIGS. 18H-18I), in some variations it may be desired to leave the cuff 2711 on an outside of the inversion support catheter 2707. In this case, as shown in FIG. 27C, if the distal end 2717 of the intermediate catheter 2713 catches on the end face 2714 of the cuff 2711, the cuff may be driven forward, towards the end of the inversion support catheter, as shown. In FIG. 17C, this is shown also driving 2725 the flexible inverting tube 2709 towards the end of the inversion support catheter.

[000165] To avoid this, the apparatus may be configured to include one or more **cuff retainers** that hold the cuff level and/or limit its movement so that it may slide into the intermediate catheter. FIGS. 28A-28C, 29A-29C, 30A-30C, and 312A-31C all describe cuff retainers that may be used.

[000166] For example, FIGS. 28A-28C illustrate an example of an inverting tube apparatus that includes a cuff at one end of the inverting flexible tube and a cuff retainer, in which the cuff and flexible tube over the inversion support catheter may be re-sheathed into the intermediate catheter after deployment. The cuff retainer may facilitate the re-sheathing of

the cuff and flexible tube into the distal end of the intermediate catheter by applying a force to hold the cuff in a fixed position on the outside of the inversion support catheter. In some variations, the cuff retainer may also or alternatively hold the face of the cuff level relative to the distal end of the intermediate catheter.

[000167] In FIG. 28A, the inverting tube apparatuses include a cuff 2811 on the end of an inverting flexible tube 2809 that inverts into the inversion support catheter 2807. A puller (or pusher) 2805 may slide within the inversion support catheter and is attached to the flexible tube 2809. The puller (or pusher) in any of these examples may be a catheter and may pass a guidewire. The cuff retainer in this example is one or more leashes or tether 2835 (e.g., a filament, wire, strand, cable, etc.) that is connected at one or more points on the cuff and one or more locations on the outer surface (or through the outer surface) of the inversion support catheter. The cuff retainer shown is helically arranged over the inversion support catheter so that it may be unwound or unspooled as the puller/pusher pulls and inverts the flexible tube into the inversion support catheter. The cuff retainer may be elastic. In some variations the cuff retainer may include multiple tethers that are spaced circumferentially around the cuff (e.g., spaced equal distances apart).

[000168] The inverting flexible tube sub-assembly (cuff, inverting flexible tube, and inversion support catheter) may be re-sheathed into the intermediate catheter 2813 after the puller has pulled the flexible tube into the inverting support catheter, so that the cuff has slid over the inverting support catheter to a predetermined position 2833 towards the distal end of the inversion support catheter, as shown in FIG. 28B.

[000169] Once the cuff retainer 2835 is engaged and applying force against the cuff to hold it in position relative to the inversion support catheter, the intermediate catheter 2813 may be slid distally 2850 over the distal end of the cuff and/or the sub-assembly including the cuff may be drawn proximally back in to the intermediate catheter. This is illustrated in FIG. 28C.

[000170] In the variation shown in FIGS. 29A-29C, the cuff retainer 2935 is configured as one or more leashes or tethers 2935 (e.g., filaments, wires, strands, cables, etc.) that is/are attached to a cuff 2911. However, in this example, the cuff retainer passes through an opening 2941 in the inversion support catheter 2907 and attaches to the puller (or pusher) 2905. Thus, as the puller 2905 is drawn proximally to pull and invert the flexible tube 2909 into the inversion support catheter 2905, the cuff retainer 2935 is also drawn with the flexible tube. This configuration may coordinate the movement of the puller with the movement of the cuff, as illustrated in FIGS. 29B and 29C. In FIG. 29B. As shown in FIG. 29B the cuff retainer also limits the axial movement of the cuff along the outside of the inversion support

catheter. Thus, by pulling the puller/pusher 2905 proximally, the cuff retainer may apply a force holding the cuff in position so that, as shown in FIG. 29C, the intermediate catheter (sheath 2913) may be advanced distally 2971 and over the cuff and outer portion of the flexible tube 2909. This configuration may also be useful in reloading the flexible tube, as (not shown) force applied to pull the cuff proximally (by pulling/pushing the cuff proximally on the inversion support catheter) may be transmitted to the puller through the cuff retainer (e.g., the one or more filaments, so that force is applied to both ends of the flexible tube to reload the device and also eject any clot within the flexible tube and inversion support catheter.

[000171] FIGS. 30A-30C illustrate another example of an apparatus including a cuff and a cuff retainer 3035, 3035' in which the cuff retainer includes a pair of leashes or tethers 3035, 3035' (e.g., filaments, wires, strands, cables, etc.) that are attached to the cuff 3011 and extend proximally through the intermediate catheter 3013 all the way to a proximal end of the device where they may be used to apply force (e.g., tension) to the cuff. In FIG. 30B, the puller 3005 has been withdrawn proximally 3072 to cause the flexible tube 3009 (attached to the puller) to roll and invert over the distal end of the inversion support tube 3007. By securing and/or pulling on the cuff retainer 3035, 3035', and in some variations also securing and/or pulling on the puller 3005, the cuff may be held in a fixed location while the intermediate catheter 3013 is driven distally 3074, as shown in FIG. 30C. In this example, the cuff retainer (e.g., tethers) may be made of a metallic (e.g., stainless steel, elgiloy, Nitinol, etc.) or polymeric material. As mentioned, in use, the cuff retainer may be locked down or free to move (e.g., slide) and may be manipulated by the user near the hub of the inversion support catheter or elsewhere on the proximal end of the apparatus.

[000172] In some variations, the cuff retainer may be used to pull back the tractor to eject clot after use. For example, the apparatus (e.g., the sup-portion including the cuff, the flexible tube and the puller) may be reloaded on the inversion support catheter and/or material such as a clot captured in the apparatus may be ejected by pulling the cuff proximally (and in some variations pushing the puller/pusher 3005 distally).

[000173] Although the cuff retainer shown in FIGS. 30A-30C is shown as one or more tethers, in some examples, the cuff retainer is a tubular structure, which may be knitted, woven, solid, etc.

[000174] In some variations the cuff retainer is a cuff stop near or on a distal region of the inversion support catheter. For example, in FIG. 31A the cuff retainer is configured as a cuff stop that is formed as a collar attached to the distal end region of the inversion support

catheter. In FIG. 31A, the cuff 3111 connected to an end of the flexible tube 3109 slides freely along the inversion support catheter 3105, so that when the puller/pusher 3105 within the inversion support catheter is drawn proximally 3172 (as shown in FIG. 31B), the cuff may be pulled distally while the flexible tube rolls and inverts over the distal end of the inversion support catheter. In FIG. 31B, the cuff is stopped from moving distally by the cuff retainer 3137 (cuff stop). The intermediate catheter (sheath 3113) may then be moved distally over the cuff and any portion of the flexible tube 3109 that is external to the inversion support catheter to re-sheath the apparatus, as shown in FIG. 31C. Alternatively, or additionally, the inversion support catheter, cuff, flexible tube and puller may be drawn proximally into the intermediate catheter. In some variations, a combination of both movements may be used. The puller may be pulled or held so that the cuff is held against the cuff retainer while re-sheathing or alternatively the intermediate catheter (sheath) may drive the cuff against the cuff retainer.

[000175] In FIGS. 31C the cuff retainer is a stop that is fixed to the outside of the inversion support catheter. Any stop that may engage with the outer distal-facing edge of the cuff and the inversion support catheter may be used. For example, the cuff retainer may be a cuff stop that is a bump, ridge, button, protrusion, band, ring, lip, or the like. One or more (e.g., two, three, etc.) discrete regions arranged around the outside of the inversion support catheter may be used. The cuff retainer may be made of any appropriate material, e.g., a polymer or metallic structure, and may be a solid element or a braid or knit structure.

[000176] In addition to these mechanical cuff retainers (cuff stops), electrical and/or magnetic cuff retainers may be used. For example, the cuff retainer may be a magnetic or paramagnetic material that interacts with cuff (which may include a magnetic or paramagnetic material) to limit movement of the cuff distally.

[000177] Any of the cuffs described herein may also include one or more tapered or shaped ends that also help re-sheath the apparatus. For example, in some variations, the proximal end of the cuff may be tapered towards the inversion support catheter.

[000178] FIGS. 32A-32C illustrate examples of tapered cuffs that may be used. In FIG. 32A, the apparatus includes a cuff 3211 that has a skived or tapered proximal end 3242. The cuff is attached at the other end to the flexible tube 3209 which inverts and rolls over the inversion support catheter 3207 when pulled by the puller 3205 from within the inversion support catheter. The sub-assembly including the inversion support catheter, flexible (inverting) tube, and the cuff is shown in a deployed configuration extending from outside of the intermediate catheter 3213. The tapered cuff may aid in re-sheathing the sub-assembly,

including the cuff, back into the intermediate catheter. A tapered cuff may be used with or without a cuff retainer, including any of those described above.

[000179] FIG. 32B is another example of a tapered cuff 3211 that includes a proximal tapered region 3245'. In this example, the tapered region includes serrations that may allow some flexibility of the narrowed proximal end so that it is still free to slide on the inversion support catheter. The serrations may be configured as one or more slots, slits or cut-out regions in the tapered region. The serrations may be limited to the tapered region.

[000180] FIG. 32C is another example of a tapered cuff 3211 having a crown-like tapered region 3255 comprising a number of larger cut-out regions, similar to the serrations of the tapered region in FIG. 22B. In FIG. 32C the tapered region may include tapered fingers or projections that may be triangular, square/rectangular, curved and/or sinuous and/or irregularly shaped tapered extensions. In some variations, the tapered region is crenelated.

[000181] The tapered regions of the cuff may extend over a portion of the cuff, e.g., between 5%-50% of the length of the cuff in the long-axis of the inversion support catheter (e.g., between 10% and 50%, between 15% and 50%, between 10% and 40%, etc.). The cuff may be any appropriate length, e.g., between 0.5 mm and 30 mm, between 1 mm and 20 mm, between 2 mm and 20 mm, greater than 2 mm, greater than 3 mm, greater than 4 mm, greater than 5 mm, greater than 6 mm, etc.).

[000182] FIGS. 32D and 32E illustrate cuffs having tapered regions that are angled on the proximal-facing sides. Thus, the proximal-facing side of the cuff is angled relative to the body of the cuff and the inversion support catheter. In FIG. 32D the cuff 3211 has an angled proximal side 3265, but the distal-facing side of the cuff is flat (e.g., perpendicular to the long axis of the inversion support catheter over which it may slide. FIG. 32E shows a cuff 3211'''' that is similar to the variation shown in FIG. 32D but is also angled on the distal-facing side. The angled proximal-facing side may be tapered (and/or may include tapered cut-out regions/perforations). Cuffs having angled proximal faces may also be used with a cuff retainer. The angled proximal face may be formed by cutting the cuff at an angle. Any appropriate angle may be used, e.g., between 5 degrees and 60 degrees (e.g., between 10 degrees and 50 degrees, between 15 degrees and 45 degrees, etc.), measured as the acute angle formed between the proximal-facing side and the sidewall of the cuff.

[000183] FIG. 32F illustrates a cuff 3211 having a proximal-facing stent like structure 3275 that is low-profile and may also help with re-sheathing. Any of the tapered and/or angled cuffs may also include a proximally-extending stent-like structure. The stent-like structure may include wires, filaments, ribbons, etc. extending from the proximal edge. These sent-like

structures may be flattened toward the inversion support catheter 3207 outer surface. A stent-like structure may also be referred to as a low-profile scaffolding, and may extend completely or partially around the perimeter of the cuff.

[000184] Any of the apparatuses described herein may also be configured to be re-loadable. For example, FIGS. 33A-33D illustrate one example of a re-loading apparatus in which a single-use subassembly including a cuff 3311 (configured as a split cuff), a flexible tube 3309, and an inner puller 3305, is loaded onto the inversion support catheter 3307, and partially deployed out of the intermediate catheter (sheath 3313). The sub-assembly, which may be referred to as an inverting flexible tube sub-assembly is removable from the inversion support catheter, and may be removed from the inversion support catheter out of the intermediate catheter after removing all or part of a clot; the intermediate catheter (sheath) may then be left in place while the intermediate catheter and inverting flexible tube sub-assembly may be removed from the vessel proximally. Once withdrawn, the sub-assembly may be removed from the inversion support catheter and a new sub-assembly may be loaded onto the inversion support catheter and inserted back through the intermediate catheter to remove additional clot material. This is illustrated in FIGS. 33A-33E.

[000185] In FIG. 33A, the apparatus is shown partially deployed, with the inversion support catheter 3307 extending out of the sheath 3313, and the flexible tube 3309 connected at one end to a split cuff 3311 and at the other end to a puller (e.g., puller assembly, including a puller wire 3305 and a puller catheter segment 3306). The cuff may be slid over the inversion support catheter distally as the puller is drawn proximally (e.g., by pulling on the puller end 3356). Pulling the puller proximally causes the flexible tube to roll and invert over the distal end of the inversion support catheter. In FIG. 33A, a guidewire 3341 may be used, and passes through the catheter segment 3306 of the puller. As described in greater detail above, this may draw a clot into the inversion support catheter. Once the cuff reaches the distal end of the inversion support catheter, as shown in FIG. 33B, the cuff may split apart and roll and invert 3372 over the distal end of the inversion support catheter as well, into the inversion support catheter. As shown in FIG. 33C, the entire sub-assembly (e.g., the puller, flexible tube 3309 and split cuff 3311) may then be housed within the inversion support catheter 3307, and withdrawn proximally out of the sheath 3313. For example, the proximal end of the inversion support catheter may include a handle or grip 3361, allowing it to be advanced and/or withdrawn from outside of the patient. The entire sub-assembly and/or inversion support catheter may be removed proximally out of the patient.

[000186] Once removed, the inverting flexible tube sub-assembly may then be removed, along with captured clot, from the inversion support catheter, and either a new inversion support-catheter pre-loaded with an inverting flexible tube sub-assembly may then be inserted into the sheath and back into the vessel to capture any additional clot material, or the same inversion support catheter may be re-loaded with a new inverting flexible tube sub-assembly, as shown in FIGS. 33D and alternative variation in FIG. 33E.

[000187] In FIG. 33D, a new inverting flexible tube sub-assembly 3360, including the puller (puller assembly including pull wire 3305 and pull catheter 3306), flexible tube 3309 and cuff 3311, is loaded 3374 into the distal end of the inversion support catheter 3307. The variation shown in FIG. 33E is similar to that shown in FIG. 33D, but the cuff 3311' is uninverted, and therefore loads on the outer surface of the inversion support catheter. As the loaded inversion support catheter is driven back through the sheath, the flexible tube 3309 and cuff may be driven proximally, so that it prepared to be withdrawn proximally by the puller to capture clot by the time it reaches the distal end region of the sheath.

[000188] In any of these variations, a guidewire may be use to insert and guide insertion of the inverting flexible tube sub-assembly and/or inversion support catheter to the clot material.

[000189] The steps of capturing clot, withdrawing the sub-assembly proximally and reloading anew sub-assembly, as illustrated in FIGS. 33A-33E, may be repeated as necessary to remove more clot material.

[000190] Alternatively, as mentioned above, any of the apparatuses described herein may be configured to reusing inverting flexible tube sub-assembly and other portions of the apparatus. For example, the apparatus may be deployed to a clot, and used to remove at least a portion of the clot, and the clot, captured by the flexible tube, may be withdrawn out of the vessel, and ejected from the flexible tube, and the flexible tube (e.g., the inverting flexible tube sub-assembly including the flexible tube) reloaded, reinserted and used to remove additional clot. An example of this is illustrated in FIGS. 34A-34C.

[000191] In FIG. 34A, a portion of clot 3490 has been captured by an apparatus. The apparatus may include an inversion support catheter 3407, a puller 3405, a flexible tube 3409 and a cuff 3411. In this example, the puller includes a proximal handle region 3465 and the inversion support catheter includes a proximal handle region 3467. The apparatus has been withdrawn from out of the patient after grabbing the clot material in FIG. 34A. The clot material may then be ejected from the apparatus, as shown in FIG. 34B. In this example, the clot material is ejected by pulling the cuff proximally 3472 and/or by pushing the puller distally 3474. In some variations, the clot may be ejected by both pushing the puller distally

and by pulling the cuff proximally. For example, in some variations it may be beneficial to use an ejection apparatus 3522, as shown schematically in FIG. 35, to coordinate the relative motion of the puller 3505 (or puller assembly) and the inversion support catheter 3507, while drawing the cuff 3511 proximally. The ejection apparatus 3522 couples to both the puller proximal handle 3565 and the inversion support catheter proximal handle 3567 and moves the two handles 3565 and 3567 closer to each other 3572, as shown by the arrows. Force may also be provided (manually or automatically) to move the cuff 3511 proximally to eject the clot material 3590 from the flexible tube 3509. For example, the ejection apparatus may be a mechanical apparatus including one or more springs (e.g., extension springs) to assist in ejecting the clot material.

[000192] Once the clot is ejected, as shown in FIG. 34C, the apparatus is prepared for re-insertion, and may be inserted back into the patient (e.g., through an intermediate catheter with or without a guidewire) to remove additional clot material. An additional cover or sheath may be used to re-introduce the apparatus through the intermediate catheter.

CLAIMS

1. An inverting tube apparatus for removing a clot from a vessel, the apparatus comprising:

an inversion support catheter;

a puller within a lumen of the inversion support catheter; and

a flexible tube extending over a distal end of the inversion support catheter, the flexible tube having a first end coupled at a distal end region of the puller and a second end comprising a cuff that is less flexible than a region of the flexible tube adjacent to the cuff, wherein the flexible tube is configured to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the flexible tube rolls and inverts over a distal end of the inversion support catheter.

2. The apparatus of claim 1, wherein the cuff comprises one or more slits along its length extending in a proximal-to-distal direction.

3. The apparatus of claim 1 or 2, wherein the cuff comprises a polymeric material.

4. The apparatus of any of claims 1-3, further comprising a cuff retainer configured to prevent the cuff from extending over the distal end of the inversion support catheter.

5. The apparatus of claim 4, wherein the cuff retainer comprises one or more filaments coupling the cuff to the inversion support catheter.

6. The apparatus of claim 4, wherein the cuff retainer comprises a mechanical stop on the inversion support catheter.

7. The apparatus of claim 4, wherein the cuff retainer comprises one or more filaments connecting the cuff to the puller through a lateral opening in the inversion support catheter.

8. The apparatus of claim 4, wherein a proximal-facing end of the cuff is tapered.

9. The apparatus of claim 4, wherein a proximal-facing end of the cuff comprises a low-profile scaffolding extending at least partially around the perimeter of the cuff.

10. The apparatus of any of claims 1-9, further comprising a first proximal port configured to couple with a vacuum source to apply vacuum through the puller.

11. The apparatus of any of claims 1-9, further comprising a second proximal port configured to couple with a vacuum source to apply vacuum between the intermediate catheter and the inversion support catheter.

12. The apparatus of any of claims 1-11, wherein the intermediate catheter is configured to push the cuff over the distal end of the inversion support catheter when the intermediate catheter is advanced distally past the cuff.

13. The apparatus of any of claims 1-12, wherein the flexible tube comprises a knit.

14. The apparatus of any of claims 1-13, wherein the cuff is radiopaque.

15. An inverting tube apparatus for removing a clot from a vessel, the apparatus comprising:

an inversion support catheter;

a puller within a lumen of the inversion support catheter; and

a flexible tube extending over a distal end of the inversion support catheter, the flexible tube having a first end coupled at a distal end region of the puller and a second end comprising a cuff that is less flexible than a region of the flexible tube adjacent to the cuff, wherein the flexible tube is configured to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the flexible tube rolls and inverts over a distal end of the inversion support catheter, and wherein the cuff is tapered at the proximal facing end.

16. An inverting tube apparatus for removing a clot from a vessel, the apparatus comprising:

an intermediate catheter;

an inversion support catheter within a lumen of the intermediate catheter;

a puller within a lumen of the inversion support catheter; and

a knitted tube extending over the inversion support catheter, the knitted tube having a first end coupled at a distal end region of the puller and a second end that is free,

wherein the knitted tube is configured to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the knitted tube rolls and inverts over a distal end of the inversion support catheter,

wherein the knitted tube comprises a filament knitted to form a plurality of interlocking loop stitches, and

wherein each loop stitch has a stitch length that is between 0.5mm and 10mm.

17. The apparatus of claim 16, wherein the knitted tube extends over the inversion support catheter with an inner diameter that is within 20% of the outer diameter of the inversion support catheter.

18. The apparatus of claim 16 or 17, wherein the second end of the knitted tube comprises a cuff that is less flexible than a region of the knitted tube adjacent to the cuff.

19. An inverting tube apparatus for removing a clot from a vessel, the apparatus comprising:

an inversion support catheter;

a puller within a lumen of the inversion support catheter; and

a knitted tube extending over the inversion support catheter in a first configuration, the knitted tube having a first end coupled to a distal end region of the puller, and a second end that is free to move relative to the inserting support catheter, wherein the knitted tube is configured to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the knitted tube rolls and inverts over a distal end of the inversion support catheter into a second configuration within the inversion support catheter;

further wherein the knitted tube in the first configuration has an expanded outer diameter that is between 0.5 mm and 12 mm for a first region of the knitted tube that is adjacent to the first end, and the knitted tube in the second configuration has an inner diameter that is greater than 30% of an inner diameter of the inversion support catheter, and wherein a second region of the knitted tube adjacent to the second end has an expanded outer diameter that is less than the expanded outer diameter of the region of the knitted tube adjacent to the first end and within 20% of an outer diameter of the inversion support catheter.

20. The apparatus of claim 19, further comprising a cuff at the second end, wherein the cuff has a stiffness that is greater than a region of the knitted tube adjacent to the cuff.

21. The apparatus of claim 19 or 20, further comprising a stop configured to limit the travel of the knitted tube so that the second end does not roll and invert over the distal end of the inversion support catheter.

22. The apparatus of any of claims 19-21, wherein the knitted tube is shape set so that the first configuration has the outer diameter between 0.5 mm and 10 mm for the region of the knitted tube adjacent to the first end, and the knitted tube in the second configuration has an inner diameter that is greater than 60% of the inner diameter of the inversion support catheter.

23. The apparatus of any of claims 19-22, wherein the first region of the knitted tube is at least 2 cm long.

24. The apparatus of any of claims 19-23, wherein the second region is at least 1 cm long.

25. The apparatus of any of claims 19-24, wherein the knitted tube comprises a filament knitted to form a plurality of interlocking loop stitches, wherein each loop stitch has a stitch length that is between 0.5 mm and 10 mm.

26. The apparatus of claim 25, wherein, at a region of the knitted tube that is inverting from the first configuration to the second configuration, a sub-set of the plurality of loop stitches forming the knitted tube extend proud from the long axis of the knitted tube by between 0.5 mm and 10 mm.

27. The apparatus of any of claims 19-26, further comprising an intermediate catheter having a lumen, wherein the inversion support catheter is within the lumen of the intermediate support catheter and may be extended distally from the intermediate catheter to deploy the knitted tube so that the knitted tube may expand into the first configuration.

28. The apparatus of any of claims 19-27, wherein the puller comprises a puller catheter.

29. A pre-loaded inverting mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortuous anatomy, the apparatus comprising:

an intermediate catheter having a distal end;

an inversion support catheter within a lumen of the intermediate catheter, the inversion support catheter having a distal end and a distal end opening;

a puller extending within the inversion support catheter; and

a flexible tube extending proximally from a distal end region of the puller so that a distal-facing face of the puller extends distally beyond the flexible tube,

wherein the puller extends from the distal end of the intermediate catheter and the distal end opening of the inversion support catheter; and wherein the distal end opening of the inversion support is held within the lumen of the intermediate catheter, and wherein the flexible tube extends between the inversion support catheter and the intermediate catheter.

30. The apparatus of claim 29, wherein the inversion support catheter comprises a plurality of slots or cut-out regions along its length to enhance flexibility while maintaining column strength such that the inversion support catheter is able to withstand at least about 500g of compressive force.

31. The apparatus of claim 29 or 30, wherein the flexible tube comprises a knitted tube.

32. The apparatus of claim 29, wherein the inversion support catheter comprises a plurality of slits or openings around the perimeter of the inversion support catheter and down the length of the inversion support catheter.

33. The apparatus of claim 29, wherein the inversion support catheter is removably secured to the intermediate catheter so that the intermediate support catheter and the intermediate catheter move relative to each other.

24. The apparatus of any of claims 19-23, further comprising a guidewire within the puller.

25. The apparatus of any of claims 19-23, wherein puller comprises a micro catheter.

26. The apparatus of any of claims 19-23, wherein the puller comprises a guidewire.

27. A pre-loaded inverting mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy, the apparatus comprising:

- an intermediate catheter having a distal end;

- an inversion support catheter extending distally from a lumen of the intermediate catheter, the inversion support catheter having a distal end and a distal end opening;

- a puller extending distally within the inversion support catheter; and

- a flexible tube extending proximally from a distal end region of the puller and between the intermediate catheter and the inversion support catheter,

wherein the puller extends from the distal end of the intermediate catheter and the distal end opening of the inversion support catheter; and wherein the distal end opening of the inversion support is held within the lumen of the intermediate catheter, and wherein the flexible tube extends between the inversion support catheter and the intermediate catheter, and

wherein the puller and inversion support catheter are releasably held together so that they move together while advancing distally within a vessel lumen.

28. The apparatus of claim 27, wherein the inversion support catheter comprises a plurality of slots or cut-out regions along its length to enhance flexibility while maintaining column strength such that the inversion support catheter is able to withstand at least about 500g of compressive force.

29. The apparatus of claim 27 or 28, wherein the tractor tube comprises a knitted tube.

30. The apparatus of claim 27, wherein the inversion support catheter comprises a plurality of slits or openings around the perimeter of the inversion support catheter and down the length of the inversion support catheter.

31. The apparatus of any of claims 27-30, further comprising a guidewire within the puller.

32. The apparatus of any of claims 27-30, wherein puller comprises a micro catheter.

33. The apparatus of any of claims 27-30, wherein the puller comprises a guidewire.

34. An inverting mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortuous anatomy, the apparatus comprising:

an inversion support catheter extending distally, the inversion support catheter having a distal end and a distal end opening, the inversion support catheter comprising a plurality of slots or cut-out regions along its length to enhance flexibility while maintaining column strength such that the inversion support catheter is able to withstand at least about 500g of compressive force;

a puller extending distally within the inversion support catheter; and

a flexible tube extending proximally from a distal end region of the puller,

wherein the flexible tube comprises a knitted material that is held in compression along an outside region of the inversion support catheter and inverts over the distal end opening of the inversion support catheter and couples to the puller, and

wherein pulling the puller proximally causes the flexible tube to roll from the outside region of the inversion support catheter, over the distal end opening and invert into the inversion support catheter.

34. A pre-loaded inverting mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy, the apparatus comprising:

- an intermediate catheter having a distal end;
- an inversion support catheter extending distally from a lumen of the intermediate catheter, the inversion support catheter having a distal end and a distal end opening;
- a puller extending distally within the inversion support catheter; and
- a flexible tube extending proximally from a distal end region of the puller and between the intermediate catheter and the inversion support catheter,

wherein the puller extends from the distal end of the intermediate catheter and the distal end opening of the inversion support catheter; and wherein the distal end opening of the inversion support is held within the lumen of the intermediate catheter, and wherein the flexible tube extends between the inversion support catheter and the intermediate catheter, and

wherein the puller and inversion support catheter are releasably held together so that they move together while advancing distally within a vessel lumen.

35. The apparatus of claim 34, wherein the inversion support catheter comprises a plurality of slots or cut-out regions along its length to enhance flexibility while maintaining column strength such that the inversion support catheter is able to withstand at least about 500g of compressive force.

36. The apparatus of claim 33 or 34, wherein the tractor tube comprises a knitted tube.

37. The apparatus of claim 27, wherein the inversion support catheter comprises a plurality of slits or openings around the perimeter of the inversion support catheter and down the length of the inversion support catheter.

38. The apparatus of any of claims 34-37, further comprising a guidewire within the puller.

39. The apparatus of any of claims 34-37, wherein puller comprises a micro catheter.

40. The apparatus of any of claims 34-37, wherein the puller comprises a guidewire.

41. An inverting mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortuous anatomy, the apparatus comprising:

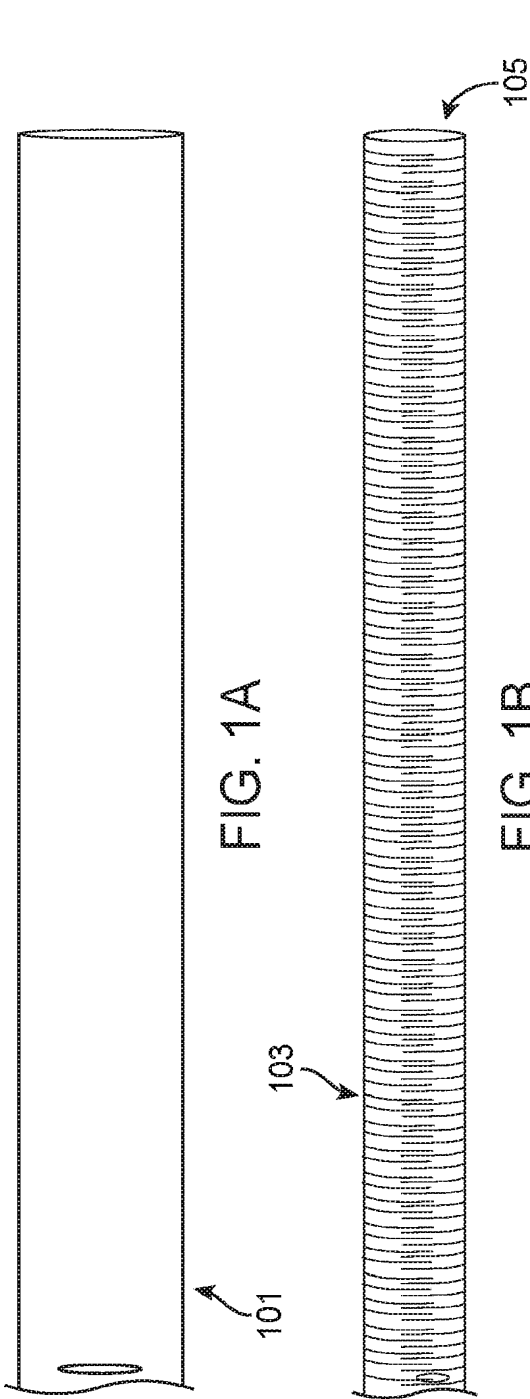
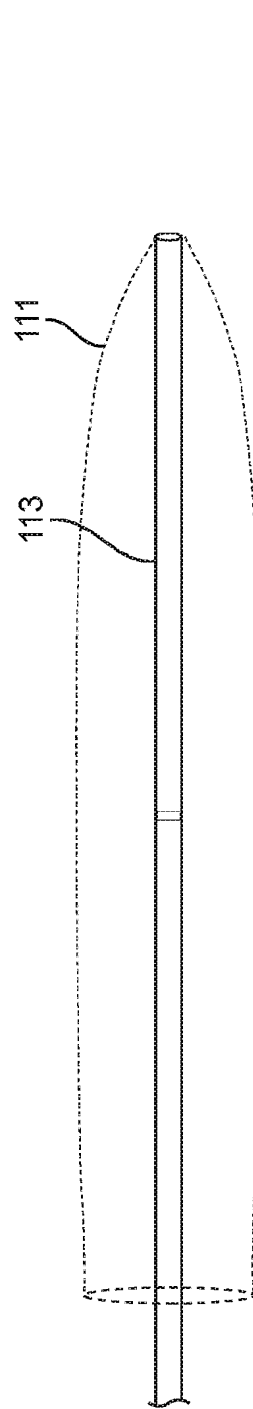
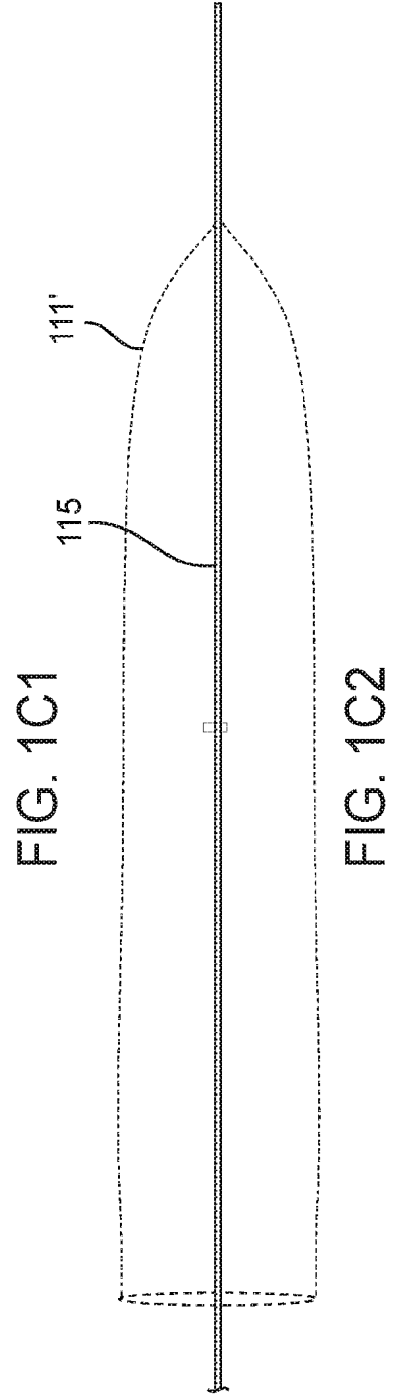
an inversion support catheter extending distally, the inversion support catheter having a distal end and a distal end opening, the inversion support catheter comprising a plurality of slots or cut-out regions along its length to enhance flexibility while maintaining column strength such that the inversion support catheter is able to withstand at least about 500g of compressive force;

a puller extending distally within the inversion support catheter; and

a flexible tube extending proximally from a distal end region of the puller,

wherein the flexible tube comprises a knitted material that is held in compression along an outside region of the inversion support catheter and inverts over the distal end opening of the inversion support catheter and couples to the puller, and

wherein pulling the puller proximally causes the flexible tube to roll from the outside region of the inversion support catheter, over the distal end opening and invert into the inversion support catheter.



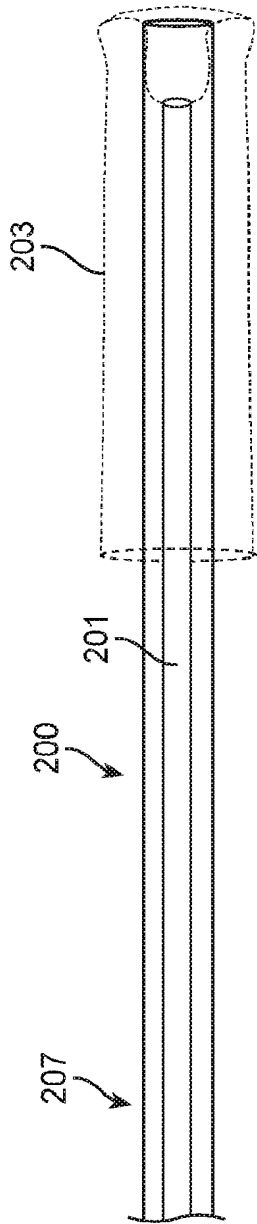


FIG. 2A

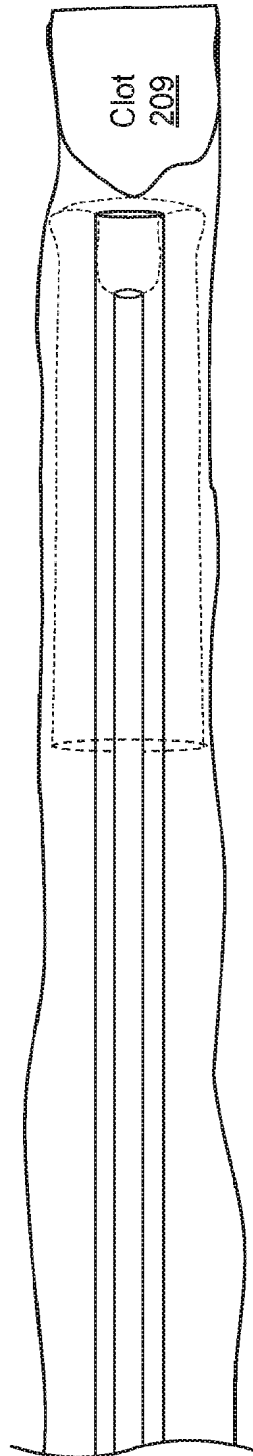


FIG. 2B

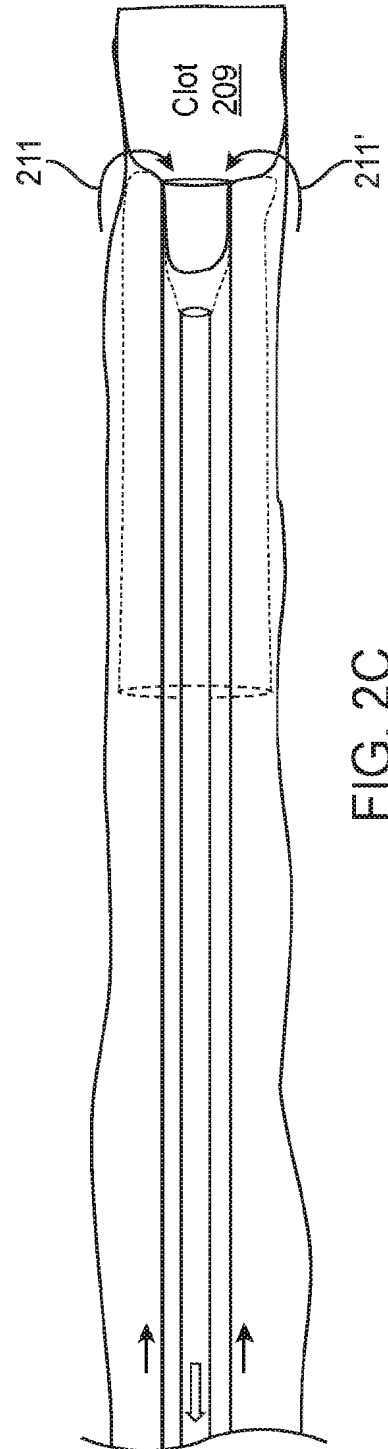


FIG. 2C

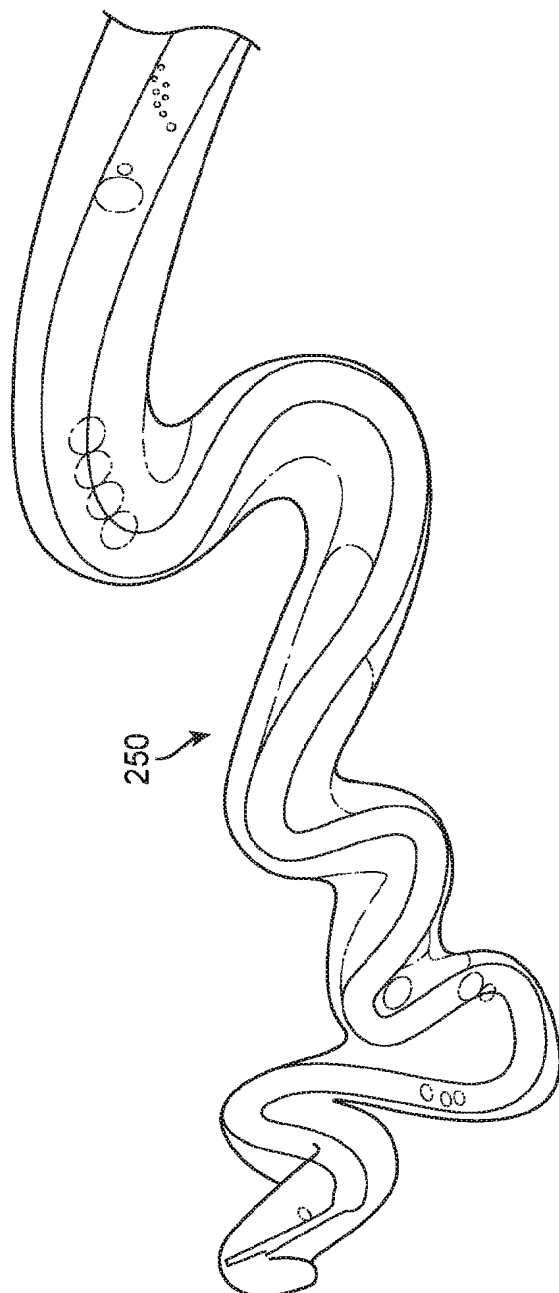


FIG. 2D

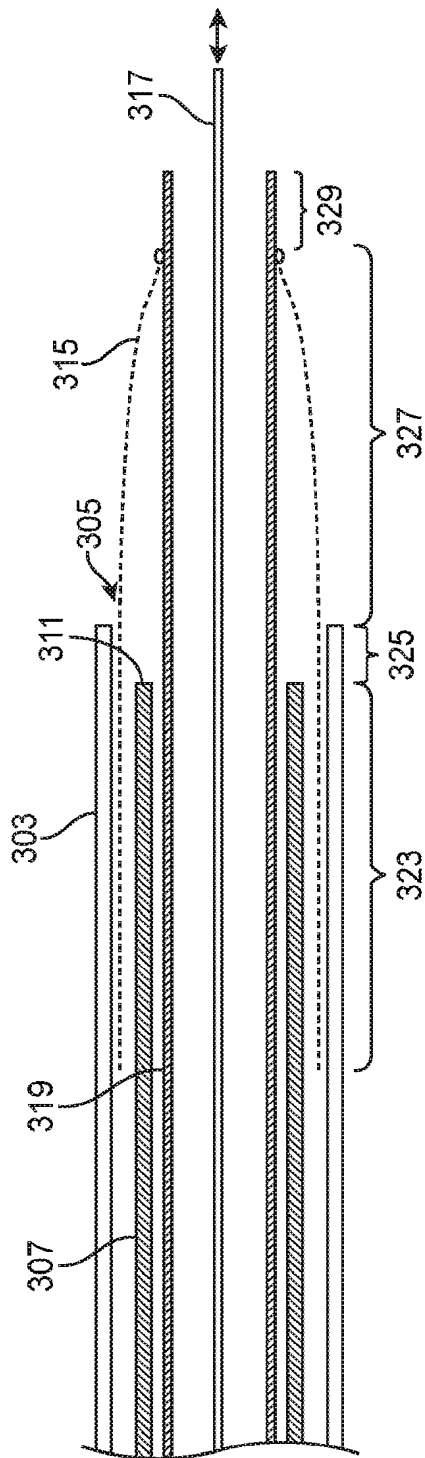
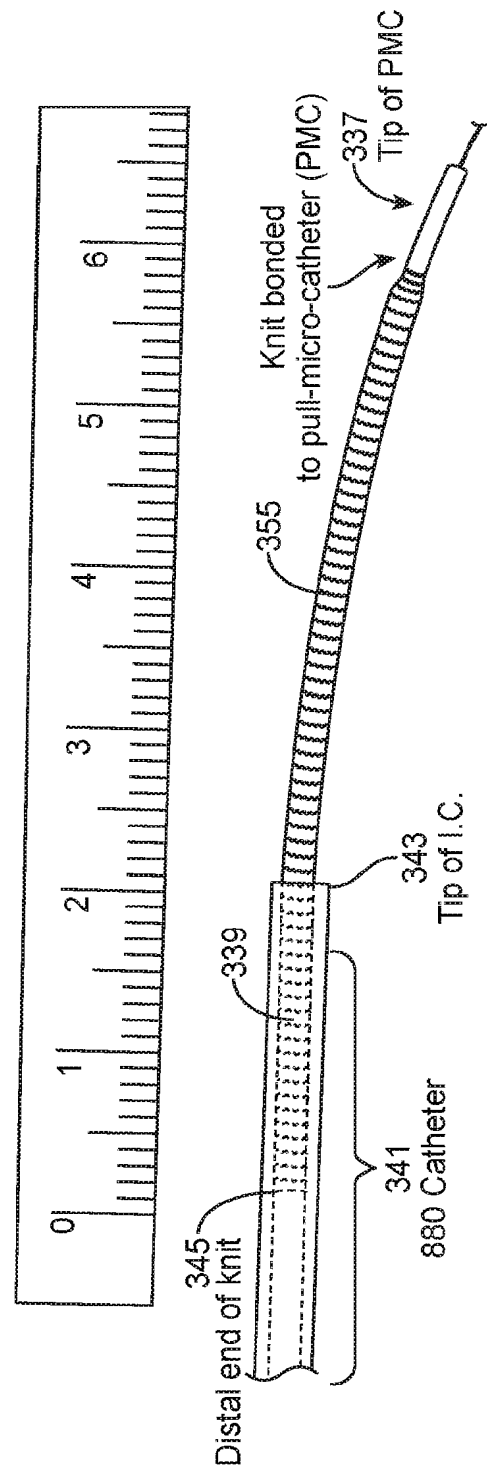


FIG. 3A



3E

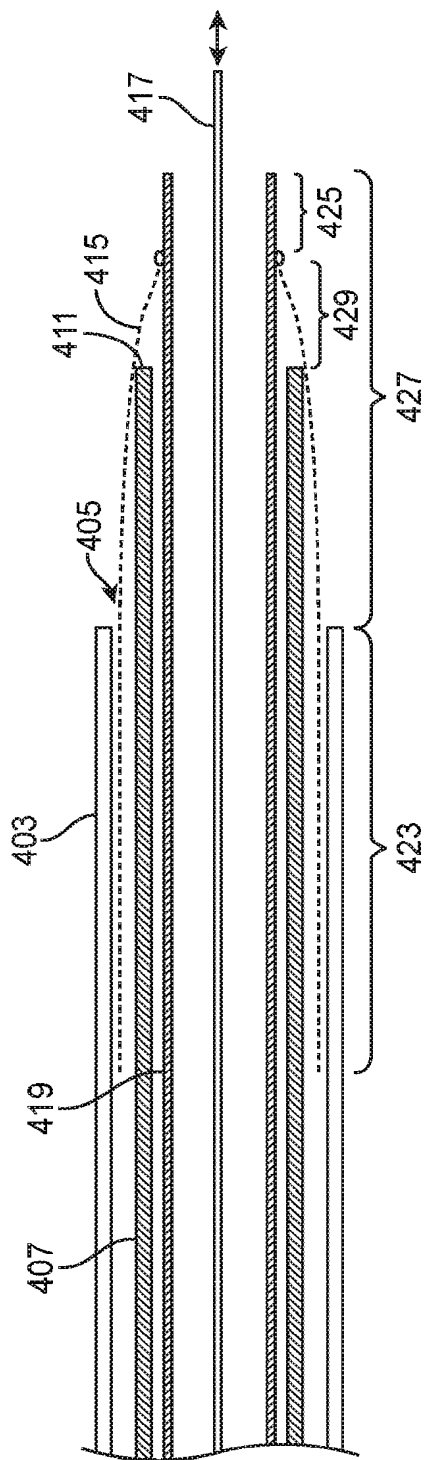


FIG. 4A

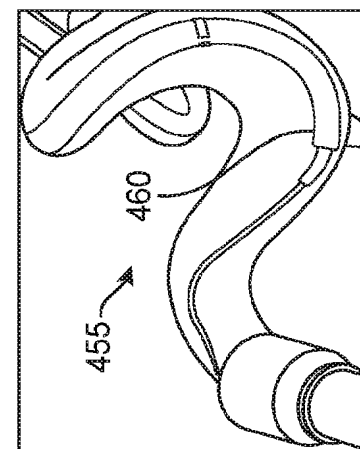


FIG. 4C

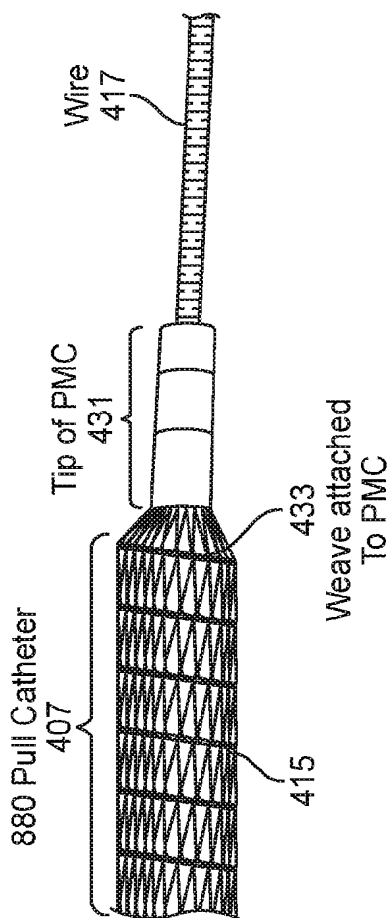


FIG. 4B

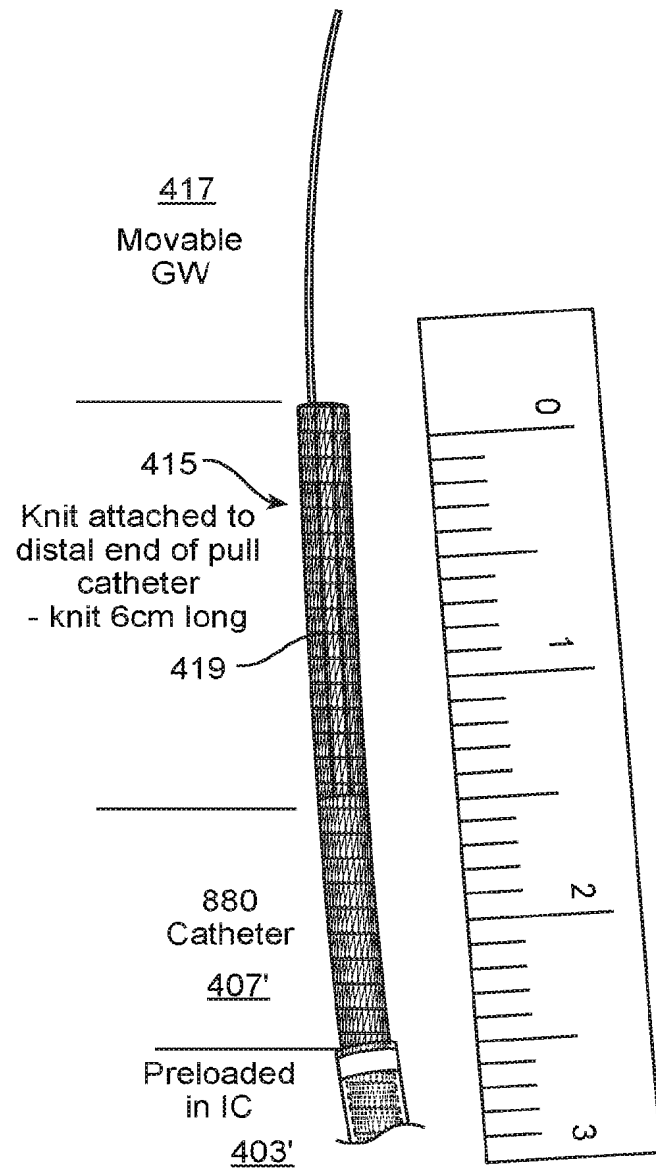


FIG. 4D

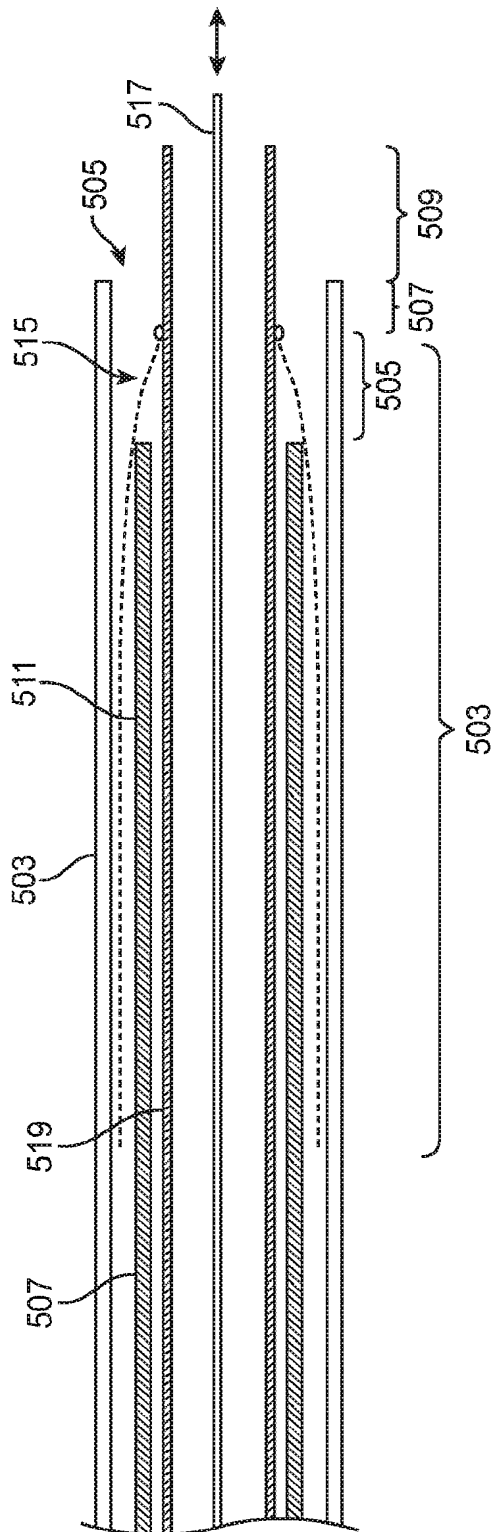


FIG. 5A

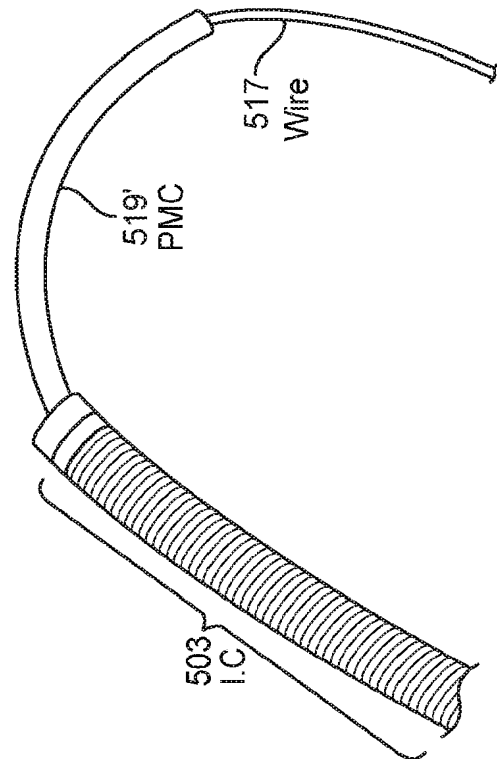


FIG. 5B

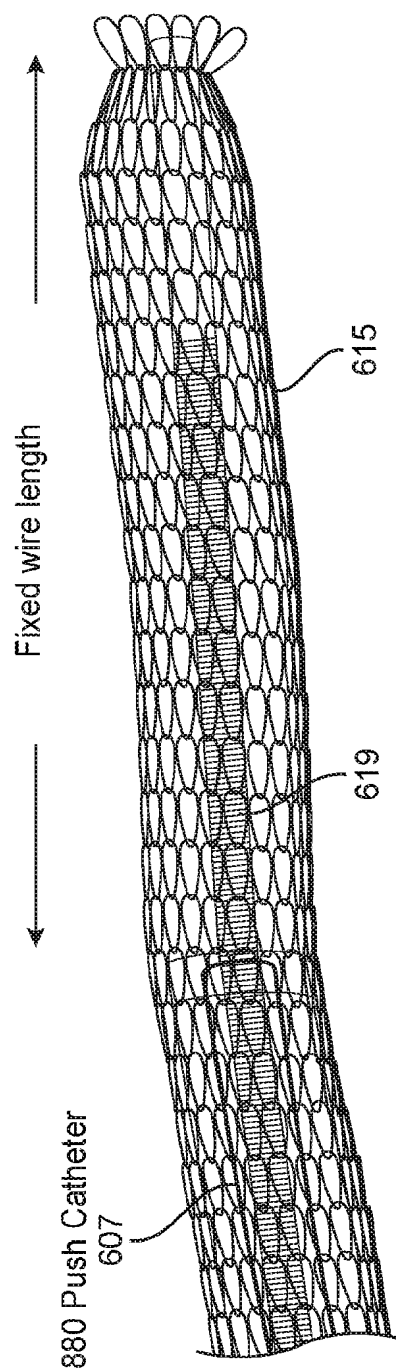
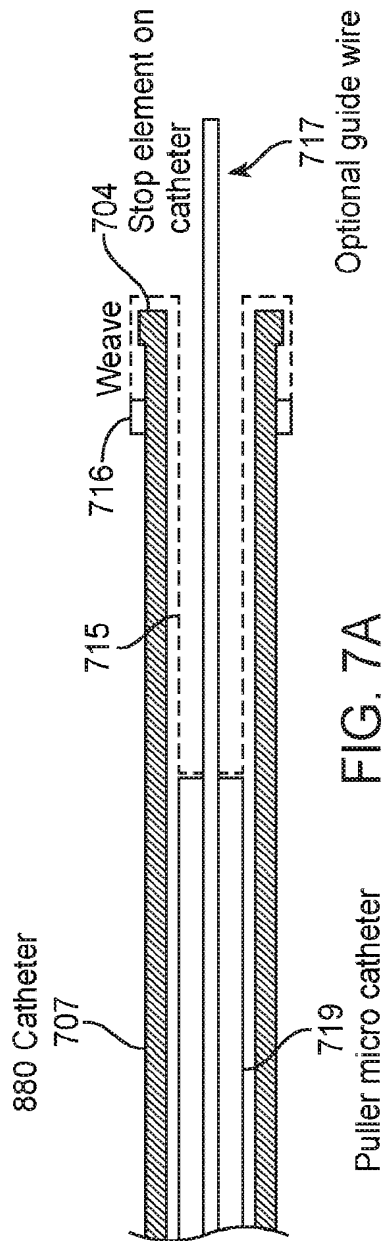
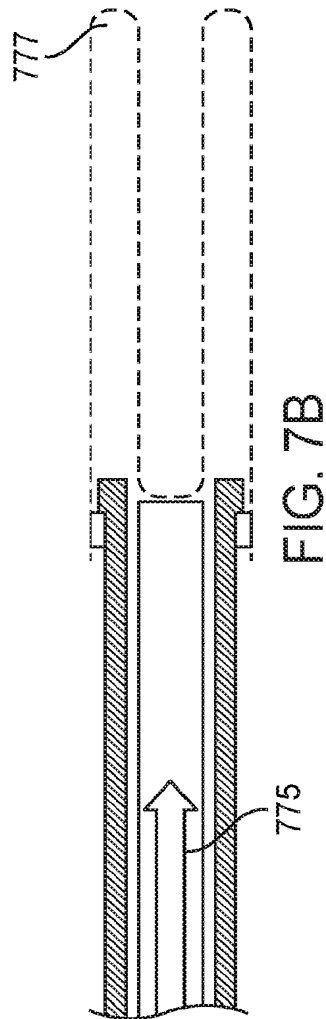
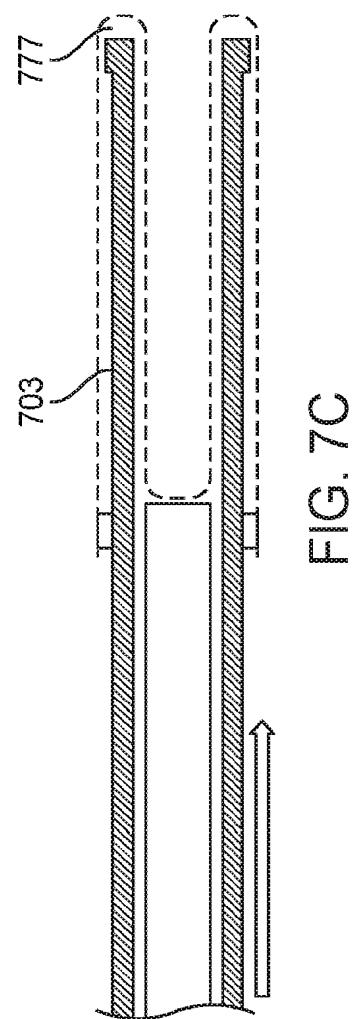


FIG. 6



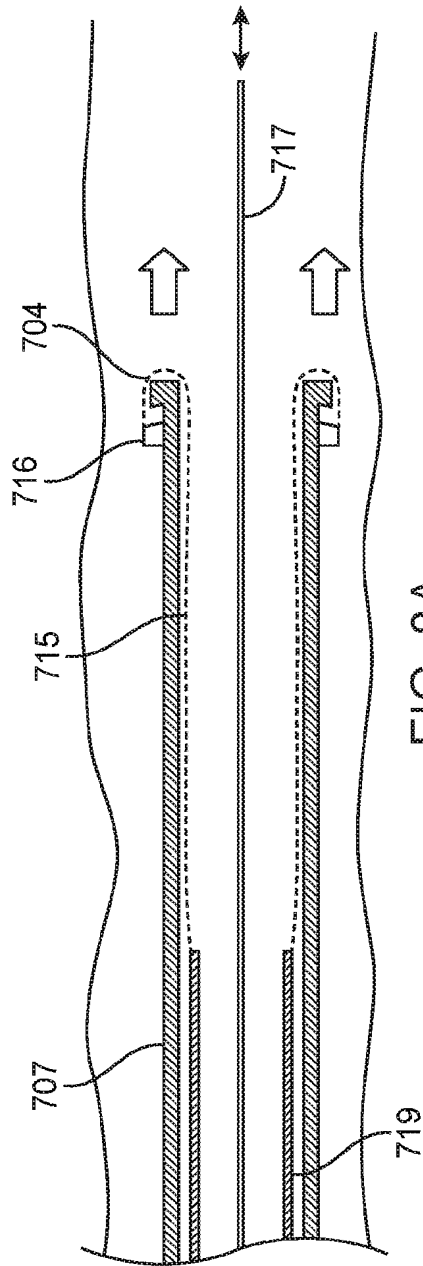


FIG. 8A

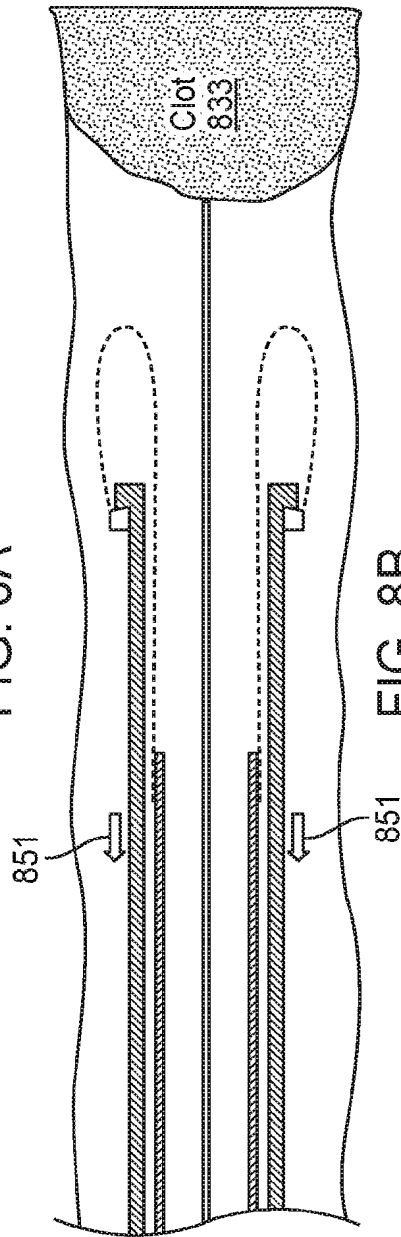


FIG. 8B

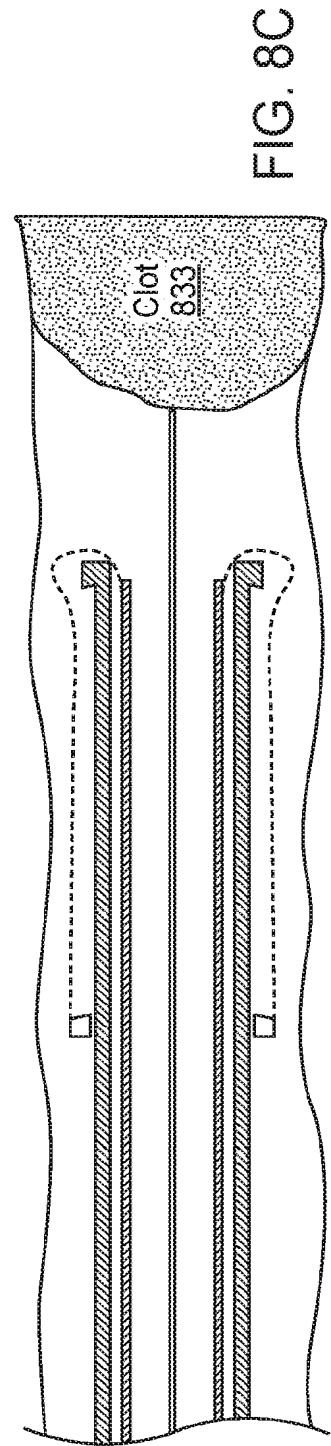


FIG. 8C

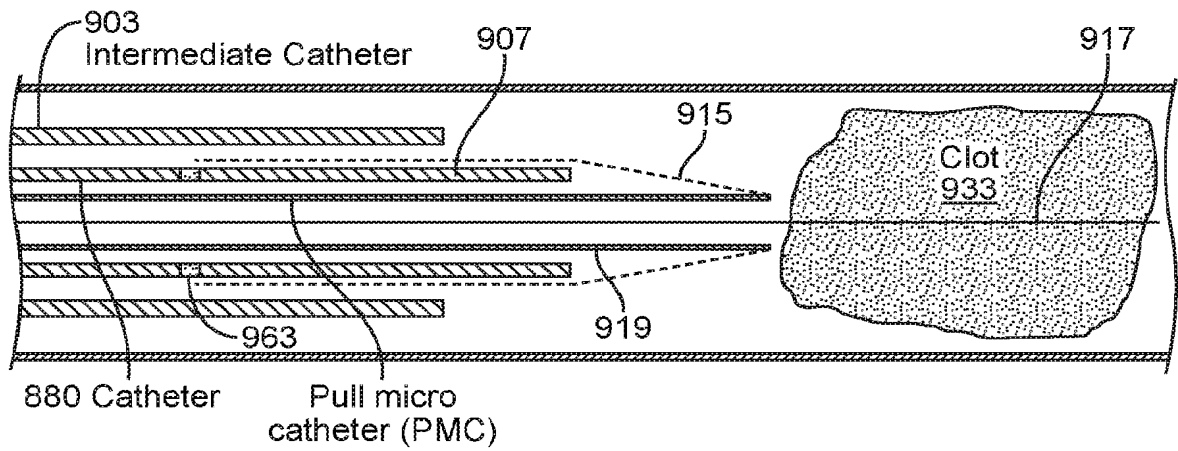


FIG. 9A

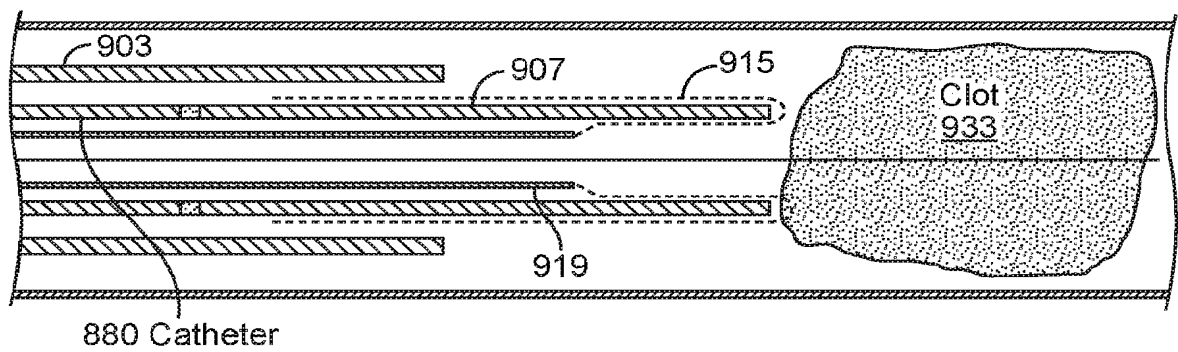


FIG. 9B

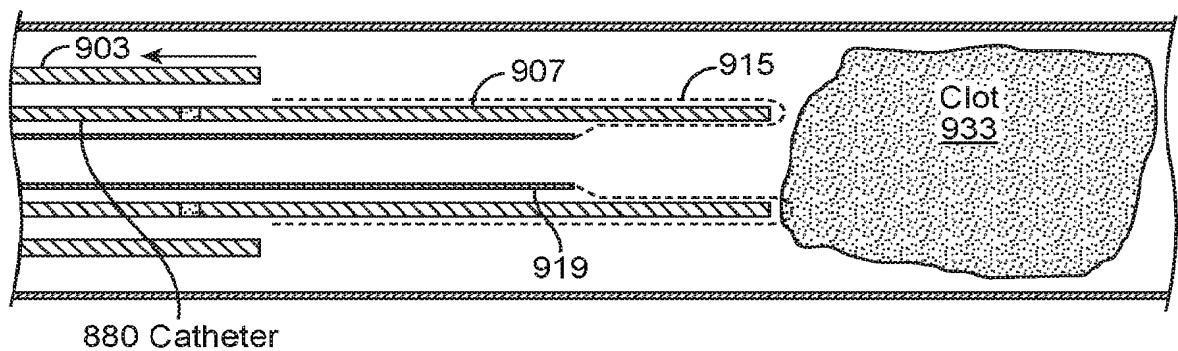


FIG. 9C

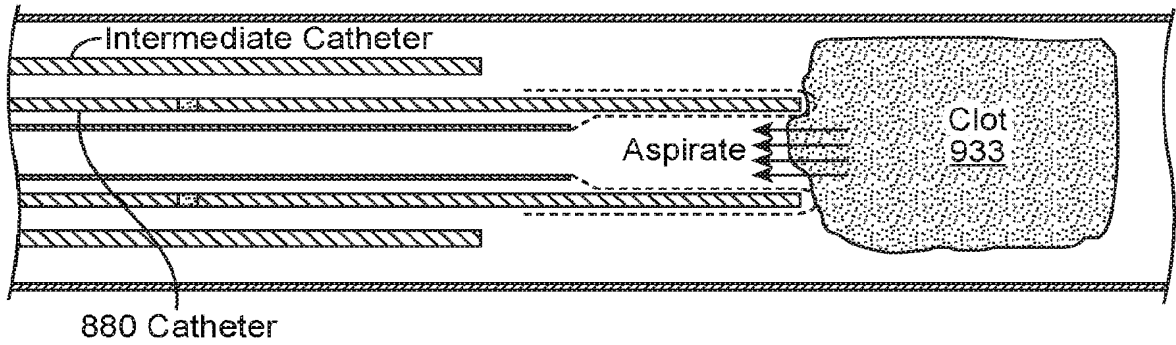


FIG. 9D

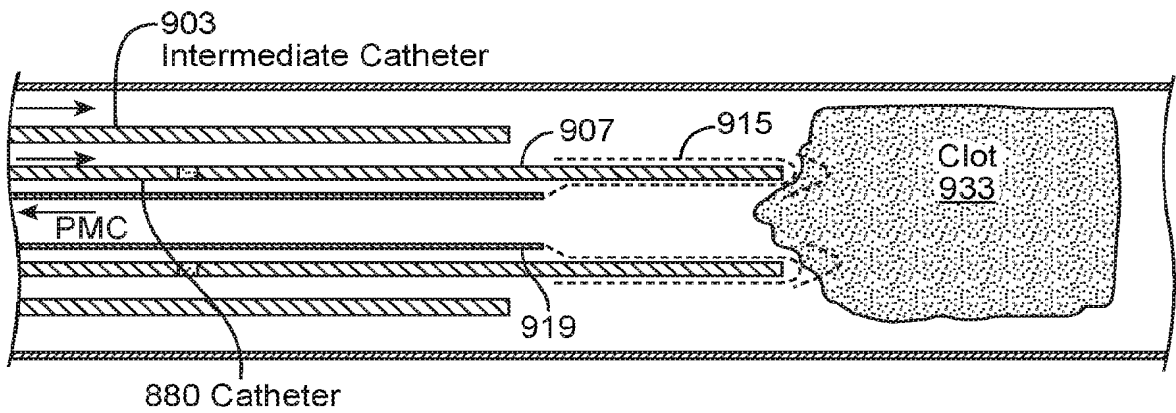


FIG. 9E

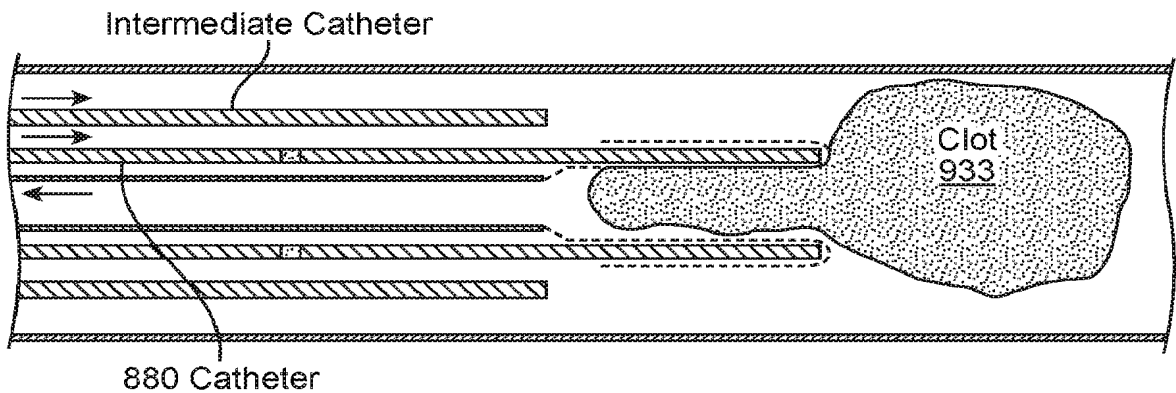


FIG. 9F

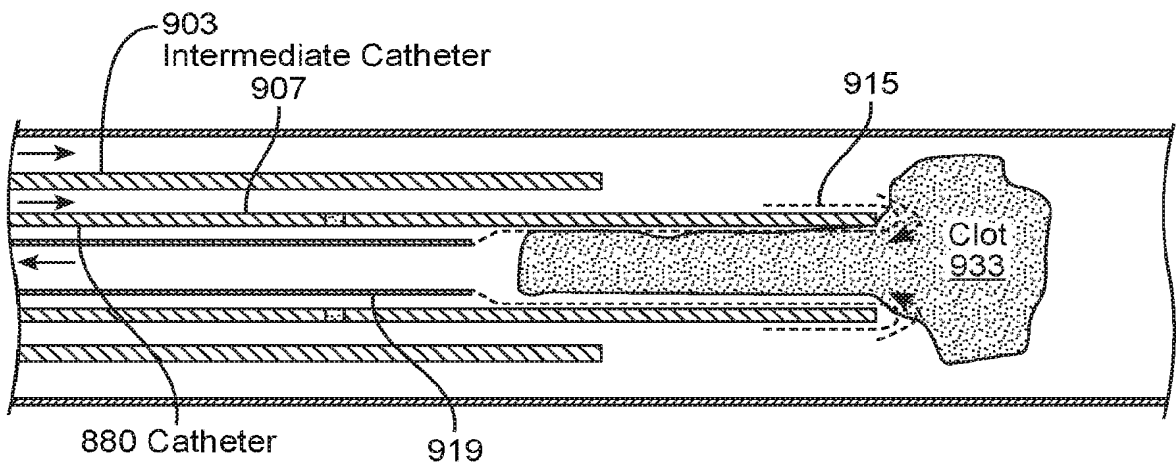


FIG. 9G

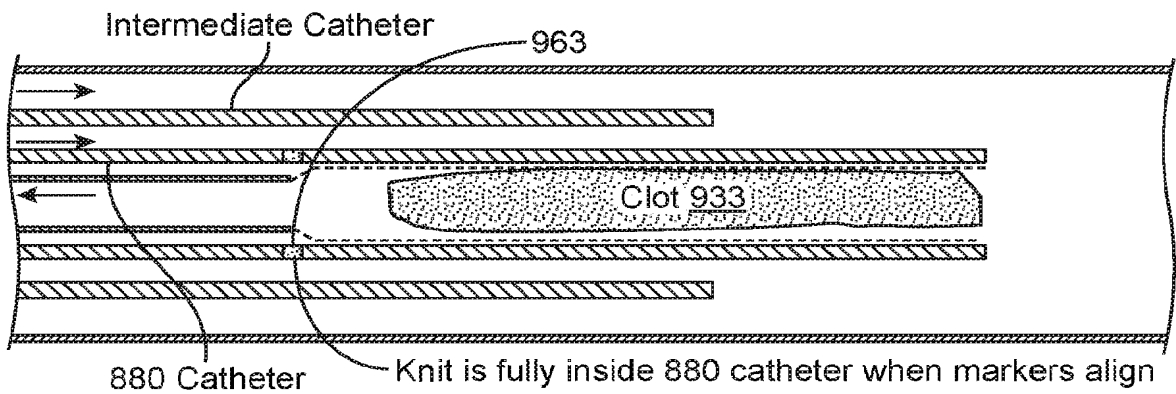


FIG. 9H

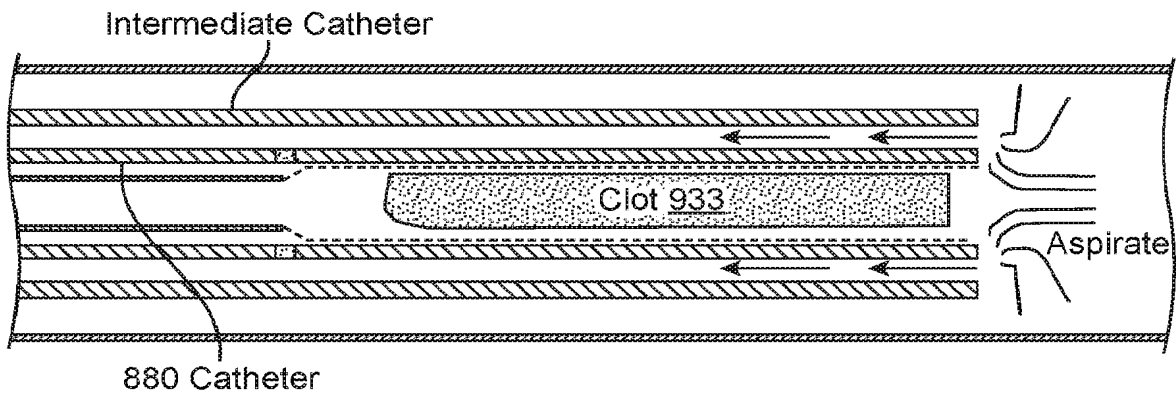


FIG. 9I

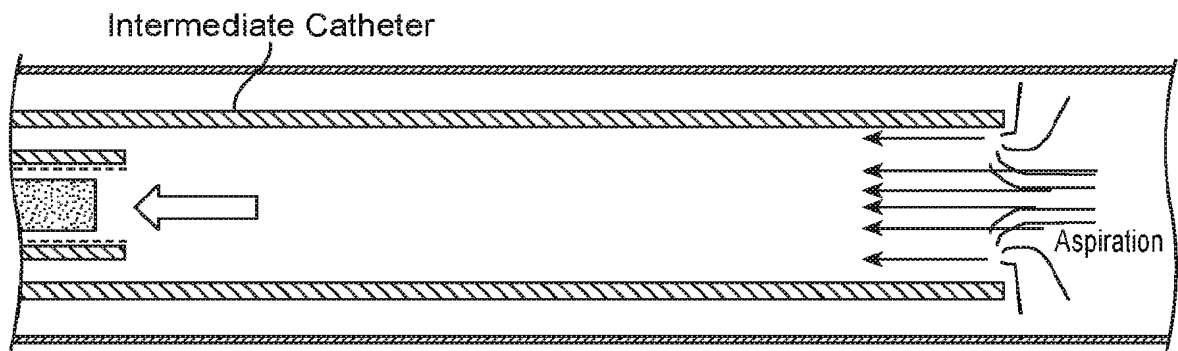


FIG. 9J

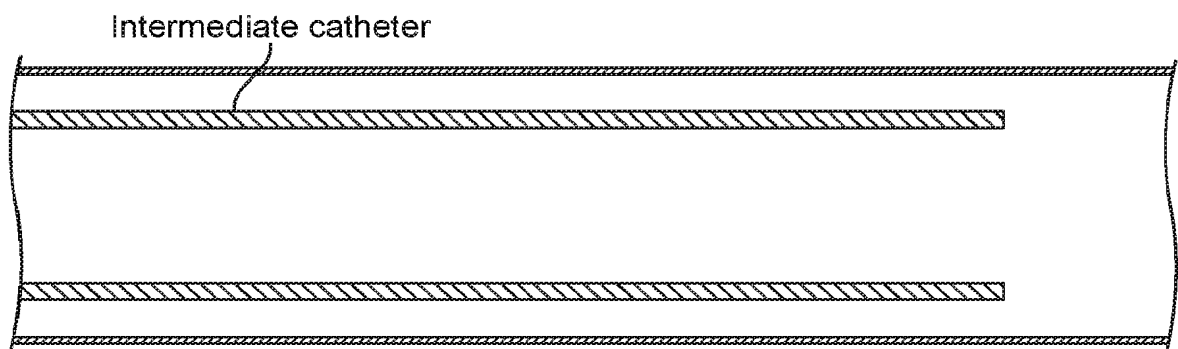


FIG. 9K

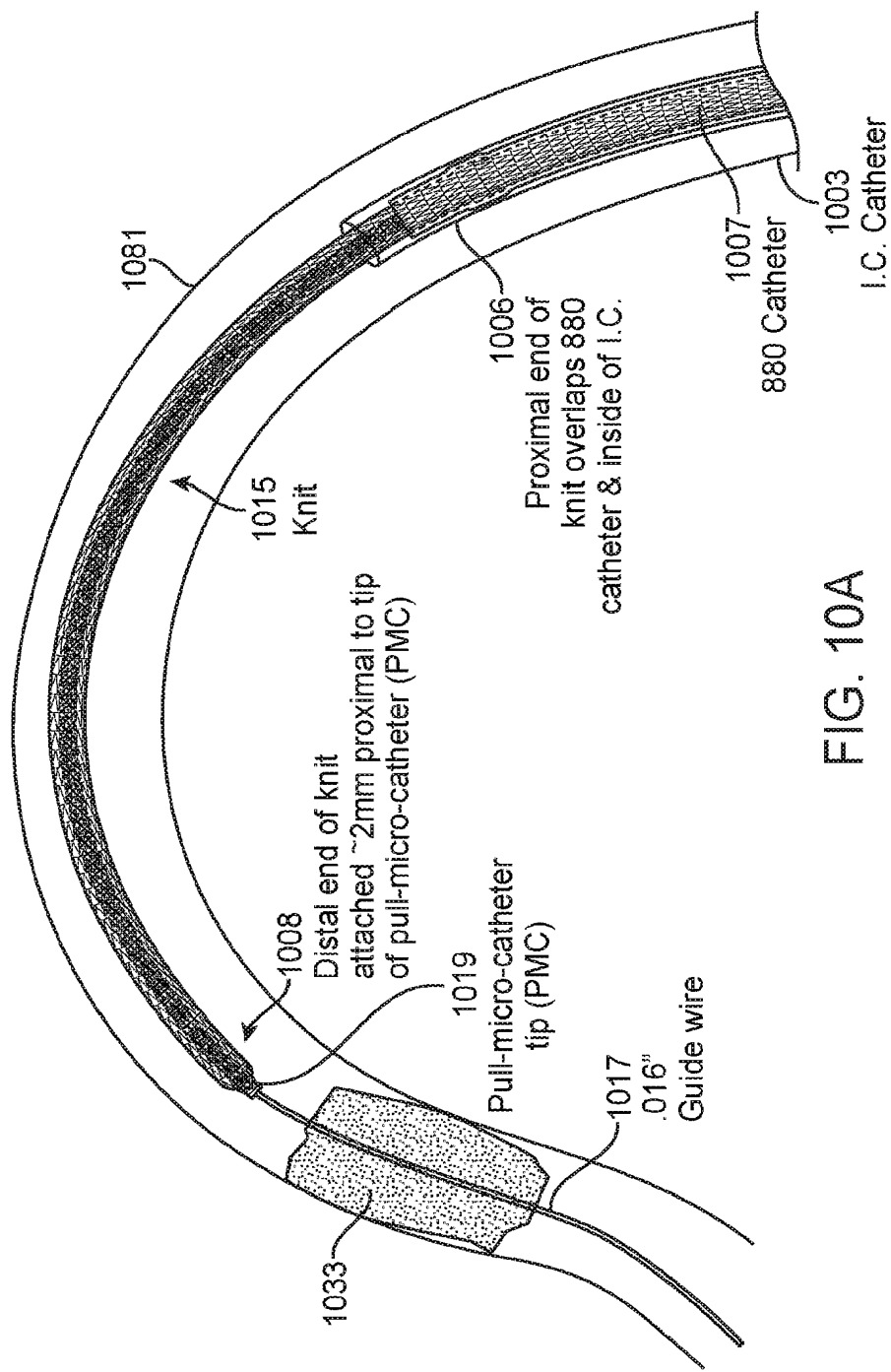


FIG. 10A

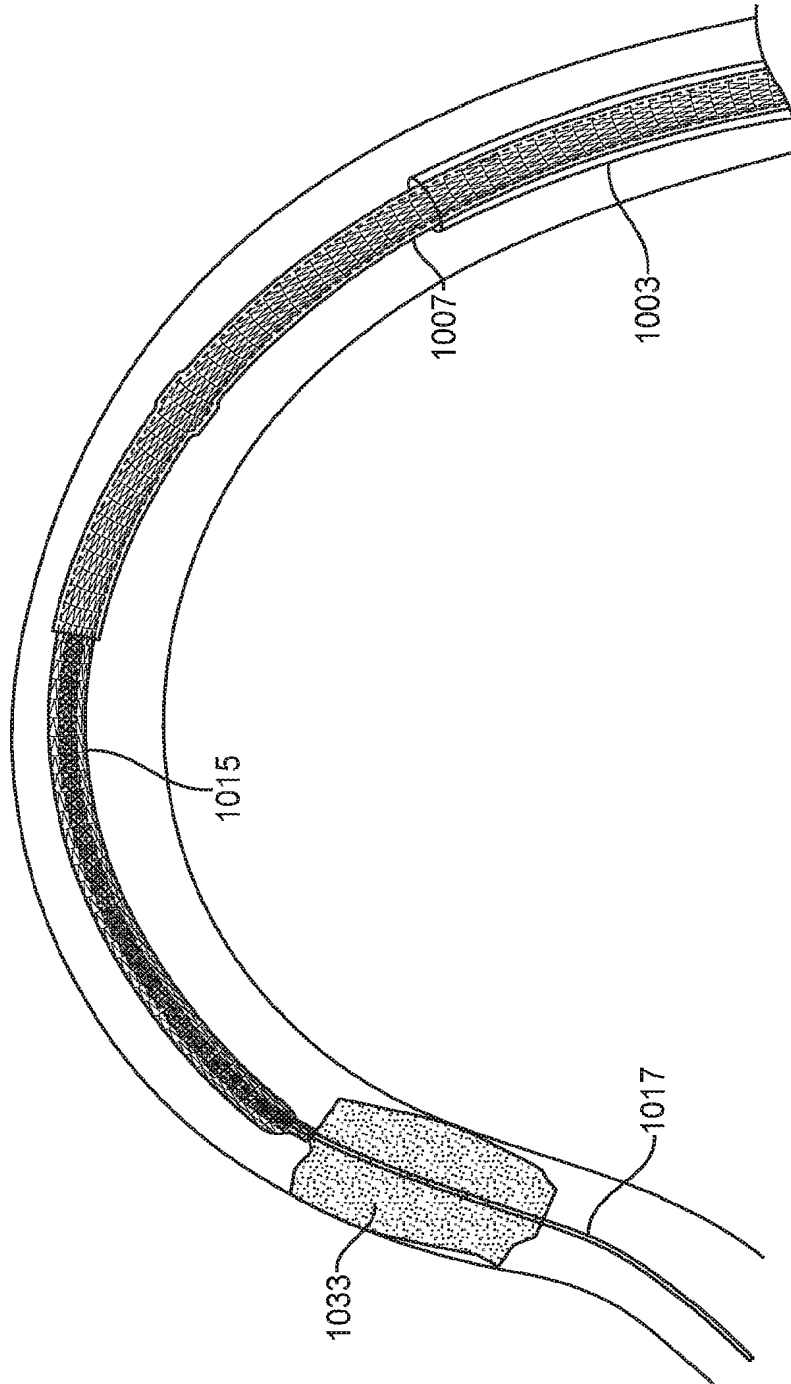


FIG. 10B

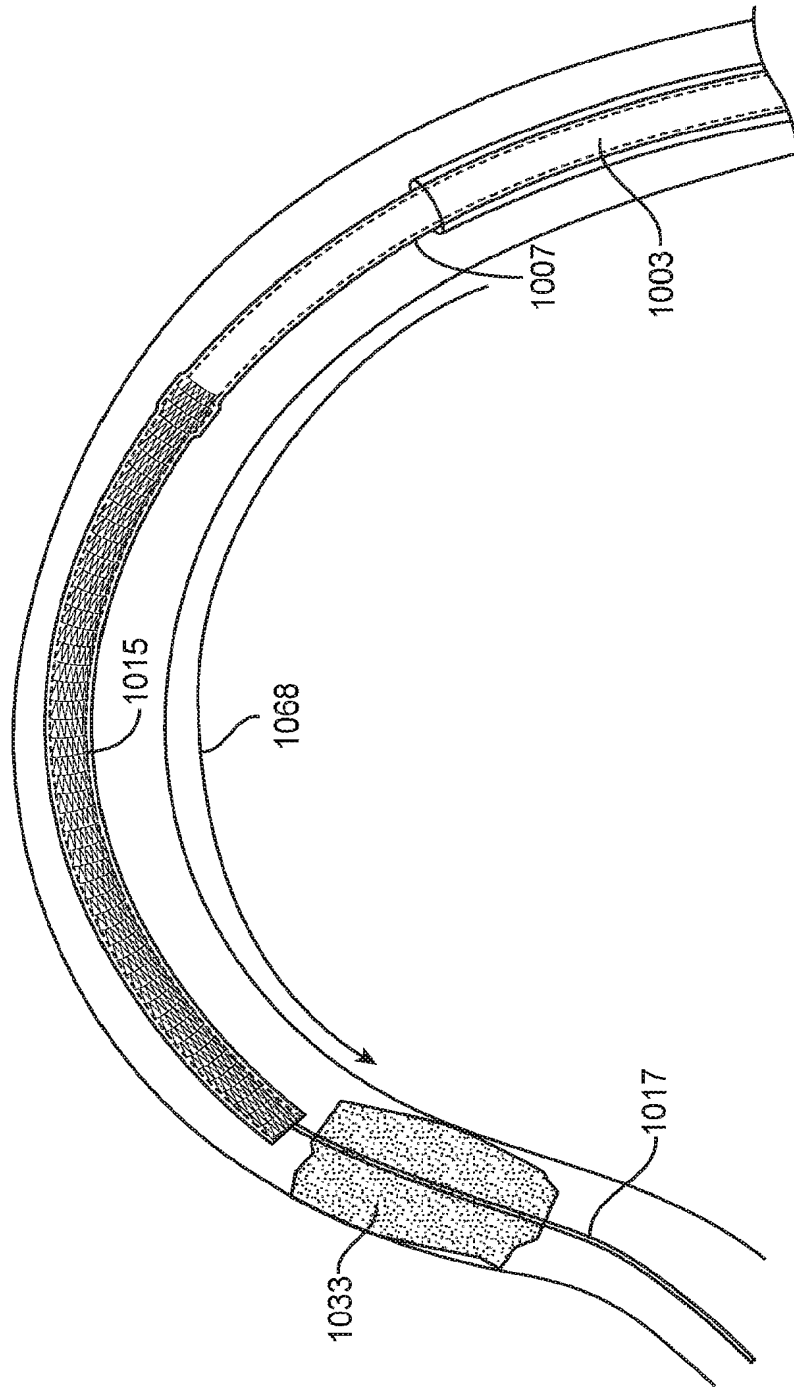


FIG. 10C

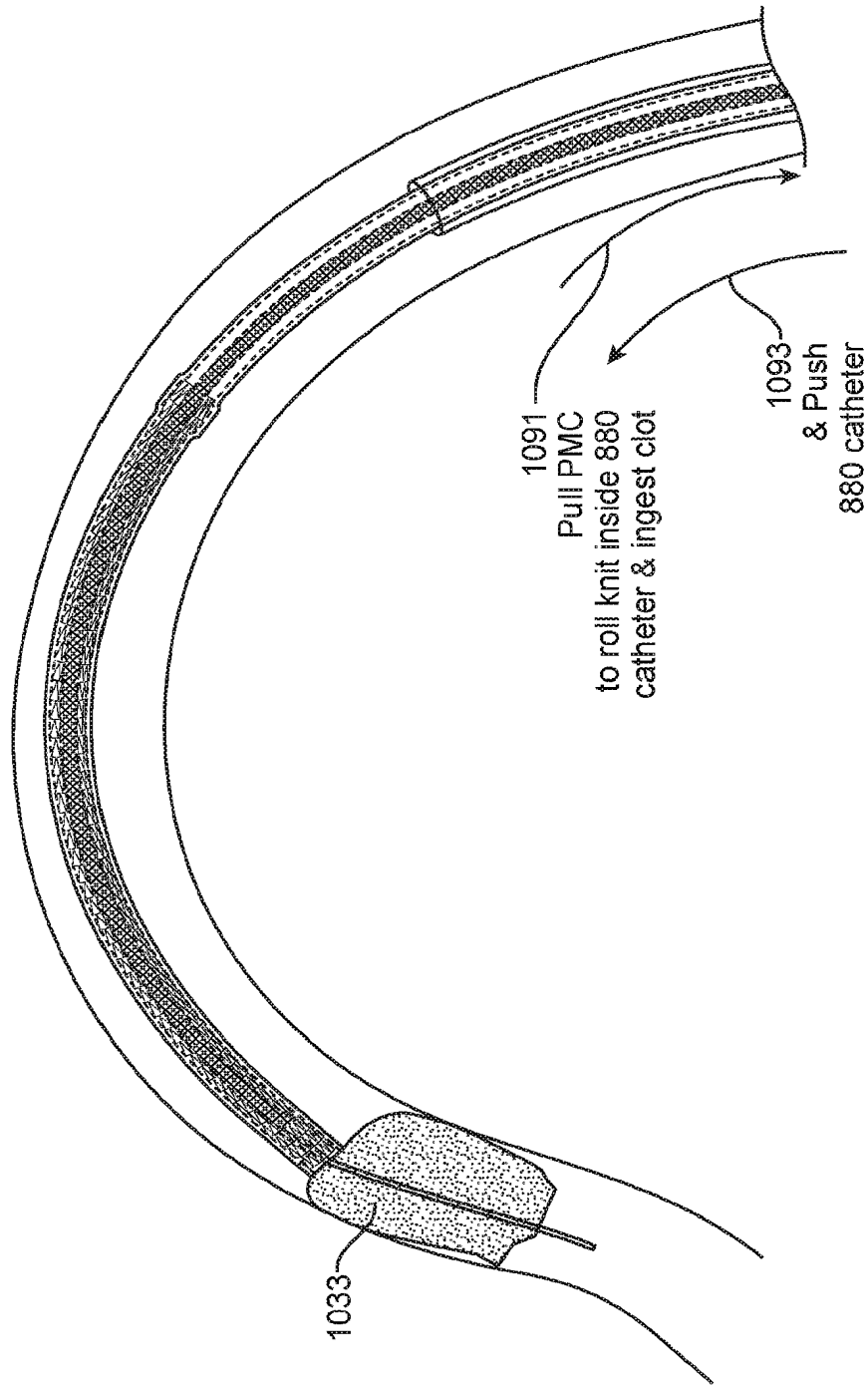


FIG. 10D

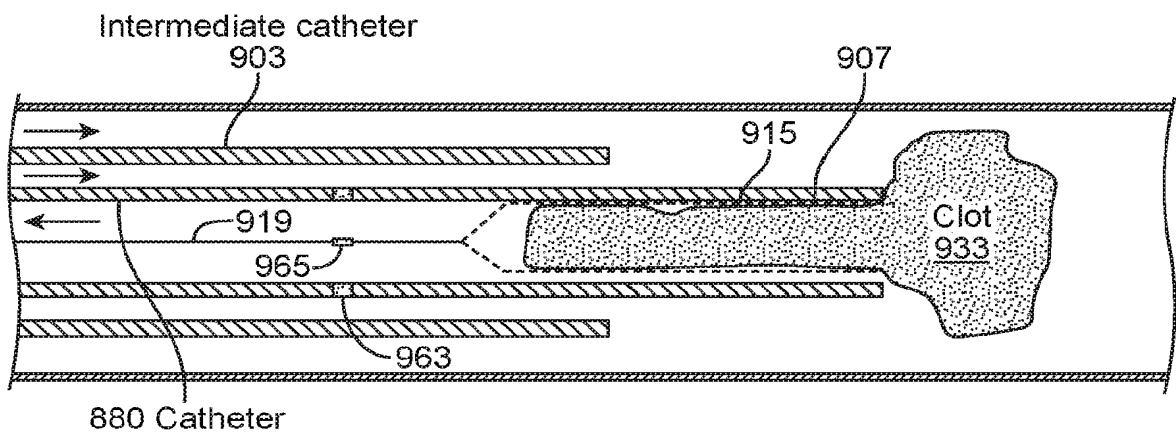


FIG. 11A

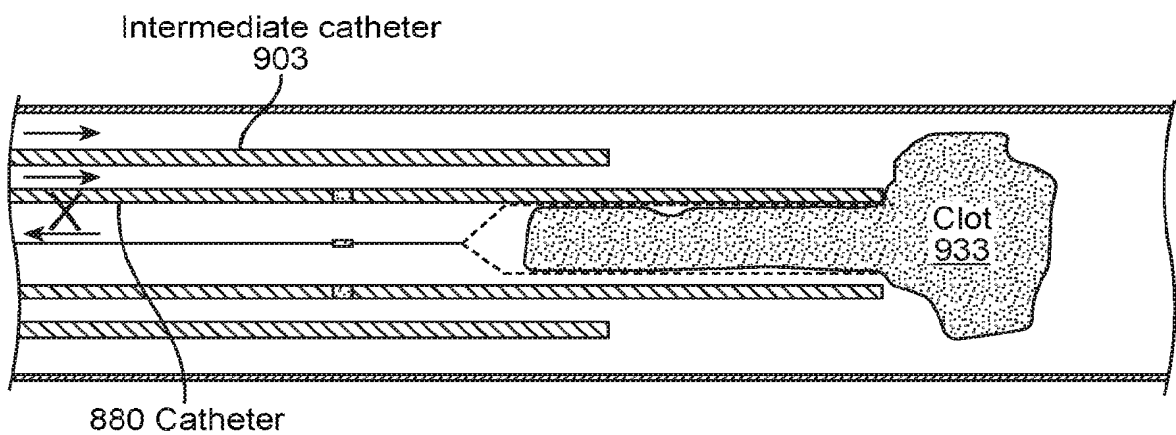


FIG. 11B

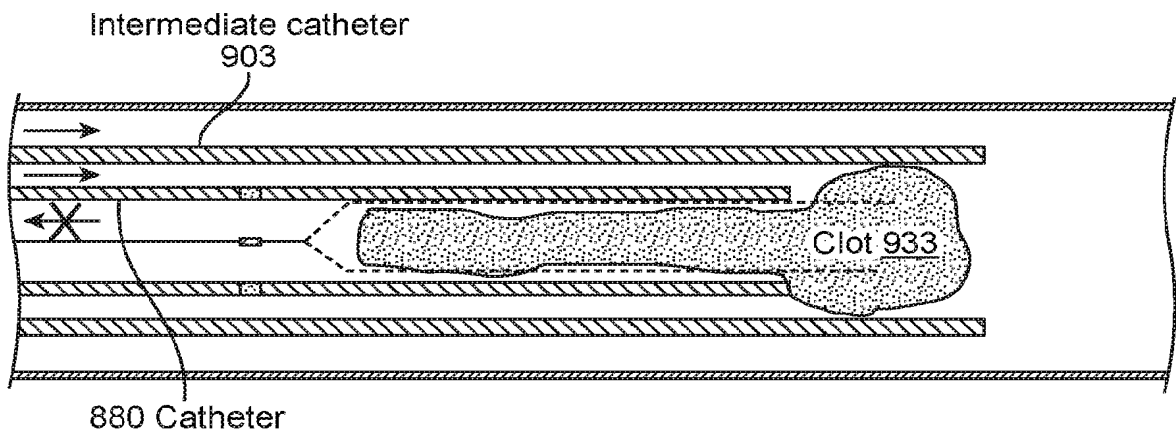


FIG. 11C

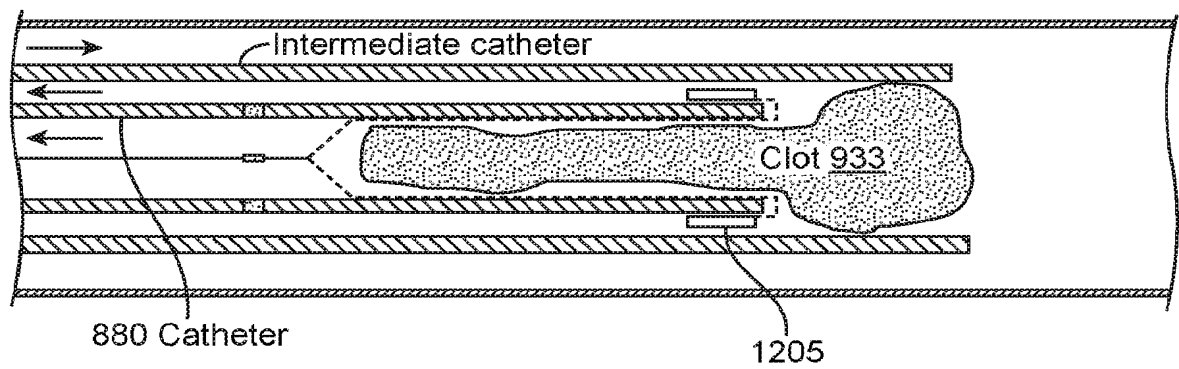


FIG. 12A

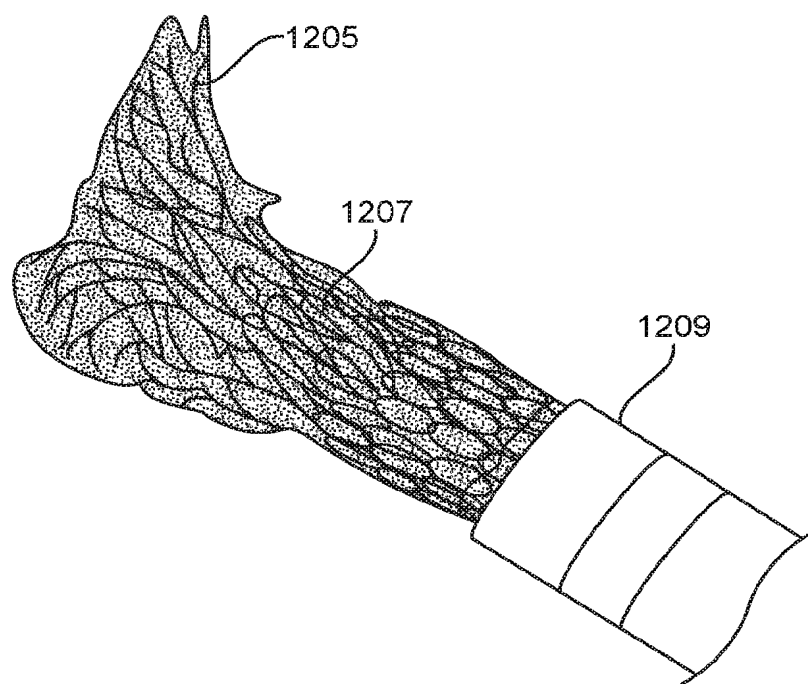


FIG. 12B

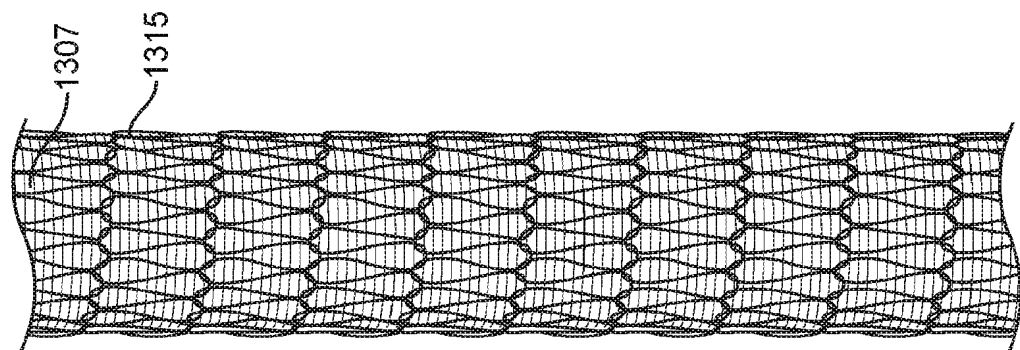


FIG. 13A

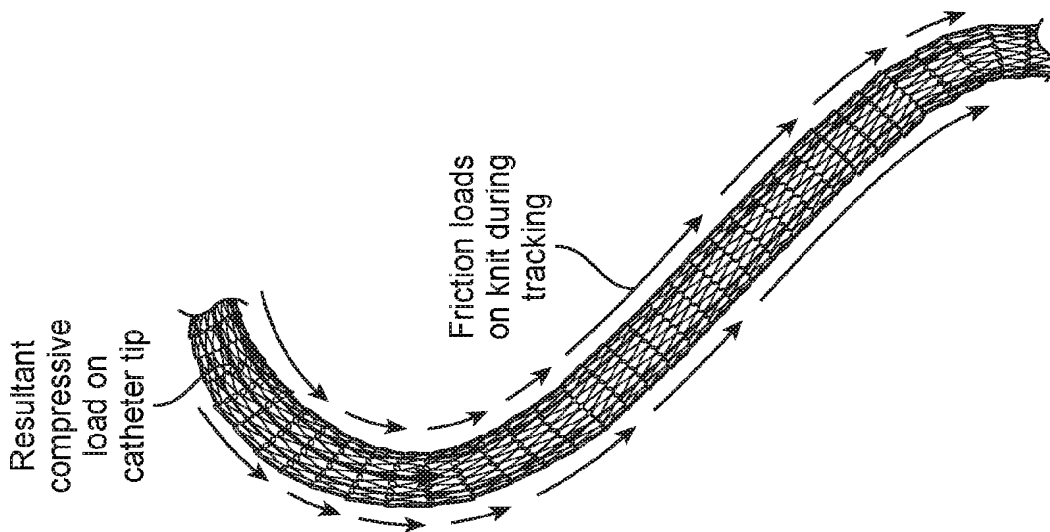


FIG. 13B

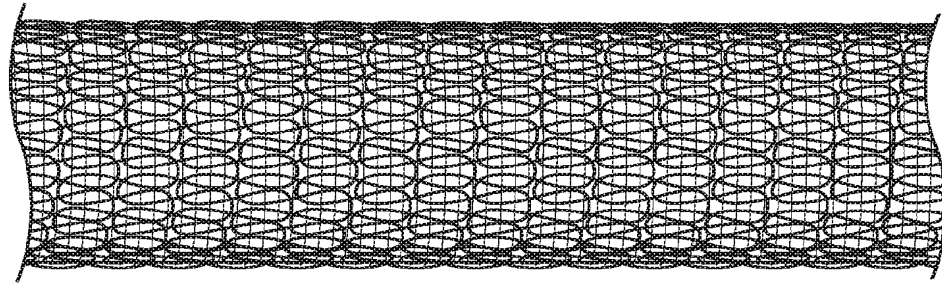
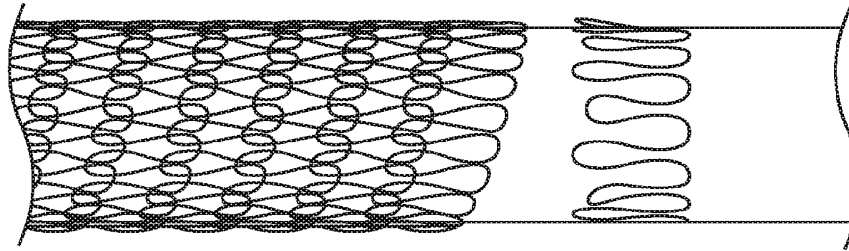
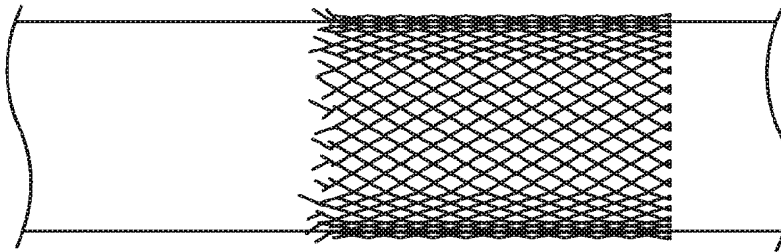


FIG. 13C



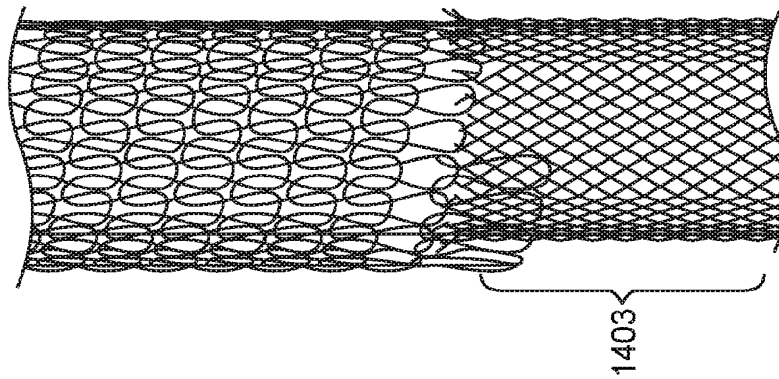
NiTi knit segment
as a stop element

FIG. 14D



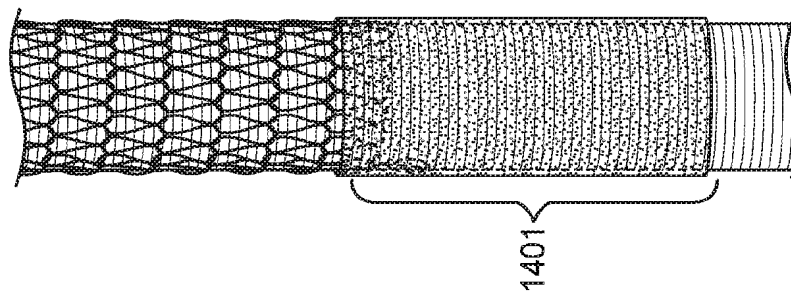
NiTi braid with
exposed fingers

FIG. 14C



NiTi braid with
exposed fingers

FIG. 14B



Polymer stop

FIG. 14A

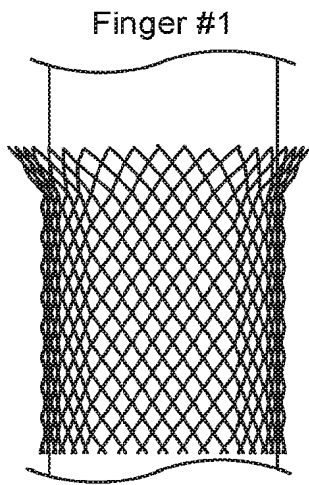


FIG. 15A

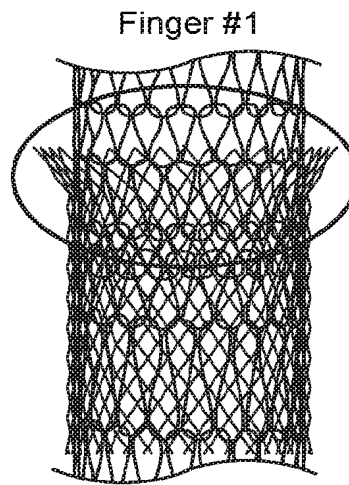


FIG. 15B

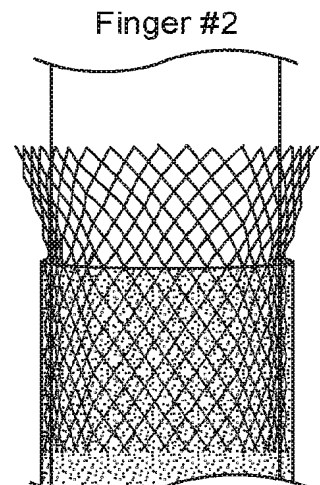


FIG. 15C

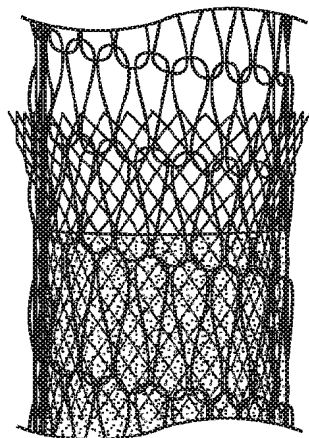


FIG. 15D

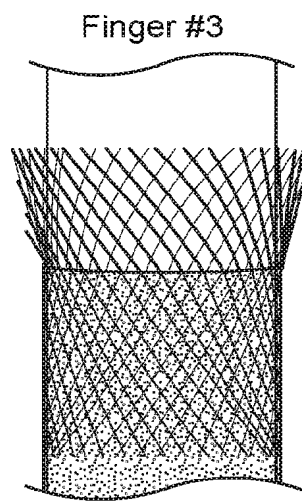


FIG. 15E

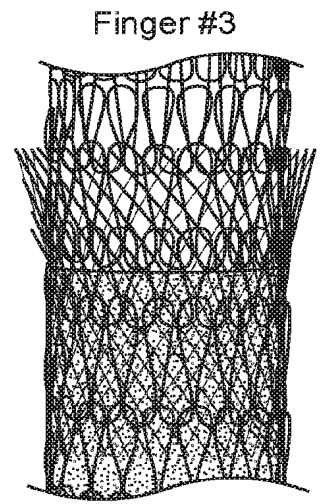


FIG. 15F

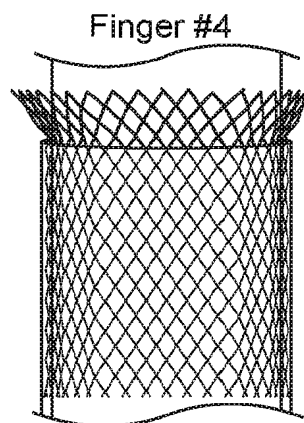


FIG. 15G

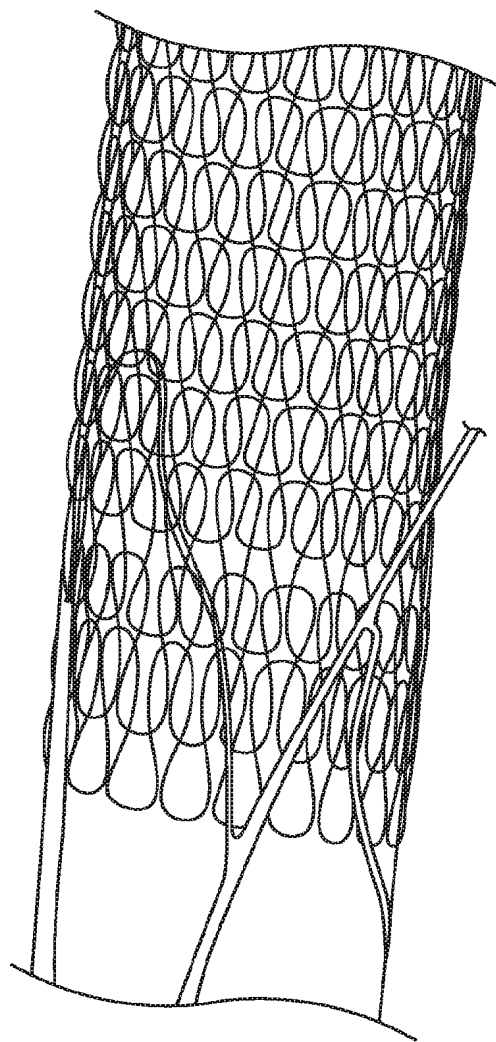


FIG. 15H

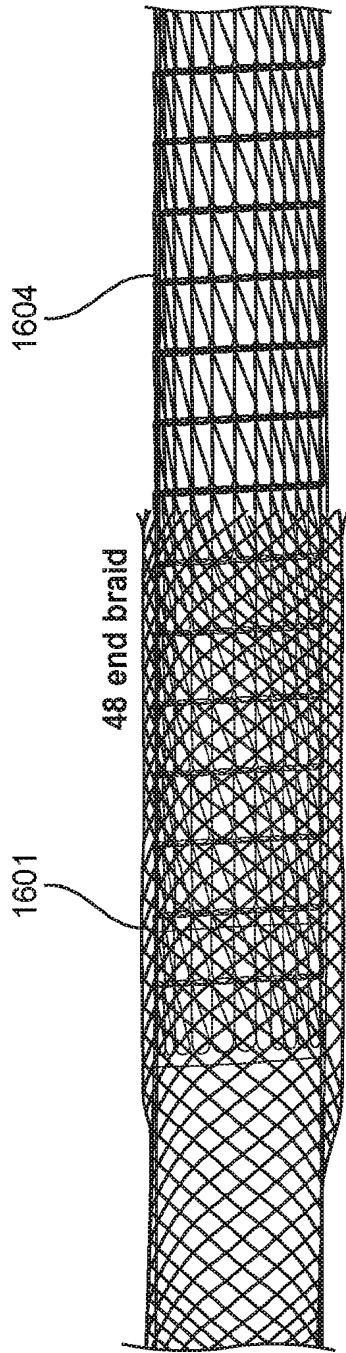


FIG. 16A

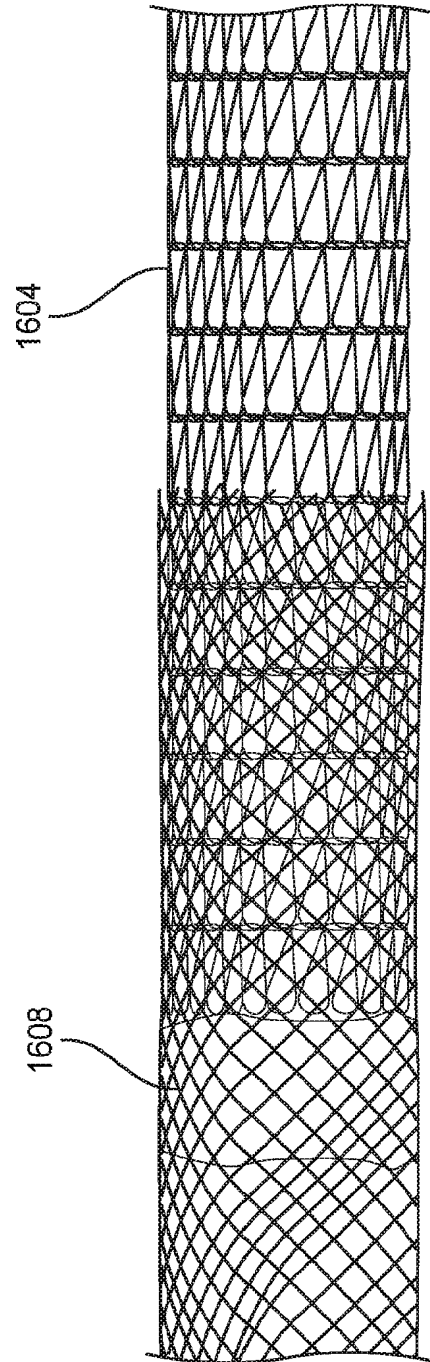


FIG. 16B

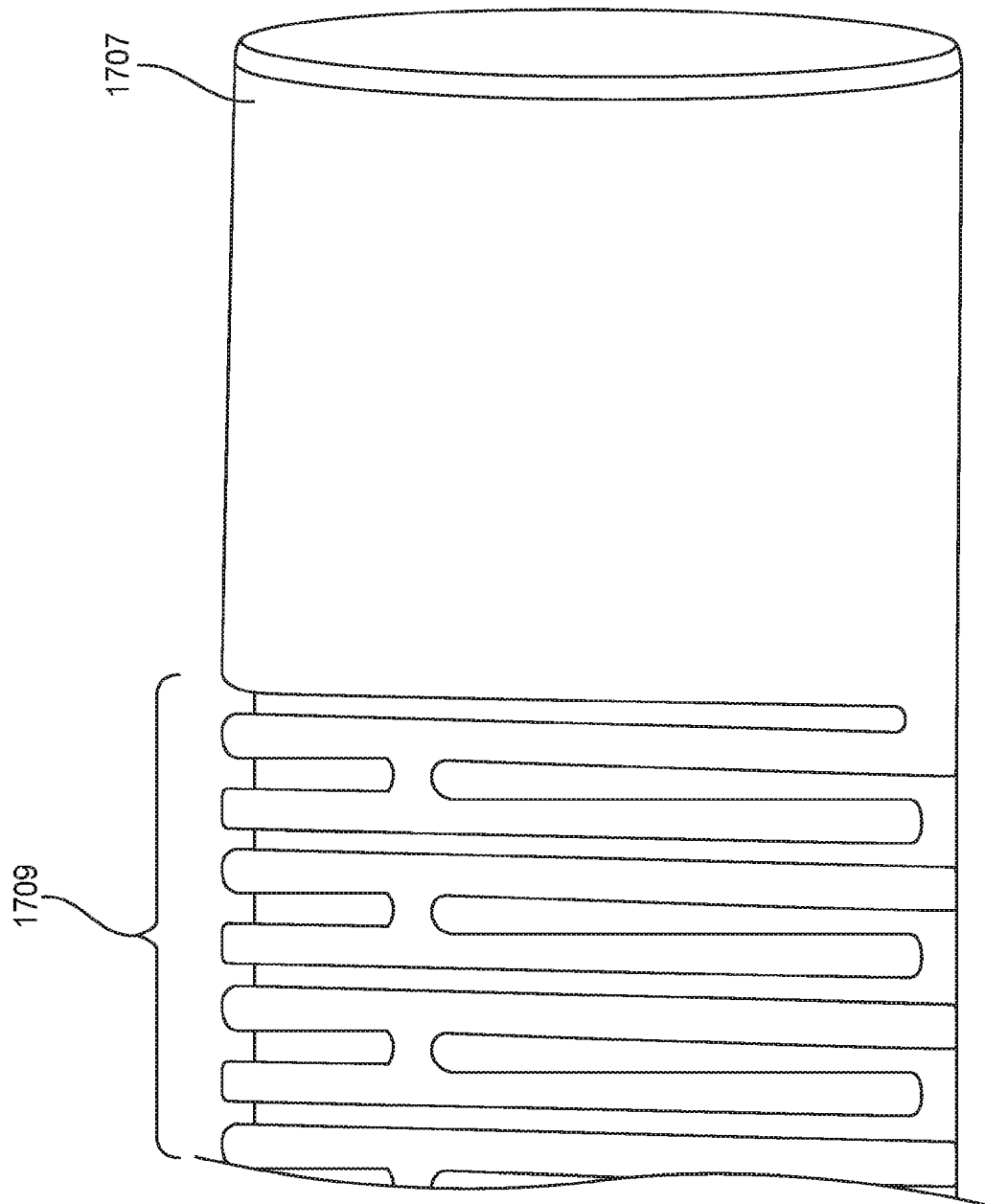


FIG. 17

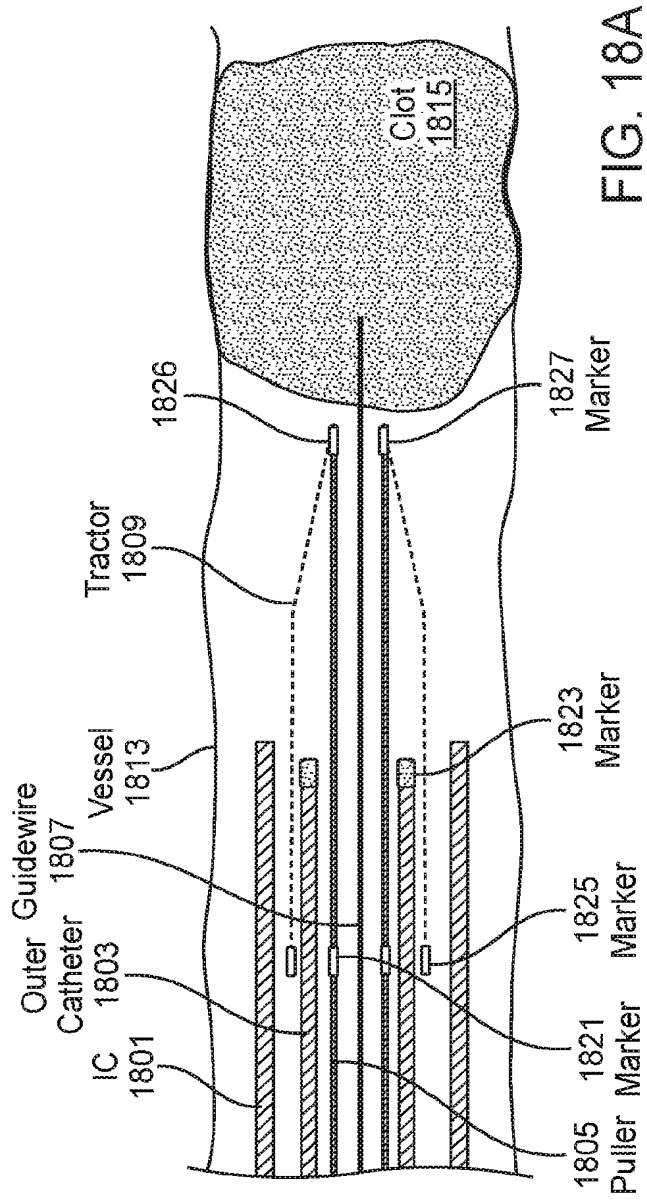


FIG. 18A

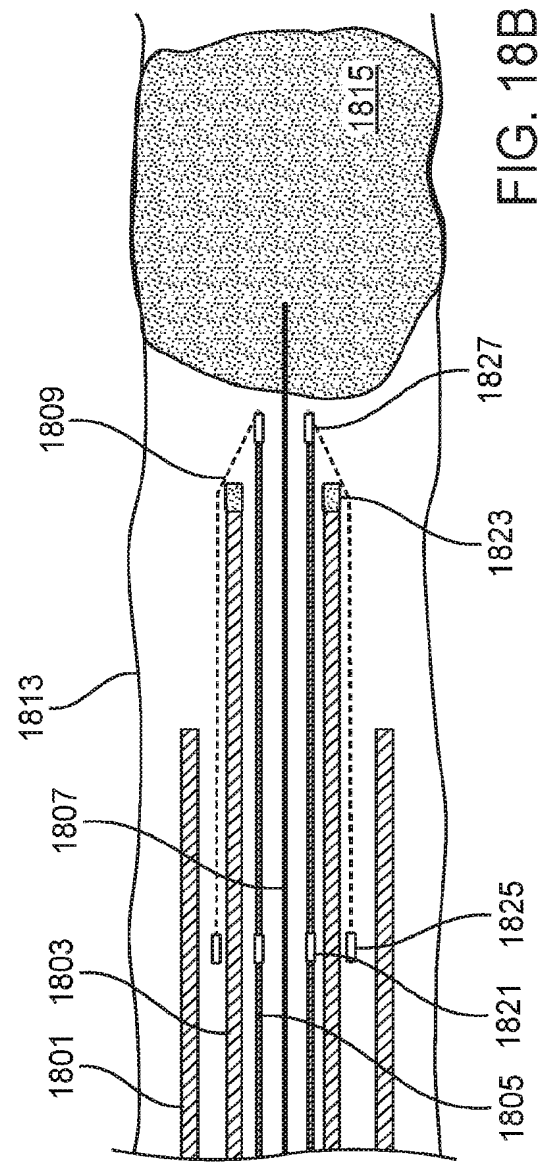


FIG. 18B

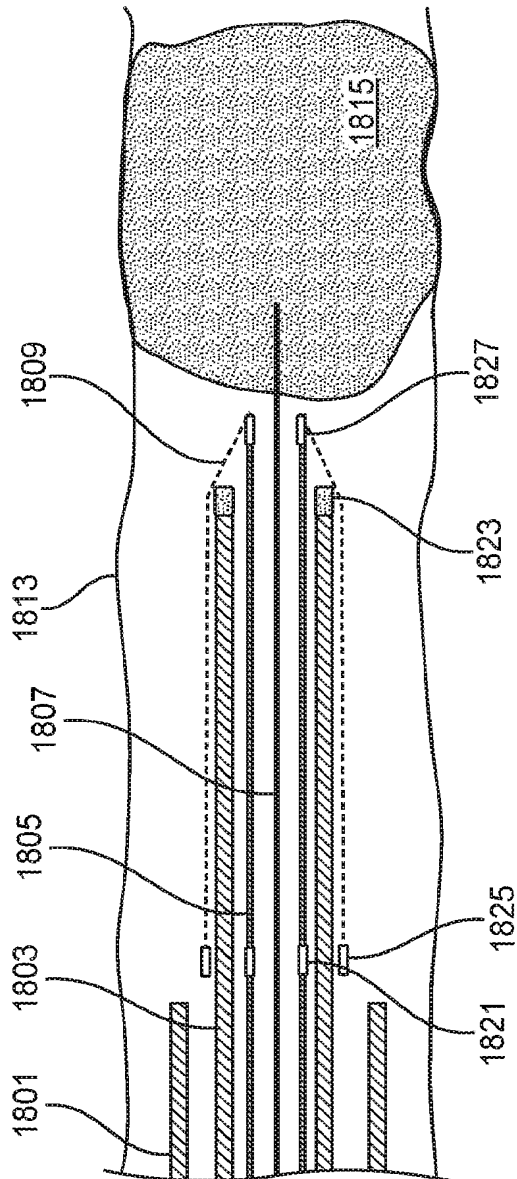


FIG. 18C

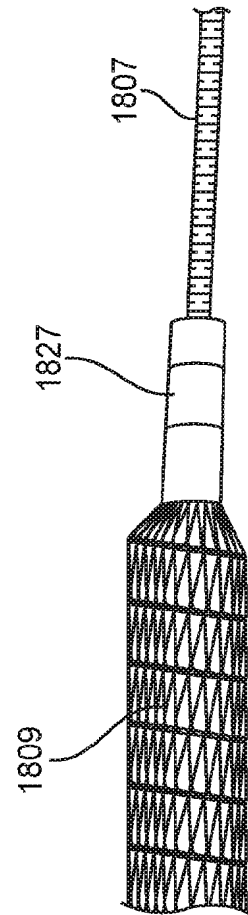


FIG. 18C1

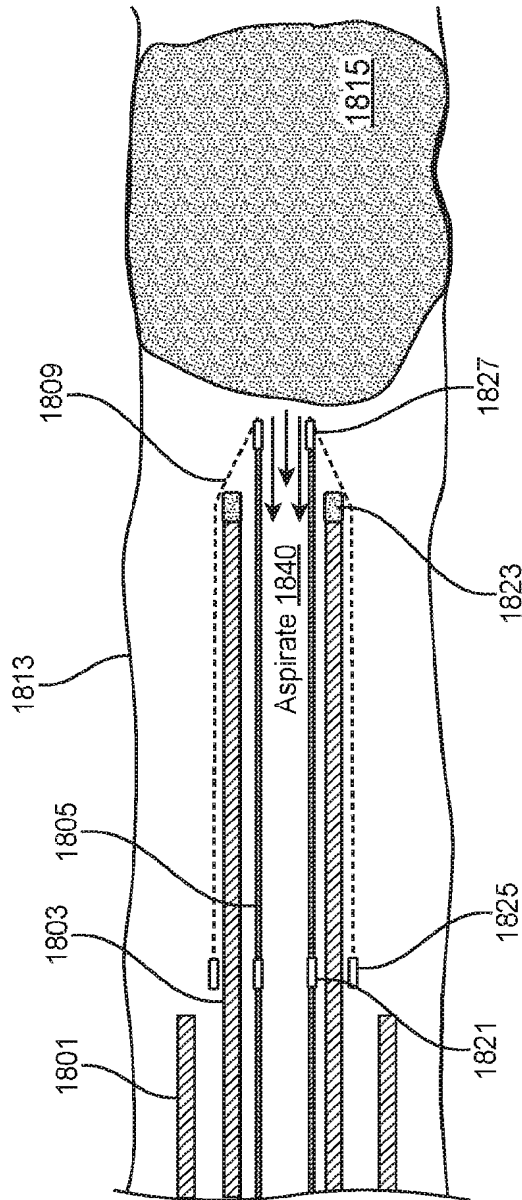


FIG. 18D

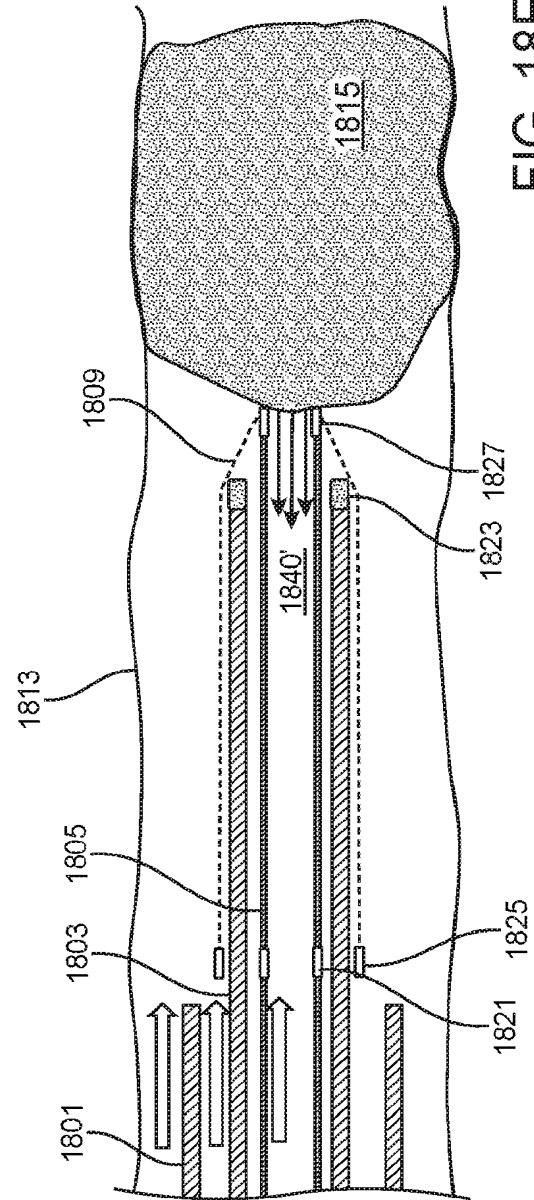


FIG. 18E

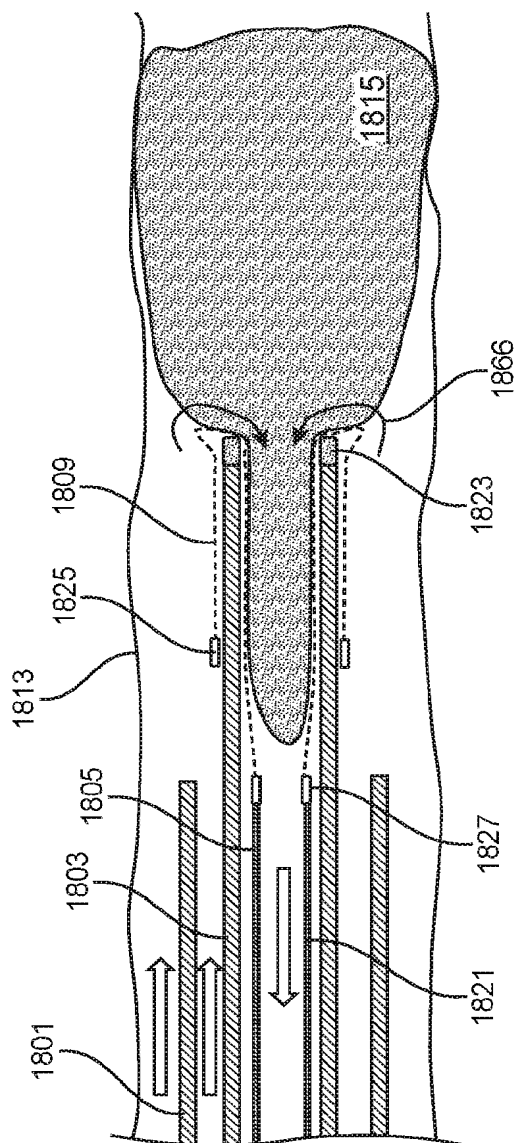


FIG. 18F

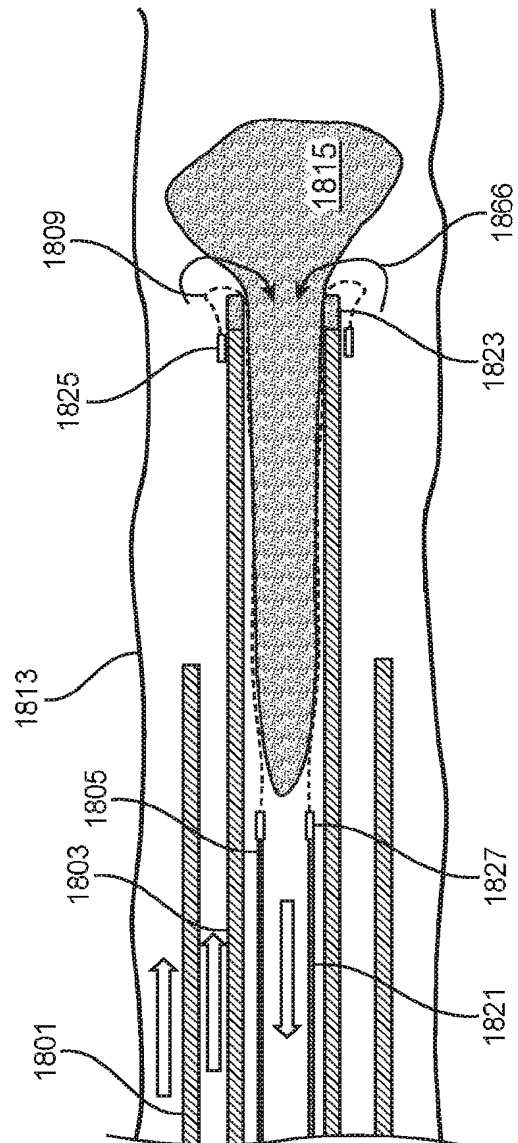


FIG. 18G

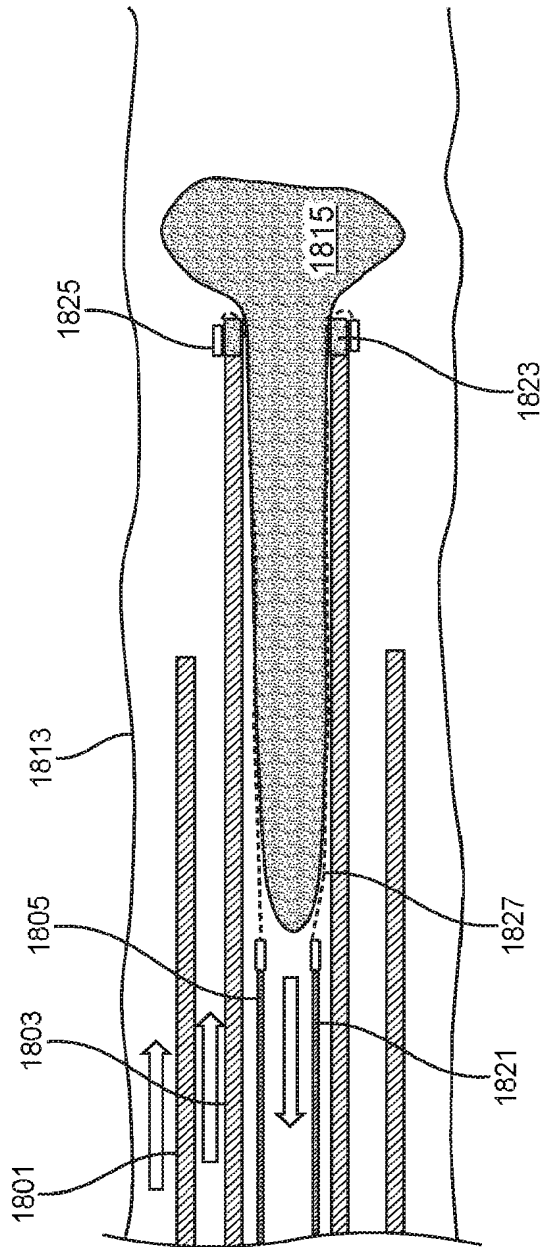


FIG. 18H

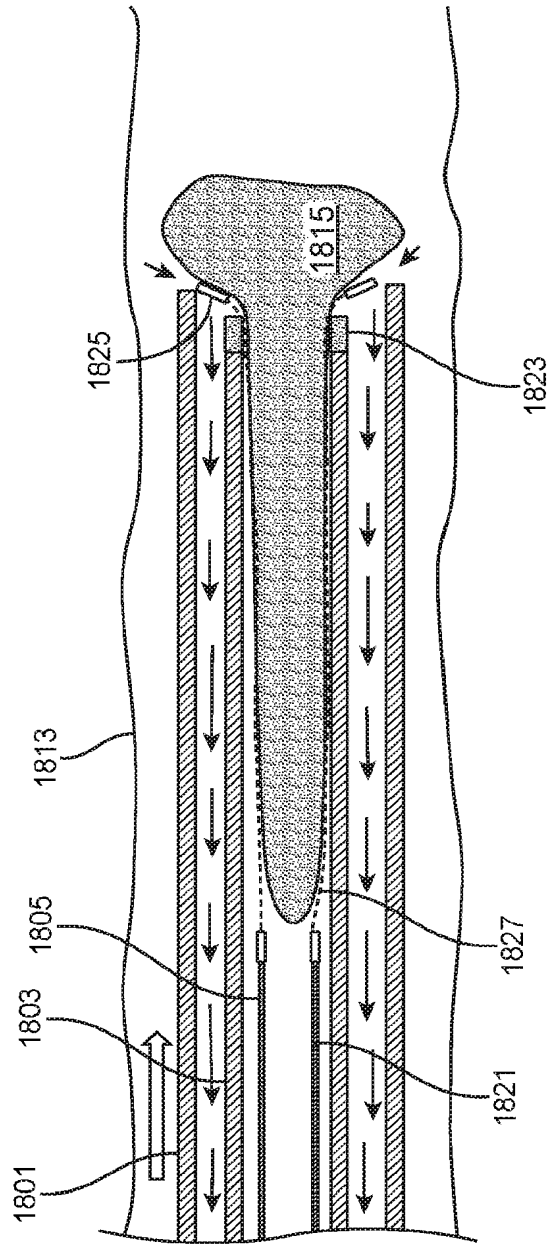


FIG. 18I

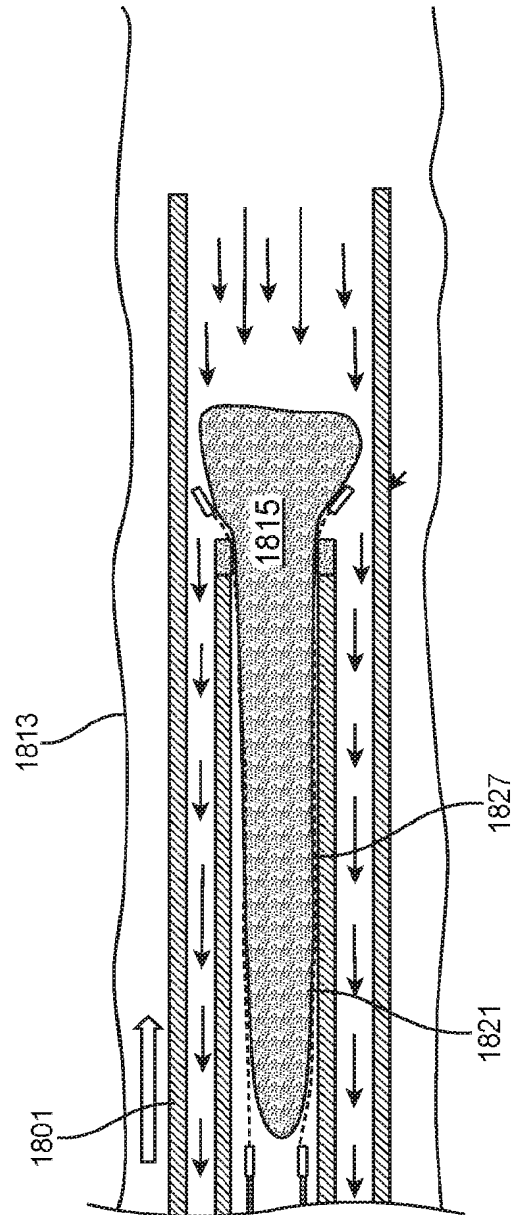


FIG. 18J

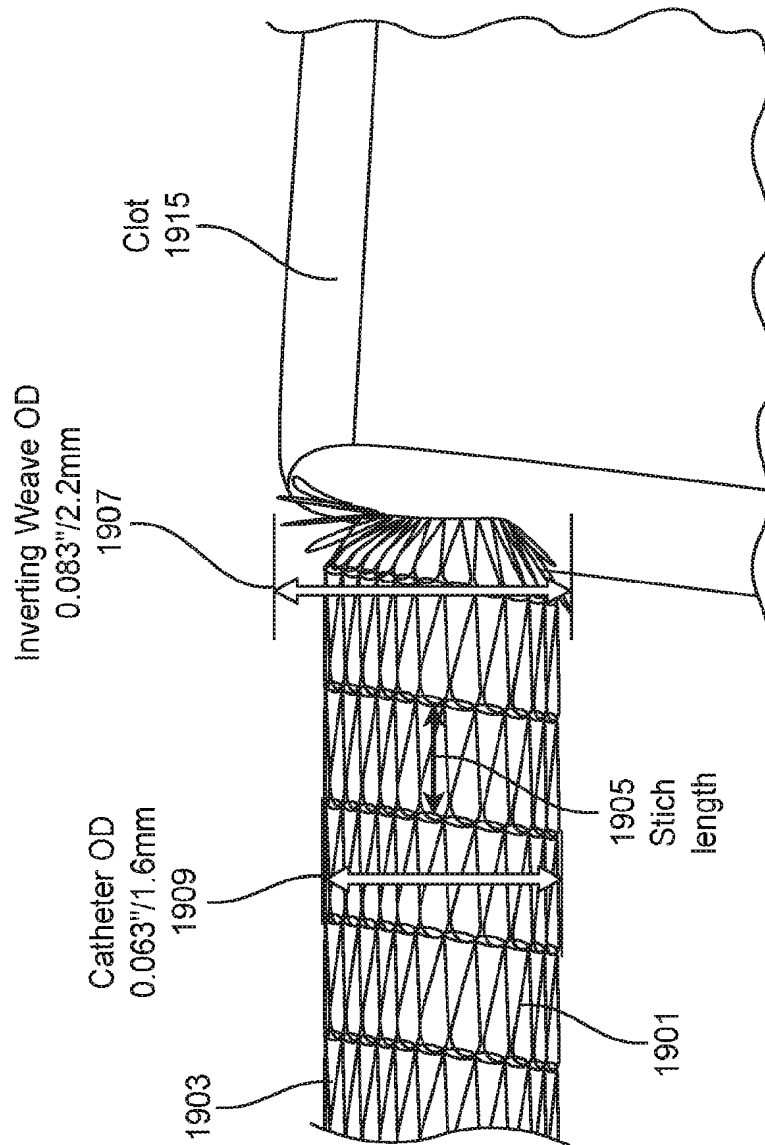


FIG. 19

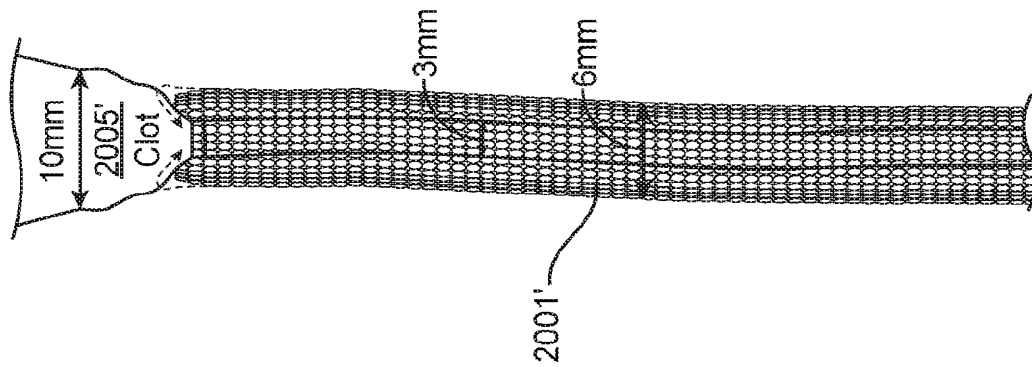


FIG. 20B

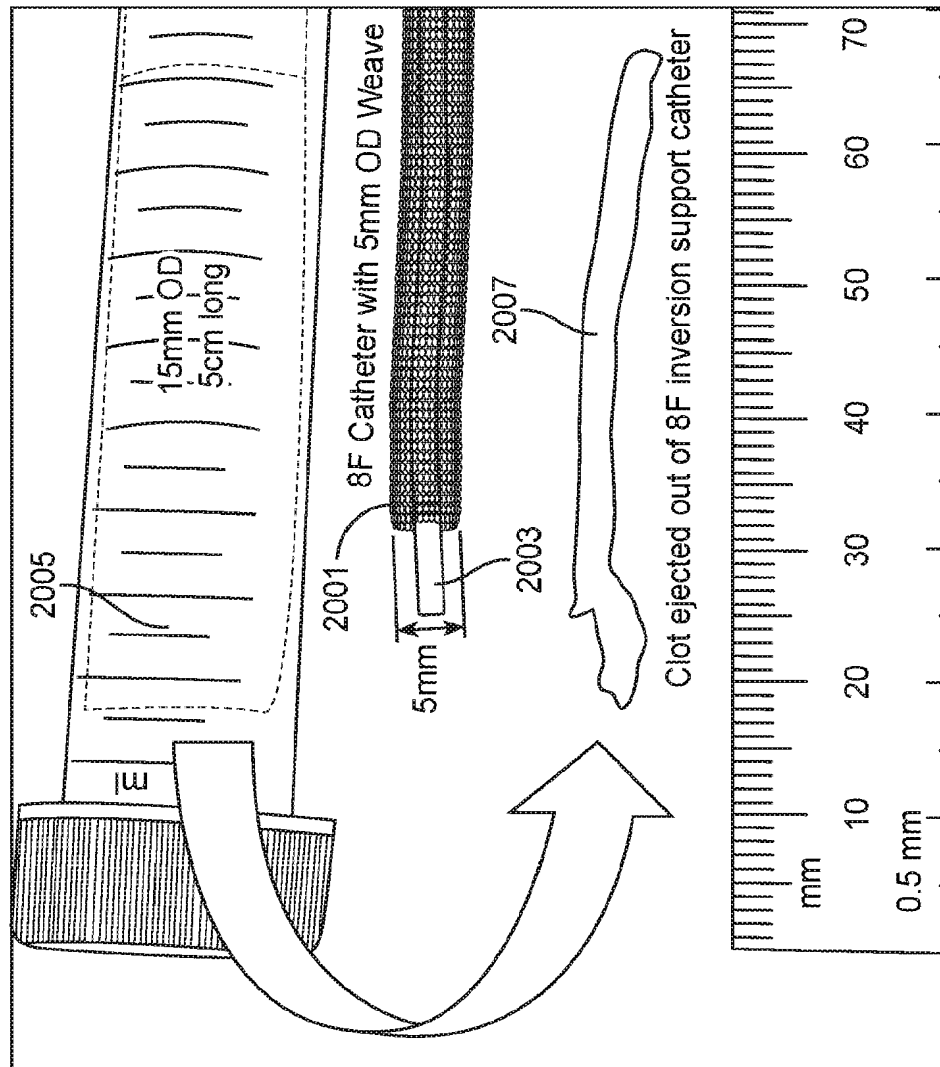


FIG. 20A

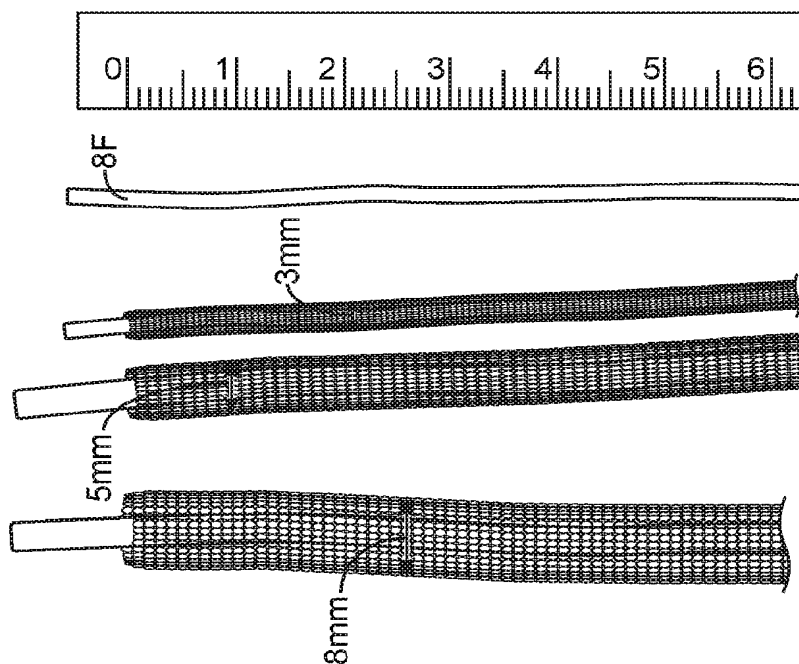


FIG. 21B

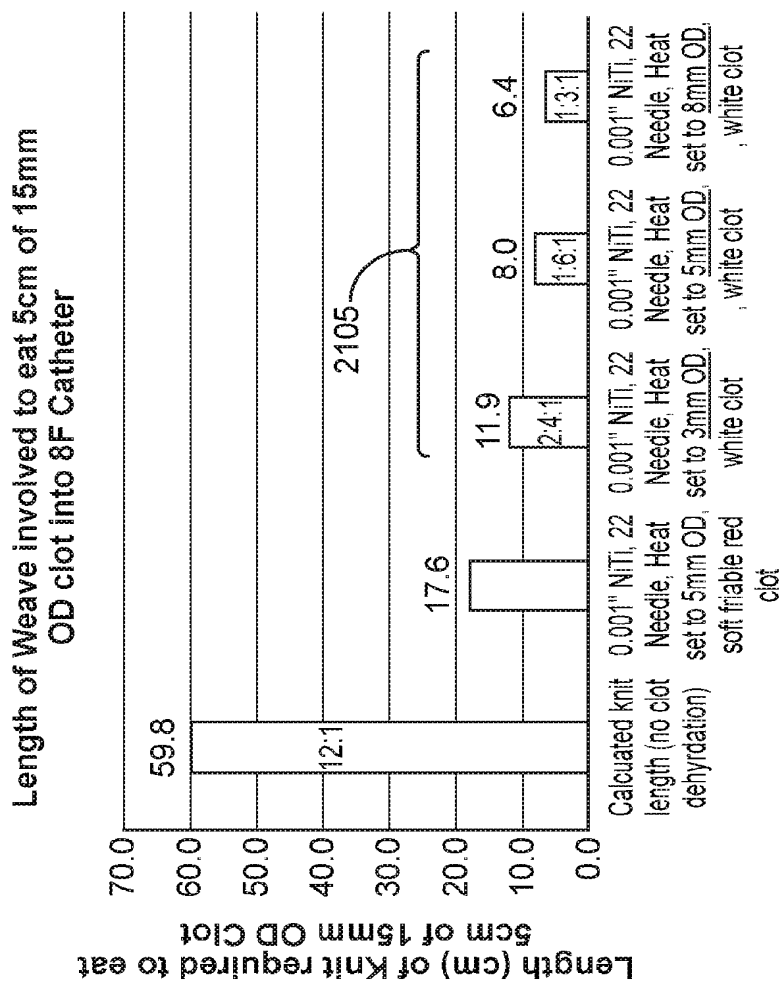


FIG. 21A

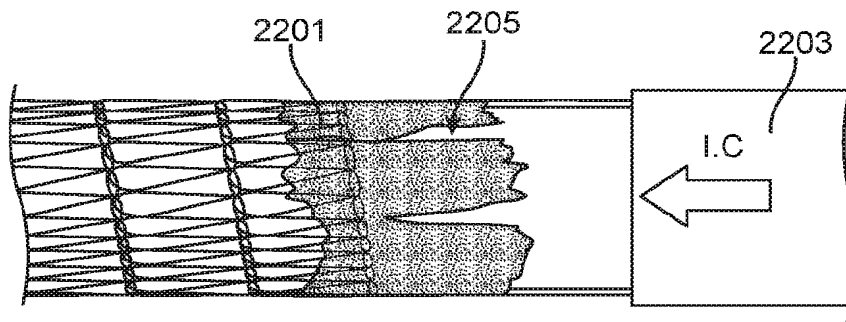


FIG. 22A

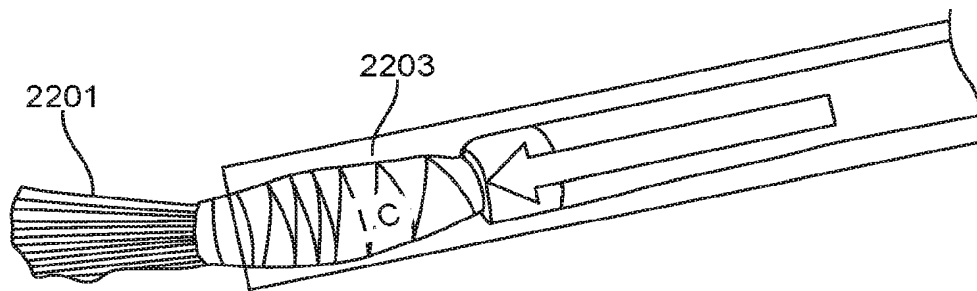


FIG. 22B

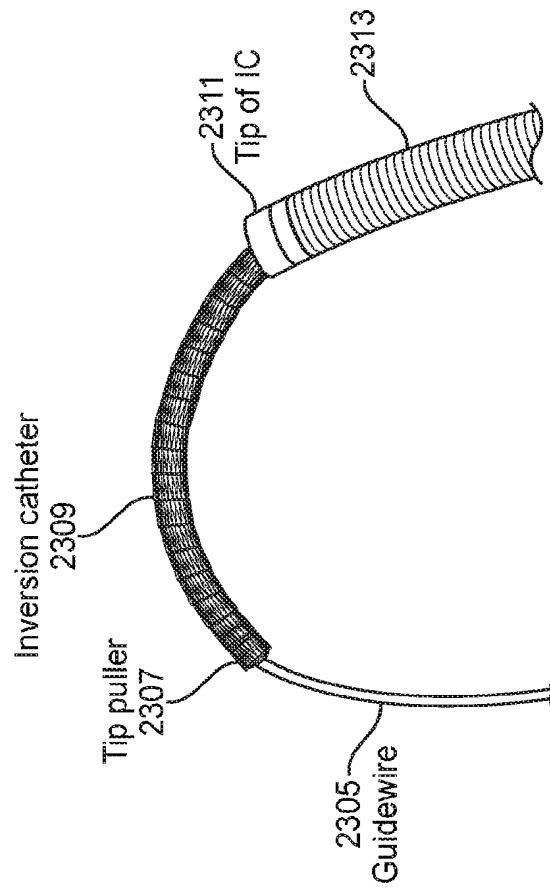


FIG. 23A

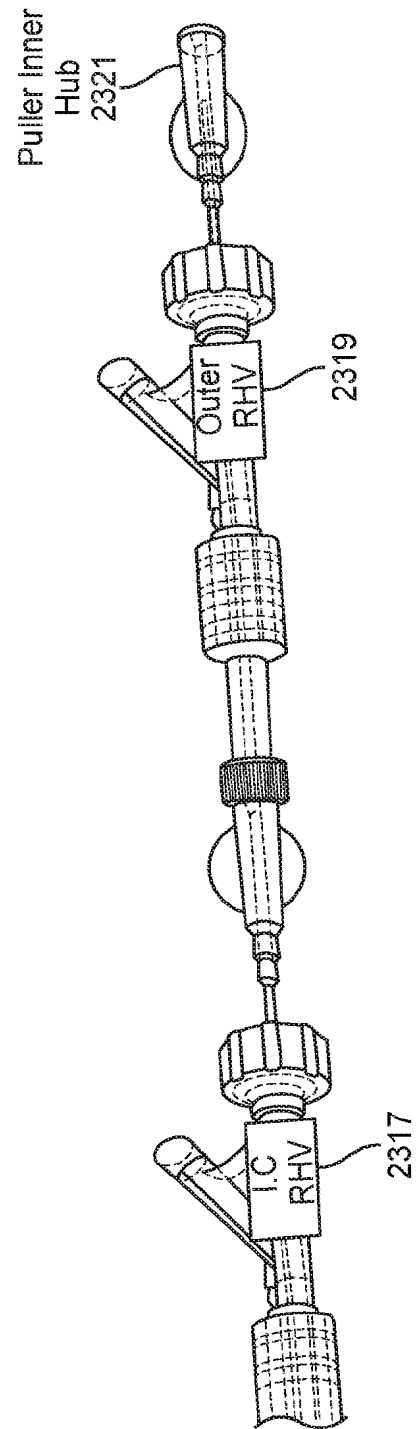
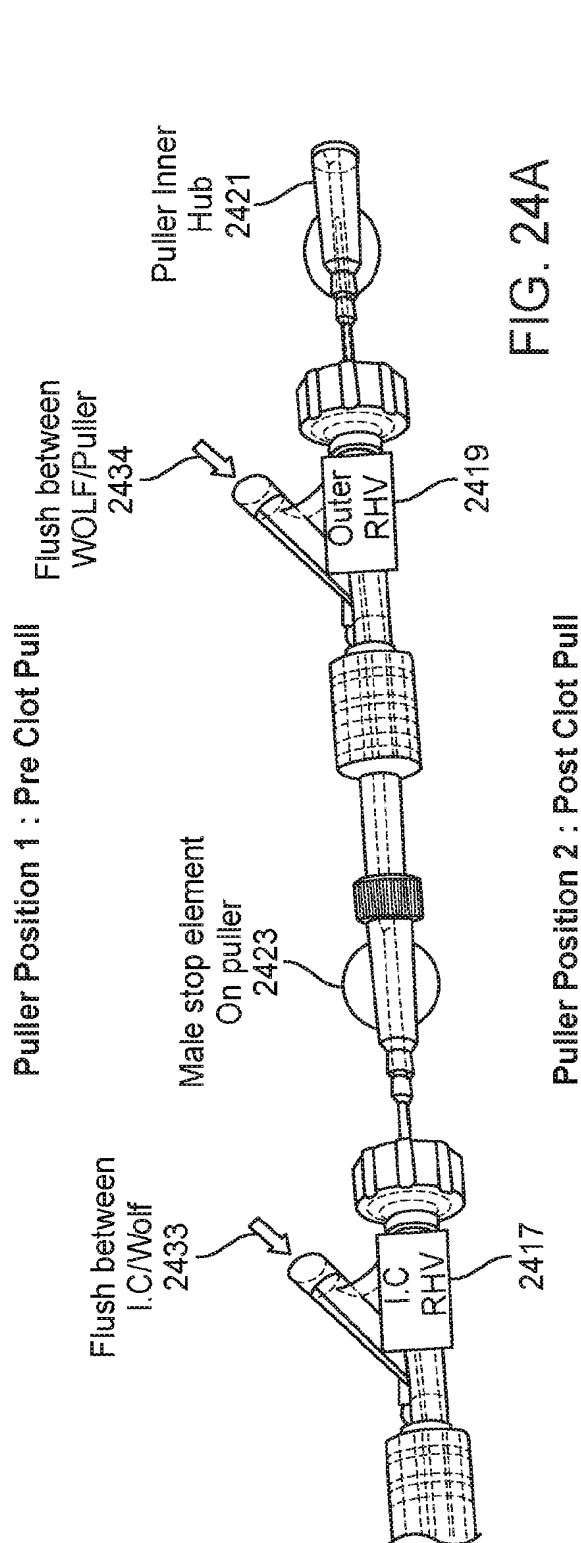
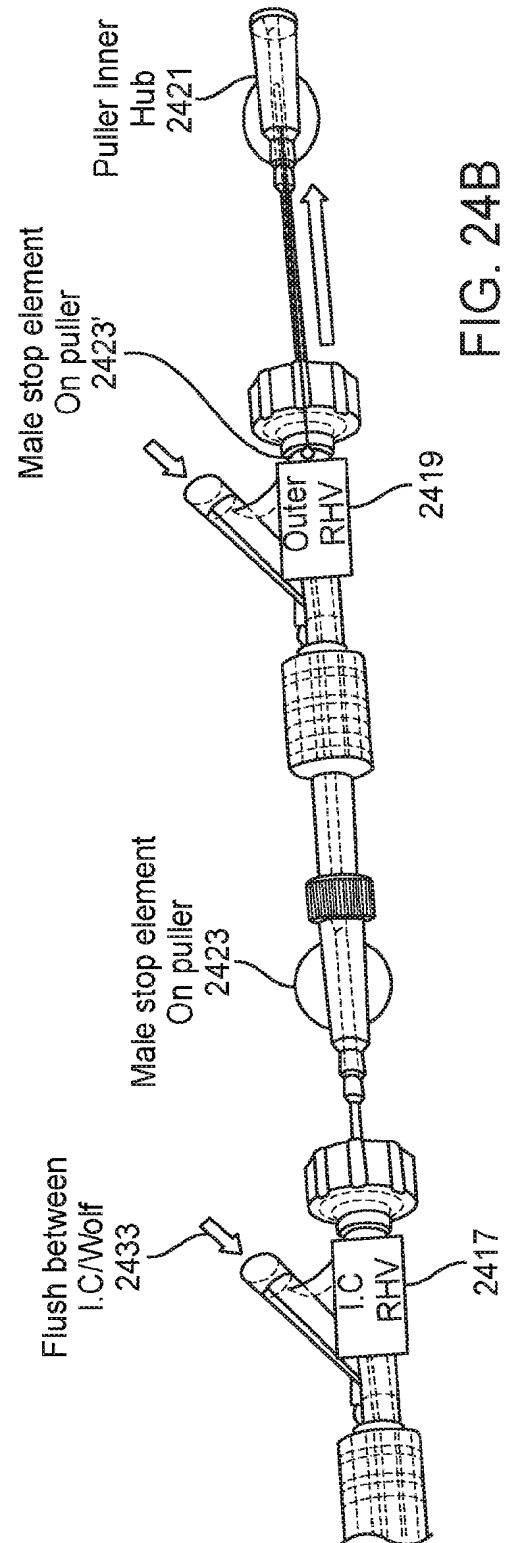


FIG. 23B



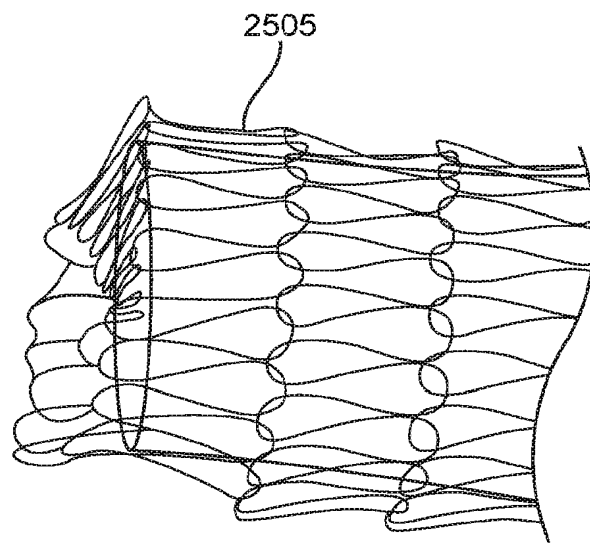
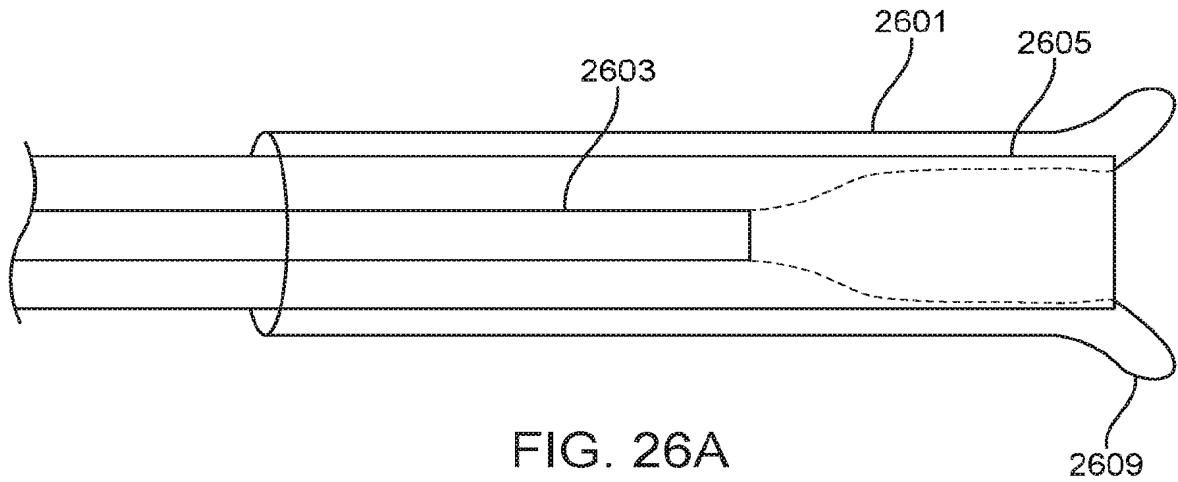
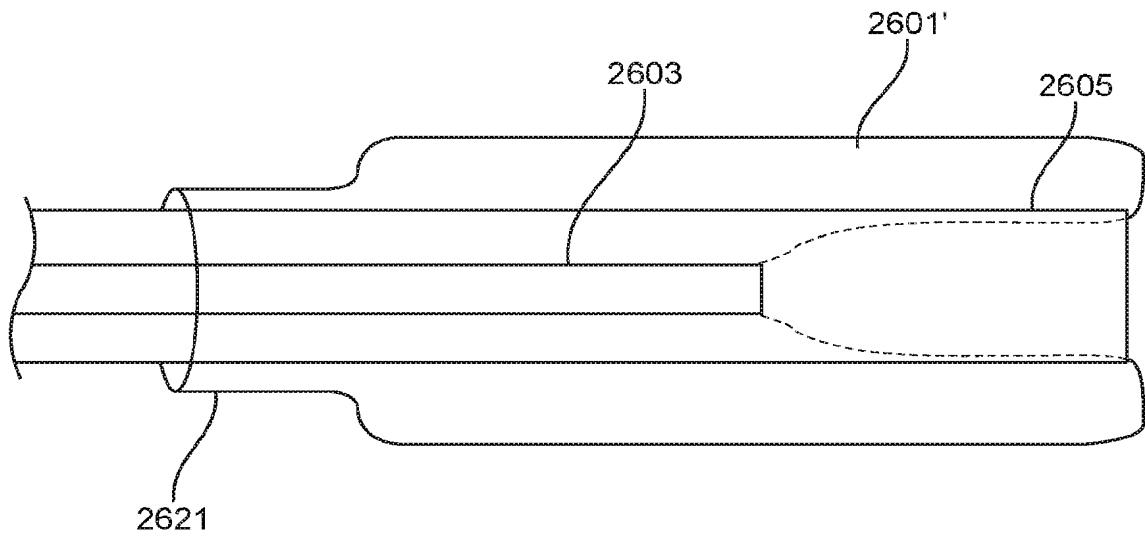


FIG. 25



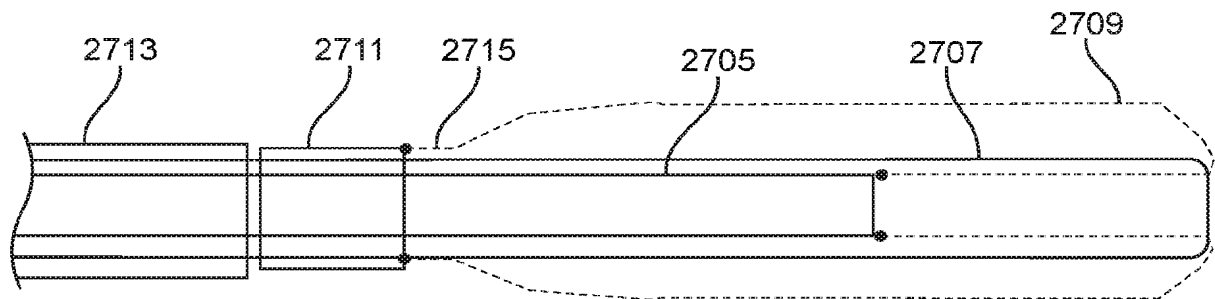


FIG. 27A

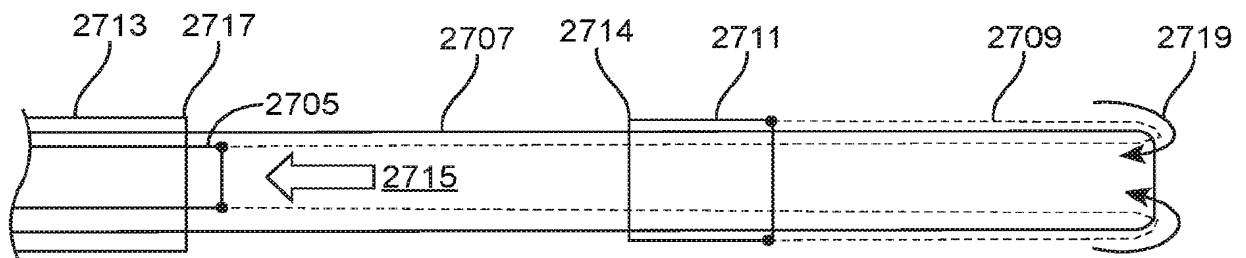


FIG. 27B

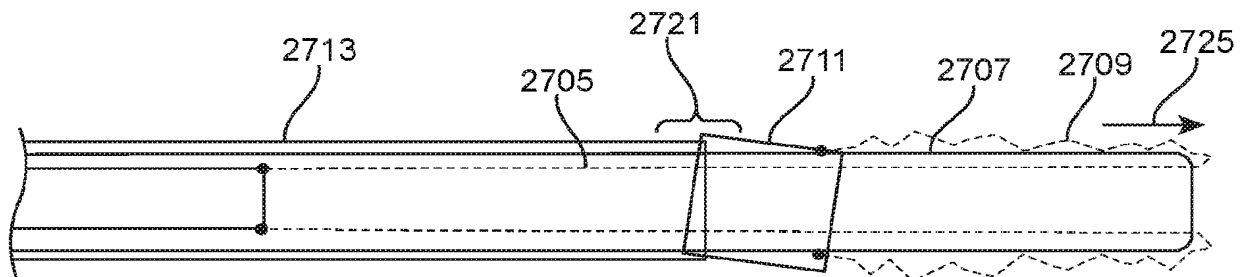


FIG. 27C

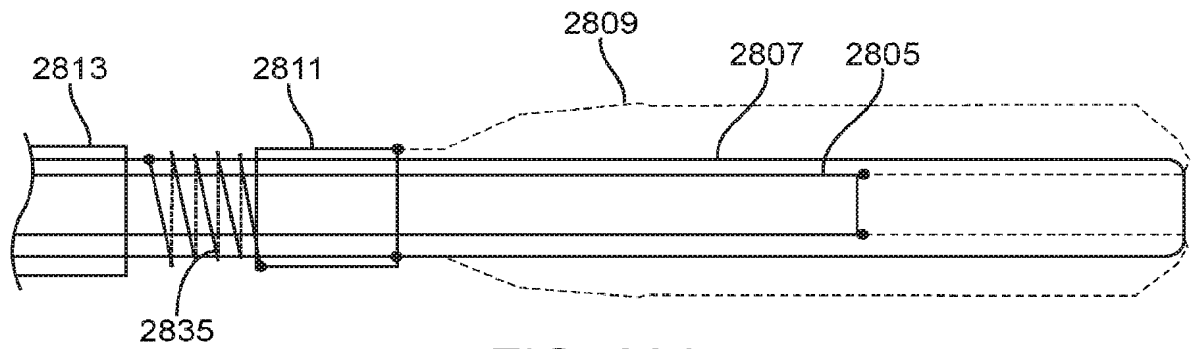


FIG. 28A

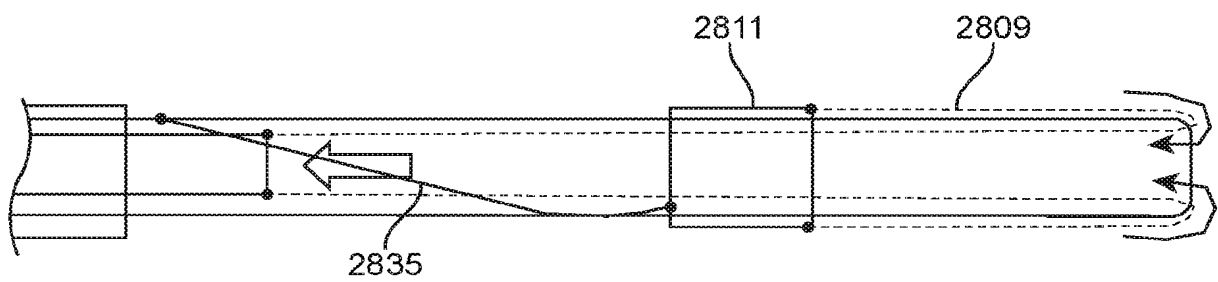


FIG. 28B

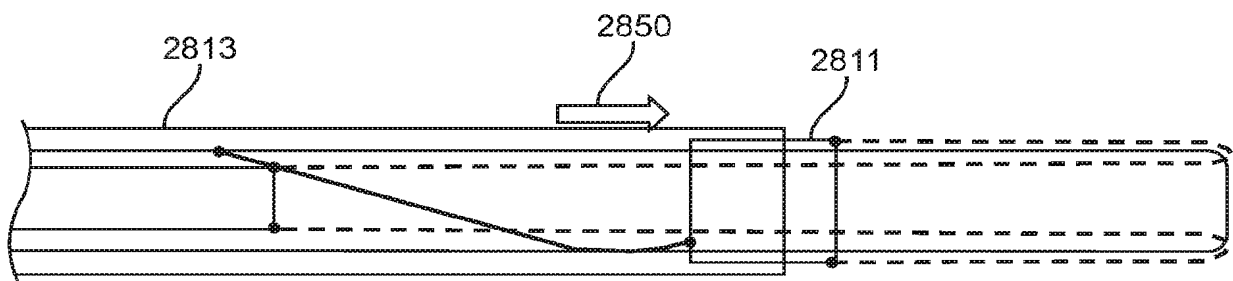


FIG. 28C

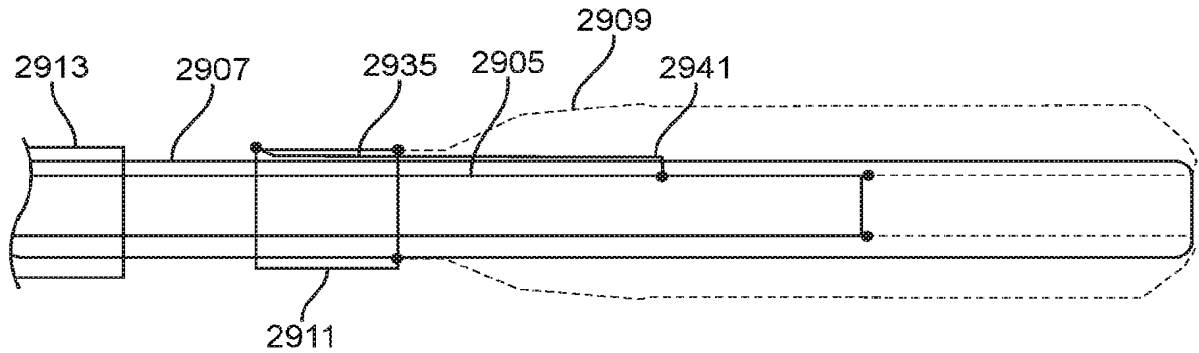


FIG. 29A

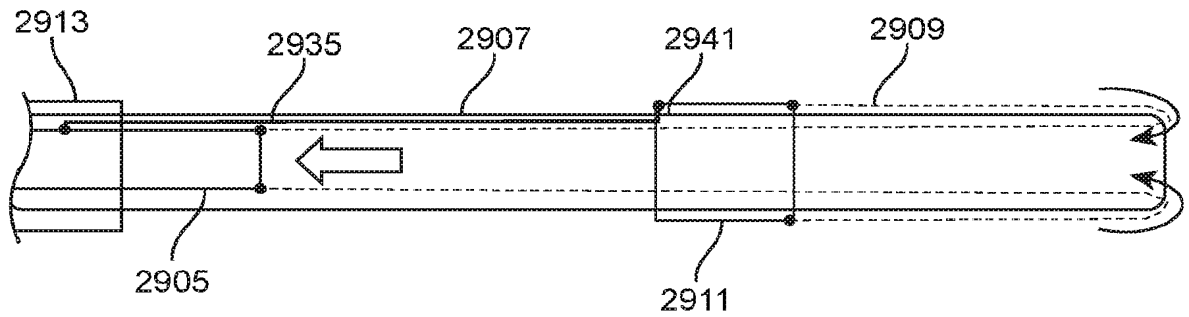


FIG. 29B

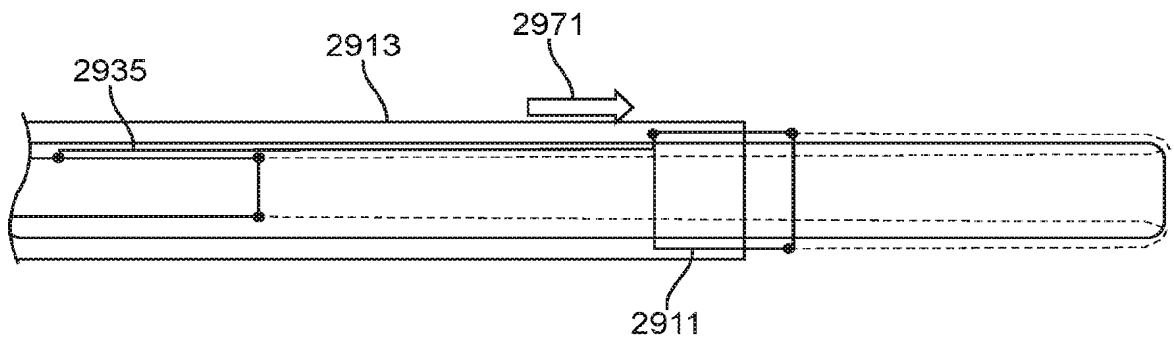


FIG. 29C

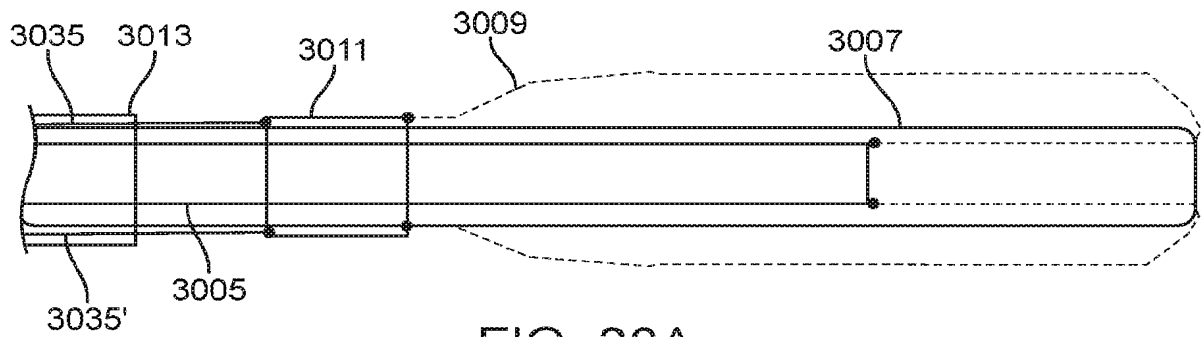


FIG. 30A

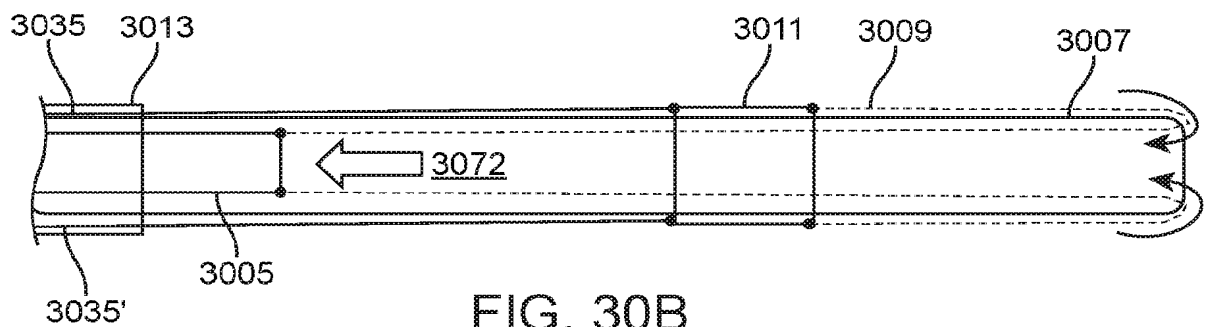


FIG. 30B

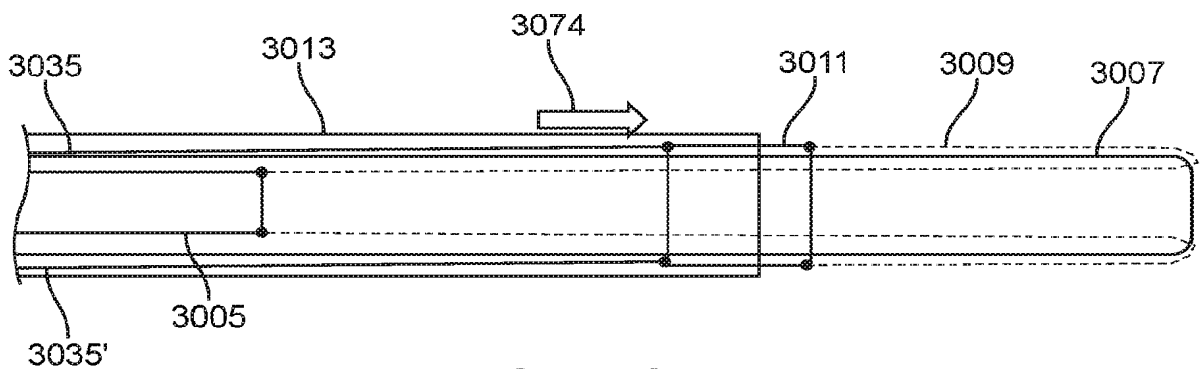


FIG. 30C

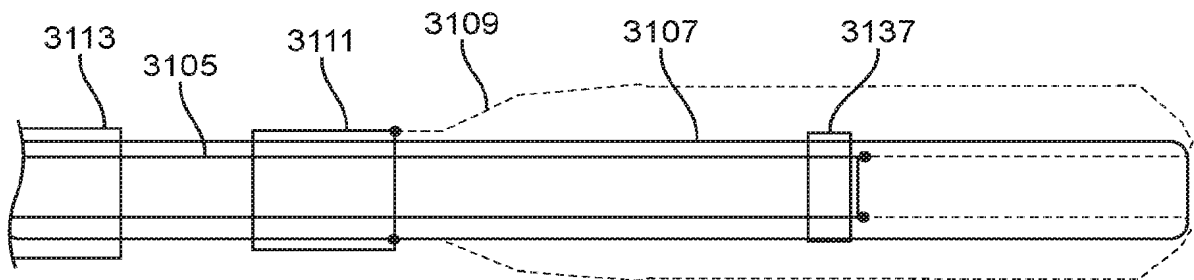


FIG. 31A

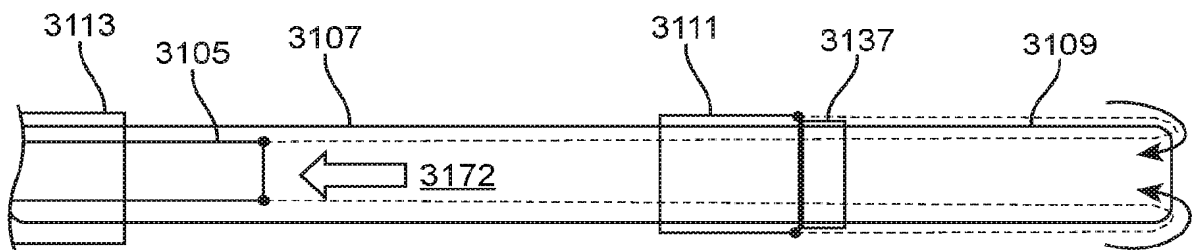


FIG. 31B

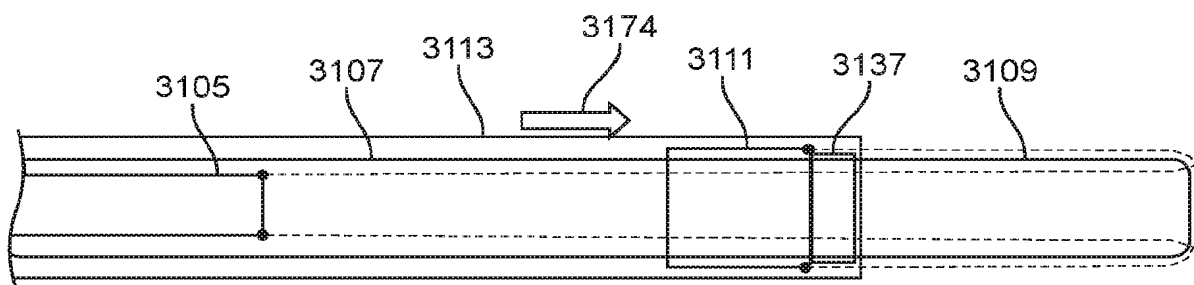
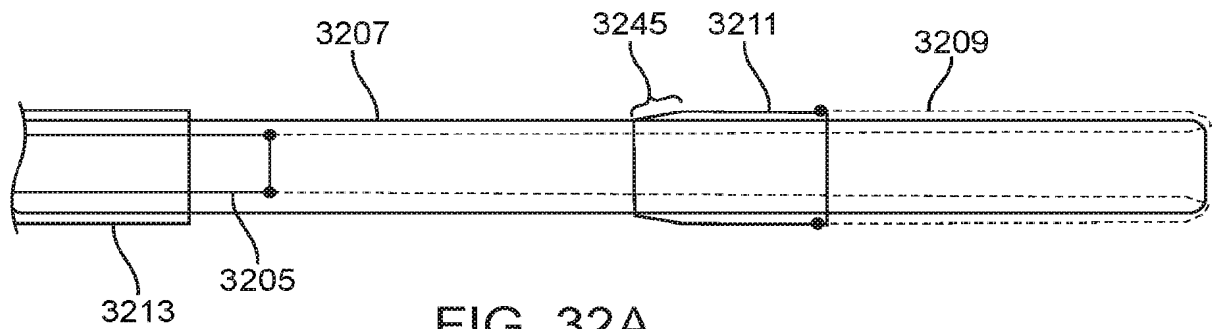
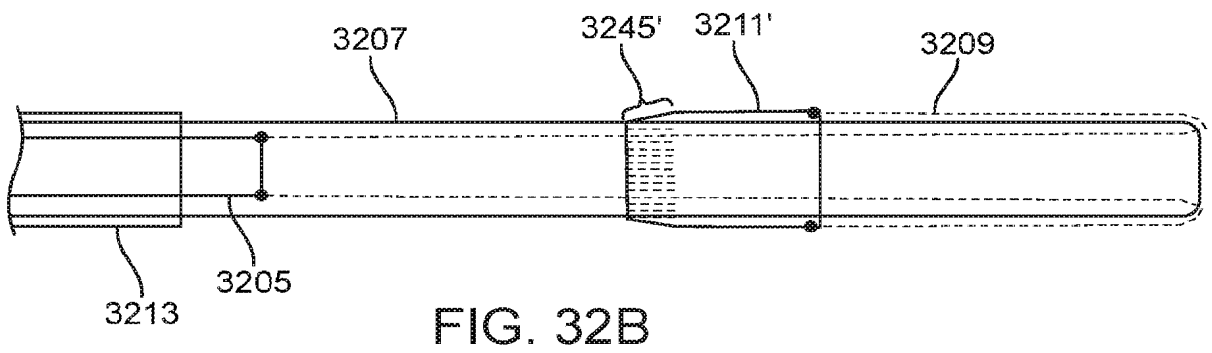
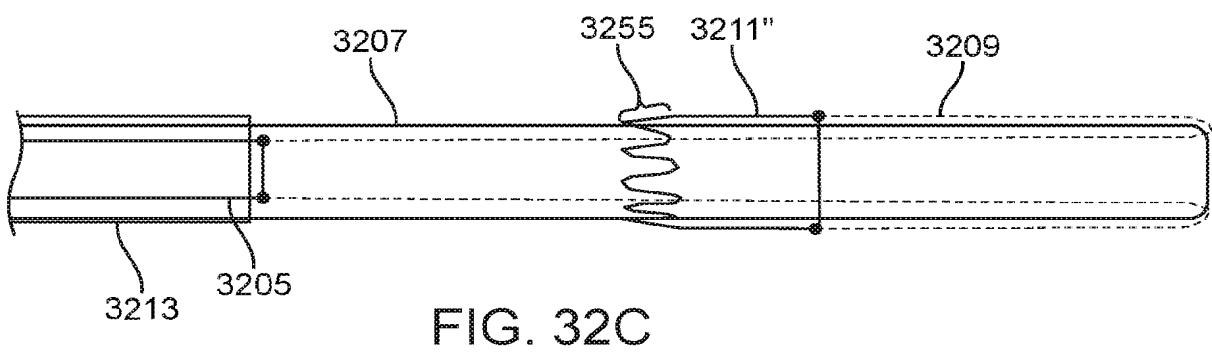


FIG. 31C



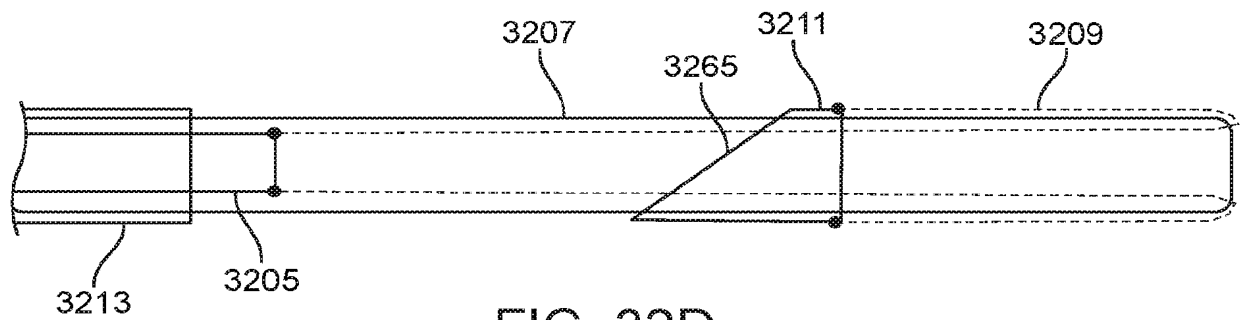


FIG. 32D

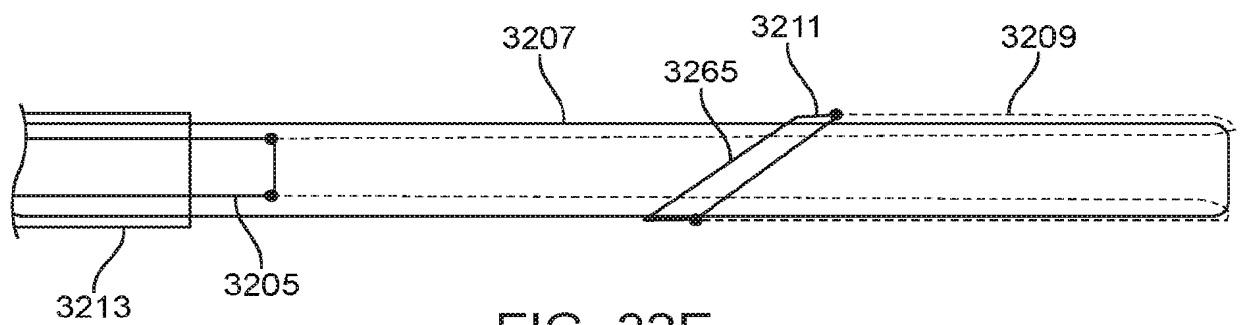


FIG. 32E

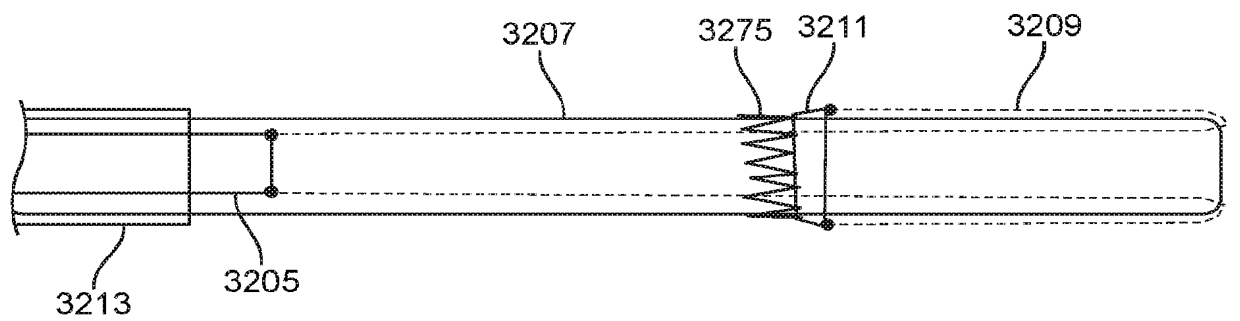


FIG. 32F

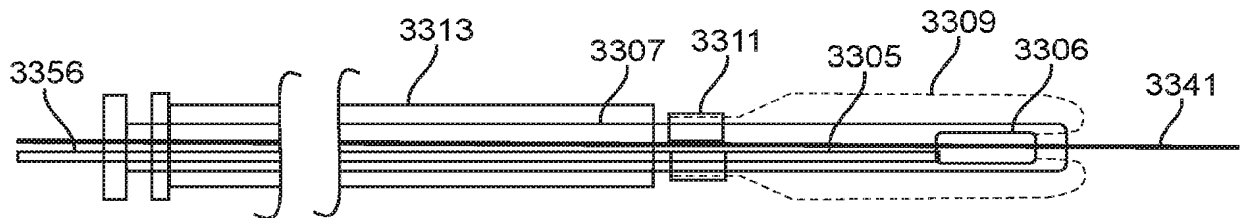


FIG. 33A

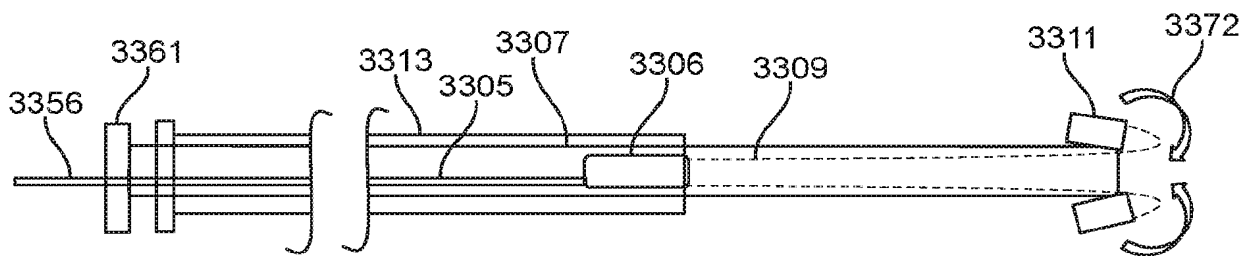


FIG. 33B

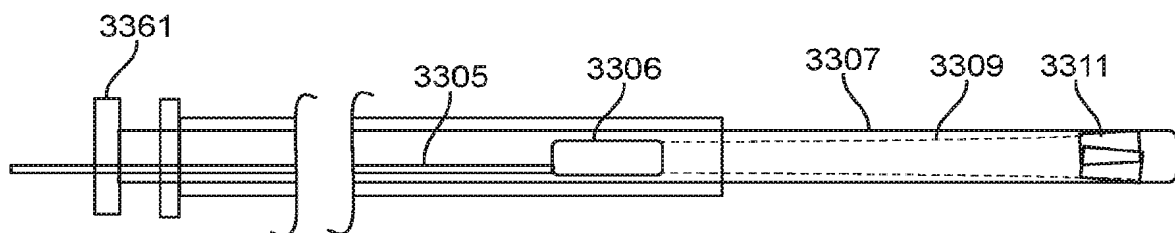


FIG. 33C

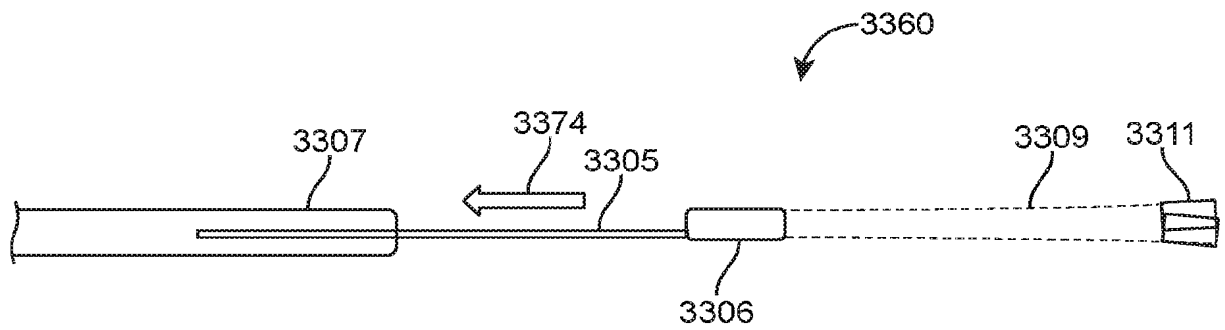


FIG. 33D

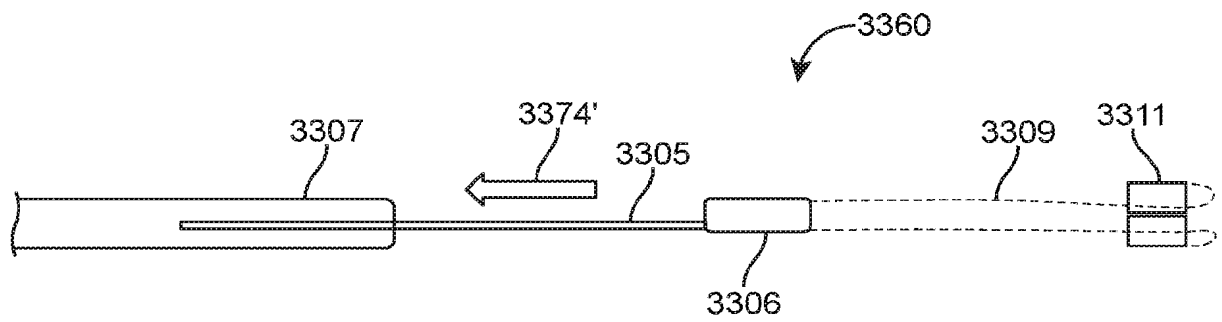


FIG. 33E

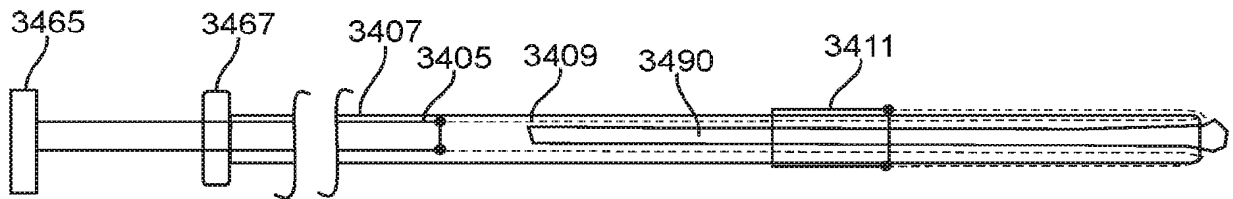


FIG. 34A

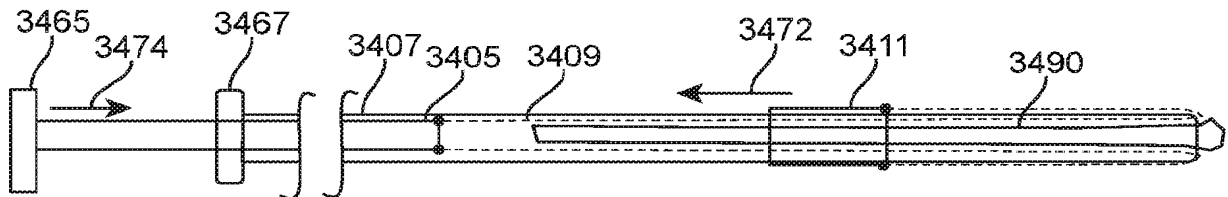


FIG. 34B

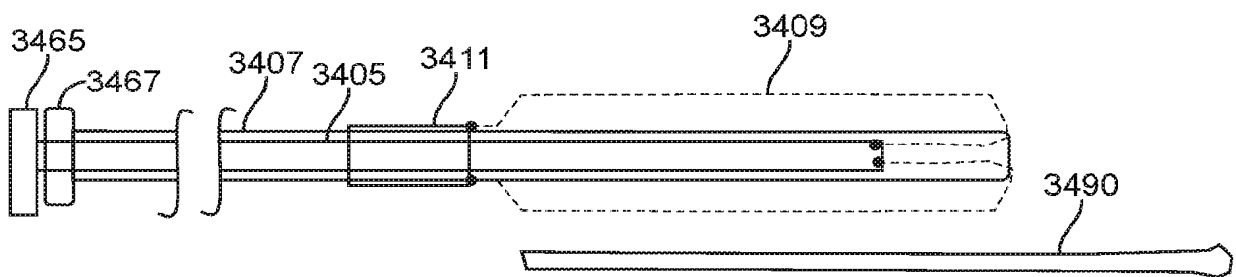


FIG. 34C

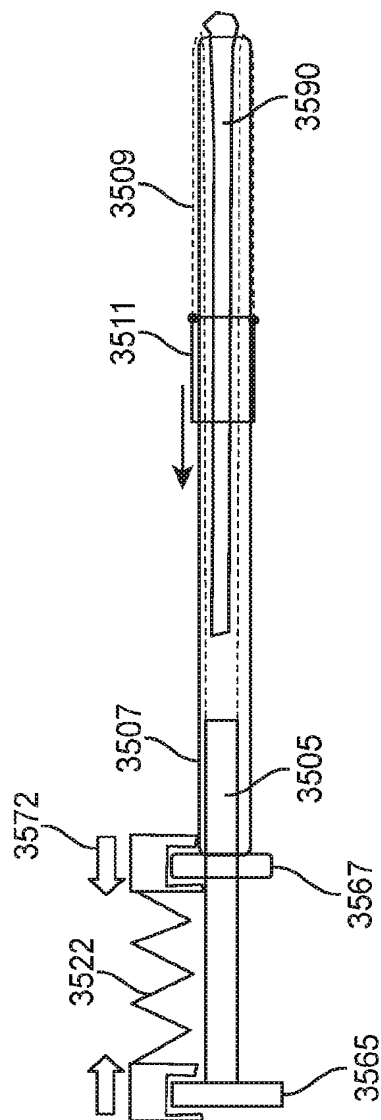


FIG. 35

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/059607

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/221 A61B17/34 A61M1/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2017/189550 A1 (STRYKER CORP [US]) 2 November 2017 (2017-11-02)	1-9, 11-15, 29-41
Y	abstract	19-28
A	paragraphs [0033], [0035] - [0036], [0049] - [0109]; figures 1-12 -----	16-18
X	WO 2017/058280 A1 (GW MEDICAL LLC [US]) 6 April 2017 (2017-04-06)	1-18, 29-40
Y	abstract	19-28
	paragraphs [0014], [0015], [0043] - [0071], [0087], [0116] - [0171], [0190]; figures 1-38 ----- -/--	



Further documents are listed in the continuation of Box C.



See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

20 March 2019

Date of mailing of the international search report

28/03/2019

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Fax: (+31-70) 340-3016

Authorized officer

Ioanovici, T

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2018/059607

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2017/303948 A1 (WALLACE MICHAEL P [US] ET AL) 26 October 2017 (2017-10-26)	1-15,41
A	abstract paragraphs [0058] - [0064], [0116] - [0148], [0159] - [0217]; figures 1-44 -----	16-40
A	WO 2012/009675 A2 (LAZARUS EFFECT INC [US]; MARTIN BRIAN B [US]) 19 January 2012 (2012-01-19) abstract paragraphs [0167] - [0171]; figures 1-22 -----	1-41
A	US 2005/085849 A1 (SEPETKA IVAN [US] ET AL) 21 April 2005 (2005-04-21) abstract paragraph [0083]; figures 5-46 -----	1-41
X,P	WO 2017/210487 A1 (STRYKER CORP [US]) 7 December 2017 (2017-12-07) abstract paragraphs [0011] - [0017], [0020] - [0031], [0035] - [0088]; figures 1-10 -----	1-4, 8-10, 13-15
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Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2018/059607

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/059607

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-15, 41

Inverting tube apparatus for removing a clot from a vessel comprising an inversion support catheter, a puller and a flexible inverting tube with a cuff at the second end

1.1. claim: 41

Inverting mechanical thrombectomy apparatus for removing a clot from a vessel comprising an inversion support catheter with a plurality of slots or cut-outs for enhancing flexibility, a puller and a flexible knitted inverting tube

2. claims: 16, 18

Inverting tube apparatus for removing a clot from a vessel comprising an intermediate catheter, an inversion support catheter, a puller and a knitted inverting tube with filament knitted to form a plurality of interlocking loop stitched having a length between 0,5 and 10 mm

3. claims: 17, 19-28

Inverting tube apparatus for removing a clot from a vessel comprising an inversion support catheter, a puller and a knitted inverting tube having a first and a second configuration, the knitted tube having an expanded outer diameter of 0,5-12 mm for the first region adjacent the first end in the first configuration, an inner diameter greater than 30% of an inner diameter of the inversion support catheter in the second configuration, and a second region of the knitted tube adjacent the second end has an expanded outer diameter less than the expanded outer diameter of the knitted tube region adjacent the first end and within 20% of an outer diameter of the inversion support catheter.

4. claims: 29-40

Pre-loaded inverting mechanical thrombectomy apparatus for removing a clot from a vessel comprising an intermediate catheter, an inversion support catheter, a puller and a flexible inverting tube extending between the inversion support catheter and the intermediate catheter, wherein the puller and the inversion support catheter are releasably held together.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2018/059607

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Form PCT/ISA/210 (patent family annex) (April 2005)

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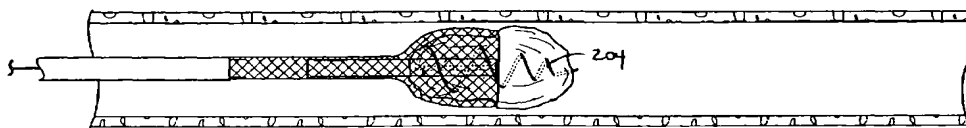
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(54) Title: SYSTEMS, METHODS AND DEVICES FOR REMOVING OBSTRUCTIONS FROM A BLOOD VESSEL



(57) Abstract: A system for removing an obstruction from a blood vessel includes an obstruction engaging element and an expandable capture element. The capture element preferably has a flexible cover and an expandable support structure. The engaging element engages the obstruction and moves the obstruction into the capture element. The capture element protects the obstruction when the obstruction is moved into the catheter.

WO 02/02162 A2

SYSTEMS, METHODS AND DEVICES FOR REMOVING OBSTRUCTIONS FROM A BLOOD VESSEL

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation in part of Serial No. 09/756,476, filed
5 January 8, 2001, which is a continuation-in-part of Application Serial No. 09/605,143, filed
June 29, 2000, entitled, "Methods and Devices for Removing an Obstruction From a Blood
Vessel," by inventors Sepetka, et al., the full disclosures of which are incorporated herein by
reference for all purposes.

BACKGROUND OF THE INVENTION

10 The present invention is directed to methods and devices for removing
obstructions from blood vessels. The device may be used to retrieve and remove clots and
other biological obstructions. The device may also be used to retrieve embolic coils and the
like which have been misplaced or have migrated to an undesirable location.

One such obstruction removal device is disclosed in U.S. Patent No. 5,895,398
15 which is hereby incorporated by reference. The device has an expandable engaging member
which is introduced into the blood vessel to engage the obstruction for removal.

The present invention is also directed to devices, systems and methods which
use an expandable capture element when removing obstructions from a blood vessel. One
such system for removing obstructions in a blood vessel is described in U.S. Patent No.
20 5,102,415 to Guenther et al. The system described in U.S. Patent No. 5,102,415 has a balloon
catheter and a catheter having an expandable tip which receives the obstruction. The balloon
catheter is passed through the obstruction while the balloon is deflated. The balloon is then
inflated and the tip of the catheter is expanded. The balloon is then moved proximally so that
the obstruction is pulled into the expanded tip of the catheter. A problem with the system of
25 U.S. Patent No. 5,102,415 is that the interaction between the balloon catheter and the leading
edge of the catheter may tend to shear off portions of the obstruction. This can cause obvious
problems when working in sensitive vascular areas.

The present invention is directed to additional devices and methods for
removing obstructions in a blood vessel.

SUMMARY OF THE INVENTION

In accordance with the present invention, device and methods for removing obstructions are provided. In a first aspect of the invention, an obstruction removal device is provided which has an obstruction engaging element extending from an insertion element.

5 The engaging element is movable from a collapsed position to an expanded position. The engaging element forms coils having varying diameter wherein the coils at a distal portion are larger than coils at an intermediate portion. The distal portion forms a relatively closed structure which prevents the obstruction, or any part thereof, from migrating downstream. The distal portion is expanded distal to the obstruction while the proximal portion engages
10 and holds the obstruction.

In another aspect of the present invention, another obstruction removal device is provided which has at least one closed loop and preferably two closed loops. The closed loop provides an advantage when advanced through a catheter or sheath in that the closed loop produces opposing radial forces on the catheter or sheath through which the loop is
15 advanced. In this manner, the obstruction removal device can be advanced more easily through the catheter or sheath to prevent binding or kinking of the device during advancement. In a preferred embodiment, the obstruction removal device has two loops of varying diameter with the distal loop having a larger diameter. Each of the loops lie in a plane with the planes of the two loops preferably being perpendicular to one another.

20 In another aspect of the invention, another obstruction removal device is provided which has wound sections formed by one or more filaments which are separated by sections substantially free of the filaments. The intermittent wound sections provide discrete portions where the obstruction can be engaged. In an embodiment, the wound sections can slide on the core element to provide flexibility when advancing the obstruction removal
25 device. The wound sections and sections free of filament are preferably about 1-5 mm long. The obstruction removal device preferably has at least three wound sections and more preferably at least five wound sections.

In still another aspect of the invention, another obstruction removal device is provided which has alternating large and small diameter portions. In a preferred embodiment,
30 the obstruction removal device has at least four large diameter sections and three smaller diameter portions. The alternating large and small diameter portions may help to engage certain types of obstructions and can also help to prevent parts of the obstruction from breaking off and migrating downstream.

Any of the obstruction removal devices described herein may also be used with a source of power coupled to the obstruction removal device for use as described below. The source of power may simply produce a positive or negative charge or may be an RF energy source. The source of power may be used to help the obstruction removal device
5 penetrate and engage the obstruction and may also be used to adhere the obstruction to the obstruction removal device as will be described. In a preferred embodiment, a negative charge is provided when advancing the obstruction removal device into the obstruction and a positive charge, or RF energy, is supplied to adhere the device to the obstruction.

The devices of the present invention may be manufactured in any suitable
10 manner. In another aspect of the present invention, the obstruction removal device has a core element surrounded by a sheath. A strand, preferably about four strands, are positioned between the core element and the tube. The strand and the tube prevent any part of the obstruction removal device from breaking free should the core element fail. The strand and tube will hold the obstruction removal device together even if the core element breaks. The
15 sheath is preferably flexible so that the sheath can undergo much larger deflections than the core element.

The obstruction removal devices of the present invention may also be advanced through a guide catheter having a flow restricting element which is preferably a balloon but may be any other suitable structure. The flow restricting element is expanded to
20 reduce blood flow through the obstructed vessel to minimize the likelihood that the obstruction will migrate downstream.

In another aspect of the invention, a system is provided which has an expandable capture element and an obstruction engaging device which together work to remove an obstruction from a blood vessel. The capture element is advanced through the
25 patient in a collapsed position and is expanded when at the desired location. The obstruction engaging device preferably has one or more filaments which provide a relatively flexible interaction between the engaging device and the capture element. This provides advantages over the use of a balloon catheter as described in greater detail below. The obstruction engaging device preferably has 1-4 filaments and more preferably 1-2 filaments. Of course,
30 the obstruction engaging device may have more filaments without departing from various aspects of the invention and, in fact, the device may form a filter which further helps to prevent portions of the obstruction from being carried downstream.

The capture element is preferably naturally biased toward the expanded position although the capture element may also be manually actuated as described below. The capture element has a support structure with a flexible cover attached thereto. The support structure preferably has a closed loop which opens the distal end of the cover. The loop is preferably integrally formed and has a number of integrally formed hinges which deflect when the loop is expanded and collapsed. The hinges are preferably V-shaped although other shapes may be used. A plurality of struts extend proximally from the loop.

The capture element may also be expanded by the user so that the user may select the appropriate time for expansion of the capture element. In this manner, the user may advance the capture element to a suitable location for expansion. The user may also collapse the capture element before withdrawing the capture element into a catheter. The capture element has an actuator for opening and closing the capture element. The actuator may have a control arm and a stable arm although any suitable actuator may be used. The control arm is manipulated to expand and contract a loop at the distal end of the capture element. Alternatively, the actuator may be a tube which cinches the loop closed. In a specific embodiment, the capture element may also evert when moving to the expanded position.

The device of the present invention may be used in various different locations and for various different purposes. In one embodiment, the device may be used in connection with a guide catheter. When used with the guide catheter, the device may be expanded to slow or even stop blood flow when performing other procedures downstream of the guide catheter such as removing a clot or placing a stent.

Alternatively, the device may be passed through a conventional guide catheter so that the device may be introduced further into the vasculature. In this system, the capture element passes through the guide catheter. The obstruction engaging device is then used to engage the obstruction and move the obstruction into the capture element.

The present invention is also directed to methods and devices for removing an obstruction where the obstruction engaging element has a shape which traps the obstruction. In one aspect, the element extends proximally and then distally to ensnare the obstruction. The element may have such a shape naturally or may be moved into this shape by manipulating the element. For example, the element may be rotated in one or both directions to ensnare the obstruction. The element may have a portion which prolapses to capture the element as the element is manipulated.

In still another aspect of the invention, the capture element inverts when the obstruction is moved into the capture element. The obstruction is preferably engaged with an engaging element having a filament which ensnares the obstruction. The obstruction engaging element may be independent from the capture element or may be connected to the engaging element. The capture element inverts upon application of a compressive force to the inverting portion or upon any other suitable actuation force. The capture element preferably inverts when the compressive force is applied by either the obstruction or the engaging element.

The present invention is also directed to actuators for medical devices. In a first aspect, an actuator is provided which has an outer member and a plurality of fingers extending from the outer member. The fingers form an end that can be opened and closed by bending and straightening the fingers. The fingers may be bent by moving an inner member coupled to the fingers or by tensioning or releasing tension on a filament. The medical devices described above may be used for any suitable purpose including capture or containment of obstructions. For this purpose, the fingers or frame may be covered with the cover that forms an enclosure to hold the obstruction.

In another aspect, the medical device may have a frame that extends from inner and outer members. The frame forms an end that also opens and closes. The frame has a first set of connectors coupled to the outer member and a second set of connectors coupled to the inner member. The inner and outer members are movable relative to one another to open and close the end. The frame may be an integral structure with the structure being deformed when the end opens and closes. In still another aspect, the frame may be made of a shape memory material which regains either the closed or open position when heated or cooled. For example, the frame may be heated using electrical energy or other suitable source to actuate the frame.

These and other advantages of the invention will become apparent from the following description, drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a system for removing an obstruction.

Figure 2 shows the obstruction removal device in a collapsed condition.

Figure 3 shows the obstruction removal device with a distal portion of the obstruction removal device expanded.

Figure 4 shows the obstruction removal device with a proximal portion expanded to engage an obstruction.

Figure 5 shows another obstruction removal device.

Figure 6 shows yet another obstruction removal device.

5 Figure 7 shows still another obstruction removal device.

Figure 8 is an end view of the obstruction removal device of Figure 7.

Figure 9 is an exploded view showing a method of constructing an obstruction removal device.

Fig. 10 shows another system for removing an obstruction from a blood vessel.

10 Fig. 11 shows a capture element in an expanded position with an obstruction engaging element engaging an obstruction

Fig. 12 shows the obstruction moved into the capture element with the obstruction engaging element.

Fig. 13 shows the capture element collapsed and contained within a catheter.

15 Fig. 14 shows an alternative structure for the capture element.

Fig. 15 shows another capture element.

Fig. 16 shows a distal end of the capture element of Fig. 15.

Fig. 17 shows the support structure for the capture element of Figs. 15 and 16.

20 Fig. 18 shows the capture element collapsed around the obstruction prior to withdrawal.

Fig. 19 shows the capture element contained within the catheter in an inverted position when collapsed.

Fig. 20 shows another support structure for the capture element with the support structure in an expanded position.

25 Fig. 21 shows the support structure of Fig. 20 in a collapsed position.

Fig. 22 shows still another support structure for the capture element.

Fig. 23 shows another capture element having a support structure which bows outward to preferentially close the distal end.

30 Fig. 24 shows the capture element of Fig. 23 with an obstruction contained within the capture element.

Fig. 25 shows another capture element.

Fig. 26 shows yet another capture element in an expanded position.

Fig. 27 shows the capture element of Fig. 26 in a collapsed position.

Fig. 28 shows another device for capturing an obstruction.

Fig. 29 shows the capture device of Fig. 28 advanced at least partially into engagement with the obstruction.

Fig. 30 shows an obstruction engaging element advanced through the capture
5 element.

Fig. 31 shows the element engaging the obstruction.

Fig. 32 shows the obstruction partially contained within the capture element.

Fig. 33 shows the obstruction completely contained within an inverted portion
of the capture element.

Fig. 34 shows still another device for capturing an obstruction.

Fig. 35 shows the element engaging the obstruction.

Fig. 36 shows the inverting portion beginning to invert to capture the
obstruction.

Fig. 37 shows the obstruction partially contained within the capture element.

Fig. 38A shows the obstruction completely contained within the capture
15 element.

Fig. 38B shows the inverting portion contained within another catheter such as
the guide catheter for removal from the patient.

Fig. 39 shows the distal end of the device of Figs. 34-38 with the engaging
20 element expanded.

Fig. 40 shows the distal end of the device of Figs. 34-38 with the engaging
element collapsed.

Fig. 41A shows an actuator for a medical device having which has a
deformable frame being used as an obstruction capture device.

Fig. 41B shows the capture device with an obstruction contained therein.

Fig. 42A shows the actuator of Fig. 40 with the distal end closed.

Fig. 42B shows the capture device withdrawn into another catheter.

Figs. 43A-D show the frame coupled to inner and outer members.

Fig. 44 shows another actuator having a frame made of a shape memory
30 material.

Fig. 45 shows the actuator of Fig. 43 with the distal end closed.

Fig. 46 shows still another actuator for a medical device.

Fig. 47 shows the actuator of Fig. 46 with a plurality of fingers in a closed position.

Fig. 48 shows an alternate embodiment of the medical device of Figs. 45 and 46.

5 Fig. 49 shows the medical device of Fig. 48 with the fingers in a closed position.

Fig. 50 shows the actuator of Figs. 46-49 used to capture or remove an obstruction.

10 Fig. 51 shows the actuator of Figs. 46-49 with the distal end closed to capture the obstruction.

Fig. 52 shows another obstruction engaging element.

Fig. 53 shows the obstruction engaging element of Fig. 52 with the element engaging an obstruction.

15 Fig. 54 shows the obstruction engaging element of Figs. 52 and 53 with the element having a prolapsed portion.

Fig. 55 shows another obstruction engaging element in an expanded position.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to Figs. 1-4, a system 2 for removing an obstruction is shown.

20 A guide catheter 4 is advanced to a location proximal to an obstruction. When accessing the cerebral vasculature, for example, the guide catheter 4 is often positioned in the carotid or vertebral artery. Of course, the guide catheter 4 may not be necessary or may be positioned in any other suitable location depending upon the location of the obstruction. The guide catheter 4 preferably has a flow restricting element 6 which restricts or even stops blood flow through
25 the vessel as described below. The flow restricting element 6 is preferably a balloon 5 coupled to a source of inflation fluid 7 which is used to inflate the balloon 5.

An obstruction removing device 8 is advanced through the guide catheter 4 to the obstruction. A microcatheter 10 may also be positioned within the guide catheter 4 to deliver the obstruction removing device 8 further into the vasculature. The obstruction
30 removing device may be advanced by itself through the microcatheter 10 or may be contained within a sheath 12 which is advanced through the microcatheter 10. A source power 14 may also be coupled to the obstruction removal device 8 for use in the manner explained below.

The power source 14 may simply produce a positive or negative charge or may be an RF or other suitable power source.

The obstruction removing device 8 has an engaging element 16 extending from an insertion element 18. The engaging element 16 is movable from a collapsed position (Fig. 2) to an expanded position (Figs. 3 and 4). When the engaging element 16 is contained within the sheath 12 or microcatheter 10, the engaging element 16 is in a relatively straight configuration. The engaging element 16 has a distal portion 20, which forms a relatively closed structure, which can catch or trap the obstruction, or any part thereof, to prevent migration of the obstruction or part thereof. The engaging element 16 has a proximal portion 22 which is formed with smaller coils than the distal portion 20. The proximal portion 22 engages the obstruction as described below.

The engaging element 16 preferably has a number of markers 23, 25, 27 which provide an indication as to how much of the engaging element 16 extends from the sheath 12 or microcatheter 10. For example, markers 23, 25, 27 may indicate when the engaging element 16 is $\frac{1}{2}$, $\frac{3}{4}$ or fully exposed. In this manner, the user may quickly advance the engaging element 16 through the sheath 12 or microcatheter 10 without inadvertently exposing and advancing the engaging element 16 out of the sheath 12 or microcatheter. The markers 23, 25, 27 can also be used to provide a controlled diameter of the engaging element 16 since the diameter of the engaging element 16 is known for the various positions corresponding to the markers 23, 25, 27. The markers 23, 25, 27 may also be used to size the vessel in which the engaging element 16 is positioned by observing when the engaging element 16 engages the vessel walls and determining the size of the engaging element 16 using the markers 23, 25, 27.

The insertion element 18 is preferably made of a superelastic material or stainless steel having a diameter of 0.004 to 0.038 inch and preferably about 0.010 inch. Although the insertion element 18 is preferably a solid, elongate element, the insertion element 18 may take any other suitable structure such as a hollow tube. The engaging element 16 is preferably made of a superelastic material, such as nitinol, and has a diameter of 0.005-0.018 inch, more preferably 0.005-0.010 inch and most preferably about 0.008 inch. The engaging element 16 has a rounded, atraumatic tip 24 to prevent damage to the vessel and facilitate advancement through the vessel, microcatheter 10 and/or sheath 12. A radiopaque wire 26, such as platinum ribbon 28 having a width of 0.004 inch and a thickness of 0.002 inch, is preferably wrapped around the engaging element 16 to improve radiopacity.

The device 8 is preferably self-expanding but may also be expanded with an actuator 29. The actuator 29 is preferably a thin filament which is tensioned to move the device 8 to the expanded position. An advantage of the invention is that the filament 29 extends through the same lumen as the device 8 thereby minimizing the overall size of the device. It is understood that throughout discussion of the devices and methods herein that any of the devices may be expanded using the actuator 29 rather than being self-expanding without departing from the scope of various aspects of the invention.

The device 8 may also include a cover 9 which extends between adjacent coils. The cover 9 may be a number of individual strands 11 which extend between the coils or may be an elastic membrane which covers the coils. The strands 11 are preferably elastic to stretch when the device 8 is expanded.

Use of the obstruction removing device 8 is now described. The guide catheter 4 is introduced into the patient and delivered proximal to the target vessel such as to the carotid or vertebral artery. The microcatheter 10 is then advanced through the guide catheter 4 further into the vasculature to a position proximal to, within or distal to the obstruction. The obstruction removal device 8 is then advanced through the microcatheter 10 either by itself or pre-loaded within the sheath 12. The obstruction removal device 8 is then advanced to the obstruction. Before advancing the obstruction removal device 8 further, the flow restricting element 6 on the guide catheter 4 is expanded to reduce and even stop flow through the vessel. Stopping flow in the vessel may help prevent the obstruction, or any parts thereof, from migrating downstream. Reducing flow through the vessel may also reduce the likelihood that the obstruction is disrupted by a combination of flow and the obstruction removal device 8.

The obstruction removal device 8 is then placed into the obstruction and preferably through the obstruction. The engaging element 16 is then advanced out of the microcatheter 10 or sheath 12 to permit the distal portion 20 of the engaging element 16 to expand at a location beyond the obstruction. In this manner, the relatively closed distal portion 20 prevents the obstruction, or any part thereof, from migrating downstream. The proximal portion 22 is then advanced out of the sheath 12 or microcatheter 10 so that the smaller coils of the proximal portion 22 engage the obstruction as shown in Fig. 4.

Referring to Fig. 5, another obstruction removal device 8A is shown wherein the same or similar reference numbers refer to the same or similar structure. The obstruction removal device 8A has a first section 30 with larger diameter coils than a second section 32.

A third section 34 also has larger coils than the second section 32 with the second section 32 positioned between the first and third sections 30, 34. The obstruction removal device 8A may have a number of alternating small and large sections 30, 32, 34 which can enhance the ability of the obstruction removal device 8A to engage various obstructions. In the preferred
5 embodiment of Fig. 5, the obstruction removal device 8A has four large sections 32, 34 with relatively large coils and three sections 30 having smaller coils.

The obstruction removal device 8A may be used in any suitable manner to engage the obstruction. For example, the microcatheter 10 or sheath 12 may be advanced through the obstruction and then retracted to expose the obstruction removal device 8A. The
10 obstruction removal device 8A is then retracted into the obstruction to engage the obstruction. The obstruction removal device 8A may be rotated when moved into the obstruction to take advantage of the generally helical shape of the obstruction removal device. The obstruction removal device 8A may also be used to engage the obstruction by simply retracting the microcatheter 10 or sheath 12 with the obstruction removal device 8A expanding within the
15 obstruction. Finally, the engaging element 16A may be exposed and expanded proximal to the obstruction and then advanced into the obstruction. When advancing the obstruction removal device 8A into the obstruction, the user may also twist the obstruction removal device 8A to take advantage of the generally helical shape. The alternating large and small sections 30, 32, 34 enhance the ability of the engaging element 16A to engage varying shapes
20 and sizes of obstructions.

Referring to Fig. 6, still another obstruction removal device 8B is shown wherein the same or similar reference numbers refer to the same or similar structure. The obstruction removal device 8B has the insertion element 18 with an engaging element 16B extending therefrom. The engaging element 16B forms a helical coil 38 with a generally
25 frustoconical shape, however, the engaging element 16B may take any other shape without departing from the scope of the invention including any shape disclosed in this application or any patent incorporated by reference herein.

A filament 40, preferably a radiopaque filament, is wrapped around the engaging element 16B. The filament 40 is wrapped somewhat loosely around the engaging
30 element 16B so that the filament 40 provides additional surface area to engage the obstruction. The filament 40 forms a wound section 42, and more preferably at least five wound sections 42, which are separated by substantially exposed sections 44 of the engaging element 16B. The wound and exposed sections 42, 44 may be 1-5 mm long. Stated another

way, the wound and exposed sections 42, 44 are at least 1 mm, more preferably at least 3 mm long, and no more than 8 mm long. The wound sections 42 may be formed by a single filament 40 which extends continuously between the wound sections 42 or may be formed by independent filaments 40 at each wound section 42 which are attached to the engaging element 16B.

The wound sections 40 may be movable along the engaging element 16B to provide flexibility when advancing the obstruction removal device 8B through small and tortuous vessels. The movable wound sections 40 may also allow different parts of the obstruction removal device 8B to grip different parts of the obstruction to hold the obstruction together or engage different parts of the obstruction. The obstruction removal device 8B is used in substantially the same manner as the other obstruction removal devices described herein. The obstruction removal device 8B has a handle 41 with a lead screw 43 which engages threads 55. The handle 41 is rotated to advance and retract the engaging element 16B.

Referring to Fig. 7, still another obstruction removal device 8C is shown wherein the same or similar reference numbers refer to the same or similar structure. The obstruction removal device 8C has an engaging element 16C, which forms a first closed loop 50, and a second closed loop 52. The first loop 50 is preferably somewhat larger than the second closed loop 52 with the first loop 50 having a diameter of about 1.5-8.0 mm and the second loop 52 having a diameter of about 1.5-6.0 mm. A tip 54 extends from the first loop 50 for a distance of about 5 mm. A radiopaque element 56, such as platinum ribbon, is preferably wrapped around the loops 50, 52 to improve radiopacity and to enhance the ability of the engaging element 16C to hold the obstruction. The radiopaque element 56 also may provide advantages when engaging an obstruction in a manner similar to the obstruction removal devices described above with reference to Fig. 6.

An advantage of the obstruction removal device 8C is that the loops 50, 52 exert substantially equal and opposing forces on the sheath 12 or microcatheter 10 through which the obstruction removal device 8C is advanced. In this manner, kinking or binding of the obstruction removal device 8C during advancement can be minimized or reduced altogether. Referring to the end view of Fig. 8, the first and second loops 50, 52 preferably lie in first and second planes 58, 60, respectively, which are preferably perpendicular to one another.

Another method of aiding mechanical capture of an obstruction is to coat the

device and elements of the present invention with a material 61 which helps to adhere the obstruction, and in particular thrombus, to the device or element. The material 61 is preferably fibrin but may be any other suitable material. Use of the material 61 may be incorporated into any of the devices described herein or other suitable device such as the devices shown in Figs. 2-8, 22 or 30.

Referring to Fig. 9, an exploded view of a construction of the obstruction removal device 8, 8A, 8B, 8C is shown. A tube 62, which is preferably a thermoplastic polymer such as polyester or urethane is positioned over a core element 64. As mentioned above, the core element 64 is preferably a superelastic or stainless steel element at either the insertion element 18 or the engaging element 16 (Figs. 2-7). A reinforcing strand 66 is trapped between the tube 62 and the core element 64 to reinforce the obstruction removal device. The strand 66 is preferably small and has a diameter or thickness of less than 0.005 inch, more preferably less than 0.0001 inch, so that the overall size of the obstruction removal device is not increased significantly with use of the strand 66. The strand 66 may be made of any suitable material including VECTRAN made by Celanese Acetate LLP or DACRON or KEVLAR which are both manufactured by Dupont. VECTRAN is a thermoplastic multifilament yarn spun from a liquid crystal polymer.

The strand 66 provides a degree of safety in that the strand 66 and tube 62 together prevent any part of the obstruction removal device from breaking free from the rest of the device. The tube 62 will resist breaking since it is more flexible than the core element 64 and can undergo larger deflections and displacements without breaking. In a preferred embodiment, 2-8 strands 66, preferably about 4 strands 66, are used. The overall size of the device is also relatively small with the outer diameter of the resulting structure being no more than 0.020 inch and more preferably no more than 0.012 inch.

The power source 14 may be also be used with any of the obstruction removal devices in the following manner, however, the methods and devices of the present invention may, of course, be practiced without the power source 14. As mentioned above, the power source 14 may simply produce a charge at the engaging element 16 or may be a source of RF energy. In one particular method of the present invention, the power source 14 produces a negative charge while advancing the engaging element 16 through the obstruction. The negative charge may aid in passing the engaging element 16 through the obstruction and may help to dissolve part of the obstruction. The power supply is then changed to produce a positive charge to adhere the obstruction to the engaging element 16. Alternatively, the

power source 14 may be an RF energy source, which delivers RF to the engaging element 16 which also adheres the obstruction to the engaging element 16 and may help provide a controlled penetration into the obstruction. The obstruction is then removed by moving the obstruction into the guide catheter 4, which is then withdrawn to remove the obstruction. Use
5 of the power source 14 is particularly useful when the obstruction is a biologic structure such as a clot.

Referring to Figs. 10-14, another system 100 for removing an obstruction is shown. The system 100 is particularly useful for removing clots and thrombus from blood vessels but may also be used to remove other obstructions such as embolic coils and the like.
10 The system 100 includes an expandable capture element 102 and an obstruction engaging device 106 which work together to capture the obstruction. The obstruction engaging device 106 engages the obstruction and moves the obstruction into the capture element 102 as described below. After the obstruction has been captured, the capture element 102 may then be used in various ways for ultimate removal of the obstruction. The capture element 102
15 may be advanced through the guide catheter 4 or through another catheter 107 which is advanced through the guide catheter 4. As will be explained below, the capture element 102 is preferably advanced over the obstruction engaging device 106.

The obstruction engaging device 106 may be any of the engaging or removal devices described herein or any other suitable device. Various aspects of the invention
20 preferably include one or more features of the obstruction removing devices described herein and all aspects, features, dimensions, and characteristics of the obstruction removing and engaging devices described herein are incorporated here. It is understood that the term obstruction removal device and obstruction engaging device are interchangeable. The obstruction engaging device 106 may be contained within the sheath 12 or may be advanced
25 by itself through the guide catheter 4 and/or catheter 107.

The engaging device 106 may have one or more filaments 108, preferably 1-4 and more preferably 1-2 filaments, which engage the obstruction. The filament 108 forms a relatively small, flexible interaction between the engaging device 106, capture element 102 and obstruction which provides advantages over the prior art method of using a balloon
30 catheter. The filament 108 may deflect and displace to accommodate the geometry and orientation of the obstruction when the obstruction enters the capture element 102. The interaction between the balloon catheter and the expandable catheter of the prior art tends to shear off portions of the obstruction due to the relatively rigid interaction between the balloon

catheter and expanded catheter. The filament 108 also has a relatively small size which further enhances the flexibility of the obstruction engaging device 108. The filament 108 may also form one or more loops 110 which further serve to create a soft, flexible interaction between the obstruction engaging device 106 and capture element 102. The filaments 108
5 may also form a filter which further prevents the obstruction or portions thereof from travelling downstream.

The capture element 102 preferably has a support structure 112 with a flexible cover 114 attached thereto. The support structure 112 is preferably self-expanding although the support structure 112 may also be selectively expanded by the user as explained below.
10 The support structure 112 preferably has a loop 116 having integrally formed hinges 117. The hinges 117 are preferably formed by V-shaped interconnecting elements 120 although other shapes, such as U-shaped, may be used. The loop 116 is preferably formed as an integral structure with the loop 116 being formed from a tube of material which is cut, etched, treated or otherwise formed into the loop 116 with hinges 117. The loop is preferably made
15 of a superelastic material although any suitable material may be used.

Struts 122 extend proximally from the loop 116. The struts 122 do not intersect and generally form a cone 124 when expanded. The struts 122 are coupled to a lumen 121 which receives the engaging device 106 so that the capture element 102 can be advanced over the engaging device 106 as described below. Referring also to Fig. 14, the
20 struts 122 may also be coupled together at a hub 126 at the proximal end. The hub 126 has a lumen 127 which receives the engaging device 106. A shaft 128 extends from the hub 126 and is used to manipulate the capture element 102. The struts 122 are preferably made of a superelastic material or stainless steel and are attached to the closed loop 116 by soldering, welding, glue or any other suitable attachment method. The struts 122 may also be integrally
25 formed with the loop 116. Of course, the supporting structure 112 may be made of any other suitable material and may be formed in any other suitable manner. The struts 122 may also be bowed outward so that the distal end of the device is preferentially closed before the entire device has been withdrawn as shown in Figs. 23 and 24.

The cover 114 is preferably attached to the support structure 112 with glue,
30 thread, suture or any other suitable method. The cover 114 preferably lies over the support structure 112 but may also be contained within the support structure 112. The cover 114 is relatively long to ensure that the entire obstruction is captured. The cover 114 is preferably at least three times, more preferably at least five times, and most preferably at least seven times

larger than the maximum expanded diameter of the support structure 112 or cover 114. Of course, the capture element 102 may have any other suitable dimensions depending upon the particular application. The cover 114 is preferably made of ePTFE but may be made of any other suitable material. The cover 114 may also be a mesh-like structure, or any other
5 suitable expandable structure which can contain the obstruction and parts thereof, without departing from the scope of the invention.

Various methods of the present invention are now described. The methods are described in connection with system 100 of Figs. 10-14 but may be practiced with other suitable devices and systems. The present invention is well-suited for use in the cerebral
10 vasculature and a cerebral application is described, however, the invention may be practiced in other vascular locations as well.

The guide catheter 4 is advanced to a suitable location. The obstruction engaging device 106 is then advanced through the guide catheter 4. Referring to Figs 11 and 12, the obstruction engaging device 106 is then used to engage the obstruction in any manner
15 described herein. For example, the sheath 10 (see Fig. 10) may be advanced through the obstruction and then retracted so that a proximal portion 111 of the device 106 is contained within the obstruction. The device 106 is then moved proximally, and is preferably twisted, so that the loops 110 engage the obstruction. In the specific embodiment of Figs. 11-14, the device 106 ensnares the obstruction with the loops 110 when twisted and moved proximally.

The capture element 102 is then advanced over the engaging device 106. The
20 capture element 102 may be advanced through the guide catheter 4 or may be advanced through the catheter 107 which is advanced through the guide catheter 4 further into the cerebral vasculature. The capture element 102 is then moved out the catheter 107 or guide catheter 4 so that the capture element 102 expands. The obstruction is then moved into the
25 capture element 102 with the device 106 as shown in Fig. 13. When the obstruction is contained within the capture element 102, the capture element 102 is then withdrawn into the catheter 107 or guide catheter 4 as shown in Fig. 14. The catheter 107 and/or guide catheter 4 are then withdrawn from the patient thereby withdrawing the obstruction.

It may be desirable to reduce or even stop blood flow through the blood vessel
30 during the procedure to reduce flow forces on the obstruction when manipulating the obstruction. Reducing flow in the vessel may also prevent some parts of the obstruction from breaking off and flowing downstream before entering the capture element 102. Referring again to Figs. 10 and 22, blood flow may be reduced by inflating a balloon 131 on the guide

catheter 4 or the catheter 107. The balloon 131 is inflated using a suitable source of inflation fluid 133. Alternatively, the capture element 102 itself may also be used to reduce blood flow through the vessel. The capture element 102 naturally impedes blood flow since it expands within the blood vessel. The capture element 102 may also be designed to only partially occlude the vessel so that some blood flow is provided to the area downstream from the capture element 102. The device 102 may be modified to include a second loop 130 extending between the struts 122 to enhance the ability of the device 102 to occlude the vessel. The loop 130 preferably has the features of the loop 116. Although it is preferred to reduce or even stop flow in the vessel, the invention may also be practiced without reducing blood flow.

The devices and methods of the present invention may also be practiced with a source of vacuum 135 providing suction during capture of the obstruction. The source of vacuum 135 may be activated during engagement of the obstruction with the device 106, movement of the obstruction into the capture element 102, and/or withdrawal of the capture element 102 into the catheter 107 or guide catheter 4. The source of vacuum 135 is coupled to the guide catheter, 4, catheter 107 and lumen 121 for these purposes.

Referring to Figs. 10 and 15-17, another capture element 132 for removing an obstruction is shown wherein the same or similar reference numbers refer to the same or similar structure. The capture element 132 is selectively expandable by the user which provides various advantages described below. The cover 114 is attached to a catheter 134 near or at the distal end 135. The catheter 134 may be the guide catheter 4 or the catheter 107 in the system 100 described above. An expandable and collapsible loop 136 is attached to the distal end of the cover 114 to expand and collapse the distal end of the cover 114. The loop 136 is expanded and collapsed by manipulating an actuator 138 which includes a control arm 140 and a stable arm 142. The control arm 140 extends and slides through an eyelet 144 when expanding and collapsing the loop 136. The stable arm 142 extends from the loop 136 at or near the eyelet 144 to stabilize the loop 136 when moving the control arm 140. The cover 114 is attached to the loop 136 using any suitable method. For example, the distal end may be inverted to create a fold 141 which surrounds the loop 136.

Another advantage of the capture element 132 is that the capture element 132 may be selectively expanded and contracted by the user. The capture element 132 may be fully or partially collapsed to trap the obstruction prior to withdrawal of the capture element 132 into the catheter 107 or guide catheter 4 as shown in Fig. 18. In fact, the capture element

132 may be withdrawn by itself by simply closing the distal end and withdrawing the capture element 132. In this manner, the capture element 132 protects the obstruction during withdrawal and prevents the obstruction from escaping. This provides obvious advantages over the system of Guenther described above.

5 Referring to Figs. 10 and 19, still another capture element 150 is shown in which the same or similar reference numbers refer to the same or similar structure. The capture element 150 has the cover 114 and the actuator 138 which includes the stable arm 142, control arm 140, and loop 136 although other actuating structures may be used. The capture element 150 is contained within the catheter 107 or the guide catheter 4 during
10 introduction and is then everted out of the catheter 107 or catheter 4 when deployed. The capture element 150 may be used in substantially the same manner as the other capture elements described herein and in particular the capture element 132 of Figs 15-17. The capture element 150 may also be used to further collapse the cover 114 since the actuator 138 may be used to close the distal end with the cover 114 deployed. After the obstruction is
15 contained within the capture element 150, the capture element 150 is withdrawn into the catheter 107 or catheter 4. Although it is preferred to withdraw the capture element 150 into the catheter 4 or catheter 107, the capture element 150 may be collapsed and then inverted back into the catheter 4, 107 thereby trapping the obstruction in the catheter 4, 107 itself.

Referring to Figs. 20 and 21, the distal end of yet another capture element 152
20 is shown in which the same or similar reference numbers refer to the same or similar structure. The capture element 152 has a self-expanding support structure 154 with an expandable loop 156 at the distal end. The loop 156 has a tube 158 which receives a wire 160 at both ends. The slidable connection between the tube 158 and wire 160 permits the loop 156 to contract and expand between the positions of Figs. 20 and 21. Struts 162 extend from
25 the loop which engage the catheter to collapse the loop 156. The cover 114 is attached to the loop 156 by any suitable method. The capture element 152 is used in any manner described herein. The capture element 152 is used in any manner described herein and those methods are incorporated here.

Referring to Fig. 25, still another device 170 is shown wherein the same or
30 similar reference numbers refer to the same or similar structure. The device 170 is similar to the device of Fig. 15 in that the device 170 may be selectively expanded and collapsed by the user. The device 170 has a collar 172, which may also be a continuous sheath or tube, which slides over the catheter 107 or sheath 12. The engaging device 106 passes through the

catheter 107 or sheath 12 (Fig. 10) and is used in the manner described herein. A 174 wire, or other elongate member, is coupled to the collar 172 for advancing and manipulating the collar 172.

The cover 114 is coupled to a loop 176 which is selectively expanded by the
5 user as now explained. The loop 176 is manipulated with the actuator 138 which may be any suitable mechanism. The actuator 138 has a wire 139 passing through an actuator tube 178 and may also include the stable arm 142. The wire 139 is coupled to the loop so that movement of the wire 139 opens and closes the loop 176. The actuator tube 178 may be simply advanced to cinch the loop 176 closed. The loop 176 is preferably naturally biased
10 toward the open position and is held closed by the tube 178.

The device 170 is used in substantially the same manner as the other devices described herein and discussion of those methods are specifically incorporated here. The device 170 may be advanced by itself through the vasculature with the tube 178 holding the loop 176 in the closed position. The cover 114 is advanced by manipulating the tube 178,
15 wire 139 and wire 174. The cover 114 is advanced over the catheter 107 or sheath 12 and the tube 178 is retracted to permit the loop 176 to expand. The obstruction is then introduced into the cover 114 and the cover 114 is then closed by advancing the tube 178 to cinch the loop 176 closed. The actuator 138 may also be manipulated to open or close the loop 176 together with the tube 178 or independently of the tube 178.

Referring to Figs. 26 and 27, still another device 180 is shown wherein the same or similar reference numbers refer to the same or similar structure. The device 180 has the cover 114 and a loop 182 coupled to the distal end of the cover 114. Stabilizing struts 184 extend from an end 186 of a tubular body 188 to the loop 182. Actuating arms 190
20 extend through the body 188 and are also attached to the loop 182. The arms 190 are manipulated to move the loop 182 between the collapsed and expanded positions of Figs. 26 and 27. The engaging device 106 passes through the body 188 and may be delivered through the catheter 107 or sheath 12. The device 180 is used in substantially the same manner as the device of Fig. 15 and discussion of those methods are incorporated here.

Referring to Figs. 28-33, another capture element 200 is shown for capturing
30 an obstruction. The capture element 200 has an inverting portion 202 that inverts to entrap the obstruction. The capture element 200 is then withdrawn into the guide catheter 4 (Fig. 1) for removal of the obstruction from the patient.

Referring to Fig. 31, the engaging element 204 is shown engaging the obstruction. The element 204 may be any suitable element such as the obstruction engaging elements and removal devices described herein. The element 204 passes through a lumen 205 in the capture element 200. The engaging element 204 may be advanced through the capture element 200 by itself or may be contained within the microcatheter 10 or sheath 12 (Figs. 1 and 2) which is advanced through the capture element 200.

The capture element 200 has a distal portion 207 which is flexible and which may be partially contained, engaged or otherwise in contact with the obstruction as shown in Fig. 29. The distal portion 207 may also invert but preferably does not invert. The distal portion 207 necks-down at a distal end 209 to a size smaller than the guidewire GW so that the capture element 200 is advanced together with the guidewire. Of course, the capture element 200 may also be advanced by itself after introduction of the guidewire and may be contained within or advanced over another catheter without departing from the invention.

The element 204 engages the obstruction in any suitable manner. The inverting portion 202 is then inverted by applying a compressive force to the inverting portion 202. The compressive force is applied by moving the capture element 200 relative to the engaging element 204 which causes the element 200 and/or obstruction to compress the inverting portion. Continued relative movement moves the obstruction into the inverted capture element 200 as shown in Figs. 32 and 33 to capture the obstruction. The capture element 200 is then moved into the guide catheter 4 (Fig. 1) for removal from the patient. The capture element 200 may be made of any suitable materials. For example, the distal portion 207 may be made of any suitable polymeric material such as those described herein and the inverting portion 202 may be made of a braided or woven material or fabric made of fibers or filaments of nitinol, stainless steel, polymer or other material.

Referring to Figs. 34-40, another capture element 210 for removing an obstruction is shown wherein the same or similar reference numbers refer to the same or similar structure. The capture element 210 also has an inverting portion 212 connected to an end 213 of a delivery element 214 which may be a hollow tube, sheath or catheter. The distal end of the capture element 210 has a collar 214 attached to a proximal end 216 of an engaging element 218. A distal end 220 of the obstruction engaging element 218 is attached to an inner element 222 such as a wire, mandrel or guidewire. The collar 214 slides over the inner element 222 so that when the inner element 222 and delivery element 214 are movable relative to one another. Relative movement between the inner element 222 and delivery

element 214 moves the obstruction engaging element 218 between the expanded and collapsed positions (Figs. 39 and 40) and also can collapse the capture element 210. The engaging element 218 is similar to the other elements and devices described herein in that the element has a filament 224 which is tensioned to collapse the filament 224. The filament 224
5 forms coils 226 around the inner element 222.

The capture element 210 and obstruction engaging element 218 are advanced through the patient in either the sheath 12 or microcatheter 10 (Figs. 1 and 2). The capture element 210 and obstruction engaging element 218 are then positioned distal to the obstruction and the obstruction is engaged with the element 218. The capture element 210
10 and engaging element 218 are then moved relative to one another to invert the capture element 210 as described above.

Referring to Figs. 41-43, another aspect of the present invention is shown which provides an actuator 228 for a medical device 230. The actuator 228 may be used for actuating any medical device and a specific example is a capture element or an obstruction
15 removal device. The medical device 230 has a frame 232, an outer member 234 and an inner member 236 positioned within the outer member 234. The frame 232 extends distally from the inner and outer members 236, 234.

The frame 232 has a distal end 238 which moves between the open (Figs. 41A and B) and closed (Figs. 42A and B) positions. The frame 232 has a first set of connectors
20 240 coupled to the outer member 234 and a second set of connectors 242 coupled to the inner member 236. The inner and outer members 236, 234 are moved relative to one another so that the frame 232 is deformed to open and close the distal end between the positions of Figs. 41A and B and 42A and B. The inner and outer members 236, 234 are preferably tubes but may be any other suitable structure that permits longitudinal movement of the connectors 240, 242
25 in the manner described. The connectors 240, 242 extend longitudinally to a ring 241 formed of V-shaped elements 243. The connectors 240 attached to the inner member 236 are coupled to intersections 245 of the ring 241 and the other connectors 240 are attached to the other intersections 247 of the ring. Stated another way, the connectors 240, 242 are attached at spaced apart positions on the ring with one connector 240 between each pair of connectors
30 242. The frame 232 is preferably integrally formed in a manner similar to a stent. For example, the frame 232 may be formed by removing material from a tube to provide the frame structure.

A cover 233 may be provided over or under the frame 232 so that the frame 232 acts as an actuator 244 to open and close the cover 233. The cover 233 may be used in the same manner as any of the capture elements described herein. To this end, any of the obstruction engaging elements described herein may be used with the device to trap and
5 remove obstructions.

Referring to Figs. 44 and 45, still another medical device 250 is shown which is similar to the medical device 230 of Figs. 41-43. The medical device also has a frame 252 having a distal end 254 which opens and closes. The frame 252 is made of a shape memory material which either recovers the open or closed position when heated. The shape memory
10 material may be heated in any suitable manner including use of a heated fluid or by applying electrical energy which heats the frame 252 to cause the frame to assume the recovered shape. Fig. 45 shows the frame 252 assuming the collapsed shape upon application of electrical energy from an energy source 253. The cover 233 may also be provided so that the frame acts as an actuator for still another capture device. Figs. 45 show the medical device 250 being
15 used to capture an obstruction. The device 250 is then withdrawn into the guide catheter or other suitable catheter for removal of the obstruction.

Referring to Figs. 46-51, still another actuator for a medical device 256 is shown. The characteristics of the medical device 256 may be used to form any device. The medical device 256 has a plurality of longitudinally extending fingers 258. The fingers 258
20 are normally in a relatively straight configuration. The fingers 258 are bent inward so that a distal end 260 closes (Fig. 47). The fingers 258 may be attached to the cover 233 to open and close the cover 233 with the fingers 258. The fingers 258 are preferably bent by tensioning flexible, elongate members 262. The elongate members 262 may be attached to an inner member 264 (Figs. 46 and 47) or an outer member 265 (Figs. 48 and 49). Any of the
25 obstruction engaging elements may be used with the medical device to remove an obstruction in any manner described herein. For example, Figs. 50 and 51 show the medical device 256 being used to capture or remove an obstruction. The device 256 may be used to capture or engage the obstruction by itself or in cooperation with any a suitable engaging element 257.

Referring to Figs. 52-55, another obstruction engaging element 270 is shown.
30 The obstruction engaging element 270 includes a filament 272 which forms windings or coils 274. The windings 274 may take any suitable shape such as helical. The obstruction engaging element 270 is advanced to an obstruction in any manner described herein. For example, the obstruction engaging element 270 may be contained within the sheath 12 or

catheter 10 (Figs. 1 and 2) and advanced through the obstruction. The obstruction engaging element 270 is then advanced out of the sheath 12 or catheter 10 (Figs. 1 and 2) to permit the obstruction engaging element 270 to expand.

When the element initially expands, the coils 274 do not overlap when viewed
5 along a longitudinal axis L. The element 270 is then engaged by manipulating the element 270. After the obstruction has been engaged, the element 270 is rotated which tends to open the coils 274. This causes one or more proximal coils 274 to prolapse over other coils to ensnare the obstruction. Stated another way, the element 270 initially extends distally in a relatively continuous manner. After rotating the element 270, the element extends distally,
10 then proximally, then distally again. Stated yet another way, the coils are manipulated so that they appear to overlap when viewed along the longitudinal axis L. The prolapsed or overlapping coils 274 may provide an even more secure engagement to the obstruction. The element 274 may also be formed to have the overlapping or prolapsed sections when in the natural, unbiased and expanded position as shown in Figs. 54.

15 While the above is a description of the preferred embodiments of the invention, various alternatives, substitutions and modifications may be made without departing from the scope thereof, which is defined by the following claims. Thus, the preferred embodiments should not be taken as limiting the scope of the invention. For example, although all of the obstruction removal devices described herein are self-expanding
20 structures, the obstruction removal devices may also have actuating mechanisms for moving the engaging element between the expanded and collapsed positions. Furthermore, the present invention is directed to a number of separate inventions and each of these inventions may be claimed independently of one another. Each feature, aspect and advantage of the invention may be claimed independent of one another without departing from the scope of the
25 invention. For example, use of the power source 14 is independent of the using the intermittent wound sections 42 but may be used with any of the devices and methods described herein. As a further example, any engaging device, even a balloon, may be used with some of the inventive aspects of the capture element and any capture element may be used with inventive aspects of the engaging device.

30 The obstruction engaging element may be used in any manner described herein and all such methods, devices and systems form part of the present invention. It can be appreciated that various aspects of each of the obstruction engaging elements may be practiced with various aspects of the capture element and, thus, all such combinations are, of

course, contemplated whether or not all such combinations are specifically identified herein. Finally, the devices of the present invention may also be used in connection with simply controlling blood flow through an area and not necessarily with removal of an obstruction.

Thus, it is understood that various aspects of the present invention are not limited to removal
5 of obstructions. Thus, the invention does not include a single essential feature, aspect or advantage and the invention should not be limited as such.

WHAT IS CLAIMED IS:

1 1. A method of removing an obstruction, comprising the steps of:
2 providing an obstruction removing device, the obstruction removing device
3 having an element movable from a collapsed position to an expanded position, the element
4 being contained within a lumen in a delivery device in the collapsed position;
5 advancing the delivery device through the patient's vascular system to an
6 obstruction in a vessel;
7 expanding at least part of the engaging element toward the expanded position;
8 coupling the engaging element to a supply of power;
9 moving the engaging element into contact with the obstruction; and
10 supplying power to the element when the engaging element is in contact with
11 the obstruction.

1 2. A method of constructing an obstruction removing device, comprising
2 the steps of:
3 providing an elongate element;
4 positioning at least one strand against the elongate element; and
5 positioning a tube over the fiber to trap the fiber.

1 3. An obstruction removal device, comprising:
2 an insertion element having an expandable element extending from the
3 insertion element;
4 at least one strand extending along at least the expandable element; and
5 a tube of material which traps the at least one strand.

1 4. The device of claim 2, wherein:
2 the strand has a diameter of less than 0.005 inch.

1 5. The device of claim 4, wherein:
2 the strand is a thermoplastic multifilament yarn spun from a liquid crystal
3 polymer.

1 6. The device of claim 2, wherein:
2 the elongate element being made of superelastic material.

1 7. The device of claim 2, wherein:
2 the elongate element having a diameter of 0.005-0.018 inch.

1 8. The device of claim 2, wherein:
2 the elongate element being biased toward an expanded position.

1 9. The device of claim 2, wherein:
2 the elongate element has an diameter of 0.005-0.010 inch.

1 10. A kit for removing an obstruction in a blood vessel, comprising:
2 an obstruction removing device having an elongate insertion element and an
3 expandable obstruction engaging element extending from the elongate insertion element; and
4 a catheter having an expandable balloon mounted thereto, the catheter having
5 at least one lumen sized to receive the obstruction removal device.

1 11. A method of removing an obstruction in a blood vessel, comprising the
2 steps of:

3 providing an obstruction removal device and a guide catheter, the obstruction
4 removing device having an elongate insertion element and an expandable obstruction
5 engaging element extending from the elongate insertion element, the guide catheter having a
6 flow restricting element mounted thereto, the delivery catheter having at least one lumen
7 sized to receive the obstruction removal device;

8 advancing the obstruction removal device through the guide catheter to an
9 obstruction in a blood vessel;

10 expanding the flow restricting element to at least reduce blood flow in the
11 blood vessel;

12 engaging the obstruction with the obstruction removal device while the flow
13 restricting element is expanded; and

14 removing the obstruction.

1 12. An obstruction removal device, comprising:
2 an elongate element extending from an insertion element, the elongate element
3 being movable from a collapse position to an expanded position, the elongate element

4 forming helical coils having varying diameter, wherein the coils at a distal portion are larger
5 than the coils at an intermediate portion.

1 13. The device of claim 12, wherein:
2 the elongate element has a proximal portion which has coils which are larger
3 than the coils at the intermediate portion.

1 14. A method of removing an obstruction from a patient, comprising the
2 steps of:
3 providing an obstruction removal device, the obstruction removal device
4 having an engaging element extending from an insertion element, the engaging element being
5 movable from a collapsed condition to an expanded condition, the engaging element having a
6 proximal portion and a distal portion;
7 passing the obstruction removal device through an obstruction in a vessel with
8 the engaging element in the collapsed position;
9 expanding the distal portion at a location distal to the obstruction so that the
10 distal portion forms a trap to prevent the obstruction from traveling downstream; and
11 engaging the obstruction with the proximal portion of the obstruction removal
12 device after the expanding step.

1 15. An obstruction removal device, comprising:
2 an elongate insertion element; and
3 an obstruction engaging element extending from the insertion element, the
4 obstruction removing element being movable from a collapsed position to an expanded
5 position, the obstruction removing device forming at least one closed loop in the expanded
6 position, the closed loop exerting substantially equal and opposing radial forces when
7 collapsed.

1 16. The device of claim 15, wherein:
2 the obstruction engaging element forms at least two loops in the expanded
3 position, a first loop lying in a first plane when expanded and a second loop lying in a second
4 plane when expanded.

1 17. The device of claim 16, wherein:
2 the first plane is substantially perpendicular to the first plane.

1 18. The device of claim 16, wherein:
2 the first loop is larger than the second loop, the first loop being positioned
3 distal to the second loop.

1 19 . The device of claim 15, wherein:
2 the engaging element is formed by a core element and a filament wrapped
3 around the core element.

1 20. An obstruction removal device, comprising:
2 an elongate insertion element; and
3 an obstruction engaging element movable from a collapsed position to an
4 expanded condition, the engaging element having at least two wound sections having a
5 filament wound around a core element, the wound sections being separated by a section
6 substantially free of the filament.

1 21. The device of claim 20, wherein:
2 the section which is substantially free of the filament is at least 1 mm long.

1 22. The device of claim 20, wherein:
2 the section which is substantially free of the filament is at least 3 mm long.

1 23. The device of claim 20, wherein:
2 the section which is substantially free of the filament is no more than 6 mm
3 long.

1 24. An obstruction removing device, comprising:
2 an elongate insertion element; and
3 an obstruction engaging element movable from a collapsed position to an
4 expanded condition, the engaging element having a first section, a second section, and a third
5 section, the second section being positioned between the first and third sections, the second
6 section forming coils having a smaller diameter than coils formed by the first and third
7 sections.

- 1 25. The device of claim 24, wherein:
2 the obstruction engaging element has a fourth section and a fifth section, the
3 fourth section being positioned between the third and fifth sections, the fourth section
4 forming coils having a smaller diameter than coils formed by the third and fifth sections.
- 1 26. A system for removing an obstruction from a blood vessel, comprising:
2 a catheter having a lumen;
3 an expandable capture element which is contained within the lumen of the
4 catheter, the capture element being slidable within the lumen of the catheter between a
5 collapsed position contained within the lumen and an expanded position in which the capture
6 element is positioned outside the lumen; and
7 an obstruction engaging device having a filament, the filament being movable
8 from a collapsed position to an expanded position, the obstruction engaging element passing
9 through the catheter.
- 1 27. The system of claim 26, wherein:
2 the expandable capture element is naturally biased toward the expanded
3 position when positioned outside the lumen.
- 1 28. The system of claim 26, wherein:
2 the expandable capture element has a support structure with a flexible cover
3 attached to the support structure.
- 1 29. The system of claim 28, wherein:
2 the self-expanding support structure has a closed loop having integrally formed
3 hinges.
- 1 30. The system of claim 29, wherein:
2 the hinges are V-shaped interconnecting elements.
- 1 31. The system of claim 28, wherein:
2 the support structure has a plurality of longitudinal struts extending from the
3 loop.
- 1 32. The system of claim 26, wherein:

2 the capture element has an expandable loop at the distal end.

1 33. The system of claim 32, wherein:

2 the loop is formed by an eyelet with a control arm extending through the
3 eyelet.

1 34. The system of claim 26, wherein:

2 the capture element has a flexible cover, the cover having a length which is at
3 least three times an expanded diameter of the capture element.

1 35. The system of claim 34, wherein:

2 the length of the cover is at least five times the expanded diameter of the
3 capture element.

1 36. The system of claim 26, wherein:

2 the engaging device has 1-4 filaments.

1 37. A method of removing an obstruction from a blood vessel comprising
2 the steps of:

3 providing a catheter, an obstruction engaging device and an expandable
4 capture element, the capture element being contained within a lumen of the catheter in a
5 collapsed position, the capture element moving to an expanded position when positioned
6 outside the lumen, the obstruction engaging device having a filament which is movable from
7 a collapsed position to an expanded position;

8 introducing the catheter into a blood vessel of a patient;

9 engaging an obstruction with the filament;

10 expanding the capture element; and

11 moving the obstruction into the capture element with the engaging device after
12 the engaging and expanding steps.

1 38. A system for removing an obstruction from a blood vessel, comprising:

2 a catheter having a lumen;

3 an expandable capture element contained within the lumen of the catheter, the
4 capture element being in a collapsed position when contained within the lumen and being in
5 an expanded position when positioned outside the lumen, the expandable capture element

6 having a support structure forming a closed loop having a plurality of integrally formed
7 hinges; and

8 an obstruction engaging device which extends through the expandable capture
9 element, the engaging device having a collapsed shape and an expanded shape.

1 39. The system of claim 38, wherein:

2 the capture element has a flexible cover attached to the support structure, the
3 cover having a distal end which is positioned at the loop so that the loop opens the distal end
4 of the cover.

1 40. The system of claim 38, wherein:

2 the support structure has a plurality of longitudinal struts which extend
3 proximally from the loop.

1 41. The system of claim 40, wherein:

2 the struts do not intersect and form a form a conical shape when the capture
3 element is in the expanded.

1 42. The system of claim 38, wherein:

2 the loop has integrally formed hinges.

1 43. The system of claim 42, wherein:

2 the hinges are formed by V-shaped elements.

1 44. The system of claim 38, wherein:

2 the obstruction engaging device has a filament configured to penetrate and
3 engage an obstruction.

1 45. A system for removing an obstruction from a blood vessel, comprising:

2 a catheter having a lumen;

3 an expandable capture element which is contained within the lumen of the
4 catheter, the capture element being slidable within the lumen of the catheter, the capture
5 element having an actuator for manually expanding and contracting the capture element; and
6 an obstruction engaging device which passes through the capture element.

1 46. The system of claim 45, wherein:

2 the obstruction engaging devices includes a filament for engaging the
3 obstruction.

1 47. The system of claim 45, wherein:
2 the actuator has a control arm and a stable arm, the control arm being
3 manipulated to expand and collapse the capture element.

1 48. The system of claim 45, wherein:
2 the actuator has a loop and a control arm which is manipulated to open and
3 close the loop.

1 49. The system of claim 45, wherein:
2 the capture element everts when moving outside the lumen.

1 50. The system of claim 45, wherein:
2 the actuator includes a tube and a wire extending through the tube.

1 51. The system of claim 45, wherein:
2 the actuator includes at least two wires.

1 52. The system of claim 51, wherein:
2 the actuator includes first and second stabilizing wires and at least one
3 actuating wire.

1 53. A catheter for capturing an obstruction, comprising:
2 a catheter having a lumen;
3 a capture element positioned in the lumen of the catheter, the capture element
4 being expandable, the capture element having an expandable support structure and a cover
5 attached to the support structure, the cover having a length which is at least three times a
6 diameter of the support structure in the expanded position.

1 54. The catheter of claim 53, wherein:
2 the cover has a length which is at least five times a diameter of the support
3 structure in the expanded position.

1 55. A device for removing an obstruction from a blood vessel, comprising:
2 an expandable loop which is movable from a collapsed position to an
3 expanded position;
4 a cover coupled to the loop, the distal end of the cover being moving from a
5 closed position to an open position when the loop moves from the collapsed to expanded
6 positions; and
7 a tube having an actuator extending therethrough, the actuator being coupled
8 to the loop so that relative movement between the tube and the actuator causes the loop to
9 move between the expanded and collapsed positions.

1 56. The device of claim 55, wherein:
2 the tube is positioned outside the cover.
3

1 57. The device of claim 55, further comprising:
2 a catheter passing through the cover; and
3 an obstruction engaging device passing through the catheter.

1 58. A device for removing an obstruction from a blood vessel, comprising:
2 a tube;
3 a support structure movable between a collapsed position and an expanded
4 position, the support structure extending through the tube and being naturally biased toward
5 the expanded position, wherein the support structure expands when moved out of the distal
6 end of the tube and is in the collapsed position when contained within the tube, the support
7 structure being bowed outward;
8 a cover coupled to the structure, the cover moving from a closed position to an
9 open position when the loop moves from the collapsed position to the expanded position.

1 59. A method of removing an obstruction from a blood vessel, comprising
2 the steps of:
3 providing a obstruction engaging element having a collapsed position and an
4 expanded position, the obstruction engaging element having at least one filament, the
5 filament being in a substantially straight configuration when collapsed;

6 advancing the obstruction engaging element through a patient's vascular
7 system to an obstruction with the obstruction engaging element in the collapsed position; and
8 engaging the obstruction with the obstruction engaging element, the filament
9 engaging the obstruction with a shape which extends from a proximal end toward a distal end,
10 turns back toward the proximal end and again turns back and extends toward the distal end.

1 60. A device for removing an obstruction from a blood vessel, comprising:
2 a delivery element having a lumen; and
3 an obstruction engaging element positioned in the lumen, the obstruction
4 engaging element having a filament which has a collapsed position and an expanded position,
5 the filament being in a substantially straight configuration when collapsed within the lumen
6 of the delivery element, the filament being movable to a shape which extends from a
7 proximal end toward a distal end, turns back toward the proximal end and again turns back
8 and extends toward the distal end.

1 61. The device of claim 60, wherein:
2 the filament is naturally biased into the shape.

1 62. The device of claim 60, wherein:
2 the distal end of the filament is a free end and the obstruction engaging
3 element has only one filament.

1 63. The device of claim 60, wherein:
2 the obstruction engaging element forms the shape by manipulating the
3 obstruction engaging element.

1 64. The device of claim 63, wherein:
2 the obstruction engaging element is rotated to form the shape.

1 65. The device of claim 64, wherein:
2 the obstruction engaging element is rotated so that coils prolapse over other
3 coils.

1 66. A method of removing an obstruction from a blood vessel, comprising
2 the steps of:

3 providing a obstruction engaging element having a collapsed position and an
4 expanded position, the obstruction engaging element having at least one filament which is
5 coated with fibrin;

6 advancing the obstruction engaging element through a patient's vascular
7 system to an obstruction with the obstruction engaging element in the collapsed position;
8 positioning the obstruction engaging element to engage the obstruction; and
9 removing the obstruction with the obstruction engaging element.

1 67. A device for removing an obstruction from a blood vessel, comprising:
2 a delivery element having a lumen; and
3 a obstruction engaging element having a collapsed position and an expanded
4 position, the obstruction engaging element having at least one filament which is coated with
5 fibrin, the obstruction engaging element being contained within the lumen of the delivery
6 element.

1 68. The device of claim 67,
2 the obstruction engaging element is in a substantially straightened
3 configuration when collapsed.

1 69. The device of claim 67, wherein:
2 the obstruction engaging element has a filament.

1 70. The device of claim 67, wherein:
2 the obstruction engaging element has only one filament which extends to a free
3 end.

1 71. A method of removing an obstruction from a blood vessel, comprising
2 the steps of:
3 providing a capture element and an obstruction engaging element;
4 moving the obstruction with the obstruction engaging element into the capture
5 element, wherein the capture element has an inverting portion which inverts when the
6 obstruction is moved into the capture element; and
7 removing the obstruction from the patient.

1 72. A device for removing an obstruction from a blood vessel, comprising:

2 a capture element having an inverting portion which inverts to capture an
3 obstruction, the inverting portion inverting upon application of a compressive force to the
4 inverting portion.

1 73. The device of claim 72, further comprising:
2 an obstruction engaging element extending through the capture element.

1 74. The device of claim 72, wherein:
2 the obstruction engaging element has a filament which is manipulated to
3 ensnare the obstruction.

1 75. The device of claim 72, wherein:
2 the filament extends through the capture element.

1 76. The device of claim 72, wherein:
2 the obstruction engaging element is movable relative to the capture element.

1 77. The device of claim 76, wherein:
2 the obstruction engaging element is movable relative to the capture element to
3 invert the capture element.

1 78. The device of claim 76, wherein:
2 the obstruction engaging element is coupled to the capture element.

1 79. The device of claim 78, wherein:
2 the obstruction engaging element is wound around a central wire with a distal
3 end of the obstruction engaging element attached to the central wire.

1 80. The device of claim 78, wherein:
2 the obstruction engaging element is connected to the capture element.

1 81. The device of claim 78, wherein:
2 the obstruction engaging element contacts the capture element to invert the
3 capture element.

1 82. The device of claim 72, wherein:
2 the inverting portion is a braided structure.

1 83. A medical device, comprising:
2 an outer member;
3 a plurality of fingers extending distally from the outer member, the plurality of
4 fingers forming an end, the end being movable between an open position to a closed position,
5 the plurality of fingers being bent when moving from the open position to the closed
6 position.

1 84. The medical device of claim 83, further comprising:
2 an inner member positioned in the outer member;
3 the plurality of fingers being moved between the open and closed positions by
4 relative movement of the inner and outer members.

1 85. The medical device of claim 83, wherein:
2 each of the plurality of fingers has a flexible actuator attached thereto, wherein
3 the actuator is manipulated to move the fingers between the open and closed positions.

1 86. The medical device of claim 83, further comprising:
2 a sheath positioned to cover at least one of an inner and outer surface of the
3 frame.

1 87. The medical device of claim 83, further comprising:
2 an obstruction engaging element extending through the outer member.

1 88. The medical device of claim 39, wherein:
2 the fingers are independent from one another and extend independently from
3 the outer member

1 89. A medical device, comprising:
2 an outer member;
3 an inner member positioned within the outer member;
4 a frame extending distally from the inner and outer members, the frame having
5 an end which is movable from an open position to a closed position, the frame having a first
6 set of connectors coupled to the outer member and a second set of connectors coupled to the
7 inner member;

8 wherein the inner and outer members are movable relative to one another to
9 move the open end between the open and closed positions.

1 90. The medical device of claim 89, further comprising:
2 a cover positioned to cover at least one of an inner and outer surface of the
3 frame.

1 91. The medical device of claim 89, further comprising:
2 an obstruction engaging element extending through the inner member.

1 92. The medical device of claim 89, wherein:
2 the frame is integrally formed.

1 93. The medical device of claim 89, wherein:
2 the frame has a ring at the distal end.

1 94. The medical device of claim 89, wherein:
2 the ring is formed by v-shaped elements.

1 95. The medical device of claim 89, wherein:
2 the first set of connectors and second set of connectors are connected to the
3 ring at space-apart locations one after the other.

1 96. A medical device, comprising:
2 an outer member;
3 a frame extending distally from the outer member, the frame having an end
4 which is movable from an open position to a closed position;
5 wherein the frame moves between the open and closed positions by applying
6 electrical energy to the frame.

1 97. The medical device of claim 94, further comprising:
2 a cover positioned to cover at least one of an inner and outer surface of the
3 frame.

1 98. The medical device of claim 94, further comprising:
2 an obstruction engaging element extending through the inner member.

1 99. The medical device of claim 94, wherein:
2 the frame is integrally formed.

1 100. The medical device of claim 94, wherein:
2 the frame comprises a shape-memory material, wherein application of the
3 electrical energy causes the shape-memory material to change shape

1 101. The medical device of claim 98, wherein:
2 the frame moves to the closed position upon application of the electrical
3 energy.

1 102. A method for removing an obstruction from a blood vessel using the
2 devices of claims 83-98.

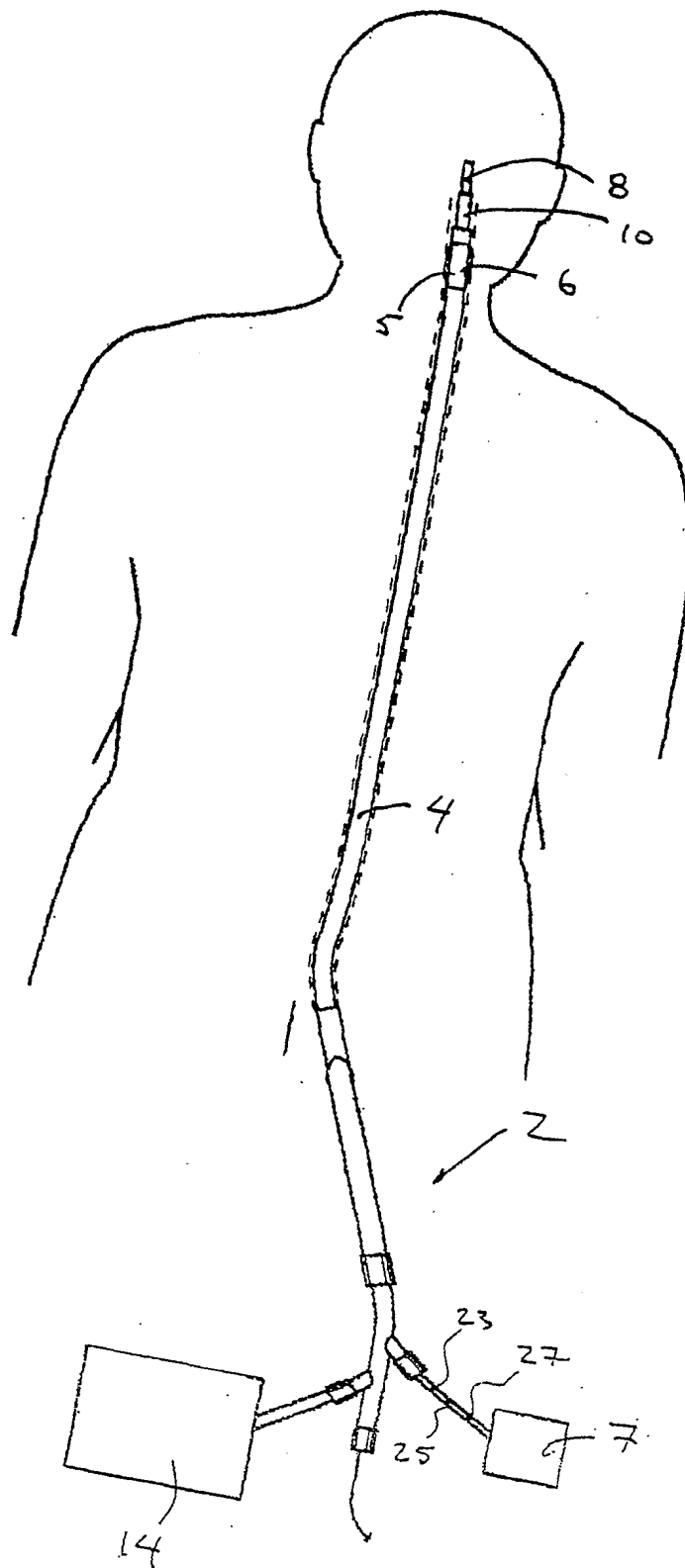


FIG. 1

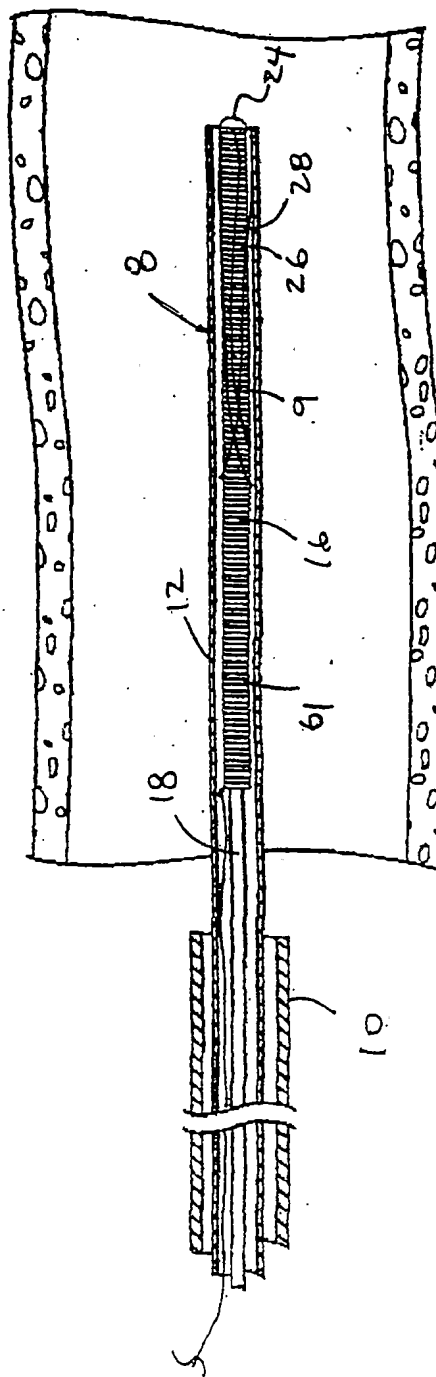


FIG. 2

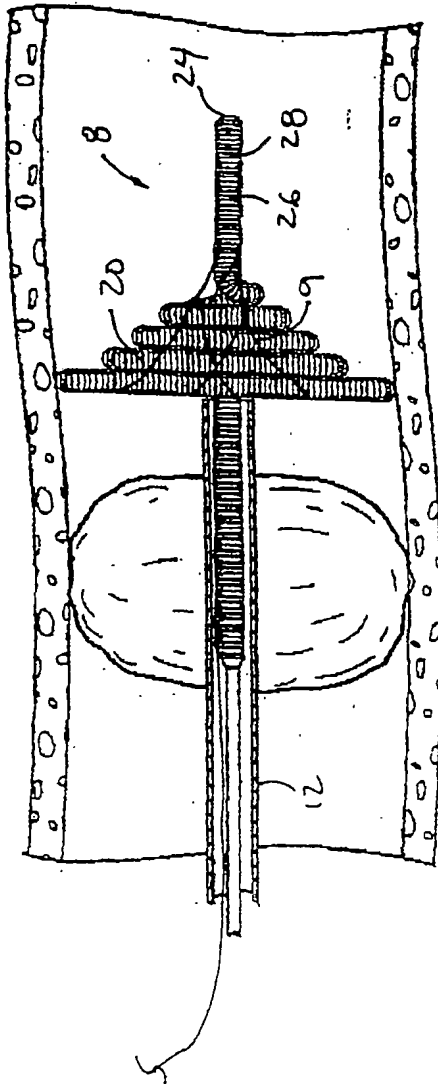


FIG. 3

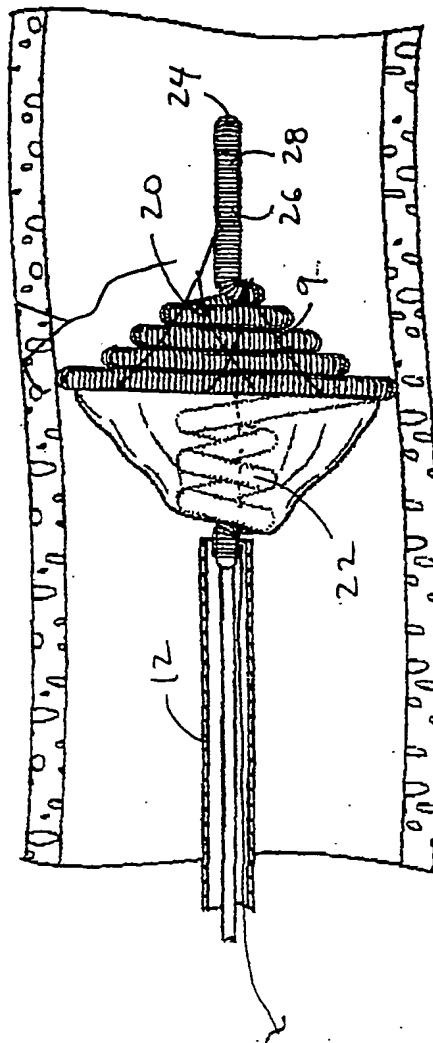
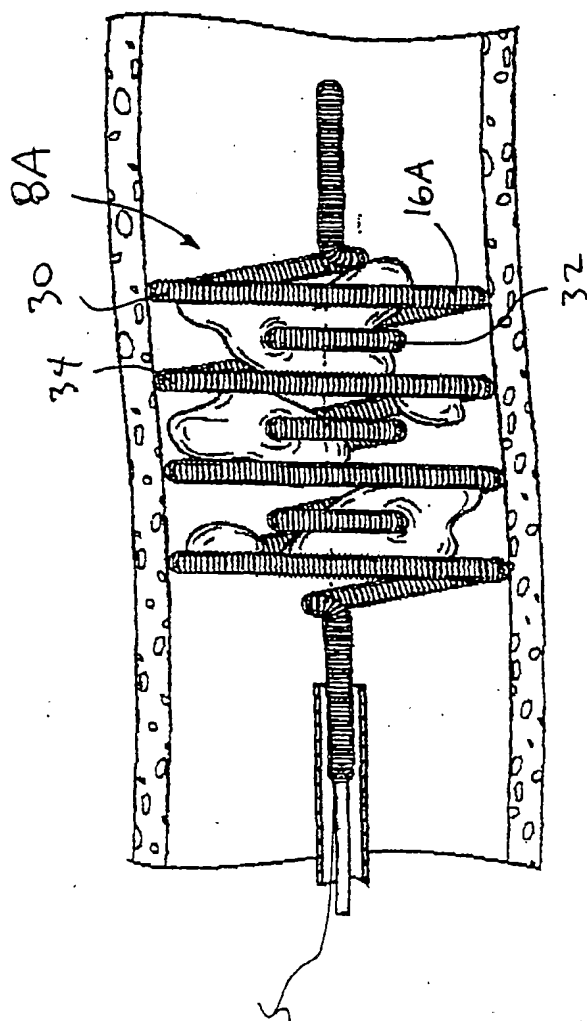


FIG. 4



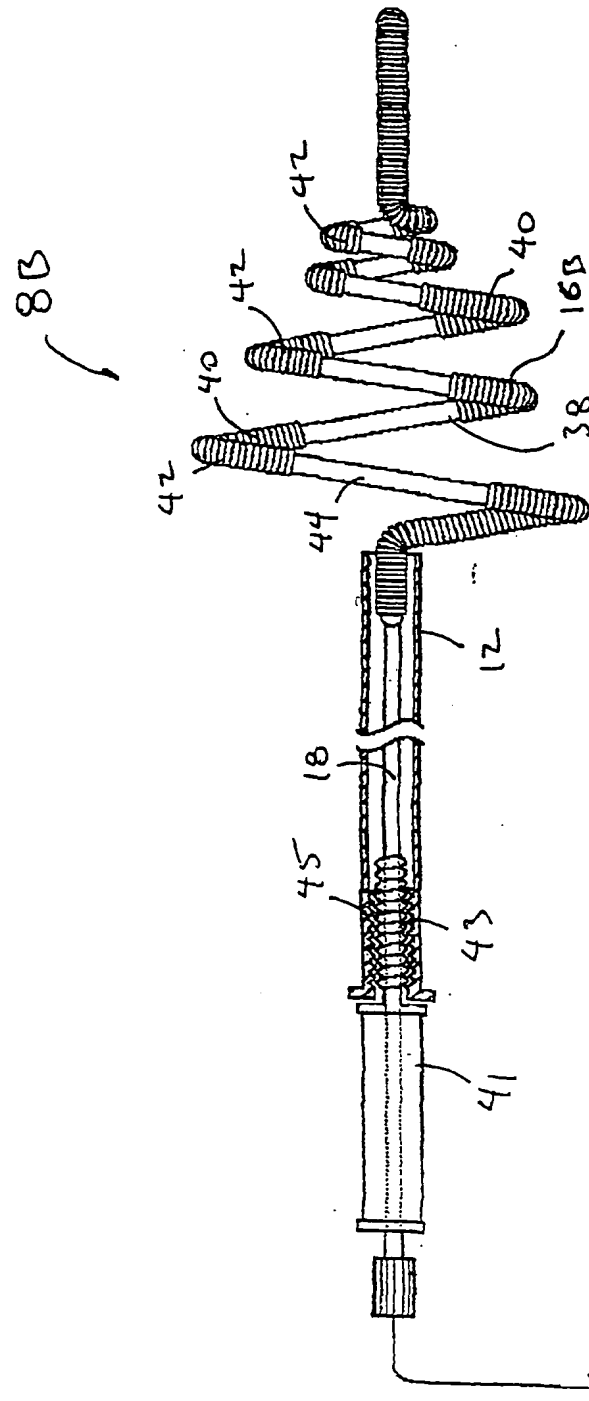


FIG. 6

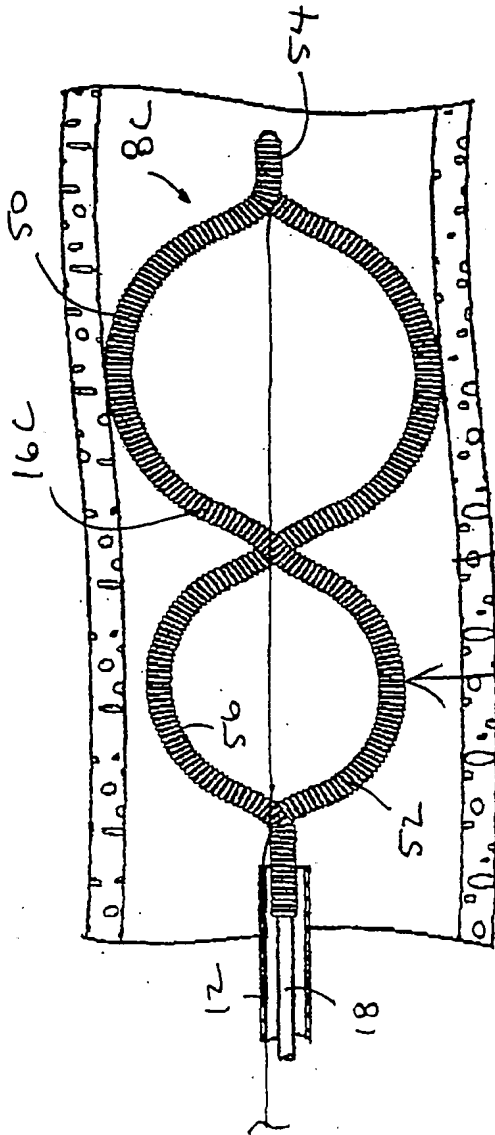
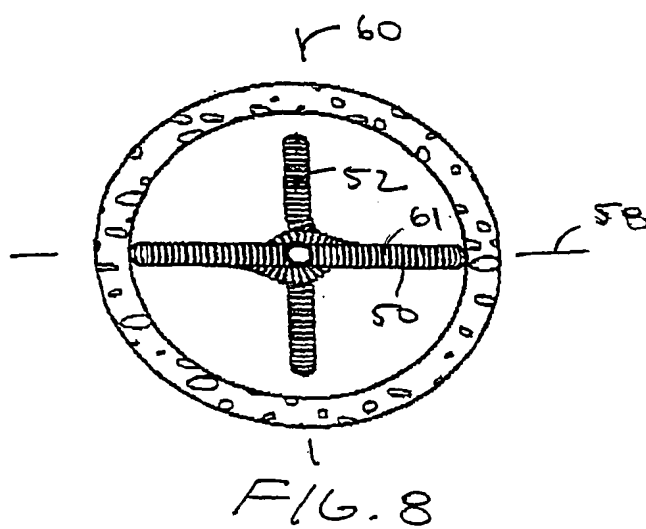


FIG. 7



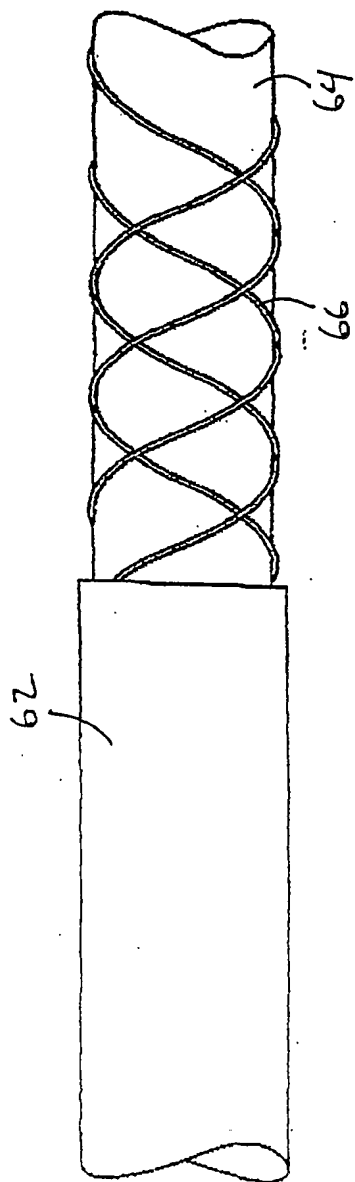
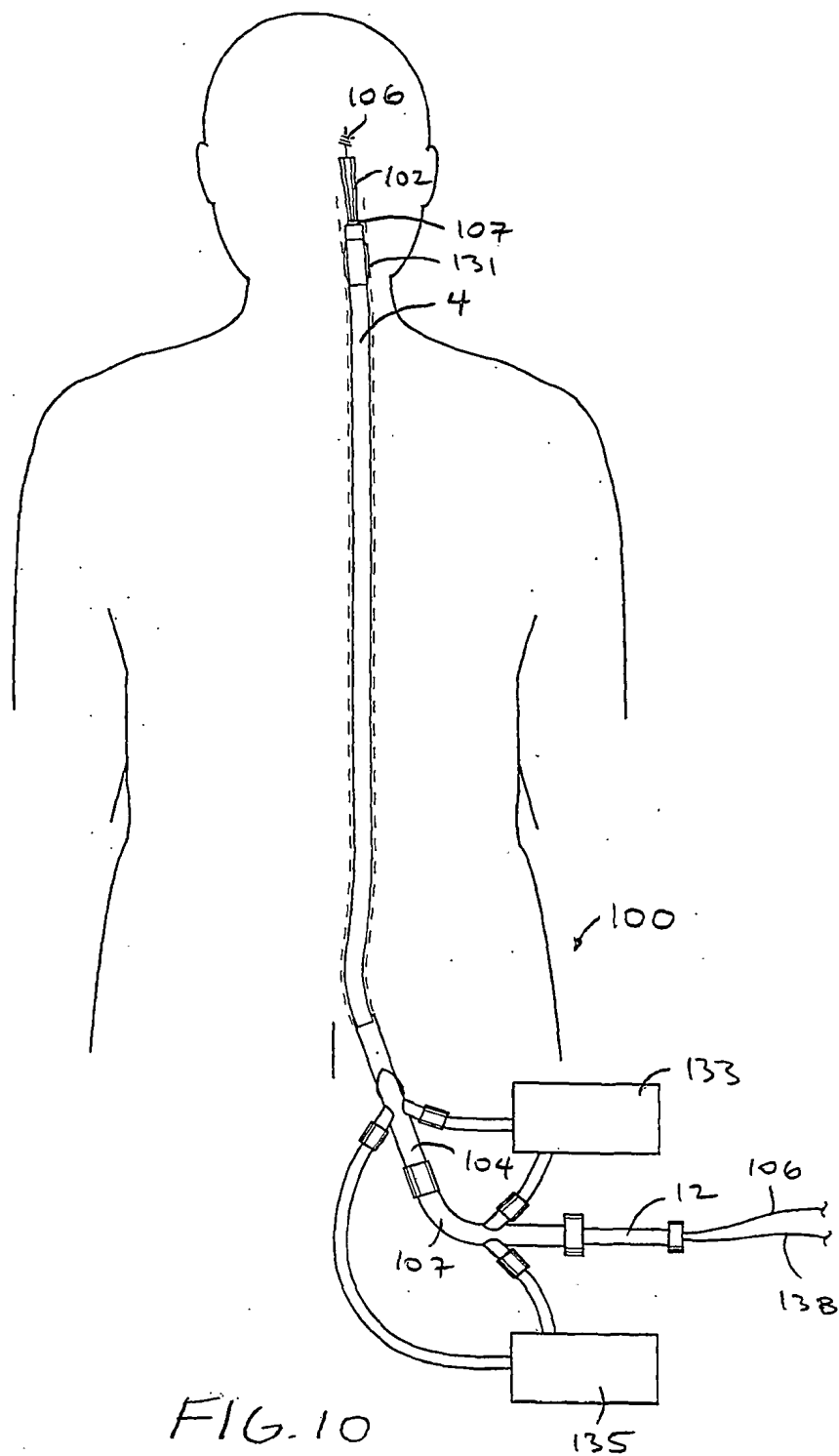
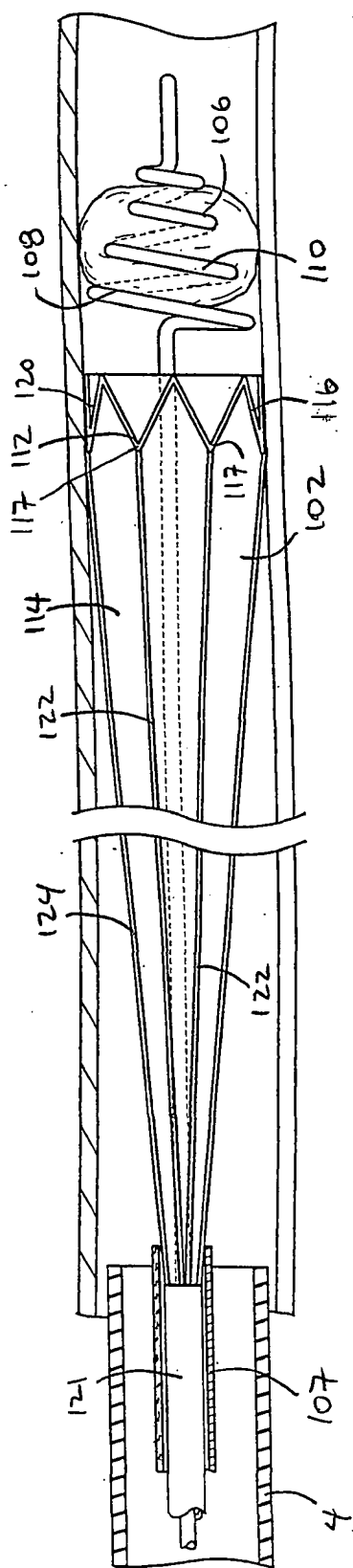


FIG. 9





F/G. 11

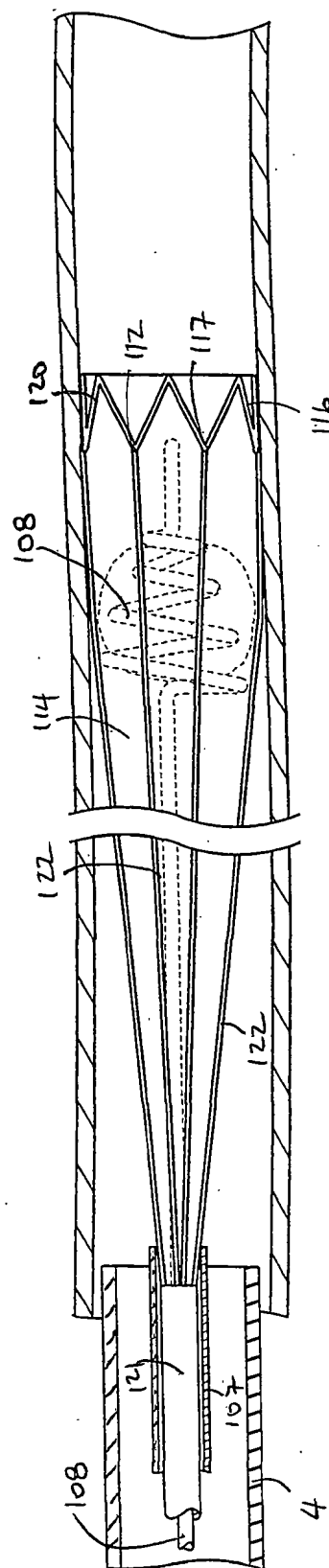


Fig. 12

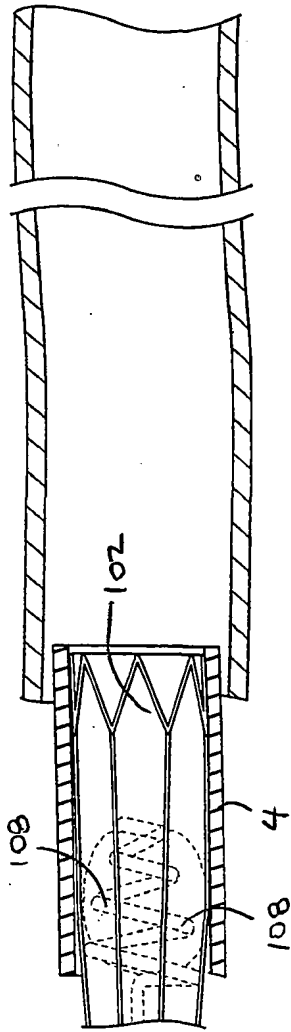


FIG. 13

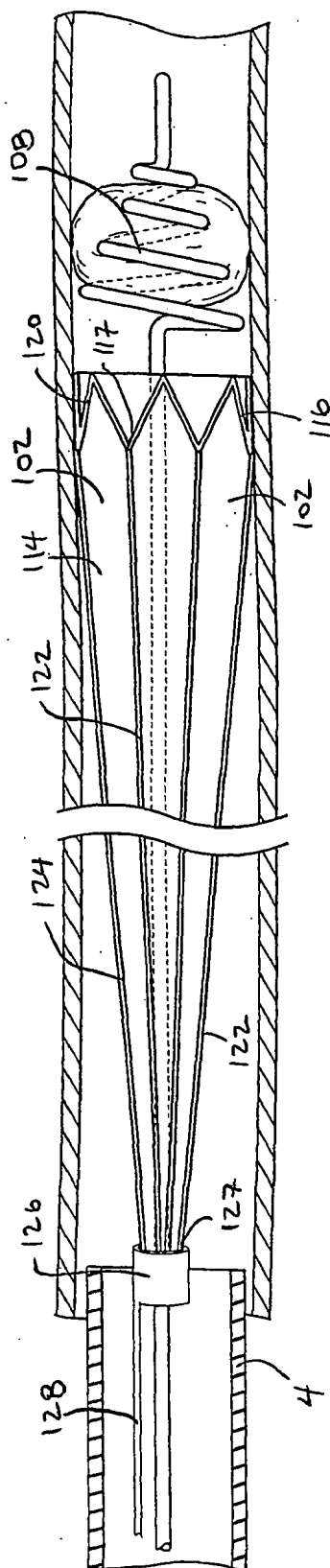
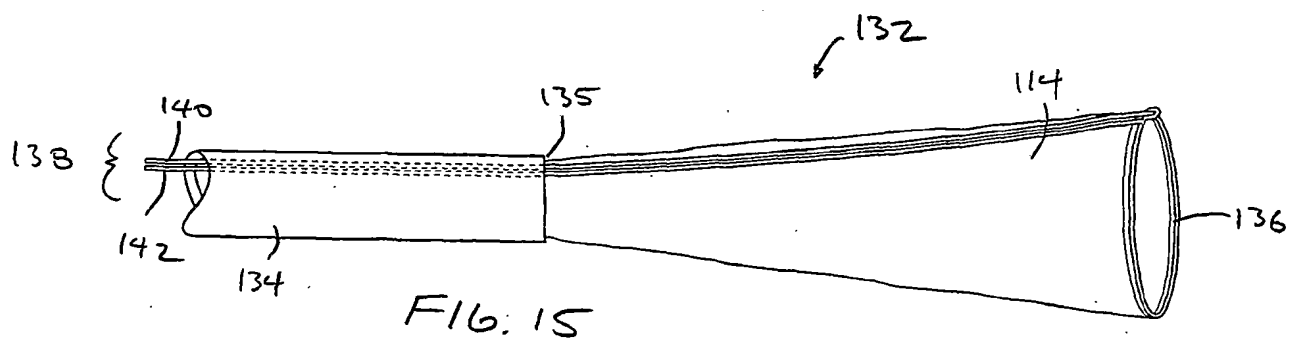
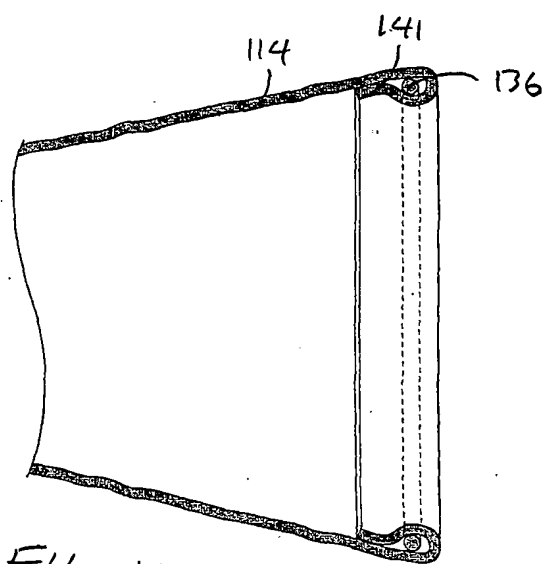
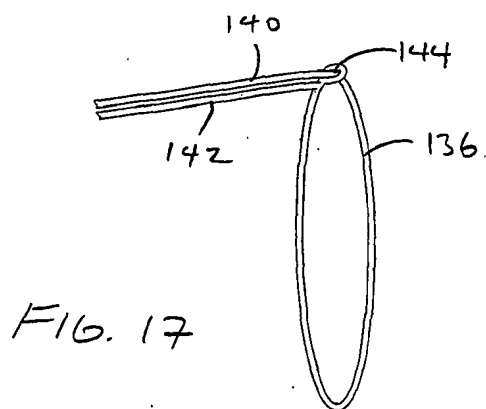
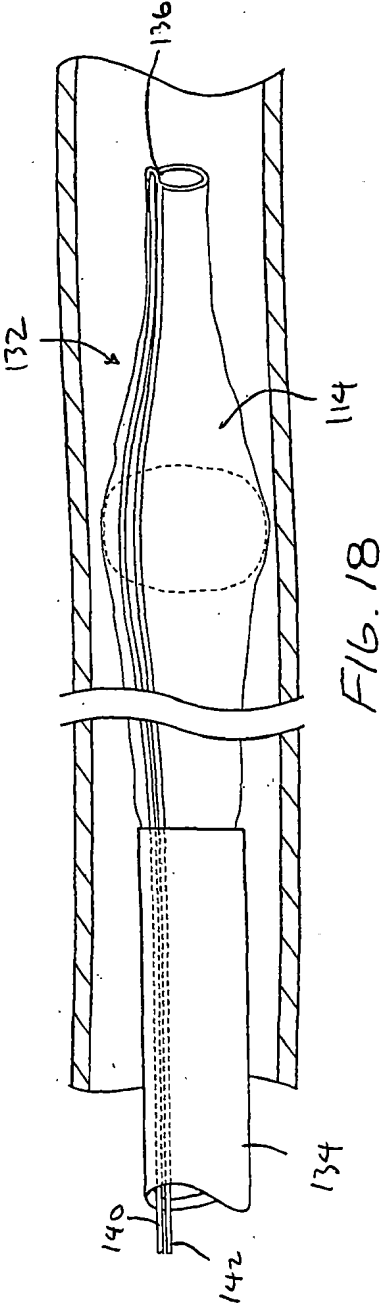
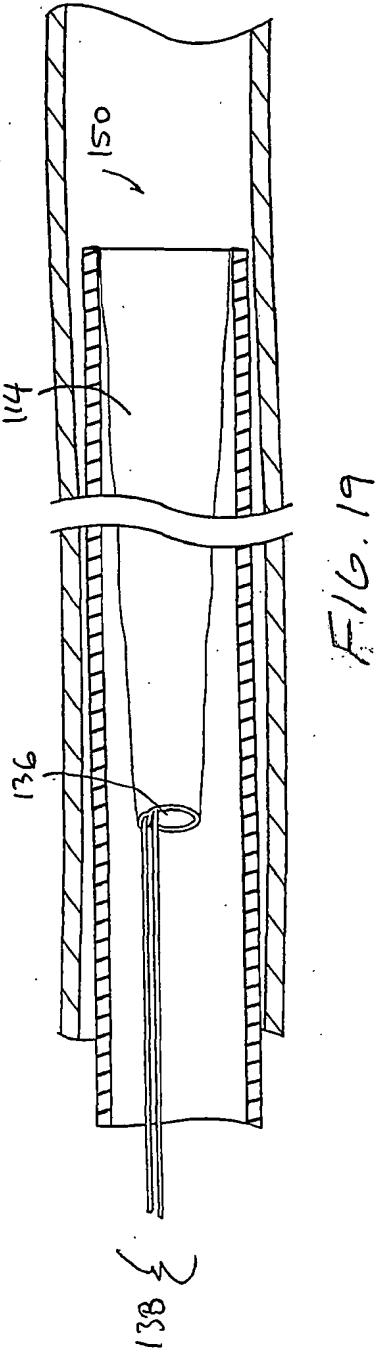
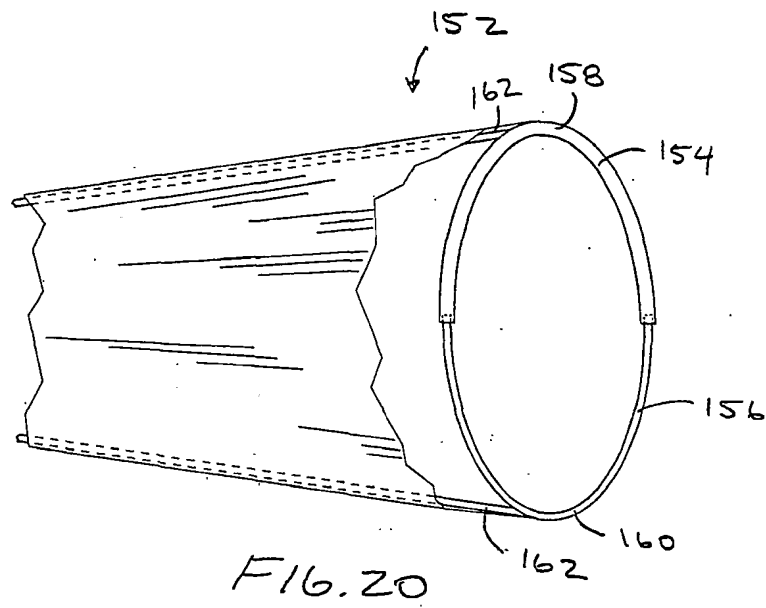
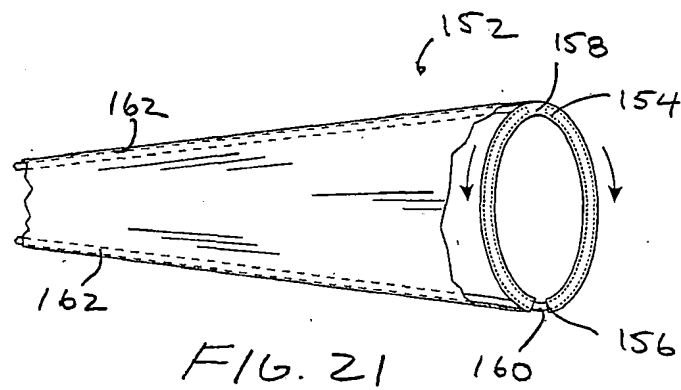


FIG. 14







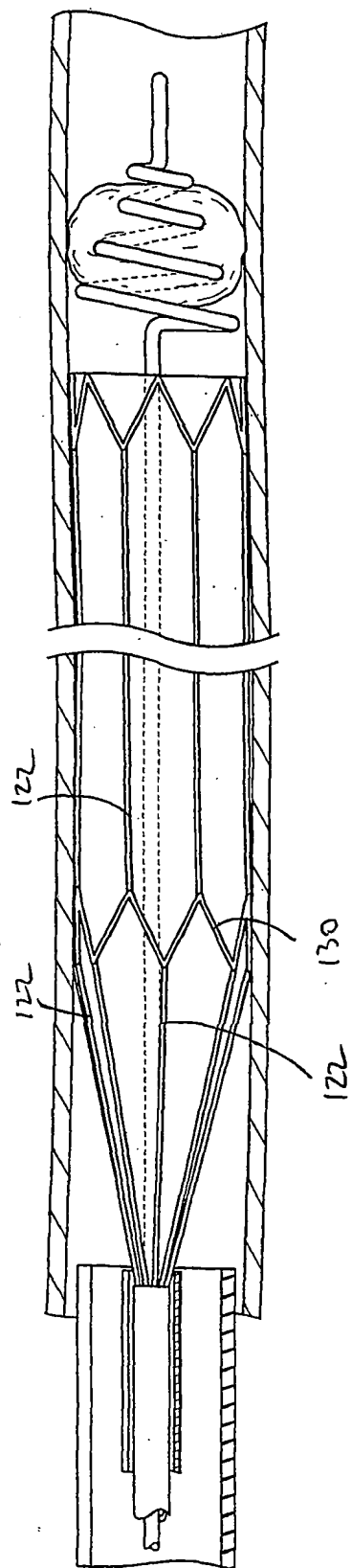
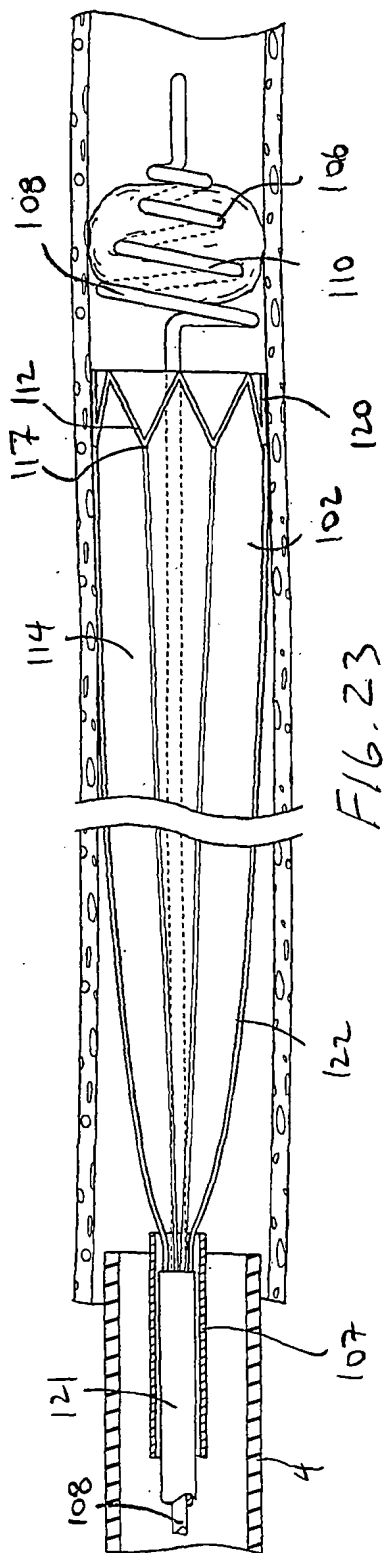
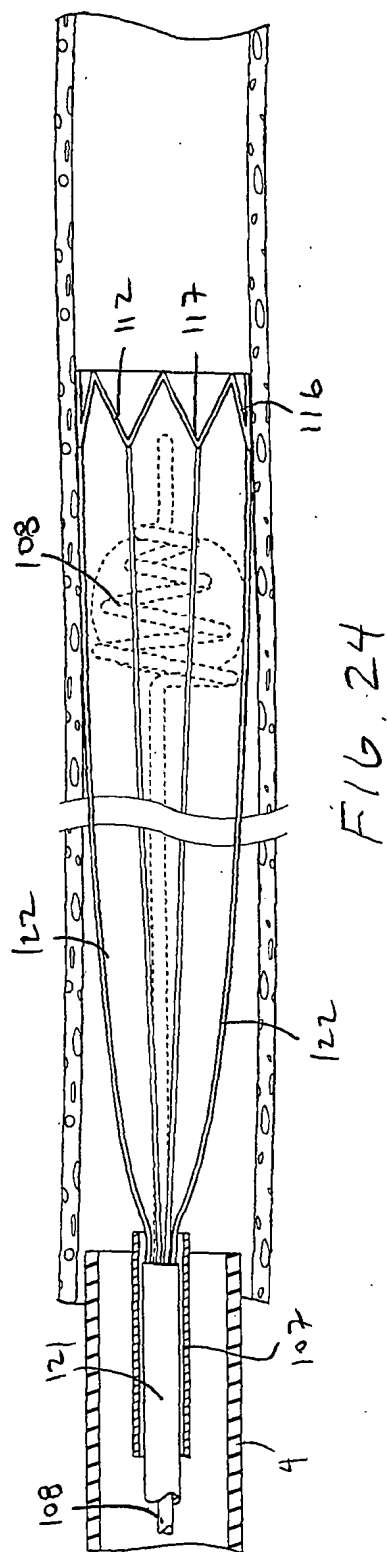
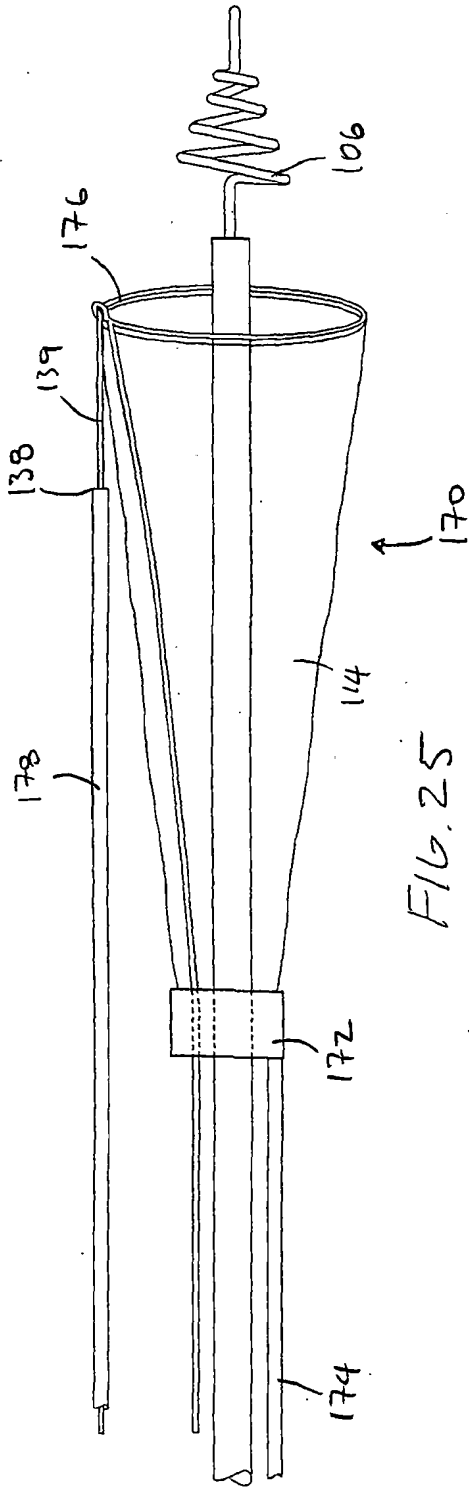


Fig. 22





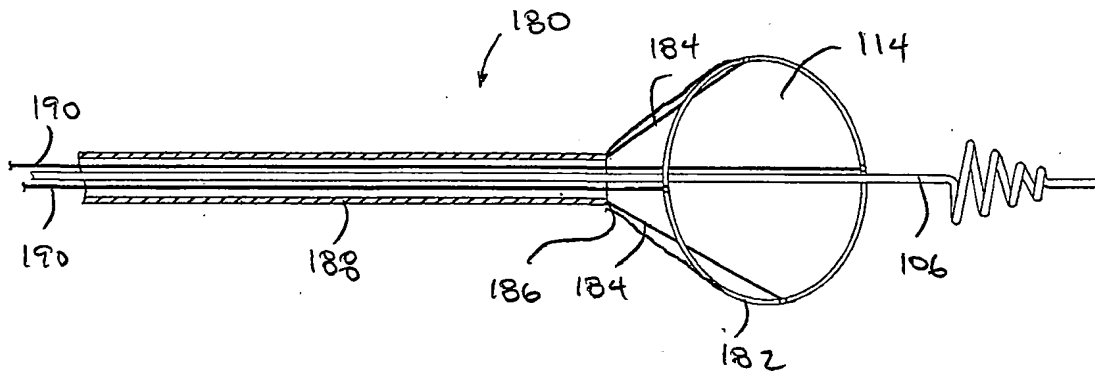


FIG. 26

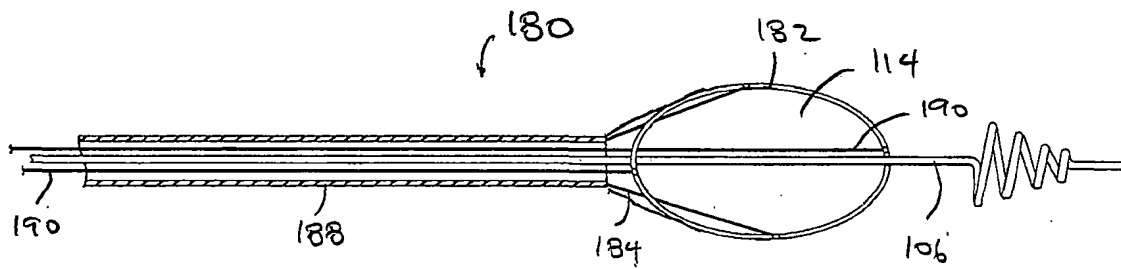


FIG. 27

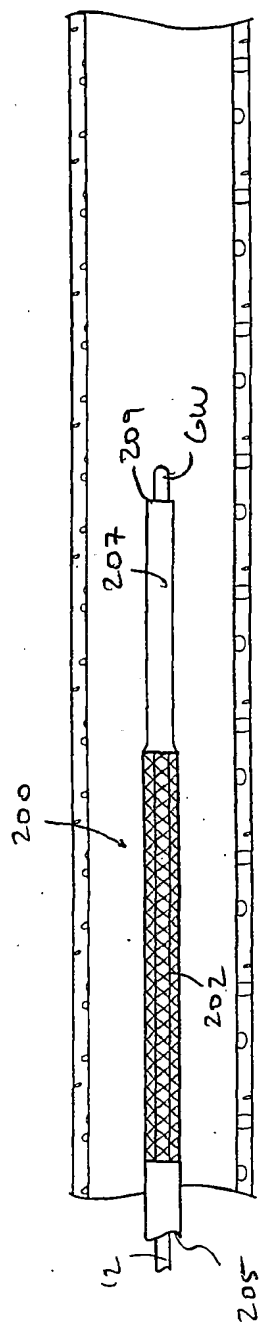


FIG 28

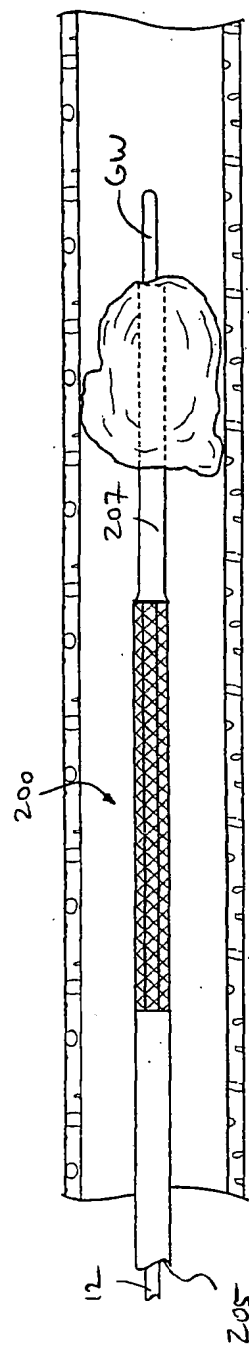


FIG 29

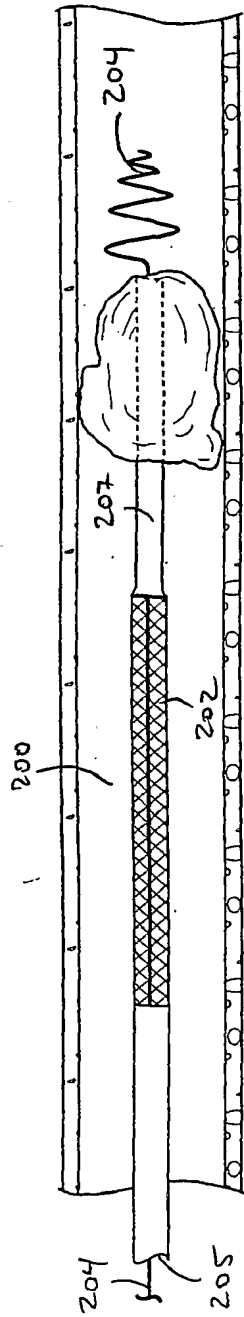


FIG 30

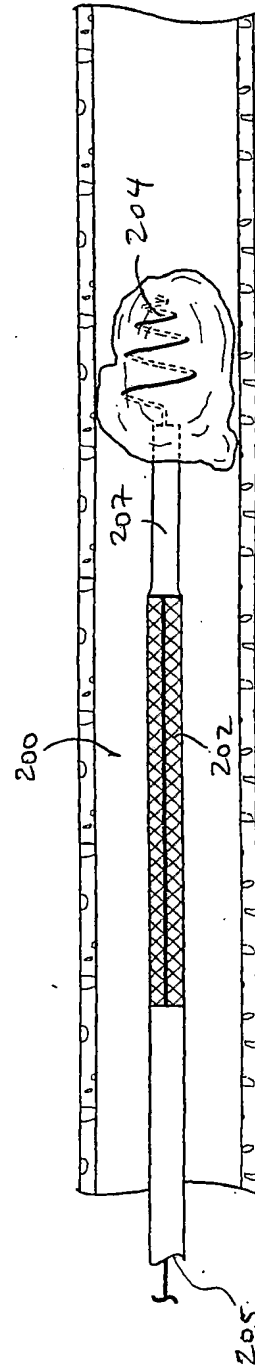


FIG 31

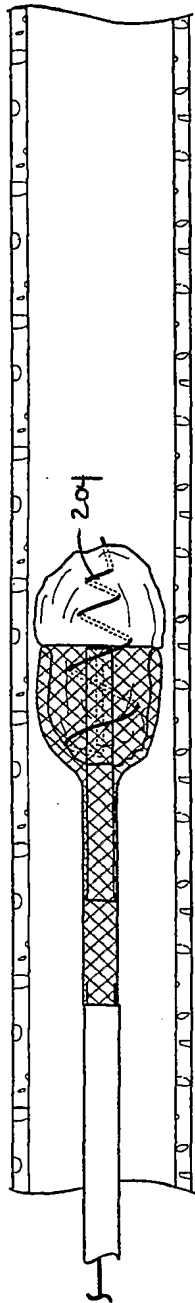


FIG. 32

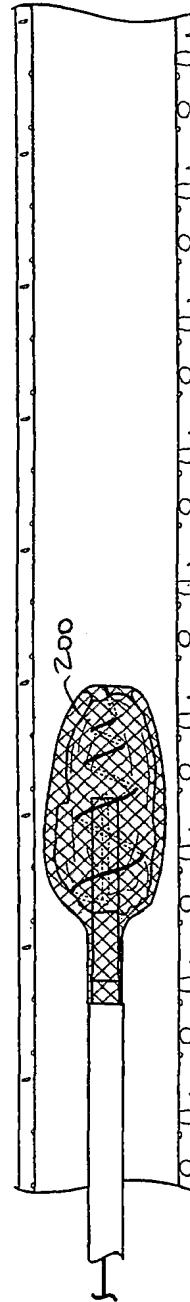
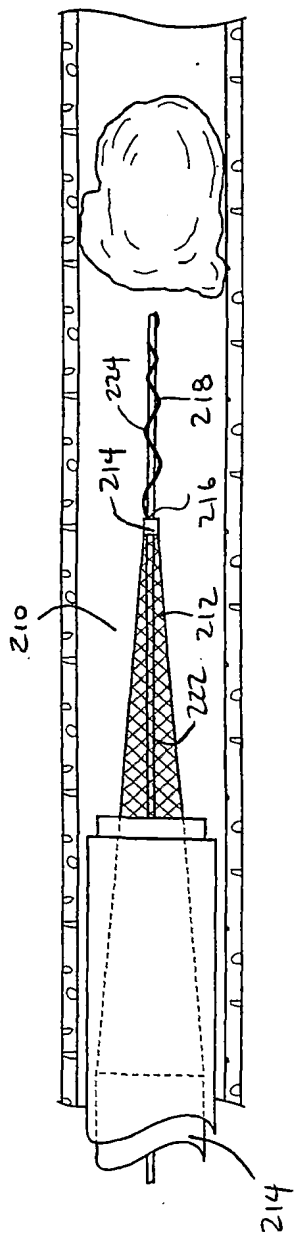
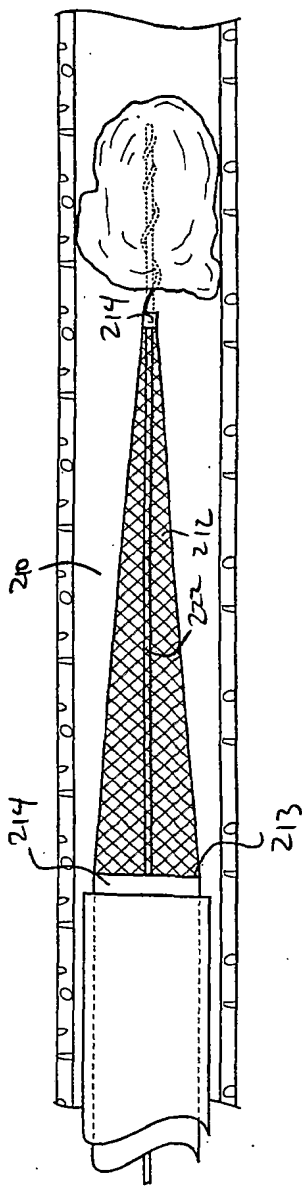
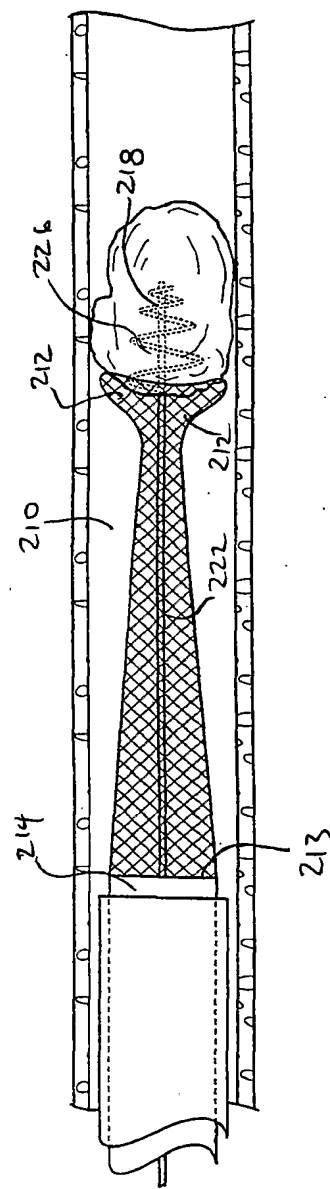
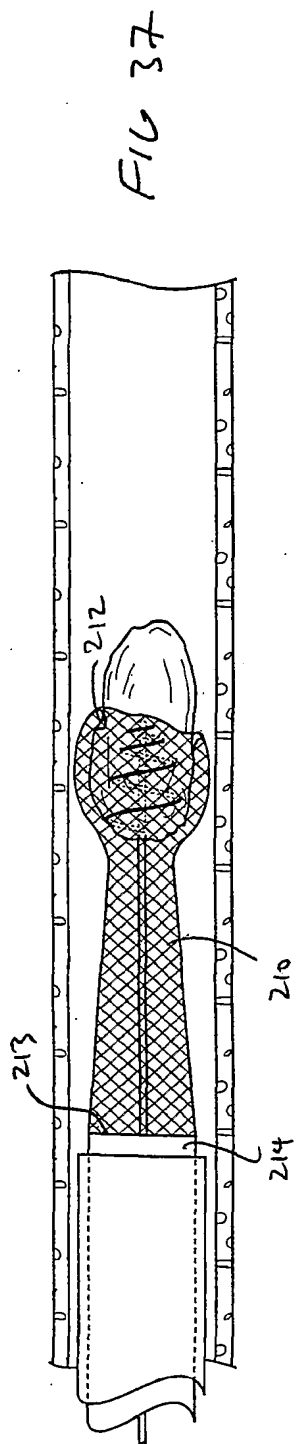
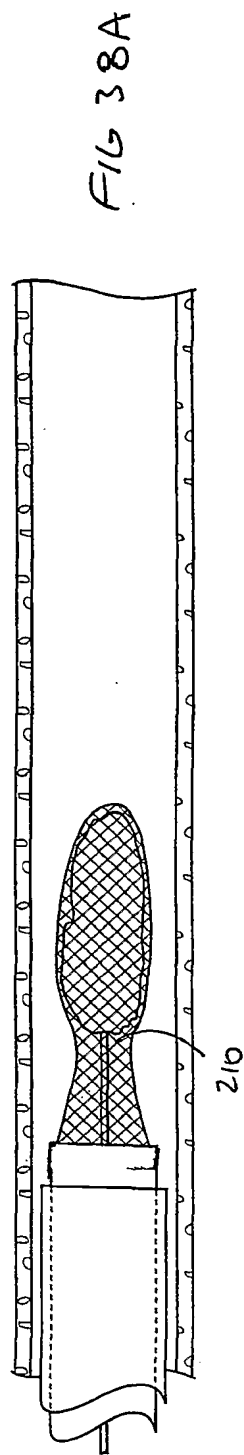
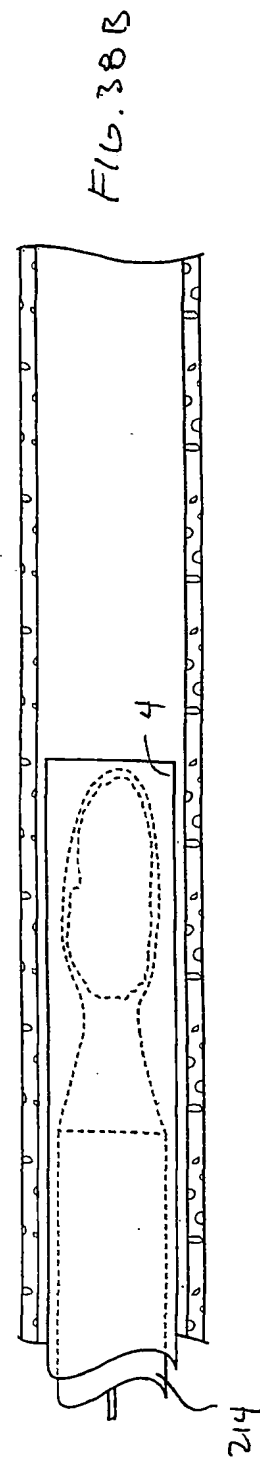
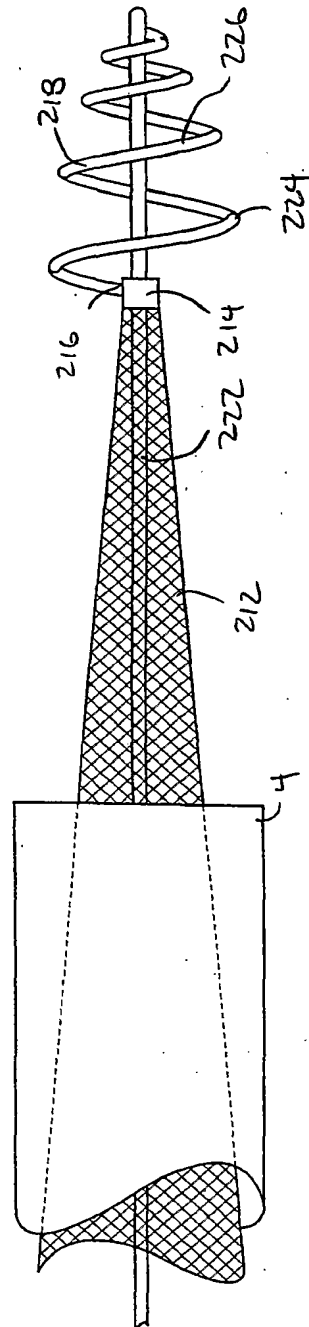
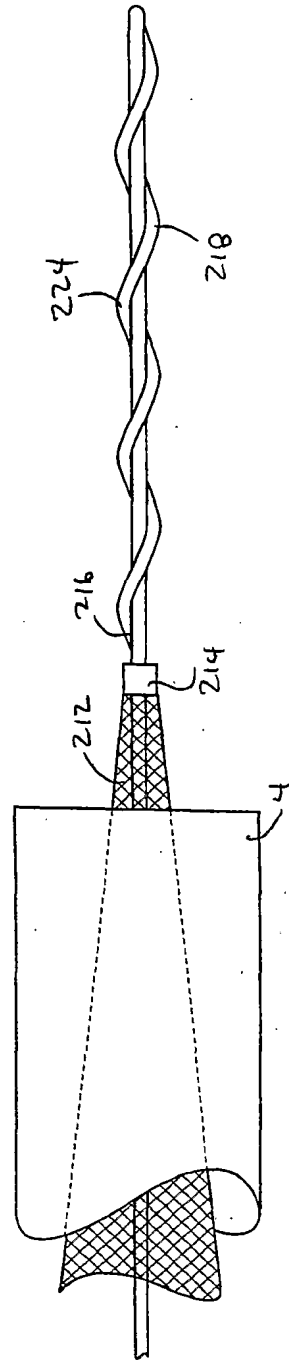


FIG. 33







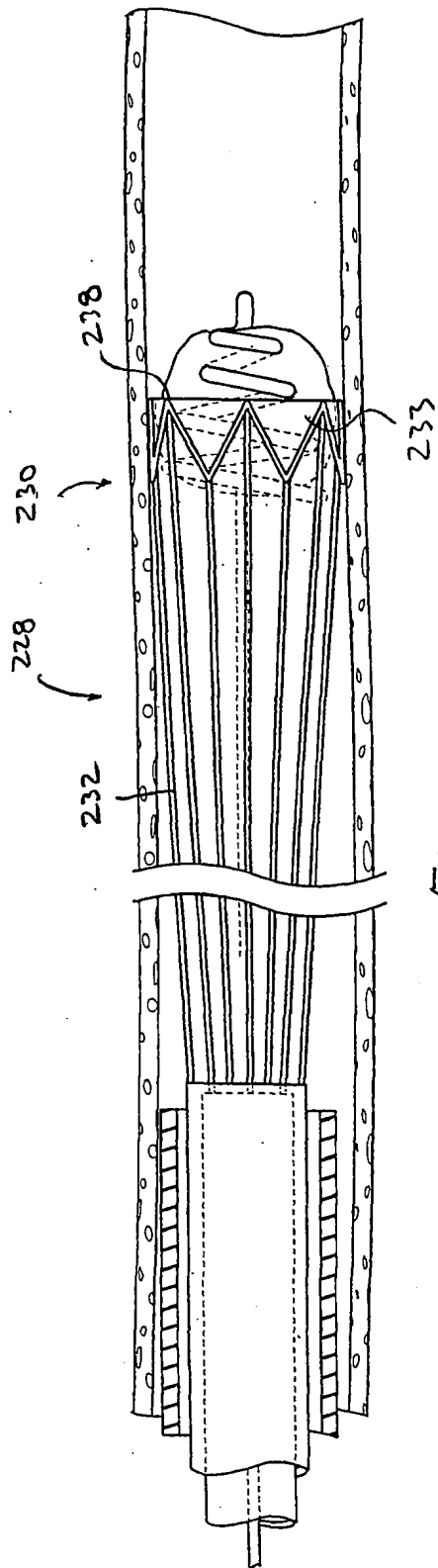


FIG. 41A

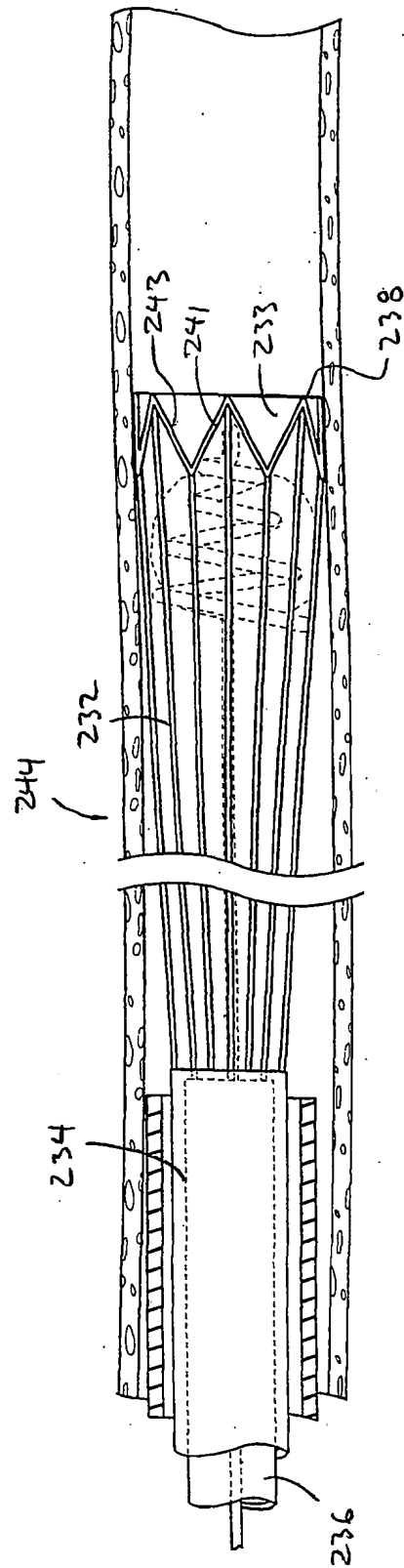


FIG. 41B

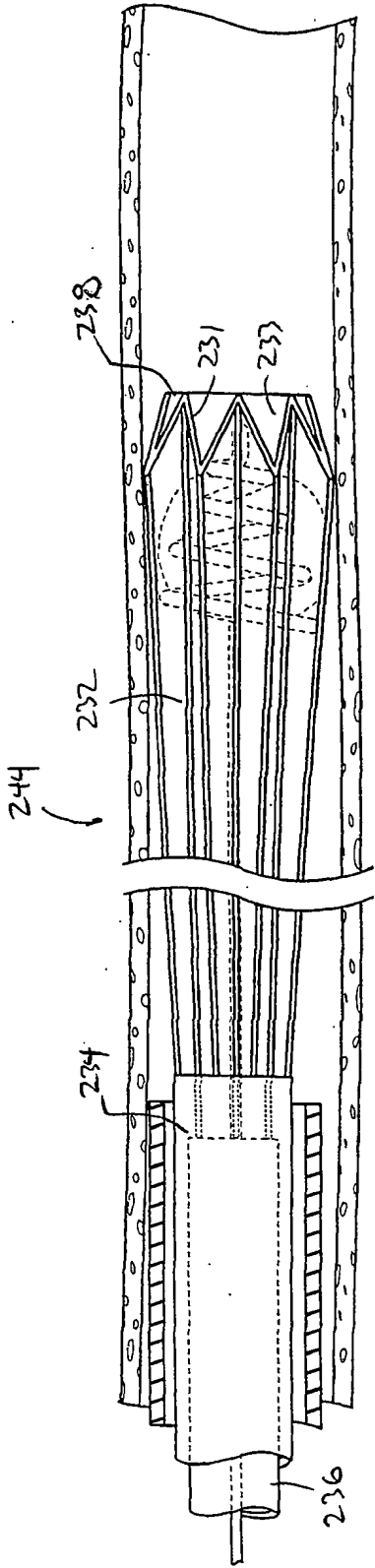


FIG 42A

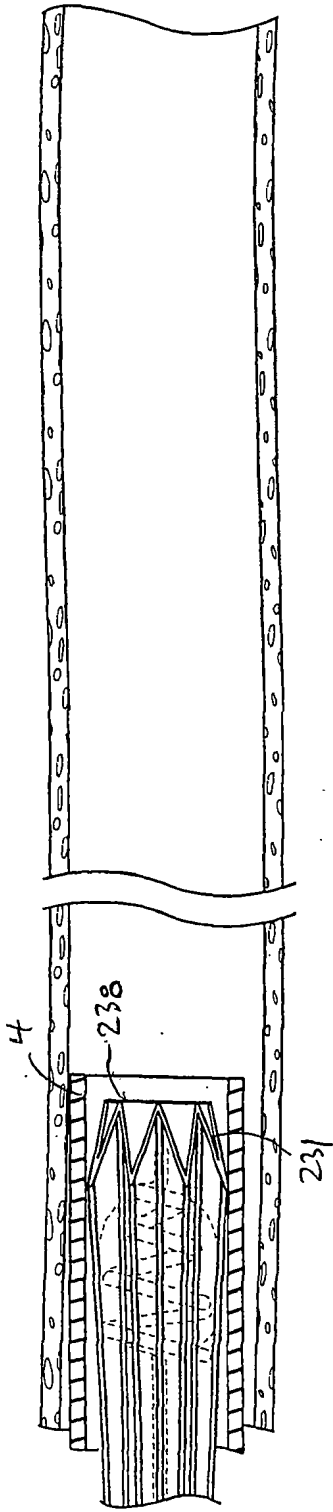
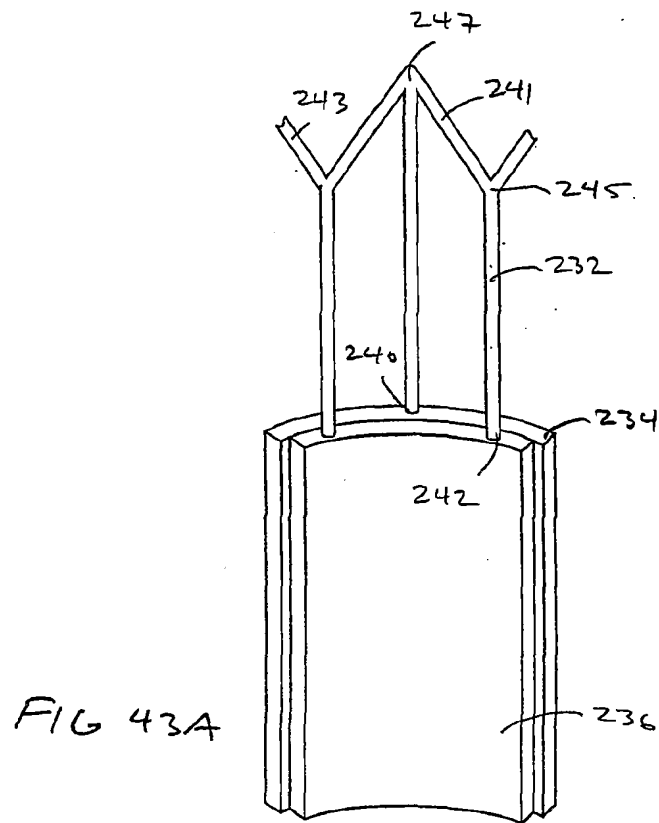
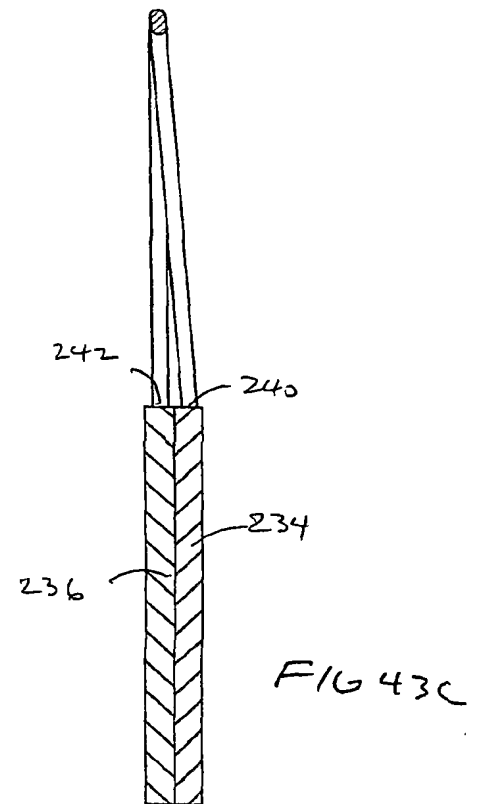
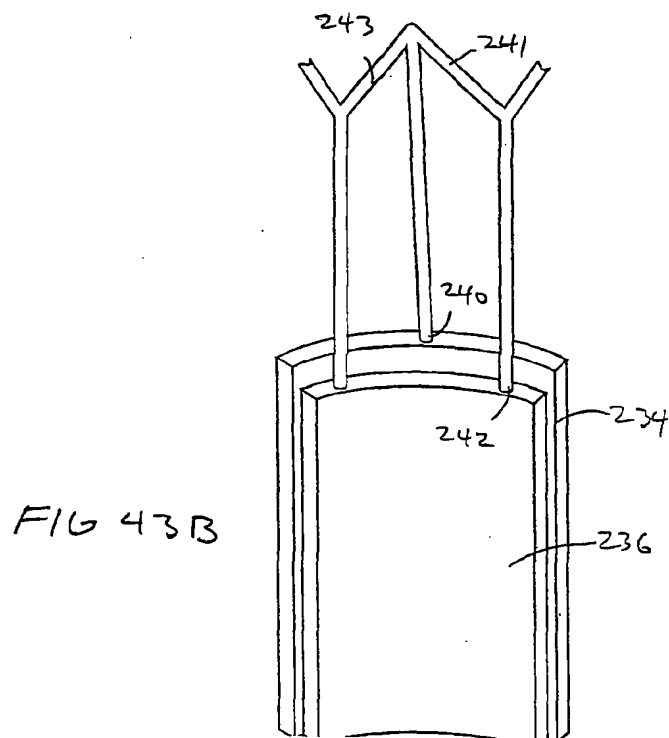
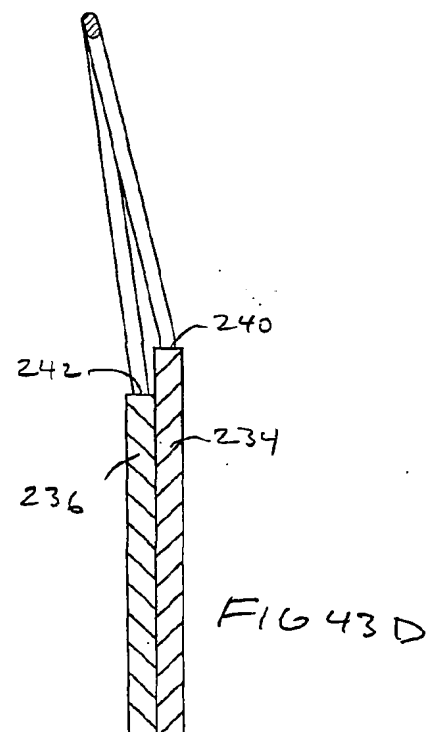
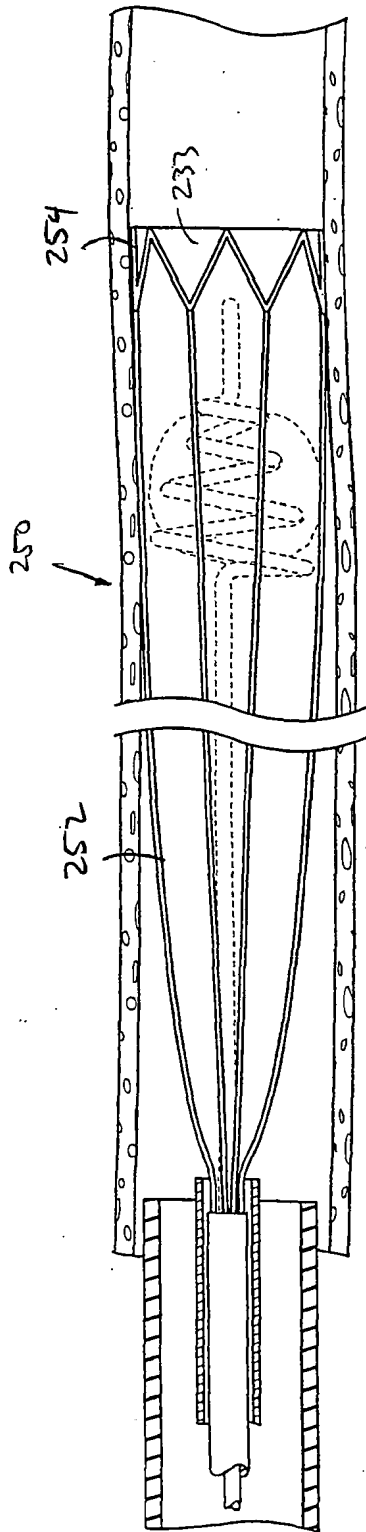
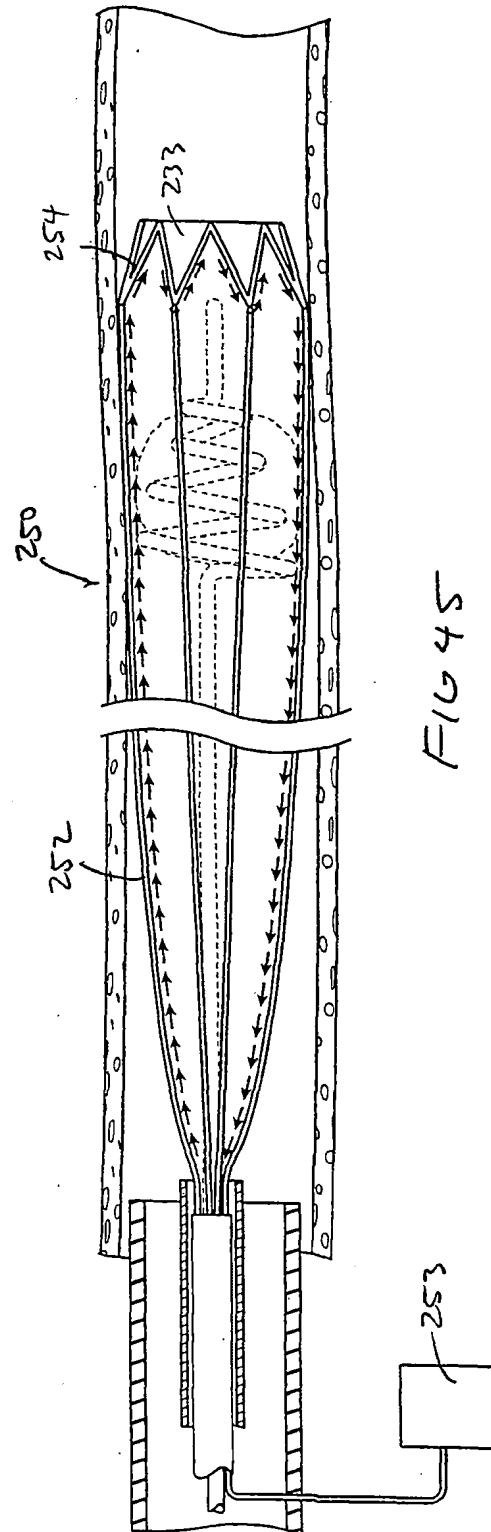
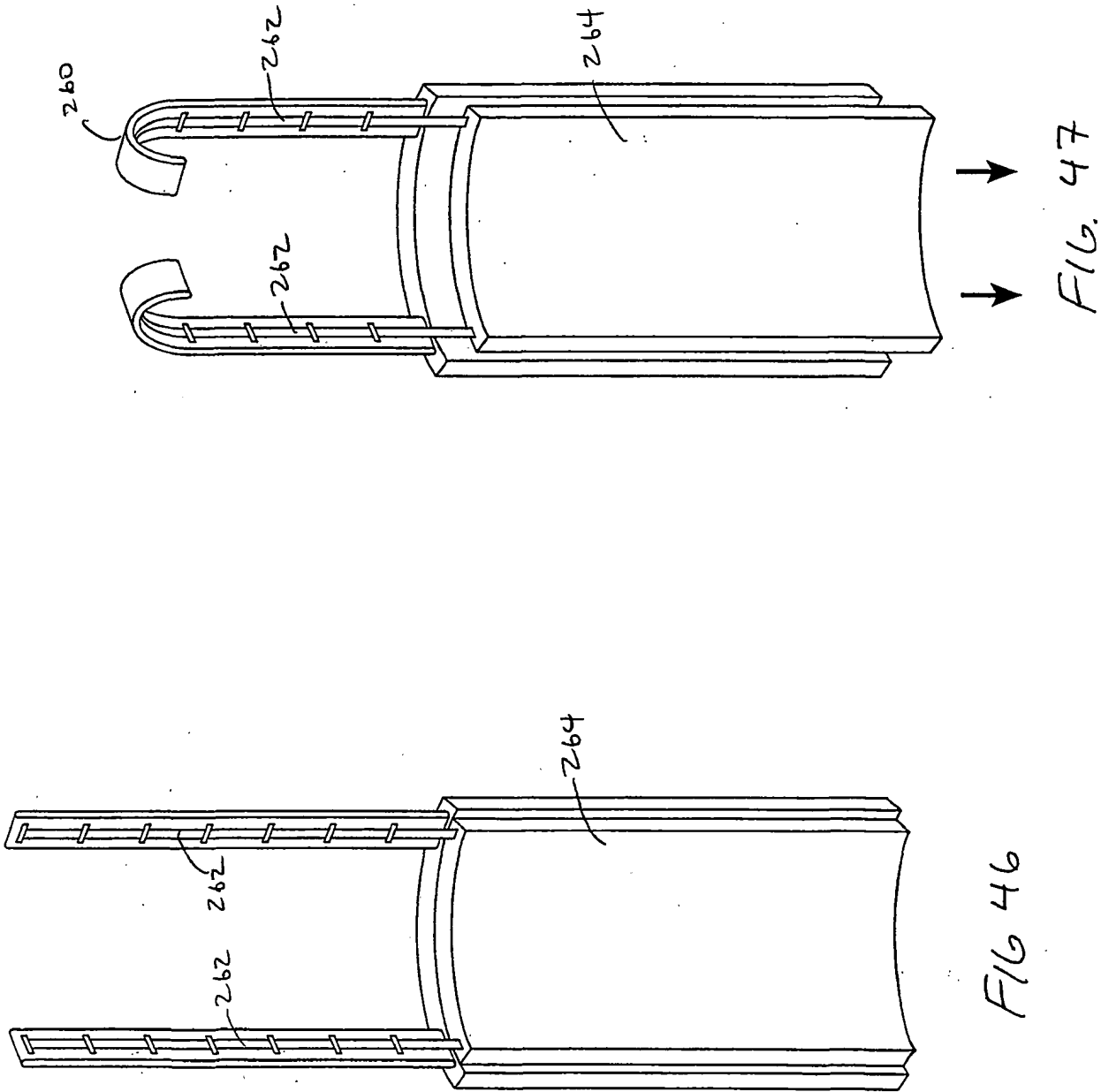
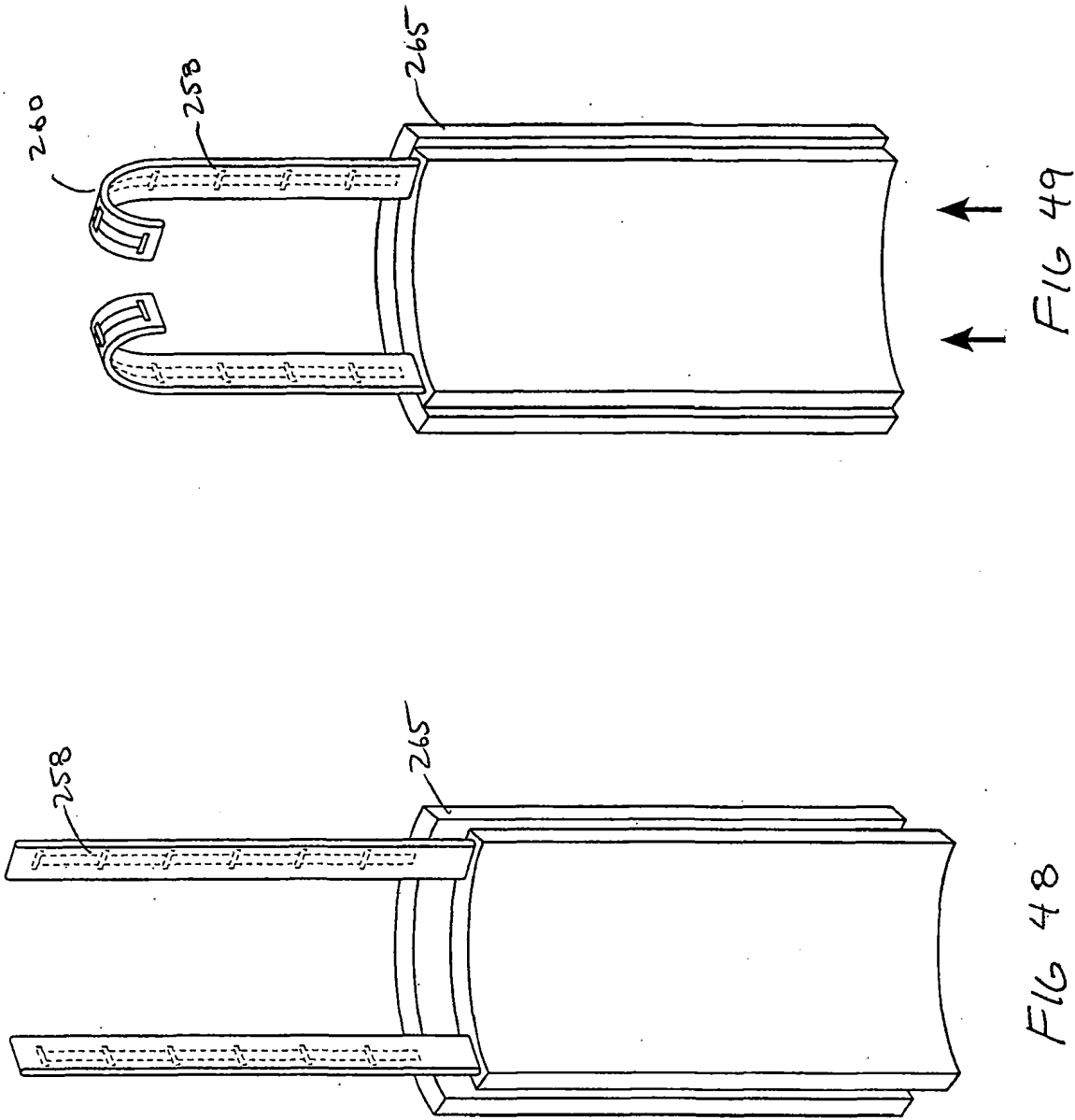


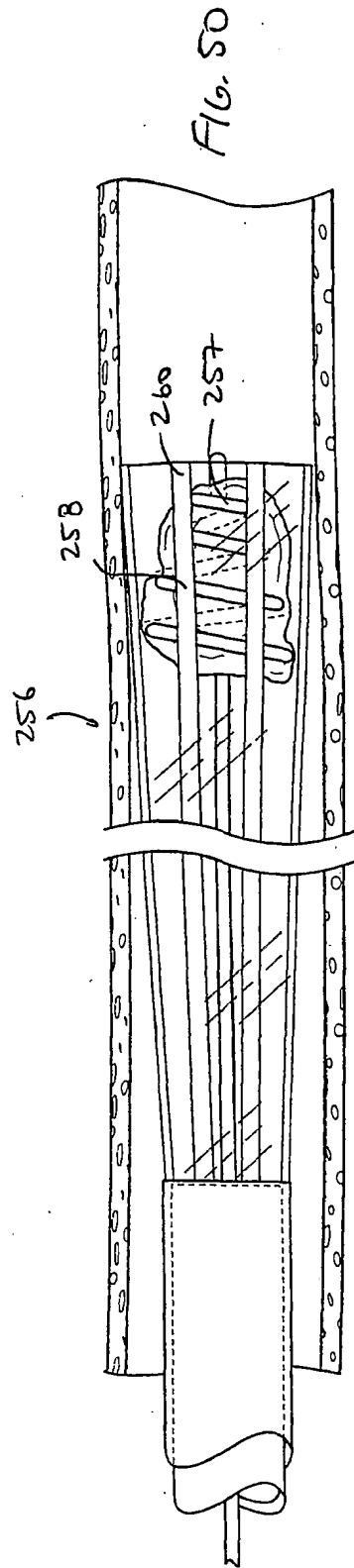
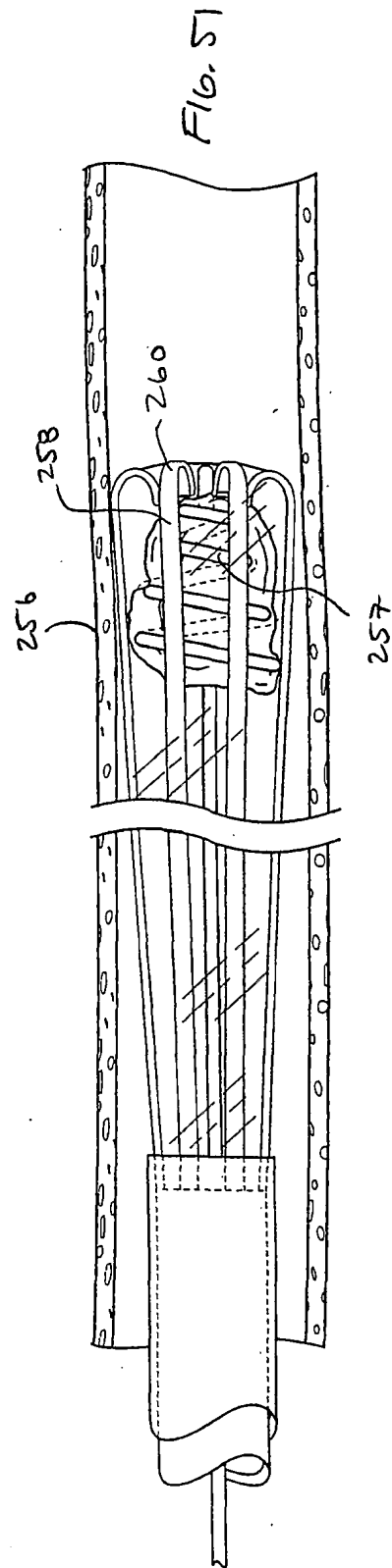
FIG 42B

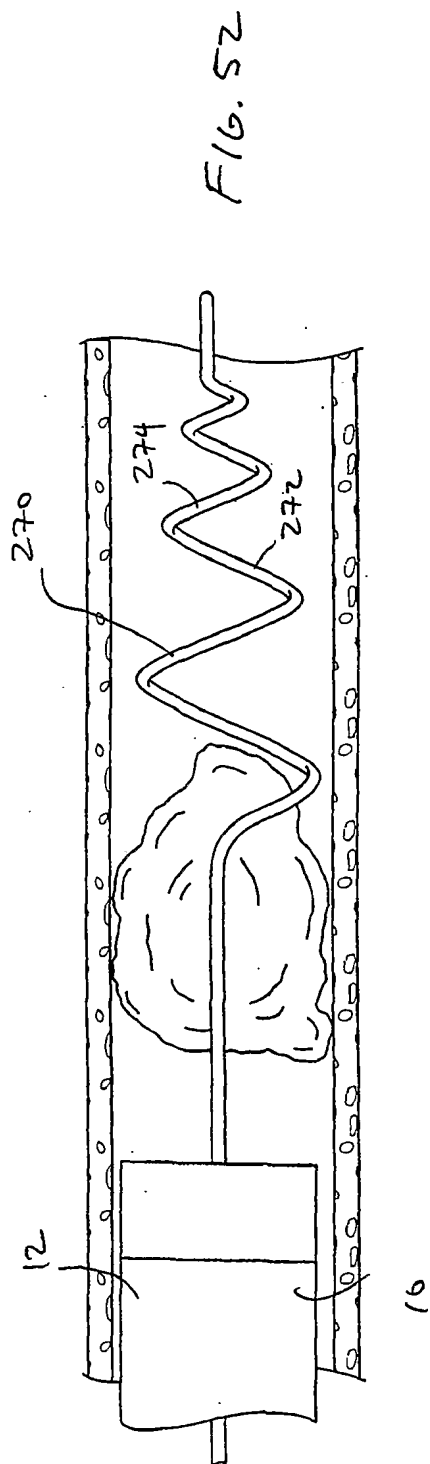
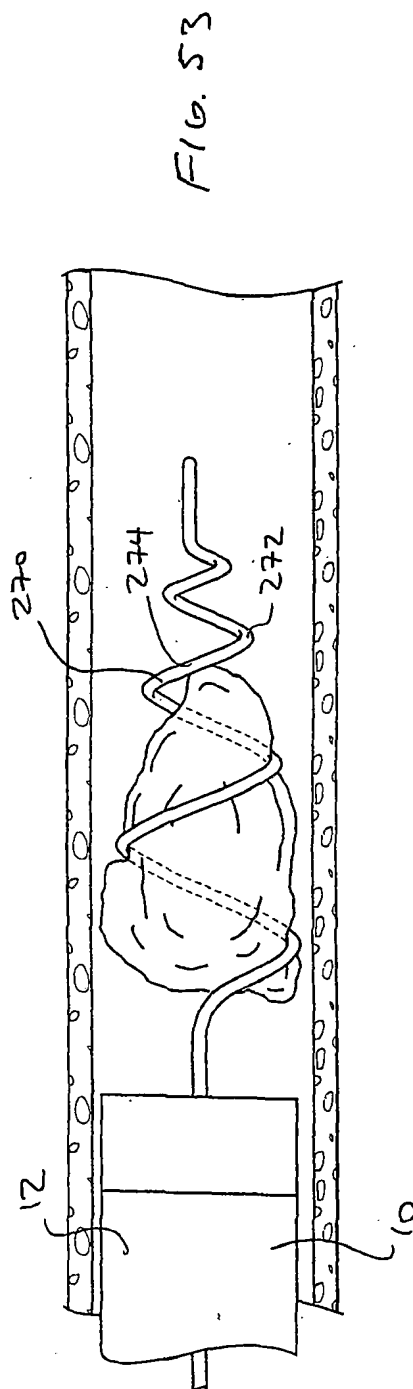


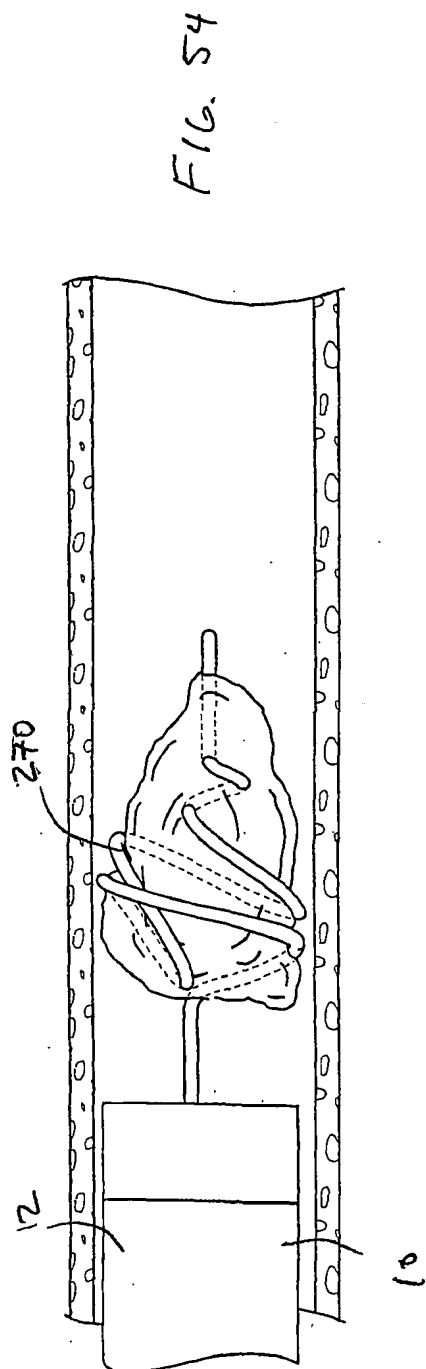
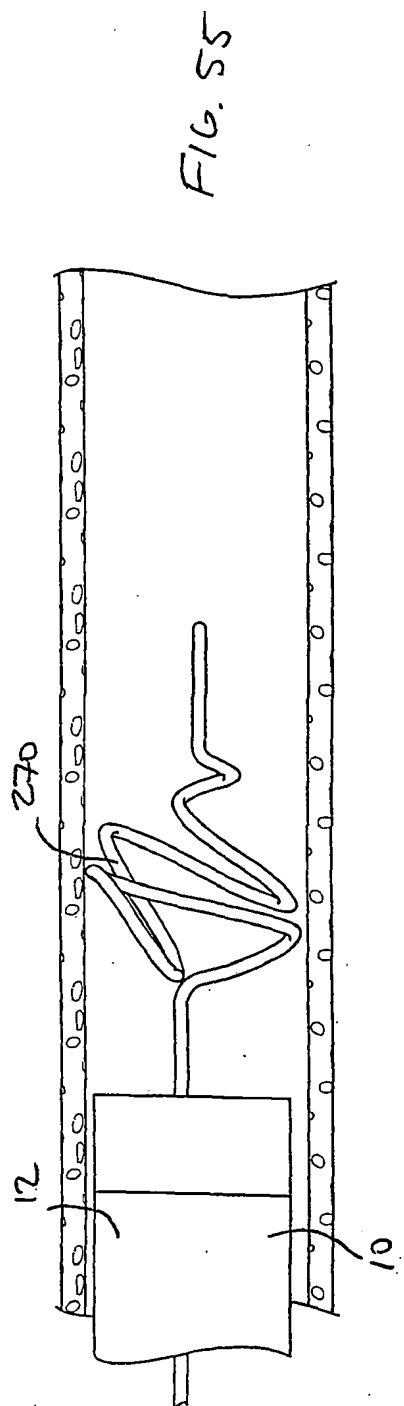














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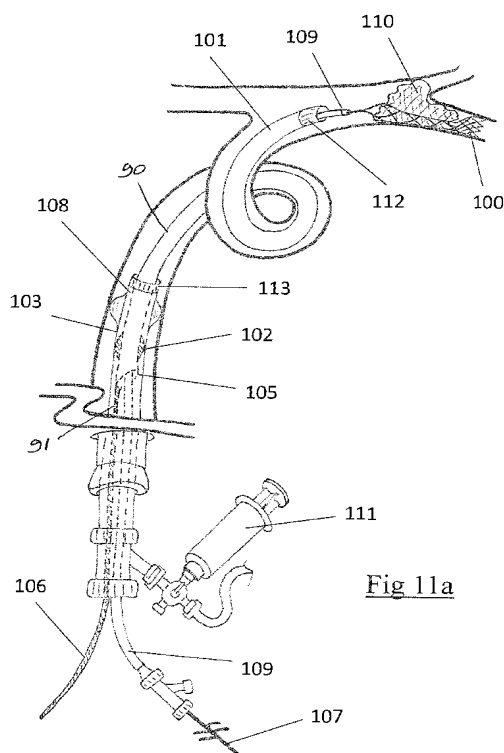
(54) **Title:** DEVICES FOR REMOVAL OF ACUTE BLOCKAGES FROM BLOOD VESSELS

Fig 11a

(57) **Abstract:** A catheter 101 provides a proximal seal 102 against a guide catheter inner lumen 103 so that aspiration may be applied through a guide catheter 108 and thus take advantage of the large proximal lumen. The catheter 101 is a rapid exchange (RX) catheter with an exit port 105 that defines a transfer port for aspiration and provides a deliverability advantage of minimal frictional engagement with the guide catheter 108 proximal of the exit port 105. Aspiration can be applied to the lumen of the guide catheter 108 and is directed to and effective at the tip of the Rx aspiration catheter 101 due to the presence of flow a restrictor or seal 102 between the outer surface of the Rx aspiration catheter 101 and the inner guide catheter 108. This seals the lumen between the outside of the Rx aspiration catheter 101 and the inner surface of the guide catheter 03 and prevents backflow of blood into the tip of guide catheter 108 reducing the effectiveness of the aspiration. An expansile tip 112 of the Rx catheter 101 facilitates aspiration and retrieval of the clot 110 by expanding under load. The expansile tip 112 can also partially or fully occlude the vessel providing flow arrest and thereby improving aspiration effectiveness.



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TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE,
DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT,
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DEVICES FOR REMOVAL OF ACUTE BLOCKAGES FROM BLOOD VESSELS

Field of the Invention

This invention relates to devices intended for removing acute blockages from blood vessels.

5 Acute obstructions may include clot, misplaced devices, migrated devices, large emboli and the like. Thromboembolism occurs when part or all of a thrombus breaks away from the blood vessel wall. This clot (now called an embolus) is then carried in the direction of blood flow. An ischemic stroke may result if the clot lodges in the cerebral vasculature. A pulmonary embolism may result if the clot originates in the venous system or in the right side of the heart and lodges

10 in a pulmonary artery or branch thereof. Clots may also develop and block vessels locally without being released in the form of an embolus - this mechanism is common in the formation of coronary blockages. The invention is particularly suited to removing clot from cerebral arteries in patients suffering acute ischemic stroke (AIS), from coronary native or graft vessels in patients suffering from myocardial infarction (MI), and from pulmonary arteries in patients

15 suffering from pulmonary embolism (PE) and from other peripheral arterial and venous vessels in which clot is causing an occlusion.

Summary of Invention

According to the invention there is provided a catheter for assisting in the retrieval of a clot from

20 a vessel comprising a distal end and a proximal end, a distal segment and a proximal segment and a lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment and a flow restrictor located on the outer surface of the catheter distal of the transfer port.

25 In one case the catheter is an aspiration catheter for aspirating a clot.

In one embodiment the flow restrictor is actuatable between engaged and disengaged configuration. The catheter may comprise an actuator for selectively engaging and/or disengaging the flow restrictor.

30

In one case the flow restrictor comprises a framework and a membrane coupled to the framework, the framework being movable by the actuator between an expanded configuration and a retracted configuration.

The aspiration catheter may comprise a proximal flow restrictor proximate the proximal end of the distal segment and a distal flow restrictor spaced distally from the proximal flow restrictor.

In one case the distal end of the catheter comprises a mouth for reception of clot. The mouth
5 may be defined by an expansile tip.

In one embodiment the distal segment includes a hinge adjacent to the distal mouth. The hinge may be defined by a region of the distal segment which is configured to have lateral flexibility.

10 In one case the mouth has an expanded configuration and a retracted configuration. The catheter may comprise a control member for controlling the movement of the mouth between the expanded and retracted configurations.

In one embodiment the mouth comprises a number of segments and the control member is
15 configured to move at least some of the segments. The control member may comprise a draw string or the like.

In another aspect the invention provides a catheter for aspirating a clot in a vessel comprising a distal end and a proximal end, a distal segment and a proximal segment and a lumen extending
20 proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment wherein the distal end of the catheter comprises a mouth for reception of clot. The mouth may be defined by an expansile tip. In one case the catheter has a flow restrictor located on the outer surface of the catheter distal of the transfer port.

25 Also provided is a system for treating an occlusion in a vessel the system comprising:-
a first catheter and a second catheter;

the first catheter comprising a proximal end, a distal end and a lumen extending between the proximal end and the distal end, the lumen of the first catheter further comprising a proximal segment and a distal segment;

30 the second catheter comprising a distal end and a proximal end, a distal segment and a proximal segment, and a lumen, said lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment;

the first catheter being configured to facilitate aspiration through the lumen;

the transfer port being configured to transmit aspiration in the proximal lumen of the first catheter into the lumen of the distal segment of the second catheter and the distal end of the second catheter being configured to receive clot into at least a portion of the lumen of the second catheter.

5

In one embodiment the system further comprises a flow restrictor between the first catheter and the distal segment of the second catheter, distal of the transfer port. The flow restrictor may be located on the inner surface of the first catheter. Alternatively or additionally the flow restrictor is located on the outer surface of the second catheter.

10

In one embodiment there is a proximal flow restrictor proximate the proximal end of the distal segment of the second catheter and a distal flow restrictor spaced distally from the proximal flow restrictor.

15 In one case the distal end of the second catheter comprises a mouth for reception of clot. The mouth may be defined by an expansile tip.

In one embodiment the transfer port comprises a rapid exchange port.

20 In one case the first catheter is a guide catheter. The second catheter may be an intermediate catheter.

The system may also include a microcatheter which is adapted to be advanced through the first catheter and the second catheter. The system may further comprise a clot engaging device for

25 delivery from the microcatheter.

Also provided is a method of removing a clot from a vessel, the method comprising:-

providing a guide catheter and an intermediate catheter, the intermediate catheter having a distal mouth and being configured such that it is advancable within the lumen of the guide catheter;

30 inserting the guide catheter into a first vessel proximal of an occlusion;

advancing the intermediate catheter through the lumen of the guide catheter until the tip of the intermediate catheter extends distal of the guide catheter into a second vessel adjacent to the occlusion;

applying aspiration to the proximal end of the guide catheter;
the intermediate catheter being configured to direct said aspiration through the distal lumen of the intermediate catheter to aspirate the clot into the mouth of said intermediate catheter.

- 5 The aspiration catheter may comprise a distal end, a proximal end, a distal segment, a proximal segment and a lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment.

In one embodiment the method comprises restricting flow between the outside surface of the
10 intermediate catheter and the inside surface of the guide catheter.

In one embodiment the method comprises the step, before or after aspiration, of delivering a microcatheter to the occlusion and deploying a clot capture device from the microcatheter. The method may comprise advancing the microcatheter to the clot, deploying a clot capture device
15 from the microcatheter, retracting the microcatheter to a location proximal of a transport port at the proximal end of a distal segment of the aspiration catheter.

In a further aspect the invention provides method of removing an occlusion from a vessel comprising:-

- 20 providing a first aspiration catheter and a second aspiration catheter, the second aspiration catheter extending distal of the first aspiration catheter and further comprising a transfer lumen proximal of the distal end of the first aspiration catheter;
inserting the first catheter into a first vessel proximal of the occlusion;
advancing the second catheter through the lumen of the first catheter until the tip of the second
25 catheter extends distal of the first catheter into a second vessel and is substantially opposing the occlusion; and
aspirating through the proximal lumen of the first catheter so as to urge the clot into the distal lumen of the second catheter.

- 30 The method may comprise restricting flow between the outside surface of the second catheter and the inside surface of the first catheter.

The method may comprise the step, before or after aspiration, of delivering a microcatheter to the occlusion and deploying a clot capture device from the microcatheter. In one case the

method as comprises the step, prior to aspiration, of retracting the microcatheter to a location proximal of the transfer port.

In one embodiment the first aspiration catheter is a guide catheter. In one case the second
5 aspiration catheter is an intermediate catheter.

In one aspect the invention provides a clot receptor device. In one case the device is a catheter which may include rapid exchange features. In one embodiment the device provides a self-expanding aspiration catheter with flow-arrest.

10

The aspiration assist device has a distal end which expands to seal against the vessel proximal of the clot and provides a large open mouth to receive clot easily without risk of dislodging the clot from the thrombectomy device (if used).

15 The inner rapid exchange expandable device is delivered through an outer catheter, which may be a conventional intermediate or aspiration catheter or a distal access catheter (DAC). In one case it is a tailored catheter with an extremely trackable distal section for ease of access. This outer catheter trackability is possible because the distal section does not require much axial stiffness, as neither clot nor thrombectomy device are retracted directly into it.

20

The rapid exchange (RX) expanding device may be supplied within the outer catheter (about 15cm proximal of the distal end) and both are delivered together over a microcatheter (or wire) until the outer catheter tip approaches the clot. The inner RX expanding device is advanced to the distal end of the outer, and the outer is then retracted to deploy the self expanding RX device.

25

The Rx device seals against the vessel wall and against the inner lumen of the outer catheter to allow highly effective aspiration, and its distal end expands to provide a large opening and reception space to receive the target clot and thrombectomy device (if used).

30 In another similar embodiment the self expanding aspiration catheter has a full length tubular proximal shaft, rather than a rapid exchange shaft, so that it does not require a proximal seal and aspiration can be applied by applying a vacuum force to its proximal hub.

The invention also provides a rapid exchange aspiration catheter.

The catheter provides a proximal seal against guide catheter inner lumen so that aspiration may be applied through the guide taking advantage of the large proximal lumen.

The catheter having deliverability advantages of minimal frictional engagement with guide or
5 microcatheter proximal of exit port.

Retracting the microcatheter just proximal of exit port (rather than completely removing it) creates a large aspiration advantage.

10 Also provided is a removable microcatheter hub that enables physician to advance a DAC over the microcatheter after the microcatheter (and thrombectomy device) are already in position (as bail, out for example).

Brief Description of the Drawings

15

Figs. 1 and 2 illustrate a clot receptor device and system according to the invention;

Figs. 3 to 9 illustrate various alternative clot receptors;

Figs. 10 and 11 illustrate a rapid exchange aspiration catheter according to the invention;

Figs. 12 and 13 illustrate various proximal and distal seals;

20 Figs. 14 to 37 illustrate various alternative distal ends and expansile tips of a clot collector device of the invention;

Fig. 38 illustrates an alternative rapid exchange configuration

Figs. 39 to 46 illustrate a removable microcatheter hub according to the invention;

25 Figs. 47 to 51 illustrate the creation of the distal segment with a continuous and smooth stiffness profile;

Figs. 52 to 55 illustrate a dual lumen aspiration catheter according to the invention;

Figs. 56 to 59 illustrate a clot receptor device and system according to the invention;

Fig. 60 illustrates a clot receptor device according to the invention;

Figs. 61a-c illustrate a clot receptor device and system according to the invention;

30 Fig. 62 illustrates a portion of a clot receptor device and system according to the invention;

Fig. 63 illustrates a clot receptor device according to the invention;

Figs. 64a-d illustrate an expansile tip of a clot collector device of the invention and

Fig. 65 illustrates a rapid exchange aspiration catheter according to the invention.

Detailed Description of the Drawings

Fig. 1 illustrates a clot receptor device 2 of this invention being used in the retrieval of a clot 1 from the blood vessel of a patient. The clot receptor device 2 comprises an elongate proximal shaft 13 and a tubular expansile distal section 4. The proximal end 5 of the expansile distal section 4 is configured to seal against the inner lumen of a distal section 6 of a catheter 7 through which it is advanced, while the distal end 8 of the expansile distal section is configured to seal against the wall of the blood vessel. The proximal seal against the lumen of the intermediate catheter 7 enables an aspiration force (such as a vacuum or a negative pressure differential, as may be induced by retracting a syringe plunger or through a vacuum pump) to be transmitted through the intermediate catheter 7 to the clot receptor device 2 and thus to the clot. The low profile proximal shaft 13 of the clot receptor device 2 minimizes the space occupied within the intermediate catheter 7, maximising the effectiveness of the transmission of this vacuum / aspiration force to and through the clot receptor 2. The seal at the proximal end of the clot receptor 2 may be provided by the expansile body of the clot receptor 2 opposing the lumen of the intermediate catheter 7. Other embodiments of this seal include a soft cuff of a foam or fibre construction, or polymer leafs or leaflets, or a balloon cuff, or a stent-like construction with a membrane cover, or combinations of these or other designs

The distal end 8 of the expansile distal section 4 is configured to open to a larger diameter than the proximal end, typically at least 50% larger, and in some embodiments up to 500% larger or more, depending on the relative size of the target blood vessel and the lumen of the catheter 7 through which the device is advanced. The large open mouth of the distal end 8 of the clot receptor 2 provides an easy path for retraction of clot into its interior space, and once within this space the clot can be safely retrieved from the patient. In one embodiment the inner lumen of the clot receptor device 2 has a profiled surface (like a sharkskin, or backward facing teeth) which allows clot to slide easily into the device, but resist the clot from escaping back out of the device.

Figs 2a to 2f illustrate a typical method of use of such a device and system. The method may include at least some of the following steps: Accessing an arterial blood vessel of a patient using conventional means such as an introducer 10 and guide catheter or sheath 11, advancing a microcatheter 12 up to and across a target occlusive clot with the aid of a guidewire 17, removing the guidewire 17 and advancing a mechanical thrombectomy device 15 such as a stent-retriever through the microcatheter 12 to the target clot 1, retracting the microcatheter 12 at least a few cm to deploy a mechanical thrombectomy device 15 within the clot 1, advancing an

intermediate catheter 7 containing the clot receptor device 2 up to a position just proximal of the clot 1 (or within the clot, or considerably proximal of the clot if vessel disease or tortuosity makes access difficult), advancing the clot receptor device 2 up the distal end of the intermediate catheter 7 (or up to and out of the catheter and into or over the clot), retracting the intermediate catheter 7 a short distance to deploy the clot receptor device 2, aspirating through the intermediate catheter 7 using a syringe or pump to suck blood and the target clot into the clot receptor device 2, withdrawing the mechanical thrombectomy device 15 into the clot receptor 2 while continuing to aspirate, withdrawing the clot receptor device 2 and its contents at least partially into the lumen of the intermediate catheter 7, withdrawing the intermediate catheter 7, clot receptor device 2, clot and mechanical thrombectomy device 15 through the guide or sheath 11 and out of the patient.

Many variants of this method are possible.

For example it may be desirable to withdraw the clot 1 and mechanical thrombectomy device 15 through the clot receptor 2, intermediate catheter 7 and guide 11 and out of the patient while leaving the intermediate catheter 7 and clot receptor 2 in place. This allows the physician to retain a protective seal in the vessel to prevent the escape of any clot particles that may be dislodged, and also preserves a means of quick and easy access back to the target site with a microcatheter and thrombectomy device in case additional passes are needed to completely clear the vessel.

Another method variant involves removing the clot receptor device 2 and thrombectomy device 15 together through the intermediate catheter 7, leaving the intermediate catheter 7 in place for easy re-access to the target site.

Yet another method variant involves using the clot receptor device 2 as the primary clot retrieval tool, without the aid of a mechanical thrombectomy device such as a stent-retriever. The clot receptor 2 is configured to expand and seal against the vessel wall adjacent the proximal end of the clot, thus aspirating through the intermediate catheter 7 and clot receptor 2 provides a highly effective suction force to draw the clot into the clot receptor 2. If the clot passes through the clot receptor 2 and into the intermediate catheter 7 it may be aspirated through the intermediate catheter 7 and right out of the patient. If the clot is too large or too firm to pass through the clot receptor 2 then the clot receptor 2 may be withdrawn into the intermediate catheter 7. Because

the clot receptor 2 has a smooth and funnel shaped exterior it can be easily retracted into the intermediate catheter 7 even when containing a bulky and/or firm clot.

The distal end 8 of the clot receptor device 2 is intended to open up upon exiting the catheter through which it is delivered to provide a large open mouth approximately equal in size to the inner diameter of the vessel in which it is located and provide a seal against this vessel or significant flow restriction such that when a suction force is applied through the clot receptor 2 this force causes blood and clot distal of the receptor 2 to flow into the receptor 2 rather than blood proximal of the receptor 2. This flow occurs because the pressure inside the clot receptor 2 is lower than that outside (distal and proximal) of the clot receptor 2. If the seal were not present two flow paths into the clot receptor 2 would exist and the less restricted proximal flow path would dominate, reducing the effectiveness of the clot retraction.

In order to adequately seal against the vessel wall the clot receptor 2 should have either a) a high radial force or hoop strength so that the pressure gradient created by the application of suction/aspiration does not collapse the clot receptor or create a flow path past it or b) a seal construction such that the presence of a pressure gradient across the clot receptor 2 serves to tighten the seal rather than reduce it. The geometry and construction of the clot receptor sealing end should be such that it can conform well to the vessel wall, which may be not be effectively circular (such as when close to bifurcations for example, or when inclined at an angle to the vessel wall).

Thus one embodiment of the distal portion of a clot receptor may comprise a self-expanding frame with a relatively non-porous cover, such that the cover prevents any significant passage of blood through the wall of the clot receptor, and the self expanding frame has sufficient radial or hoop strength to resist the pressure gradient created by the application of suction/aspiration. The cover may be a polymeric membrane, or may be a woven or braided or knitted structure. In one embodiment the membrane is a polymer membrane, preferably with a high elastic strain limit and a low modulus to permit its expansion by a low radial force frame structure. A preferred membrane is a polyurethane membrane, which might be extruded or blow moulded or ideally dip coated directly onto the frame. The membrane may be coated with a low friction coating such as a hydrophobic silicone or a hydrophilic material. In one embodiment the membrane is a hydrophilic material itself, comprising a hydrogel with sufficient thickness and modulus to retain its structure under the force of aspiration. Other suitable materials for this cover include PTFE,

ETFE and PFA. Materials such as PET, UHMWPE, PET and PEN would be particularly suitable for use in the making of a cover that is woven, braided, knitted or otherwise formed from fibres

Another embodiment of the distal portion of a clot receptor may comprise a combination of a self-expanding frame with a relatively non-porous membrane cover, and a plurality of flexible leaflets or vanes disposed around its outer circumference in a manner similar to that of a leaflet valve. In yet other embodiments the additional seal provided by these flexible leaflets is instead provided by an outer cuff, and this outer cuff may comprise a compressible material such as a foam or a hydrogel or a fibre bundle or a shaped polymer.

In yet another embodiment the expansion of the distal end of the clot receptor may be actuable by the user, by retraction of a pull wire within the device shaft for example, or by inflation of a balloon cuff.

Some of the various embodiments of the distal end of the clot receptor are illustrated in Figs. 3 to 9.

Fig. 3 depicts one embodiment of the distal end of the clot receptor comprising a stent-like self-expanding frame 25 with an outer membrane covering 27. A proximal shaft 21 is connected to the frame and membrane at a proximal entry port 20. The proximal end 24 of the expansile section is configured to gently appose the wall of a catheter through which it is delivered, while the distal end 23 is configured to expand and appose the vessel wall, creating a large opening 22 into the internal reception space. The frame structure 25 is in one embodiment a Nitinol structure laser cut from a tube or sheet, and in another embodiment is a wire structure, wound or braided from Nitinol or stainless steel or other such biocompatible metallic material as are commonly used in the construction of stents or snares. The membrane 27 may comprise a lip 26 which is folded over and wrapped inside the frame 25.

Figs 4 and 5 depict a typical embodiment of the distal end of the clot receptor. Fig. 4 shows a clot receptor 30 housed in an outer intermediate catheter 31, positioned in a vessel 32. The distal end 35 of the clot receptor is folded to wrap it into a suitable profile to fit into the lumen of the intermediate catheter 31. Fig. 5 shows the deployed clot receptor upon retraction of the intermediate catheter 31, such that distal end 35 has expanded and is contacting the vessel wall 32, and proximal end 34 is sealing against the inner lumen of the intermediate catheter 31. In

another embodiment the distal end 35 expands to a smaller diameter than that of the vessel, but a larger diameter than that of the intermediate catheter.

The intermediate catheter inner lumen may be as small as 0.75mm or as large as 2.0mm, but is preferably between 1.0mm and 1.7mm. The clot receptor distal end may be configured to expand to a diameter equal to or slightly larger than the target vessel in order to provide a seal, or to a diameter slightly smaller than the target vessel in cases where a low profile, deliverable device is a higher priority than a perfect seal. In one embodiment configured for use in middle cerebral arteries of the brain, the clot receptor distal end is configured to expand to a diameter of between 2mm and 4mm. In another embodiment such as might be used in the internal carotid artery, the clot receptor distal end is configured to expand to a diameter of between 4mm and 7mm.

Figs 6a and 6b illustrate the collapsed (for delivery) and expanded forms of the distal end of a clot receptor 40 of this invention. In this case the mechanism of collapse for delivery through an intermediate catheter is a creasing and folding mechanism, similar to that used to wrap angioplasty balloons. The material of the distal expansile end 42 is configured into pleats or folds 41 to wrap it efficiently into delivery form.

Figs 7a and 7b illustrate the collapsed (for delivery) and expanded forms of the distal end of a clot receptor 50 of this invention. In this case the mechanism of collapse for delivery through an intermediate catheter is a rolling mechanism, with an unrolling mechanism taking place for expansion. The distal expansile end 52 exists in its minimum strain state when fully expanded as shown in Fig. 7b. It is configured with a seam 51 running from its distal most end to a point distal of its proximal end. The seam allows the self-expanding clot receptor to be rolled up like a cigarette paper to assume a lower profile shape for delivery.

Figs 8a and 8b illustrate the collapsed (for delivery) and expanded forms of a frame 60 of the distal end of a clot receptor of this invention. This frame may be formed from Nitinol or another material with a sufficient elastic strain limit such that this limit is not exceeded when the device is collapsed for delivery through an intermediate catheter. In one embodiment the frame is laser cut from a Nitinol tube or sheet, and comprises struts 61 connected at crowns 62. The distal end of the frame comprises terminal crowns 63, which may be formed with atraumatic ends of a higher radius of curvature than that used for the more proximal crowns. The frame may be covered with a polymeric membrane as described earlier.

Fig. 9 illustrates the expanded form of a frame 70 of the distal end of a clot receptor of this invention, which is similar to frame 60 of Fig. 8 but is formed from wires 73 rather than cut from a tube or sheet. One advantage of such a structure is that non superelastic materials (such as SS, MP35N or other materials commonly used in the manufacture of balloon expandable stents) can be used in its construction. This is because a much lower strain is induced in the frame in moving from its expanded to collapsed state, because the wires are free to move and slide relative to one another, even at crossover points 72. The wires form crowns 71 of a large and gentle radius at the distal end of the frame, rendering the tip of the device atraumatic to a blood vessel.

10

Referring to Figs. 10 and 11 there is illustrated an aspiration catheter 101 according to the invention. In Fig. 11a the aspiration catheter 101 is illustrated as part of a clot retrieval system for retrieval of a clot 110. The clot retrieval system further comprises a clot engaging device 100, a microcatheter 109 through which the clot engaging device is delivered and a guide catheter 108 through which the aspiration catheter 100 and microcatheter 109 are delivered. The aspiration catheter 101 comprises a distal segment 90 and a proximal segment 91. The distal segment 90 comprises a distal end provided with a distal tip 112 and a proximal end provided by a transfer port 105. A lumen of the distal segment 90 extends proximal of the distal end 112 and terminates at the transfer port 105. The proximal segment 91 extends from the distal segment 90 and in this case is provided by a proximal shaft 106. A flow restrictor 102 is located on the outer surface of the aspiration catheter 101 distal of the transfer port 105. The aspiration catheter 101 provides a proximal seal 102 against a guide catheter inner lumen 103 so that aspiration may be applied through the guide catheter 108 and thus take advantage of a large proximal lumen.

Fig.10 shows a simplified view of a distal region of the system, illustrating more clearly how the aspiration catheter flow restrictor 102 interacts with the inner lumen of the guide catheter 108. The guide catheter 108 may also have a flow restrictor component such as the inflatable balloon portion 104 shown in this illustration.

The aspiration catheter 101 is a rapid exchange (RX) catheter in which the exit port 105 defines a transfer port for aspiration and provides a deliverability advantage of minimal frictional engagement with the guide catheter 108 proximal of the exit port 105.

In some cases a microcatheter 109 may be provided through which a clot capture device 100 is delivered. Retracting the microcatheter 109 just proximal of the exit port 105 (rather than completely removing it) creates large aspiration advantage.

- 5 In one case the microcatheter 109 and the Rx aspiration catheter 101 are introduced together into the guide catheter 108.

The guide wire and microcatheter 109 are then advanced across the clot 110. The guidewire can be removed and a clot retrieval device such as a stent retriever device 100 is introduced.

10

Using the microcatheter 109 for support, the Rx aspiration catheter 101 can be forwarded to a position proximal to the clot 110 by pushing the proximal shaft 106 or handle into the guide catheter 108. The stentriever device 100 can be deployed by retracting the micro catheter 109.

- 15 The Rx aspiration catheter 101 can then be forwarded to contact the clot 110 or be positioned just proximal to or at the proximal face of the clot 110. The microcatheter 109 can then be retracted sufficiently to be proximal of the Rx port 105 of the Rx aspiration catheter 101. This facilitates an increased lumen for aspiration without the necessity of removing the microcatheter 109 fully from the intermediate / aspiration catheter.

20

Aspiration can be applied to the lumen of the guide catheter 108 with a manual syringe 111 or vacuum pump. This aspiration is directed to and effective at the distal tip 12 of the Rx aspiration catheter 101 due to the presence of the flow restrictor or seal 102 between the outer surface of the Rx aspiration catheter 101 and the inner guide catheter 108. This seals the lumen
25 between the outside of the Rx aspiration catheter 101 and the inner lumen 103 of the guide catheter 108 and prevents backflow of blood into the tip of the guide catheter 108 which would reduce the effectiveness of the aspiration. The seal 102 may not need to stop flow in the lumen completely but needs to restrict flow sufficiently so as not to have a significant effect on aspiration performance. This seal 102 can be generated in a number of ways such as those
30 described in Figs 12 to 13l. In some cases the seal 102 is located on the inside surface of the guide catheter 108 and/or on the outside surface of the aspiration catheter 101.

The Rx aspiration catheter 101 is constructed of a proximal handle (not shown) to facilitate grip and a proximal shaft 106 constructed from a wire or tube formed preferably from Nitinol,

stainless steel, PEEK or some other similar material. An additional seal may be provided on a proximal haemostasis valve to assist in sealing against the proximal shaft 106. The material of the shaft 106 has high compressive and tensile strength and may have a low friction coating or jacket to minimise insertion and retraction forces. The low friction coating or jacket could be
5 formed from PTFE, HDPE or a similar material.

The Rx exit port 105 on the aspiration catheter 101 can facilitate forwarding a microcatheter 109 through the port 105 and through the distal section 90 of the Rx catheter 101 prior to insertion into the guide catheter 108. The Rx exit port 105 may be formed in a funnel shape to make it
10 easier to forward a microcatheter 109 into the port even in position in the guide catheter 108. The port 105 may be formed from a moulded component or from the tubing of the distal section 90 of the catheter 101.

The distal section of the Rx aspiration catheter 101 has good push and trackability characteristics
15 to allow it to be forwarded to the target location. Therefore it may be constructed of one or more materials to give a reducing stiffness profile along the length. A braided wire or coil wire construction or combination of both may be used to improve compressive strength and track ability. Linear wire supports running parallel to the tube axis may also be used.

20 A top layer of low friction material may be applied to the distal section of the catheter 101 or alternatively a hydrophilic coating or silicon oil coating may be applied to the surface. The inner lining of the distal section of the catheter 101 consists of PTFE or similar low friction material to minimise insertion and retraction forces.

25 The seal 102 on the outer surface of the Rx aspiration catheter 101 distal section 90 prevents or significantly reduces blood flow travelling from the guide catheter distal tip 113 to the Rx port 105 of the Rx aspiration catheter 101 as shown in Fig. 12a. Various embodiments of proximal seals 102 are illustrated in Figs. 12 to 13l.

30 In another embodiment of the device shown in Fig. 12b an additional seal 114 is provided on the distal end of the catheter 101 to seal between the Rx catheter and the target vessel. This seal 114 is spaced distally from the proximal flow restrictor 102 and occludes blood flow in the vessel and improves aspiration effectiveness without the need for a balloon guide catheter. The seal 114 can be constructed in a similar manner to those shown in Figs 12a to 13l.

The seal 102 can be formed from an outer sleeve on the catheter which may be smooth or have a grooved or profiled surface 116 as shown in Fig. 13a. Fig. 13j shows a profiled surface with a spiral groove 125. The seal could also be formed from one or more moulded rings with a sealing lip or “O” ring profile 117 as shown in Fig. 13b. It could also be formed from an inflatable balloon 115 which is inflated by injecting saline through a lumen in the shaft and catheter as shown in Figs 12a, 12b and 13g.

In another embodiment illustrated in Fig. 13d the seal 102 can be constructed of fibres in a brush / bristle configuration 119 or from a fibre mesh 123 formed of PET fibres or similar material as shown in Fig. 13h. Similarly the seal could be formed of a sponge material 121 which is compressed when inserted into the lumen of the guide catheter 108 as shown in Fig. 13f.

In a further embodiment the seal 102 could be provided by a body 124 formed from a hydrophilic 124 or similar material which swells and increases in diameter when in contact with saline or blood. The seal 102 may also be formed by having a close tolerance clearance fit between the outer diameter of the distal end of the Rx aspiration catheter 101 and the inner diameter of the guide catheter 103. In another embodiment, the seal 102 is formed from a lip 118 or membrane 120 which restricts flow particularly in one direction as shown in Figs 13c and 13e.

In another embodiment of the seal 102 shown in Figs 13k and 13l, the occlusion between the Rx aspiration catheter 101 and the guide catheter 108 is achieved through longitudinal compression of the aspiration catheter 101. This can be achieved by having an expansile section 127 which increases in diameter when the catheter is under compression. The compression can be a result of retrieving clot 110 and the stentriever device 100 into the tip 112 or may be manually actuated through a pull wire 126. This pull wire 126 may run through a separate lumen from the proximal end of the device as shown in the cross sectional view A-A in Fig. 13l.

The clot 110 and stentriever type device 100 can be fully or partially retrieved into the Rx aspiration catheter 101 as controlled by the physician and depending on the resistance felt by the user or clot obstruction of the lumen as indicated by an increase in vacuum / loss of suction. The expansile tip 112 of the Rx aspiration catheter 101 facilitates aspiration and retrieval of the clot 110 and stentriever device 100 by expanding under load to reduce the retraction force and lessen the risk of scraping clot off the surface of the stentriever device 100. The expansile tip

112 can also partially or fully occlude the vessel providing flow arrest improving aspiration effectiveness.

The expansile tip 112 can be formed in a number of ways and various embodiments are shown in
5 Figs 14 to 37.

In one embodiment the expansile tip 112 can be formed from a co-extrusion of materials with different properties such as a soft expansile polymer 131 co-extruded with a higher modulus polymer 130 to provide longitudinal support. A fully expansile ring 132 could then be connected
10 to this tip as shown in Fig. 14. The tip 112 may also include one or multiple metallic wire supports 133 as shown in Figs 15 and 24. In another embodiment shown in Fig. 18 the tip has a skived profile to increase contact area with the clot during retrieval or aspiration. The tip may be formed with holes 134 or perforations 137 to allow it to split and change shape when a device 100 and clot 110 is retracted into the tip as shown in Figs 16 and 17. These features can be
15 combined with tip constructions containing materials of different durometers such as shown in Figs 16, 17, 18, 21 and 25. In these embodiments the tip materials 143, 136, 146, 151, 164 have a lower durometer and are more expansile than the support materials 135, 144, 145, 150, 165. These support materials may be embedded within the wall of the tubing or may be on the inner or outer surface. They may also be formed in a spline, coil, stripe, 'U' shape or other
20 configuration to provide longitudinal support to the expansile material to prevent it collapsing or buckling under compressive load, such as occurs during retrieval of a clot or stentriever device, or during insertion through a guide or access catheter. Fig. 19 shows another embodiment where multiple holes 139 produce a lattice or framework in the tip. Single or multiple protrusions or "teeth" 141 may also be applied to the inner surface 142 at the distal tip to improve grip on the
25 clot as shown in Fig. 20.

The expansile tip may be pre shaped to form a flared profile (Fig. 22a) or a tapered profile as shown in Fig. 22b. Alternatively the tip shape may be a combination of these profiles such as bulbous or 'pear' shaped as shown in Fig. 23a to 23d. In the configuration shown in Fig. 23a the
30 tip 160 has an increased diameter larger than the proximal catheter diameter 161 which then tapers to a reduced diameter 162 for ease of insertion. In the configuration shown in Fig. 23b the tip 166 has an increased diameter larger than the proximal catheter diameter 161 which then tapers to a reduced diameter 167, however the reduced diameter 167 is still larger than the proximal catheter diameter 161. This tip configuration provides benefits of improved aspiration

effectiveness and reduced retrieval force but also low insertion force and trackability benefits due to the distal tip radius or taper 167. The tip radius 167 also prevents the tip snagging on a bifurcation on insertion, such as at the ostium of the ophthalmic artery in the internal carotid artery. Fig. 23c shows how the tip 160 elongates during insertion through a guide or access catheter 108, while Fig. 23d shows the tip 160 expanding to accommodate the retrieval of a clot 110 and stentriever device 100. The profiled tips can also be constructed using multiple materials of varying durometer and expansile characteristics.

The expansile tip 112 could also be profiled and contain one or more slot cuts 170 to facilitate expansion as shown in Figs 26, 29 and 30. Other embodiments of profiled tips to facilitate expansion and retrieval of the clot 110 and stentriever device 100 are shown in Figs 27 and 28.

In another embodiment of the Rx aspiration catheter tip 112 shown in Fig. 31, the distal end of the tip has a collar 171 which tracks closely over the guidewire. This helps direct the catheter over the guidewire to the target location reducing the risk of snagging. The tip configuration shown in Fig. 32 has a flattened section 173 which contains a large number of aspiration pores 174, and aspiration windows 172. This design potentially increases the contact area with the clot improving grip where the catheter is used without a stentriever device. Fig. 33 shows an end view of Fig. 32 with the arrows indicating the direction of blood flow.

Referring to Figs. 34 to 35 there is illustrated a catheter with an expandable distal end 180, which is expanded by means of a lifebelt shaped annular balloon 181 at or adjacent its distal end. The balloon is inflated by injecting a fluid through an inflation lumen 182 running from the proximal to distal end of the device. The distal end of the catheter has a ring of petals 183 which act as a seal or occluder to limit the volume of blood flowing from proximal of the tip into the catheter, when aspirating through the catheter. The petals 183 may be formed from a polymeric material. Fig. 34a shows the tip in the collapsed configuration and Fig. 34b shows the tip when the annular balloon 181 is inflated. Fig. 35 shows an additional embodiment where the catheter has an Rx construction with the inflation lumen 182 running through the shaft to the proximal end of the device.

In another embodiment of the catheter tip 112, shown in Figs 36a and 36b, the tip 184 is constructed so that it can invert as the stentriever device 100 and clot 110 are retrieved into the

catheter. This can reduce the retraction force and constrain the clot so fragments are not released during the retrieval process. Fig. 36b shows the tip after inversion.

Referring to Figs. 37a and 37b there is illustrated a clot retrieval catheter with a self-expanding
5 distal tip 190 that is constrained by a tapered cap 191 for ease of deliver and atraumatic access to a target site. The cap component 191 can be retracted to allow the catheter mouth 192 to expand, creating a large opening to accept clot or other material into its lumen. The cap component 191 has a distal end whose outer diameter is ideally lower than that of the catheter shaft immediately proximal of the cap, and an inner lumen sized to enable the device to be advanced over a
10 thrombectomy device shaft and microcatheter. The cap component 191 may also comprise a guide tube 193 to aid the device in moving smoothly over a thrombectomy device shaft or microcatheter.

In another embodiment of the device shown in Fig. 38 the distal section of the catheter 194 is
15 shortened so that distance X is typically between 5 and 50 mm long. This device can be forwarded over the shaft of the stentriever device 100 to the target location to facilitate partial or full retrieval of the stentriever 100 into the expansile tip 112. In this embodiment the distal section 194 is forwarded out of the guide catheter 108 and does not translate aspiration to the distal tip 112, but has improved trackability and access performance to reach the target vessels
20 due to reduced friction and pushability of the wire shaft. The short length distal section 194 and tip 112 are connected to a shaft 106 constructed from a wire or tube formed preferably from Nitinol, stainless steel, PEEK or some other similar material. The shaft material has high compressive and tensile strength and has a low friction coating or jacket to minimise insertion and retraction forces. The expansile tip 112 can be constructed in a similar manner to those
25 shown in Figs 14 to 37.

The Rx aspiration catheter 101, microcatheter 109, stentriever device 100 and clot 110 can be retracted as a unit back to the tip of the guide catheter 113 and then fully into the guide catheter 108. The guide or access catheter 108 may also have an expansile tip 113 to facilitate retraction
30 of the devices and clot, with a reduced force and lower risk of dislodging the clot from the devices. This expansile tip 113 on the guide catheter may be constructed in a similar manner to those shown in Figs 14 to 37. Likewise the expansile tip 112 construction and seal 102 construction shown in Figs 12 to 37 may also be applied to a standard length intermediate or aspiration catheter.

The Rx aspiration catheter 101, microcatheter 109, stentriever device 100 and clot 110 can then be retrieved from the guide catheter 108 and removed fully from the patient.

- 5 Referring to Figs. 39 to 46 there is illustrated a removable microcatheter hub according to the invention. The removable hub enables a physician to advance an intermediate or access catheter over the microcatheter after the microcatheter (and thrombectomy device) are already in position (as bail out for example). It is not possible with a standard microcatheter to forward an intermediate or access catheter over the proximal end as the fixed hub is in the way, therefore the
10 standard microcatheter has to be removed to introduce an intermediate catheter.

Use of a microcatheter with a removable hub that facilitates the use of an extension wire facilitates improved control on the microcatheter position as the intermediate catheter is introduced.

15

In Figs. 39 to 46 the following numerals are used:

- 300 detachable hub
- 301 microcatheter shaft
- 302 strain relief element extending from microcatheter hub
- 20 303 internal connector (see Figs. 42/43 for detail)
- 304 end of microcatheter shaft which has detached
- 305 extendable shaft for intermediate catheter exchange
- 306 internal thread on microcatheter hub
- 307 microcatheter connector
- 25 308 O-ring seal
- 309 external thread on microcatheter connector
- 310 bond
- 311 closed end to prevent outbleed
- 312 bond
- 30 313a extension wire
- 313b extension wire housing
- 314 laser cut hypotube which acts as a core reinforcement for microcatheter
- 315 stiff proximal shaft so that it can be gripped and pulled/twisted during microcatheter removal

316 compressible O-ring which locks the microcatheter into recess incorporated into moulded catheter hub

317 detachable hub

318 extension tube

5 319 spring clip – e.g. stainless steel or Nitinol

320 injection moulded hub

D1 0.021 inch ID approx.

D2 0.029 inch OD approx.

10 D3 0.039 inch OD approx.

D4 0.045 inch OD approx.

Fig. 39 shows the microcatheter hub 300 assembled with the microcatheter shaft 301. Fig. 40 shows the microcatheter shaft after detachment and Fig. 41 shows the mating end of the extendable shaft 305. By connecting the extendable shaft 305 to the microcatheter shaft 301 the working length of the catheter is increased to facilitate forwarding an intermediate or access catheter over the microcatheter while maintaining positional control. The extendable shaft 305 can then be removed and the detachable hub reconnected to the microcatheter.

20 Fig. 42 illustrates the construction of the microcatheter connector 307 and detachable hub 300. The detachable hub 300 can be screwed onto the microcatheter connector 307 due to thread 309 on the connector and the mating thread 306 on the hub. 'O' ring 308 prevents any blood loss or air ingress between the connector 307 and the hub 300 when tightened.

25 Fig. 43 shows a section view of an embodiment of the extendable shaft 305 which utilises an extension wire 313a and extension wire hub 313b. The extension wire 313a and hub 313b are shown screwed onto the microcatheter shaft 301 and connector 307.

Figs 44 to 46 show another embodiment of a detachable hub where the microcatheter shaft 301 is connected to the detachable hub 317 by a compressible 'O' ring 316. The 'O' ring 316 sits in a groove on the moulded hub 320 which is connected to the microcatheter shaft 301. The 'O' ring is compressed by rotating part of the housing 321 on the detachable hub 317. The extension tube 318 can be pushed over the moulded hub 320 on the microcatheter shaft 301 after the hub 317

has been removed. The extension tube 318 is then held in position by the spring clip 319 engaging with the groove on the moulded hub 320.

Figs. 47 to 50 illustrate a method of manufacture of a large diameter aspiration catheter. The aspiration catheter is highly trackable so that it can be navigated to tortuous/distal cerebrovascular location.

Fig. 47 is a graph of lateral stiffness with distance from the tip.

Fig. 48 illustrated a conventional diagram in which different tubular segments 200, 201, 202, 203, 204 are of different materials. The segments are used to create a stepped material stiffness profile (gradually increasing modulus/share hardness).

Fig. 49 illustrates a distal segment according to the invention in which a smooth stiffness profile is created by blending elements 205, 206 of different modulus. For example, tapered tubes 205, 206 (Figs. 50, 51) may be placed on a mandrel overlapping each other and use heat to cause them to melt and flow into each other. The resultant tube may then be applied to a threaded or spiral wire or unreinforced base, or use as a stand-alone catheter.

Referring to Figs. 52 to 55 there is illustrated a dual lumen aspiration catheter to aid with aspiration and prevent the lumen of the catheter getting blocked with clot.

Lumen A – a smaller diameter lumen can be used to retrieve the device into and cause the clot to shear off. The distal end of *Lumen A* could be flush with or recessed from the distal tip of *Lumen B*.

Lumen B – the larger lumen would have aspiration constantly applied to it, to aspirate the clot that is sheared off the device when it is retrieved into the smaller lumen (*Lumen A*).

The smaller lumen A may have an inner diameter to facilitate the introduction of a microcatheter through the lumen. The microcatheter can then be inserted through this lumen and across the clot as per standard procedure. The stentriever device can then be deployed across the clot. Retrieving the stentriever and clot into the catheter causes the clot to be sheared off the stentriever within the aspiration catheter. This configuration prevents the clot snagging on the

struts of the stentriever device and blocking the aspiration lumen. The larger diameter lumen may have a diameter of about 0.058 inch and may have aspiration applied to it to aspirate the clot as the device is being retrieved into the smaller diameter lumen.

- 5 One clot receptor catheter tip according to the invention the clot receptor tip is expanded by means of a balloon, which may be attached to the shaft of a thrombectomy device, or to a microcatheter, or may be integral to the clot receptor catheter itself.

One embodiment of such a device is shown in these Figs 56 to 59. The device comprises a
10 thrombectomy device 400 with an inflation lumen 402 extending from the proximal end of the shaft to a balloon 401 at the distal end of the shaft, and an clot receptor catheter 404 with a flexible expandable distal section 405. The thrombectomy device 400 is expanded in the clot 403. Either the thrombectomy device and clot are then retrieved towards the clot receptor catheter 404 or the clot receptor catheter is advanced towards the thrombectomy device. The
15 balloon 401 at the distal end of the device is positioned so that the distal end is in line with the distal end of an intermediate catheter. The balloon is expanded to plastically deform 406 the distal end of the clot receptor catheter and then deflated. The resultant open mouth 407 of the clot receptor catheter allows the entire device and clot to be retrieved into the intermediate catheter. This prevents loss of clot on retrieval into a small lumen of a conventional intermediate
20 catheter. The expansile distal portion 405 of the clot receptor catheter may be formed of a polymeric material with a low modulus and a high elongation strain to break of greater than 100%, and ideally greater than 300%. It may also comprise a support structure of a metallic material such as stainless steel which can be plastically deformed by the balloon and can then retain its deformed shape with sufficient integrity to accept the thrombectomy device and clot.

25

The balloon expandable tip of the invention can be applied to any catheter – standard or rapid exchange, and can be used with or without a thrombectomy device to aid in the aspiration and/or retrieval of clot from blood vessels.

- 30 Fig. 60 illustrates an RX clot removal catheter 500. This device 500 is very similar in design and in use to that shown in figs 11a-d, except that the element 504 is an actuatable flow restrictor or seal, which can be selectively engaged or disengaged by the operator. The catheter 500 comprises a proximal elongate shaft 501 and a distal generally tubular portion 502. The distal portion 502 comprises reinforcement member 507 and a polymeric cover member 510, and

extends from an entry/exit port 517 to a distal clot reception tip 503. The cover member 510 may comprise multiple layers and segments. A low friction inner layer may be employed as a lining for the lumen of the tubular section, a highly compliant membrane 506 may be employed to cover the actuatable flow restrictor / seal region, and a low modulus polymer may be employed to cover the main tubular body. The distal end or tip 503 may comprise any of the designs shown elsewhere in this document. In a preferred embodiment the tip 503 is connected to the distal end of the tubular portion 502 by a hinge element 511. This hinge element may simply be a short region of the tubular section configured to have a high degree of lateral flexibility relative to the rest of the tubular section. This flexibility may be achieved by having a short region of the tubular section without any reinforcement element 507, or alternatively the reinforcement at that region could be a highly flexible reinforcement such as a generally spiral metallic coil.

The actuatable flow restrictor or seal 504 comprises a framework 508, with a membrane covering 506. The framework 508 is at least partially collapsible by retraction of actuation member 512, which runs through proximal elongate shaft 501 and is connected at its proximal end to slider element 514, which is in turn slidably constrained within handle 513, and coupled to spring element 515. Proximal elongate shaft 501 may comprise a tube of stainless steel, Nitinol or other metallic or high modulus polymeric material, and may contain a liner in order to provide a low friction internal surface against which the actuation member 512 may slide. The shaft 501 may be tapered or may be slotted in order to provide a smooth transition in stiffness over its length. In the embodiment shown a portion of the shaft material has been removed from the distal portion 516 of shaft 501 in order to provide an exit port for actuation member 512 and to provide a connection member to the proximal end of tubular portion 502. This distal portion 516 may also be flattened, which may assist in creating a similar curvature to that of the tubular portion 502 so that the two portions can be smoothly joined together by welding, soldering, bonding or other appropriate method of fixation. The main body of the shaft may also have an oval or somewhat flattened profile, as this may be beneficial in allowing the user to seal a haemostasis valve around the shaft and a microcatheter when the two are side by side in the guide/sheath as shown previously in Fig. 11a.

30

The reinforcement member 507 may be formed from a metal (such as stainless steel or Nitinol or MP35N or other suitable alloy) or from a high modulus polymer material. In one embodiment (as shown) the reinforcement is formed from a tube from which sections 509 have been cut away to add lateral flexibility while maintaining column and hoop strength.

In the catheter illustrated in Fig. 60 the actuatable seal 504 is located adjacent to the proximal end of the distal tubular section, where it also forms the exit/entry port to the proximal end of the distal tubular section 502, but it could be positioned more distally in other variants of the invention. Once the catheter has been advanced to a position proximal of or adjacent the target clot the seal can be actuated to effect a seal between the proximal portion of the tubular section of the RX clot removal catheter and the inner lumen of the guide catheter. A vacuum force can then be applied to the proximal end of the guide catheter using a syringe or pump. This vacuum force will create a low pressure region inside the guide catheter which will extend (via the seal) into the distal tubular portion of the RX clot removal catheter. This low pressure will create a pressure gradient at the tip of RX clot removal catheter which will encourage the flow of clot into the catheter.

In some scenarios, such as when retrieving a firm clot with a high fibrin content, it may not be possible to aspirate the clot fully into and through the RX clot removal catheter, and the clot may become lodged at the tip of the catheter. In such a case it may be necessary to remove the RX clot removal catheter with the clot through the guide catheter and out of the patient. It may be desirable to create reverse flow in the cerebral vasculature during this retrieval process in order to prevent the escape and distal migration of any fragments of the clot being retrieved. This can be done by disengaging the RX clot removal catheter seal so that the low pressure zone is redirected into the distal lumen of the guide catheter. Thus pressure gradient between the blood in the cerebral vasculature and the fluid within the guide catheter lumen causes a flow of the blood from the high pressure region to the low pressure region. The seal as shown can also serve to create a guiding feature to assist the advancement of another device into the tubular distal section of the clot removal catheter. This might be advantageous if for example the catheter was used as a primary clot debulking tool - so that it was advanced to a target clot and aspiration was applied to it through the guide catheter to remove the occlusive clot but was not successful in removing all of the clot. In this case a microcatheter (and guidewire if desired) could be advanced through the RX clot removal catheter and across the remaining clot so that a thrombectomy device could then be advanced through the microcatheter. The thrombectomy device and remaining clot could then be withdrawn into the RX clot removal catheter (under aspiration if desired) to complete the recanalisation of the patient's vessel.

Figures 61a – 61c illustrate a method of use of the RX clot removal catheter 500. This catheter can be used in a similar manner and for a similar purpose to catheter 101 illustrated previously in figures 10 and 11, except that the seal / flow restrictor of catheter 500 can be selectively activated or deactivated by the user. The catheter can be used as the primary clot retrieval device as shown in figures 61a-c, or as an adjunctive device as shown in figures 11a-d. Fig. 61a shows the catheter 500 advanced through a guide catheter 550 towards a target clot 555 located in blood vessel 554. In this case the catheter 550 has an external flow restrictor in the form of a balloon at its distal end.

10 The method of use of such a system could entail: Accessing the patient's vasculature using standard methods, advancing a guiding catheter or sheath 550 to a region proximal of the target occlusive clot 555, advancing the RX clot removal catheter 500 through the guide/sheath to a location proximal or adjacent to or within the target clot as shown in Fig. 61a (which may be achieved with the aid of a microcatheter and/or guidewire and/or thrombectomy device),
 15 activating the proximal flow restrictor/seal 504 of the catheter 500 to connect the lumens of the two catheters, inflating the external balloon (if present and if desired) at the end of the guide/sheath, aspirating using a syringe 556 or vacuum pump (not shown) through the a connector 551 attached to the proximal end of the guide/sheath 550 so that a pressure gradient is created which sucks blood and clot into the mouth 503 of the Rx clot removal catheter 500 and
 20 through the catheter 500 and the guide/sheath 550 and into the syringe as shown in Fig. 61b. If any clot remains caught in the end of the catheter tip 503 (as may happen if the clot has a significant organized fibrin component such as may occur in clots originating from a heart valve or an atrial appendage for example) it may be necessary to withdraw the catheter 500 and the trapped clot 555 together through guide/sheath 550 and out of the patient as shown in Fig. 61c.
 25 In such a scenario the flow restrictor/seal 504 may be de-activated so as to enable a vacuum force applied by the syringe to the guide/sheath to be transmitted to the distal end 553 of the guide/sheath and thus create flow reversal and draw blood and any clot fragments 557 back into the tip of the guide/sheath as the captured clot is retracted.

30 Fig. 62 depicts another system of this invention which functions in a similar manner to the previously described Rx catheter systems, but in this case the flow restrictor or seal between the inside of the guide/sheath 600 and the outside of the Rx catheter 603 is created by a sealing element 602 attached to the inside of the guide/sheath 600. This sealing element 602 may

comprise an inflatable balloon, similar to the external flow restricting balloon 601 shown on the outside of the guide/sheath.

Fig. 63 depicts another system of this invention in which an Rx clot retrieval catheter 650 has
5 two flow restrictor / seal elements 651 and 652. The more proximal restrictor 651 is used to restrict flow between the Rx catheter 650 and the guide catheter 655 within which it is positioned, while the more distal restrictor 652 is used to create a flow restriction within vessel 656. The combination of these two flow restrictors means that a vacuum or negative pressure can be applied to the proximal end of guide catheter 655 and transmitted to the distal end of Rx
10 catheter 650 in such a way that any blood aspirated into the mouth of Rx catheter 650 is not supplied from the body of blood proximal to seal 652 in vessel 656.

This system enables a physician to use a standard guide or sheath to rapidly create an access path to the region of the target occlusion, and then use the Rx catheter 650 to quickly access and
15 aspirate the target clot from the vessel. This system provides a major advantage in the speed and ease with which a physician will be able to access and retrieve the clot. The provision of the distal vessel seal 652 on the Rx catheter rather than on the guide or sheath means that this seal can be placed more distally in the vasculature, past the petris portion of the carotid vasculature when used in the ICA for example, which means less likelihood of vessel collapse when a
20 suction force is applied, and less likelihood of vessel spasm.

In a preferred embodiment the flow restrictors / seals are actuatable and are formed from compliant balloons, which are inflated via a hollow shaft 657 by means of a syringe or inflator 653 applied to handle 654 of the Rx catheter 650. In other embodiments the proximal flow
25 restrictor may be passive (i.e. it cannot be selectively activated or inactivated) as shown in several other designs in this disclosure. In yet other embodiments the distal seal may be actuated by means of an actuating member rather than an inflation lumen.

Most of the Rx (rapid exchange) catheters disclosed herein share some common features and
30 geometry. Taking catheter 500 of Fig. 60 as an example: They have a distal generally tubular portion 502 comprising an inner lumen which starts with an opening or entry/exit port 517 and ends in a distal tip or mouth 503 into which clot is received. They have a proximal elongate shaft 501 which is connected at its distal end to the entry/exit port 517 and at its proximal end in some embodiments to a handle 513. The preferred geometry of these catheters depends on the target

clot location. For clots located in the anterior or posterior cerebral anatomy the distal tubular portion 502 is preferably greater than 10cm (so that it can extend from within the distal end of a guide/sheath which may be located in an internal carotid artery or a vertebral artery, right up to the proximal face of a target clot), and less than 40cm so that the minimum possible length of tubular portion 502 is located within the lumen of the guide/sheath, thus maximising the internal volume of the combined guide/Rx catheter system for optimum aspiration efficacy).

The optimal internal and external diameters of the Rx catheter depends very much on the site of the target clot and the size of the guide catheter or sheath through which the catheter is to be advanced. In the case of retrieval of occlusive clots from cerebral vessels the likely vessel diameters range from approximately 1.5mm up to 6mm, with 3mm being a very typical diameter. Guide catheters / sheaths used in these scenarios have typically an internal diameter of between 0.060" and 0.095", so that a suitable system might consist of a guide catheter with an internal diameter of 0.078" and an Rx clot retrieval catheter whose distal tubular section has an outside diameter of 0.070" and an inside diameter of 0.062". Such a system provides a very significant benefit in terms of flow resistance over an equivalently sized conventional combination of a guide and intermediate/aspiration (not rapid exchange) catheter. In particular the effective proximal lumen of the system of this invention is that of the guide catheter (0.078"), while the effective proximal lumen of the conventional system would be that of the intermediate/aspiration catheter (0.062"). This results in a significantly lower flow restriction in the Rx system of the invention, which means that for a given vacuum / suction force applied to the proximal end of the system, a much greater flow will be created through the system of this invention. While a conventional (not rapid exchange) intermediate/aspiration catheter may be stepped in diameter to maximise its proximal internal diameter, this proximal internal diameter must always be significantly smaller than the guide/sheath in which it is positioned. This is not the case in the system of this invention.

Yet another embodiment of this invention is shown in Figures 64a-d, which depict a distal end configuration which could be employed with any of the clot retrieval catheters previously shown. The catheter distal end 700 has an integrated control member 701, which forms a loop 704 at the tip where it is connected to tip members 703 so that it acts like a draw string when pulled. The tip may comprise relatively stiff members 703 interspersed with relatively compliant members 702, so that the tip has both axial stiffness (to permit effective operation of the drawstring mechanism) and radial compliance (to allow expansion and contraction of the tip).

Therefore when actuated by pulling as shown in Fig. 64b, the control member causes the tip of the catheter to reduce in diameter. This can improve the ability of the catheter to track through tortuosity and across obstacles such as the origin of the ophthalmic artery.

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Similarly when the control member is pushed forward it can cause or allow the catheter tip to expand forming a funnel shape as shown in Fig. 64c. This can improve the ability of the catheter to aspirate clots and also act as a flow restrictor in the vessel.

- 10 In use the control member may be pulled back during insertion of the catheter to improve accessibility. It can then be forwarded to increase the diameter of the tip and aspirate the occlusion.

- If the occlusion or blood clot can only be partially aspirated, then the tip diameter can be reduced
15 again by pulling the control member, causing the clot to be trapped as shown in Fig. 64d, reducing the risk of the clot travelling to a new territory during retraction of the catheter and improving dislodgement.

- The flaps 703 of the catheter tip are not rigidly connected to the integrated control member 701
20 but form a loop which can slide over the control member. The control member distal end 706 may also be fixed to the inner surface of the catheter.

- Referring to Fig. 65 there is illustrated an aspiration catheter 801 according to this invention in use in a thrombectomy procedure. The catheter 801 is similar to catheter 101 of Figs 10 and 11
25 and provides a proximal seal 802 against a guide catheter inner lumen 803 so that aspiration applied by syringe 811 (or a pump or by other means) through guide catheter 808 (via a rotating haemostasis valve (RHV) 814) can be transferred through to the distal end 812 of the aspiration catheter. Thrombectomy device 800 is shown deployed within clot 810, having been delivered through microcatheter 809 by means of proximal shaft 807. The method of use of the system
30 illustrated is very similar to that described in Figs 11a-d, except that in this embodiment the proximal end 815 of the microcatheter 809 and proximal end 806 of Rx aspiration catheter 801 are positioned within separate branches of a rotating hemostasis valve (RHV) 813. This configuration provides significant ease of use advantages over the configuration described in Fig. 11. In particular the RHV 813 can be more easily sealed around the proximal shaft 806 of the

aspiration catheter to prevent any air ingress (or fluid leakage) during aspiration. In addition the user has better control over the aspiration catheter 801, microcatheter 809 and thrombectomy device 800 relative to the guide catheter 808, and can use RHVs 813 and 814 to lock and hold the aspiration catheter or microcatheter independently of each other.

5

One embodiment of the method of use of such a system could consist of the following steps:

Accessing an arterial blood vessel of a patient using conventional means such as an introducer and guide catheter 808 and/or sheath, advancing Rx aspiration catheter 801 through a first branch of RHV 813 attached to proximal end of guide catheter 808, advancing a microcatheter 809
10 through a second branch of RHV 813 and through the aspiration catheter 801 and guide catheter 808 up to and across a target occlusive clot 810 with or without the aid of a guidewire, removing the guidewire (if used) and advancing a mechanical thrombectomy device 800 such as a stent-retriever through the microcatheter 809 to the target clot 810, retracting the microcatheter 809 at least a few cm to deploy a mechanical thrombectomy device 800 within the clot 810, advancing
15 the aspiration catheter 801 up to a position just proximal of the clot 810 (or within the clot, or considerably proximal of the clot if vessel disease or tortuosity makes access difficult), optionally creating flow arrest by inflating the balloon of the guide catheter 808 (if used, or by other means), aspirating through the aspiration catheter 801 using a syringe 811 or pump connected to the guide catheter 808 while withdrawing the mechanical thrombectomy device 800
20 towards and into the distal mouth 812 of the aspiration catheter 801, withdrawing the clot 810, mechanical thrombectomy device 800 and microcatheter 809 through the aspiration catheter 801 and guide catheter 808 and out of the patient while continuing to aspirate.

A possible variant of the final step of the above method could involve removing the aspiration
25 catheter along with the clot 810, mechanical thrombectomy device 800 and microcatheter 809. This variant is useful if a large and/or firm clot is encountered which the physician cannot (or does not wish to) fully withdraw into the mouth of the aspiration catheter. In such a situation the RHV 813 must be removed once the exit port 805 of the aspiration catheter 801 reaches the RHV 813.

30

Another method of use of such an Rx aspiration catheter system is to retrieve clot using aspiration without the use of a thrombectomy device. The rapid exchange shaft of this invention provides great advantages in terms of speed, deliverability, ease of use and aspiration lumen. A microcatheter or other similar catheter and guidewire may be used to provide support to assist in

tracking the aspiration catheter to the target site in a similar manner to that illustrated in either Fig. 65 or Figs 11a-d.

It will be apparent from the foregoing description that while particular embodiments of the present invention have been illustrated and described, various modifications can be made without departing from the spirit and scope of the invention. For example, while the embodiments described herein refer to particular features, the invention includes embodiments having different combinations of features. The invention also includes embodiments that do not include all of the specific features described.

The invention is not limited to the embodiments hereinbefore described which may be varied in construction and detail.

Claims

1. A catheter for assisting in the retrieval of a clot from a vessel comprising a distal end and a proximal end, a distal segment and a proximal segment and a lumen extending proximal
5 of the distal end and terminating at a transfer port at the proximal end of the distal segment and a flow restrictor located on the outer surface of the catheter distal of the transfer port.
2. A catheter as claimed in claim 1 wherein the flow restrictor is actuatable between
10 engaged and disengaged configuration.
3. A catheter as claimed in claim 2 comprising an actuator for selectively engaging and/or disengaging the flow restrictor.
- 15 4. A catheter as claimed in claim 2 or 3 wherein the flow restrictor comprises a framework and a membrane coupled to the framework, the framework being movable by the actuator between an expanded configuration and a retracted configuration.
5. A catheter as claimed in any of claims 1 to 4 comprising a proximal flow restrictor distal
20 of the proximal end of the distal segment and a distal flow restrictor spaced distally from the proximal flow restrictor.
6. A catheter as claimed in any of claims 1 to 5 wherein the distal end of the catheter comprises a mouth for reception of clot.
25
7. A catheter as claimed in claim 6 wherein the mouth is defined by an expansile tip.
8. A catheter as claimed in claim 6 or 7 wherein the distal segment includes a hinge adjacent to the distal mouth.
30
9. A catheter as claimed in claim 8 wherein the hinge is defined by a region of the distal segment which is configured to have lateral flexibility.

10. A catheter as claimed in any of claims 6 to 9 wherein the mouth has an expanded configuration and a retracted configuration.
- 5 11. A catheter as claimed in claim 10 comprising a control member for controlling the movement of the mouth between the expanded and retracted configurations.
12. A catheter as claimed in claim 11 wherein the mouth comprises a number of segments and the control member is configured to move at least some of the segments.
- 10 13. A catheter as claimed in claim 12 wherein the control member comprises a drawstring.
14. A catheter for aspirating a clot in a vessel comprising a distal end and a proximal end, a distal segment and a proximal segment and a lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment wherein the
15 distal end of the catheter comprises a mouth for reception of clot.
15. A catheter as claimed in claim 13 having a flow restrictor located on the outer surface of the catheter distal of the transfer port.
- 20 16. A catheter as claimed in claim 15 wherein the mouth is defined by an expansile tip.
17. A catheter as claimed in claim 15 or 16 wherein the distal segment includes a hinge adjacent to the distal mouth.
- 25 18. A catheter as claimed in claim 17 wherein the hinge is defined by a region of the distal segment which is configured to have lateral flexibility.
19. A catheter as claimed in any of claims 15 to 18 wherein the mouth has an expanded configuration and a retracted configuration.
- 30 20. A catheter as claimed in claim 19 comprising a control member for controlling the movement of the mouth between the expanded and retracted configurations.

21. A catheter as claimed in claim 20 wherein the mouth comprises a number of segments and the control member is configured to move at least some of the segments.

5 22. A catheter as claimed in claim 21 wherein the control member comprises a draw string.

23. A catheter as claimed in any of claims 1 to 22 wherein the catheter is an aspiration catheter for aspirating a clot.

10

24. A system for treating an occlusion in a vessel the system comprising:-

a first catheter and a second catheter;

the first catheter comprising a proximal end, a distal end and a lumen extending between the proximal end and the distal end, the lumen of the first catheter further comprising a proximal segment and a distal segment;

15

the second catheter comprising a distal end and a proximal end, a distal segment and a proximal segment, and a lumen, said lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment;

the first catheter being configured to facilitate aspiration through the lumen;

20

the transfer port being configured to transmit aspiration in the proximal lumen of the first catheter into the lumen of the distal segment of the second catheter and the distal end of the second catheter being configured to receive clot into at least a portion of the lumen of the second catheter.

25 25. A system as claimed in claim 24 wherein the second catheter is a catheter as claimed in any of claims 1 to 23.

26. A system as claimed in claim 24 further comprising a flow restrictor between the first catheter and the distal segment of the second catheter, distal of the transfer port.

30

27. A system as claimed in claim 26 wherein the flow restrictor is located on the inner surface of the first catheter.

28. A system as claimed in claim 26 or 27 wherein the flow restrictor is located on the outer surface of the second catheter.
29. A system as claimed in any of claims 26 to 28 comprising a proximal flow restrictor distal of the proximal end of the distal segment of the second catheter and a distal flow restrictor spaced distally from the proximal flow restrictor.
30. A system as claimed in any of claims 24 to 29 wherein the distal end of the second catheter comprises a mouth for reception of clot.
31. A system as claimed in claim 30 wherein the mouth is defined by an expansile tip.
32. A system as claimed in any of claims 24 to 31 wherein the transfer port comprises a rapid exchange port.
33. A system as claimed in any of claims 24 to 32 wherein the first catheter is a guide catheter.
34. A system as claimed in any of claims 24 to 33 wherein the second catheter is an intermediate catheter.
35. A system as claimed in any of claims 24 to 34 further comprising a microcatheter which is adapted to be advanced through the first catheter and the second catheter.
36. A system as claimed in claim 35 further comprising a clot engaging device for delivery from the microcatheter.
37. A system as claimed in claim 33 wherein the guide catheter is mounted in a proximal rotating haemostasis valve through which aspiration is applied.

38. A system as claimed in claim 35 or 36 wherein a proximal end of the microcatheter and a proximal end of the aspiration catheter are locatable within separate branches of a proximal rotating haemostasis valve.
- 5 39. A method of removing a clot from a vessel, the method comprising:-
providing a guide catheter and an intermediate catheter, the intermediate catheter having a distal mouth and being configured such that it is advancable within the lumen of the guide catheter;
inserting the guide catheter into a first vessel proximal of an occlusion;
10 advancing the intermediate catheter through the lumen of the guide catheter until the tip of the intermediate catheter extends distal of the guide catheter into a second vessel adjacent to the occlusion;
applying aspiration to the proximal end of the guide catheter;
the intermediate catheter being configured to direct said aspiration through the
15 distal lumen of the intermediate catheter to aspirate the clot into the mouth of said intermediate catheter.
40. A method as claimed in claim 39 wherein the aspiration catheter comprises a distal end, a proximal end, a distal segment, a proximal segment and a lumen extending proximal of
20 the distal end and terminating at a transfer port at the proximal end of the distal segment.
41. A method as claimed in claim 39 or 40 comprising restricting flow between the outside surface of the intermediate catheter and the inside surface of the guide catheter.
- 25 42. A method as claimed in any of claims 39 to 41 comprising the step, before or after aspiration, of delivering a microcatheter to the occlusion and deploying a clot capture device from the microcatheter.
- 30 43. A method as claimed in claim 42 comprising advancing the microcatheter to the clot, deploying a clot capture device from the microcatheter, retracting the microcatheter to a location proximal of a transport port at the proximal end of a distal segment of the aspiration catheter.

44. A method of removing an occlusion from a vessel comprising:-

providing a first aspiration catheter and a second aspiration catheter, the second aspiration catheter extending distal of the first aspiration catheter and further comprising a transfer lumen proximal of the distal end of the first aspiration catheter;

inserting the first catheter into a first vessel proximal of the occlusion;

advancing the second catheter through the lumen of the first catheter until the tip of the second catheter extends distal of the first catheter into a second vessel and is substantially opposing the occlusion; and

aspirating through the proximal lumen of the first catheter so as to urge the clot into the distal lumen of the second catheter.

45. A method as claimed in claim 44 comprising restricting flow between the outside surface of the second catheter and the inside surface of the first catheter.

46. A method as claimed in claim 44 or 45 comprising the step, before or after aspiration, of delivering a microcatheter to the occlusion and deploying a clot capture device from the microcatheter.

47. A method as claimed in claim 46 comprising the step, prior to aspiration, of retracting the microcatheter to a location proximal of the transfer port.

48. A method as claimed in any of claims 44 to 47 wherein the first aspiration catheter is a guide catheter.

49. A method as claimed in any of claims 44 to 48 wherein the second aspiration catheter is an intermediate catheter.

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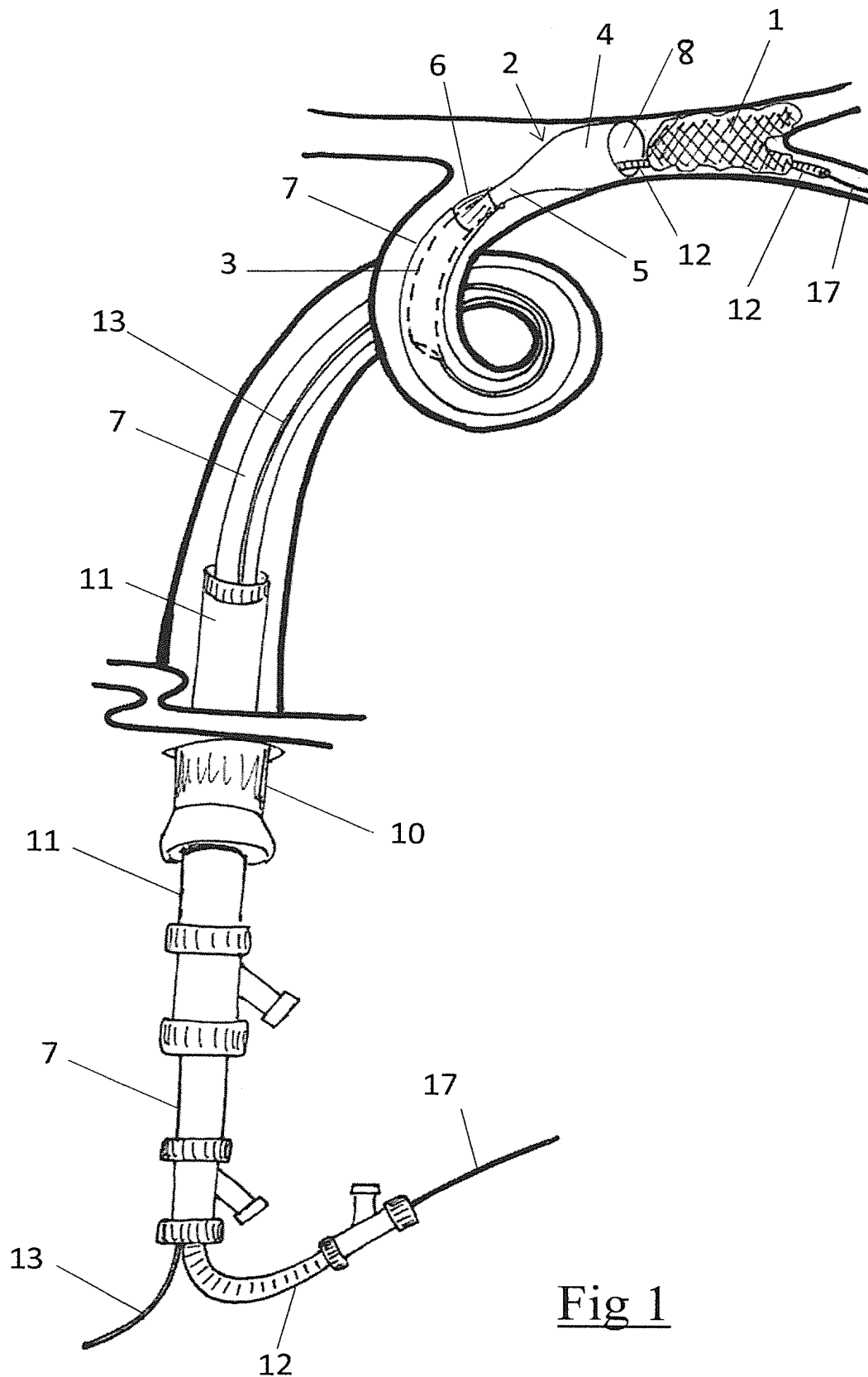


Fig 1

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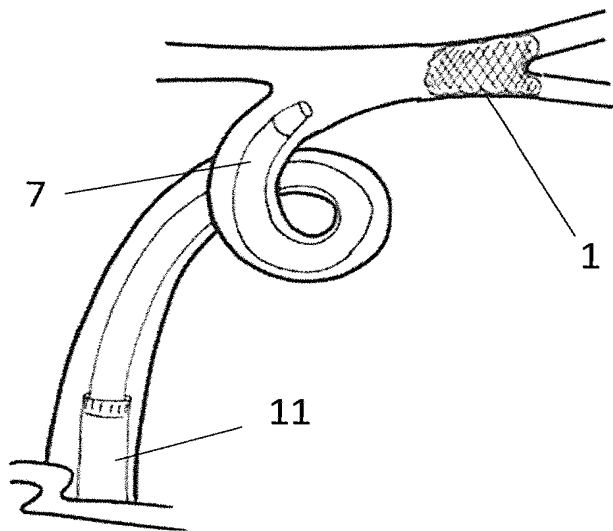


Fig 2a

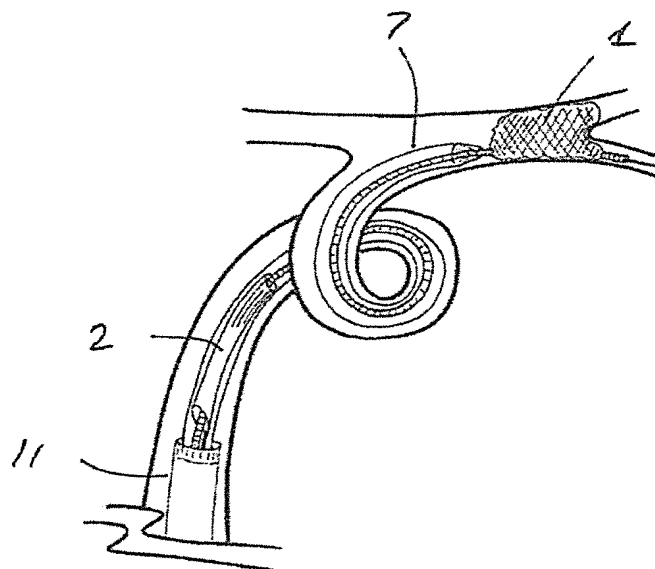


Fig 2b

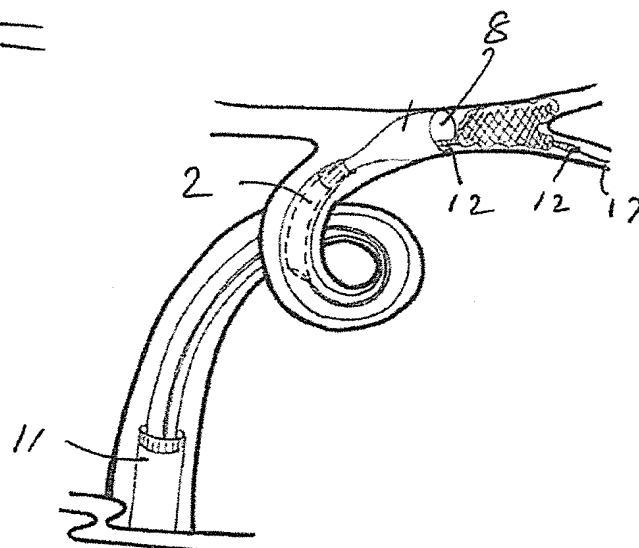


Fig 2c

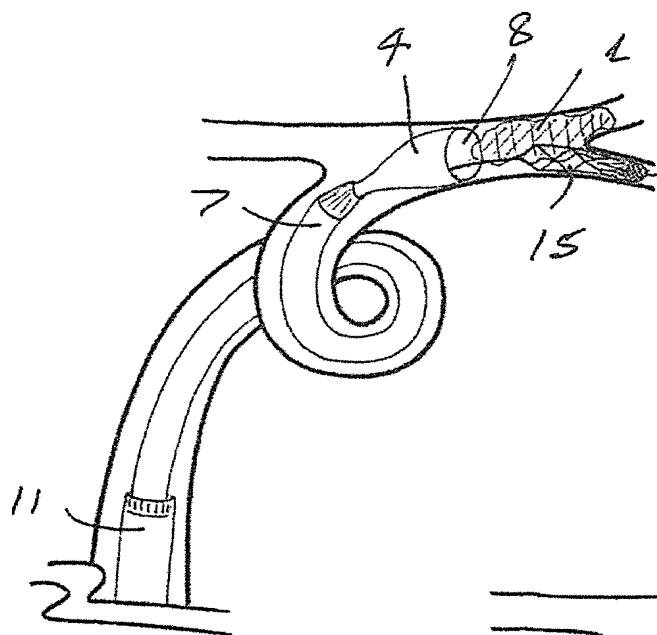


Fig 2d

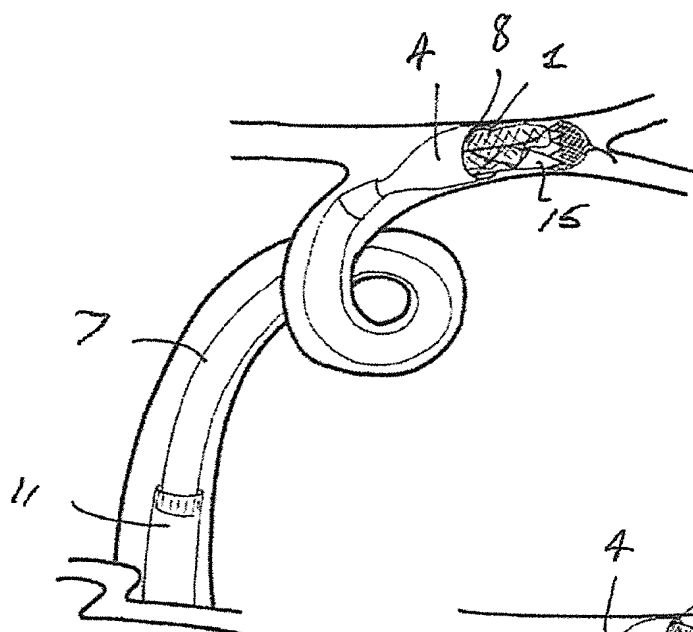


Fig 2e

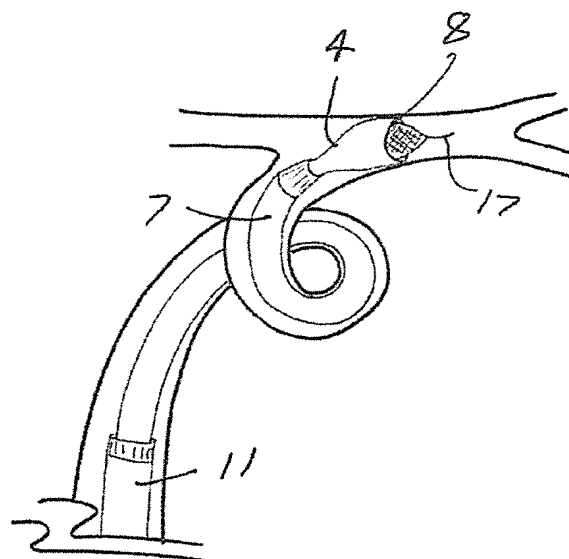


Fig 2f

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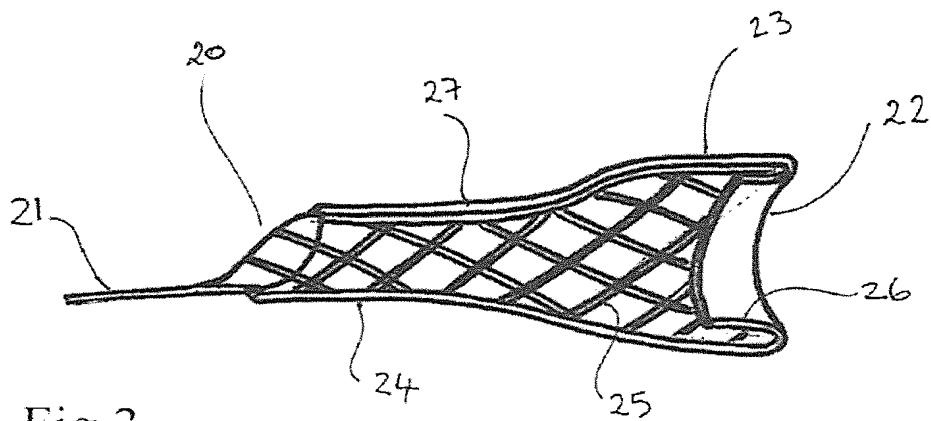


Fig 3

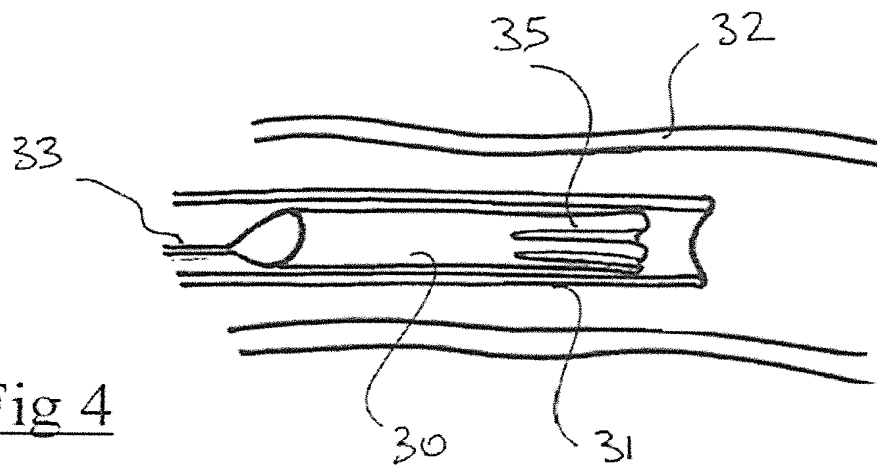


Fig 4

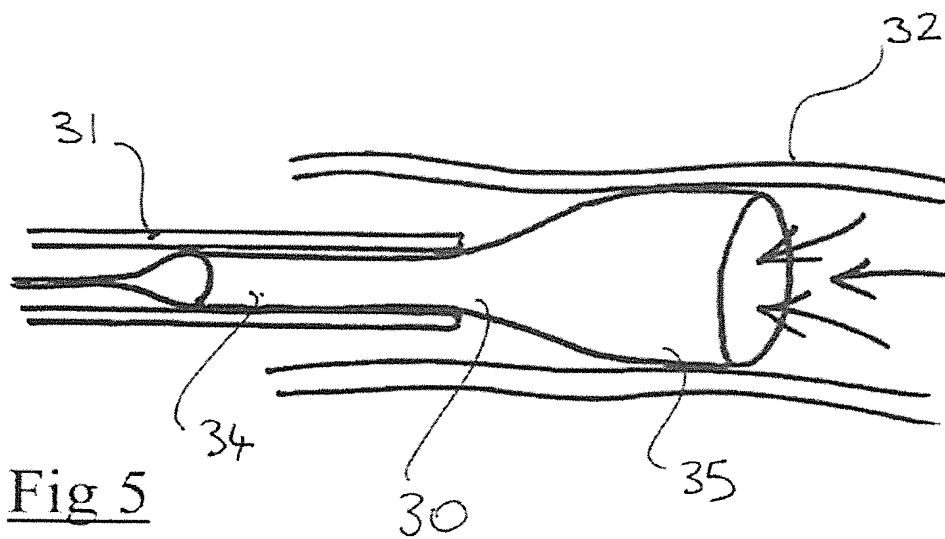


Fig 5

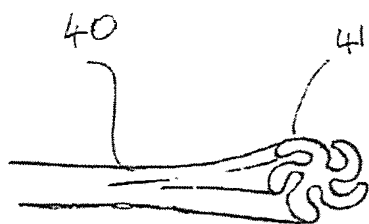


Fig 6a

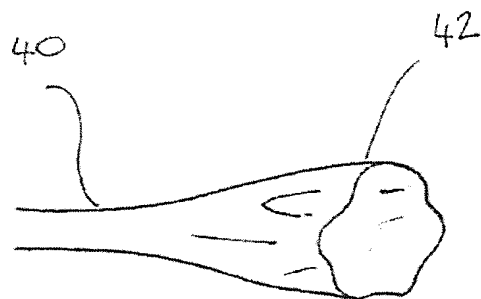


Fig 6b



Fig 7a

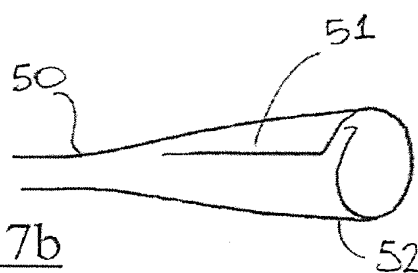


Fig 7b



Fig 8a

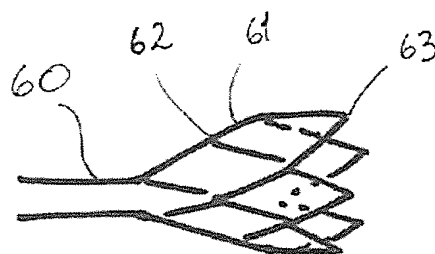


Fig 8b

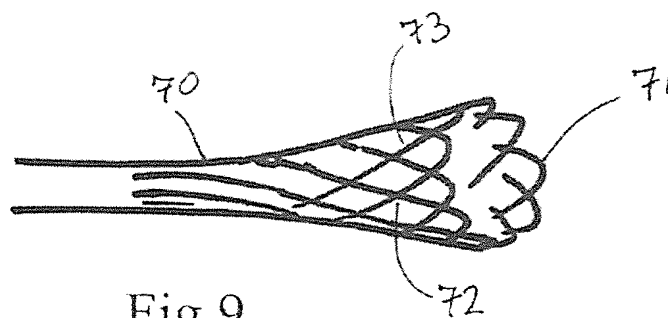
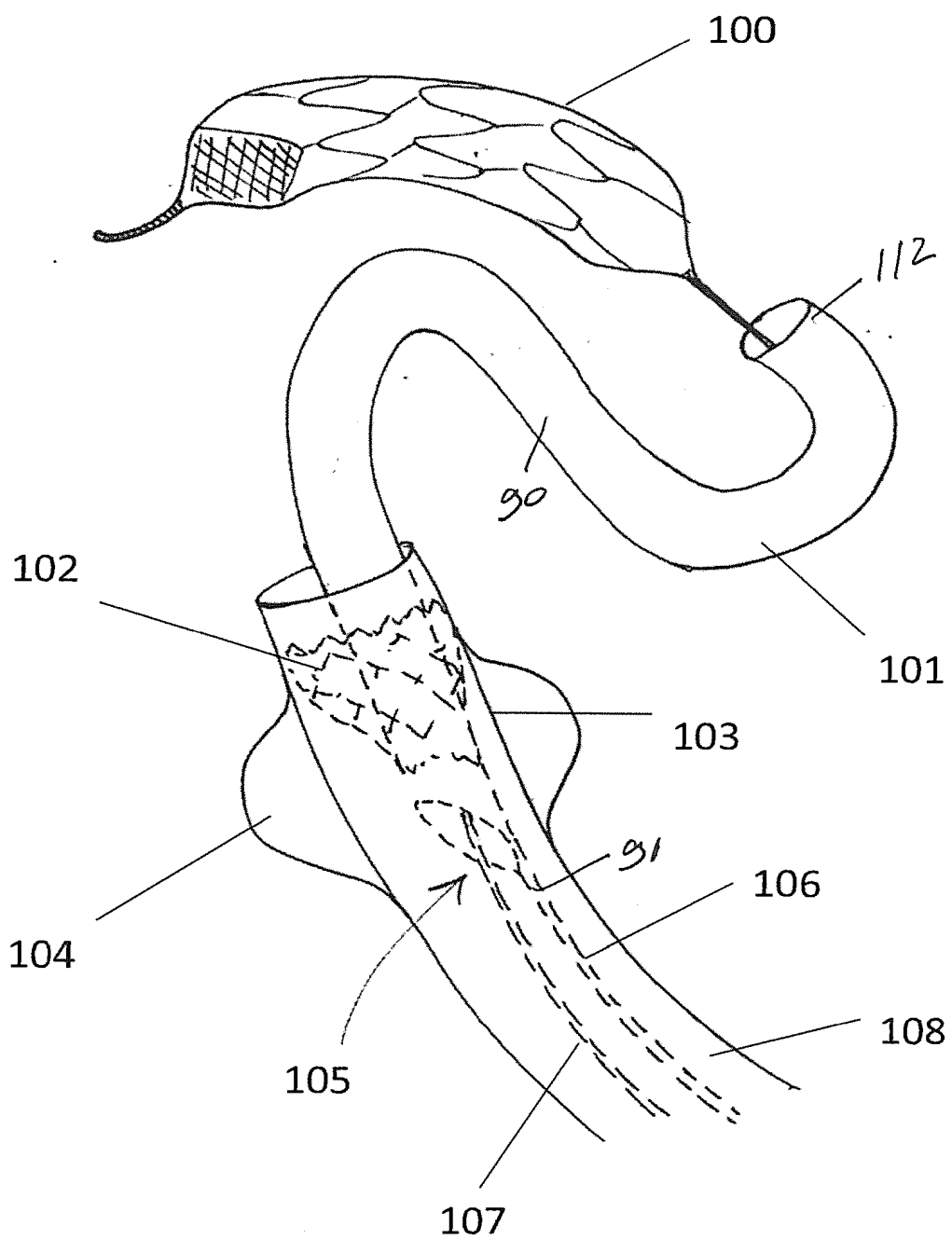


Fig 9

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Fig 10

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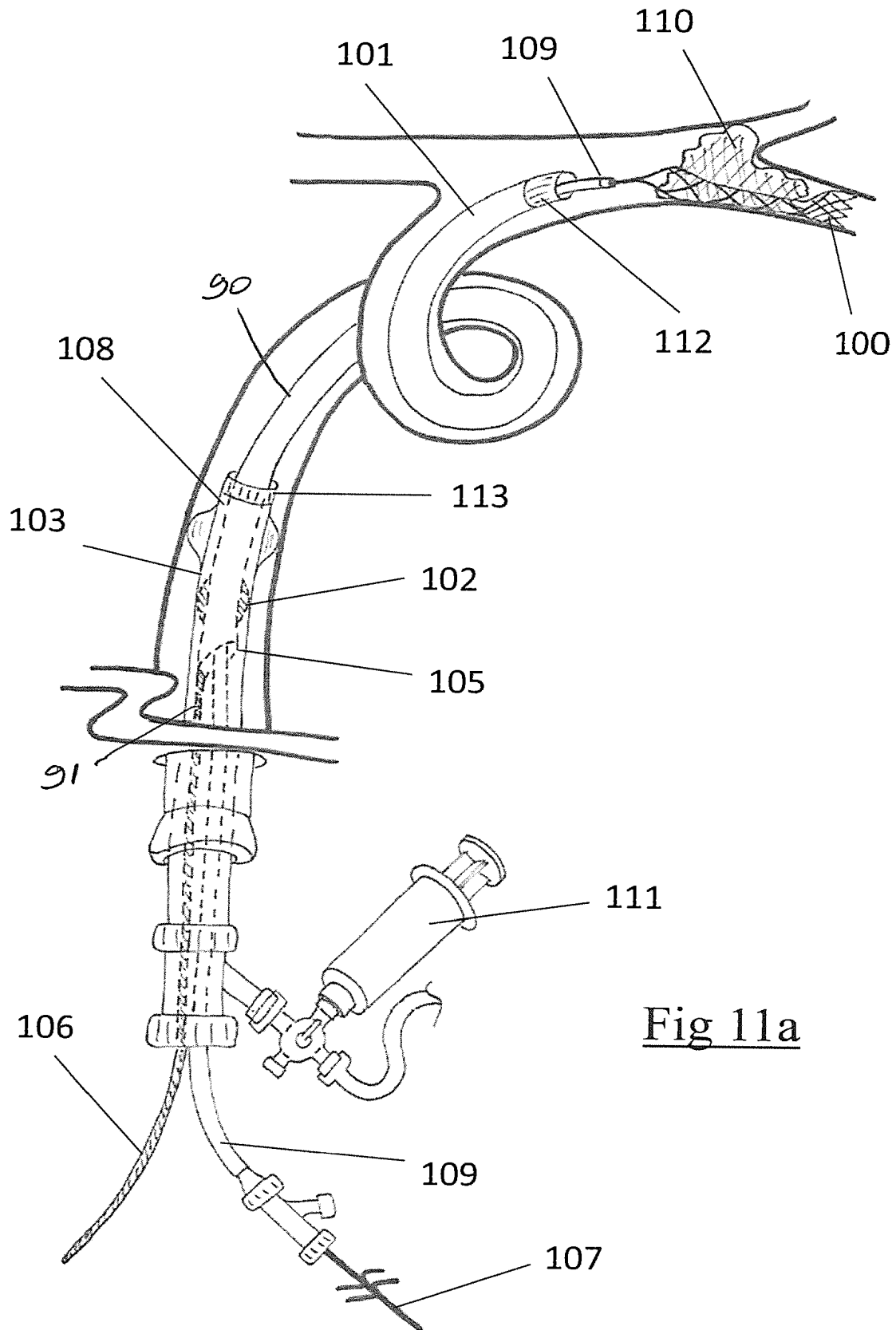


Fig 11a

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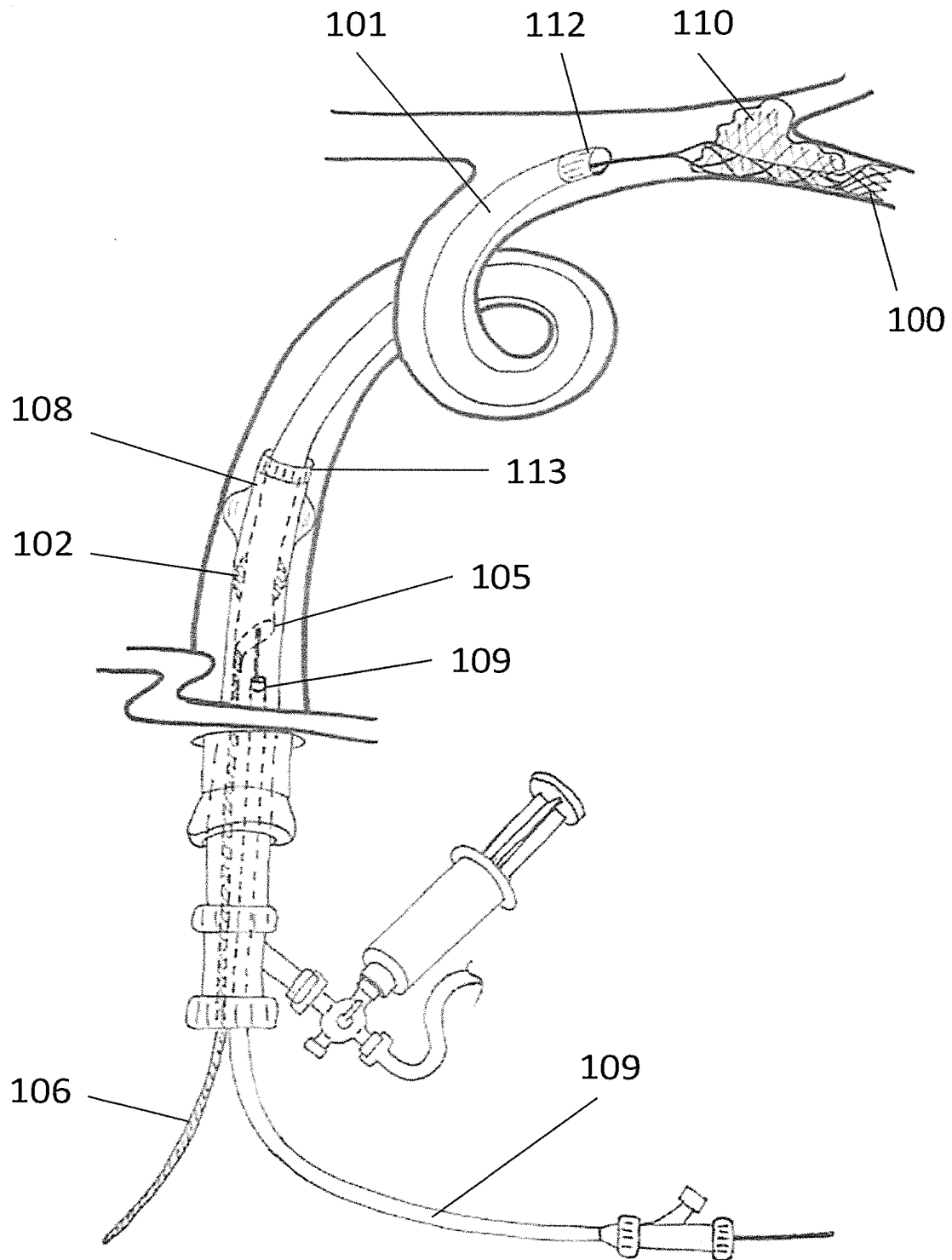
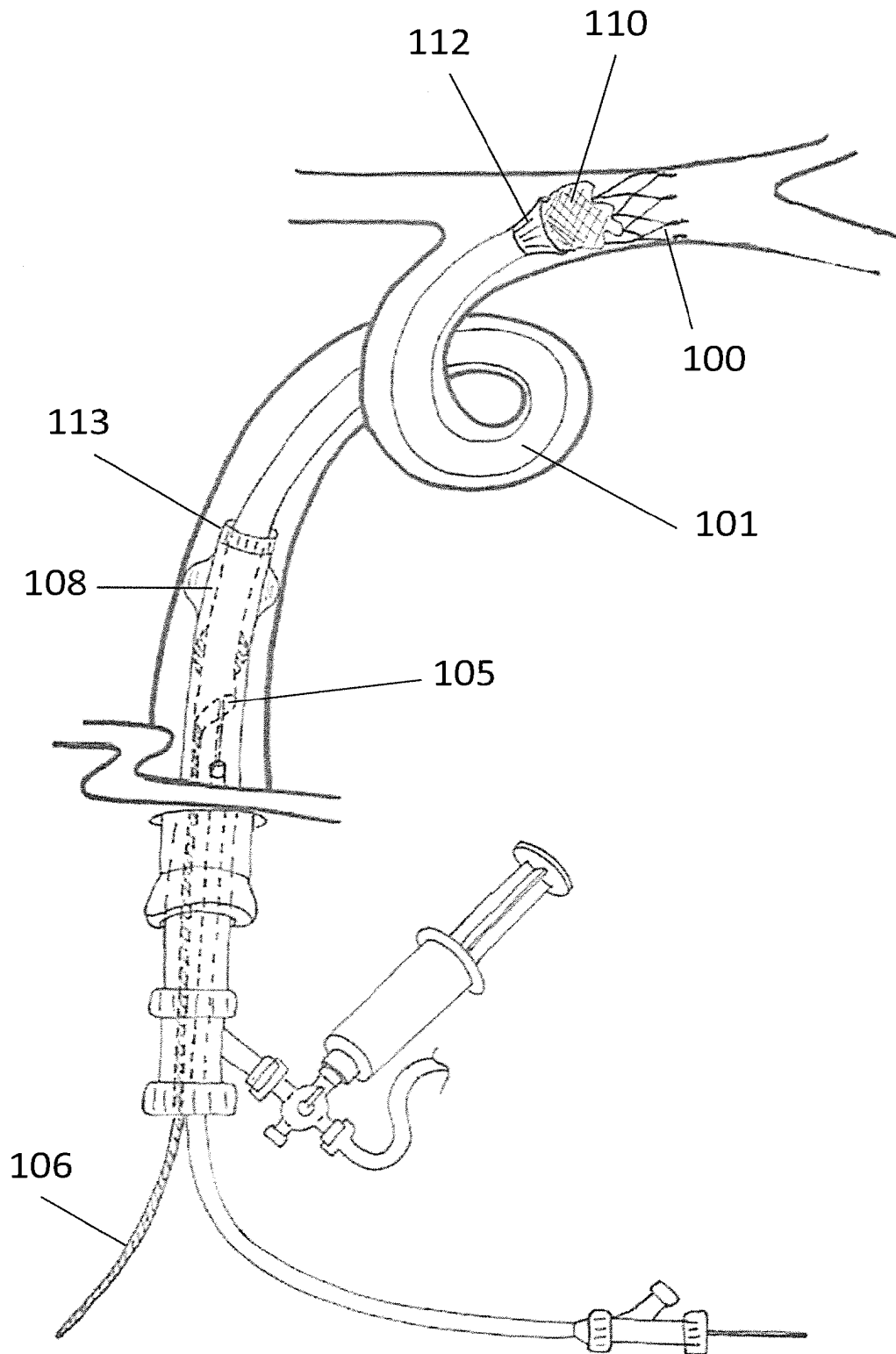
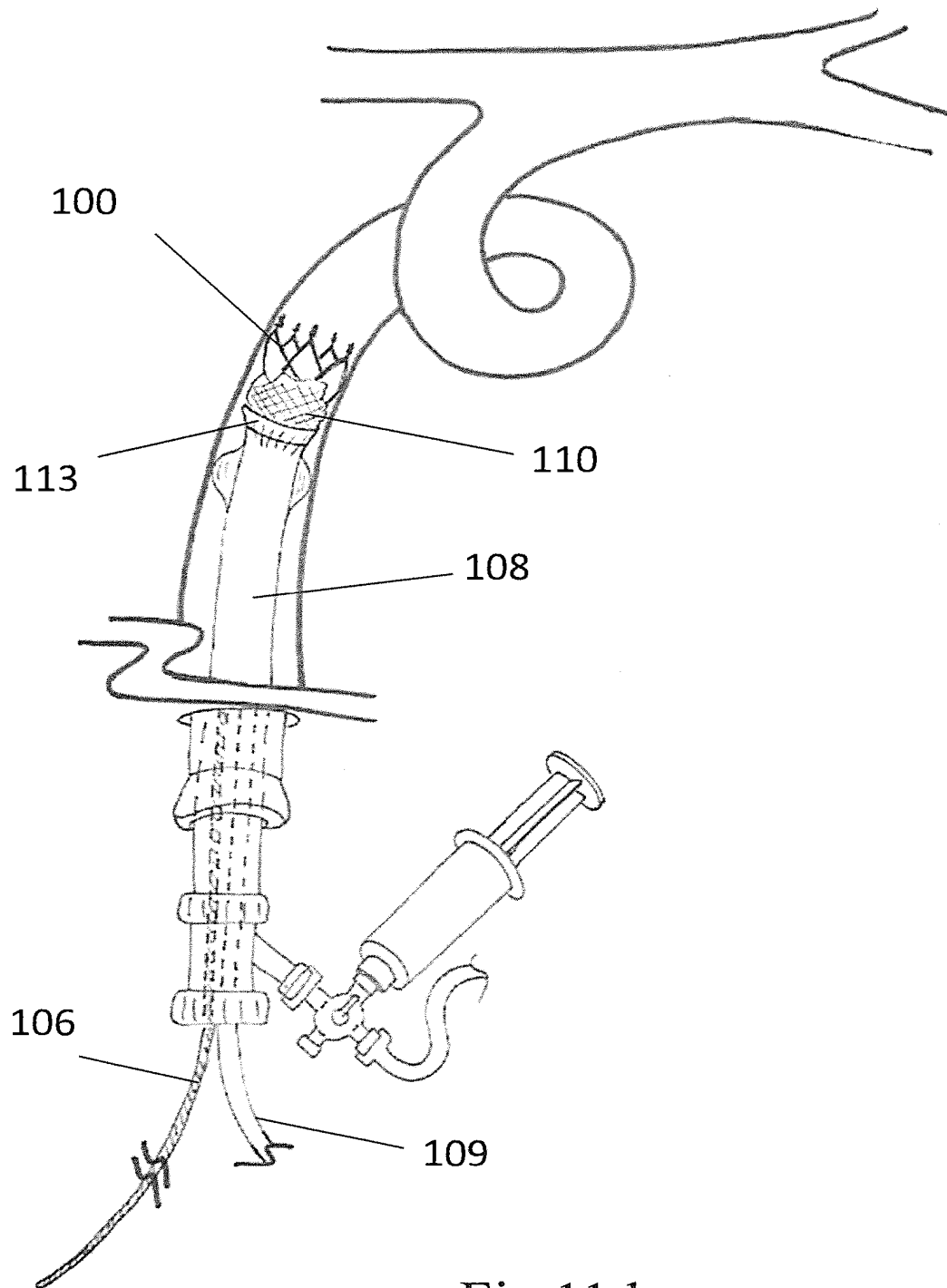


Fig 11b

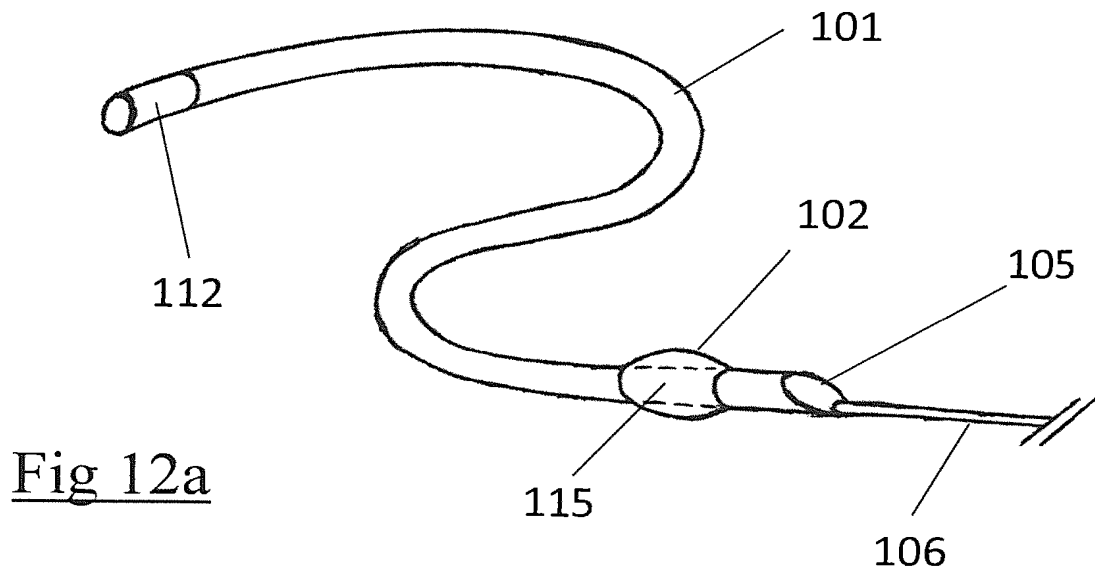
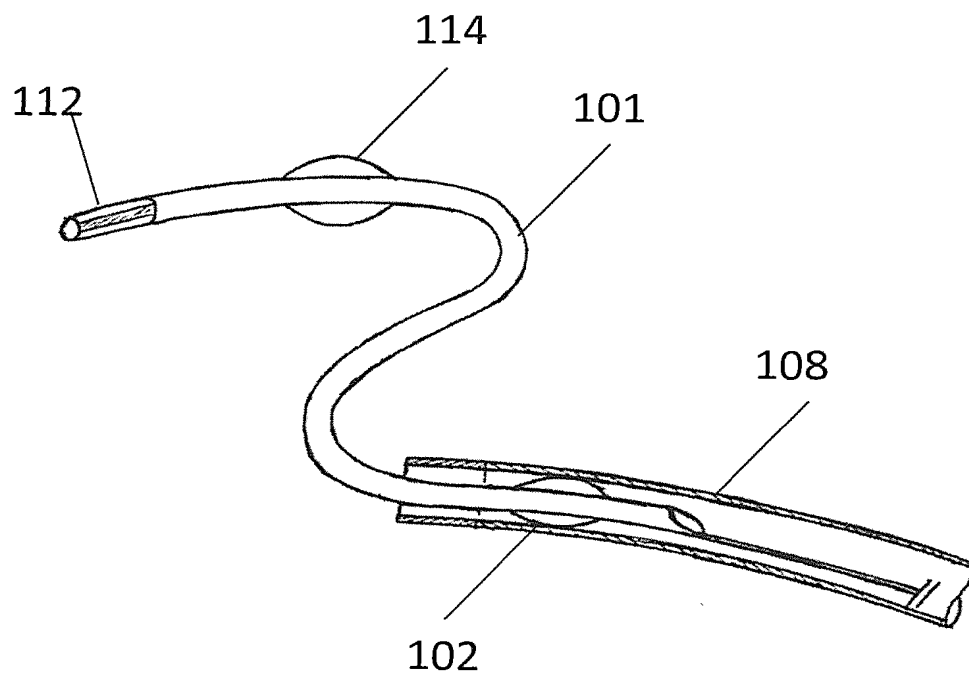
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Fig 11c

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Fig 11d

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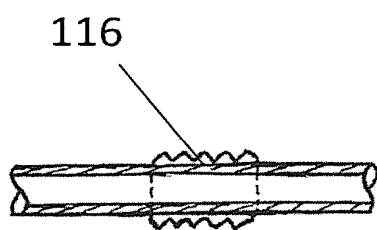


Fig 13a

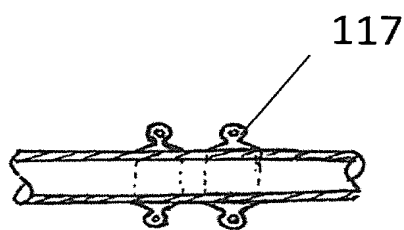


Fig 13b

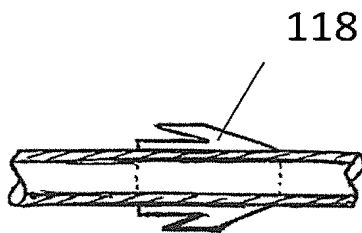


Fig 13c

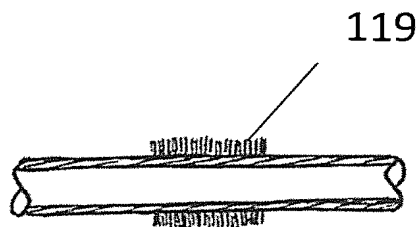


Fig 13d

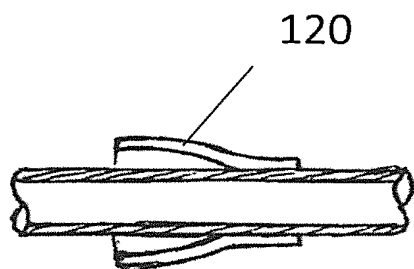


Fig 13e

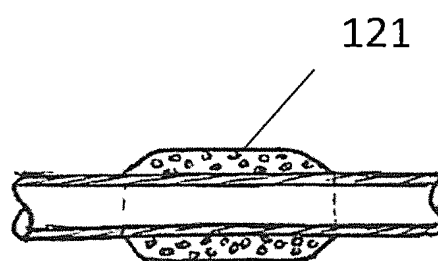


Fig 13f

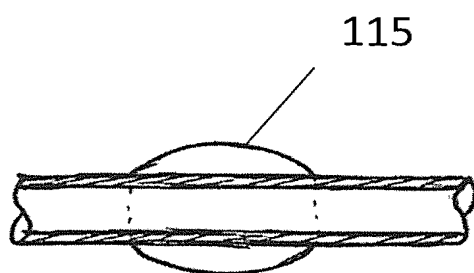


Fig 13g

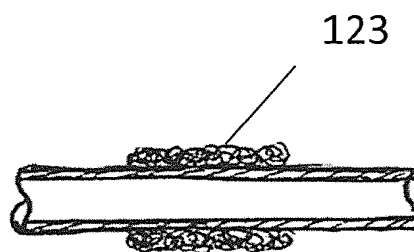


Fig 13h

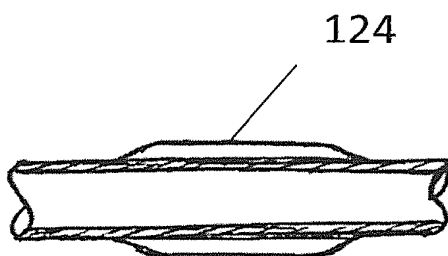


Fig 13i

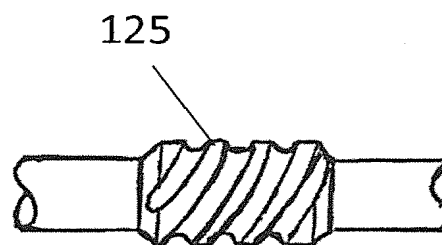


Fig 13j

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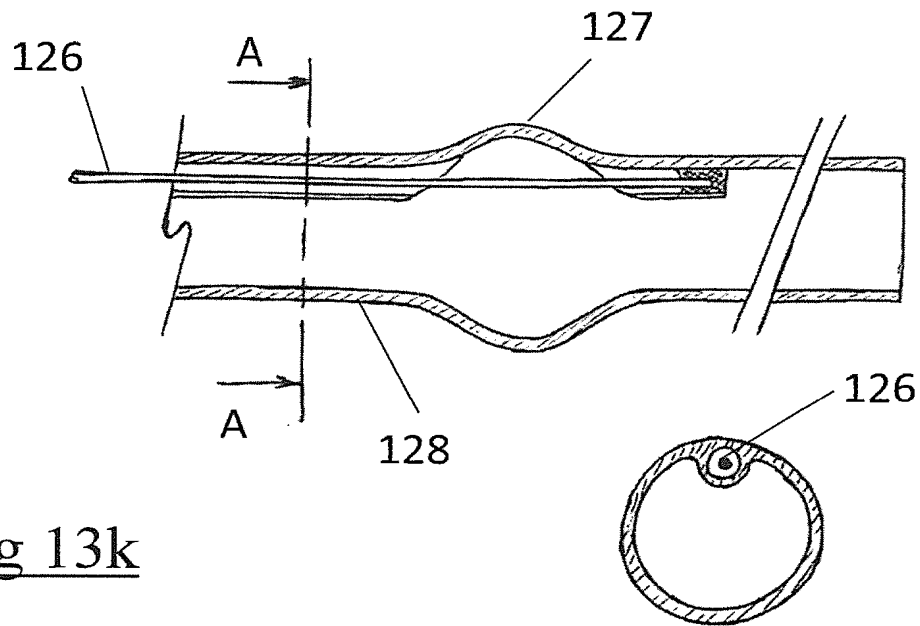


Fig 13k

Fig 13L

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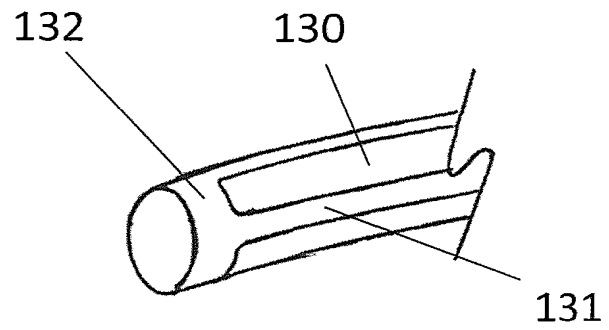


Fig 14

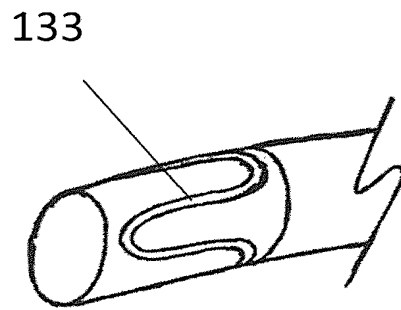


Fig 15

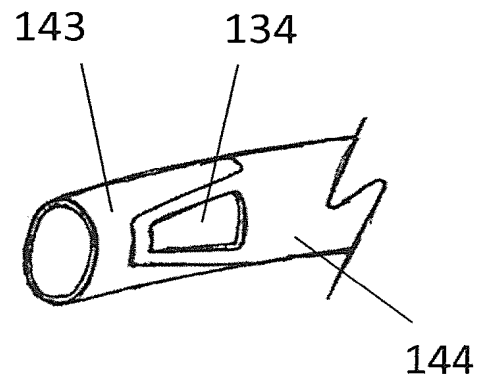


Fig 16

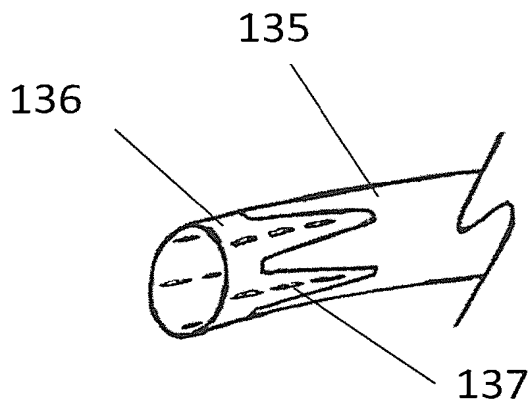
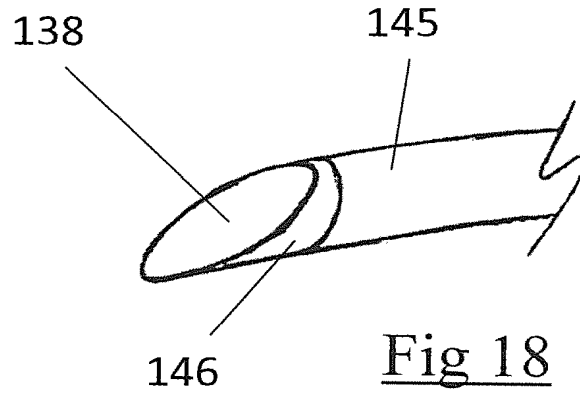
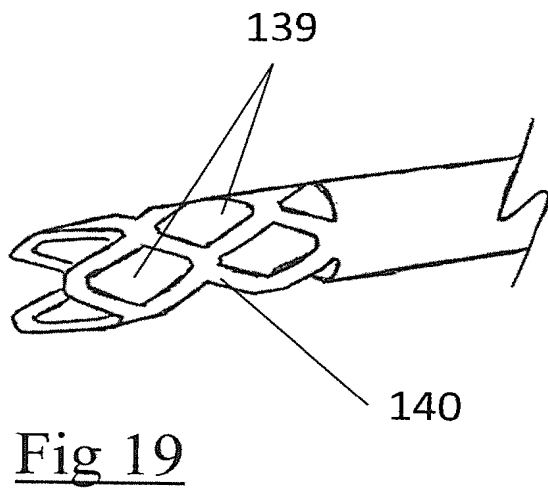
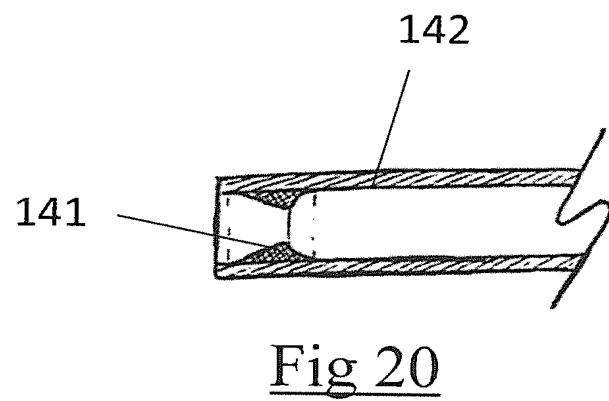
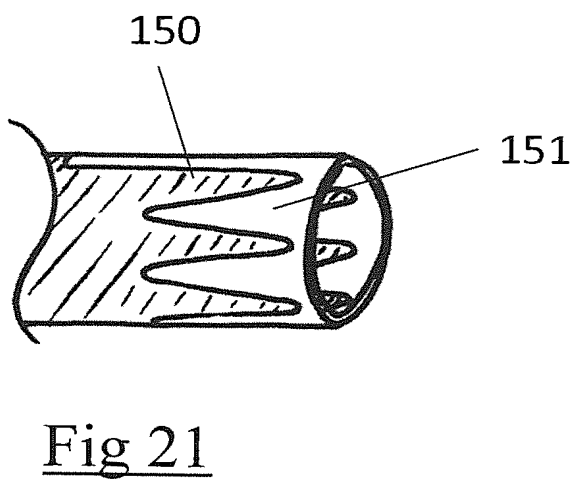


Fig 17

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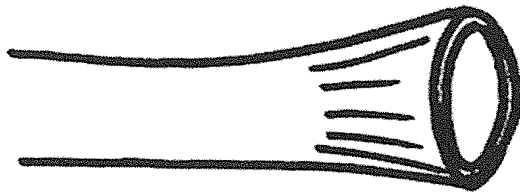


Fig 22a

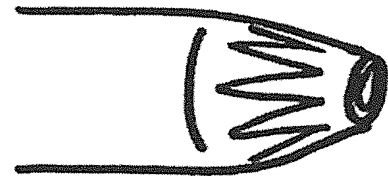


Fig 22b

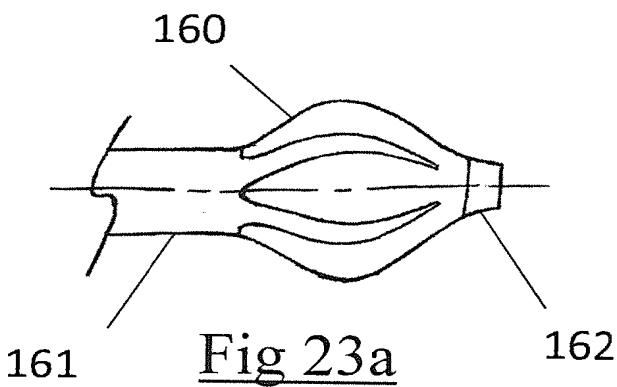


Fig 23a

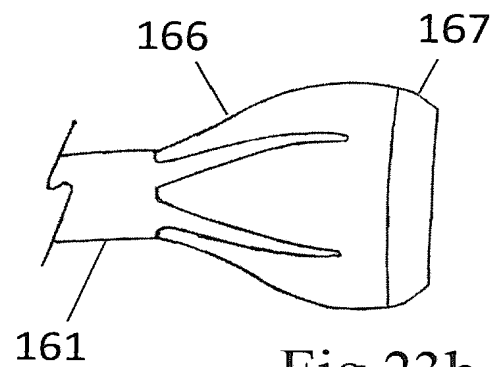


Fig 23b

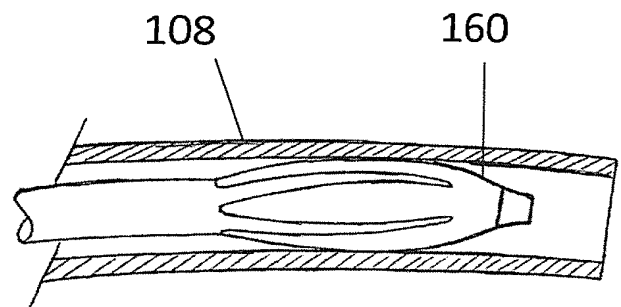


Fig 23c

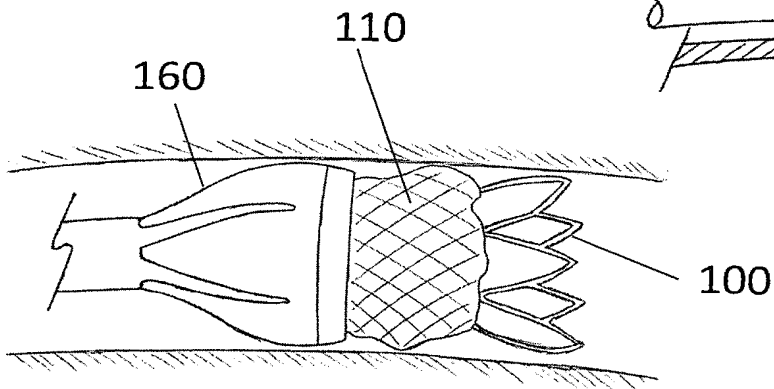


Fig 23d

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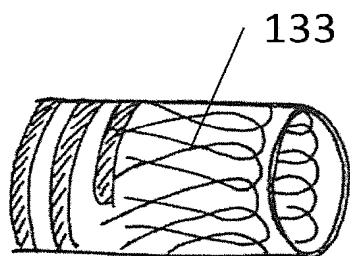


Fig 24

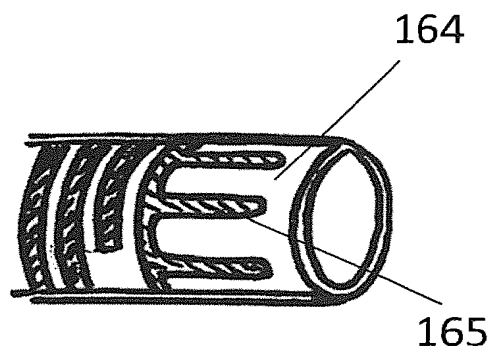


Fig 25

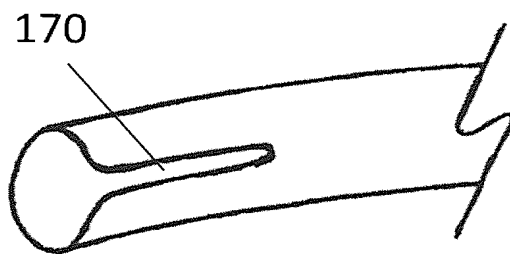


Fig 26

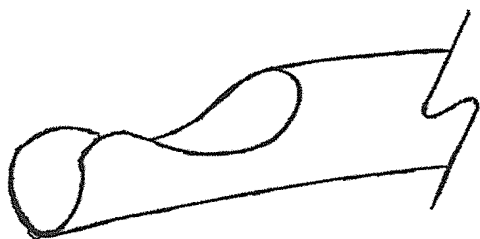


Fig 28



Fig 27

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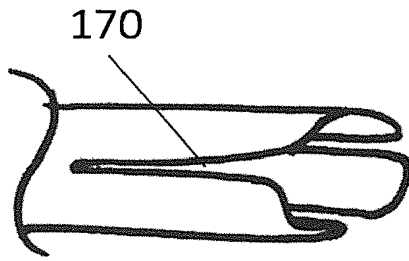


Fig 29

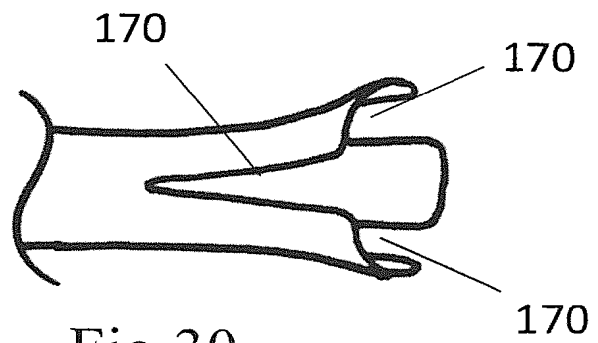


Fig 30

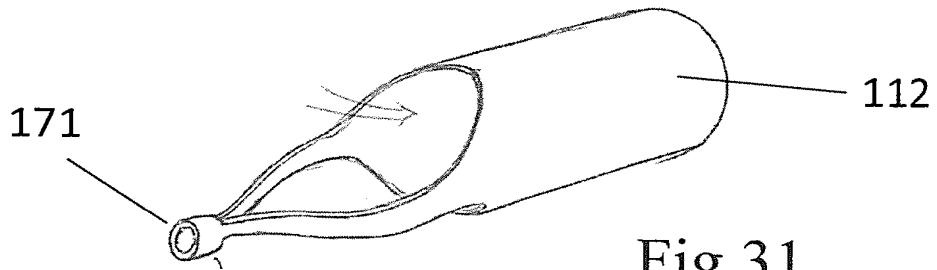


Fig 31

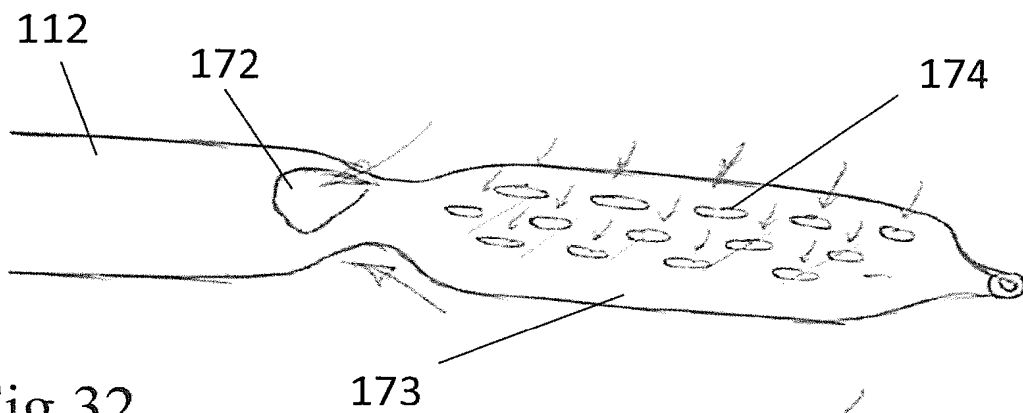


Fig 32

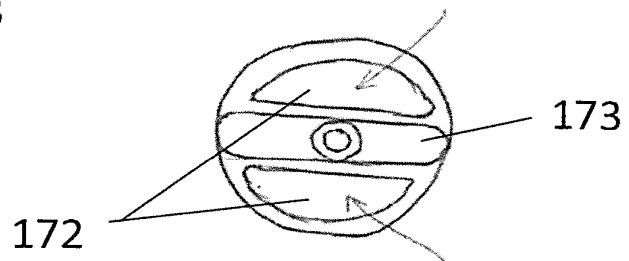


Fig 33

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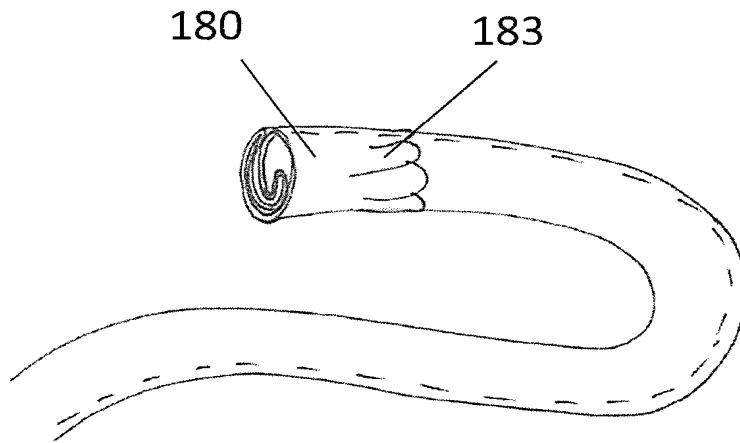


Fig 34a

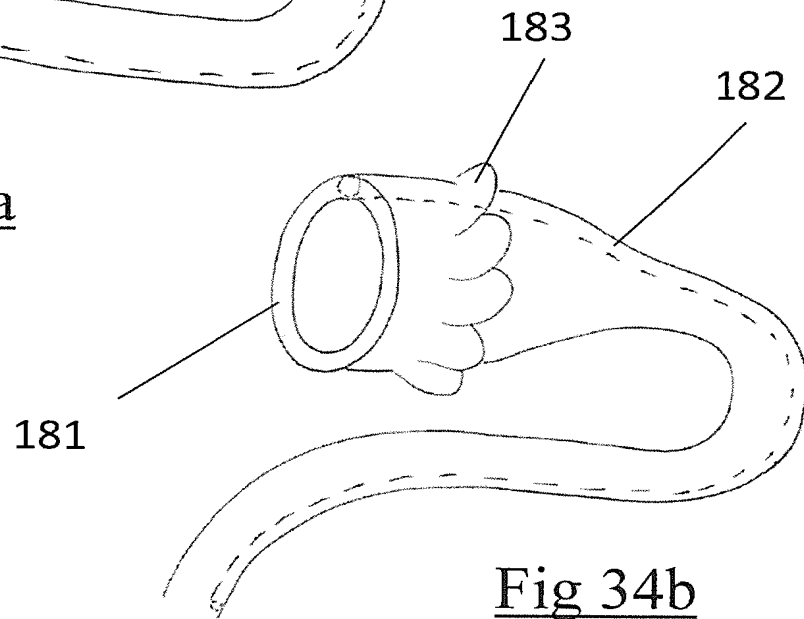


Fig 34b

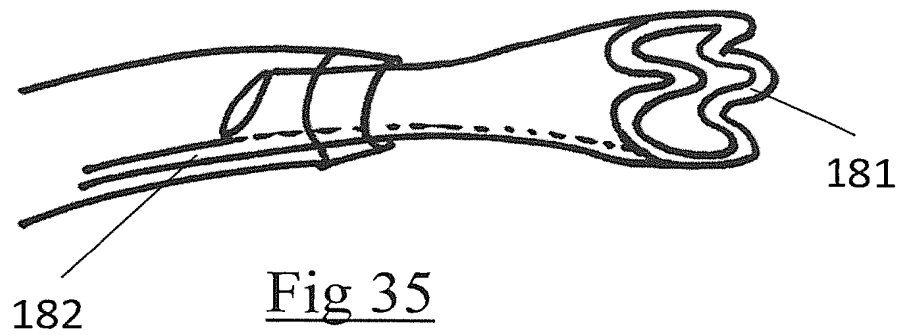


Fig 35

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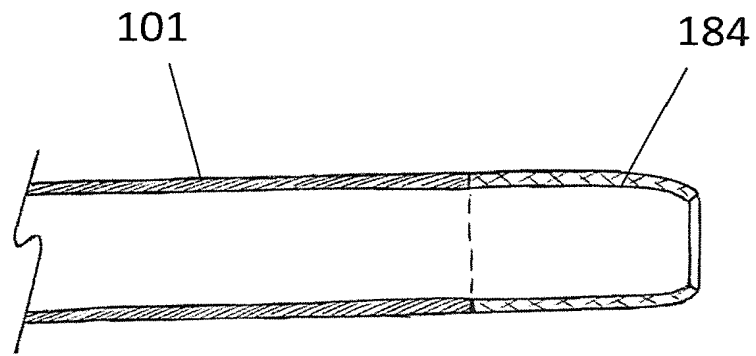


Fig 36a

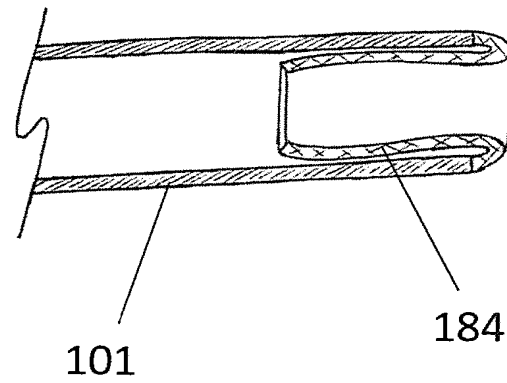


Fig 36b

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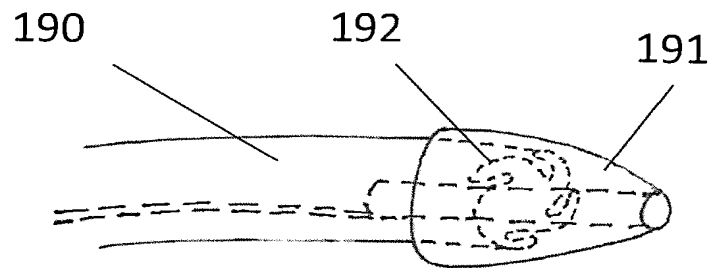


Fig 37a

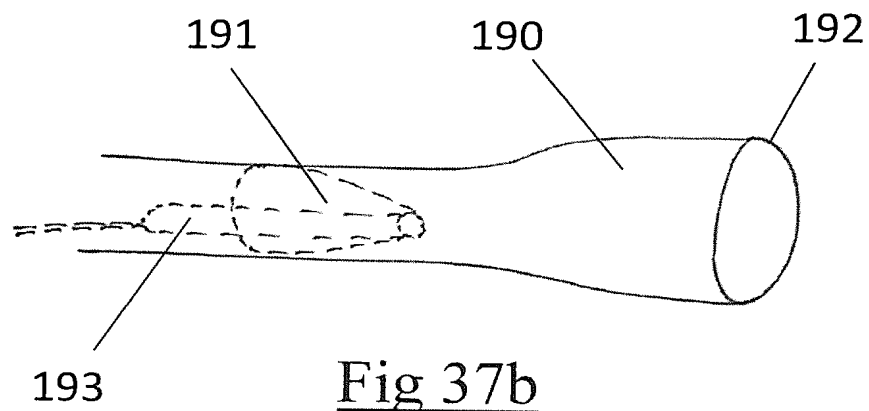


Fig 37b

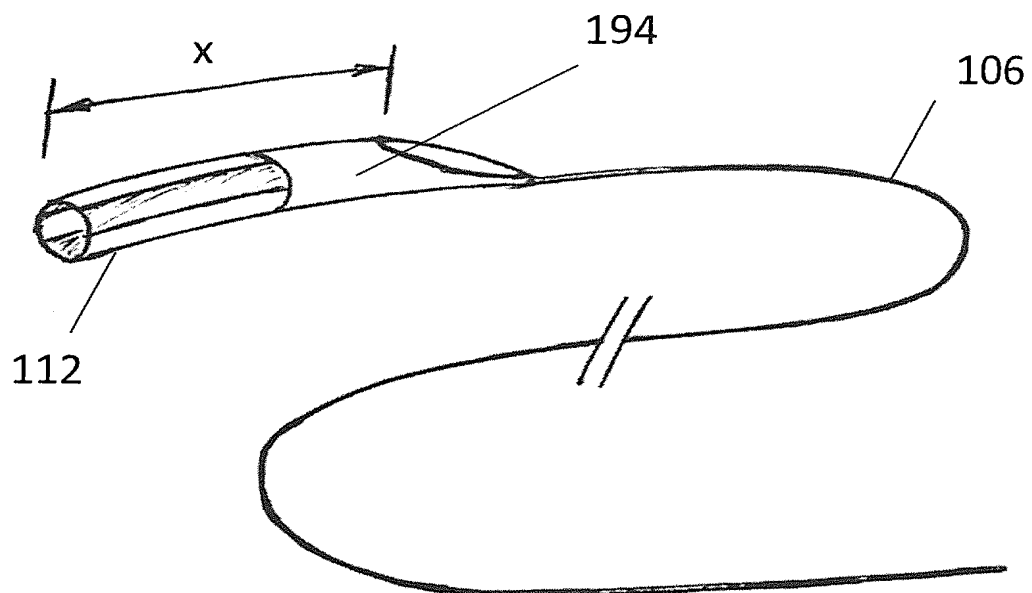
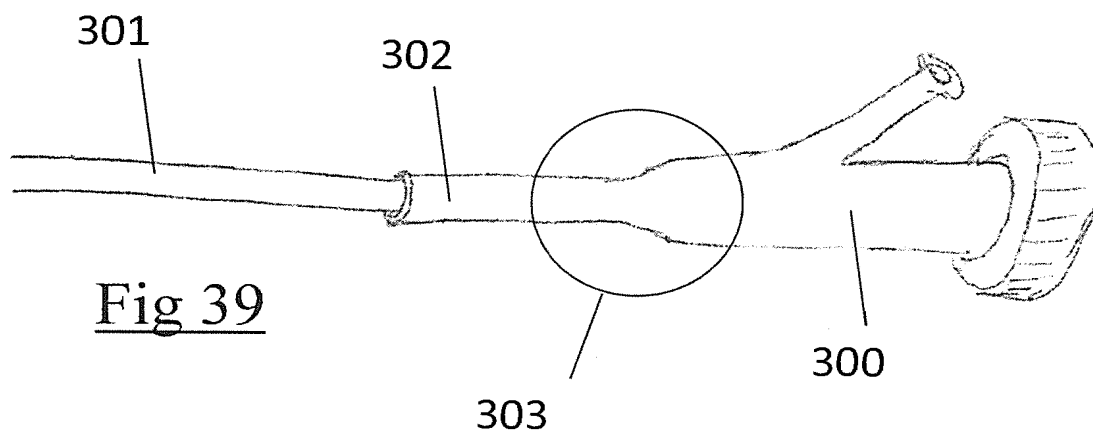
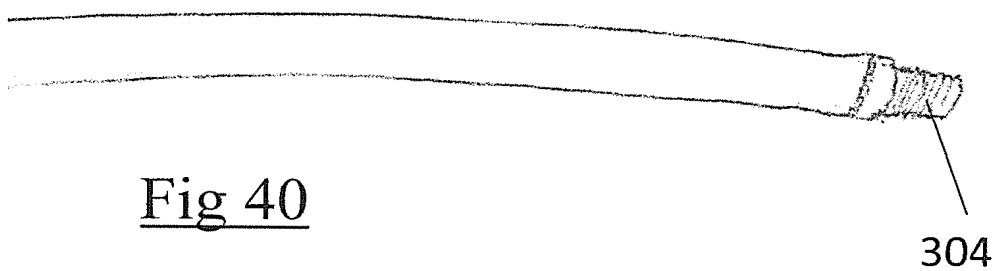
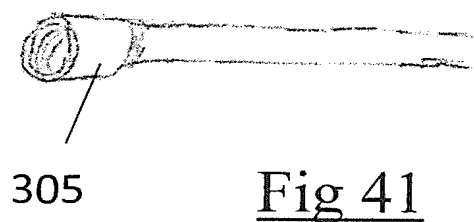
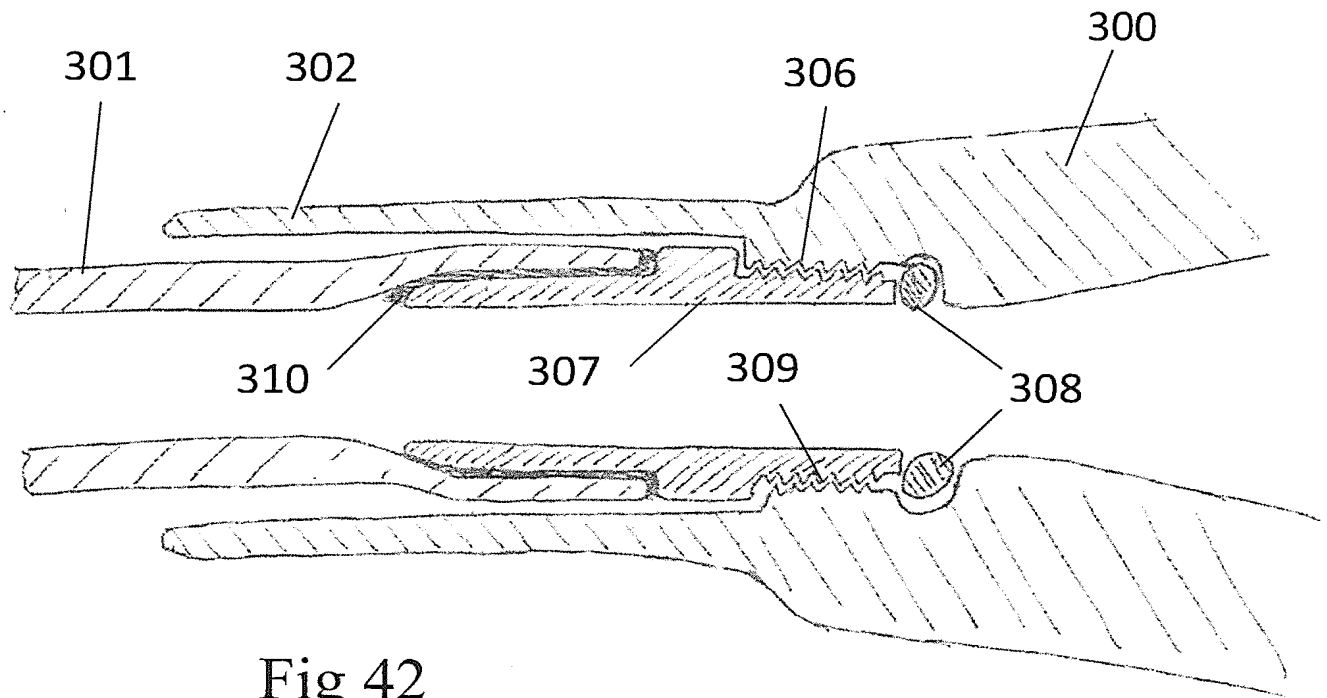
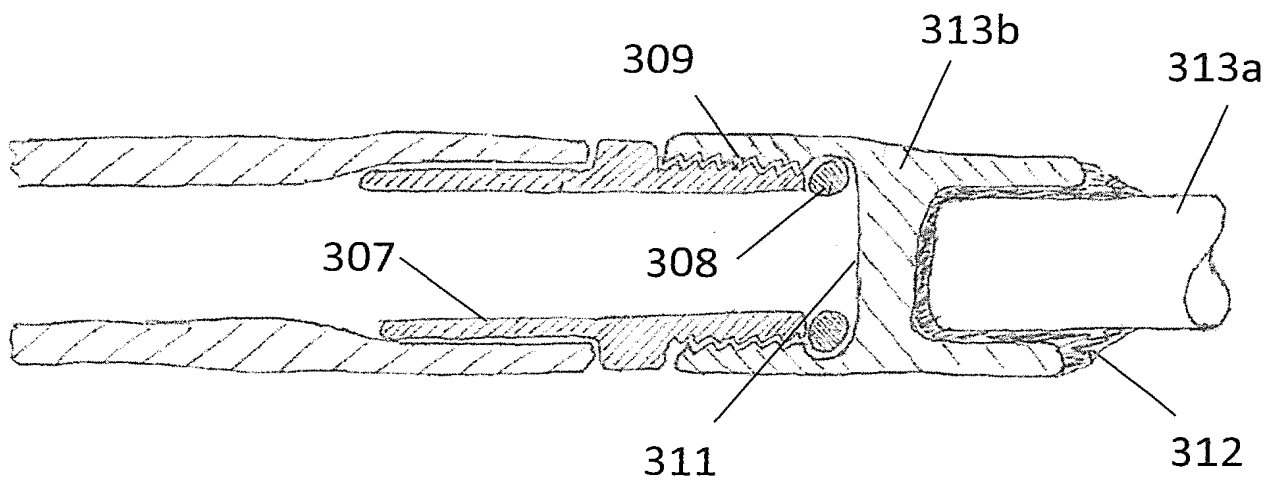


Fig 38



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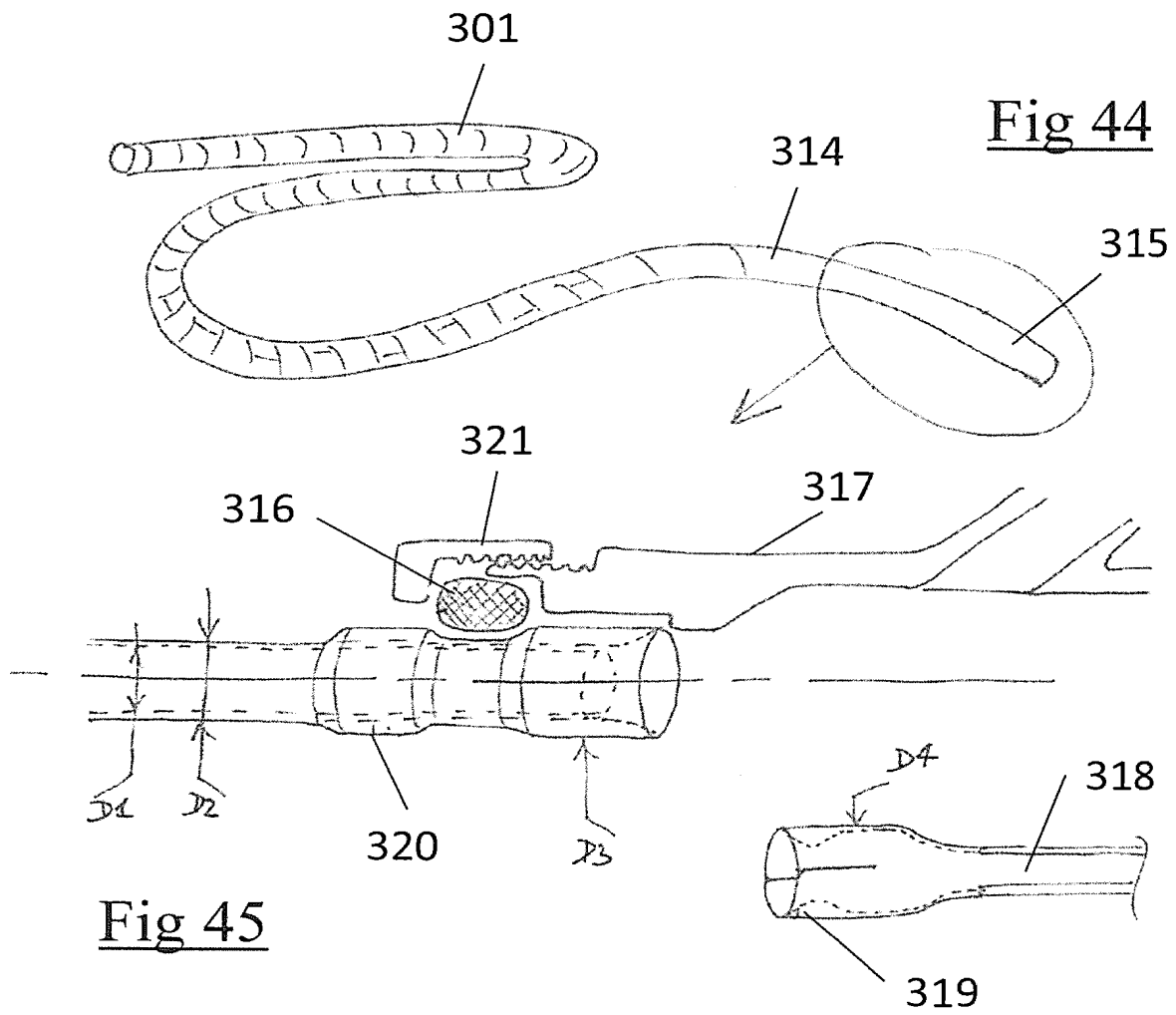


Fig 46

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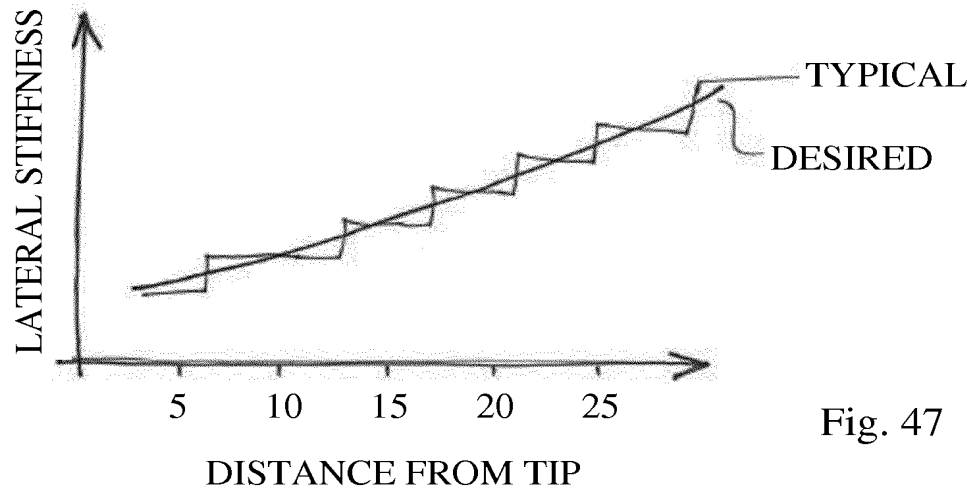


Fig. 47

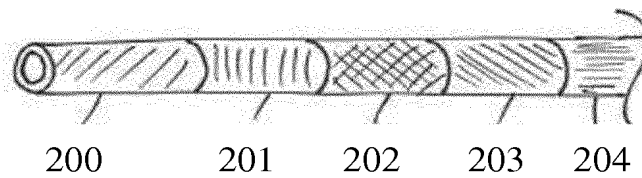


Fig. 48

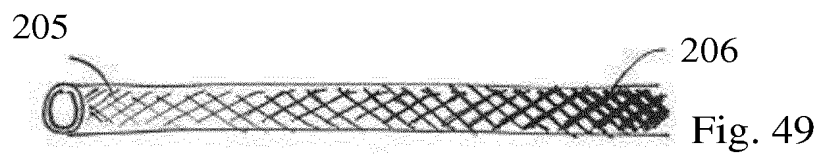


Fig. 49

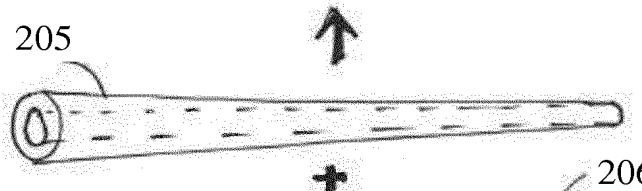


Fig. 50



Fig. 51

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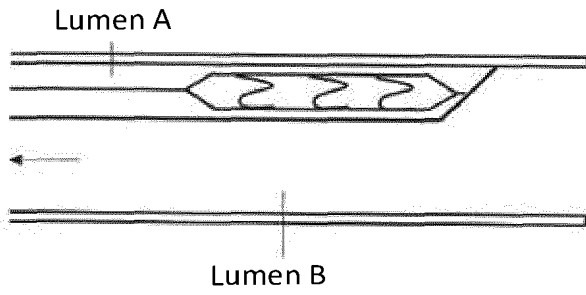


Fig. 53

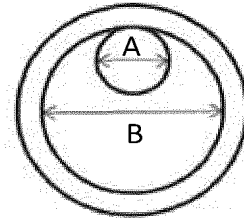


Fig. 52

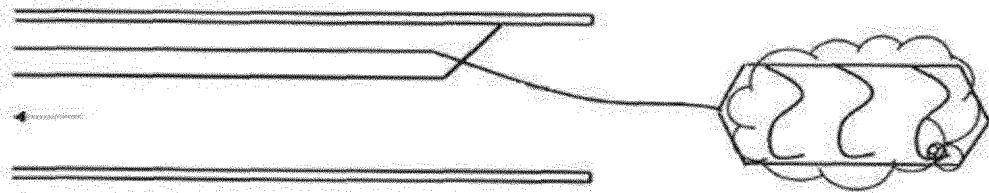


Fig. 54

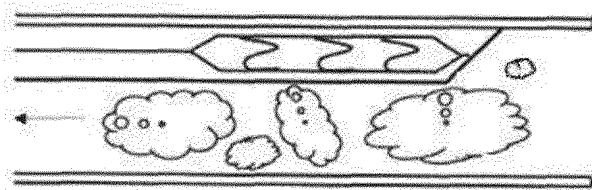
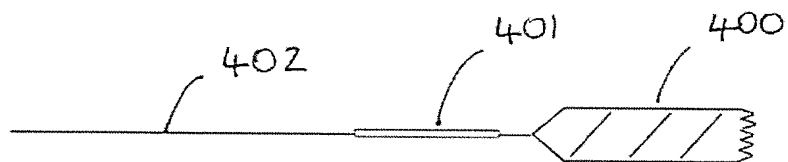
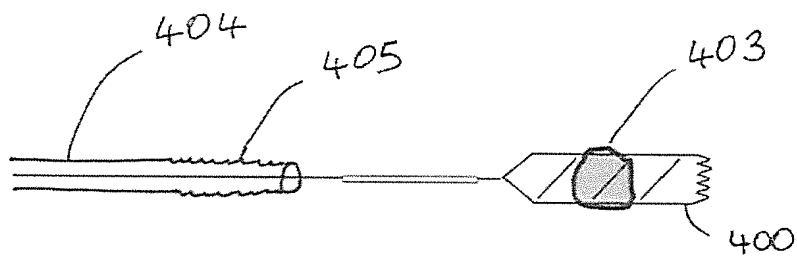
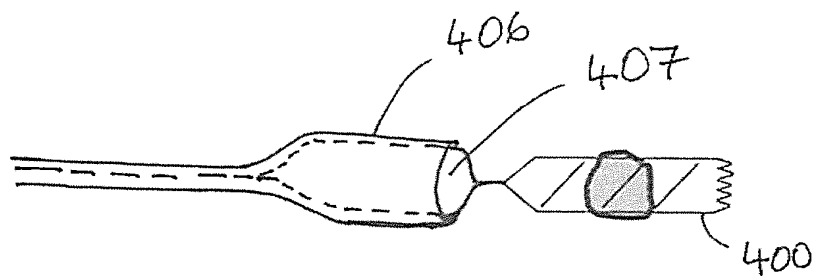
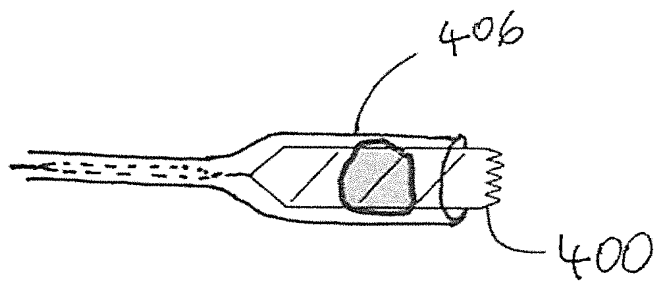
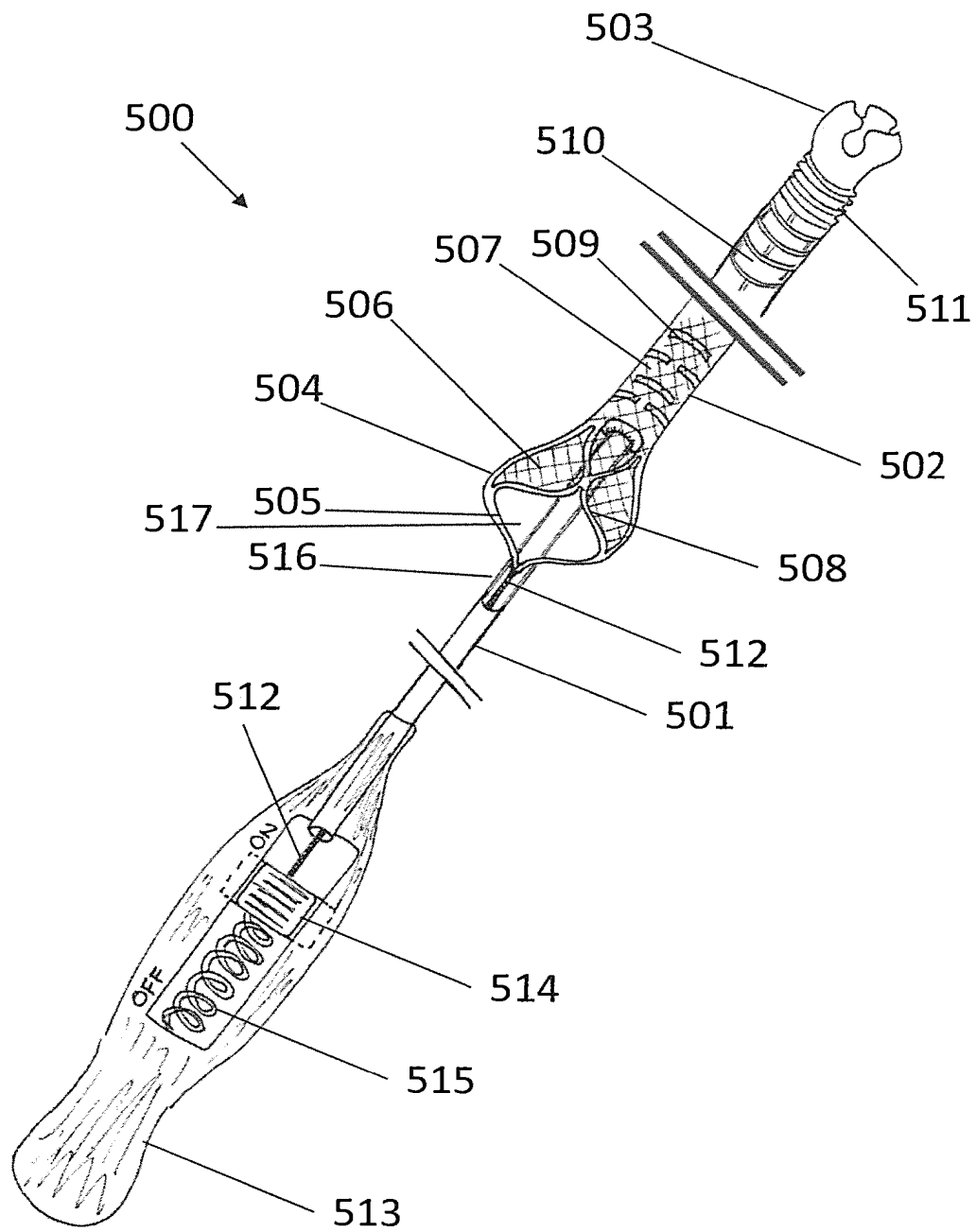


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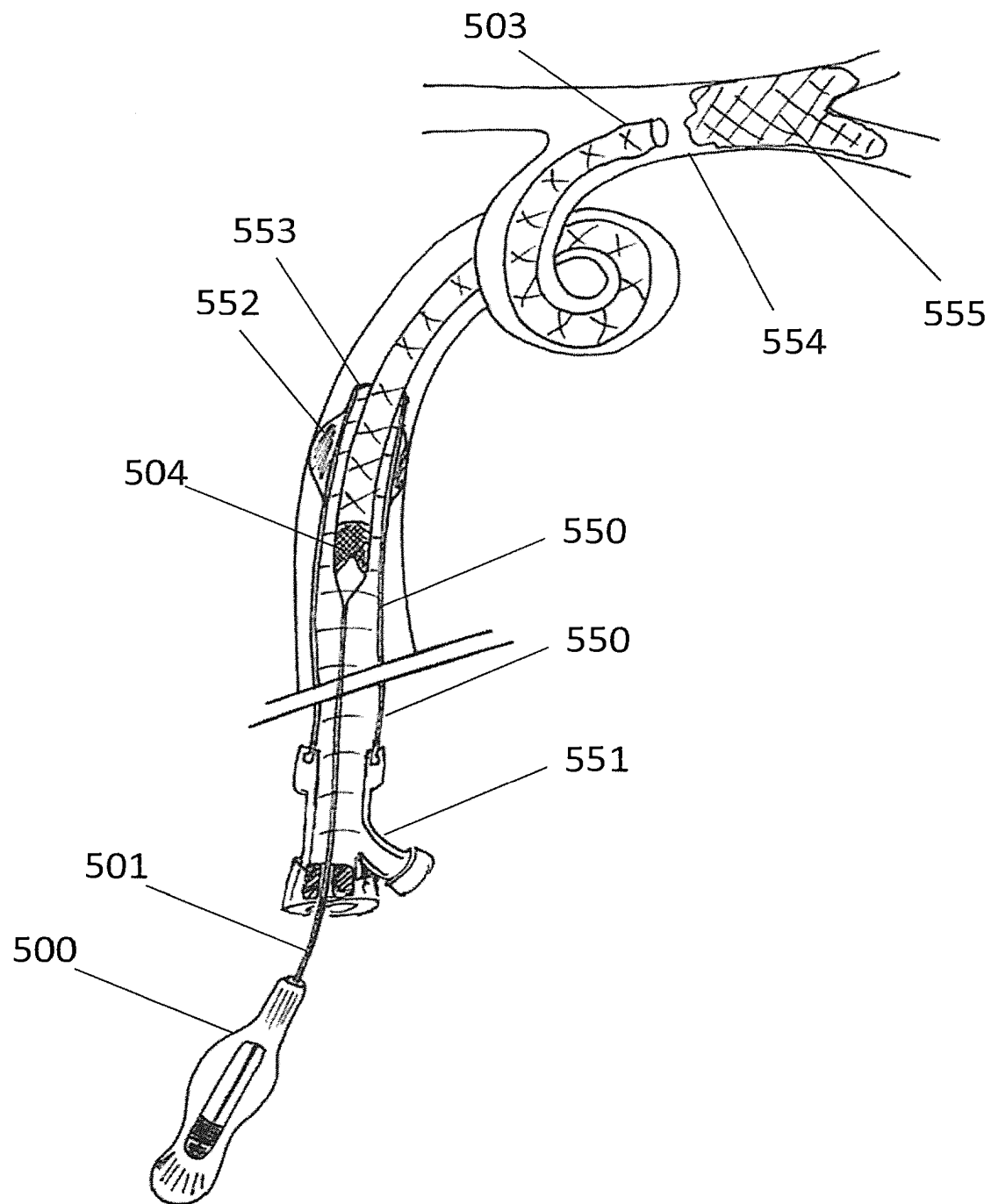
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Fig 56Fig 57Fig 58Fig 59

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Fig 60

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Fig 61a

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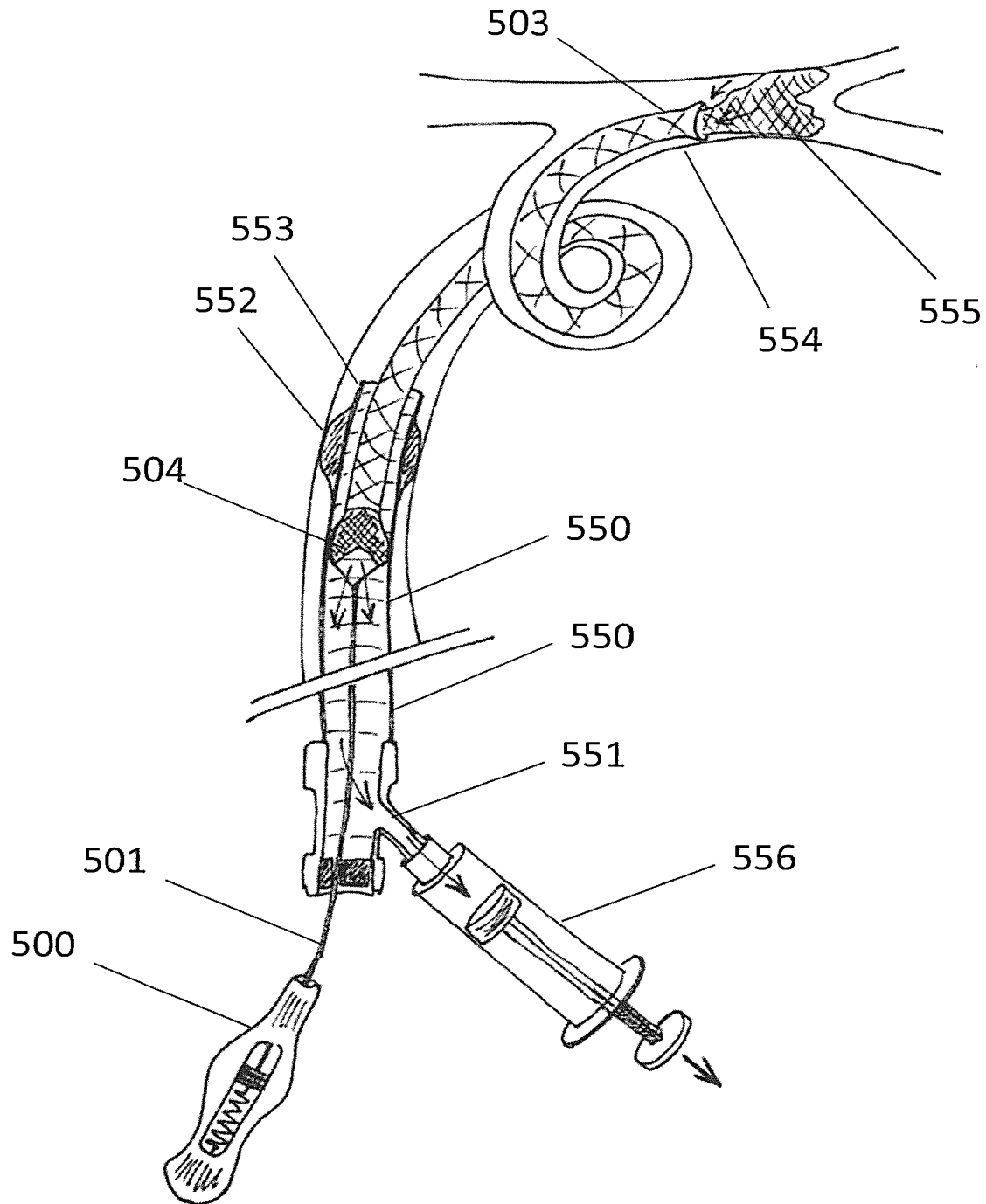


Fig 61b

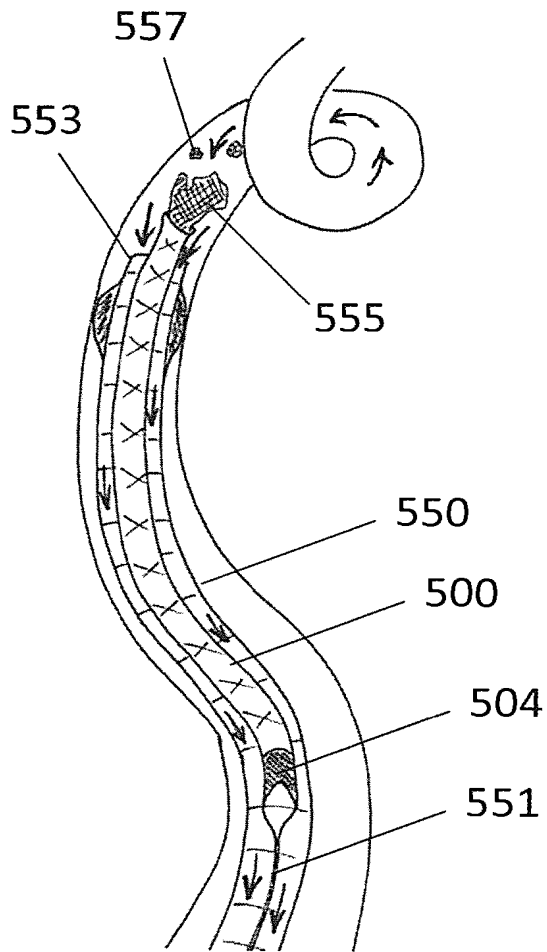


Fig 61c

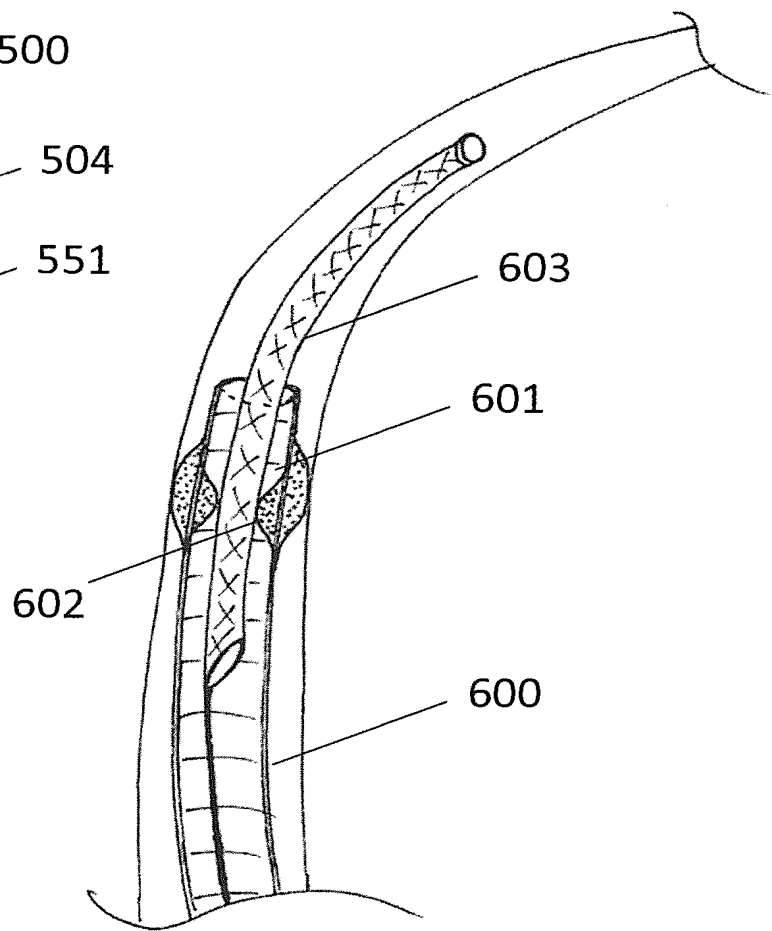
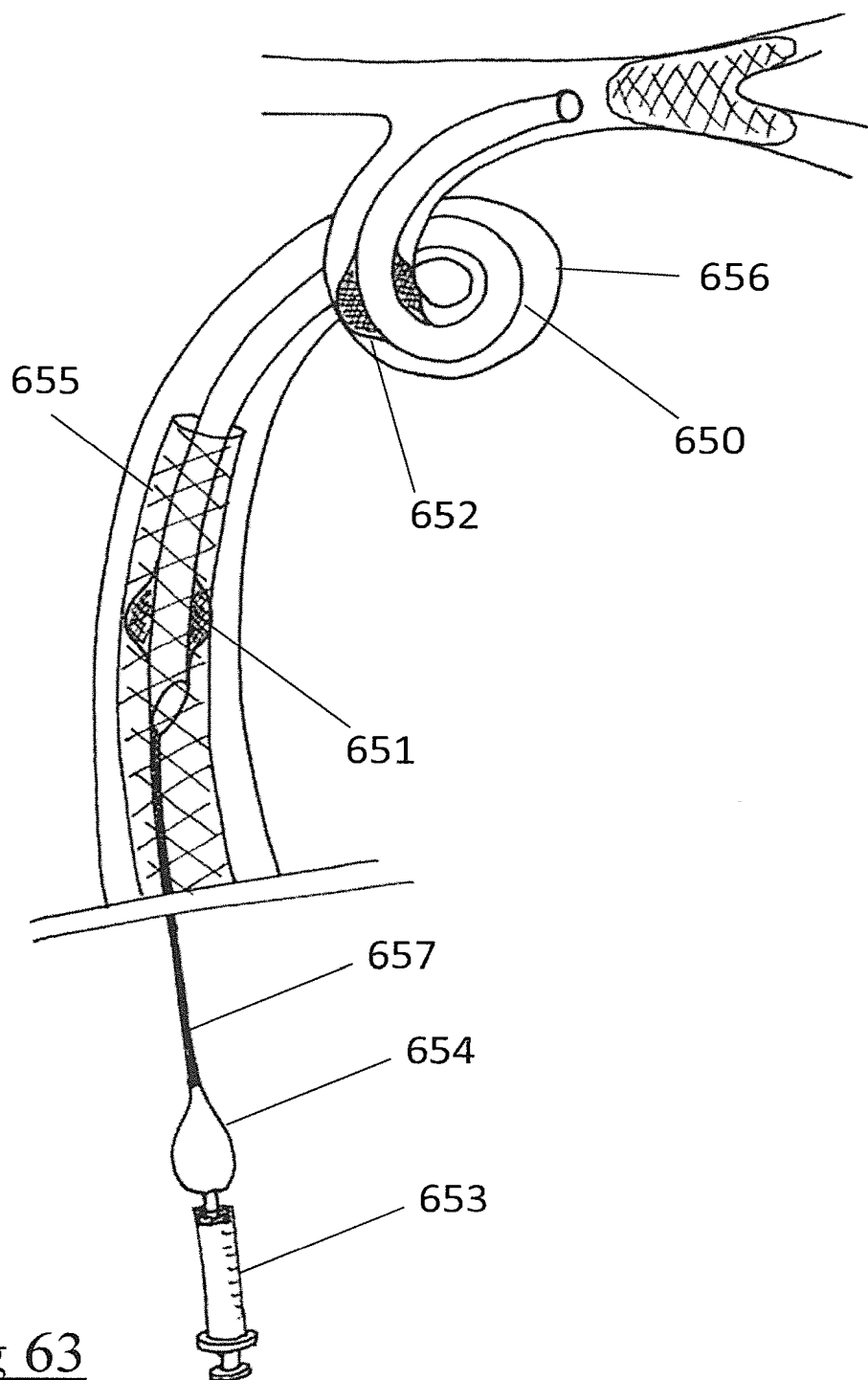


Fig 62

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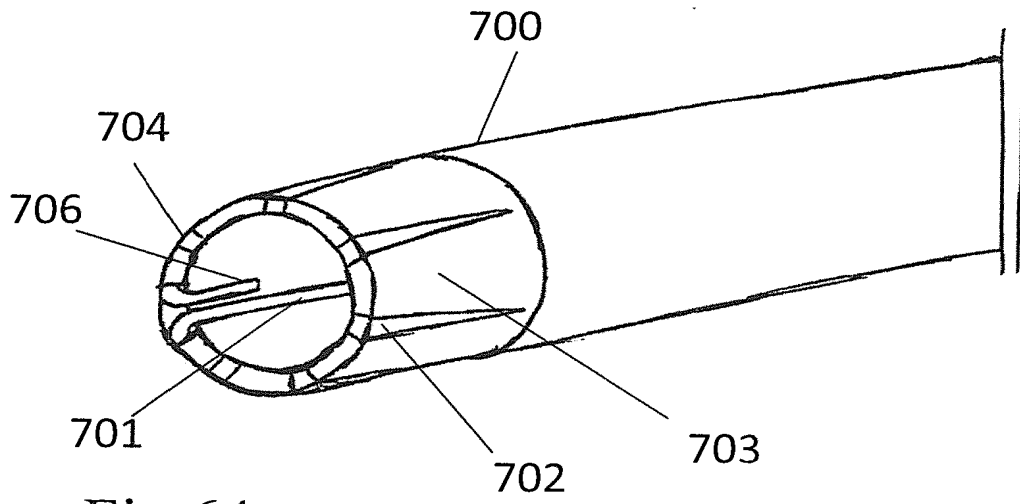


Fig 64a

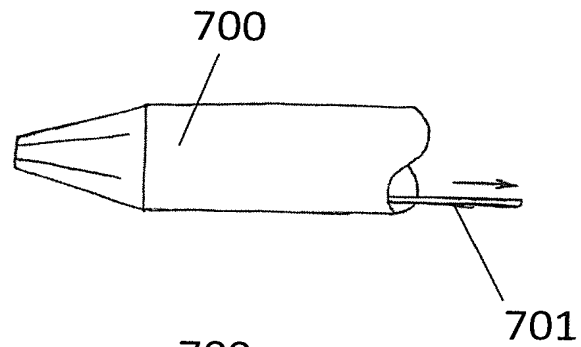


Fig 64b

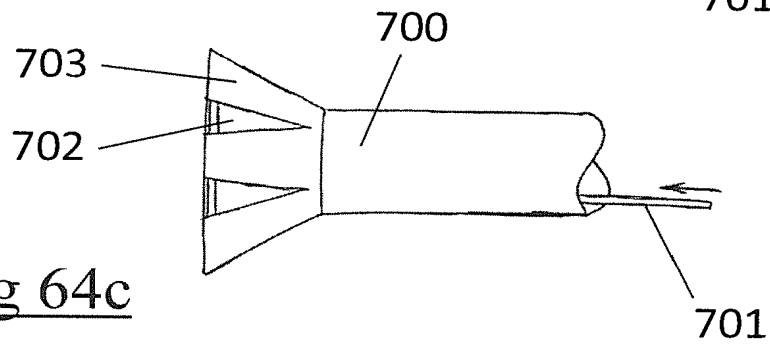


Fig 64c

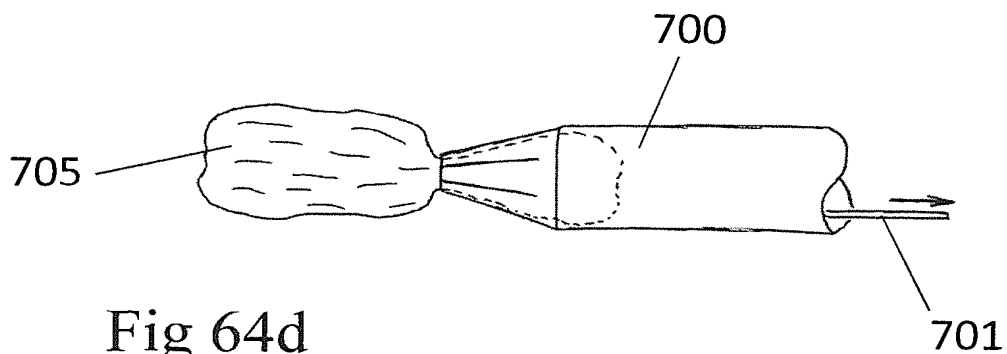


Fig 64d

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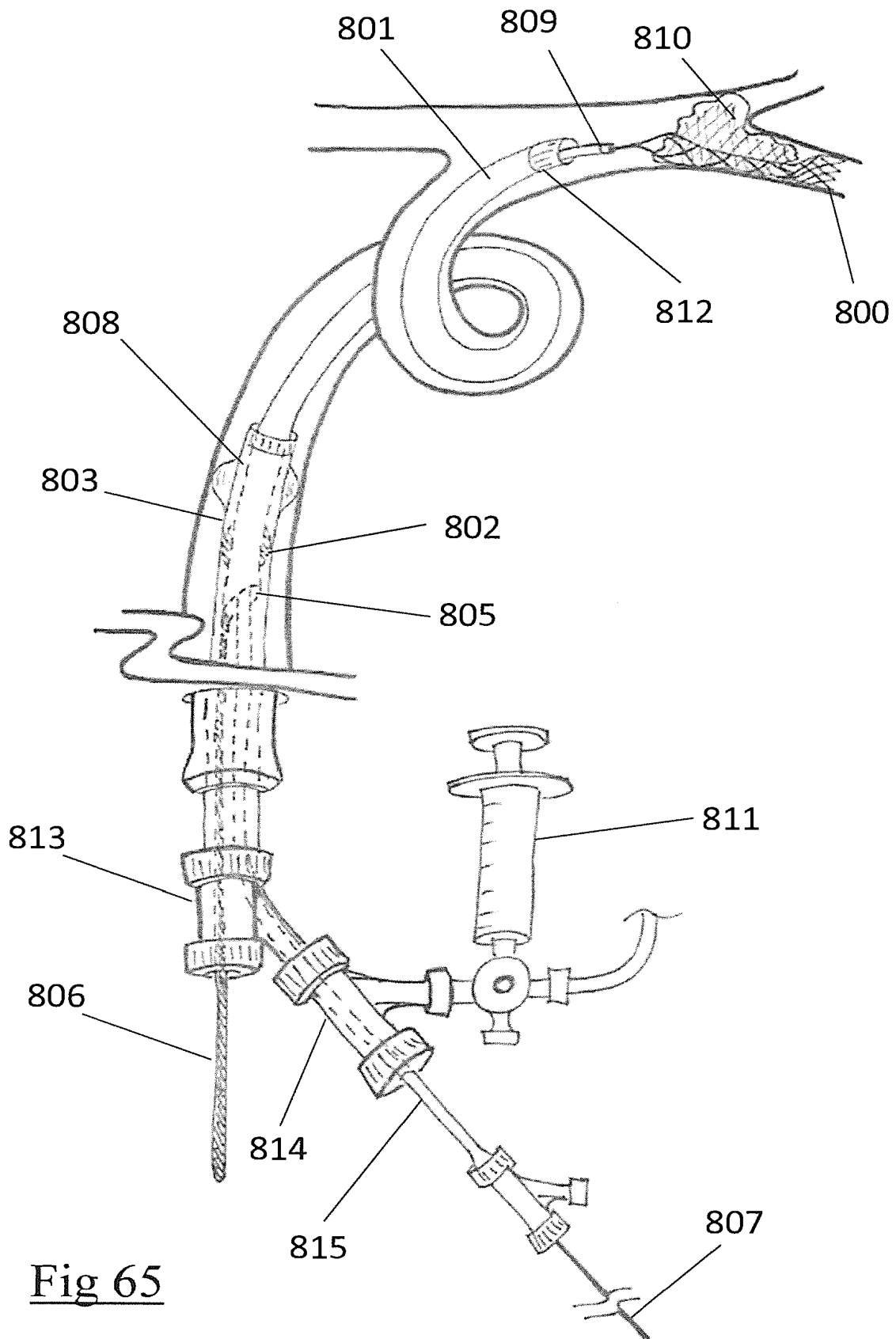


Fig 65

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2015/063104

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/22
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 8 057 497 B1 (RAJU SESHADRI [US] ET AL) 15 November 2011 (2011-11-15)	1-7, 10-12, 14-16, 19-21, 23-34, 36-38
Y	column 4, lines 17,18, 29-64; figures 2,2a,6 page 5, lines 33-40 page 7, lines 61-67	8,9,13, 17,18, 22,35
Y	----- US 5 769 871 A (MERS KELLY WILLIAM C [US] ET AL) 23 June 1998 (1998-06-23) column 4, line 64 - column 5, line 13; figures 1-3 ----- -/--	8,9,13, 17,18, 22,35



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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Date of the actual completion of the international search

2 July 2015

Date of mailing of the international search report

09/07/2015

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
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Fax: (+31-70) 340-3016

Authorized officer

Lee, Ronan

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2015/063104

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2010/004607 A1 (WILSON SCOTT [US] ET AL) 7 January 2010 (2010-01-07) paragraphs [0007], [0016]; figures 2,4 -----	1-38
A	WO 99/56801 A2 (MICROVENTION INC [US]) 11 November 1999 (1999-11-11) page 21, line 22 - page 23, line 5; figure 6 -----	1-38

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2015/063104

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 8057497	B1	15-11-2011	US 8057497 B1 15-11-2011
			US 8252010 B1 28-08-2012
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			US 2010145371 A1 10-06-2010
			US 2014257245 A1 11-09-2014
			WO 9956801 A2 11-11-1999

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW S. WILLIAMS PERKINS COIE LLP P.O. BOX 1247 SEATTLE, WA 98111-1247
RECEIVED PATENT DOCKETING MAR 28 2022 PERKINS COIE LLP

PCT

NOTIFICATION OF TRANSMITTAL OF
 THE INTERNATIONAL SEARCH REPORT AND
 THE WRITTEN OPINION OF THE INTERNATIONAL
 SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference: 111552-8028W000	Date of mailing (day month year) MAR 22 2022
International application No. PCT/US 21/59718	International filing date (day month year) 17 November 2021 (17.11.2021)
Applicant INARI MEDICAL, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46).

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

How? Directly to the International Bureau preferably through ePCT, or on paper to:
 The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland.

For more detailed instructions, see the *PCT Applicant's Guide, International Phase*, paragraphs 9.004 - 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) is thus effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ With regard to any protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
 - ☐ no decision has been made yet on the protest: the applicant will be notified as soon as a decision is made.

4. Reminders:

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 9(bis.1) and 9(bis.3)).

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 30 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices. In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide, National Chapters*.

Within 22 months from the priority date, the applicant may request that a supplementary international search be carried out by a different International Searching Authority that offers this service (Rule 43bis.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide, International Phase*, paragraphs 2.096-2.032.

Name and mailing address of the ISA/IJS: Mail Drop PCT, Attn: ISAAUS Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: <div style="text-align: center; padding: 10px;">Kari Rodriguez</div> Telephone No. PCT Helpdesk: 571-272-4200
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Form PCT/ISA/220 (revised January 2010)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 111552-6028W000		FOR FURTHER ACTION <small>on Form PCT/ISA/220 as well as, where applicable, item 5 below</small>	
International application No. PCT/US 21/59718	International filing date (day/month/year) 17 November 2021 (17.11.2021)	(Earliest) Priority Date (day/month/year) 18 November 2020 (18.11.2020)	
Applicant INARI MEDICAL, INC.			

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.2(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 11.5b(iv)).

c. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. 1.

2. ☐ Certain claims were found unsearchable (see Box No. II).

3. ☒ Unity of invention is lacking (see Box No. III).

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.7, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 7C
☒ as suggested by the applicant.
☐ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IS 21/59718

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-14 directed to an aspiration catheter.

Group II: Claims 15-20 directed to a method of removing clot material from a blood vessel.

^Continued in Supplemental Box^

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos. 1-14.

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/53716

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61M 25/00; A61B 17/22 (2022.01)

CPC - A61M 25/0041; A61M 25/0045

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claims No
Y	CN 110652645 A (Shanghai Warbey Medical Technology Co Ltd) 07 January 2020 (07.01.2020), entire document, especially	1-14
Y	US 2006/0074401 A1 (Rose) 06 April 2006 (06.04.2006), entire document, especially	1-14
A	US 2019/0151608 A1 (GMEDIX, INC.) 02 June 2019 (02.06.2019), entire document	1-14
A	US 2013/0197454 A1 (Terumo Kabushiki Kaisha) 01 August 2013 (01.08.2013), entire document	1-14

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"I" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"Z" document member of the same patent family

Date of the actual completion of the international search

03 March 2022

Date of mailing of the international search report

MAR 22 2022

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents

P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Kari Rodriguez

Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group II includes the special technical feature of positioning a distal tip of the aspiration catheter proximate the clot material; activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter, not required in Group I.

The inventions of Groups I-II share the technical features of an aspiration catheter, comprising: a distal portion and a proximal portion, wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion. Specifically, Groups I and II are related as an apparatus (Group I) and methods for using the apparatus (Group II). The apparatus is known in prior art as shown in CN 110652645 A to Shanghai Warbey Medical Technology Co Ltd (hereinafter "Shanghai"). Therefore, Groups I and II lack unity since the shared technical features do not represent a contribution over Shanghai.

Shanghai discloses of an aspiration catheter (Fig 1A-1B; para [0053]-[0090]; para [0115] further teaches wherein the catheter can be used for aspiration), comprising: a distal portion (left half of 10; Fig 1A-1B; para [0053]) and a proximal portion (right half of 10; Fig 1A-1B; para [0053]); wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion (Fig 1A, 1B; para [0075]); Shanghai teaches wherein the distal region of the aspiration catheter has good flexibility wherein the flexibility of the distal end of the catheter allows for a distal end of the braid of wires within the distal end of the catheter taught by Shanghai to be flexible and deflectable with respect to the longitudinal axis of the proximal portion taught by Shanghai).

As the common features were known in the art at the time of the invention, they cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: MATTHEW S. WILLIAMS
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

Date of mailing
(day/month/year)

MAR 22 2022

Applicant's or agent's file reference
111552-8028WO00

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US 21/59718

International filing date (day/month/year)

17 November 2021 (17.11.2021)

Priority date (day/month/year)

18 November 2020 (18.11.2020)

International Patent Classification (IPC) or both national classification and IPC

IPC - A61M 25/00; A61B 17/22 (2022.01)

CPC - A61M 25/0041; A61M 25/0045

Applicant INARI MEDICAL, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/IS
Mail Stop PCT, Attn: ISA/IS
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300

Date of completion of this opinion

03 March 2022

Authorized officer

Kari Rodriguez

PCT Help Desk

Telephone No. 571-272-4300

Form PCT/ISA/237 (cover sheet) (revised January 2019)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 21/59718

Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 12bis.1(b)).
3. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. ☐ forming part of the international application as filed.
☐ in the form of an Annex C/ST.25 text file.
☐ on paper or in the form of an image file.
 - b. ☐ furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
☐ in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
☐ on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 21/59718

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/200) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees.
- ☐ paid additional fees under protest and, where applicable, the protest fee.
- ☐ paid additional fees under protest but the applicable protest fee was not paid.
- ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1, in order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-14 directed to an aspiration catheter.

Group II: Claims 15-20 directed to a method of removing clot material from a blood vessel.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group II includes the special technical feature of positioning a distal tip of the aspiration catheter proximate the clot material, activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter, not required in Group I.

The inventions of Groups I-II share the technical features of an aspiration catheter, comprising: a distal portion and a proximal portion, wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion. Specifically, Groups I and II are related as an apparatus (Group I) and methods for using the apparatus (Group II). The apparatus is known in prior art as shown in CN 110652845 A to Shanghai Warbey Medical Technology Co Ltd (hereinafter "Shanghai"). Therefore, Groups I and II lack unity since the shared technical features do not represent a contribution over Shanghai.

Shanghai discloses of an aspiration catheter (Fig 1A-1B; para [0093]-[0099]; para [0115] further teaches wherein the catheter can be used for aspiration), comprising: a distal portion (left half of 10; Fig 1A-1B; para [0093]) and a proximal portion (right half of 10; Fig 1A-1B; para [0093]), wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion (Fig 1A-1B; para [0076]; Shanghai teaches wherein the distal region of the aspiration catheter has good flexibility wherein the flexibility of the distal end of the catheter allows for a distal end of the braid of wires within the distal end of the catheter taught by Shanghai to be flexible and deflectable with respect to the longitudinal axis of the proximal portion taught by Shanghai).

As the common features were known in the art at the time of the invention, they cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-14.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 2015/07118

Box No. V Reasoned statement under Rule 43bis(1a)(ii) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-14	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-14	NO
Industrial applicability (IA)	Claims	1-14	YES
	Claims	None	NO

2. Citations and explanations

Claims 1-7 lack an inventive step under PCT Article 33(3) as being obvious over CN 110852645 A to Shanghai Werbey Medical Technology Co Ltd (hereinafter "Shanghai") in view of US 2008/0074401 A1 to Ross.

As per claim 1, Shanghai teaches an aspiration catheter (Fig 1A-1B; para [0090]-[0099]; para [0115] further teaches wherein the catheter can be used for aspiration), comprising:
an inner liner (20; Fig 1A-1B; para [0093]) defining a lumen (21; Fig 1A-1B; para [0093]) and having a proximal region (right half of 20; Fig 1A-1B; para [0093]) and a distal region (left half of 20; Fig 1A-1B; para [0093]);
a braid of wires over the inner liner (40; Fig 1A-1B; para [0095]), [wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained];

a wire coiled over at least a portion of the distal region of the inner liner (30; Fig 1A-1B; para [0093], [0099]); and
an outer sheath over the braid of wires (Box VIII), the wire, and the inner liner (50; Fig 1A-1B; para [0093]).

While Shanghai teaches wherein the distal region of the aspiration catheter has good flexibility (Fig 1A-1B; para [0076]), the flexibility of the distal end of the catheter allows for a distal end of the braid of wires within the distal end of the catheter taught by Shanghai to be flexible and deflectable. Shanghai does not specifically teach wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained. However, Ross teaches a similar catheter (Fig 1-2; para [0024]-[0034]) comprising a braid of wires (24; Fig 1-2; para [0027]); reinforcing material 24 is taught to be formed of a braid made of resilient elements over an inner liner (22; Fig 1-2; para [0027]) wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the catheter is unconstrained (Fig 1-2; para [0025]-[0026], [0035]). Ross teaches wherein the elongate shaft 16, including the reinforcing material 24 can be bent depending on the desired application - see Fig 6 further showing a configuration of the catheter that is formed to a bent configuration at the distal tip of the catheter. Accordingly, it would have been obvious to one of ordinary skill in the art to have employed deflectable portion taught by Ross with the aspiration catheter taught by Shanghai, in order to allow for improved navigation of tortuous vessels (para [0006]-[0010]).

As per claim 2, Shanghai in view of Ross teach the aspiration catheter of claim 1, and Ross further teaches wherein the wires in the deflectable portion of the braid of wires (Box VIII) is pre-shaped to deflect away from the longitudinal axis (Fig 1-2; para [0032]-[0035]); the catheter is taught to be formed as shown in Fig 6 by constraining the catheter in a desired curvature of position and then heating the shaft to shrink the shrink tubing 28, such that the reinforcing material 24 is pre-shaped in the curved configuration.

As per claim 3, Shanghai in view of Ross teach the aspiration catheter of claim 1, and Ross further teaches wherein the deflectable portion of the braid of wires (Box VIII) is configured to deflect away from the longitudinal axis to have a bend angle of between about 185-195 degrees (Box VIII) when the aspiration catheter is unconstrained (Fig 1-2; para [0032]-[0035]); the catheter is taught to be formed as shown in Fig 6 by constraining the catheter in a desired curvature of position and then heating the shaft to shrink the shrink tubing 28, such that the reinforcing material 24 is pre-shaped in the curved configuration - Fig 6 further shows the bend angle to be almost exactly 180 degrees at the distal end, such that the bend angle is reasonably considered to be between 185-195 degrees).

As per claim 4, Shanghai in view of Ross teach the aspiration catheter of claim 1, and Ross further teaches wherein the deflectable portion of the braid of wires (Box VIII) is configured to deflect away from the longitudinal axis to have a bend angle [of about 270 degrees] when the aspiration catheter is unconstrained (Fig 1-2; para [0032]-[0035]); the catheter is taught to be formed as shown in Fig 6 by constraining the catheter in a desired curvature of position and then heating the shaft to shrink the shrink tubing 28, such that the reinforcing material 24 is pre-shaped in the curved configuration. While Ross teaches wherein the catheter can have a bent shape depending on the desired application (para [0025]), Ross does not specifically teach a bend angle of about 270 degrees. However, it is well known that optimizing size, shape and angle is of the ordinary skill in the art. Accordingly, it would have been obvious to one of ordinary skill in the art to have arrived at a bend angle of about 270 degrees, in order to allow for improved navigation of tortuous vessels.

Continued in Supplemental Box.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 2005/0718

Box No. VIII - Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-4 and 9-10: The term "the braid" is confusing and lacks proper antecedent basis. The term "the braid" appears to be referring to the braid of wires previously referred to. For purposes of this opinion, the term "the braid" has been interpreted as "the braid of wires."

Claim 3: The recitation "between about between about 165-195 degrees" appears to be a typographical error that is inconsistent with known grammatical standards and has been interpreted to be "between about 165-195 degrees."

Claim 4: The recitation "between about 270 degrees" appears to be a typographical error that is inconsistent with known grammatical standards and has been interpreted to be "about 270 degrees."

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of

-Box V.2 - Citations and explanations-

As per claim 5, Shanghai in view of Ross teach the aspiration catheter of claim 1. While Shanghai teaches wherein the aspiration catheter can be used as a neurovascular catheter (para [0007]-[0008]), Shanghai does not specifically teach wherein the lumen has a diameter of 20 French or greater. However, it is well known in the art that routine experimentation and various engineering design choices could have been made to have arrived at wherein the lumen has a diameter of 20 French or greater (Note: providing a larger diameter allows for aspiration of larger vessels, such as the aorta, which help provide oxygenated blood to the brain and spinal cord). Accordingly, it would have been obvious to one of ordinary skill in the art to have arrived at wherein the lumen has a diameter of 20 French or greater, in order to allow for use in larger blood vessels.

As per claim 6, Shanghai in view of Ross teach the aspiration catheter of claim 1. While Shanghai teaches wherein the aspiration catheter can be used as a neurovascular catheter (para [0007]-[0008]), Shanghai does not specifically teach wherein the lumen has a diameter of 24 French or greater. However, it is well known in the art that routine experimentation and various engineering design choices could have been made to have arrived at wherein the lumen has a diameter of 24 French or greater (Note: providing a larger diameter allows for aspiration of larger vessels, such as the aorta, which help provide oxygenated blood to the brain and spinal cord). Accordingly, it would have been obvious to one of ordinary skill in the art to have arrived at wherein the lumen has a diameter of 24 French or greater, in order to allow for use in larger blood vessels.

As per claim 7, Shanghai in view of Ross teach the aspiration catheter of claim 1 wherein the inner liner is formed from polytetrafluoroethylene material (Fig 1A-1B, para [0097]), and wherein the outer sheath is formed from a thermoplastic elastomer material (Fig 1A-1B, para [0110]); the outer layer 50 is taught to be made of Pebax).

Claims 1 and 8-14 lack an inventive step under PCT Article 33(3) as being obvious over Shanghai in view of Ross (second treatment).

As per claim 1, Shanghai teaches an aspiration catheter (Fig 1A-1B; para [0093]-[0095]; para [0115] further teaches wherein the catheter can be used for aspiration), comprising:

an inner liner (20; Fig 1A-1B; para [0093]) defining a lumen (21; Fig 1A-1B; para [0093]) and having a proximal region (right half of 20; Fig 1A-1B; para [0093]) and a distal region (left half of 20; Fig 1A-1B; para [0093]);

a braid of wires over the inner liner (40; Fig 1A-1B; para [0093]), wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained;

a wire coiled over at least a portion of the distal region of the inner liner (30; Fig 1A-1B; para [0093], [0099]); and

an outer sheath over the braid of wires (Box VIII), the wire, and the inner liner (50; Fig 4; para [0111]; Shanghai teaches an outer layer 50, which can be reasonably considered to be used with the catheter 10 shown in Fig 1A-1B).

While Shanghai teaches wherein the distal region of the aspiration catheter has good flexibility (Fig 1A-1B; para [0076]; the flexibility of the distal end of the catheter allows for a distal end of the braid of wires within the distal end of the catheter taught by Shanghai to be flexible and deflectable), Shanghai does not specifically teach wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained. However, Ross teaches a similar catheter (Fig 1-2; para [0024]-[0034]) comprising a braid of wires (24; Fig 1-2; para [0027]; reinforcing material 24 is taught to be formed of a braid made of metallic filaments) over an inner liner (22; Fig 1-2; para [0027]) wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the catheter is unconstrained (Fig 1-2; para [0025]-[0026], [0035]; Ross teaches wherein the elongate shaft 16, including the reinforcing material 24 can be bent depending on the desired application - see Fig 6 further showing a configuration of the catheter that is formed to a bent configuration at the distal tip of the catheter). Accordingly, it would have been obvious to one of ordinary skill in the art to have employed deflectable portion taught by Ross with the aspiration catheter taught by Shanghai, in order to allow for improved navigation of tortuous vessels (para [0006]-[0010]).

As per claim 8, Shanghai in view of Ross teach the aspiration catheter of claim 1 wherein the outer sheath has a first hardness over the proximal region (Fig 4; para [0111]); the proximal region of outer layer 50 is taught to comprise a material with about a 750 shore hardness), and wherein the outer sheath has a second hardness over the distal region of the inner liner that is less than the first hardness (Fig 4; para [0111]; the distal part of the outer layer 50 is taught to comprise an ultra-low hardness material, which has a hardness of about 60A shore hardness).

-Continued in next Supplemental Box-

Supplemental Box

In case the space in any of the preceding boxes is not sufficient,

Continuation of

-Box V.2 - Claims and explanations-

As per claim 8, Shanghai teaches an aspiration catheter (Fig 1A-1B, 4; para [0080]-[0089], [0111]-[0112]; para [0115] further teaches wherein the catheter can be used for aspiration), comprising:
a proximal region defining a longitudinal axis (region of 10 comprising proximal part of outer layer 50; Fig 1A-1B, 4; para [0093]-[0095], [0111]-[0112]; the outer layer 50 is taught to comprise three parts, including a proximal part, positioned at the proximal end of the catheter body 10);
an intermediate region extending from the proximal region (region of 10 comprising transition section of outer layer 50; Fig 1A-1B, 4; para [0093]-[0099], [0111]-[0112]; the outer layer 50 is taught to comprise three parts, including a transition section extending from the proximal part of the proximal end of the catheter body 10);
a distal region extending from the intermediate region (region of 10 comprising distal part of outer layer 50; Fig 1A-1B, 4; para [0093]-[0099], [0111]-[0112]; the outer layer 50 is taught to comprise three parts, including a distal part, positioned at the distal end of the catheter body 10);
an inner liner (20; Fig 1A-1B; para [0093]) defining a lumen (21; Fig 1A-1B; para [0093]) and extending through the proximal region, the intermediate region and the distal region (Fig 1A-1B; para [0093]-[0099]);
a braid of wires extending over the inner liner and through the proximal region, the intermediate region and the distal region (40; Fig 1A-1B; para [0093]); (wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained);
a wire coiled in the distal region (30; Fig 1A-1B; para [0093], [0099]); and
an outer sheath extending over the braid of wires (Box VIII), the wire, and the inner liner and through the proximal region, the intermediate region, and the distal region (50; Fig 4; para [0111]-[0112]; Shanghai teaches an outer layer 50, which can be reasonably considered to be used with the catheter 10 shown in Fig 1A-1B).
While Shanghai teaches wherein the distal region of the aspiration catheter has good flexibility (Fig 1A-1B; para [0076]; the flexibility of the distal end of the catheter allows for a distal end of the braid of wires within the distal end of the catheter taught by Shanghai to be flexible and deflectable), Shanghai does not specifically teach wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained. However, Ross teaches a similar catheter (Fig 1-2; para [0024]-[0034]) comprising a braid of wires (24; Fig 1-2; para [0027]; reinforcing material 24 is taught to be formed of a braid made of metallic filaments) over an inner liner (22; Fig 1-2; para [0027]) wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the catheter is unconstrained (Fig 1-2; para [0025]-[0026], [0035]). Ross teaches wherein the elongate shaft 18, including the reinforcing material 24 can be bent depending on the desired application - see Fig 6 further showing a configuration of the catheter that is formed to a bent configuration at the distal tip of the catheter). Accordingly, it would have been obvious to one of ordinary skill in the art to have employed deflectable portion taught by Ross with the aspiration catheter taught by Shanghai, in order to allow for improved navigation of tortuous vessels (para [0006]-[0010]).
As per claim 10, Shanghai in view of Ross teach the aspiration catheter of claim 1, and Ross further teaches wherein the deflectable portion of the braid of wires (Box VIII) is configured to deflect away from the longitudinal axis to have a bend angle of between about 165-195 degrees (Box VIII) when the aspiration catheter is unconstrained (Fig 1-2; para [0032]-[0035]; the catheter is taught to be formed as shown in Fig 6 by constraining the catheter in a desired curvature of position and then heating the shaft to shrink the sheath tubing 28, such that the reinforcing material 24 is pre-shaped in the curved configuration - Fig 6 further shows the bend angle to be almost exactly 180 degrees at the distal end, such that the bend angle is reasonably considered to be between 165-195 degrees).
As per claim 11, Shanghai in view of Ross teach the aspiration catheter of claim 9 wherein the outer sheath has: (a) a first hardness in the proximal region of between about 65D-75D (Fig 4; para [0111]; Shanghai teaches wherein the proximal part of outer layer 50 has a shore hardness of about 75D); (b) a second hardness in the intermediate region of between about 50D-60D (Fig 4; para [0111]; Shanghai teaches wherein the transition section has a shore hardness of between 50D-63D allowing for a shore hardness of 60D to make up the transition section), and (c) a third hardness in the distal region of between about 30D-40D (Fig 4; para [0111]; Shanghai teaches wherein the distal part has a shore hardness of about 60A). While Shanghai teaches wherein a third hardness is less than the first hardness and the second hardness (Fig 4; para [0111]), Shanghai does not specifically teach between about 30D-40D. However, it is well known in the art that routine experimentation and various engineering design choices could have been made to have arrived at between about 30D-40D. Accordingly, it would have been obvious to one of ordinary skill in the art to have arrived at between about 30D-40D, in order to provide improved structural integrity in the distal region of the aspiration catheter.
As per claim 12, Shanghai in view of Ross teach the aspiration catheter of claim 9 wherein the outer sheath (a) has a first hardness in the proximal region (Fig 4; para [0111]; Shanghai teaches wherein the proximal part of outer layer 50 has a shore hardness of about 75D); (b) a second hardness in the intermediate region less than the first hardness (Fig 4; para [0111]; Shanghai teaches wherein the transition section has a shore hardness of between 50D-63D); and (c) a third hardness in the distal region less than the second hardness (Fig 4; para [0111]; Shanghai teaches wherein the distal part has a shore hardness of about 60A).
As per claim 13, Shanghai in view of Ross teach the aspiration catheter of claim 12 wherein (a) the proximal region has a first length (Fig 4; para [0112]; the proximal part is taught to have a length of 1050-1200mm); (b) the intermediate region has a second length less than the first length (Fig 4; para [0112]; the transition section is taught to have a length of 10-30mm); and (c) the distal region has a third length greater than the second length and less than the first length (Fig 4; para [0112]; the distal part is taught to comprise a length of 100-200mm).

-Continued in next Supplemental Box-

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International application No.

PCT/US 21/59718

Supplemental Box

In case the space in any of the preceding boxes is not sufficient,

Continuation of:

Box V.2 - Citations and explanations:

As per claim 14, Shanghai in view of Ross teach the aspiration catheter of claim 13. While Shanghai teaches wherein the overall length of the catheter body can be easily modified to suit specific applications, Shanghai does not specifically teach wherein the first length is between about 20.0- 28.0 inches, the second length is between about 2.0-3.0 inches, and the third length is between about 11.00-15.00 inches. However, it is well known that optimizing size, shape and angle is of the ordinary skill in the art. Accordingly, it would have been obvious to one of ordinary skill in the art to have optimized the size of the first length, the second length and the third length to have arrived at wherein the first length is between about 20.0- 28.0 inches, the second length is between about 2.0-3.0 inches, and the third length is between about 11.00-15.00 inches. Accordingly, it would have been obvious to one of ordinary skill in the art to have arrived at wherein the first length is between about 20.0- 28.0 inches, the second length is between about 2.0-3.0 inches, and the third length is between about 11.00-15.00 inches, in order to improve navigation of the aspiration catheter within blood vessels.

Claims 1-14 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.



ELECTRONIC ACKNOWLEDGEMENT RECEIPT

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Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
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PATENT # -

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CUSTOMER # 25096

FIRST NAMED
INVENTOR Ben Merritt

CORRESPONDENCE
ADDRESS -

AUTHORIZED BY Matthew Williams

Documents

TOTAL DOCUMENTS: 56

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
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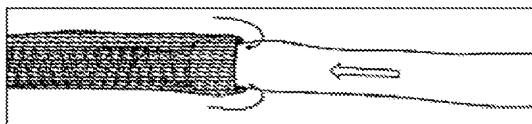
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(54) Title: ANTI-JAMMING AND MACERATING THROMBECTOMY APPARATUSES AND METHODS

PULLING CLOT IN: VESSEL ID ~ SAME AS CATHETER TIP

**FIG. 8A**(57) Abstract: Mechanical thrombectomy apparatuses that may be config-
ured to prevent or reduce jamming (e.g., "anti-j amming" thrombectomy de-
vices), grab clot, and/or macerate the thrombus, e.g., clot, being removed.
These mechanical thrombectomy apparatuses may include a tractor compris-
ing a flexible tube of material that inverts as it rolls over itself while be-
ing drawn into a catheter in a conveyor-like motion. In particular, described
herein are mechanical thrombectomy apparatuses having tractors selectably
extendable projections that may aid in grabbing and/or macerating a clot.
Also described herein are seesawing tractors for mechanical thrombectomy
apparatuses.

ANTI-JAMMING AND MACERATING THROMBECTOMY APPARATUSES AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims priority to U.S. provisional patent application no. 62/327,024, filed on April 25, 2016 and titled “DOZER THROMBECTOMY SYSTEM”; U.S. provisional patent application no. 62/345,152, filed on June 3, 2016, and titled “DOZER THROMBECTOMY SYSTEM 2”; and U.S. provisional patent application no. 62/393,460, filed on September 12, 2016, and titled “DOZER II THROMBECTOMY SYSTEM PROV”.

[0002] This patent application may be related to U.S. patent application no 15/291,015, filed on October 11, 2016, titled “MECHANICAL THROMBECTOMY APPARATUSES AND METHODS”, which is a continuation of U.S. Patent Application No. 15/043,996, filed February 15, 2016, now U.S. 9,463,035, which claims priority to each of the following provisional patent applications: U.S. Provisional Patent Application No. 62/284,300, filed September 28, 2015; U.S. Provisional Patent Application No. 62/284,752, filed October 8, 2015; and U.S. Provisional Patent Application No. 62/245,560, filed October 23, 2015.

[0003] Each of these patents and patent applications is herein incorporated by reference in its entirety.

INCORPORATION BY REFERENCE

[0004] All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

[0005] The apparatuses and methods described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses and methods.

BACKGROUND

[0006] It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue from within a vasculature, such as blood clots, may improve patient conditions and quality of life.

[0007] Many vascular system problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery.

[0008] When a thrombus forms, it may effectively stop the flow of blood through the zone of formation. If the thrombus extends across the interior diameter of an artery, it may cut off the flow of blood through the artery. If one of the coronary arteries is 100% thrombosed, the flow of blood is stopped in that artery, resulting in a shortage of oxygen carrying red blood cells, e.g., to supply the muscle (myocardium) of the heart wall. Such a thrombosis is unnecessary to prevent loss of blood but can be undesirably triggered within an artery by damage to the arterial wall from atherosclerotic disease. Thus, the underlying disease of atherosclerosis may not cause acute oxygen deficiency (ischemia) but can trigger acute ischemia via induced thrombosis. Similarly, thrombosis of one of the carotid arteries can lead to stroke because of insufficient oxygen supply to vital nerve centers in the cranium. Oxygen deficiency reduces or prohibits muscular activity, can cause chest pain (angina pectoris), and can lead to death of myocardium which permanently disables the heart to some extent. If the myocardial cell death is extensive, the heart will be unable to pump sufficient blood to supply the body's life sustaining needs. The extent of ischemia is affected by many factors, including the existence of collateral blood vessels and flow which can provide the necessary oxygen.

[0009] Clinical data indicates that clot removal may be beneficial or even necessary to improve outcomes. For example, in the peripheral vasculature, interventions and procedures can reduce the need for an amputation by 80 percent. The ultimate goal of any modality to treat these conditions of the arterial or venous system is to remove the blockage or restore patency, quickly, safely, and cost effectively. This may be achieved by thrombus dissolution, fragmentation, thrombus aspiration or a combination of these methods.

[00010] Mechanical thrombectomy devices may be particularly advantageous. Depending on the size, location and extent of a clot, it may also be particularly advantageous to

mechanical retrieve and break apart the clot in a manner that is both safe and effective. There is a definite need for a thrombectomy device, and particularly a mechanical thrombectomy device that can be more effective in removing tissue such as clots from within a body. Described herein are apparatuses (devices, systems and kit) and methods of using them that may address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[00011] Described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and methods of using and making them. These apparatuses may be configured to prevent or reduce jamming and enhance grabbing and/or macerating a thrombus, e.g., clot, being removed. Typically, the mechanical thrombectomy apparatuses described herein are inverting tractor thrombectomy apparatuses that includes a tractor (e.g., tractor region, tractor portion, etc.) comprising a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support. The elongate inversion support typically comprises a catheter having a distal end opening into which the tractor inverts. The flexible tractor inverts and rolls back into itself and may be drawn into the elongate inversion support in a conveyor-like motion; the outward-facing region rolls around to become an inward-facing region, e.g., within the lumen of the elongate inversion support. The rolling motion may thus draw a clot or other object within a vessel into the elongate inversion support.

[00012] Implementation of a rolling tractor that is sufficiently flexible to easily roll at the distal end (e.g., over a catheter) but sufficiently stiff to prevent jamming at the distal end of the elongate inversion support has proven challenging.

[00013] The elongate inversion support portion of the apparatus described herein may be or may include (particularly at its distal end) any appropriate catheter, e.g., a flexible tube that can be inserted into a body vessel (e.g., blood vessel) into which the more flexible tractor portion can be withdrawn by pulling against the elongate inversion support. The elongate inversion support may, in some variations, also be referred to as outer catheters (e.g., when the puller for the tractor is referred to as an inner catheter) and/or inversion catheters and/or support catheter, as it may support the inversion of the tractor. The elongate inversion support, including a catheter forming the elongate inversion support, may include a braided or woven portion, a spiral or coiled portion, etc. (e.g., having a braided shaft), may have a single layer or multiple layers, and may be formed of biocompatible materials, including polymers, metals, etc. (e.g., PTFE). Examples of vascular catheters that may form the elongate inversion support include micro catheters.

[00014] The mechanical thrombectomy apparatuses described herein include a tractor region and/or elongate inversion support that are configured to prevent jamming, while still able to efficiently “grab” a clot from within a vessel. For example, described herein are mechanical thrombectomy apparatuses that may be configured to grab or grasp and/or macerate a clot as it is mechanically drawn into the apparatus for removal. Although suction may be used in addition to the mechanical grabbing of the clot, in some variations suction is not used.

[00015] The tractor regions described herein may include projections that extend from the tractor region, particularly or exclusively as it bends around during inverting (e.g., at the distal end of the device). These projections may remain flat or non-extending when the tractor is held in parallel with the elongate inversion support. Alternatively, the projections may extend at all times. In general, the tractor may be formed of a woven materials, knitted material, or laser-cut sheet of material. The knitted and/or woven materials may be fibrous materials (including natural fibers, synthetics fibers, etc.), polymeric materials, or the like. For example, the material (e.g., strands) forming the woven or knitted material may be one or more of: monofilament polymer, multifilament polymer, NiTi filament, NiTi tube with radiopaque metallic center, Cobalt chromium alloy filament, Cobalt chromium alloy tube with radiopaque metallic center, Nylon, Polyester, Polyethylene terephthalate, and Polypropylene. The sheets of material (e.g. a solid sheet of material) formed into the tractor region may be one or more of: polymeric material (e.g., PTFE), silicone materials, polyurethanes, shape memory alloys, stainless steels, etc. The sheets may be extruded, glued, or the like. The sheets may be cut to form pores and/or projections. For example, the sheets may include one or more laser-cut projections. Any of these apparatuses may be coated with a hydrophilic and/or hydrophobic coating, and/or may include pores. The tractor may have a porosity of greater than >60% (greater than 70%, greater than 75%, greater than 80%, greater than 85%, etc., between 60-95, 65-95, 70-95%, etc.).

[00016] For example, described herein are clot-grabbing mechanical thrombectomy apparatuses that include a tractor region. The tractor region may include a plurality of clot-grabbing projections extending from one face of the tractor. In some variations, the clot-grabbing projections may be configured so that they move to extend (e.g., out of the plane of the tractor) when the tractor region bends around, e.g., around the distal end of the catheter of the elongate inversion support, to invert.

[00017] In general, a mechanical thrombectomy apparatus for removing a clot from a vessel may include: a elongate inversion support comprising a catheter having a distal end

and a distal end opening; a tractor comprising a flexible tube extending longitudinally within the catheter and doubling back over the distal end of the catheter to extend along the distal end of the catheter, an inner puller coupled to a distal end of the tractor; and a guidewire lumen extending through the catheter, tractor and the inner puller and configured to pass a guidewire. The proximal end of the tractor may be loose (e.g., may be free to slide over the catheter. The tractor may also be configured so that is it biased to hold itself against outer diameter of the catheter, and simultaneously biased to expand when inverted within the catheter; in this configuration, the inverting distal-facing end of the tractor may be flared outward slightly so that the diameter of the tractor expands slightly near the distal-facing inverting end of the apparatus. This configuration may also maintain the portion of the tractor within the catheter so that it is close to the inner diameter of the catheter; e.g., the inner diameter of the portion of the tractor within the catheter may be greater than 50 % of the inner diameter of the catheter, greater than 55% of the inner diameter of the catheter, greater than 60% of the inner diameter of the catheter, greater than 65% of the inner diameter of the catheter, greater than 70% of the inner diameter of the catheter, greater than 75% of the inner diameter of the catheter, etc.

[00018] For example, a mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube that extends distally in a first configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in a second configuration (that is inverted relative to the first configuration) along the distal end of the catheter, wherein the tractor comprises a tubular wall, further wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter; and a plurality of projections that extend from a portion of the tractor that is inverted over the distal end opening of the catheter as the tractor rolls over the distal end opening of the catheter, wherein the plurality of projections do not extend from the tractor as it extends proximally in the inverted configuration along the distal end of the catheter.

[00019] As mentioned, in general, the mechanical thrombectomy apparatuses described herein may include a clot-grabbing projection. For example, a mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube extending within the catheter and doubling back over the distal end of the catheter to extend along the distal end of the catheter, the flexible tube comprising a tube

wall, wherein the tractor is configured to invert over the distal end opening when a first end of the tractor is pulled proximally within the catheter, further wherein the tractor comprises a plurality of projections configured so that the plurality of projections extend out of a plane of the tube wall as the tube wall inverts over the distal end opening, further wherein the plurality of projections remain in the plane of the tube wall as the tube wall extends along the distal end of the catheter; and a guidewire lumen extending through the catheter and the tractor and configured to pass a guidewire.

[00020] In particular, the tractor may be a tube of woven ribbons, further wherein the plurality of projections is formed from edges of the ribbons. The ribbons may comprise flattened strips or strands of material having at least one (through typically four) elongate edges. For example, the ribbons may have a rectangular cross-section. In some variations the ribbons may have square or triangular or other cross-sections having one or more edges. Ribbons having edges may be woven, e.g., so that they are arranged in a helical pattern as they extend over the distal end of the elongate inversion support. Thus, the edge(s) of the ribbon may extend outward, out of the plane of the tractor, when the tractor inverts. These extending edges may bend up, forming scooping, cutting and/or grabbing projections over the bending region of the tractor. The ribbons may be formed of any appropriate material, including those discussed above, such as a metallic or polymeric material.

[00021] The projections from the tractor regions described herein may be formed by cut-out regions in the tractor material. For example, a sheet or tube of material may be used to form the tractor, such as a tube of steel (e.g., stainless steel), polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric, and projections may be formed, e.g., by cutting, from the tube or sheet. For example, the projections may be cut from the tube wall. In some variations the projections may be cut in addition to openings, slits, slots, or gaps (e.g., forming pores). For example, a tractor may have at least one porous section having a pore pattern having a longitudinal separation between pores of less than about 0.005 inches in width. In some variations, the projections may be cut from the tube wall at an angle of less than 90° tangent to the tube wall. For example, each of the plurality of projections may have a width in a direction transverse to the flexible tube and a length in a direction along a long axis of the flexible tube; the ratio of length to width may be between, e.g., 2 and 100 (e.g., 5 and 100, 10 and 100, 5 and 90, 5 and 80, 5 and 70, 5 and 50, 10 and 90, 10 and 80, 10 and 70, 10 and 60, etc.).

[00022] The projections may be shaped to grab and/or macerate the clot. For example, all or some of the plurality of projections may have one or more of: a paddle shape, a scoop

shape, and spike shape. The projections may extend proud of the plane of the tractor (e.g., at 90° or perpendicular to the tractor surface from which the projection extends, or between about 45-135° from the plane of the tractor surface, etc.). The projections may be sharp (e.g., may have sharp ends). The projections may extend between 0.01 mm to 5mm from the tractor surface (e.g., between 0.01 mm and 2 mm, between 0.05 mm and 1 mm, etc.). The size of the projections may be scaled to the size of the tractor and/or the size of the vessel into which the apparatus is intended to be inserted into.

[00023] In any of the apparatuses described herein, the elongate inversion support (e.g., catheter) may be adapted to enhance rolling of the tractor region (inverting) over the distal end. For example, in any of the apparatuses described herein, the catheter may be configured so that the material hardness of the catheter decreases over the distal end of the catheter until the distal end opening, wherein the distal end opening has a material hardness that is greater than a material hardness of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile. The catheter distal end may be stiffer because it is thicker (e.g., it may be formed by inverting the distal end of the catheter back over itself, and/or it may be formed of a stiffer material than the adjacent more proximal region (including by including a reinforcing material).

[00024] The projections configured to help grab clot may be distributed over the entire length of the tractor, or only over a region of the tractor (e.g., the distal end region, e.g., the distal 5 mm, 7mm, 10 mm, 15 mm, 20 mm, etc. or less). In some variations, the distribution of projections may be non-uniform distributed, e.g., the tractor may include a non-uniform density of projections along the length of the tractor. The projections may be oriented relative to the tractor so that the projections extend in the distal direction when the tractor is on the outer diameter of the catheter, which may help them grab clot.

[00025] The projections may be configured (e.g., by laser cutting the tube forming the tractor) as a plurality of slots or openings through the tractor.

[00026] In any of the apparatuses described herein, the tractor may include one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating. In particular the tractor may include a uniform or non-uniform lubricious (e.g., hydrophilic) coating. Such coatings may assist in making the tractor slide more easily to invert (e.g., over the distal end of the catheter), but may make it particularly hard to grab clot. The projections described herein may address this issue.

[00027] Any of the apparatuses described herein may include a releasable attachment between the tractor and an outer surface of the elongate inversion support (e.g., catheter),

configured to release when the tractor is pulled with a force that is greater than a predetermined force threshold. This may prevent premature deployment of the apparatus. The releasable attachment may be a breakable (e.g., frangible) region, e.g., of an adhesive, etc. or a releasable tie, etc. The releasable attachment may be formed by regions of different hydrophobicity/hydrophilicity. Any of these apparatuses may be configured so that the force required to deploy the apparatus is greater than a predetermined threshold, e.g., the releasable force threshold may be greater than 50 g, 100 g, 200 g, 300 g, 400 g, 500 g, 600 g, 700 g, 800 g, 900 g, 1000 g, etc. of force (e.g., greater than 200 g of force). In addition, any of these apparatuses may include a cover, an outer elongate inversion support comprising a catheter, sleeve, sheath, etc., holding the proximal end of the tractor against the catheter until it is ready to be deployed. Deployment may mean releasing the end (e.g., the end on the outer surface of the catheter) from a releasable attachment; once deployed, the force required to pull the tractor proximally in the catheter, including drawing the tractor from along the outer diameter of the catheter, inverting the tractor and pulling the tractor into the catheter distal end opening (without a clot or other material in the tractor) may be substantially less than the initial deployment force. For example, the force required to pull the tractor into the catheter proximally may be 1 gram (g) of force or less (or 2 g, 3 g, 4 g, 5 g, 6 g, 7 g, 8 g, 9 g, 10 g, 20 g, 30 g, 40 g, 50 g, etc., of force or less). Alternatively or additionally, any of these apparatuses may include a material between the tractor and the catheter (e.g., a sleeve, coating, etc.) to reduce the amount of force required to invert the catheter over the distal end of the catheter, and/or to prevent jamming of the tractor in the catheter.

[00028] As mentioned, any of these apparatuses may include a puller, e.g., an elongate puller coupled to a distal end of the tractor. Any of these apparatuses may include an elongate puller within the catheter coupled to a distal end of the tractor. The elongate puller may comprise a hypotube having an inner lumen that is continuous with the guidewire lumen through the flexible tube.

[00029] In general, the tractor may be any appropriate length. For example, the tractor may be between 3 to 100 cm long (e.g., between 3 and 50 cm, between 3 and 40 cm, between 3 and 30 cm, between 3 and 20 cm, between 10 and 100 cm, between 10 and 50 cm, between 20 and 100 cm, between 20 and 50 cm, etc.).

[00030] In any of these apparatuses, the apparatus may be configured so that the tractor may be retracted into the catheter by applying less than 300 grams of force (e.g., less than 400 g of force, less than 300 g of force, less than 200 g of force, less than 100 g of force, less than 90 g of force, less 80 g of force, less than 70 g of force, less than 60 g of force, less than

50 g of force, less than 10 g of force, etc.) to a distal end of the flexible tube. For example, as mentioned above, the apparatus may include a hydrophilic coating, a lubricant on the catheter and/or tractor, a sleeve between the tractor and catheter, etc. This force required to retract the tractor into the catheter typically refers to the force required to roll the tractor over the distal end of the tractor; an initial deployment force (e.g., to release the end of the tractor outside of the catheter) may be greater than the force required to retract the catheter (e.g., greater than 100 g of force, 200 g of force, 300 g of force, 400 g of force, 500 g of force, 600 g of force, 700 g of force, 800 g of force, 900 g of force, 1000 g of force, 1500 g of force, 2000 g of force, etc.).

[00031] For example, a mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube that extends distally in a first (e.g., “un-inverted”) configuration within the catheter, inverts over the distal end opening of the catheter into a second configuration (that is inverted relative to the first configuration) and extends proximally in an inverted configuration along the distal end of the catheter, the flexible tube comprising a plurality of ribbons having a square or rectangular cross-section woven together, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter, wherein a plurality of edges of the plurality of ribbons extend from a portion of the tractor that is inverted over the distal end opening of the catheter as the tractor rolls over the distal end opening of the catheter, further wherein the projecting edges are not extended from the tractor in a portion of the tractor that extends over the distal end of the catheter; and a guidewire lumen extending through the catheter and the tractor and configured to pass a guidewire.

[00032] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate inversion support comprising an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube extending within the catheter and doubling back over the distal end of the catheter to extend along the distal end of the catheter, the flexible tube comprising a tube wall formed from a plurality of woven ribbons having a square or rectangular cross-section, wherein the tractor is configured to invert over the distal end opening when a first end of the tractor is pulled proximally within the catheter, further wherein the tractor comprises a plurality of projections configured so that the plurality of projections extend out of a plane of the tube wall as the tube wall inverts over the distal end opening, further wherein the plurality of projections are

formed from edges of the ribbons and the projections remain in the plane of the tube wall as the tube wall extends along the distal end of the catheter; and a guidewire lumen extending through the catheter and the tractor and configured to pass a guidewire.

[00033] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube extending within the catheter and doubling back over the distal end of the catheter, the flexible tube comprising a tube wall, wherein the tractor is configured to invert over the distal end opening when a first end of the tractor is pulled proximally within the catheter, further wherein the tractor comprises a plurality of projections formed in the tube wall and configured so that the plurality of projections extend proud of the tractor when the tractor inverts over the distal end opening and otherwise remain in a plane of the tube wall; wherein each of the plurality of projections have a width in a direction transverse to the flexible tube and a length in a direction along a long axis of the flexible tube, further wherein the ratio of length to width is between 10 and 100; and a guidewire lumen through the catheter and the tractor configured to pass a guidewire.

[00034] Any of the apparatuses described herein may be configured so that the tractor is highly soft, and therefore rolls around the distal end of the catheter forming the elongate inversion support easily without jamming and/or requiring a large force to roll the tractor over the distal end opening of the catheter. In particular, tractors having a low axial compression strength, that would, but for the elongate inversion support, typically buckle, have been found to prevent jamming of the elongate inversion support as the tractor inverts. In particular, unsupported tractors (e.g., tractor that are not rolling over a catheter supported annular opening) that are configured to collapse radially under an axial compression of less than about 500g of force (e.g., less than: about 500g force, about 400g force, about 300g force, about 200g force, about 150 g force, about 100 g force, about 50 g force, etc.) may be particularly helpful in preventing jamming. For most knitted, woven, and braided tractors, including those described herein, when the tractor is configured to withstand greater than this amount of axial compression force, the tractor may jam, and/or may require excessive force to invert. Thus, in any of the apparatuses and methods described herein, the tractor may be sufficiently soft such that without support from the catheter, the tractor collapses radially under an axial compression of less than 200g of force when inverting (and may instead buckle).

[00035] Further, in any of the apparatuses described herein, the tractor may be biased to expand to greater than the outer diameter of the catheter in a second configuration (that is

inverted relative to the first configuration) where the tractor is extending over the outer diameter of the catheter. The same tractor may be biased to expand to greater than the inner diameter of the catheter of the elongate inversion support in the first (e.g., un-inverted), configuration where the tractor is within the catheter of the elongate inversion support. Thus, in relaxed configuration, prior to assembling with the elongate inversion support, the tractor may be oversized compared to the catheter of the elongate inversion support; the portion of the tractor that extends within the catheter of the elongate inversion support, referred to as “un-inverted,” may have an inner diameter that is greater than the inner diameter of the catheter, which may tend to drive the tractor toward the walls of the inner diameter of the catheter without collapsing down into the catheter. Further, the inner diameter of the tractor in the “inverted” configuration, e.g., the configuration of the portion that is doubled back over and along the catheter of the elongate inversion support, may be greater than the outer diameter of the catheter of the elongate inversion support. This arrangement may prevent jamming and an increased resistance between the tractor and the outside of the catheter of the elongate inversion support. The catheter may be biased to expand in both the inverted and un-inverted configurations by, e.g., heat setting. The tractor may be inverted to transition between the first and second configurations by rolling over the distal end of the catheter; the terms “inverted” and “un-inverted” are therefore relative terms.

[00036] Also described herein are methods of removing a clot using a mechanical thrombectomy apparatus. For example, a method of removing a clot using a mechanical thrombectomy apparatus may include: positioning a distal end of the mechanical thrombectomy apparatus adjacent to a clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of an elongate inversion support having a catheter and inverts over a distal end of the catheter so that a distal end of the tractor extends proximally within the catheter; pulling the distal end of the tractor proximally within the catheter to invert the tractor over the distal end of the catheter to extend a plurality of projections from the tractor and grab the clot; and drawing the clot into the catheter.

[00037] Any of these methods may include macerating the clot with the plurality of projections.

[00038] For example, a method of removing a clot using a mechanical thrombectomy apparatus may include: positioning a distal end of the mechanical thrombectomy apparatus adjacent to a clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of

the catheter so that a first end of the tractor extends proximally within the catheter; pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter and extends a plurality of projections from the tractor; grabbing the clot with the plurality of projections; and drawing the clot into the catheter.

[00039] As mentioned above, the tractor may comprises a plurality of woven ribbons having a square or rectangular cross-section, further wherein pulling the distal end of the tractor proximally within the catheter to invert the tractor over the distal end of the catheter to extend a plurality of projections from the tractor comprises extending a plurality of edges of the woven ribbons from out of a plane of the tractor as the tractor is inverted over the distal end of the catheter to grab the clot with the extended edges.

[00040] Alternatively or additionally, the tractor may comprise a plurality of cut-out regions formed in the tractor, further wherein pulling the distal end of the tractor proximally within the catheter to invert the tractor over the distal end of the catheter extends the cut-out regions forming the plurality of projections from the tractor to grab the clot. Any of these methods may include sliding a loose proximal end of the tractor over the catheter as the distal end of the tractor is pulled proximally.

[00041] Any of these methods may include using a guidewire. For example, positioning the distal end of the mechanical thrombectomy apparatus may comprise sliding the mechanical thrombectomy apparatus over a guidewire.

[00042] Similarly, any of these methods may include releasing a releasable attachment between the tractor and an outer surface of the catheter.

[00043] Pulling the distal end of the tractor proximally may comprises maintaining an inner diameter of the tractor within the catheter at greater than 60 % of an inner diameter of the catheter to prevent the tractor from locking over the distal end of the catheter.

[00044] Also described herein are apparatuses having tractor regions with variable stiffness along the length of the tractor. These apparatuses may invert (roll) at their distal-facing end of the tractor with a ratcheting motion. These apparatuses, and methods of using them, may provide a movement that prevents jamming, and may also help grab clot.

[00045] For example, described herein are mechanical thrombectomy apparatuses for removing a clot from a vessel that may include: a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube extending longitudinally within the catheter and doubling back over the distal end of the catheter to extend along the distal end of the catheter, wherein the flexible tube comprises longitudinally alternating regions of higher and lower

stiffness, wherein the regions of higher stiffness have a stiffness that is greater than the regions of lower stiffness; an inner puller coupled to a distal end of the tractor; and a guidewire lumen extending through the catheter, tractor and the inner puller and configured to pass a guidewire.

[00046] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube extending longitudinally within the catheter and doubling back over the distal end of the catheter to extend along the distal end of the catheter, wherein the flexible tube comprises longitudinally alternating regions of higher and lower stiffness, wherein the regions of higher stiffness have a stiffness that is greater than the regions of lower stiffness, further wherein a diameter of the distal-facing end of the tractor oscillates as the tractor is pulled proximally within the catheter to invert the tractor over the distal end of the catheter; an inner puller coupled to a distal end of the tractor; and a guidewire lumen extending through the catheter, tractor and the inner puller and configured to pass a guidewire.

[00047] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: a catheter having a distal end and a distal end opening having a radius; a tractor comprising a flexible tube extending longitudinally within the catheter and doubling back over the distal end of the catheter to extend along the distal end of the catheter, wherein the flexible tube comprises longitudinally alternating regions of higher and lower stiffness helically arranged around the flexible tube, wherein the regions of higher stiffness have a first length and a stiffness that is greater than the regions of lower stiffness, wherein the first length is between about 0.1 and 1.1 times the radius of the catheter; an inner puller coupled to a distal end of the tractor; and a guidewire lumen extending through the catheter, tractor and the inner puller and configured to pass a guidewire.

[00048] Thus, the regions of higher stiffness may have a longitudinal length along the flexible tube that is between about 0.05 and 1.2 (e.g. between 0.1 and 1.1 between 0.2 and 1 between 0.3 and 1 between 0.5 and 1, between 0.5 and 1.1, etc.) times the radius of the catheter. The the regions of higher and lower stiffness may be helically arranged around the flexible tube. In any of these apparatuses, the ratcheting motion may be seen by an oscillation of the diameter of the distal end-facing end of the tractor as it rolls over the catheter. For example, the diameter of the distal-facing end of the tractor may oscillate as the tractor is pulled proximally within the catheter to invert the tractor over the distal end of the catheter.

[00049] As mentioned, the tractor may be formed of a woven and/or knitted material. For example tractor may comprise a knitted material comprising one or more of: steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), and Nitinol. The tractor may comprise a sheet of one or more of: steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric. The sheet may comprise a plurality of cut-out regions modifying the stiffness.

[00050] Methods of operating any of the apparatuses described herein (including the apparatuses including a ratcheting or see-saw tractors) are also described herein.

[00051] As mentioned above, any of the apparatuses described herein may be configured to prevent jamming by pre-biasing the tractor region so that it has an inner diameter in a first configuration within the lumen of the catheter (referred to for convenience herein as the “un-inverted” configuration, relative to the configuration of the portion of the tractor that has rolled over the distal end opening of the catheter) has a greater outer diameter than the inner diameter of the catheter. Further, any of the apparatuses described herein may also have an inner diameter in a second configuration over the catheter (referred to herein as the “inverted” configuration, relative to the first configuration) that is greater than the outer diameter of the catheter.

[00052] For example, described herein are mechanical thrombectomy apparatus for removing a clot from a vessel without jamming comprising: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube that extends distally in a first configuration (e.g., an “un-inverted” configuration) within the catheter, inverts over the distal end opening of the catheter and extends proximally in a second (e.g., “inverted”) configuration along the distal end of the catheter, wherein the tractor comprises a tubular wall, further wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter, wherein the tractor is biased to expand to have an inner diameter that is greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to have an inner diameter that is greater than the inner diameter of the catheter in the un-inverted configuration; and an elongate puller coupled to the first end of the tractor.

[00053] A mechanical thrombectomy apparatus for removing a clot from a vessel without jamming may include: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube that extends distally in a first (an “un-inverted”) configuration within the catheter, inverts over the distal end opening

of the catheter and extends proximally in a second (an “inverted”) configuration along the distal end of the catheter, wherein the tractor comprises a tubular wall, further wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter, wherein the tractor is biased to expand to greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to greater than the inner diameter of the catheter in the un-inverted configuration; an elongate puller coupled to a first end of the tractor and configured to pull the tractor proximally to invert the tractor over the distal end opening; and a guidewire lumen extending through the elongate inversion support, puller, and tractor that is configured to pass a guidewire. The tractor may be any of the tractors described herein, e.g., a woven tube, a braided tube, a knitted material, etc.

[00054] Any of the apparatuses described herein may be used with or may include an outer catheter within which the elongate inversion support extends distally; this outer catheter may be referred to as a sleeve or sheath, or in some variations an “intermediate” catheter, as it may be positioned, e.g., using a guidewire or by itself, first within the vasculature and then the elongate inversion support and tractor may be inserted within it to guide them to the clot to be removed, including after removing the guidewire, or leaving the guidewire in position. Any of these devices may be used with a vacuum to help capture and pull clot. For example, if an outer catheter is used, the outer catheter (within which the elongate inversion support can extend distally) may be proximally coupled to a vacuum source. The elongate inversion support may be configured as described herein to permit drawing the vacuum to the end of the elongate inversion support and/or outer catheter. For example, the elongate inversion support may have a diameter that leaves sufficient clearance. In particular, the apparatus may be configured so that there is at least about 0.002 inches or greater (e.g., 0.003 inches or greater, 0.004 inches or greater, 0.005 inches or greater, 0.006 inches or greater, etc.) between the outer diameter of the catheter and the inner diameter of the outer catheter. The elongate inversion support may have a catheter with the distal end opening about which the tractor inverts that extends only part ways from the distal end towards the proximal end of the elongate inversion support. For example, the full catheter portion of the elongate inversion support may extend less 0.5 cm or less, 1 cm or less, 2 cm or less, 3 cm or less, 4 cm or less, 5 cm or less, etc. In some variations the elongate inversion support comprises a catheter that is skived at the proximal end. The catheter, and particularly the distal end region of the elongate inversion support, may include one or more openings, slots, holes, windows, cut-out

regions, etc. for allowing vacuum to pass from the outer sleeve and preventing choking of the flow of vacuum from the distal end of the apparatus.

[00055] As mentioned, in any of the variations described herein, the tractor may be configured to collapse radially under an axial compression of less than 200g of force. Thus, the tractor may be sufficiently soft and easy to roll (and invert) over the distal end aperture (distal end opening, e.g. of a catheter of the elongate inversion support). Similarly, the elongate inversion support may be configured to withstand buckling of an axial compression of greater than 500 g of force, sufficient to allow pulling of the tractor over the distal end opening (e.g. aperture) of the elongate inversion support without collapsing, kinking or displacing the elongate inversion support. In some variations, and particularly peripheral vascular variations, the elongate inversion support is configured to withstand buckling of an axial compression of greater than 1500 g of force.

[00056] Any of the apparatuses described herein may include a tractor having one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating.

[00057]

BRIEF DESCRIPTION OF THE DRAWINGS

[00058] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00059] FIGS. 1A-1H illustrate an example of an apparatus for mechanically removing an object such as a clot from a body region. FIG. 1A shows an example of an elongate inversion support portion of an apparatus, configured as a catheter portion. For example, at least the distal end of the elongate inversion support may be configured as a catheter. FIG. 1B shows an enlarged view of a distal end (opening) of the catheter of the elongate inversion support of FIG. 1A, showing the aperture formed by the distal end opening; FIG. 1C shows an example of a distal tractor region of a flexible tube (tractor tube) extending from a puller (the puller in this example is configured as a catheter. The tractor is shown in a first (e.g., un-inverted) configuration) and may be biased open, e.g., by heat setting, to have an outer diameter that is greater than the inner diameter of the catheter of the elongate inversion support, as shown in FIG. 1D. FIG. 1D shows the same distal tractor region of FIG. 1C with

the expandable first end region expanded. This first configuration may be compressed down into the elongate inversion support and the distal end inverted over the catheter portion of the elongate inversion support, as shown in FIG. 1E. In FIG. 1E, the assembled mechanical thrombectomy apparatus with the elongate inversion support and the flexible tube forming the tractor is shown. The tractor extends through the catheter of the elongate inversion support and doubles back over the distal end opening of the catheter and extends over the outer diameter of the catheter. The outer portion of the tractor (extending along the outer diameter of the catheter) may be held in a collapsed configuration (as shown in FIG. 1E), or it may be expanded, as shown in FIG. 1F. Thus, the tractor may be biased so that in the second configuration (inverted over the distal end of the catheter), the tractor has a 'relaxed' outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. FIGS. 1G and 1H illustrate the use of the apparatus of FIGS. 1E and 1F to remove a clot by drawing the flexible tube proximally and/or advancing the catheter distally towards the clot so that the expandable first end region inverts as it is drawn into the distal end of the catheter, pulling the clot into the catheter.

[00060] FIG. 1I illustrates an alternative variation of a tractor and puller. In FIG. 1I, the tractor is shown attached to the distal end of a tapered or narrow puller; the distal end region is tapered, and includes a radiopaque marker at or near the attachment site to the tractor; the tractor may be knitted, braided, woven, etc. Thus, in some variations the distal end region of the puller may have a greater flexibility than the proximal end of the puller. The puller may be hollow (e.g., a catheter or hypotube) or solid (e.g., like a wire).

[00061] FIGS. 2A and 2B illustrate jamming of a mechanical thrombectomy apparatus. In FIG. 2A the mechanical thrombectomy apparatus includes a tractor region that collapses within the inner diameter (lumen) of the catheter portion of the elongate inversion support, jamming so that the tractor region cannot roll, without applying excessive force, or at all, around the open end of the catheter. Similarly, in FIG. 2B, the tractor region is loose, and also jams on the distal open end of the catheter as it inverts.

[00062] FIG. 2C illustrates an example of an anti-jamming configuration, in which the distal-facing, inverting portion of the tractor is flared outwards at an angle, so that the portion of the tractor on either side of the catheter end approaches at an angle of less than 45 degrees relative to a length of the tractor (e.g., 0.5 mm, 1 mm, 2mm) on either side of the opening. In this example, the portion of the tractor that is around the outer diameter is biased to contract down onto the outer diameter of the catheter, and after inverting the bias is to expand outward slightly, resulting in the trumpet-shaped inverting region. Even in this configuration, the

tractor may be set (e.g., biased) so that the outer diameter of the first configuration (within the catheter of the elongate inversion support) has a greater outer diameter than the inner diameter of the catheter in the relaxed state (e.g., when not compressed and constrained in the catheter inner diameter), and the outer diameter of the tractor in the second configuration (inverted over the outer diameter of the catheter of the elongate inversion support) is greater than the outer diameter of the catheter. In some variations the unconstrained first configuration has a greater OD than the unconstrained OD of the second configuration. Alternatively, the unconstrained OD of the first configuration may be less than the OD of the unconstrained OD of the second configuration.

[00063] FIGS. 3A-3C illustrate the operation of a mechanical thrombectomy apparatus having a tractor region such as that shown in FIG. 2C capturing a clot. In FIG. 3A the apparatus is positioned adjacent to the clot. FIG. 3B shows an alternative variation in which a guidewire is used to position the apparatus; the guidewire may remain in place during capture of the clot, or it may be removed. FIG. 3C shows the apparatus capturing the clot by rolling the tractor portion of the apparatus over the end of the catheter of the elongate inversion support as the tractor portion is drawn proximally; the apparatus may be advanced distally within the lumen of the vessel.

[00064] FIGS. 4A and 4B illustrate another example of a mechanical thrombectomy apparatus having a tractor in which an anti-jamming sleeve portion is included between the catheter outer diameter and the tractor. In FIG. 4A the tractor portion is configured to include a central guidewire lumen and a hypotube (inner catheter) is used to pull the proximal end of the tractor; in FIG. 4B the tractor is configured to collapse down to a puller wire.

[00065] FIGS. 5A-5B illustrate formation of catheter tip having a stiffer distal end adapted to prevent jamming and/or collapse of the catheter distal opening when inverting a tractor over the distal end. In FIG. 5A the tip is shown with a slightly proximally-offset from the distal end marker band; in FIG. 5B the tip of the catheter has been folded back over itself, increasing both the diameter of the catheter at the distal end and the stiffness of the distal end.

[00066] FIGS. 6A-6B is an example of a distal tip or end region of a catheter such as that shown in FIG. 5B, over which a tractor is inverting. FIG. 6A is an example of a side perspective view and FIG. 6B shows the distal end face of the apparatus.

[00067] FIGS. 7A-7E illustrate examples of heat set 0.085" ID PET (FIGS. 7A-7C) tractors and nickel titanium heat-set 0.085" ID tractors.

[00068] FIGS. 8A-8D illustrate operation of mechanical thrombectomy apparatus pulling in a clot. FIGS. 8E-8F illustrate reversal of the apparatus of FIGS. 8A-8D, ejecting the clot.

[00069] FIGS. 9A-9C illustrate operation of an apparatus having a 48-end PET (0.002" monofilament) tractor. FIG. 9D illustrates reversing the apparatus of FIGS. 9A-9C.

[00070] FIGS. 9E-9G illustrate operation of an apparatus having a 72-end PET (0.002" 4x0.0008" filament) tractor drawing in a clot.

[00071] FIGS. 10A-10E illustrate examples of knitted tractors.

[00072] FIGS. 11A-11D illustrate patterns that may be used to form a tractor for a mechanical thrombectomy apparatus.

[00073] FIGS. 12A-12I show examples of microstructures that may be included in any of the mechanical thrombectomy apparatuses described herein.

[00074] FIGS. 13A and 13B show side and cross-sectional views, respectively, illustrate an example of a tractor having selectively deployable projections that may extend from the inverting region of the tractor to assist in grabbing and/or macerating a clot.

[00075] FIG. 14 illustrates an example of an apparatus including a plurality of projections extending from the tractor region that may aid in grabbing and/or macerating a clot.

[00076] FIG. 15A shows an example of a distal end of a mechanical thrombectomy apparatus having a tractor formed from a plurality of filaments having a round cross-sectional profile; the tractor of FIG. 15A does not include any projections extending therefrom. FIG. 15B illustrates the outer profile of a filament of the device of FIG. 15A as it inverts over a distal catheter opening of the elongate inversion support. FIG. 15C illustrates the rounded profile of the filaments forming the tractor of FIG. 15A.

[00077] FIG. 15D is a section through a rectangular filament (e.g., ribbon filament) having four edges. FIG. 15E illustrates the projection of a ribbon filament as it inverts over a catheter filament; because it approaches from an angle relative to the catheter opening (and because it is constrained by the adjacent filaments) the edge of the ribbon forming the inverting region may project up and out of the plane of the tractor.

[00078] FIGS. 16A and 16D illustrate an example of a tractor having a plurality of projections formed by rectangular filaments (e.g., ribbon filaments) as schematically illustrated in FIGS. 15D-15E. FIG. 16A shows a top perspective view and FIG. 16B is a side view.

[00079] FIGS. 17A-17D illustrate exemplary tractors formed by cutting (e.g., laser cutting) a tubular material.

[00080] FIGS. 18A-18C illustrate different slotted patterns that may be cut into a tube (or sheet) to form a tractor region.

[00081] FIG. 19 is another example of a pattern that may be use to form a tractor region.

[00082] FIGS. 20A-20B show an example of a pattern that may be use to form a tractor region. FIG. 20B is an enlarged view of the pattern of FIG. 20A.

[00083] FIGS. 21A-21B show an example of a pattern that may be use to form a tractor region. FIG. 21B is an enlarged view of the pattern of FIG. 21A.

[00084] FIGS. 22A-22B show an example of a pattern that may be use to form a tractor region. FIG. 22B is an enlarged view of the pattern of FIG. 22A.

[00085] FIGS. 23A-23B show an example of a pattern that may be use to form a tractor region. FIG. 23B is an enlarged view of the pattern of FIG. 23A.

[00086] FIGS. 24A-24B show an example of a pattern that may be use to form a tractor region. FIG. 24B is an enlarged view of the pattern of FIG. 24A.

[00087] FIGS. 25A-25C illustrate tractor regions having different patterns of slots and openings.

[00088] FIG. 26A illustrates bending of a typical small bore catheter distal tip.

[00089] FIGS. 26B-26C show examples of a catheter comprising a keyed slotted tube extending along the entire length of the catheter.

[00090] FIG. 27 shows an example of a catheter design formed as a slotted tube.

[00091] FIGS. 28A-28B is an example of a catheter design.

[00092] FIGS. 29A-29B is an example of a catheter design.

[00093] FIG. 30A schematically illustrates a portion of a tractor having alternating stiff/less stiff regions. FIGS. 30B-30D illustrate the seesawing motion of a tractor having alternating stiff/less stiff regions.

[00094] FIG., 31A is an example of a knitted tractor having alternating more stiff/less stiff regions extending in a corkscrewing/helical pattern along the length of the tractor.

[00095] FIGS. 31B-31C show side and end views, respectively of an apparatus having a knitted tractor, similar to that shown in FIG. 31A.

[00096] FIGS. 31D and 31E show side and end views, respectively of an apparatus having a knitted tractor.

[00097] FIGS. 32A-32B illustrate jamming in an apparatus having a seesawing tractor region that has alternating stiff regions that are too long for the diameter of the catheter over which it is inverting.

[00098] FIGS. 32C-32D illustrate jamming in an apparatus having a seesawing tractor region that has alternating stiff regions that are too small for the catheter over which it is inverting.

[00099] FIGS. 33A and 33B illustrate another example of an apparatus having a knitted tractor.

[000100] FIG. 34 is a schematic of a knitted tractor.

[000101] FIGS. 35A-35C illustrate movement of the loops of a knitted tractor having loops of a nickel titanium filament forming alternating stiff/less stiff regions (arranged down the long axis of the tractor).

[000102] FIGS. 36A-36B illustrate end perspective and side perspective views, respectively, or an apparatus having a knitted tractor.

[000103] FIGS. 37A-37C illustrate seesawing operation of the apparatus of FIGS. 36A-36B.

[000104] FIGS. 38A-38B show an example of an apparatus having a motor-driven tractor.

[000105] FIGS. 39A-39C illustrate operation of the apparatus of FIGS. 38A-38B.

[000106] FIGS. 40A-40C illustrate apparatuses as described herein including patterned coatings (e.g., hydrophilic and/or hydrophobic coatings).

[000107] FIG. 41A illustrates a method for removing clot using an intermediate catheter (e.g., sleeve) and a vacuum, in which a mechanical thrombectomy apparatus is extended from a distal end of the intermediate catheter to remove a clot.

[000108] FIG. 41B illustrates a method for removing clot using an intermediate catheter (e.g., sleeve) and a vacuum, in which a mechanical thrombectomy apparatus removes a clot that has been drawn into the distal end of the intermediate catheter.

[000109] FIGS. 42A-42B illustrate a variation of a catheter of an elongate inversion support having both different diameters (e.g., a larger-diameter distal catheter connected to a smaller-diameter proximal region extending longitudinally in the proximal-to-distal axis), and a plurality of openings (e.g., cut-out regions, holes, etc.).

[000110] FIGS. 42C-42D illustrate another variation of a catheter of an elongate inversion support having a plurality of opening formed therethrough.

[000111] FIGS. 42E-42F illustrate another variation of a catheter of an elongate inversion support having a distal catheter region and an elongate support member formed by skive cutting the catheter.

[000112] FIGS. 42G-42H illustrate another variation of an elongate inversion support having a distal catheter region and an elongate support member extending from the catheter region.

[000113] FIGS. 42I-42J illustrate another variation of an elongate inversion support having a plurality or openings along the distal-to-proximal length.

[000114] FIGS. 42K-42L illustrate another variation of an elongate inversion support having a minimal catheter region at the distal end forming a distal end opening that is connected to an elongate support (e.g., wire, tube, bar, rod, etc.).

[000115] FIG. 43A is another variation of an elongate inversion support having a minimal catheter region at the distal end. FIGS. 43B-43D illustrate an elongate inversion support such as the one shown in FIG. 43A having additional supports (FIG. 43B) and used as part of a mechanical thrombectomy apparatus (FIG. 43C and 43D).

[000116] FIGS. 44A-44C illustrates an example of the operation of a mechanical thrombectomy apparatus with an expandable distal end region.

DETAILED DESCRIPTION

[000117] In general, described herein are mechanical thrombectomy apparatuses having an inverting tractor that is configured to prevent jamming and grab a blood clot. These apparatuses may include an elongate elongate inversion support support that supports an annulus over which the tractor inverts at the distal end. The tractor may comprise a flexible tube that doubles back over (e.g., inverts) over the distal end of the elongate inverting support (e.g., a catheter) so that it extends into the annulus opening of the elongate inverting support and an inner puller coupled to the inner end of the tractor that the tractor can be pulled proximally to pull and invert the tractor over the annulus at the distal end of the elongate inverting support to roll and capture a clot. The apparatus may include a guidewire lumen extending through the elongate inverting support, and/or tractor puller that is configured to pass a guidewire.

[000118] Any of the apparatuses described herein may be adapted to prevent jamming, e.g., by including a coating (e.g., hydrophilic, lubricious coating, etc.) or the like to enhance the sliding and inverting of the tractor over the distal end. Further, any of these apparatuses may include one or more projections that are configured to enhance grabbing and/or maceration of a clot. Grabbing of a clot may be particularly, but not exclusively, helpful when the tractor is lubricious. Although lubricious tractors may resist jamming and require less force to operate, e.g., inverting over the distal end of the catheter, it may be more difficult to initially grab or grasp clot when the tractor is more lubricious. It may also be particularly helpful to include projections that are retracted along the length of the tractor adjacent to the outer diameter of the elongate inverting support (e.g., catheter), for example, when positioning the

apparatus within a vessel, but extend the projections outward from the tractor when rolling and inverting to grab a clot.

[000119] In general, a mechanical thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an elongate inversion support having a distal end and a distal annulus, and a flexible tractor assembly at least partially inverted and configured to roll and invert over the distal annulus of the elongate inverting support.

[000120] In many of the examples described herein, the elongate inversion support is a catheter (or a portion of a catheter at the distal end) and the annulus is formed by the distal end opening of the catheter; the tractor extends within the catheter and doubles back over the distal end of the catheter to extend over the outer diameter of the catheter at the distal end of the catheter, although it may extend proximal for any appropriate distance (including between 1-30 cm, between 2-20 cm, greater than 1 cm, 2 cm, 3 cm, 4 cm, 5 cm, 6 cm, 7 cm, 8 cm, 9 cm, 10 cm, 11 cm, 12 cm, 15 cm, 20 cm, etc.). The end of the tractor within the catheter may be coupled to a puller (e.g., at a proximate puller region connected to the distal or inner end of the tractor). The tubular tractor may include an elongate lumen that is configured to allow passage of a guidewire. The tubular tractor may also be configured to slide along the long axis within the catheter lumen and invert over the distal end opening of the catheter when the proximal end region is pulled proximally. The tractor may be referred to herein as a tractor assembly, tractor portion, tractor tube, or simply a tractor, and is typically positioned and longitudinally slideable within the catheter, and arranged so a portion of the tractor (sometimes referred to as the “distal tractor region” or “distal-facing” tractor region) doubles back over itself.

[000121] For example, FIG. 1A shows one variation of a catheter of an elongate inversion support that may form part of the apparatuses described herein. In this example, the elongate inversion support includes a catheter 100 having a distal end region 103 that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing hardness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1 mm, 0.8 mm, 0.5 mm, 0.3 mm, 0.2 mm, etc., and z is always at least three times less than x)

has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[000122] In FIG. 1A, the elongate inversion support is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include a elongate inversion support that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like (as will be described in greater detail below in reference to FIGS. 42A-43D) or may be skived. Thus, any of the apparatuses and methods described herein may be adapted for use with an elongate inversion support that is not limited to catheters, including elongate inversion supports that include a portion of a catheter, or that include a ring or other structure forming the annulus at the distal end. In FIG. 1A the catheter 100 of the elongate inversion support may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[000123] In some variations the distal end 105 of the elongate inversion support is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in some variations the distal tip (end) may be curved or radiused 109 as shown in FIG. 1B, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[000124] FIG. 1C shows an example of a flexible tractor 144 coupled to a puller 146. In this example to form a pullable tractor assembly 140, the tractor is shown integrated with the puller, forming the assembly. In FIG. 1C, the tractor is a tube of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The tractor is shown extended from the puller in a first configuration. It may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 144 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The puller 146 may typically be a less-expandable (or non-

expandable) structure (tube, puller, etc.). In the example shown in FIG. 1C, the tractor 144 is configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first configuration to a radial diameter that is between 1.1 and 10 times the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained, as shown in FIG. 1D. In FIG. 1D, the tractor of FIG. 1C is shown in an expanded, relaxed, configuration. Thus the expandable tractor may be biased to expand open. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[000125] In FIGS. 1C and 1D the tractor and puller have two portions, a tractor 144 and a less expandable (or non-expandable) proximal portion comprising the puller 146. The puller may be a separate region, such as a wire, catheter or hypotube, which is connected to an end region of the tractor (e.g., a flexible mesh, woven, braided, etc.), e.g., the distal end or near the distal end. The inverting region of the tractor, where it rolls and inverts over the distal end opening of the catheter may be referred to as the distal-facing region of the tractor, which may actively grab clot when rolling.

[000126] In FIG. 1E, the flexible tractor of FIG. 1C is shown with the tractor doubled back over itself an over the the distal end of the catheter of the elongate inversion support 101. The distal end region is collapsed down, e.g., onto the puller and the elongate inversion support, and may be held collapsed. In this example a tractor hold 188 may be used to hold the tractor collapsed down onto the outer diameter of the elongate inversion support. However, in an unconstrained or deployed configuration, as shown in FIG. 1F, the tractor in this second configuration (e.g., the portion that is inverted over the distal end of the catheter) has an outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. Thus, the tractor 144 may be biased so that it has a relaxed expanded configuration in the first configuration (as shown in FIG. 1C) that is greater than the inner diameter (ID) of the catheter of the elongate inversion support portion of the apparatus and the relaxed expanded configuration of the second configuration (shown in FIG. 1F) inverted over the catheter has an OD that is greater than the OD of the catheter. The tractor is expandable and may be coupled to the puller. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to a push/pull wire or catheter.

[000127] FIGS. 1G and 1H illustrate the removal of a clot using an apparatus such as the apparatus assembled from the components of FIGS. 1A and 1E. In this example the apparatus is configured as a thrombectomy apparatus including a catheter of an elongate

inversion support 101 and a flexible tractor that extends over the distal end region of the catheter and doubles-over itself at the distal end of the catheter to invert so that the external tractor end region is continuous with an inner less-expandable (in this example, less-expandable includes non-expandable) second distal end region 146 (puller) that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The pusher/puller member that may be a rod or other member that is continuous with the distal end region of the tractor. In FIG. 1G the apparatus is shown positioned and deployed within the vessel 160 near a clot 155. The clot may be drawn into the catheter by pulling the tractor 140 proximally into the catheter 101, as indicated by the arrow 180 showing pulling of the inner portion of the flexible tractor (e.g., using a handle, not shown) resulting in rolling the tractor over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled into the catheter, shown by arrows 182. The end of the tractor outside of the catheter may be “loose” relative to the outer wall of the catheter. FIG. 1I illustrates another example of a tractor assembly 154 including a tractor 144 that is coupled to a puller 156. The puller in this example is tapered (having tapering region 161) and may therefore have a different flexibility of the distal end region than the proximal end region. For example the proximal end region may be less flexible than the narrower-diameter distal end region 195 to which the tractor is coupled. The assembly includes a radiopaque marker 165. The tractor may be attached to the puller by any appropriate means. For example, the tractor may be crimped, glued, fused, or otherwise attached to the puller, typically permanently.

[000128] In general the mechanical thrombectomy apparatuses described herein may be highly flexible, both before actuating and during operation. For example, the flexible tractor may not increase the stiffness/flexibility of the catheter of the elongate inversion support, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortuous vessels of the neurovasculature. Described herein are flexible tractor tube portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[000129] Jamming may occur if the tractor cannot easily invert over the distal end of the catheter, as shown in FIGS. 2A and 2B. In FIG. 2A, pulling the tractor 201 proximally from within the catheter 207 of the elongate inversion support, e.g., by pulling 204 on the inner puller catheter 205, would normally cause the tractor to roll 211 over the distal end of the catheter tip. If the force required to pull the tractor so that it inverts and rolls into the catheter is too great, such as 200 g of force (e.g., greater than 10 g force, greater than 20 g force, greater than 30 g force, greater than 40 g force, greater than 50 g force, greater than 60 g force, greater than 70 g force, greater than 80 g force, greater than 90 g force, greater than 100 g force, etc.), exclusive of any initial deployment force to release the tractor, described herein, then the device is jammed. Typically the tractor may be pulled and inverted over the distal end opening with significantly less force than this jamming force. Jamming may lead to collapse of the elongate inversion support, and device failure. Jamming may occur when, for example, the tractor gets caught on the distal end opening of the catheter of the elongate inversion support. In FIG. 2A, one failure mode leading to jamming results when the portion of the tractor within the catheter 213 collapses inward, as shown. The inventors have found that it is desirable, and may prevent jamming, if the portion of the tractor within the catheter collapses only so that it has a diameter (e.g., inner diameter) of 40% or more of the inner diameter of the catheter (e.g., 45% or more, 50% or more, 55% or more, 60% or more, 65% or more, 70% or more, 75% or more, etc. of the inner diameter of the catheter).

[000130] Similarly, FIG. 2B illustrates another example of an apparatus in which jamming has occurred, as indicated by the “X” through the arrows showing the proximal movement of the tractor within the catheter 204’ and rolling 211’ of the distal-facing inverting portion of the tractor. In FIG. 2B, the tractor bends sharply around the distal end of the catheter. This sharp bend may result in jamming over the distal end of the catheter, as shown.

[000131] Various features that may be used alone or in any combination to prevent jamming of the tractor on the catheter are described herein. For example, in FIG. 2C, a the tractor may be biased so that the portion of the tractor within the catheter in the first configuration 223 (e.g., extending from the puller in an un-inverted configuration in FIG. 2C) would have a relaxed outer diameter (OD) that is approximately equal to or greater than the ID of the catheter (e.g., the relaxed OD of the tractor is between 0.8x to 3x the ID of the catheter), and the OD of the tractor in a second configuration (inverted relative to the first configuration) 221 is typically greater than or approximately equal to the OD of the catheter (e.g., the relaxed OD of the tractor in the second configuration is between about 0.9x and 5x the OD of the catheter, e.g., >1x the OD of the catheter, etc.). It should be noted that the

tractor may be configured so that the relaxed OD of the first configuration of the tractor is greater than the relaxed OD of the tractor in the second (inverted) configuration, or vice versa. This combination of biasing may result in a distal-facing inverting region that is slightly trumpet-shaped 227, as shown. This trumpet shape may result in an angle of approach between the surface of the tractor and the open end of the catheter that is more close to perpendicular relative to the open end, as can be seen by comparing FIG. 2C with FIGS. 2A and 2B. The outwardly-flaring distal-facing tractor region may therefore prevent jamming. FIGS. 3A-3C illustrate the operation of an apparatus including a tractor region that flares outward at the distal-facing rolling/inverting region as it rolls over the distal end of the catheter. In FIG. 3A, the apparatus 305 is driven down the vessel 160 into proximity with the clot 155. A guidewire 309 may be used to aid in positioning, as shown in the alternative view of FIG. 2B. For example, a guidewire may be first guided to the clot, and the apparatus may then be slid over the guidewire to position adjacent to the clot. The guidewire may be left in place or removed before actuating the apparatus as shown in FIG. 3C to remove the clot. In FIG. 3C, the apparatus is actuated by drawing proximally 309 on the inner portion of the tractor 311 so that it rolls and inverts 182 over the distal end of the catheter, as shown. The inverting tractor grabs and pulls the clot into the catheter, compressing and/or distorting it as it pulls it inside. The apparatus may be advanced distally as the tractor is pulled proximally. In some variations the tractor may be expanded longitudinally (distally-proximally) within the catheter as it is drawn proximally within the catheter, because it may be a woven, knitted or elastic material. This may allow the clot to be drawn in quickly and may secure it within the catheter.

[000132] The tractors may be woven, braided and/or knitted materials. For woven and braided materials, which may include a plurality of fibers that are woven or braided to form the inverting tube, these structures may be tuned to prevent jamming and/or to reduce the force necessary to pull the tractor and invert over the catheter tip. For example, the mechanical atherectomy apparatus may include a braid-type tractor that can roll freely around the tip of catheter even in a tortuous anatomy and when grabbing clot by tuning one or more of the braid structure; minimizing the braid angle; including a hydrophilic coating on the distal aspect of the catheter outer diameter (OD) or the inner diameter (ID) of the braid (e.g., tractor); including a radiused wall on the catheter; and/or increasing the stiffness of the distal tip region relative to adjacent proximal regions.

[000133] As mentioned, the tractor (e.g., braided, woven, knitted, etc.) may be configured to collapse down into the inner diameter (ID) of the catheter as little as possible. For example

the tractor may collapse to an ID that is greater than, equal to, or within 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter inner diameter (ID)/Catheter Tip OD, since, when the tractor is being pulled around catheter tip it may create axial tension on the tractor (e.g., braid, knit, etc.) that can inadvertently cause the tractor to jam on the catheter tip. When tractor is pulled around catheter tip, the tractor is being pulled in the axial orientation creating axial tension on tractor structure as the tractor is being pulled through the catheter ID. By having the tractor elements jam at an ID greater than or equal to 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter ID (or in some variations, OD), when being axially tensioned, the tractor is less likely to grab/synch down onto the catheter tip, helping the braid roll around the catheter tip with less axial force applied by the user. If less axial force is required by the user to pull the tractor structure around the tip then the catheter tip is less likely to buckle or deflect when retracting the tractor. It may be advantageous to minimize the chance the catheter tip will buckle. The tractor can be tuned to "jam" at a specific ID by controlling any of the following variables and in any combination: selecting a specific number of braid ends, selecting the size/diameter of the braid ends; selecting the braid material (e.g., multifilament or monofilament); heat setting the bias on the braid (e.g., braid diameter); and selecting a braid pattern, e.g., 1x2, 1x1 or any other pattern.

[000134] The braid angle may be minimized to prevent locking up of the rolling of the tractor over the catheter end opening. Typically, the lower the braid angle (e.g., 45 degrees or less, 40 degrees or less, 35 degrees or less, 30 degrees or less, 25 degrees or less, 20 degrees or less, etc.) the less likely it is to have the braid cross over points catch on the catheter tip.

[000135] In any of the variations described herein, the catheter and/or a surface of the tractor may be coated to enhance rolling over the distal end region of the catheter. It may be helpful to have a hydrophilic coating on the distal aspect of the catheter OD or the ID of the tractor so the tractor can more easily slide over the catheters distal end and around the tip of the catheter when pulled through the inside of the catheter.

[000136] The radius wall of the catheter tip may be chosen/set to within a range that allows sliding. For example, it may be helpful for the tip of the catheter to have the largest radius possible but at least 0.0025" radius wall on the catheter, ideally approximately 0.005" radius wall.

[000137] The stiffness of the distal of the catheter may be sufficiently stiff to prevent collapse as the tractor is pulled; it may also be lubricious (e.g., by a coating or material property). The distal most section of the catheter tip (e.g., the last 5mm) may be fabricated of

a material which is stiff enough and lubricious enough so the distal tip of the catheter does not collapse or buckle inward ward when the braid structure is rolling around the catheter tip. Thus, the distal tip may have a stiffness that is greater than the more proximal region at the distal end of the catheter.

[000138] As will be described in greater detail below, it may be helpful or desirable to have pores in the tractor. A lack of gaps or small pore size may limit the ability of the braid to grab clot. Alternatively or additionally, it may be desirable to form a braid structure with texture. One example is to braid 2 or more different diameter braid ends into the same structure: the difference in braid end diameters will help form a texture to the braid structures outer surface, aiding the grabbing of the clot when rolling the braid-dozer around the catheter tip.

[000139] As an alternative (or in addition) the tractor may be configured to lock so it does not compress in diameter during axial load by adding a coating, laminate or adhesive to the braid at a desired diameter. Adding a thin coating, laminate or adhesive can inhibit the braid elements from sliding with respect to each other, thereby locking the braid to a specific diameter. The coating can be applied while leaving the majority of the pores and pore area substantially open. Examples of thin coatings include urethanes and silicones with and without hydrophilic coatings and hydrophilic coatings with no tie layer.

[000140] Reducing the sliding friction of tractor to outer catheter wall, improving tractor to tip rolling, and/or enhancing tractor to inner catheter sliding may also be achieved by including a sliding skin or sleeve. For example, a thin (e.g., ultrathin) sleeve may be used. The sleeve would be made from low friction polymer (PET, PE, PP, PTFE, ePTFE, pebax, urethanes) by braiding, knitting, weaving, extrusion, melt blown, melt spinning, etc. The sleeve could be made from laser slotted tubing, chemical etching, micro machining. The sleeve could be also coated with a lubricious coating such as a hydrophilic coating. Lubricious coatings can be located on the outside and/or inside surfaces. The sleeve may be placed between the dozer element and the catheter wall and attached to the puller element. The sleeve may be less than 0.002" thick, ideally, less than 0.001" wall thickness. The sleeve may decouple the tractor clot grabbing system from the catheter wall, tip rolling and inner catheter dragging friction. The sleeve could be totally free from the tractor, connected to the tractor in discrete locations or connected fully to the tractor. This may allow the tractor to be designed to grab clot (larger wires: 0.001" to 0.002" for neuro, and 0.002" to 0.007" for other applications) and the skin to minimized in thickness and structure to reduce friction and skin bending stiffness.

[000141] FIG. 4A shows one example of a sleeve that may be used. In this example, the sleeve 403, such as those described above, may be positioned between the catheter 401 outer diameter and the tractor 405. The sleeve (or “skin”) may be inverted with the tractor, or it may be held on the outer diameter and the tractor moved over it. FIG. 4B is another example in which the tractor is pulled by a pull wire 409; in FIG. 4A the tractor is pulled by a puller catheter 408 within the outer device catheter 401.

[000142] In some variations, the tractor region may be formed of with a mixed or hybrid structure, combining one or more of interwoven or knitted braid polymer filaments with metallic filaments. The mixed structure (hybrid structure) may leverage both metallic elements interwoven with low friction polymer elements. The metallic filaments may create stiffness elements that may grip/grab a clot. The polymer filaments may aid in grabbing clot but may provide surface friction reduction to the outer catheter wall, the catheter tip and the inner catheter wall once around the tip.

[000143] Any of the apparatuses described herein may include a tractor having a hydrophilic/lubricous coating on the inside surface, e.g., for braided/knitted tractors, on the inside surface (contacting the outer and inner diameter of the catheter) of the braid/knit, which is in contact with the outside of the catheter. Examples of lubricous coatings include hydrophilic coatings (e.g., hydrogels) and hydrophobic coatings (e.g., fluorine coating such as PTFE & FEP, parylene, silicone, siloxane (silicone additive) added to various polymers including pebax to make any material more lubricious, Polyethylene, polypropylene, FEP)

[000144] As mentioned above, any of these apparatuses may include a distal tip that is less rigid (e.g., ‘softer’) than the more proximal regions of the distal tip. This may be achieved by having a structural supporting member reinforcing the distal tip, or by modifying the material forming the distal tip. In some variations, the distal tip of the catheter may be stiffened (made more rigid) by inverting over the catheter end. See, e.g., FIGS. 5A-5B showing an inverted soft tip of a catheter. In this example, a 72-end PET braid was used to invert the tip 501 of the 0.071 catheter back over itself 505 as shown in FIG. 5B. Inverting the distal section of the catheter tip, which may include a hydrophilic coating, inside of the catheter and (in this example, though not a necessity) a radiopaque marker band 507. This may crease a larger radius tip which is relatively stiffer than the tip and has a hydrophilic coating around the outer diameter and inner diameter all the way on the last 2-5 mm of the catheter. Optionally, the catheter may be delivered with a tip similar to that show in FIG. 5A, but when the tractor is pulled initially into the catheter, the distal end of the catheter may invert to form the tip as shown in FIG. 5B.

[000145] FIGS. 6A and 6B show another example of an inverted soft-tip catheter over which a tractor 601 (in this example, a PET braid having 72 ends and a 4 x 0.0008" material). The tractor in FIG. 6A is rolled over the hydrophilic coated tip 603 showing a large collapsed radius (e.g., it does not collapse down on itself). The coating of hydrophilic material enhanced the rolling of the material over the catheter. The catheter was loaded with the tractor having a small (2 mm) ID tube, which is very close to the catheter OD. In this example, 23 cm of tractor was pulled easily into the catheter having a rolled tip as shown in FIG. 5B. In this example, the tip did not collapse, however other tractor materials (e.g., metallic, such as Nitinol materials) may collapse the tip, even when inverted as shown.

[000146] FIGS. 7A-7F illustrate examples of braided tractors that may be used. In these examples, FIGS. 7A-7C show PET braids that are heat-set to 0.085" IDs (at 395°F for 10 min). For example, FIG. 7A is a 0.001 inch PET, having 36 ends and a 77° braid angle at 9 mm, and 0.008 OD filaments. This example was highly porous, but was the least stable of all of the examples shown in FIGS. 7A-7F. FIG. 7B is a 72-end 0.001 polyester strand braid of 8 mm, 90° braid angle, with 4 filaments in each strand. FIG. 7C is a 48-end braid tractor of 0.002" polyester, 90° angle over 9 mm mandrel. The braid shown in FIG. 7A collapses 50% of the diameter, while the braided tractor shown in FIG. 7B collapsed less than 5% of the diameter, and the braided tractor of FIG. 7C collapsed less than 25% of the diameter. FIGS. 7D and 7E show Nitinol braided tractors heat-set to 0.085" ID (at 510 °C for 8 min). These braided tractors were constrained to 0.070 inches to show the pore size when pulling into a 0.071 catheter. Other examples of braided tractors had between 96 or 144 ends of 0.0005"-0.0015" PET mono or 0.0005" - 0.001" filaments with a <35° braid angle.

[000147] FIGS. 8A-8D illustrate the operation of a 72-end 0.001" NiTi tractor capturing clot in a model vessel. In this example showing pulling the clot into the catheter, the ID of the vessel is nearly the same as the OD of the catheter tip. Drawing the tractor into the vessel shows that the tractor region does not collapse down with inverted into the vessel, preventing locking of the end, and leaving space for drawing the clot, as shown. FIGS. 8E and 8F illustrate reversing the rolling movement of the device to eject the clot from the apparatus.

[000148] Similarly, FIGS. 9A-9C illustrate using a 48-end 0.002" PET monofilament braided tractor capturing a clot in a vessel. FIG. 9D shows reversing of the same apparatus to eject the clot. FIGS. 9E-9G show another example of a braided tractor, comprising a 72-end 0.001" PET (4x 0.0008" fil) material drawing clot into the device by rolling the tractor region into the catheter, as shown.

[000149] As discussed above, tractors may also be formed of a knitted material. A knitted material typically includes materials in which the same filament (or a series of filaments connected in tandem) is knitted to itself to form the tractor. It may be particularly advantageous to use a knit to form a tractor as described herein. For example, FIGS. 10A-10F illustrate an example of a 0.002" knitted tractor 26 needle (SN5923) material, which is a circular weft knit of 0.002" PET monofilament 26 needle head Greige (from Secant Medical). In FIGS. 10A-10C, the knit material is not heat set; the tractor regions shown in FIG. 10E is heat set, knot post-heat treated (at 395°F, 10 min on 0.085" mandrel).

[000150] Any of the apparatuses described herein may include a tractor region that is configured to grab a clot. In particular, described herein are apparatuses that may include a tractor region that has a plurality of projections extending from the tractor, particularly when the tractor rolls around the distal end of the catheter and inverts; these projections may help grab and/or macerate the clot.

[000151] For example, described herein are apparatuses including a plurality of projections that are formed as part of the tractor region. For example, any of these apparatuses may be configured to include projections that are formed by cutting (e.g., laser cutting) or forming from the tractor. Cutting and may be used to form projections or protrusions from a tube of material (or a sheet formed into a tube during processing) such as a sheet or tube of NiTi, thin-film NiTi, cobalt chromium, stainless steel, etc. Projections may be formed from a laser cut NiTi hypotube, a NiTi laser cut sheet, or the like. Projections may also be formed on any of these devices by welding. For example, projections may be formed by welding to a thin-film NiTi tube or sheet. The cut or formed tractor regions may be configured to have virtually any pattern or shape. For example a tractor region having projections that extend from an inverting/rolling tractor region may be formed of a metallic or polymeric material that can include any cut or shaped pattern so that the pattern lays flat (e.g., in the plane of the tractor) on outside of catheter and extend from the tractor (e.g., out of the plane of the tractor) as it rolls around the catheter. The projections may comprise portions of the tractor region pattern that extend and may grab and/or cut, e.g., macerate, the clot as they stick into the clot. These same regions of the tractor may then lie relatively flat against the ID of the catheter when fully inverted and pulled into the catheter.

[000152] In general, cut may be made in the tubes or sheets (e.g., sheets to be formed into tubes) in order to enhance flexibility, porosity and/or to add projections that may extend from the tractor as it is rolled over the distal end opening of a flexible tube (e.g., catheter). A

tractor may therefore be formed into any appropriate pattern, so long as it is sufficiently flexible.

[000153] For example, FIGS. 11A-11D illustrate examples of patterns that may be used for a flexible tractor region. These two dimensional (2D) patterns (e.g., textured surfaces) may provide flexibility of the tractor region in rolling and inverting over the catheter distal end; in some variations, such patterns may help grab a clot when the tractor is rolled and pulled into catheter. These patterns or textures could be formed by laser cutting, molding of plastics or thin film metal (e.g., NiTi Technology), stamping, etching, or the like. The patterns shown in FIGS. 11A-11D generally form closed-cell shapes having angled arms forming the cell walls. The angles may allow deformation in one or more directions. The pattern may mimic the patterns of woven, braided and/or knitted materials, or may be different.

[000154] In any of the apparatuses described herein, the tractor region may also include surface micropatterns that may be added or formed onto the tractor. These micropatterns may help with grabbing a clot. For example, FIGS. 12A-12I illustrate micropatterns protrusions, projections, knobs, bumps, spikes, etc. that may extend from the surface of the tractor. In some variations, e.g., in FIGS. 12A-12C, 12E and 12F, the micropatterns may extend from the tractor region at all times, not just when rolling over the end of the catheter. Another example of an apparatus including a tractor having projections that extend from the tractor including the portion of the tractor that is over the catheter is shown in the apparatus of FIG. 14. In FIG. 15, the tractor 1401 includes a plurality of projections 1403 that extend from the tractor at all times, including the portion of the tractor that is rolling over the distal end opening of the catheter (the distal-facing tractor portion) as well as the portion that is over the outer diameter of the catheter, and within the inner diameter of the catheter. Other variations (e.g., FIG. 12D-12I, FIGS. 13A-13B, and 16A-16B) may project only from the portion of the tractor that is rolling over the distal end opening of the catheter.

[000155] For example, FIGS. 13A and 13B illustrate an example of a tractor region having a plurality of projections that extend from the portion of the surface of the tractor only when that portion of the tractor is inverting and rolling. FIG. 13B illustrates the extension of the projections 1105 from the tractor as the tractor is rolling over the distal catheter opening 1109 to invert. In this example, the tractor is a tubular structure 1101 having longitudinally arranged lengths of tractor material 1103 forming a backbone. Spanning between these flat, elongate regions 1103 are regions that extend between adjacent elongate regions first distally in the long axis, then back proximally. As the tractor rolls over the end of the catheter opening, e.g., as shown in cross-section in FIG. 13B, the loops of material 1105 extend out of

the tractor (out of the plane of the tractor that is defined by the long axis of the tractor), and form projections 1105 that, as the tractor rolls over itself (inverting), extend outward, as shown in FIG. 11B. These projections may help grab a clot.

[000156] Projections formed in the tractor may be formed by cutting (e.g., laser cutting, press cutting, etc.), etching, etc., or they may be woven, braided or knitted into the tractor. For example when the tractor is formed of tube or sheet of material, the projections may be formed from the plane of the tractor material by removing material to leave a projection that may extend up and out of the material. When the tractor is not bending (e.g., inverting), the projections may have a low profile that does not substantially impact tracking of the tractor region when positioning the apparatus, e.g., moving it through a vessel in a patient's anatomy, while still enabling and enhancing rolling around the tip of the catheter. A projection that may help grab a clot may extend distally (e.g., towards the distal tip of the catheter when positioned on the outer catheter surface), so that as the tractor is rolled into the catheter, they extend distally (e.g., shown in FIG. 11B). Thus, the projections may create a grabbing effect. In some variations the projections may also cut into the clot and may macerate it. The projections may also help with catheter removal.

[000157] In some variations the tractor is a woven, braided or knitted tractor that may be formed of one or more strands that have one or more (e.g., 2, 3, 4, etc.) edges that may project from the plane of the tractor as it rolls over the distal end of the catheter. When the strand(s) forming the tractor have a rounded profile (see, e.g. FIG. 15C), as the tractor inverts over the catheter, the face of the inverting distal-facing tractor region remains smooth, as shown in FIG. 15A. FIG. 15B shows a single strand inverting over the distal end opening of a catheter.

[000158] If the strand forming the braided or woven tractor region is instead formed of a material having an edge (e.g., a ribbon, such as a ribbon having a rectangular profile, as shown in FIG. 15D), when the tractor rolls over the distal end opening of the catheter, particularly where the strand (e.g., ribbon) is at an angle relative to the distal end opening (and the distal-facing inverting portion of the tractor), as shown in FIG. 15E, the edge of the strand projects upwards and away from the tractor, out of the plane of the tractor. This is schematically shown in FIG. 15E, showing a rectangular strand or ribbon that may be woven, e.g., in a helical weave, and the edge 1505 of the woven strand twists up and out of the plane of the tractor as it inverts over the catheter to form a projection 1507 as shown in FIG. 15E. This projection may act as a scoop or shovel-like element that may help grab the clot, even if the tractor is lubricated and/or lubricious.

[000159] FIGS. 16A-16B illustrate an example of a tractor formed from a plurality of strands having an edge; shown here as strands that are ribbons having an edge (forming a rectangular profile).

[000160] In FIG. 16A and 16B, the apparatus includes a catheter having a distal end and a distal end opening (not visible beneath the distal end-face of the tractor shown), and a tractor 1600 that includes a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter. The tractor forms a tubular wall and is configured to invert by rolling over the distal end opening of the catheter, as shown in FIG. 16A, when a first end of the tractor is pulled proximally within the catheter. The tractor includes a plurality of projections 1603 (in this example, formed by the edges of the ribbon-shaped strands, that extend from the distal-facing portion of the tractor as it is inverted over the distal end opening of the catheter. As the tractor rolls over the distal end opening of the catheter, the ribbon-shaped strands twist up and out 1603 of the tractor. These twisting edges form projections that can help grab a clot. Thus, FIG. 16A shows a distal end-face of the tractor inverting region as it rolls over the distal end opening of the catheter from the outer diameter to the inner diameter of the catheter. The plurality of projection regions 1603 are formed as the strands (ribbons) twist so that the edges of the strands extend up out of the plane of the tractor. As shown in FIG. 16B, when the tractor is over the outer diameter of the catheter, including the catheter distal end and more proximal regions, these strands do not project out of the tractor, but remain flush against the outer diameter, even when the catheter, and therefore the tractor, are bent and positioned in a tortuous vessel; only when inverting do they project outward. Thus, the projections are not extended from the tractor in the portion of the tractor that extends over the distal end of the catheter. The center of this apparatus forms a guidewire lumen extending through the catheter and the tractor and may pass a guidewire. When the tractor is extended along the outer diameter of the catheter proximal to the inverting region, the strands, which are helically woven to form the tractor, remain flat, in the flat cylindrical surface (“plane”) of the tractor.

[000161] As will be described in greater detail below, in some variations, including knitted tractor variations, the cells of the tractor may extend up and out of the inverting distal-facing region as it rolls around the catheter. These projections may also act as scoops, shovels, etc. and may help grab onto a clot.

[000162] Some variations of the tractors described herein may be formed of a non-woven, non-braided and non-knitted material. The tractor may be formed of a sheet and/or tube of material that may be directly fabricated (e.g., extrusion, etc.). This tractor may be cut,

including laser cut, to form slots. In some variations these cuts may form projections. For example, the tractor may be formed of a solid (including porous) material into which a pattern is formed (e.g., slots, cut-out regions, etc.) including patterns that produce projections as described above. A tractor region may be formed of a tube of material into which slots or cut-out regions are formed. Such apparatuses may include a tractor formed from a tube of material such as ePTFE (which may be relatively soft, strong in tension and radial compression), NiTi (a super elastic and/or thermally settable material), a fabric (which may be a soft, thin walled material having a reasonably high radial/axial strength), or the like. The tractor may have material frictional properties and material surface hardness that are appropriate to grabbing a clot. In general, materials that are softer may be easier to track the apparatus in the anatomy. As mentioned, the tractor may have pores and may therefore have a tube porosity. The pores may be formed by removing material (or shaping into the openings) and may be oriented to aid in flexibility, rolling and/or tissue grabbing. A tube forming a tractor may be laser cut at an angle relative to axial length, or it may be laser cut (e.g., perpendicular versus angled relative to the tube thickness). Angled cuts may create a cutting surface to mince or macerate a clot, whereas perpendicular or rounded cuts through the thickness of the tractor may enhance grabbing of clot. Any of the tractors described herein may have a final shaped cross-section that is heat-set and/or formed on a mandrel (e.g., formed shape as set on heat treatment mandrel). The tractor regions described herein may be self-expanding. For example, in particular, the tractor may be set (e.g., as a shape-memory material) to expand outwards when inverted (e.g., within the catheter) and may therefore collapse inward slightly when inverted over the outside of the catheter. As discussed above in reference to FIGS. 2C and 3A-3C, this may aid in forming a trumpet shaped distal-facing region of the tractor, where the tractor is inverted over itself. Some variations of tractors may not be self-expanding. As mentioned, the tractor may be formed of a polymeric material (e.g., ePTFE, PET, PP, Nylon), metals (including alloys) or combinations of these. The tractor may have a low profile (e.g., minimum thickness), may be highly flexible and able to navigate through tortuous vessels, may be able to invert around the catheter tip, may have clot grabbing properties (including projections and/or surface roughness) and may provide a column strength in compression (e.g., strut stiffness), and may be partially or completely radiopaque. The tractors described herein may scale from 1 mm OD fully formed to 15 mm. Any of these tractors may include a lubricious surface on one or both sides (particularly the side that faces outwards when extending over the outer diameter).

[000163] Examples of slotted laser cut tubes forming a tractor are provided herein, including those shown in FIGS. 17A-25B. The starting tubes may be flexible or rigid. For example, a soft flexible tube, strip, or roll of material such as ePTFE or a dense fabric (e.g., knit or weave or braid) may be used. Flexible tubes may provide tractors and/or combinations of tractors and catheters that allow tracking of the apparatus to the treatment site even in tortuous vessels. Tracking allows pushing of the apparatus through tortuous vessels of small caliber over long distances from their introduction site to the human body, over length that can exceed 1 meter in some uses. A flexible tube (pre-laser cutting to form the tractor) may have a softness resulting in a low radial crush force, such as a micro-porous, polymer based tube. The tube may be processed (e.g., by cutting or any of the other techniques mentioned herein) to provide flexibility (e.g., the ability to pull the tractor into catheter, invert, and expand over catheter outer diameter) and/or to create a textured/porous surface that may aid in grabbing a clot (e.g., emboli) and may provide free spaces (voids) that may help store and/or masticate emboli, making them easier to store within the apparatus and transport. Prior to forming into the tractors the sheets or tubes (e.g., films, rolls, etc.) may have a smooth surface. Patterns may be formed into the sheet or tube to form the tractor. For example, laser slot patterns may be formed in the material to increase macro-surface roughness. Holes, slots, edges, divots, and bumps may be formed on the material. In addition to helping grab and hold emboli, such holes or slots may create free space in the tube wall to cut the clot and/or carry it away. The patterns used to form any of the tractors described herein may have a shorter strut length to strut width ratios. Short, wider struts may create tractors that are stiffer and may grab clot better. In combination with strut length to width, in some variations, thicker walls may be preferred. Thicker slotted walls may create stiffer struts and more aggressive surface texture to grab clots. Furthermore, thicker walls may enhance clot storage capacity within the slot gaps.

[000164] In some variations, it may be beneficial to provide slot designs which do not foreshorten. For example, if the slotted tube design is pulled axial (e.g., down its length), the tube diameter may not decrease. A decreasing diameter slotted tube may grab the outside of the catheter and cleat, increasing drag force when the tube is pulled.

[000165] In variations in which the initial tube or sheet of material used to form the tractor tube is relatively rigid (e.g., formed of a material such as Steel, Nitinol, Polyester, PTFE, Nylon, etc.), the initial tube stiffness/hardness may enhance the clot-grabbing ability when the tractor is slotted properly, to allow both increased flexibility, expansion and rolling. For example, a rigid tube may include slot designs that focuses in catheter tracking and creates a

flexibly bending tractor with minimal foreshortening, that is able to be pulled into a catheter (inverting) structure. As with the more flexible starting tubes discussed above, tractors formed of more rigid starting materials may grab and transfer a clot, and the number of slots and/or voids may be increased to increase clot grabbing and/or carrying capacity. A slotted tube forming a tractor may include surface grabbing features, such as channels/corrugations (e.g. any of the microstructures such as those shown in FIGS. 12A-12I above. More rigid tubes may create harder or stiffer slotted tractors. For example, when struts are formed into the tractor (e.g., by cutting, etc.), the slot strut length to strut width may be greater than with less rigid starting materials, and may be a function of the rigid tubes elastic modulus. Higher elasticity materials (e.g., Niti, PET, PTFE) may have strut length to width ratios from 10 to 100. Stiffer materials (e.g., steel, MP35N) may have a length to width ratio greater than 50. The wall thickness to strut width for elastic materials may be, for example, between 0.5 to 10; for stiffer materials it may be between 0.25 to 5.

[000166] As mentioned, any of the apparatuses described herein may include a tractor region that is non-foreshortening. The foreshortening of the tractor may depend at least in part on the slot designs for non-woven, non-braided, non-knitted designs (e.g., tractors that are not formed of a strand or strands of material). FIGS. 17A-17D illustrate an example of non-foreshortening design. Also, for both flexible and rigid starting tubes forming a non-woven tractor, the tube inner diameter can be slightly bigger than catheter tube outer diameter pre-slotting. Slotted tube designs which foreshorten may reach their smallest diameter limit when tensioned axially. If the tube is sized to be slightly larger than the catheter outer diameter, then it may jam (preventing any foreshortening) before it cleats to the catheter outer diameter. Tractor regions formed of an initially rigid material may grab clot more efficiently than tractors having an equivalent thickness but formed of a more flexible material. More flexible materials may deform as a function of stiffness.

[000167] FIGS. 17A-17D illustrate an example of tractors that are formed by cutting slots and/or windows into tubes of material. In FIGS. 17A-17D, an initially soft material (e.g., ePTFE) was formed by a subtractive manufacturing technique to form, slots, pores and textures in the soft flexible tube. In FIGS. 17A-17D, a 3mm ID ePTFE tube (configured to be used with a 2.9mm OD catheter) was made to be highly flexible and have some level of column stiffness and radial/hoop stiffness by laser-cutting slot patterns into the tube wall to create textures and bend zones which impart clot grabbing and rolling. The ePTFE itself is highly lubricous. Addition of a lubricant (e.g., hydrophilic coating) may improve tracking and rolling. Lubricant can be applied to ID and OD or to either separately. FIG. 17A shows

a first pattern 1701, having minimal cuts to create a smooth rolling of the tractor around the catheter 1703 portion of the apparatus.

[000168] A second exemplary pattern is shown in FIG. 17B. In this example, the apparatus slightly larger cut-out regions 1709 (removed by laser cutting in this example), which may create better clot grabbing properties and more clot holding capacity. In FIG. 17B, the ePTFE tube forming the tractor region is slotted on the outside of the catheter. Note that the porosity (14 holes around the circumference) may help grab and hold clot. In both FIG. 17A and 17B, the laser pattern may foreshorten, but may jam before it grips/cleats the catheter outer surface.

[000169] Another example of a tractor was made from a 2.9 mm OD ePTFE tube (configured for use with a 3 mm ID catheter). This example was made to be highly flexible and have some level of column stiffness and radial/hoop stiffness by laser-cutting slot patterns into the tube wall in a pattern to create textures and configured to include bend zones which impart clot grabbing and rolling. Similarly, a tractor may be made of, e.g., a 2.9mm OD PET woven fabric tube (for use with a 3mm ID catheter). The tractor may be formed of 30 Denier PET multi-filaments, 0.003" thickness. The resulting tractor may be configured to be soft and have some level of column stiffness and radial/hoop stiffness by laser cutting slot patterns into the tube wall in a patterns providing texture and bend zones which may impart clot grabbing and rolling. As with ePTFE, the PET material may itself be lubricous although additional lubricant may be added to improve tracking and rolling. Lubricant can be applied to ID and OD or to either separately.

[000170] An example of a tractor made from a somewhat rigid starting material was formed from a nickel titanium (NiTi) tube having a 3mm OD (which may be used with, e.g., a 2.9 mm ID catheter). The wall thickness in these examples was between 0.001" and 0.002". Laser slot patterns were cut into the tube wall in various patterns to create textures and purpose-designed bend zones which may help impart clot grabbing and rolling. A lubricant may be applied, e.g., as a coating, to the ID and OD or to either separately. A first pattern similar to that shown in FIG. 17A was made by minimal laser cutting to create a smooth rolling tractor. The strut length to width ratio was between 25-50. A second pattern having larger slots/openings (similar to that shown in FIG. 17B) was formed by laser cutting. These patterns may foreshorten, but typically minimize or stop foreshortening before the tractor grips/cleats the catheter outer surface (which may result in jamming). The Niti design has the additional benefits of radiopacity, thermal shaping and super elasticity.

[000171] Any of these designs or patterns may for projections that may extend from the rolling distal-facing and inverting portion of the tractor, as discussed above. Such projection may be cut out as “teeth” or elongate members. The regions forming the projections may be sharp, e.g., pointy and/or cutting. Sharp projections may be chew and cut a mature clot. These projections regions may be short or long, may extend in one or more directions (e.g., forward or backward or bidirectional), and may be scoop-shaped (e.g., paddle-shaped). The number of projections may be selected based on the desired coarseness, e.g., the number of projections, the size (length/width/thickness), etc. The projections may change density down their length. For example, the laser pattern can be designed to allow tractor rolling (e.g., long struts) more easily initially, then have grabbing teeth at higher density; alternatively the tractor may be configured for greater initially grabbing, having a pattern with more and/or larger projections initially (distally) then transitioning to more slits (and flexibility) toward the proximal end, which may make it easier to pull. Further, the distribution of projections can be uniform around the tube perimeter and/or non-uniform (e.g., forming a spiral pattern, distributed in patches, having open areas, etc.).

[000172] Any of the tractors described herein may include a marker or markers (e.g., radiopaque markers, such as gold, Pt, etc.). When forming the tractor from a tube or sheet, the tubes may be cut, then shaped to have any profile, such as straight, rolled over the tip, flaring at the proximal end, etc. Any of the microstructure described herein may be included or formed, as mentioned above, e.g., wells on the struts may help carry and grab clot. Tractors formed of tubes from which material was removed (or sheets formed into tubes) may be configured to have less cleating of the tractor onto the outer diameter of the clot, preventing jamming, particularly compared to woven or braided or knitted materials. However any of the slotted tube tractor configurations described herein may be used with, e.g., in combination with, a braid or knit or polymer sleeve, including either in parallel or in series. In general, any of these tractors may be formed as multi-layers, particular these slotted tube tractors.

[000173] For example, a tractor portion of an apparatus may be formed by removing material from a Niti tube that is slightly smaller than the inner diameter of the catheter that it will be used with, or it may be made from a tube that is slightly larger than the outer diameter of the catheters. The tube may be cut with a pattern that increase the coarseness of the outer surface (e.g., to include projections such as struts/scoops/teeth). For example a 0.001" tube wall thickness or smaller may be used.

[000174] FIGS. 17C and 17D illustrate an example of a tractor region cut from paper. In FIG. 17C a rigid paper tube was cut to include slots and the distal end expanded, as shown. It may be inverted over itself and used as a tractor region. This paper prototype was prepared to illustrate the effectiveness of this pattern. Similarly, FIG. 17D is an example of a prototype tractor region.

[000175] FIGS. 18A-18C illustrate examples of patterns that may be formed into a flat sheet or tubular member to form a tractor (e.g., slotted tractor). Similar to those shown in FIGS. 17A-17D. In FIG. 18A, the pattern may be cut to form the tractor. White regions 1801 may represent or form struts, while the lines indicate slots 1803 from which material is removed. This pattern is one of many resulting in a flexible tube having stout struts. FIG. 18B shows a similar example having a higher density of slots forming thinner struts and potentially higher porosity, which may result in a larger clot-carrying capacity. FIG. 18C illustrates an example of a pattern having curves that may produce a slightly more bendable (flexible in bending stiffness) slotted tractor. In FIGS. 18A-18C, the pattern is oriented so that the distal direction of the tractor formed by the pattern is at the right or left of the pattern shown (e.g., the tube is oriented right and left, relative to the figures, so that the tube is formed by rolling up from the bottom of the figure).

[000176] FIG. 19 is an example of a pattern that may be formed into a tube as part of a tractor having a plurality of both slots 1903 and cut-out regions 1901 (holes). Another example of a pattern having a plurality of cut-out holes 2001 formed into it is shown in FIGS. 20A and 20B. FIG. 20B shows an enlarged view.

[000177] An example of a pattern having a plurality of projections is shown in FIGS. 21A-24B. For example in FIGS. 21A and 21B, the pattern includes a plurality of slots 2101 and cut-out regions that leave a projecting strut or tooth 2105 behind. In these examples, the tooth 2105 is pointed and oriented to the left of the page, which may be the distal end direction of the tractor. (e.g., the left side of the image may correspond to the distal end of the tractor); thus when the pattern is formed into a tubular body to form the tractor, and the tractor is inverted over itself (e.g., rolling over the distal end opening of a catheter) the plurality of pointed projections 2105 may extend out of the tractor, and may help grab and draw clot into the catheter.

[000178] Similarly, the pattern shown in FIGS. 22A-22B illustrate another example include a slot 2201, a projection 2203 and a cut-out portion 2205. As in FIGS. 21A and 21B, the projection may extend out of the plane of the tubular tractor (shown here as the plane of the paper, even when rolled up to form the tractor region). FIG. 23A, and enlarged view of FIG.

24B, shows another example of a pattern for a tractor that is similar to that shown in FIG. 21A-21B, but with smaller projecting regions. In this example, the projections 2305 are sharp, and open into an opening 2303 connected to a slot 2301. The pattern shown in FIGS. 24A-24B is similar to that shown in FIG. 23A-23B but with additional openings (cut out regions 2407) which may increase the carrying capacity (e.g., clot carrying capacity) of the tractor region.

[000179] FIGS. 25A-25C are examples of laser-cut tube prototypes of tractor regions. In FIGS. 25B and 25C the tractor region is inverted over the distal end opening of the catheter.

[000180] In any of the tractor regions described herein, the tractor may have sufficient coarseness to grab the clot, yet still roll easily around catheter tip. Coarseness may relate to the thickness profile of the tractor region. For example, knitted tractors may be more coarse than braided tractors, due to the macro structure (e.g., cells, wire cross overs, shape of cells). The ability of the tractor to capture and transfer (like a conveyor) clot material through the catheter may be aided by coarser macro structures. In addition, as mentioned above, projections may both increase the coarseness and may help aid in grabbing clot. However, projections that extend only when inverting the tractor may be desirable; e.g., the tractor may feel smooth to the touch unless the dozer is rolled around a corner. The act of rolling the tractor may expose or activate the passive grabbing elements (projections). As mentioned, any of these apparatuses may include pores. For example, any of these apparatuses may include pores having a size that is greater than 1/50th of the catheter circumference. For example, the pore size may be 200 μm or greater (e.g., 300 μm or greater, 400 μm or greater, 500 μm or greater, etc.). In some variations the number pores (openings) per circumference may be between 5-20, 5-10, 10-15, 15-20, etc. pores on per catheter circumference on the tractor. As mentioned, the projections may be sharp, or dull, or may have an enlarged surface area (e.g., paddle-shaped). Sharp strut edges may grab and/or cut clots, while projections may also help grab clot. For example, a tractor may have a texture/roughness of at 0.0005" or greater (e.g., 0.0001"-0.0010"). The tractor may be formed of an inherently lubricious material, and/or may be lubricated through the use of hydrophilic coating on the tractor and/or OD of aspiration catheter or construction of lubricious hydrophobic materials such as Polyethylene, Polypropylene, fluoropolymers, FEP, PTFE.

TRACTORS HAVING ALTERNATING STIFFNESS

[000181] Also described herein are tractors having alternating stiffness along their length. For example, a mechanical thrombectomy apparatus for removing a clot from a vessel may

include a elongate inversion support including a catheter and having a distal end and a distal end opening and a tractor that is configured as a flexible tube that extends longitudinally within the catheter and doubles back over the distal end of the catheter to extend over the distal end of the catheter. The tractor may be formed of longitudinally alternating regions of higher and lower stiffness, wherein the regions of higher stiffness have a stiffness that is greater than the regions of lower stiffness. In some variations this may allow the lower stiffness regions to act as hinge-regions relative to the stiffer regions, when the tractor is pulled into the catheter. These variations may result in a seesawing motion at the distal end opening of the catheter, as the tractor is inverted and pulled into the catheter. This is illustrated schematically in FIGS. 30A-30D. For example, a portion of a length of tractor may include more stiff regions 3001 and less stiff regions 3003 that are alternating along the long axis of the tractor, as shown schematically in FIG. 30A. As the tractor region is inverted over the distal opening of the catheter (shown in FIG. 30B, in which a portion of the catheter wall is shown 3009), pulling the tractor over the wall 3009 causes the more flexible portions to bend over the wall, while the less flexible regions 3001 bend less or not at all. FIGS. 30B-30D illustrate progression of a tractor portion over the distal end opening, showing the bending of the less stiff/more flexible regions 3003 over the wall, while the more stiff/less flexible regions 3001 do not bend. The result is that, as shown by the arrows on the bottom, the diameter of the distal-facing region changes, and oscillates, as the tractor is pulled into the catheter.

[000182] Thus, the tractor may be configured so that it rolls around the catheter tip opening an inverts in a ratcheting fashion, in which parts of the tractor that are stiffer than other sections alternate with more stiff regions. These differently-stiff sections may cause the tractor rolling around the catheter tip to move in a semi-rigid manor and/or a pivoting/seesawing motion around the distal face of the catheter opening and the regions adjacent to the distal opening.

[000183] Tractors having alternating stiff/less stiff regions down the length of the catheter (including arranged in a helical manner spiraling down the length) may be formed in a variety of different manners, including constructing braids, laser cut tubes, knits, weaves, and laminates. For example, FIGS. 31A-31D illustrate an example of a knitted tractor region having this configuration. As the the variable stiffness tractor rolls around the catheter, sections of the tractor may temporarily dive to towards the center of the catheter ID, which may also aid in grabbing clot or a foreign body to pull into the catheter. The apparatus may be configured so that the tractor includes sections that sea-saw around the catheter tip so the

dozer protrudes into the catheter ID by a distal equivalent to 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 70%, 80%, 90% of the catheter's inner radius length, or any range of the numbers.

[000184] The tractor shown in FIG. 31A is a knit construct which has sections that are stiffer alternating with others sections that are less stiff. A first region 2401 of FIG. 31A, is stiffer than the adjacent second region 2403, which is also adjacent to another stiffer region 2401'; the stiffer/less stiff regions alternate and spiral in a helix along the length of the tractor. As the knit tractor shown in FIG. 31A rolls around the catheter, the less stiff section 2403 of the knit shown may temporarily bend, diving the stiffer region 2401 towards the center of the catheter inner diameter in a seesawing motion. FIG. 21B shows a side view of an apparatus including a knit tractor such as shown in FIG. 31A, having alternating stiff/less stiff regions extending down the length of the tractor. FIG. 31C illustrates the distal-facing and inverting tractor that is rolling (in a seesawing manner) over the distal end opening in the catheter. FIGS. 31D and 31E show alternative side and end views, respectively, of a mechanical thrombectomy apparatus including a tractor region such as is shown in FIG. 31A.

[000185] In this example, when the tractor rolls over the distal end opening of the catheter, the alternating stiff/less stiff construction causes the stiffer region to moves towards the center of the catheter, which may aid in grabbing clot or a foreign body to pull into the catheter. The tractor may therefore seesaw around the catheter tip opening so that the tractor protrudes into the catheter ID by a distal equivalent to 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, etc. of the catheter's inner radius length, before withdrawing, and then repeating the cycle.

[000186] The alternating stiff and less stiff regions may have a distance (e.g., axial distance, along the long axis of the tractor) that is related to the inner diameter of the catheter. In particular, if the stiff regions are too large relative to the catheter inner diameter, then the tractor may jam in the catheter, as illustrated in FIGS. 32A and 32B. In FIGS. 32A and 32B, for example, the stiff regions are greater than half the diameter of the inner diameter of the catheter. As shown in FIG. 32B, pulling the tractor into the catheter results in locking or jamming the tractor in the end of the catheter. In some variations the stiff region may be slightly larger than half the diameter without jamming, for example, if the adjacent stiff and less stiff regions wind around the tractor at a sufficiently large angle (e.g., greater than 10 degrees, 15 degrees, 20 degrees, etc.) so that only a subset of the stiff regions moving into the inner diameter of the catheter at the same time. Thus, the length of the stiffer regions may be 0.7 times the diameter of the catheter ID or less (e.g., 0.65 times, 0.6 times, 0.55 times, 0.5

time, 0.45 times, 0.4 times, etc., the diameter of the catheter ID or less). This may also be expressed the length of the stiff region being 1.3 times the radius of the catheter ID or less (e.g., 1.2 times, 1.1 times, 1.0 times, 0.9 times, 0.8 times, etc. the radius of the catheter ID or less).

[000187] Similarly, if the length of the stiff regions is too small, it will not see-saw in any appreciable amount and may, in some variations, jam onto the end of the catheter, as illustrated in FIGS. 32C and 32D. In FIGS. 32C and 32D, the length of the stiffer alternating regions is not substantially larger than the thickness of the catheter (e.g., the distance between the ID and OD of the catheter), so that no seesawing motion will occur. For example, the length of the stiff region may be 1.1 times or more than the thickness of the catheter (e.g., 1.2 times, 1.3 times, 1.4 times, 1.5 times, 1.6 times, 1.7 times, 1.8 times, 1.9 times, 2 times, etc. or more than the thickness of the catheter). Alternatively the length of the stiff regions may be 0.1 times the radius of the catheter or greater (e.g., 0.2 times the radius of the catheter, 0.3 times the radius of the catheter, etc.).

[000188] In FIG. 32A-32B, the tractors formed of knit materials having different sizes post-heat treatment (e.g., 0.002" knit 26 needle (SN5923) heat treated on a 0.085" mandrel) than those shown in FIG. 32C and 32D. In FIGS. 32A-32B, the knit material locked on and could not be rolled over the catheter. Relative to the size of the knit, the ID of the catheter (0.045" ID/0.055" OD) was too small. In contrast, in FIGS. 32C and 32D, the catheter dimensions were too large for the knit (e.g., 0.085" ID 72D Pebax, 0.95" OD); the knit material could not pull around and invert on the tubing of this size.

[000189] FIGS. 33A and 33B illustrate another example of a seesawing tractor formed from a knitted material. FIG. 34 shows an enlarged view of a portion of knitted material forming a tractor. The knitted tractor is formed from a filament (a monofilament or group of fibers collected into a filament) that is knitted to itself. The knit may be a tubular knitted material formed from a filament (monofilament or group of filaments) forming interlocking loops as shown in FIG. 34. In this example, the regions of overlap 3401 between the loops form the stiffer region, while the non-overlapping regions form the less stiff regions 3403. In any of the variations described herein, the loops formed by the knit may also act as protrusions as discussed above, and may aid in drawing the clot into the catheter and/or macerating the clot. For example, the sequence of illustrations in FIGS. 35A-35C show a portion of a knitted tractor having loops of nickel titanium forming alternating stiff/less stiff regions (arranged down the long axis of the tractor) as they roll in a seesawing manner over the distal end opening of the catheter. In this example, a single loop 3501 has been indicated showing it's

progression from flush against the wall of the outer diameter of the catheter as the tractor is pulled into the catheter, until, as it approaches the distal opening of the catheter, it inverts by swinging the loop portion 3501 out of the plane of the tractor and up, where it may help grab clot material, as shown in FIGS. 35B-35C. The seesawing motion of a knitted tractor may also be seen in FIGS. 36A-36B and 37A-37C. An example of a mechanical thrombectomy apparatus is shown in FIGS. 36A-36B from end and side perspective views. FIGS. 37A-37C illustrate a method (e.g., that may be used for grabbing and removing a clot from a vessel) including pulling the distal end of the tractor (in this example, a knitted, seesawing tractor) proximally into the catheter. As shown in FIG. 37A the tractor may initially pull a stiff region 3703 towards the catheter opening. Because it is sufficiently stiff that it does not bend over the edge of the catheter, but is 'hinged to an adjacent stiff region, as the tractor is pulled proximally, the stiff region eventually tilts over the edge (in a seesawing motion), so that one end flips up away from the opening, as shown in FIG. 37B (stiff segment 3703 is indicated); finally it slides forward into the inner diameter of the catheter, as shown in FIG. 37C.

[000190] As discussed above, it may be desirable to have a tractor region that is sufficiently and/or selectively coarse so that it may grab a clot. In some variations a rougher tractor may grab clot despite the lubriciousness of the tractor. Knits may be generally more coarse than braids due to their macro structure (e.g., cells, wire cross overs, shape of cells). Knits may also have the desired porosity discussed above (e.g., having a porosity that permits the tractor to grab and store clot/clot carrying capacity). The size of the pores may be, e.g., between 5-20, 5-10, 10-15 or 15-20 pores on the tractor per circumference. The knit may be formed of any appropriate material, including, e.g., Nickle titanium (Niti) wire. For example, a knit may be formed of a PET monofilament, a PTFE monofilament, etc. A knitted tractor may also have a surface lubricity based on either material properties (e.g., metal, polymer, etc.) or added lubricant (inside, outside, both), and may be radiopaque (e.g., including an inter weave in Pt., DFT, over braid wires with Pt., etc.)

Patterned Tractors

[000191] Also described herein are tractors having a pattern of lubricious and/or non-lubricious regions on their outward-facing surfaces. These patterned regions may be coatings and/or surface modification, they may be formed by the material properties of the tractor, and/or they may be due to the application of a lubricious material (e.g., lubricant) in the pattern. A pattern of lubrication and/or non-lubricous material may assist in reducing friction while enhancing clot grabbing. A uniform lubricant (e.g., hydrophilic surface) on the outer-

facing surface of the tractor has been found to reduce the ability of the tractor to grab a clot, particularly in the absence of other clot-grabbing features, such as the protrusions and edges discussed and illustrated above. Thus, described herein are patterns of lubricious and/or non-lubricious (including less lubricious, and tacky or adhesive) materials that may be included on the outward-facing surface of the tractor that may enhance pulling the tractor proximally into the device (e.g., the catheter of the elongate inversion support) and inverting the tractor, while still permitting or even enhancing clot grabbing.

[000192] For example, any of the methods and apparatuses described herein may also include a pattern of non-uniform hydrophilic and/or hydrophobic coating (e.g., a patterned lubricious coating) that may assist with the positioning of the apparatus within the tortuous vessels before or during grabbing a clot. Even a partial hydrophilic coating (e.g., lubricious coating) on the outer-facing surface of the tractor element may reduce friction within the vessel ID. These lubricious regions (e.g., coatings) may be arranged in a pattern such as alternating regions (e.g., bands, stripes, checkerboard pattern, grid, spots, etc.). For example, it may be preferred to partially coat the tractor (e.g., braid) with a hydrophilic material such as using, e.g., a 5 mm coated length of braid followed by a 5 mm non-coated section. This coating may be in other patterns, as mentioned, including strips (longitudinal strips), a spiral pattern coating, a random pattern coating, etc. FIGS. 40A-40C illustrate examples of hydrophilic coating options.

[000193] For example, FIG. 40A shows an example of an apparatus including a tractor region and 4001 a catheter of an elongate inversion support 4005 into which the tractor is inverted and drawn proximally at the distal end of the tractor. The tractor 4001 may be attached to a puller 4009 (e.g., pull wire or pull catheter) to pull, or in any of these variations, push and pull, the tractor within the catheter from the distal end of the tractor. The proximal end of the tractor is attached over the outer surface (OD) of the outer catheter 4005. In FIGS. 40A-40C the tractor is shown as a braided tractor, but any of the tractor types (braided, woven, knitted, solid/cut-out, etc.) described herein may be configured to include a pattern of more/less lubricious regions.

[000194] The tractor shown in FIG. 40A includes a pattern of lubricious regions arranged in bands along the distal-to-proximal elongate length of the tractor. For example, regions coated with a lubricious material 4011 and uncoated (less lubricious or even sticky) regions 4013 alternate down the length of the tractor. Alternatively, the pattern may be formed of a grid or checkered pattern, a spiral/helical pattern along the length of the tractor, etc. As the tractor is drawn into the catheter and inverted 4017, the alternating lubricious/non-lubricious

regions may help grab clot, which is particularly or only important when initially pulling the clot material into the inverting tractor and therefore the catheter.

[000195] FIG. 40B illustrates another example of a tractor 4001 in which elongate (in the long axis of the tractor) lengths of lubricious 4021 and non-lubricious 4023 regions alternate to form a stripe pattern down the length of the tractor. These “stripes” may be varying in size (e.g., diameter) and may be curved, zig-zag, wavy, etc.

[000196] In some variations, lubricious regions may be separated by non-lubricious regions by a minimum and/or maximum distance. For example the lubricious regions may be alternated with non-lubricious regions (including less lubricious and/or sticky/adhesive regions) by between 0.05mm and 15 mm (e.g., by greater than at least: 0.005 mm, 0.01 mm, 0.02 mm, 0.03 mm, 0.04 mm, 0.05 mm, 0.06 mm, 0.07 mm, 0.08 mm, 0.09 mm, 0.1 mm, 0.2 mm, 0.3 mm, 0.4 mm, 0.5 mm, 0.6 mm, 0.7 mm, 0.8 mm, 0.9 mm, 1mm, 2 mm, 3 mm, 4 mm, 5 mm, etc.). Similarly the maximum separation between lubricious regions may be less than about: 20 mm, 15 mm, 10 mm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, etc.). The minimum and maximum distance may be determined based on the size of the tractor (e.g., diameter), and/or the rate at which the tractor is to be pulled. The minimum distance may also or alternatively be based on the lubriciousness of the coating. More highly lubricious materials may be separated by a greater minimum distance.

[000197] In some variations only a portion of the tractor is coated, either completely or in a pattern, and the proximal end portion (e.g., the last portion to be drawn into the catheter) is not lubricious (e.g., uncoated or coated in a tacky/sticky material); the region distal to that (e.g., the region near the initial distal-facing inverting portion of the tractor) is lubricious.

Alternatively, the proximal end portion is lubricious (e.g., coated with a lubricious material) but the region distal to that (e.g., the region near the initial distal-facing inverting portion of the tractor) is uncoated or is tacky/sticky to help initially grab the clot.

[000198] For example, FIG. 40C shows an example of an apparatus including a sleeve 4035 or cover over the most proximal end of the tractor 4001. This sleeve may itself be lubricious on the outer-facing surface, and may protect or hold the tractor in position until it is drawn distally over the catheter, exposed, and inverted to grab/pull clot 4017. The proximal end of the tractor under the sleeve may be lubricious and/or non-lubricious (e.g., patterned) 4033. The region proximal to the inverting portion, and distal to the sleeve, 4037 may be lubricious or (preferably) non-lubricious and/or a pattern of non-lubricious and lubricious regions.

ELONGATE INVERSION SUPPORTS

[000199] In general, the elongate inversion supports described herein may be or may include catheters that are operated with the tractor and are configured so that the tractor may invert over the distal end opening (aperture) of the elongate inversion support. Any appropriate elongate inversion support may be used and may be configured as a catheter (or micro catheter). Since the tractor region is pulled against the catheter to invert it, the catheter may be configured to have high compression resistance while maintaining superior tip bending (e.g., flexible tip) which may allow it to reach distal vessel segments within the human vasculature.

[000200] Small bore catheters including those for use herein may have braid reinforced segments combined with coil reinforcement. A braid may be used on the proximal end of the catheter to provide column stiffness and medium shaft flexibility, and coils are typically used distally to enhance flexibility while sacrificing column strength. The apparatuses described herein may use a catheter having a slotted tube distal segment element that, when activated, can create a significant axial column compression through the entire catheter shaft. Typically, this column compression may result in some catheter foreshortening and catheter bending (e.g., cork screwing). Described herein are catheters that may reduce this foreshortening and corkscrewing by leveraging slotted tube elements into the catheter distal segment (e.g., the last 8cm or less).

[000201] FIGS. 26A illustrates bending of a typical small bore catheter distal tip. As seen in FIG. 21A, the catheter may bend around a small radius (as compared to the reference dime). The distal segment of this catheter may include a coil, and a low-durometer thin-walled polymer that is relatively soft, flexible and stretchy.

[000202] FIGS. 26B-26C illustrate, for comparison, a catheter comprising a keyed slotted tube extending along the entire length of the catheter. In this variation, the interlocking key segment 2601 of the design provides a axial stiffness when the structure sees compressive loads in the axial direction through the interlocking segments stacking or contacting a one or more point about its circumference. This structure still allows for adequate conformability around a tight radius allowing it to be push-able through a tortuous anatomy (ie neuro tortuous vessel). In order to increase bending flexibility and therefore the ability to make tighter turns, the keys may be shorter or longer and/or nested.

[000203] In general, the bending stiffness of the catheter is a function of the material, material composite structure, wall thickness, strut length, strut width, cell angle, strut shape,

and cell length. FIG. 27 shows an example of a catheter design formed as a slotted tube. The tube includes cut-out regions that provide flexibility while leaving column strength.

[000204] Another example of a catheter configured to have a high column strength and stiffness along its entire length is shown in FIGS. 28A-28B. In FIG. 28A, a hybrid laser-formed coil (spiral) has compaction-resistant features, along the entire continuous length of the catheter. The coil bending stiffness in this design is a function of the material, wall thickness, coil width, helix angle, hinge shape, hinge height, hinge location (e.g., linear axial or out of phase/helix), shape of coil surface and the catheter material stiffness.

[000205] The catheter configuration shown in FIGS. 29A-28B illustrate variations in which individual hoop/ring segments are linked by a polymer wall of the catheter only. The ring bending stiffness is a function of the material, wall thickness, ring width, hinge shape, hinge height, hinge location (linear axial or out of phase/helix), shape of ring surface and the catheter material stiffness.

[000206] Any of the apparatuses described herein may include a catheters having a hard distal tip (e.g., formed of a PTFE, PEEK, stainless steel, etc.) and may be radiused to enhance rolling. The tip opening may be radiused from a middle of catheter wall, without an outer radius. Any of these catheters may include a lubricious coating. Finally, any of these catheters may also be configured to permit aspiration (e.g., drawing suction) through them, which may be helpful.

[000207] FIGS. 42A-43D, described in greater detail below, including examples of elongate inversion supports that may be used in any of the apparatuses described.

[000208] For example, any of the apparatuses described herein may include or be configured for use with a vacuum. The vacuum may aid in initially gasping or grabbing the thrombus. The vacuum may be applied from the distal end of the apparatus and/or of an intermediate or outer catheter or sleeve that is used with the apparatuses (e.g., elongate inversion support and inverting tractor) described herein. Also described herein are apparatuses that are adapted for use with a vacuum, including for use with an intermediate or outer catheter through which the apparatus may be delivered to the clot. The apparatus may grab clot from within the outer catheter, or it may be extended distally out of the intermediate or outer catheter.

[000209] FIG. 41A shows an example of a configuration in which an outer/intermediate catheter or sleeve that is highly flexible may be maneuvered, for example with a guidewire, to a distal end of the device. Thus, the intermediate catheter may be maneuvered near, or adjacent to, the thrombus. As in any of these methods of use described herein, imaging (such as fluoroscopy, contrast imaging, etc.) may be used. Once in positioned, the guidewire may

be removed or left in place, and the apparatus including the elongate inversion support and inverting tractor may be extended within the intermediate catheter/sleeve. In FIG. 41A, the intermediate catheter 4104 is shown positioned within the vessel 4109 distally. As with any of the illustrations here, in the vessel may be highly tortuous and branching, although for convenience it is shown as straight in the figures. The apparatus 4100 is extended distally through the intermediate catheter, and extends out of the distal opening of the intermediate catheter to grab the clot 4111, as shown. The puller 4105 may thus be drawn proximally (to the left in the figure) to pull the tractor 4103 from over the catheter portion of the elongate inversion support 4113, so that it inverts and rolls into the lumen of the elongate inversion support, capturing and drawing the clot in with it. The clot may be compressed.

[000210] Thus, this configuration may be referred to as a vessel cleaner. In addition to the rolling of the tractor to grab and pull the clot, the clot may be pulled by a vacuum applied from one or both of the intermediate catheter 4121 and/or the elongate inversion support 4123. Vacuum may be applied, e.g., within the intermediate catheter, before the apparatus is positioned distally (or even within the intermediate catheter at all) or after it has been extended distally from the intermediate catheter. This configuration shown in FIG. 41A may introduce the tractor through outer catheter to the face of clot. As mentioned, the mechanical thrombectomy apparatus may be extended distally from the intermediate catheter either by pushing it out distally and/or by pulling back the intermediate catheter to deploy all or part of the tractor into vessel, as shown. If vacuum is applied through the catheter, the catheter forming the elongate inversion support may be jacketed or sealed to allow aspiration through this catheter.

[000211] Optionally pull vacuum through outer and/or inner and/or puller. As mentioned, thereafter the tractor may be pulled proximally relative to the the elongate inversion support to pull the clot. The intermediate catheter may then be advanced distally and/or the mechanical thrombectomy apparatus may be withdrawn proximally to remove the apparatus once the clot has been removed. Thereafter an angiogram may be taken to confirm that the clot has been removed.

[000212] Alternatively, in FIG. 41B, a clot may be removed using the intermediate catheter to draw a vacuum with the mechanical thrombectomy apparatus within the lumen (e.g., near the distal end, but not extending fully from the distal end) of the intermediate catheter. As described for FIG. 41A, in FIG. 41B the intermediate catheter may be inserted into the vessel (e.g., using a guidewire) so that the distal end is positioned near the clot. Suction may be

used to draw the clot into the intermediate catheter either before the mechanical thrombectomy device is inserted or after it has been inserted.

[000213] In FIG. 41B, the elongate inversion support 4113' is particularly well suited for use with a vacuum applied through the intermediate catheter 4104 surrounding the apparatus. For example, in FIG. 41B, the elongate inversion support 4113' include a distal catheter region 4125 that extends just a few cm from the distal end opening in which the clot is drawn. The elongate inversion support then tapers down to an elongate support, which may be formed by a wire, hypotube or skived region. This configuration may prevent the catheter from blocking the lumen of the intermediate catheter and therefore increasing the resistance of the vacuum before it can reach the open distal end and apply suction to draw the clot. Alternatively or additionally, the outer diameter of the catheter portion of the elongate inversion support may be sized to allow more of the vacuum to pass. For example, the apparatus may be sized such that there is at least about 0.002 inches or greater (e.g., 0.003, 0.004, 0.005, 0.006, etc., inches) between the outer diameter of the catheter and the inner diameter of the intermediate catheter ("outer catheter"). This may also permit unimpeded rolling of the tractor over the distal end opening of the elongate inversion support.

[000214] In operation, the method of removing clot such as shown in FIG. 41B may include pulling at least the tip of a clot into the intermediate catheter through the use of a vacuum 4121. Typically the clot may clog within the intermediate catheter; the mechanical thrombectomy apparatuses described herein may be used to remove the clot from within the intermediate catheter. For example, while maintaining vacuum, the mechanical thrombectomy apparatus may be inserted (or it may be preloaded in intermediate catheter as mentioned) and the tractor puller 4105 may be pulled to pull the clot out of the intermediate catheter and the vessel, compress and/or macerate it and pull it into the apparatus and therefore the intermediate catheter, where it can be withdrawn proximally, e.g., by removing the mechanical thrombectomy apparatus. As mentioned, an angiogram may be taken through intermediate catheter (e.g., leaving it in place in case the mechanical thrombectomy apparatus needs to be re-inserted and used to remove more clot) to confirm clot has been removed.

[000215] As mentioned, a full catheter such as shown in FIG. 41A may block or prevent the vacuum from reaching the distal end of the intermediate vessel. Therefore it may be beneficial to adapt the mechanical thrombectomy apparatus so that it can be used with vacuum within an intermediate catheter or sleeve, as shown in FIG. 41B. This may be achieved as mentioned above, by minimizing the larger-diameter catheter portion of the elongate inversion support forming the distal end opening over which the tractor inverts. In

FIG. 42A for example, the elongate inversion support 700 has a distal catheter portion 701 having a larger diameter than the more proximal region 703, and also includes a plurality of openings, holes, gaps, cut-out regions, slots, etc. 709 that may allow the flow of vacuum through the elongate inversion support more easily. The elongate inversion support shown also includes a distal end 707 into which a tractor 711 inverts, as shown in FIG. 42B. IN FIG. 42B, the elongate inversion support is shown transparent so that the puller 713 and tractor within the elongate inversion support is visible.

[000216] Similarly, in FIGS. 42B and 42C, the entire length of the elongate inversion support includes a plurality of cut-out regions 713 which may increase the ability to allow the flow of a vacuum or other fluid within the apparatus, but may still allow the elongate inversion support to provide column strength to resist collapsing up to at least 500 g of compressive longitudinal force applied by, e.g., pulling on the tractor. Similarly, the elongate inversion support of FIGS. 42E and 42F show a skived catheter that also includes openings 709 along its length. The puller and tractor 412 are shown within the elongate inversion support in FIG. 42F. FIGS. 42G and 42H illustrate an example in which rather than a skived portion of the catheter, the distal catheter region of the elongate inversion support is formed by a wire, bar, tube, 721 etc., that is attached to the catheter at the distal end. The catheter may also optionally include openings 709. The elongate inversion support of FIGS. 42I and 42J includes openings 709' along all or much of its length (particularly near the distal end region) as shown.

[000217] Finally, the variation of the elongate inversion support shown in FIG. 42K includes a minimal catheter portion 732 that is connected to a wire, bar, tube, hypotube, skived region, etc.

[000218] FIGS. 43A-43D illustrate the operation of a similar minimal elongate inversion support 800. In this example, the apparatus includes a distal aperture 743 bonded securely to a wire, bar, tube, hypotube, skived region, etc. 746 forming an elongate support. The elongate support may be hollow (e.g., may include a lumen for a guidewire) or solid. The elongate support may also include one or more additional support guides 750 as shown in FIG. 43B. These supports may help contain the puller and/or tractor within the elongate inversion support. Any of the elongate inversion supports described herein may include additional support guides. The elongate inversion support of FIG. 8B is shown with a tractor 711 and puller 712 in FIG. 43C. As mentioned, this variation may be particularly well suited for use with an intermediate (e.g., “outer”) catheter, sleeve, or the like 809, as shown in FIG. 43D.

POWER DRIVEN TRACTORS

[000219] Also described herein are mechanical thrombectomy apparatuses in which the tractor is power driven. Any of the tractors described herein may also be driven by a motor, instead of or in addition to the manual driven tractor described. For example, a power-driven tractor may be shown in FIGS. 38A-38B and 39A-39C. In FIG. 38A the tractor is a continuous tractor. FIG. 38B illustrates the catheter and tractor region, without the motor shown in FIG. 38A. The tractor comprises a plurality of belts, chains, lengths, etc. that run longitudinally and may act like a conveyor to pull clot into the apparatus. The loops of material may therefore be run as a power-driven tractor. FIGS. 39A-39C illustrate the operation of the apparatus of FIGS. 38A-38B, shown grabbing a clot.

[000220] Any of the methods (including user interfaces) described herein may be implemented as software, hardware or firmware, and may be described as a non-transitory computer-readable storage medium storing a set of instructions capable of being executed by a processor (e.g., computer, tablet, smartphone, etc.), that when executed by the processor causes the processor to control perform any of the steps, including but not limited to: displaying, communicating with the user, analyzing, modifying parameters (including timing, frequency, intensity, etc.), determining, alerting, or the like.

EXPANDABLE DISTAL ENDS

[000221] Any of the mechanical thrombectomy apparatuses described herein may include an elongate inversion support having a distal end that is expandable from a smaller diameter aperture (e.g., distal end opening) to a larger-diameter aperture. This expansion may be performed by pulling the clot within the catheter. For example, FIGS. 44A-44C illustrates the operation of an example of an elongate inversion support configured as a catheter having an expandable distal end. In this variation the catheter distal end 4401 may include slots or slits 4403 formed or cut, e.g., by laser-cutting, in the distal end of the catheter of the elongate inversion support. The apparatus may be operated as described above, positioning near (e.g., against or adjacent to) a clot, and pulling proximally on the puller to draw the tractor 4405 into the catheter, as shown in FIG. 44B. Although the apparatuses described herein may generally compress a clot greatly, compression may be made easier and/or more efficient by providing a more gradual decrease in radial diameter. As shown in FIG. 44B, when the tractor is rolled over the distal end opening and inverted, the clot may be drawn in along with the tractor. As the large clot 4413 is brought into the distal end opening, the distal end

opening may expand and open along the slots or slits 4403, as shown in FIG. 44C, so that the distal end opening flares out. In some variations an elastic sleeve, gasket, ring or cover (not shown in FIG. 44A-44C) may be included at least partially covering the distal end to prevent the edge from catching the tractor. For example, an elastic or stretchable layer may cover the cut distal end so that the distal end may be opened to form an outward flare. In FIG. 44C the outward-flared distal end is shown forming a funnel-shape into which the clot may be pulled. This funnel-shaped opening may help compress the clot so that it may be drawn into the mechanical thrombectomy apparatus.

[000222] In some variations the elongate inversion support may be configured to have, or to assume, a funnel-shape at the distal-facing end. The distal-facing end may always have a funnel-shaped mouth at the distal end opening, or the distal end opening may be configured to assume a funnel shape, as shown in FIGS. 44A-44C. In some variations the distal end of the elongate inversion support is configured to be elastic in a radial direction, but maintain stiffness along the proximal-to-distal axis (in compressive load). For example, the distal end of the elongate inversion support may be configured with strands or rods extending in the proximal-to-distal axis that have a high compressive load strength, but which may separate from each other to enlarge the distal end opening; for example they may be connected by rings in which more distal rings are more elastic/stretchable than more proximal rings.

[000223] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[000224] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the

context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[000225] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[000226] Although the terms "first" and "second" may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[000227] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising" means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term "comprising" will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

[000228] In general, any of the apparatuses and methods described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may

alternatively be exclusive, and may be expressed as “consisting of” or alternatively “consisting essentially of” the various components, steps, sub-components or sub-steps.

[000229] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word “about” or “approximately,” even if the term does not expressly appear. The phrase “about” or “approximately” may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is $\pm 0.1\%$ of the stated value (or range of values), $\pm 1\%$ of the stated value (or range of values), $\pm 2\%$ of the stated value (or range of values), $\pm 5\%$ of the stated value (or range of values), $\pm 10\%$ of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For example, if the value “10” is disclosed, then “about 10” is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that “less than or equal to” the value, “greater than or equal to the value” and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value “X” is disclosed the “less than or equal to X” as well as “greater than or equal to X” (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point “10” and a particular data point “15” are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[000230] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary

purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[000231] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term “invention” merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

What is claimed is:

1. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:
 - an elongate inversion support comprising a catheter having a distal end and a distal end opening;
 - a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor comprises a tubular wall, further wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter; and
 - a plurality of projections that extend from a portion of the tractor that is inverted over the distal end opening of the catheter as the tractor rolls over the distal end opening of the catheter, wherein the plurality of projections do not extend from the tractor as it extends proximally in the inverted configuration along the distal end of the catheter.
2. The apparatus of claim 1, wherein the tractor is sufficiently soft such that without support from the catheter, it collapses radially under an axial compression of less than 200g of force when inverting.
3. The apparatus of claim 1, wherein the tractor is biased to expand to greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to greater than the inner diameter of the catheter in the un-inverted configuration.
4. The apparatus of claim 1, further comprising a guidewire lumen extending through the elongate inversion support and the tractor and configured to pass a guidewire.
5. The apparatus of claim 1, wherein the proximal end of the elongate inversion support comprises a skived proximal end of the catheter.
6. The apparatus of claim 1, wherein the catheter comprises a plurality of lateral openings along the distal end.

7. The apparatus of claim 1, wherein the tractor comprises a plurality of woven ribbons forming the tubular wall, further wherein the plurality of projections comprises edges of the ribbons.
8. The apparatus of claim 7, wherein the ribbons have a rectangular cross-section.
9. The apparatus of claim 7, wherein the ribbons are arranged in a woven helical pattern.
10. The apparatus of claim 7, wherein the ribbons are formed of a metallic or polymeric material.
11. The apparatus of claim 1, wherein the tractor comprises a knitted material.
12. The apparatus of claim 1, wherein the tubular wall of the tractor comprises steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric.
13. The apparatus of claim 1, wherein the projections are cut from the tubular wall.
14. The apparatus of claim 1, wherein each of the plurality of projections have a width in a direction transverse to a long axis of the tractor and a length in a direction along the long axis of the tractor, further wherein the ratio of length to width is between 10 and 100.
15. The apparatus of claim 1, wherein each of the plurality of projections has one or more of: a paddle shape, a scoop shape, and spike shape.
16. The apparatus of claim 1, wherein the plurality of projections comprise sharp ends.
17. The apparatus of claim 1, wherein the material hardness of catheter decreases over the distal end of the catheter until the distal end opening, wherein the distal end opening has a material hardness that is greater than a material hardness of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile.
18. The apparatus of claim 1, wherein there is a non-uniform density of projections along the length of the tractor.

19. The apparatus of claim 1, wherein the projections are oriented relative to the tractor so that the projections extend in the distal direction when the tractor is on the outer diameter of the catheter.
20. The apparatus of claim 1, wherein the projections further comprising a plurality of slots or openings through the tubular wall of the tractor.
21. The apparatus of claim 1, wherein the tractor comprises one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating.
22. The apparatus of claim 1, wherein the tubular wall of the tractor has a pore pattern having a longitudinal separation between pores of less than about 0.005 inches.
23. The apparatus of claim 1, further comprising a releasable attachment between the tractor and an outer surface of the catheter, wherein the releasable attachment is configured to release when the tractor is pulled with a force that is greater than a predetermined force threshold.
24. The apparatus of claim 19, wherein the releasable force threshold is 0.01 N.
25. The apparatus of claim 1, further comprising a sleeve extending over the catheter and tractor.
26. The apparatus of claim 1, further comprising an elongate puller extending proximally from the first end of the tractor, wherein the puller is coupled to the first end of the tractor.
27. The apparatus of claim 26, wherein the elongate puller comprises a hypotube having an inner lumen that is continuous with a lumen through the tractor.
28. The apparatus of claim 1, wherein the tractor a lumen within the catheter having an inner diameter that is 80 % or greater than an inner diameter of the catheter, so that the tractor does not collapse closed within the catheter.
29. The apparatus of claim 1, wherein the tractor is 3 cm to 50 cm long.

30. The apparatus of claim 1, wherein the apparatus is configured so that the tractor is retractable into the catheter by applying 300 g of force or less to a distal end of the tractor.
31. The apparatus of claim 1, wherein the proximal end of the tractor is loose so that it may be pulled along an outer diameter of the catheter as the tractor is pulled proximally within the catheter.
32. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:
- an elongate inversion support comprising a catheter having a distal end and a distal end opening;
 - a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, the flexible tube comprising a plurality of ribbons having a square or rectangular cross-section woven together, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter, wherein a plurality of edges of the plurality of ribbons extend from a portion of the tractor that is inverted over the distal end opening of the catheter as the tractor rolls over the distal end opening of the catheter, further wherein the projecting edges are not extended from the tractor in a portion of the tractor that extends over the distal end of the catheter; and
 - a guidewire lumen extending through the catheter and the tractor and configured to pass a guidewire.
33. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:
- an elongate inversion support comprising a catheter having a distal end and a distal end opening; and
 - a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, the tractor comprising a tubular wall, wherein the tractor

is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter, further wherein the tractor comprises a plurality of projections formed from the tube wall that extend from a portion of the tractor that is inverted over the distal end opening of the catheter as the tractor rolls over the distal end opening of the catheter, wherein the plurality of projections are not extended from the tractor in a portion of the tractor that extends proximally in the inverted configuration along the distal end of the catheter;

wherein the tractor is sufficiently soft such that without support from the catheter, the tractor collapses radially under an axial compression of less than 200g of force when inverting.

34. A method of removing a clot using a mechanical thrombectomy apparatus, the method comprising:

positioning a distal end of the mechanical thrombectomy apparatus adjacent to a clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter;

pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter and extends a plurality of projections from the tractor;

grabbing the clot with the plurality of projections; and
drawing the clot into the catheter.

35. A method of removing a clot using a mechanical thrombectomy apparatus, the method comprising:

positioning a distal end of the mechanical thrombectomy apparatus adjacent to a clot within a vessel, wherein the mechanical thrombectomy apparatus includes a soft tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter, wherein the tractor is sufficiently soft such that without support from the catheter, the tractor collapses

radially under an axial compression of less than 200g of force when inverting;

pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter and extends a plurality of projections from the tractor;

grabbing the clot with the plurality of projections; and
drawing the clot into the catheter.

36. The method of claim 34 or 35, further comprising macerating the clot with the plurality of projections.
37. The method of claim 34 or 35, wherein the tractor comprises a plurality of ribbons having a square or rectangular cross-section, further wherein pulling the distal end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter comprises extending a plurality of edges of the ribbons from an inverting portion of the tractor as the tractor is rolled over the distal end of the catheter.
38. The method of claim 34 or 35, wherein the tractor comprises a plurality of cut-out regions formed in the tractor, wherein pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter extends the cut-out regions from an inverting portion of the tractor as the tractor is rolled over the distal end of the catheter.
39. The method of claim 34 or 35, further comprising sliding a loose second end of the tractor over the catheter as the first end of the tractor is pulled proximally.
40. The method of claim 34 or 35, wherein positioning the distal end of the mechanical thrombectomy apparatus comprises sliding the mechanical thrombectomy apparatus over a guidewire.
41. The method of claim 34 or 35, further comprising releasing a releasable attachment between the tractor and an outer surface of the catheter.
42. The method of claim 34 or 35, wherein pulling the first end of the tractor proximally comprises maintaining an inner diameter of the tractor within the catheter at greater

than 60 % of an inner diameter of the catheter to prevent the tractor from locking over the distal end of the catheter.

43. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

- an elongate inversion support comprising a catheter having a distal end and a distal end opening;

- a tractor comprising a flexible tube extending longitudinally within the catheter and doubling back over the distal end of the catheter to invert and extend over the distal end of the catheter, wherein the flexible tube comprises longitudinally alternating regions of higher and lower stiffness, wherein the regions of higher stiffness have a stiffness that is greater than the regions of lower stiffness; and

- a puller coupled to a first end of the tractor and configured to pull the tractor proximally to invert the tractor over the distal end opening.

44. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

- an elongate inversion support comprising a catheter having a distal end and a distal end opening;

- a tractor comprising a flexible tube extending longitudinally within the catheter, doubling back over the distal end of the catheter, and extending over the distal end of the catheter, wherein the flexible tube comprises longitudinally alternating regions of higher and lower stiffness, wherein the regions of higher stiffness have a stiffness that is greater than the regions of lower stiffness, further wherein a diameter of a distal-facing doubled-back region of the tractor oscillates as the tractor is pulled proximally within the catheter to invert the tractor over the distal end of the catheter;

- a puller coupled to a first end of the tractor and configured to pull the tractor proximally to invert the tractor over the distal end opening.

45. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

an elongate inversion support comprising a catheter having a distal end and a distal end opening having a radius and a catheter wall thickness at the distal end opening;

a tractor comprising a flexible tube extending longitudinally within the catheter and doubling back over the distal end of the catheter to extend over the distal end of the catheter, wherein the flexible tube comprises longitudinally alternating regions of higher and lower stiffness helically arranged around the flexible tube, wherein the regions of higher stiffness have a first length and a stiffness that is greater than the regions of lower stiffness, wherein the first length is between 1.1 times the catheter wall thickness at the distal end opening and 1.1 times the radius of the catheter; and

a puller coupled to a first end of the tractor and configured to pull the tractor proximally to invert the tractor over the distal end opening.

46. The apparatus of claim 43 or 44, wherein the regions of higher stiffness have a longitudinal length along the flexible tube that is 1.1 times the radius of the catheter or less.
47. The apparatus of claim 43 or 44, wherein the regions of higher and lower stiffness are helically arranged around the flexible tube.
48. The apparatus of claim 43 or 45, wherein a diameter of the distal-facing end of the tractor oscillates as the tractor is pulled proximally within the catheter to invert the tractor over the distal end of the catheter.
49. The apparatus of claim 43, 44 or 45, wherein the tractor comprises a knitted material.
50. The apparatus of claim 43, 44 or 45, wherein the tractor comprises a knitted material comprising one or more of: steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), and Nitinol.
51. The apparatus of claim 43, 44 or 45, wherein the tractor comprises a sheet of one or more of: steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric.
52. The apparatus of claim 51, wherein the sheet comprises a plurality of cut-out regions modifying the stiffness.

53. The apparatus of claim 43, 44 or 45, wherein the tractor comprises one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating.
54. The apparatus of claim 43, 44 or 45, wherein the tractor has at least one porous section having a pore pattern having a longitudinal separation between pores of less than about 0.005 inches in width.
55. The apparatus of claim 43, 44 or 45, further comprising a releasable attachment between the tractor and an outer surface of the catheter, configured to release when the tractor is pulled with a force that is greater than a predetermined force threshold.
56. The apparatus of claim 55, wherein the releasable force threshold is 0.01 N.
57. The apparatus of claim 43, 44 or 45, further comprising an outer catheter or sleeve extending over the catheter and flexible tube.
58. The apparatus of claim 44 or 45, further wherein the puller comprises a hypotube having an inner lumen that is continuous with a guidewire lumen through the flexible tube.
59. The apparatus of claim 43, 44 or 45, wherein an inner diameter of the portion of the tractor within the catheter is greater than 80 % of an inner diameter of the catheter so that the tractor does not collapse closed within the catheter.
60. The apparatus of claim 43, 44 or 45, wherein the tractor is 3 to 50 cm long.
61. The apparatus of claim 43, 44 or 45, wherein the apparatus is configured so that the tractor may be retracted into the catheter by applying less than 300 grams of force to a distal end of the flexible tube.
62. A mechanical thrombectomy apparatus for removing a clot from a vessel without jamming, the apparatus comprising:
 - an elongate inversion support comprising a catheter having a distal end and a distal end opening;
 - a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the

catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor comprises a tubular wall, further wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter,

wherein the tractor is biased to expand to have an inner diameter that is greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to have an inner diameter that is greater than the inner diameter of the catheter in the un-inverted configuration; and
an elongate puller coupled to the first end of the tractor.

63. A mechanical thrombectomy apparatus for removing a clot from a vessel without jamming, the apparatus comprising:

an elongate inversion support comprising a catheter having a distal end and a distal end opening;

a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor comprises a tubular wall, further wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter,

wherein the tractor is biased to expand to greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to greater than the inner diameter of the catheter in the un-inverted configuration;

an elongate puller coupled to a first end of the tractor and configured to pull the tractor proximally to invert the tractor over the distal end opening; and

a guidewire lumen extending through the elongate inversion support, puller, and tractor that is configured to pass a guidewire.

64. The apparatus of claim 62 or 63, wherein the tractor comprises a woven tube.

65. The apparatus of claim 62 or 63, wherein the tractor comprises a braided tube.

66. The apparatus of claim 62 or 63, wherein the tractor comprises a knitted material.

67. The apparatus of claim 62 or 63, further comprising an outer catheter within which the elongate inversion support extends distally.
68. The apparatus of claim 62 or 63, further comprising outer catheter within which the elongate inversion support extends distally and a vacuum source coupled to a proximal end of the outer catheter.
69. The apparatus of claim 62 or 63, further comprising outer catheter within which the elongate inversion support extends distally, and a vacuum source coupled to a proximal end of the outer catheter, wherein there is at least about 0.002 inches or greater between the outer diameter of the catheter and the inner diameter of the outer catheter.
70. The apparatus of claim 62 or 63, wherein the tractor is sufficiently soft such that without support from the catheter, it collapses radially under an axial compression of less than 200g of force when inverting.
71. The apparatus of claim 62 or 63, wherein the elongate inversion support is configured to withstand buckling of an axial compression of greater than 500 g of force.
72. The apparatus of claim 62 or 63, wherein the elongate inversion support is configured to withstand buckling of an axial compression of greater than 1500 g of force.
73. The apparatus of claim 62 or 63, wherein the tractor comprises one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating.

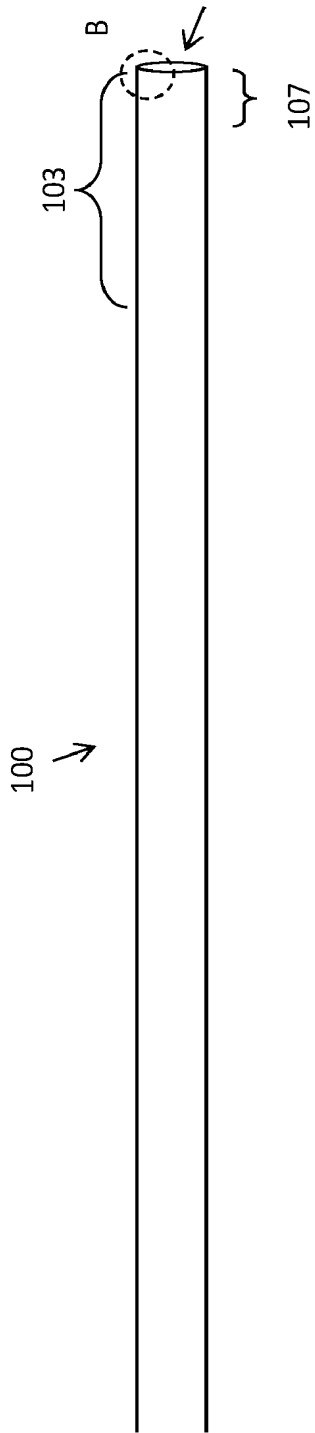


FIG. 1A

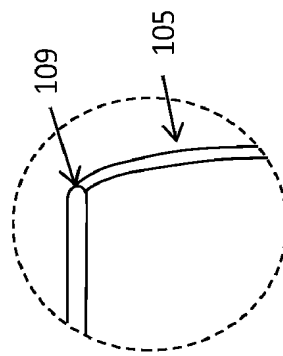


FIG. 1B

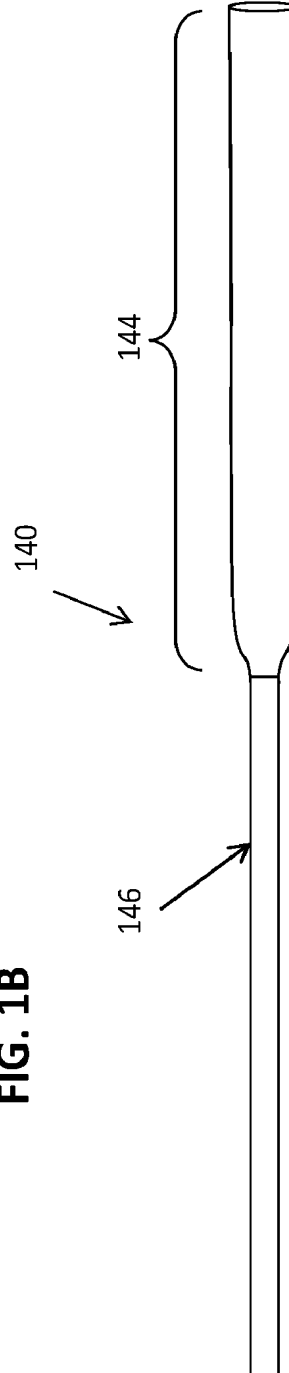


FIG. 1C

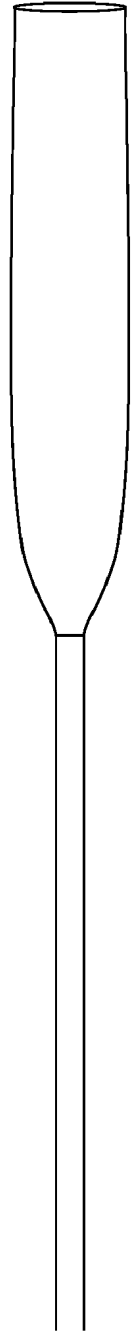


FIG. 1D

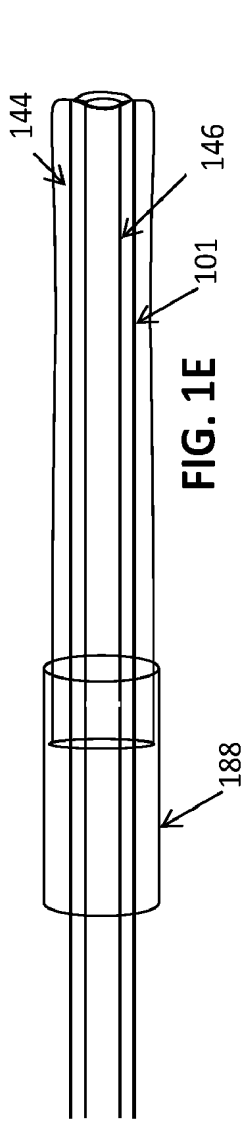


FIG. 1E

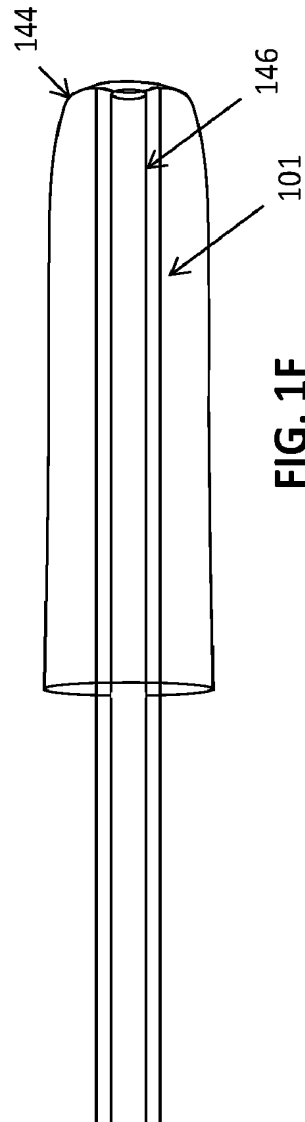


FIG. 1F

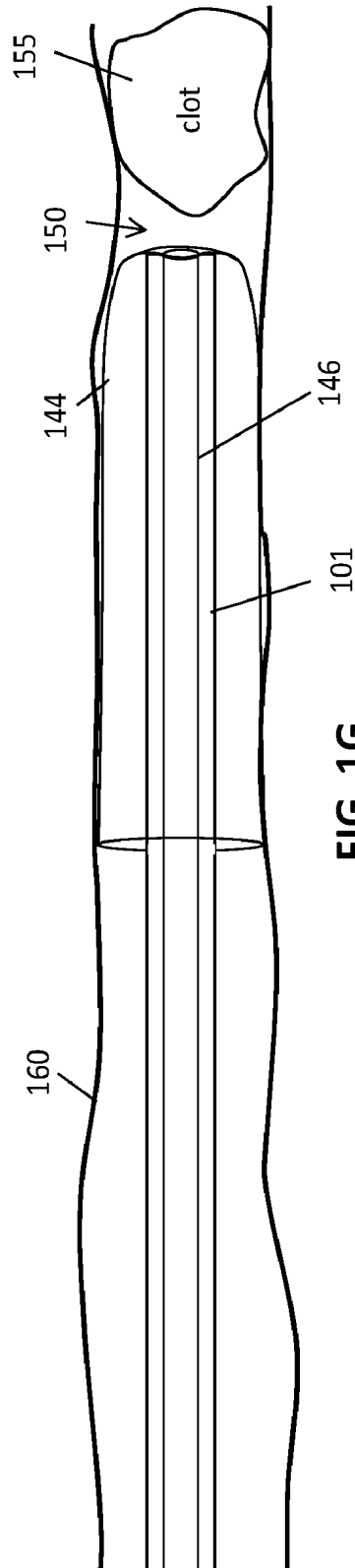


FIG. 1G

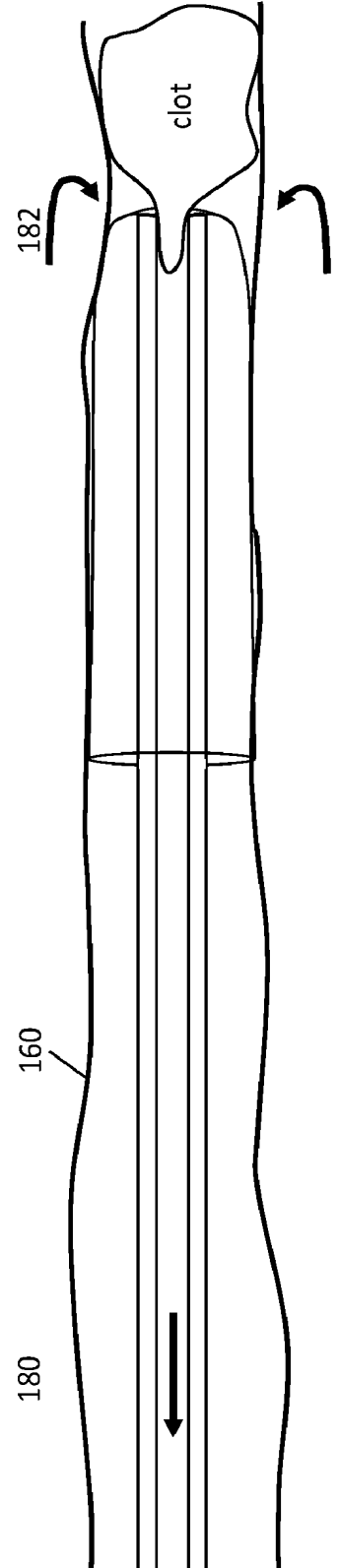


FIG. 1H

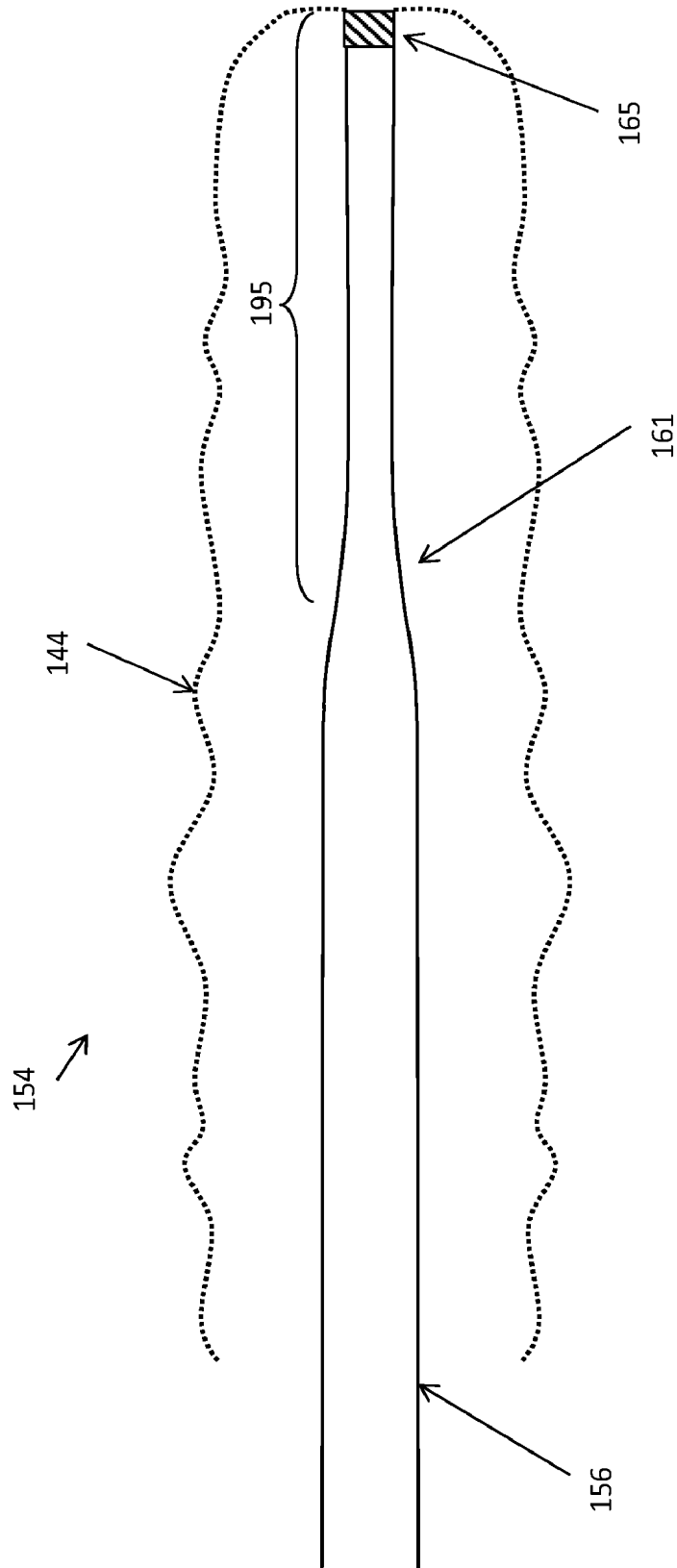
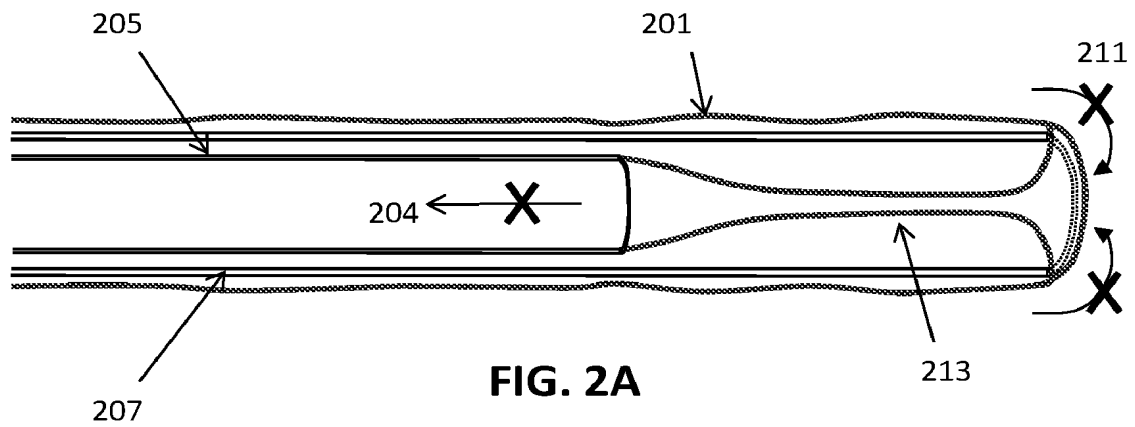
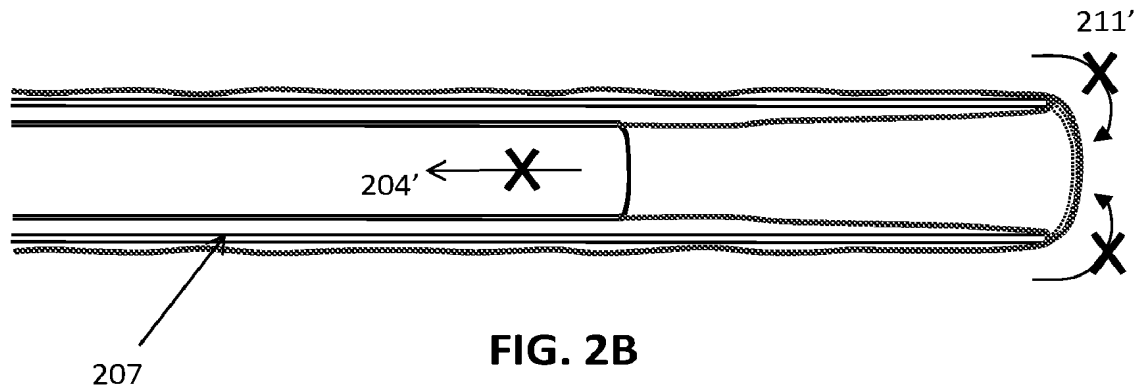
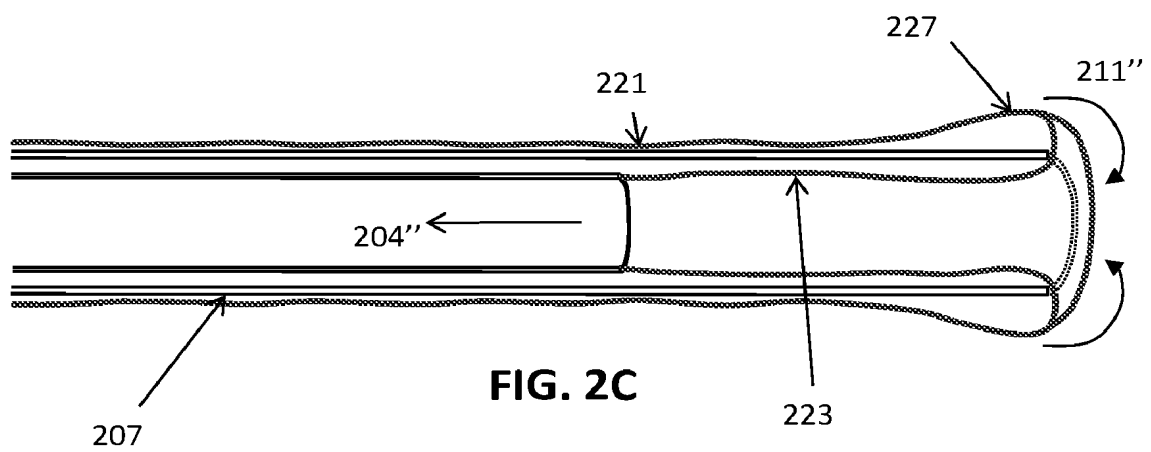


FIG. 1I



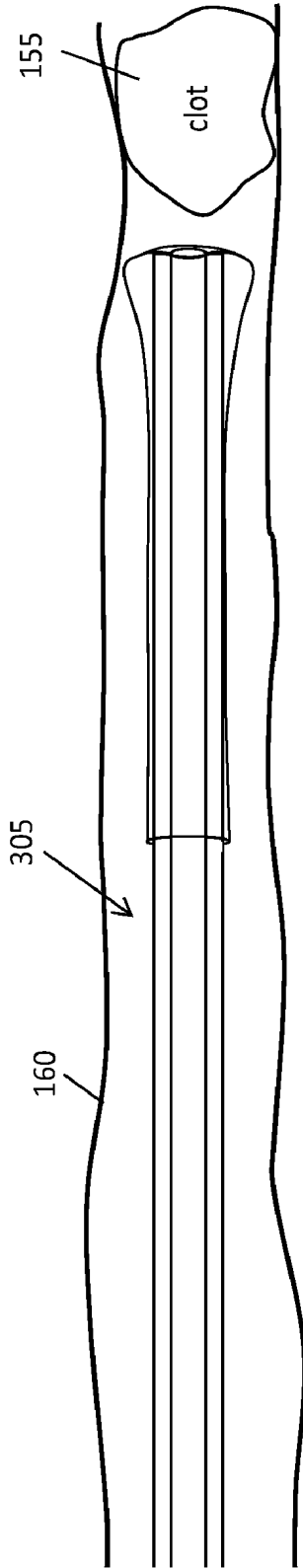


FIG. 3A

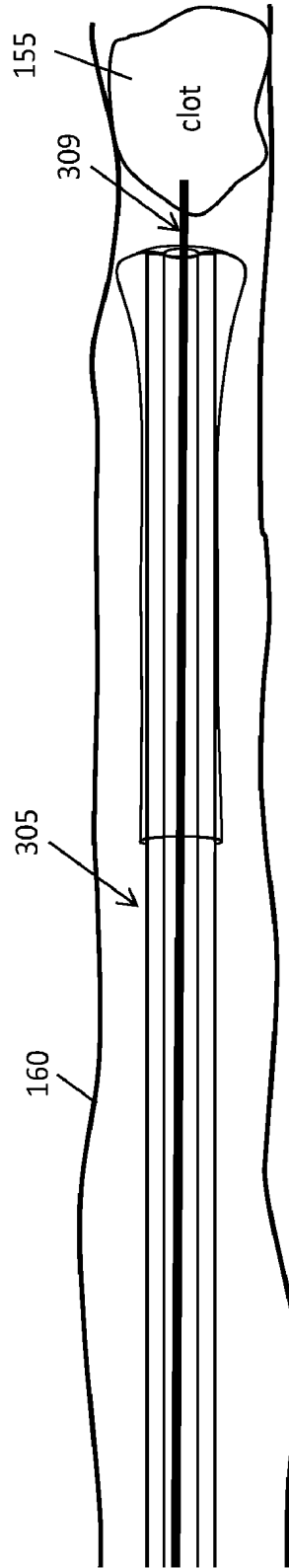


FIG. 3B

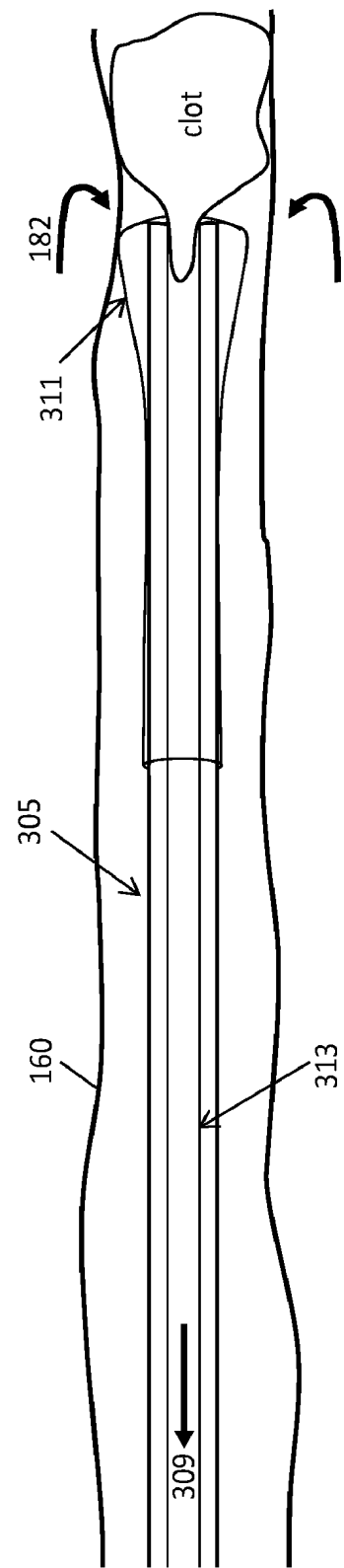


FIG. 3C

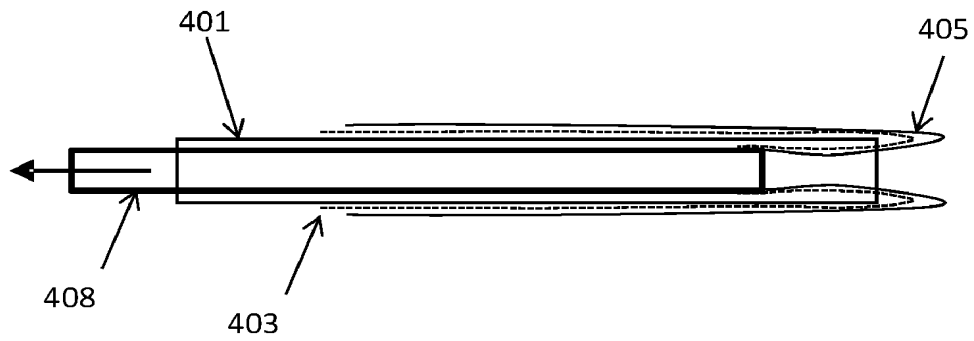


FIG. 4A

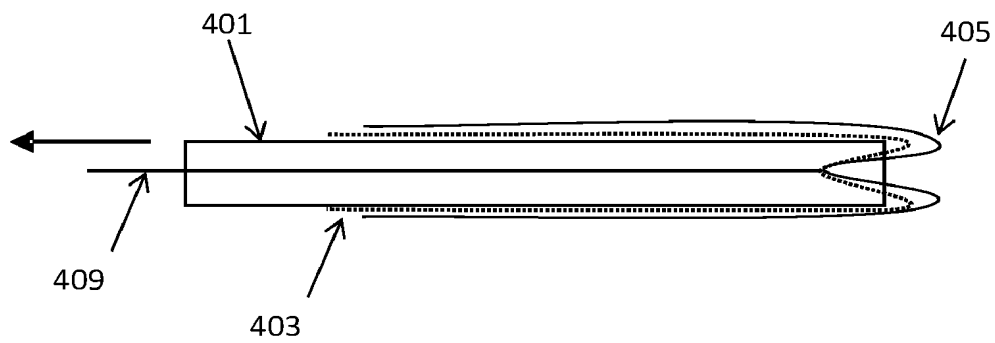


FIG. 4B

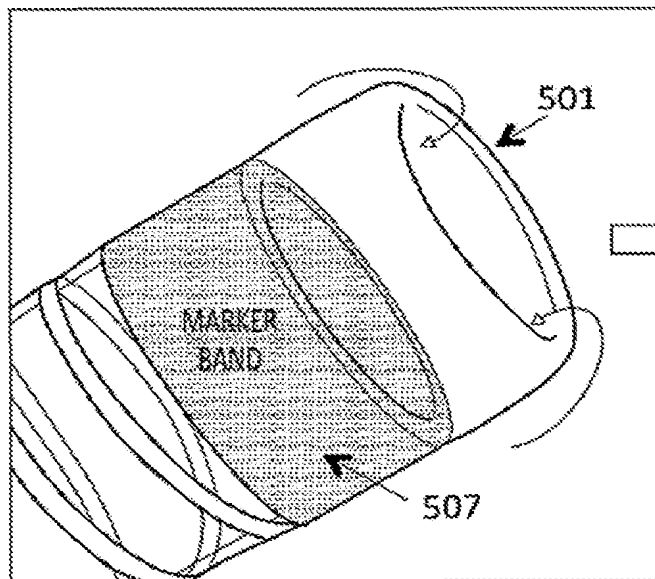


FIG. 5A

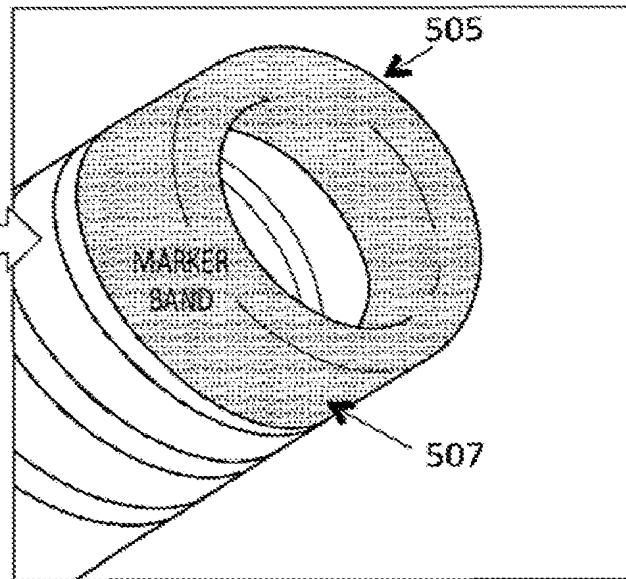


FIG. 5B

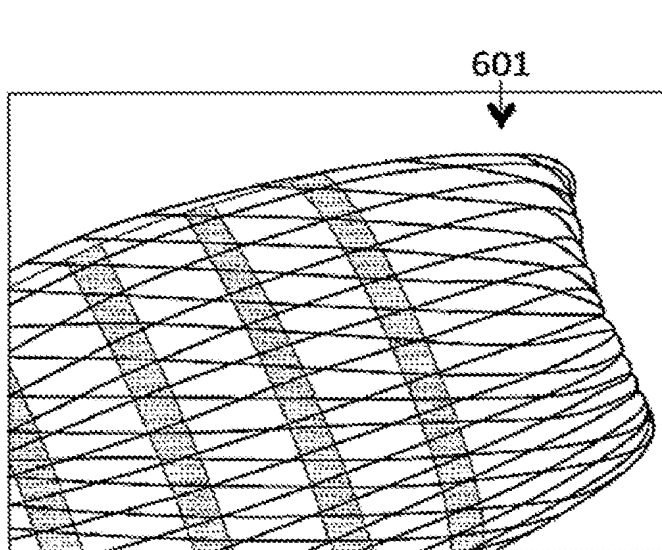


FIG. 6A

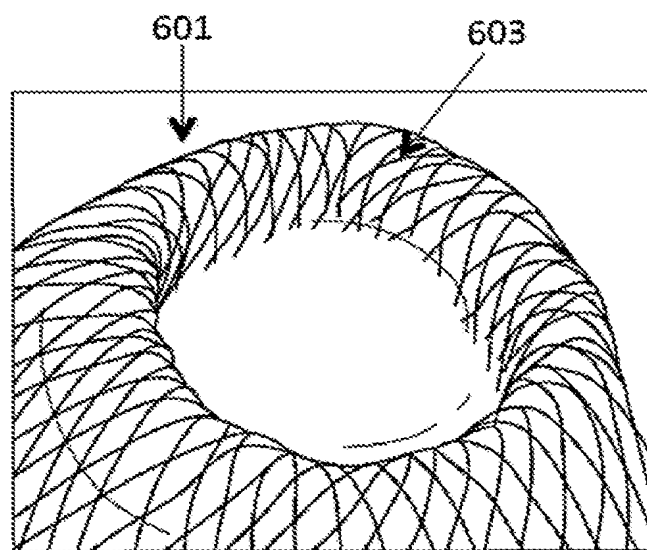
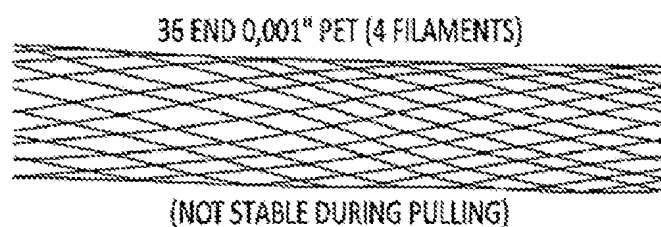
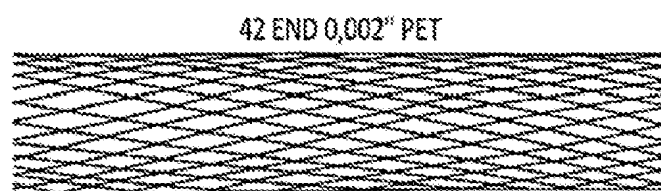
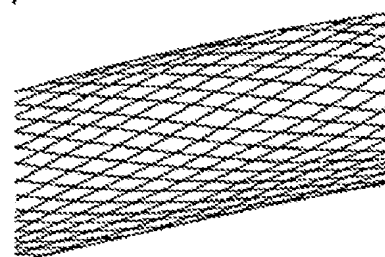


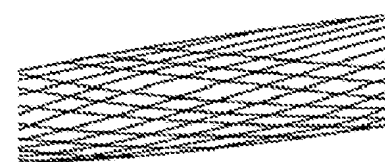
FIG. 6B

**7A****7B****7C**

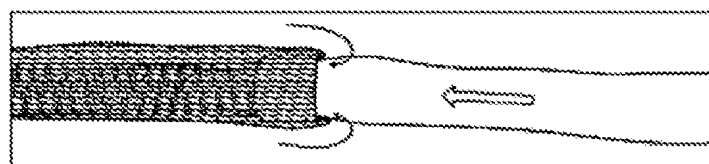
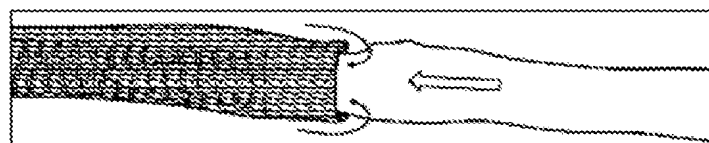
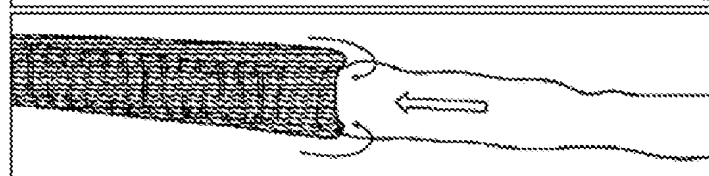
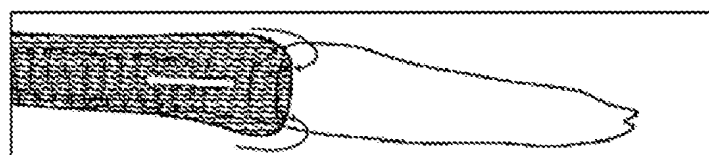
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(ON MANDREL PRE HEAT TREATING)

**7D**

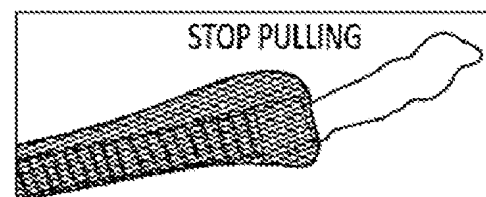
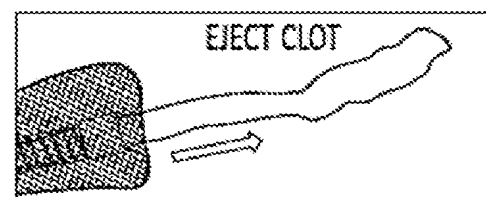
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(POST HEAT TREAT & CONSTRAINED IN 0.071)

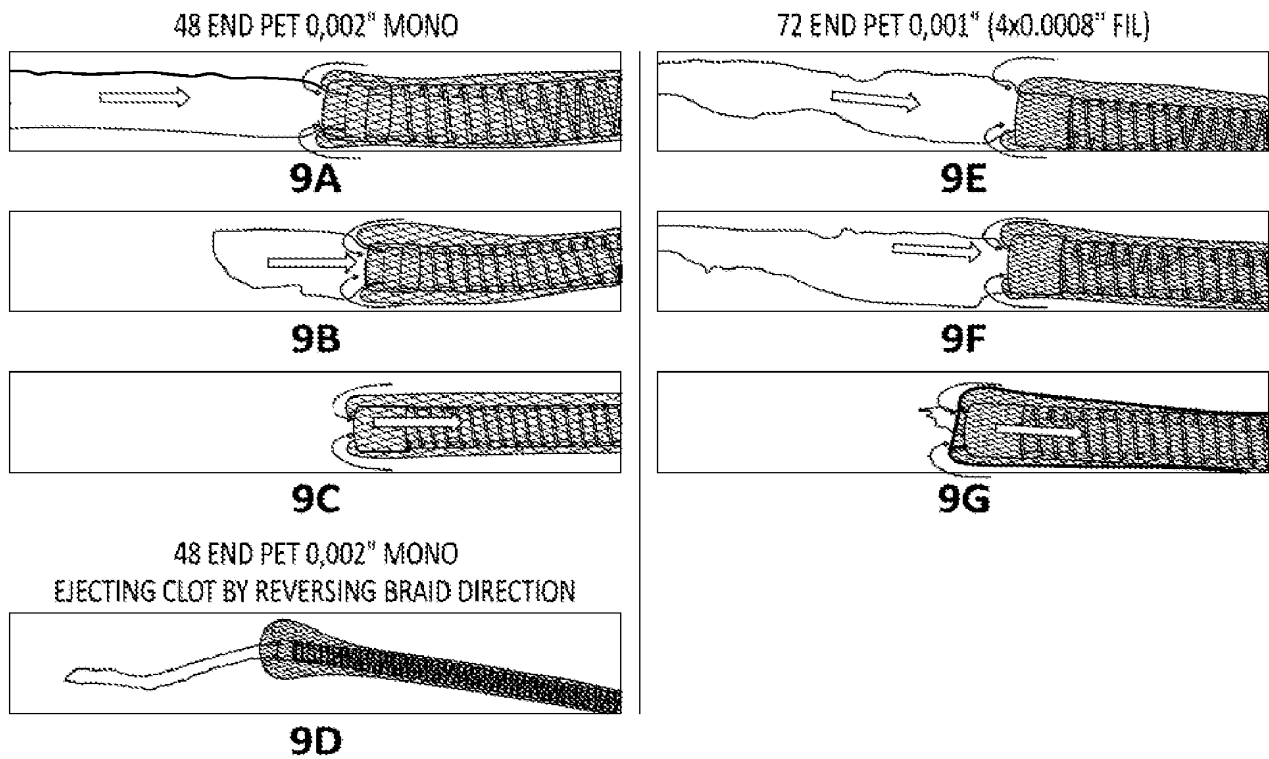
**7E****FIGS. 7A-7E**

PULLING CLOT IN: VESSEL ID ~ SAME AS CATHETER TIP

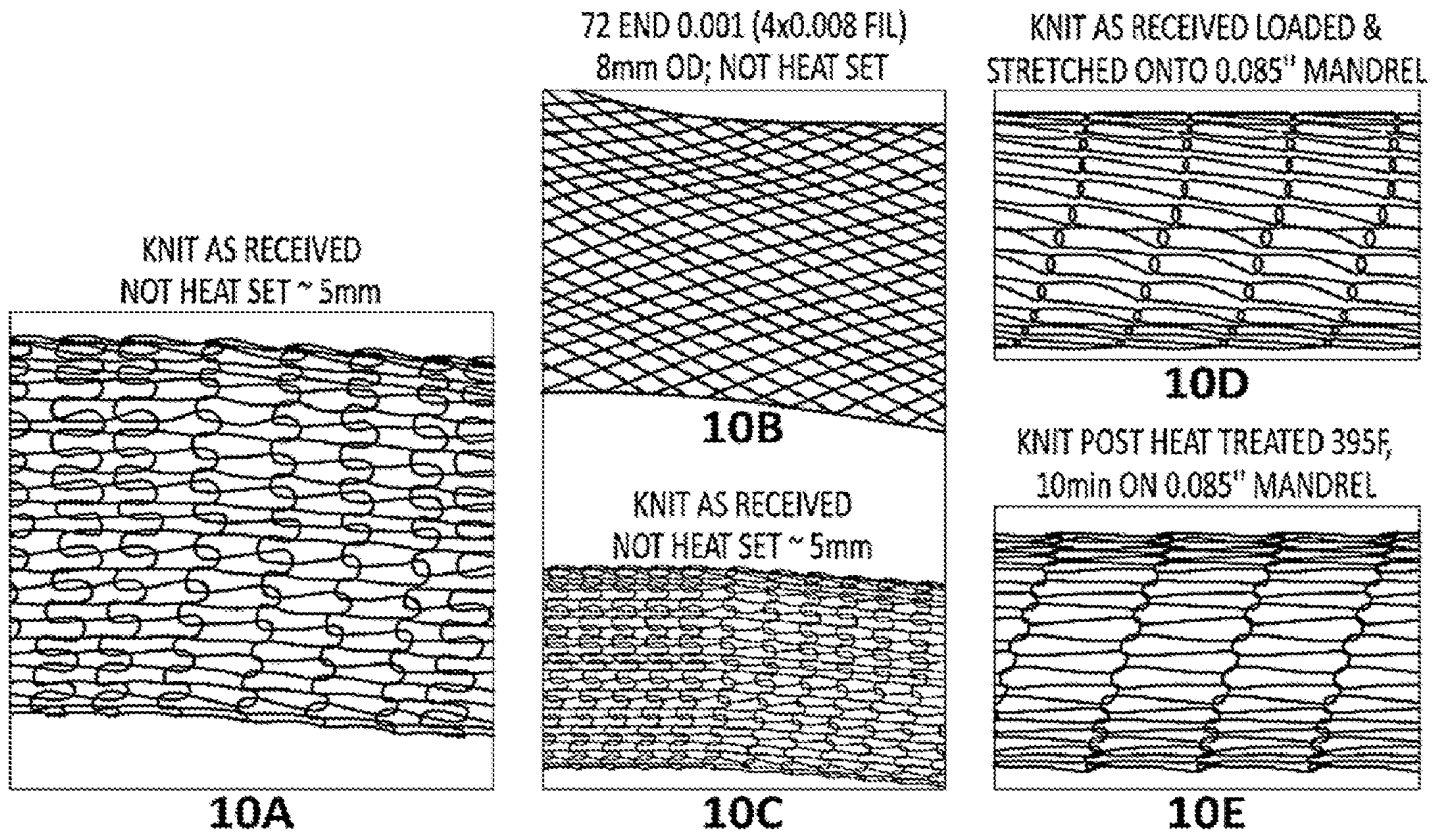
**8A****8B****8C****8D**

BRAID IN REVERSE: EJECTING CLOT
(DIFFERENT PIECE OF CLOT)

**8E****8F****FIGS. 8A-8F**



FIGS. 9A-9F



FIGS. 10A-10E

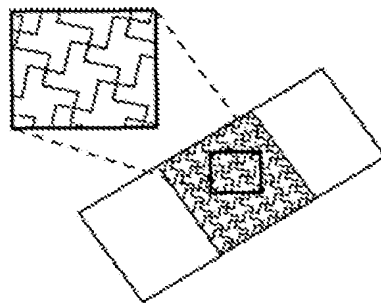


FIG. 11A

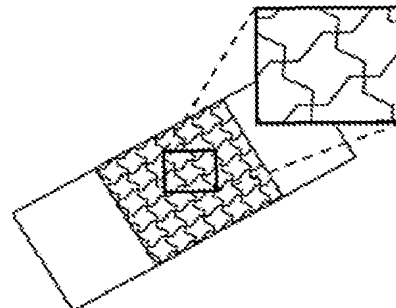


FIG. 11B

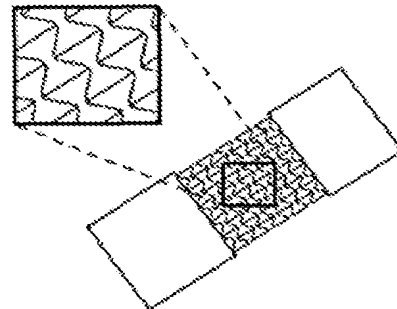


FIG. 11C

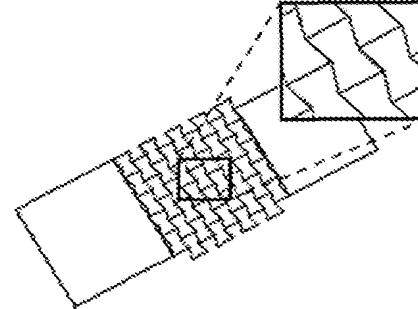


FIG. 11D

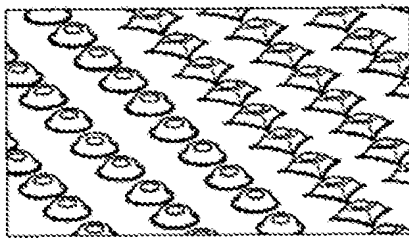


FIG. 12A

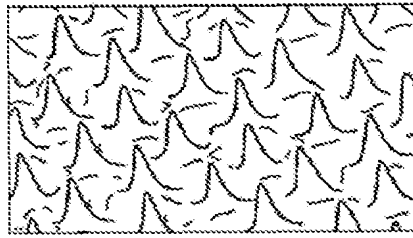


FIG. 12B

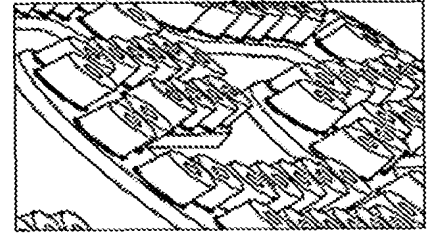


FIG. 12C

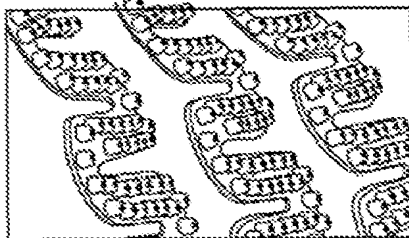


FIG. 12D

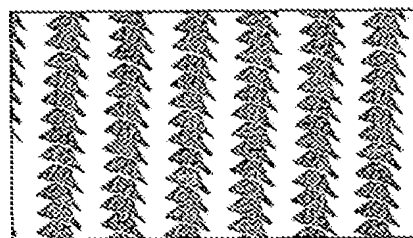


FIG. 12E

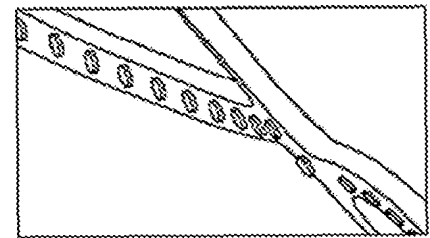


FIG. 12F

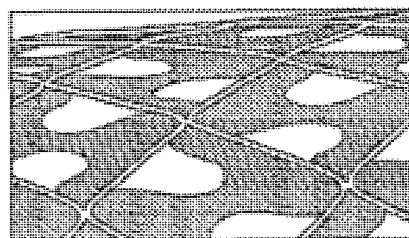


FIG. 12G

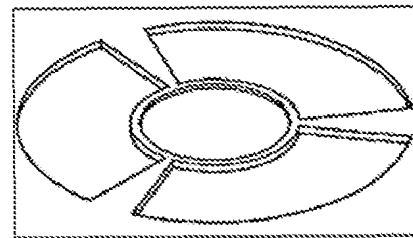


FIG. 12H

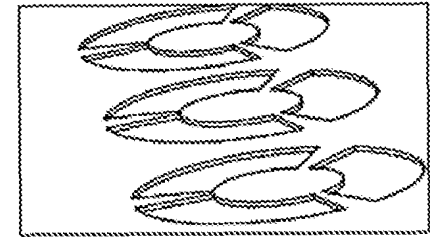


FIG. 12I

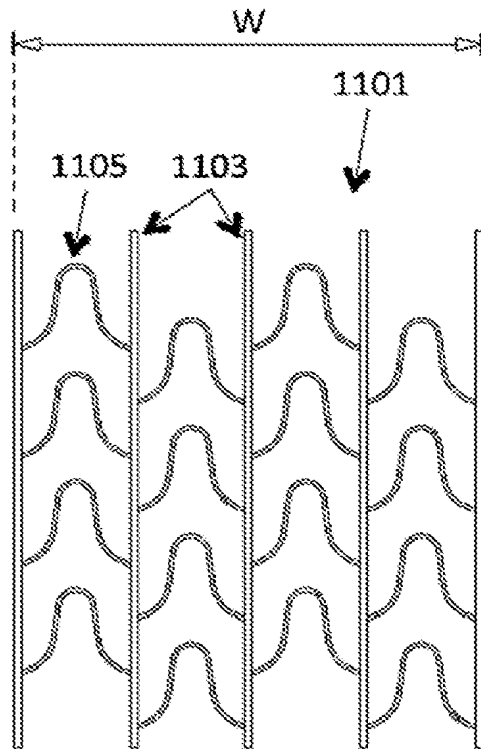


FIG. 13A

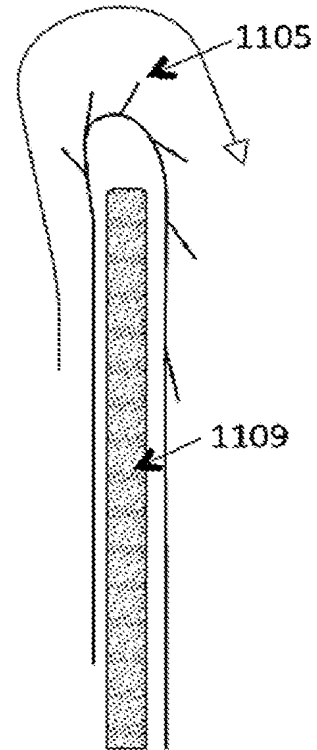


FIG. 13B

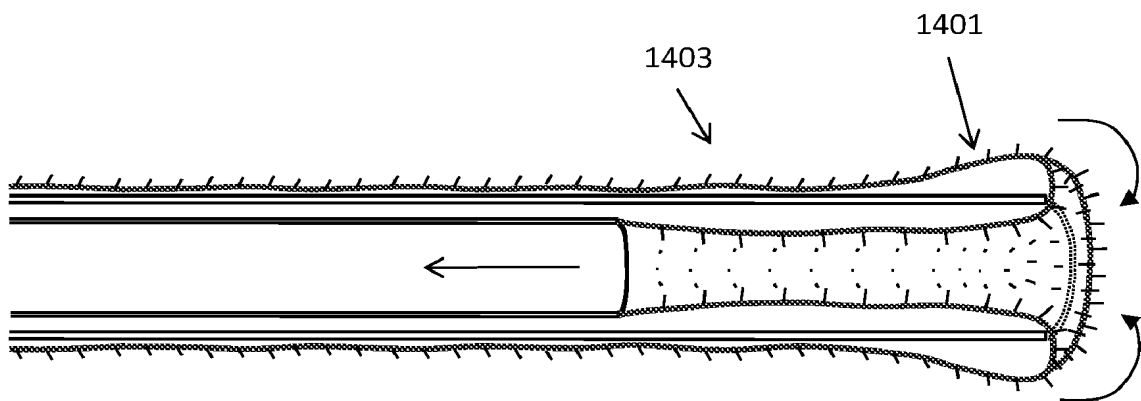


FIG. 14

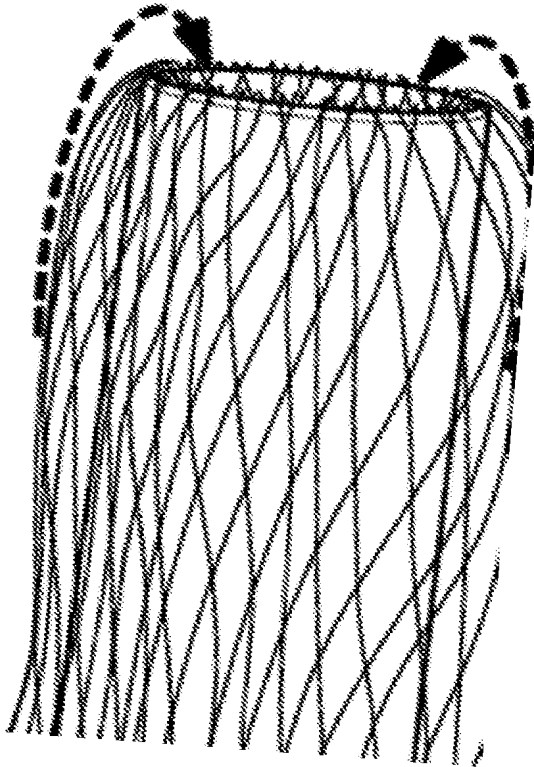


FIG. 15A

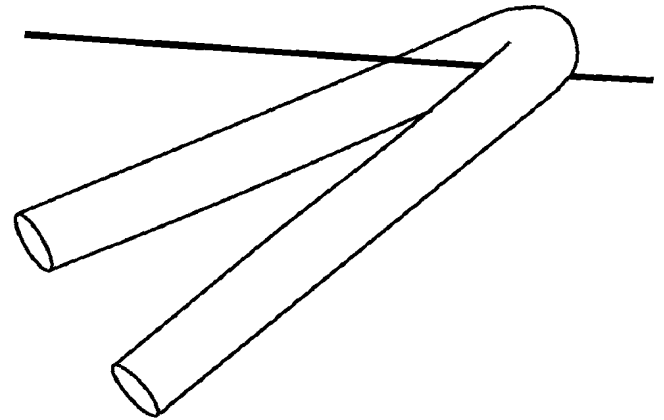


FIG. 15B



FIG. 15C

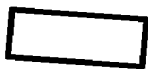


FIG. 15D

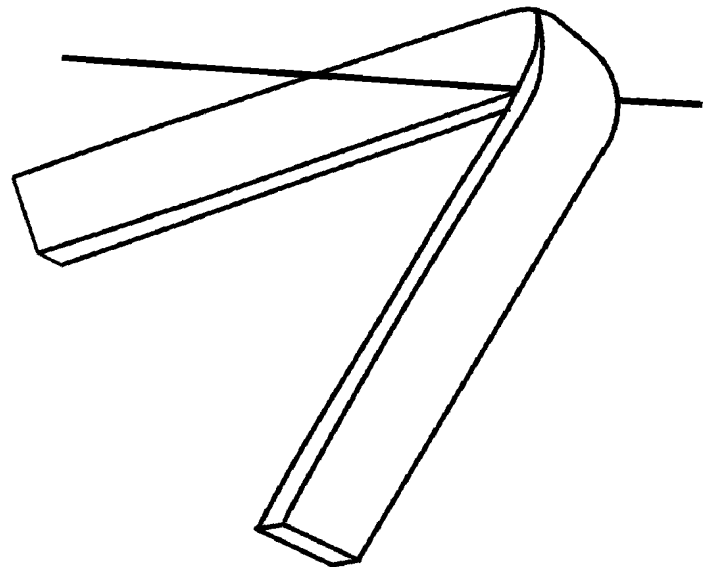
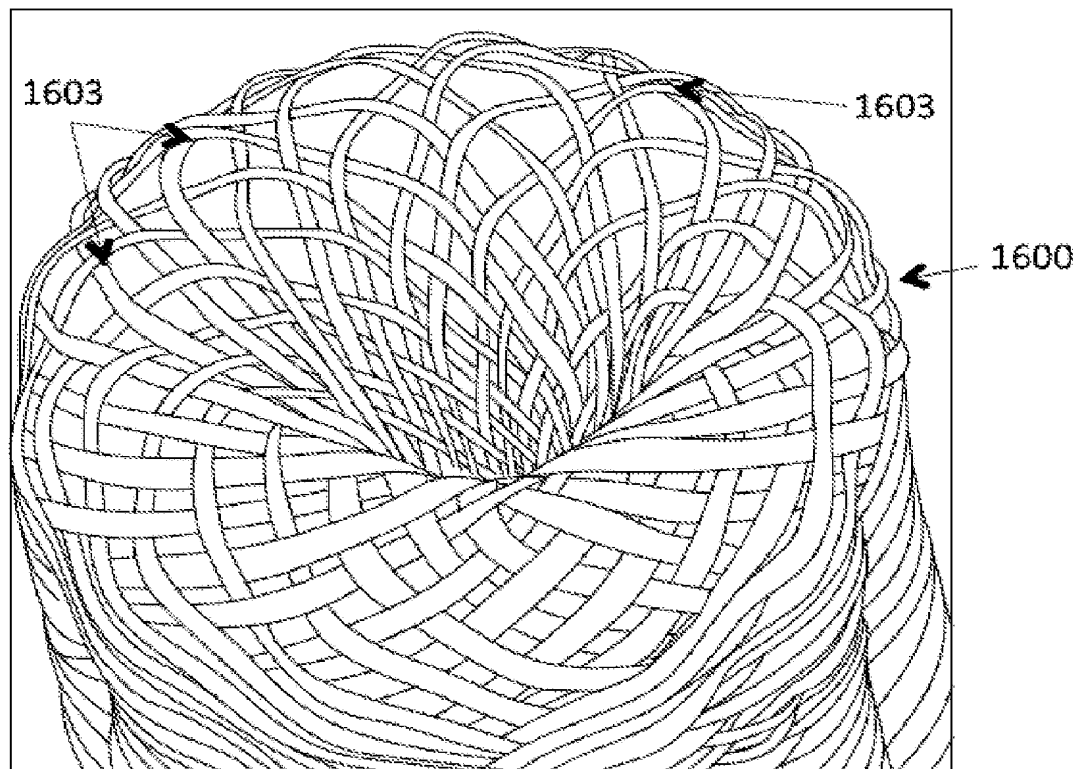
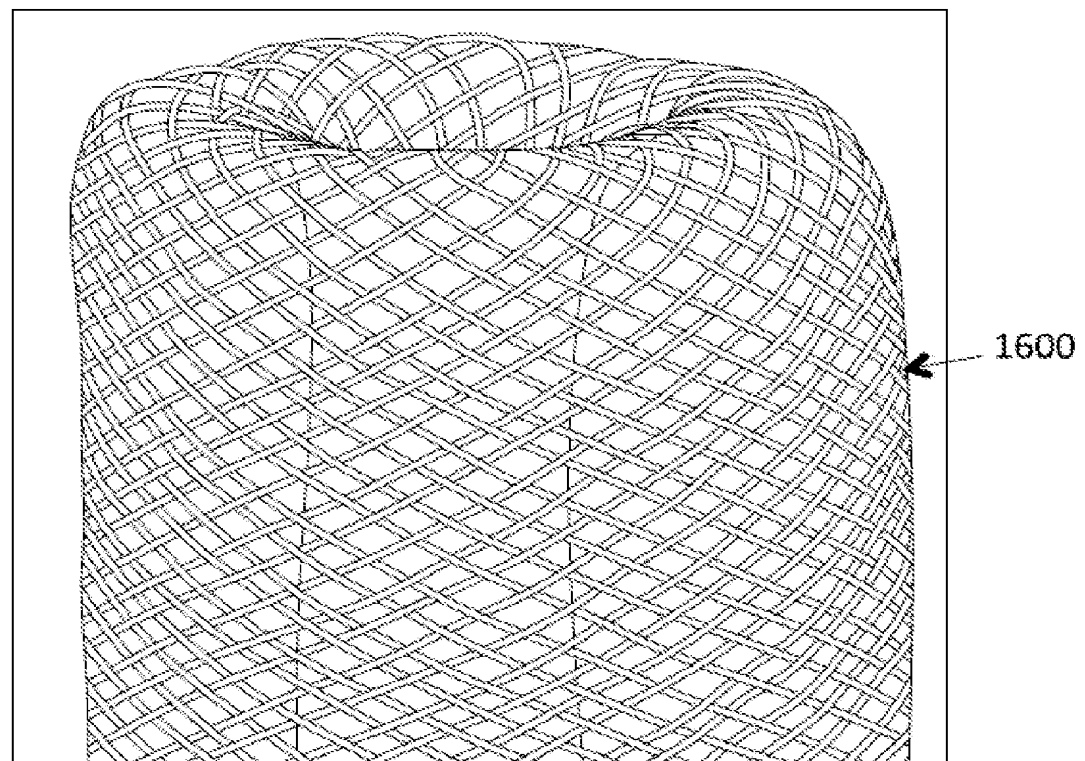
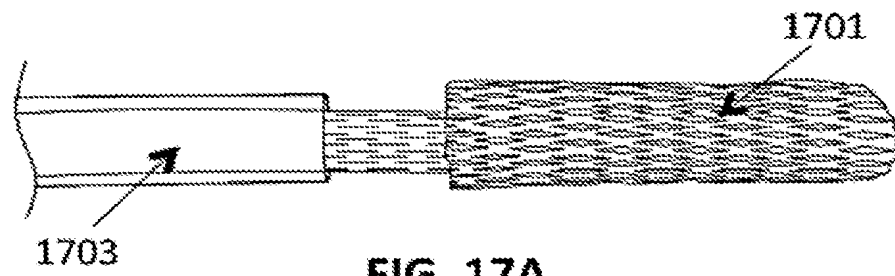
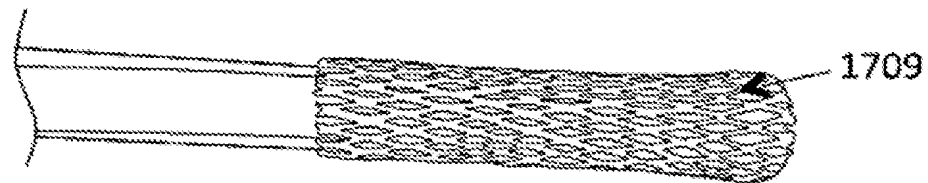
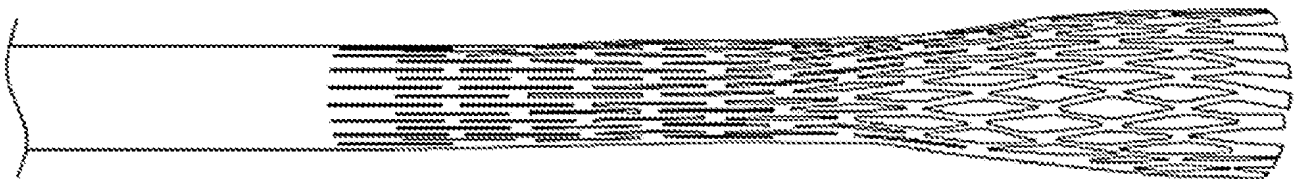
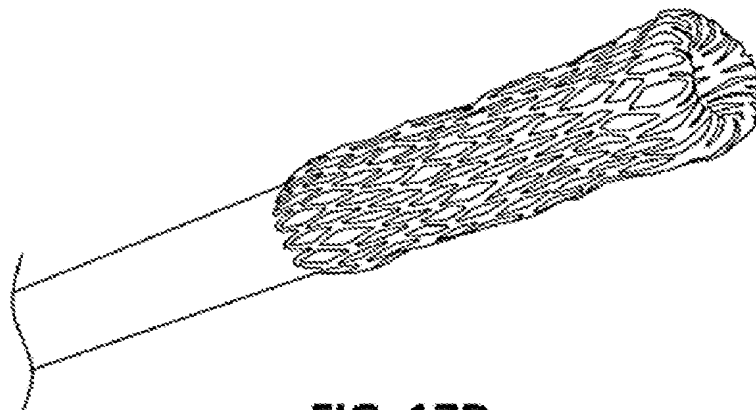
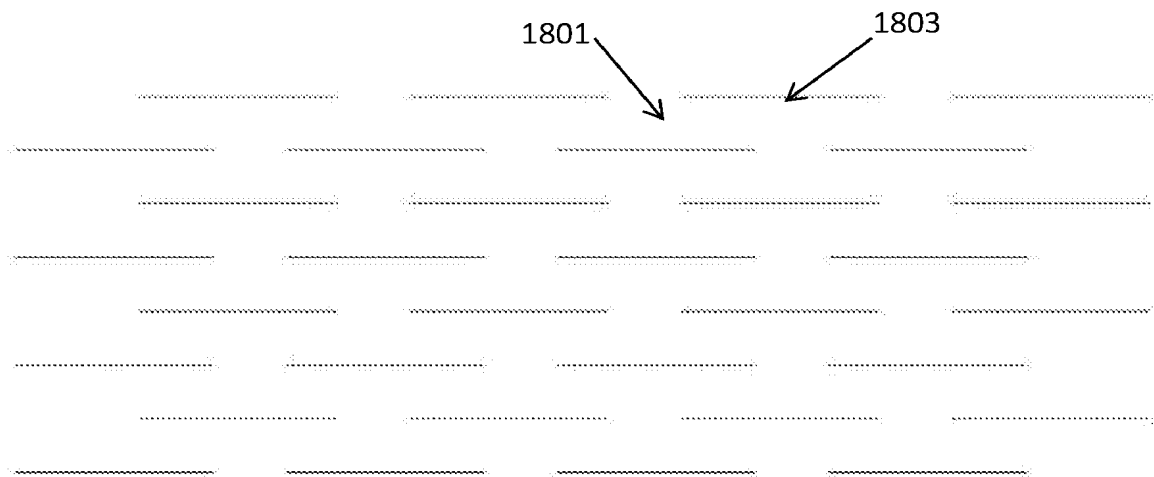
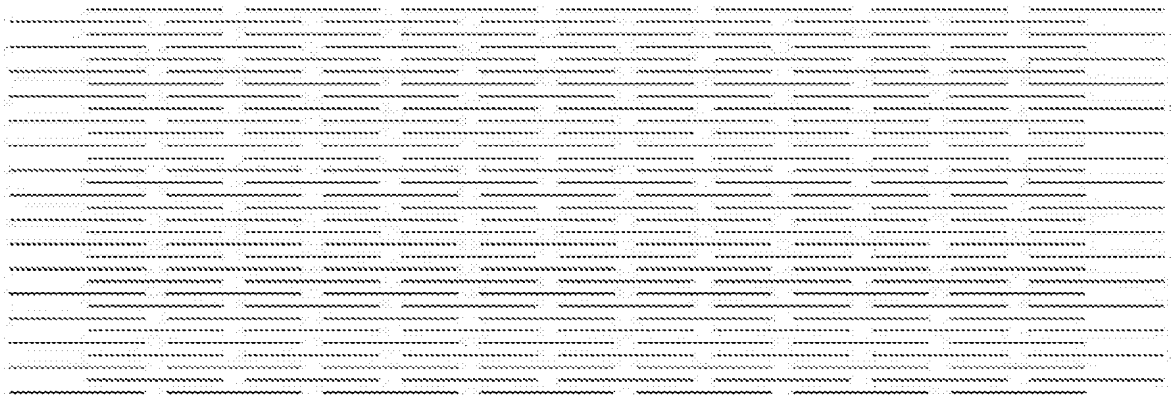
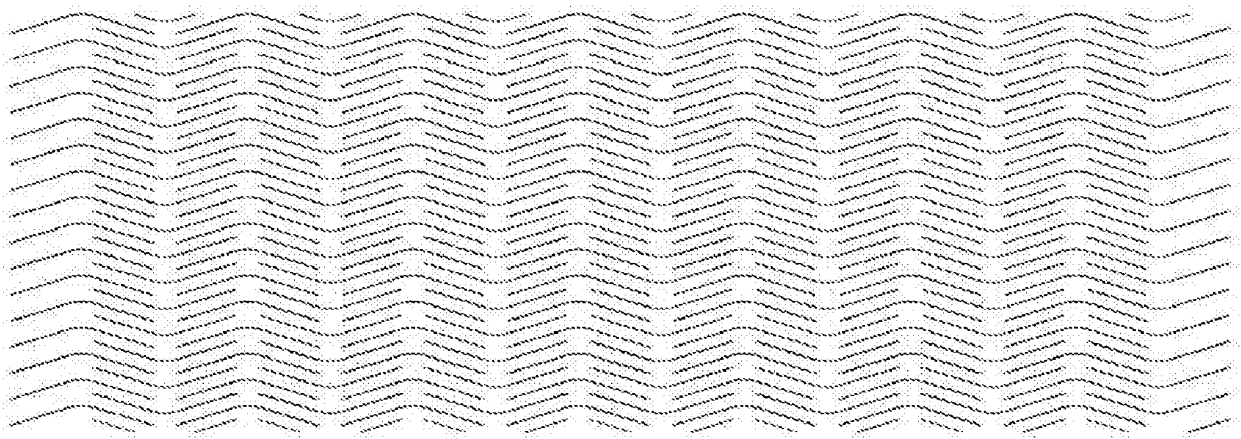
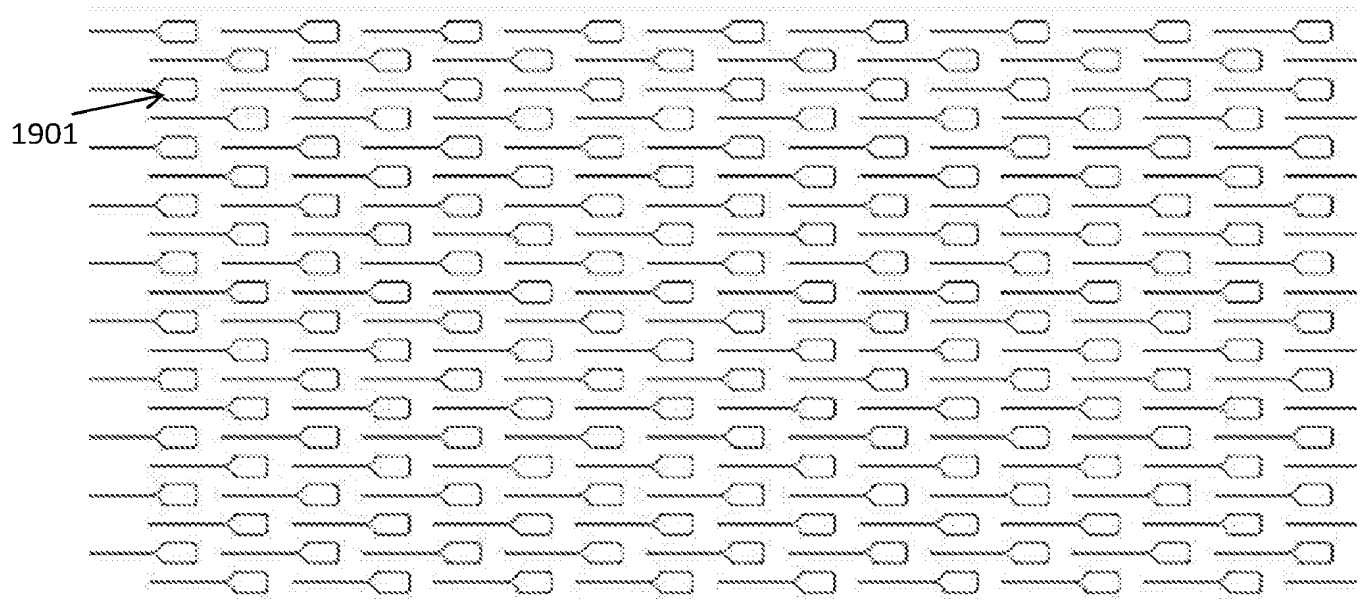
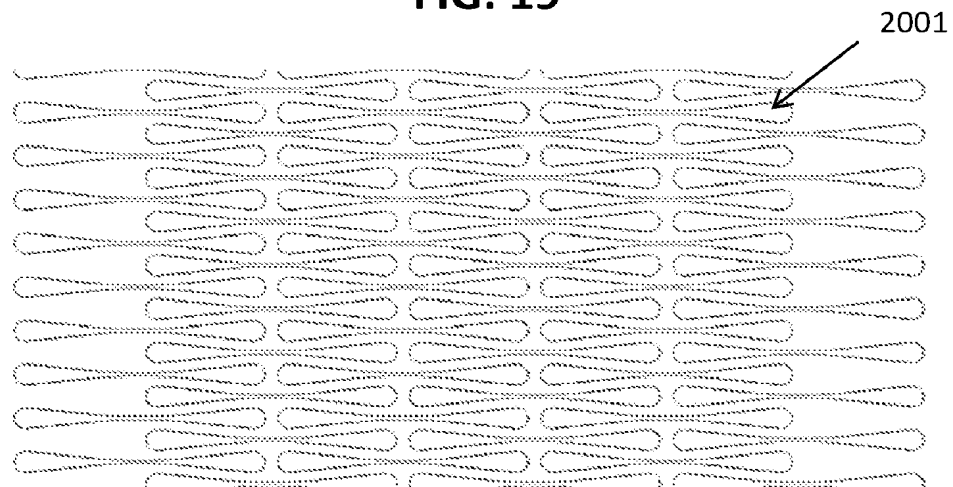
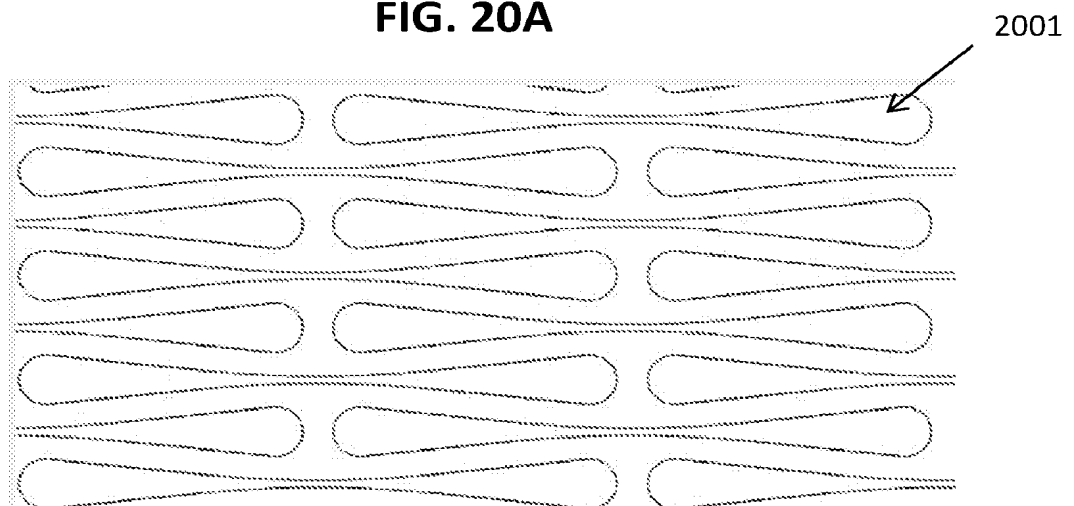


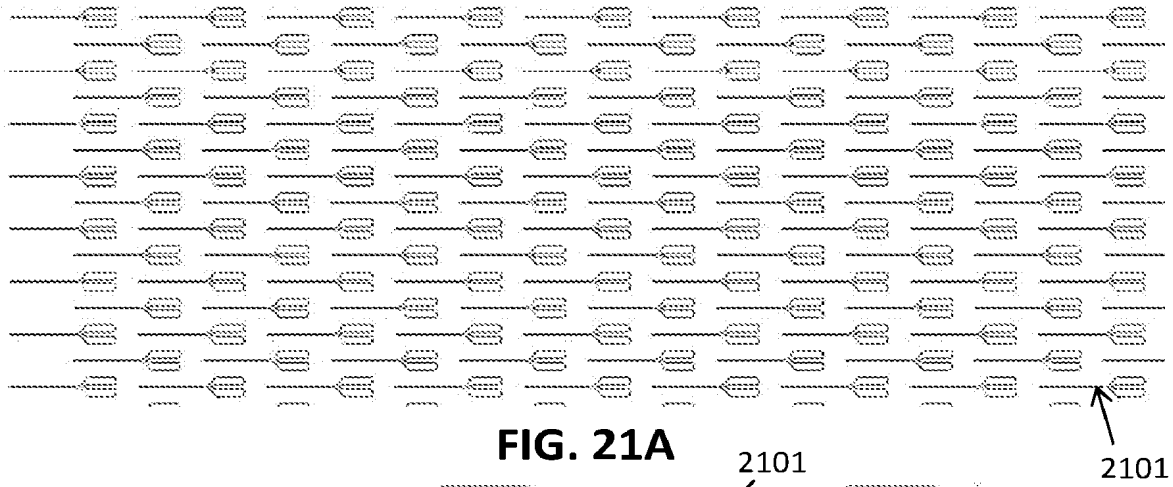
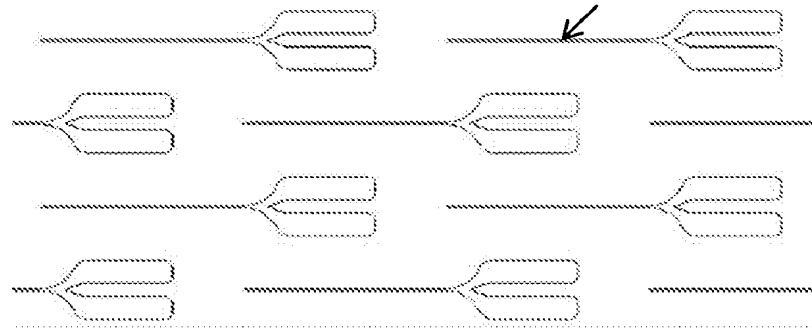
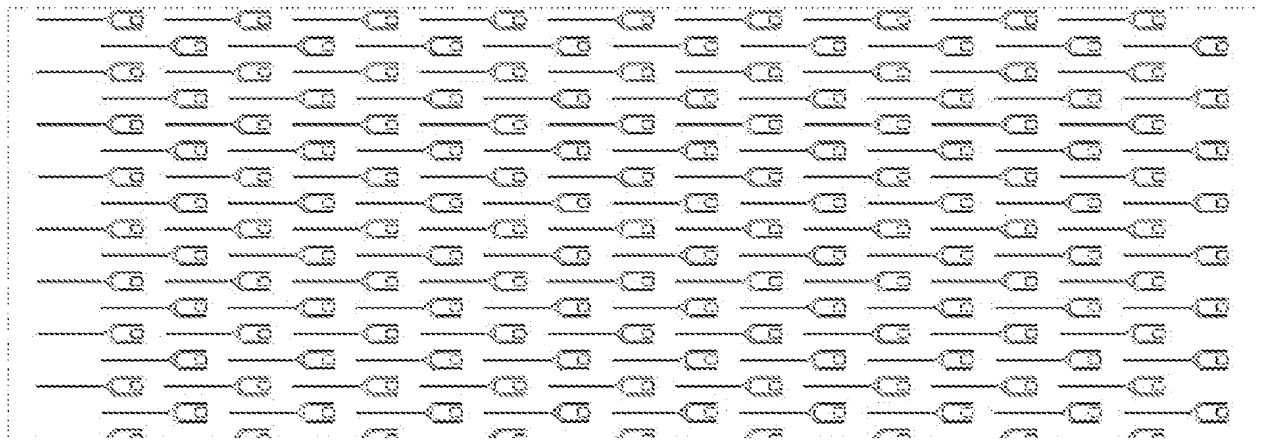
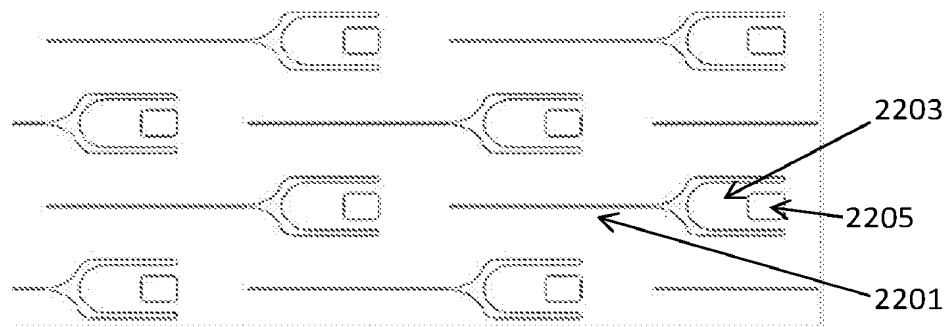
FIG. 15E

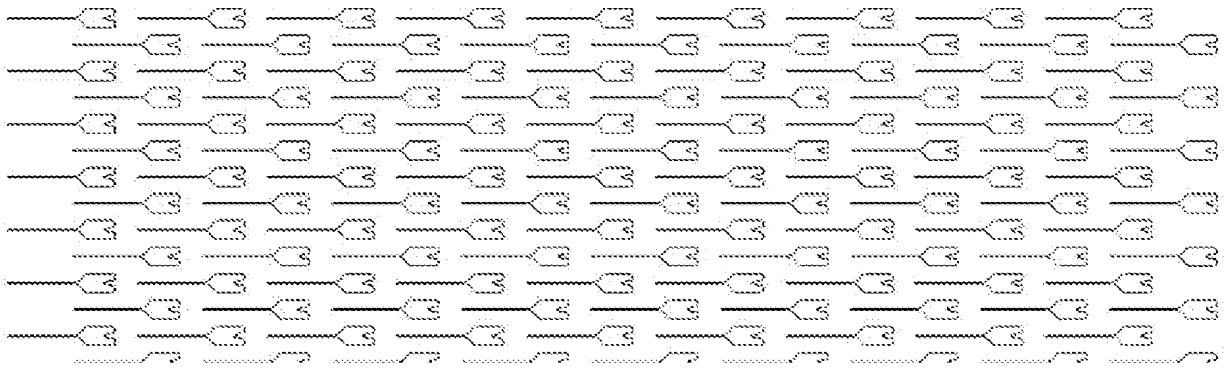
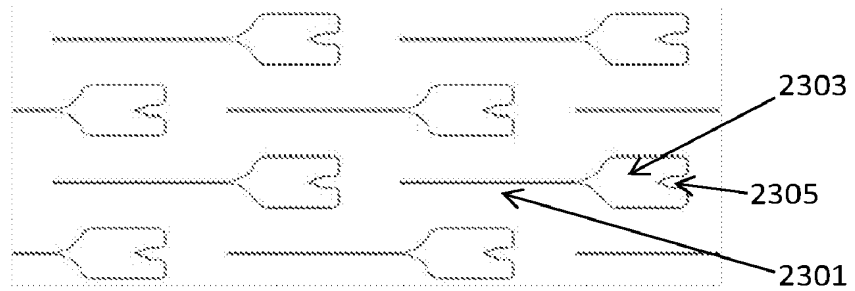
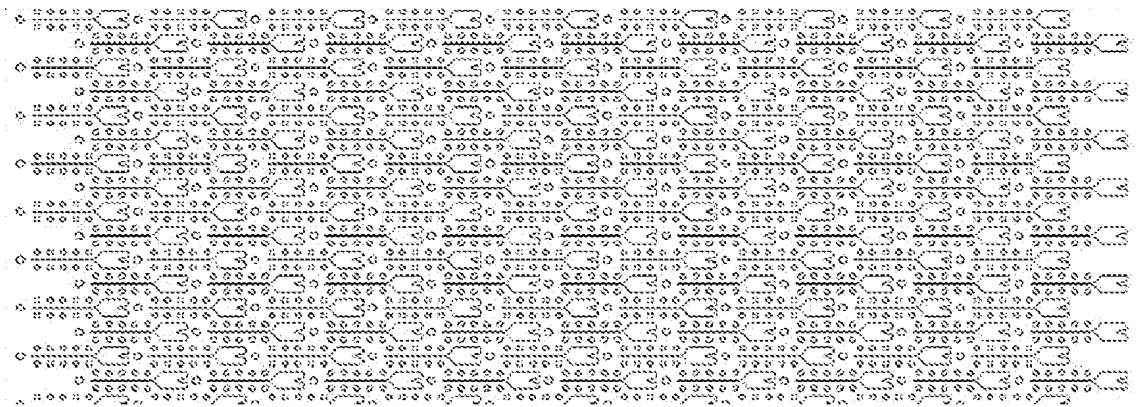
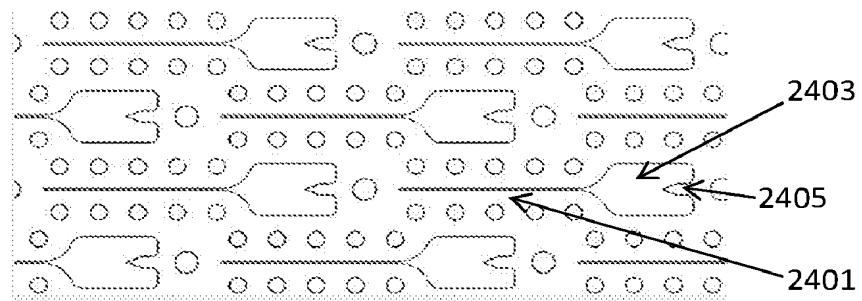
**FIG. 16A****FIG. 16A**

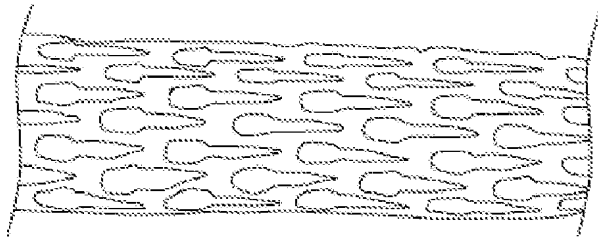
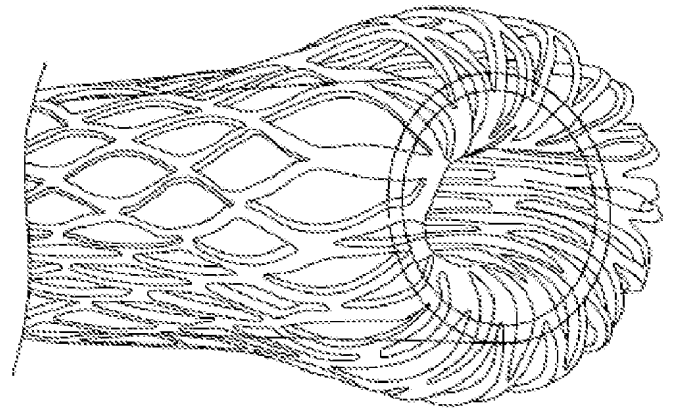
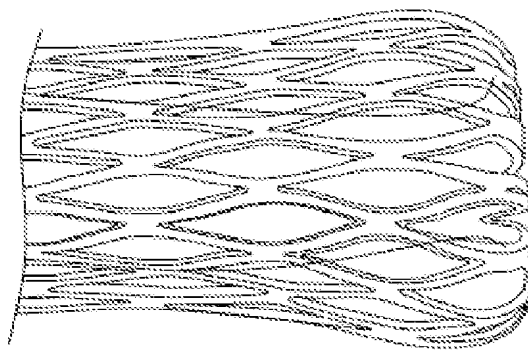
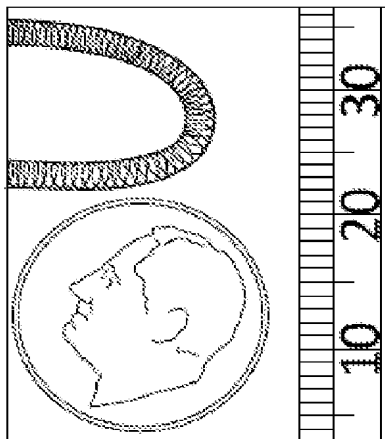
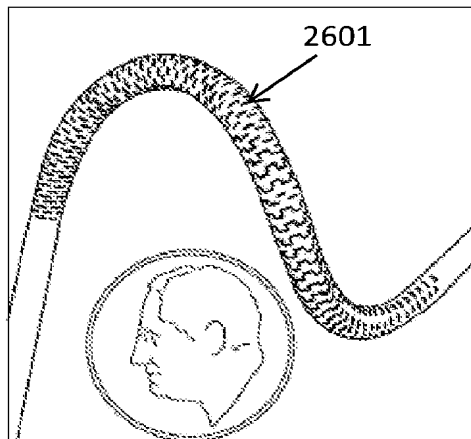
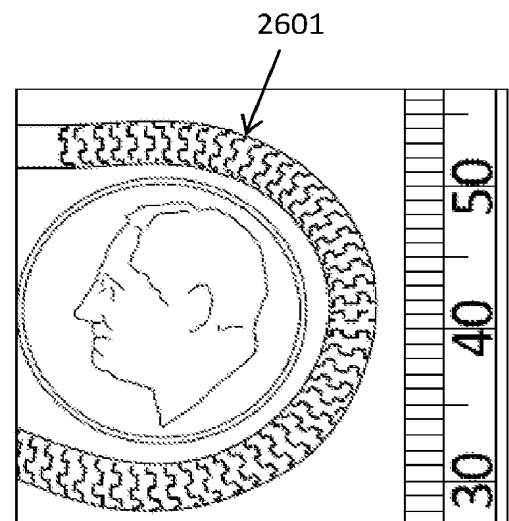


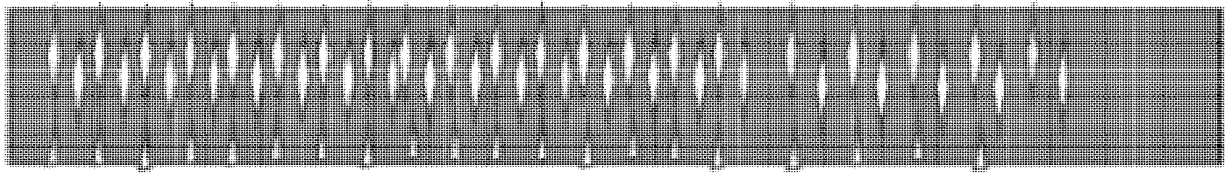
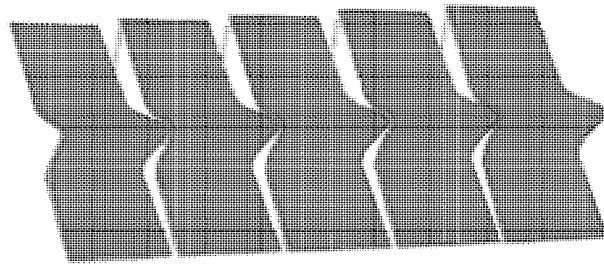
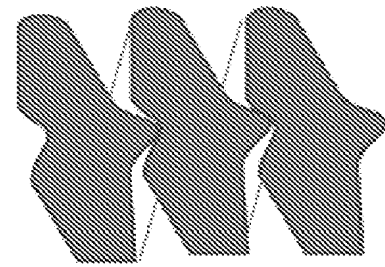
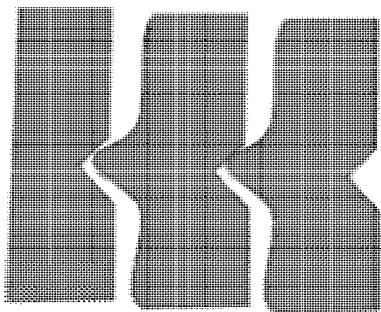
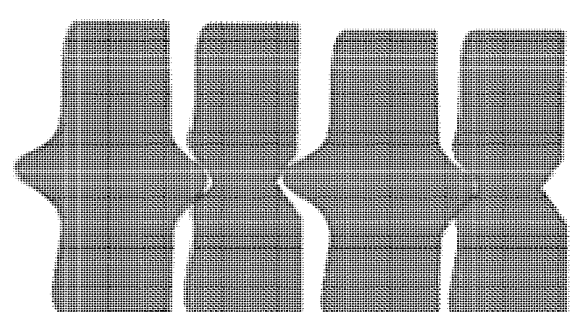
**FIG. 18A****FIG. 18B****FIG. 18C**

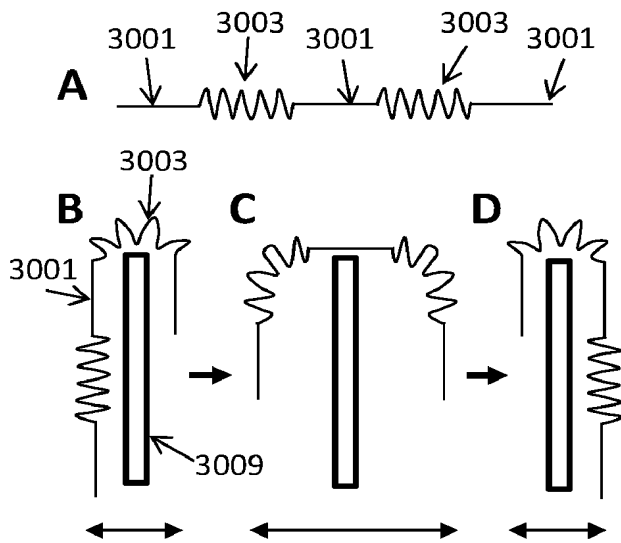
**FIG. 19****FIG. 20A****FIG. 20B**



**FIG. 23A****FIG. 23B****FIG. 24A****FIG. 24B**

**FIG. 25A****FIG. 25C****FIG. 25B****FIG. 26A****FIG. 26B****FIG. 26C**

**FIG. 27****FIG. 28A****FIG. 28B****FIG. 29A****FIG. 29B**



FIGS. 30A-30D

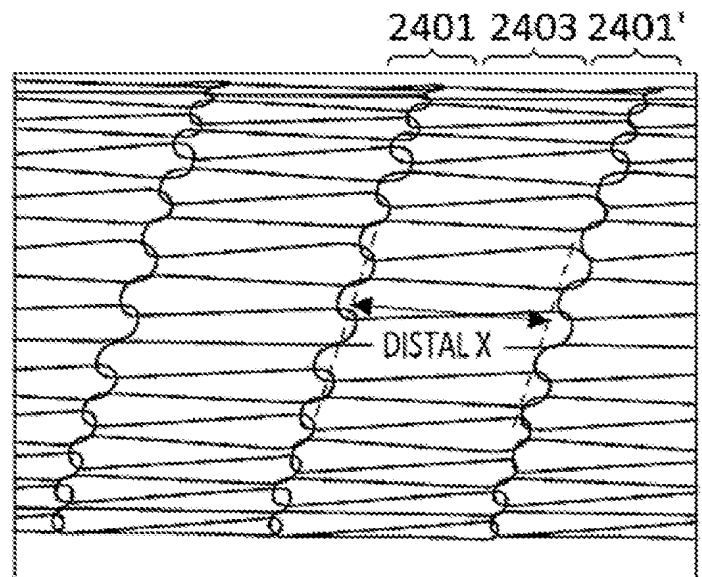
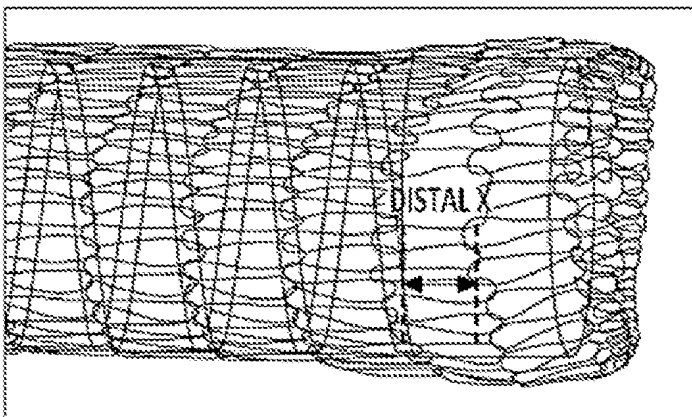
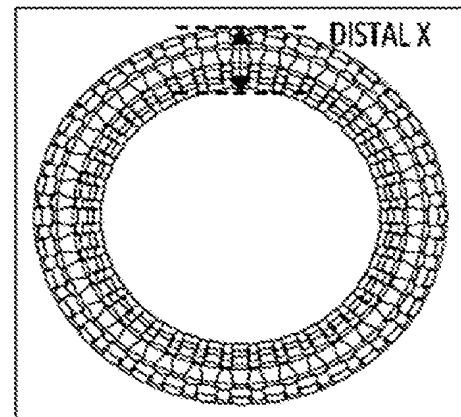


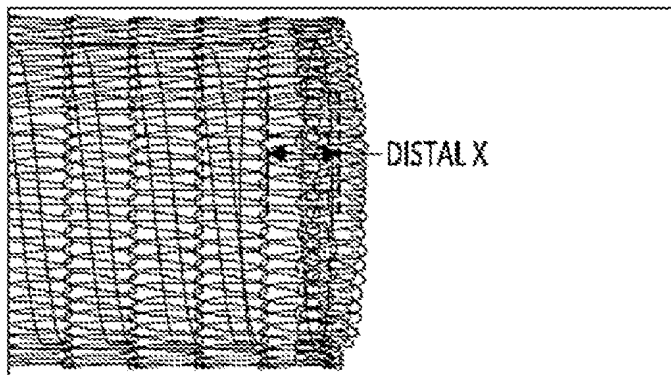
FIG. 31A



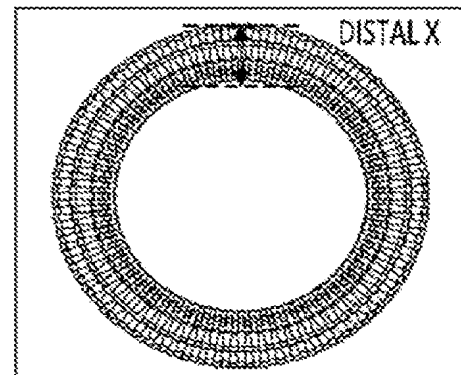
31B



31C



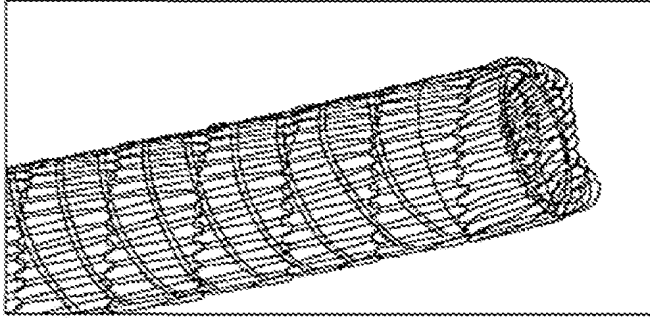
31D



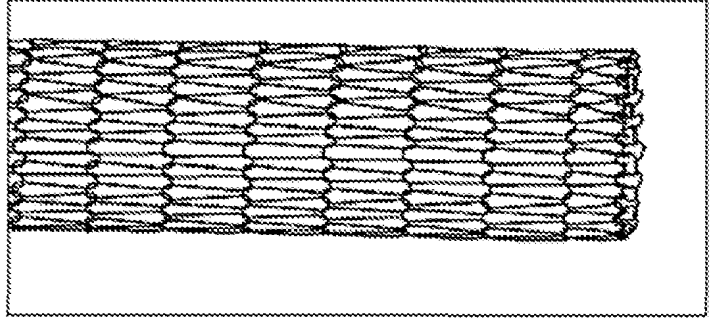
31E

FIGS. 31B-31E

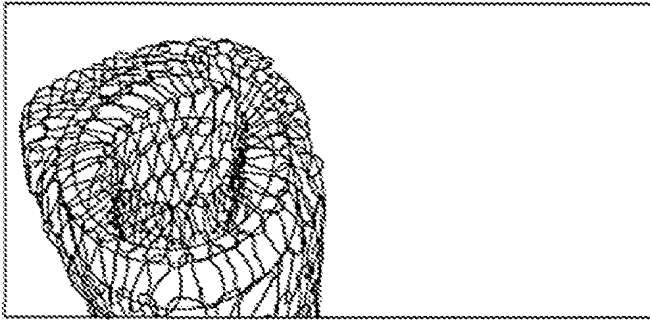
32A 0.045" ID CATHETER, 0.055 OD
(TOO SMALL)



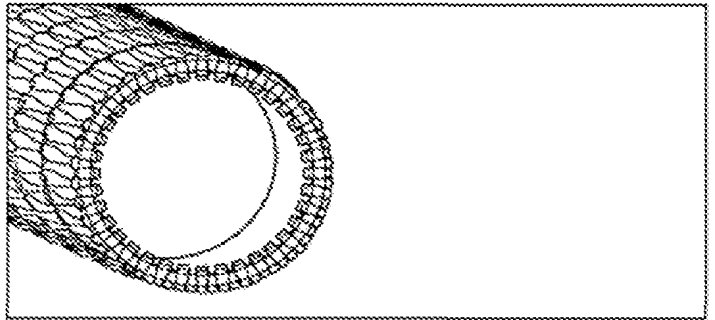
32C 0.085" ID 72D PEBAX, 0.95" OD
(TOO BIG)



32B



32D



FIGS. 32A-32D

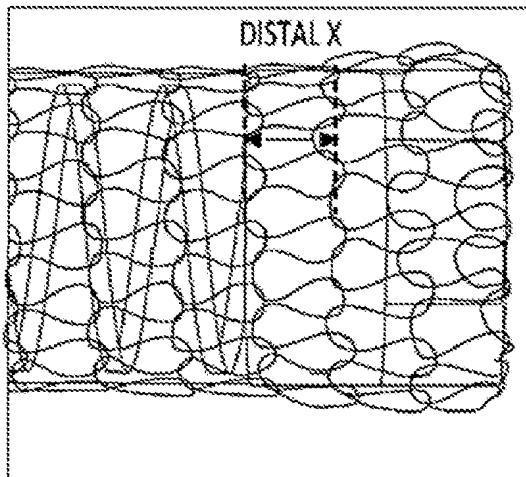


FIG. 33A

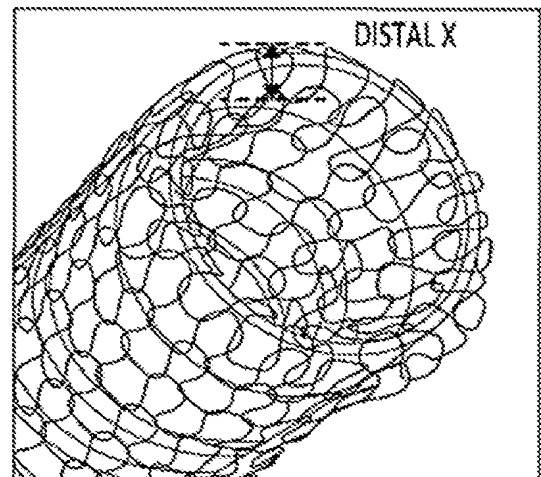


FIG. 33B

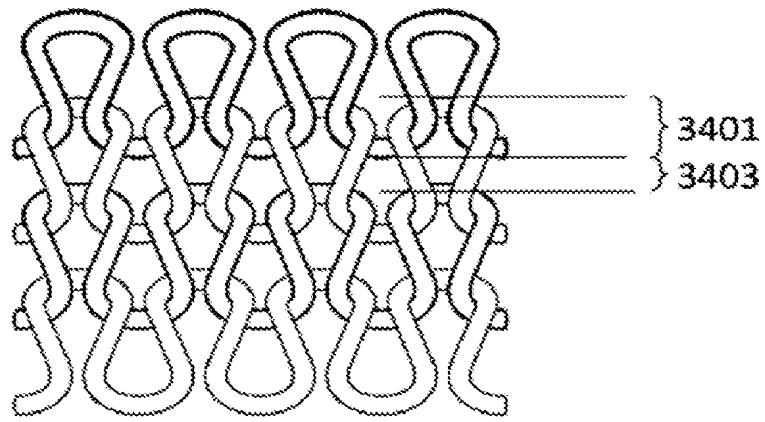


FIG. 34

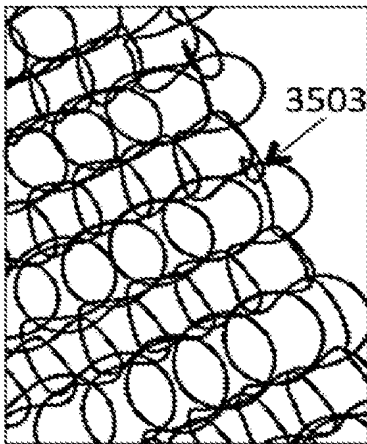


FIG. 35A

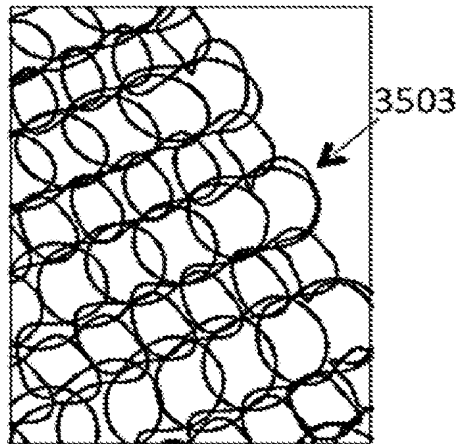


FIG. 35B

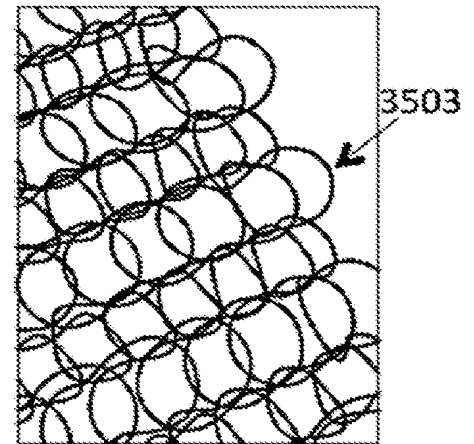


FIG. 35C

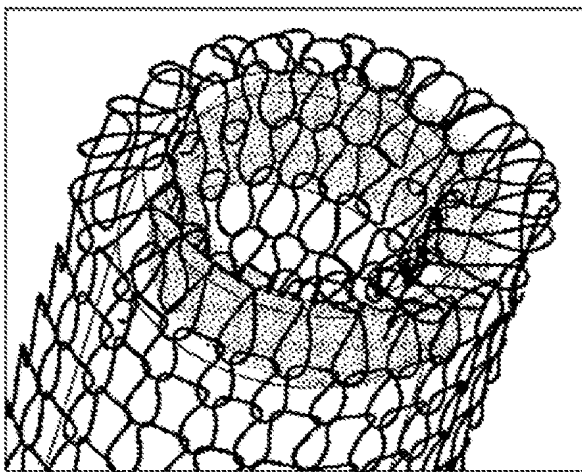


FIG. 36A

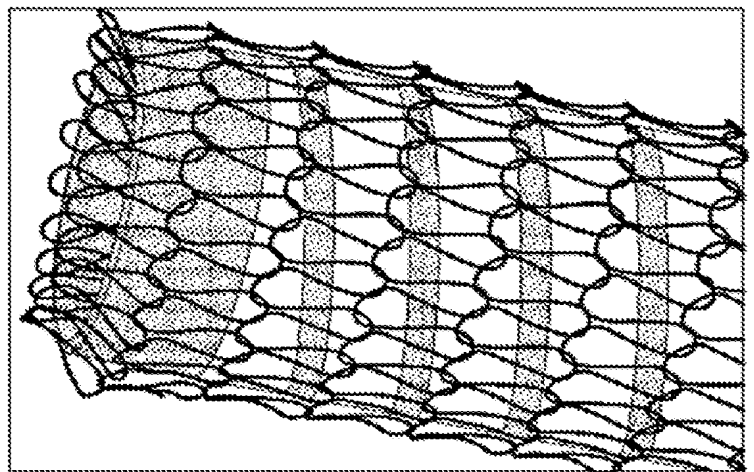


FIG. 36B

FIG. 37A

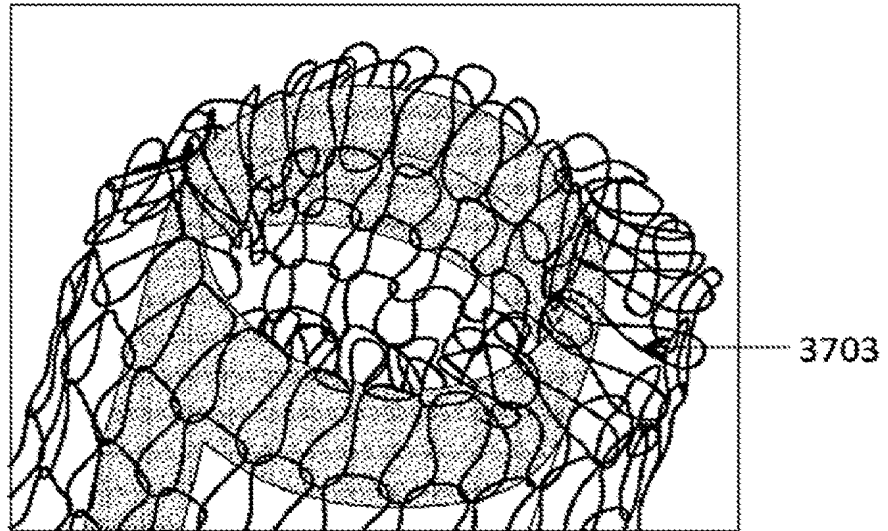


FIG. 37B

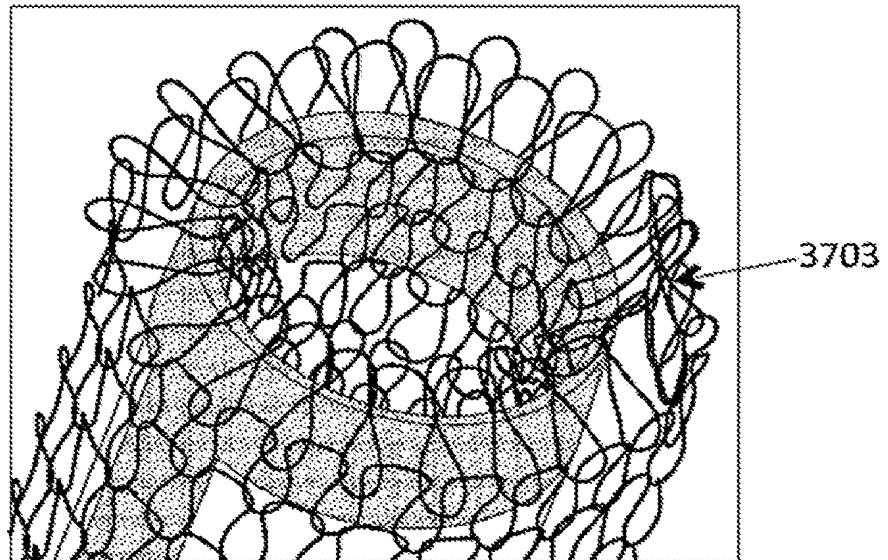
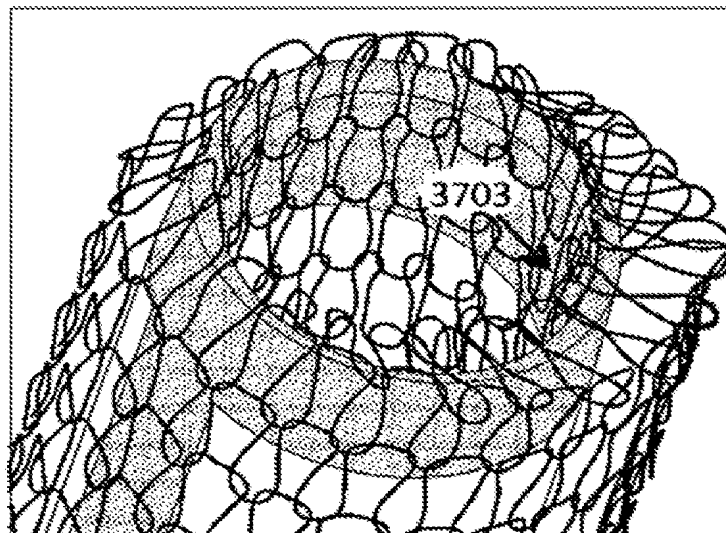
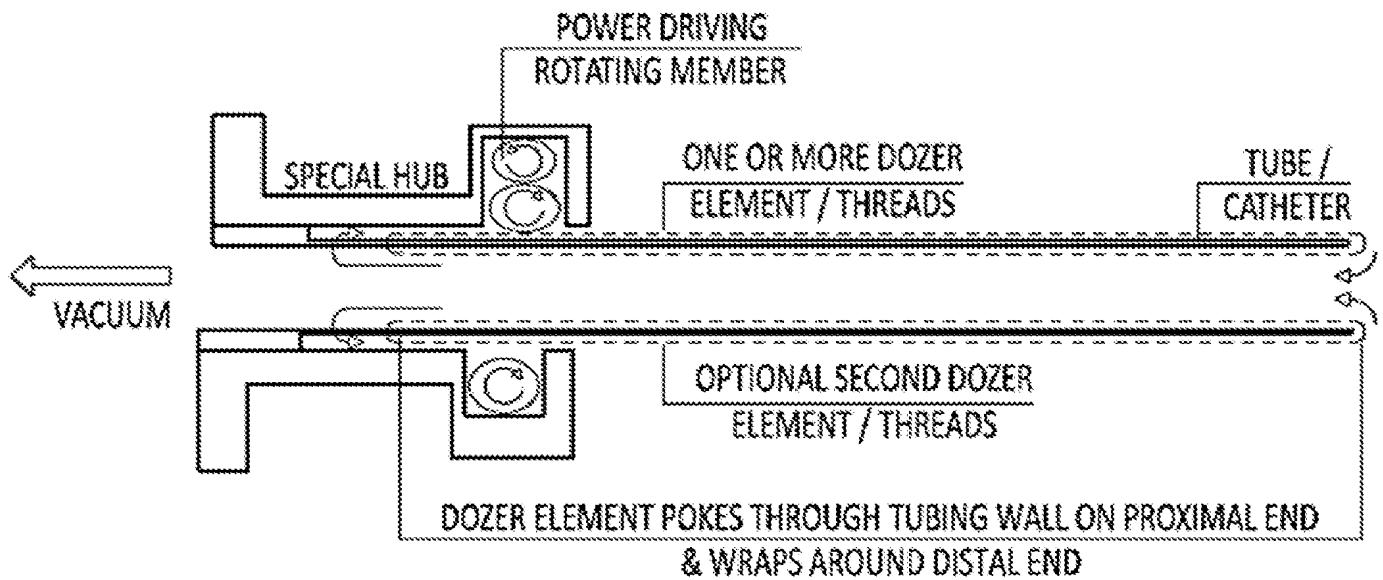
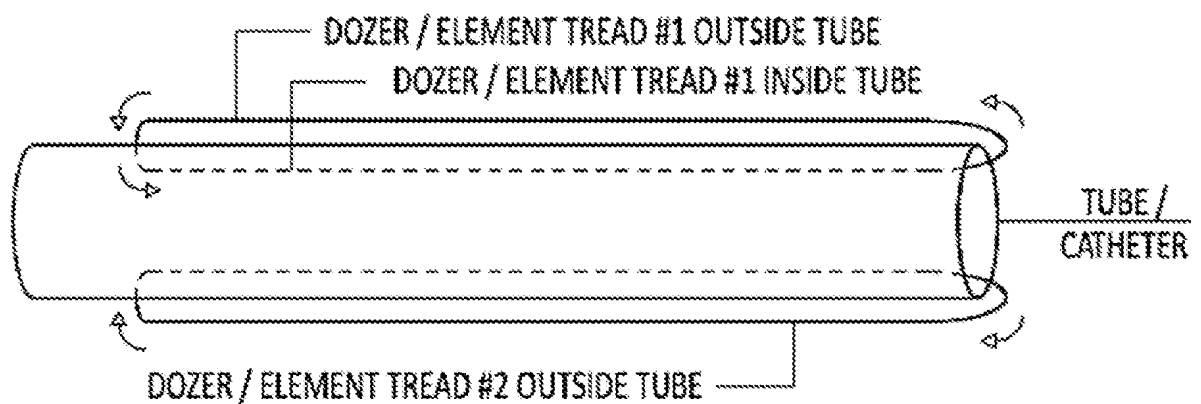
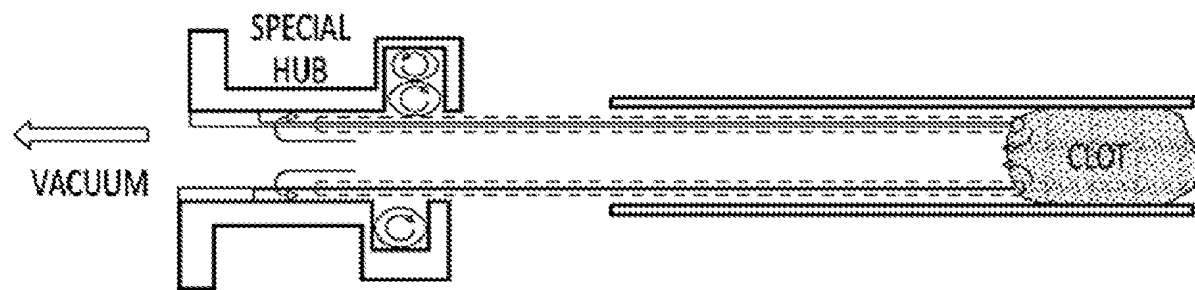
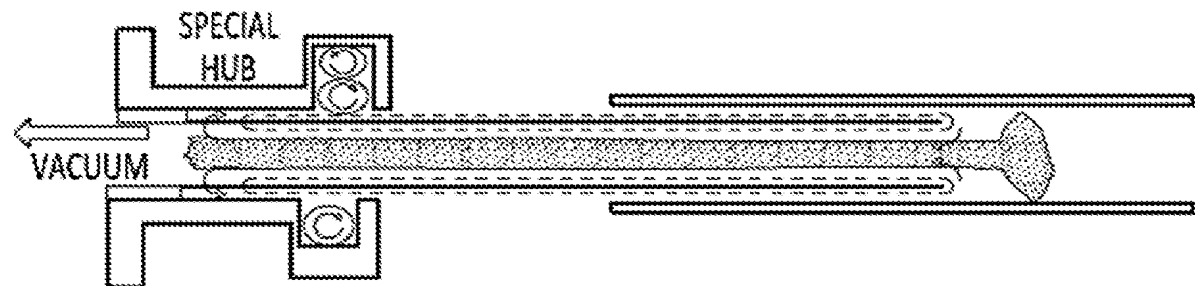


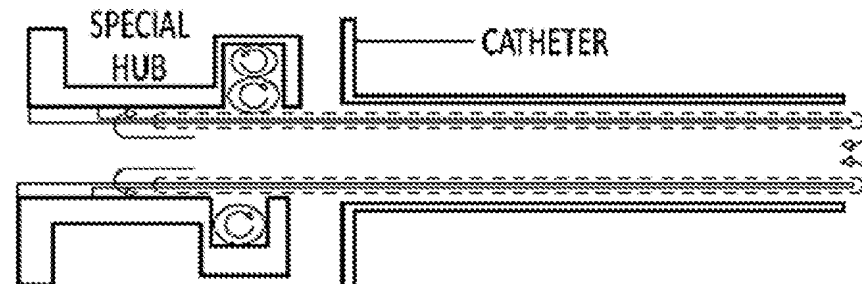
FIG. 37C

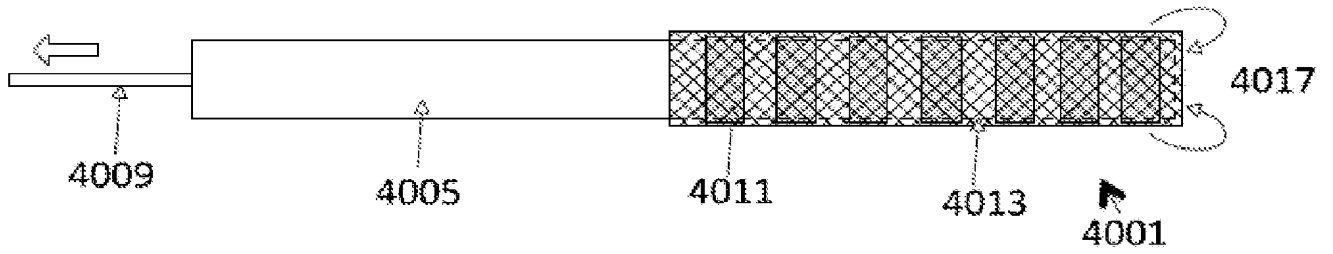
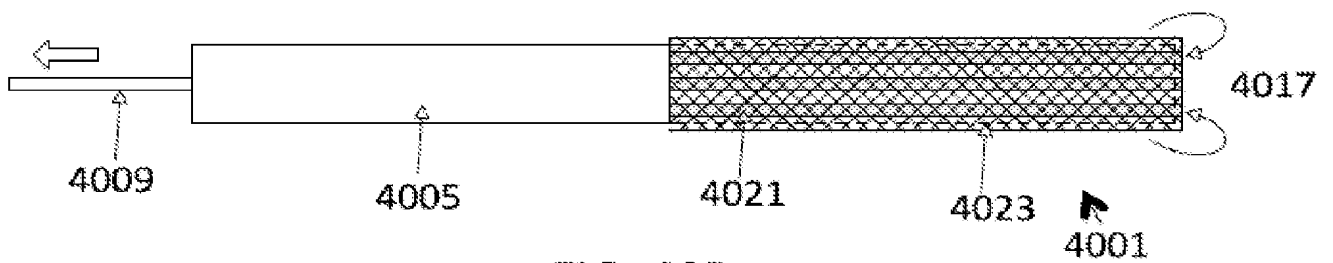
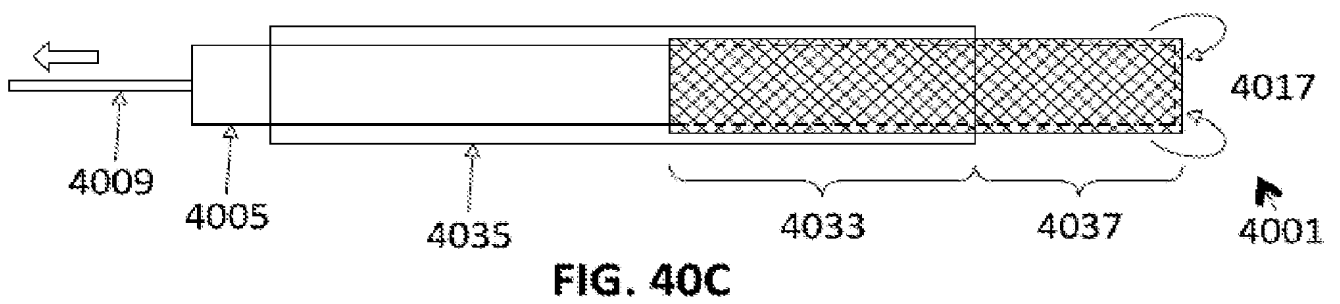


**FIG. 38A****FIG. 38B**

**FIG. 39A****FIG. 39B**

POWER DRIVEN CONTINUOUS TRACTOR OPTIONALLY LOADED INTO
LARGER ID CATHETER, WHICH MAY BE DELIVERED FIRST TO FACE OF SLOT

**FIG. 39C**



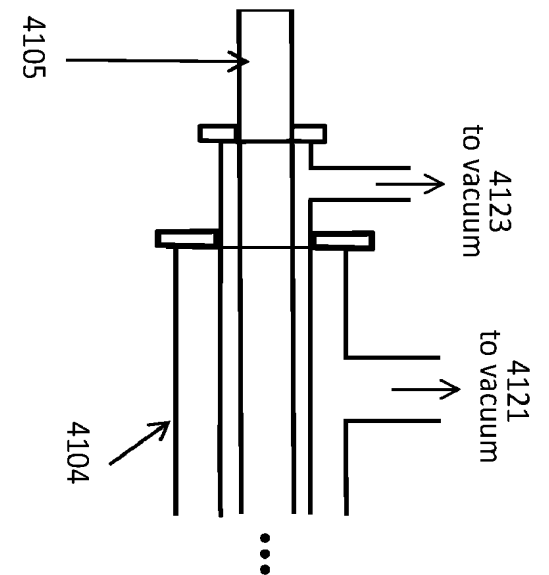
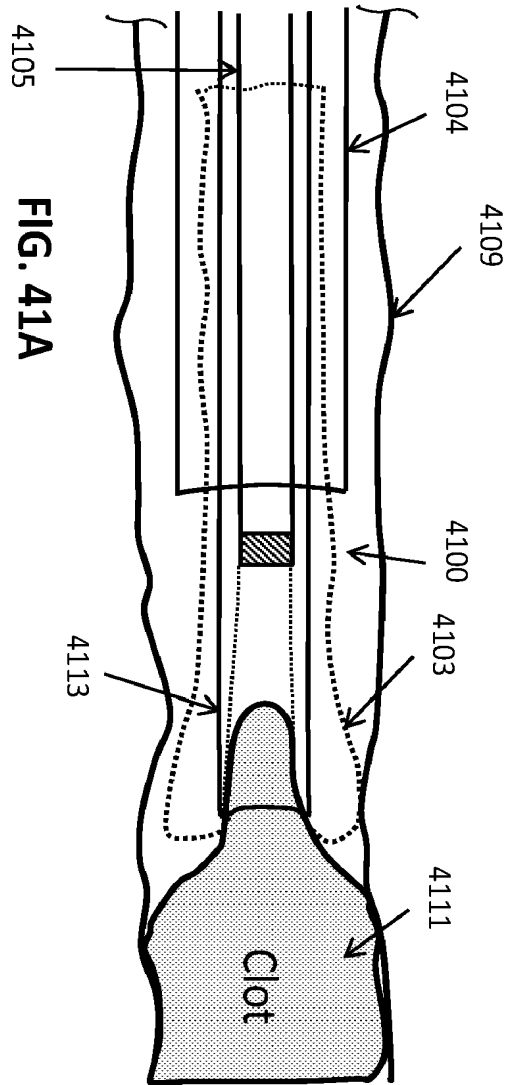


FIG. 41A

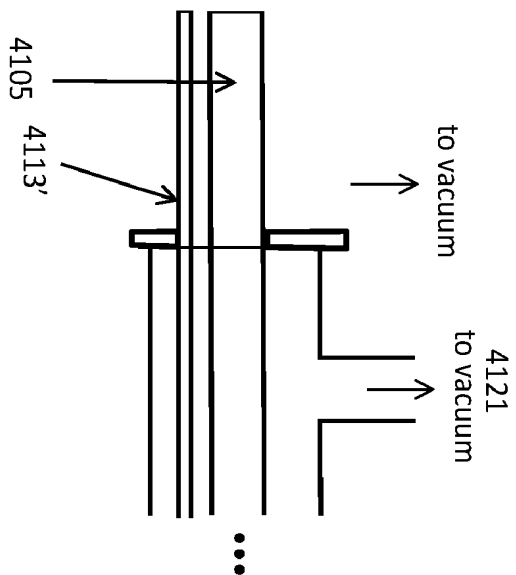
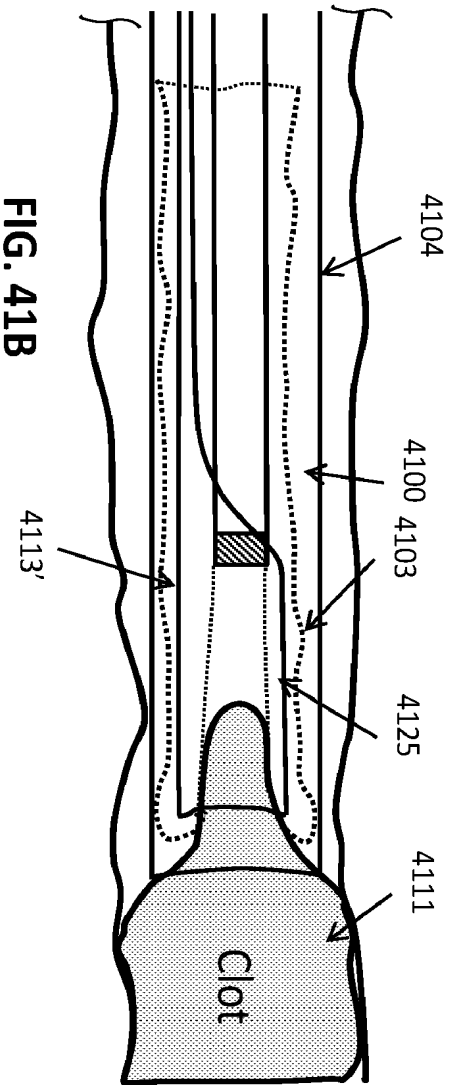
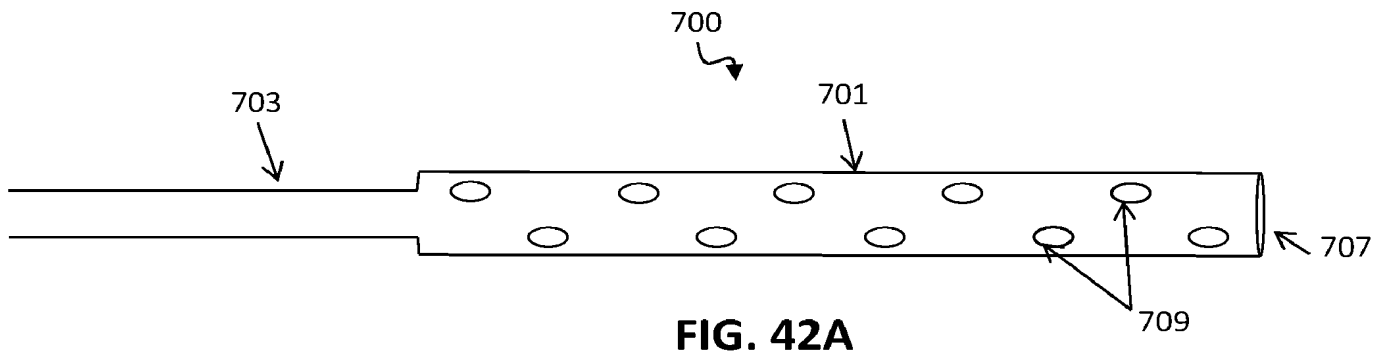
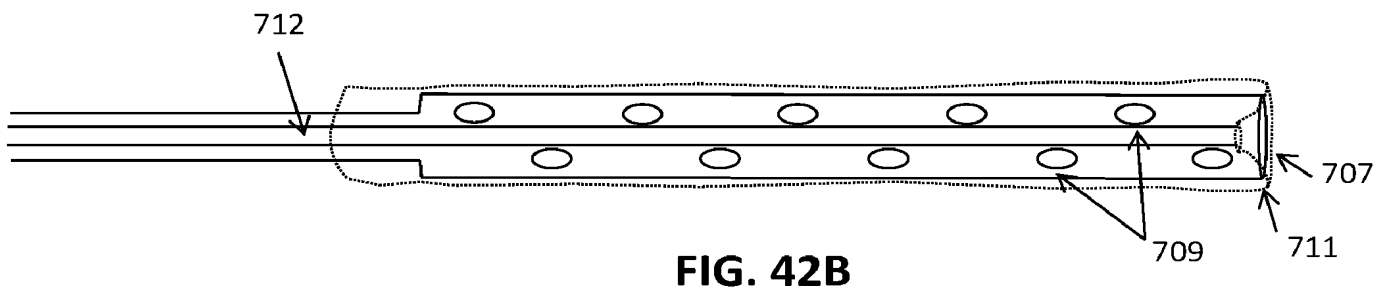
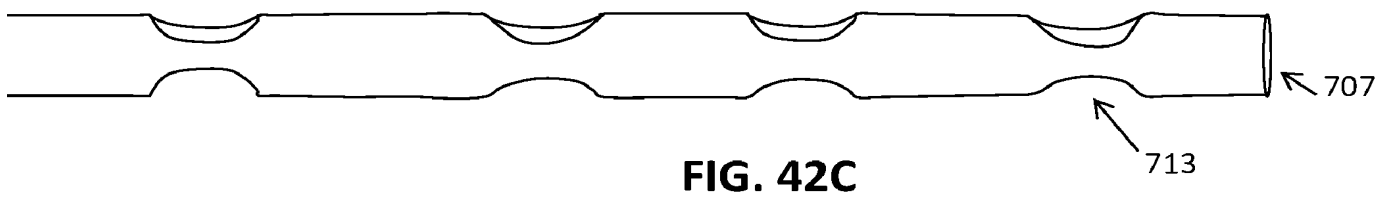
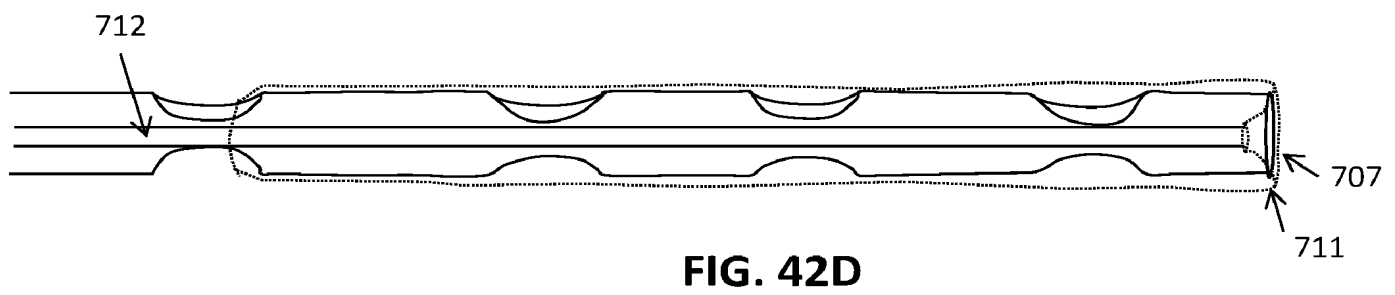
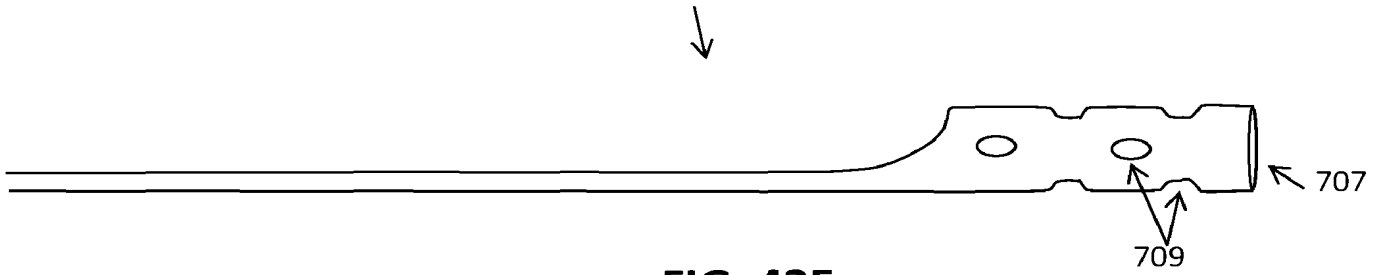
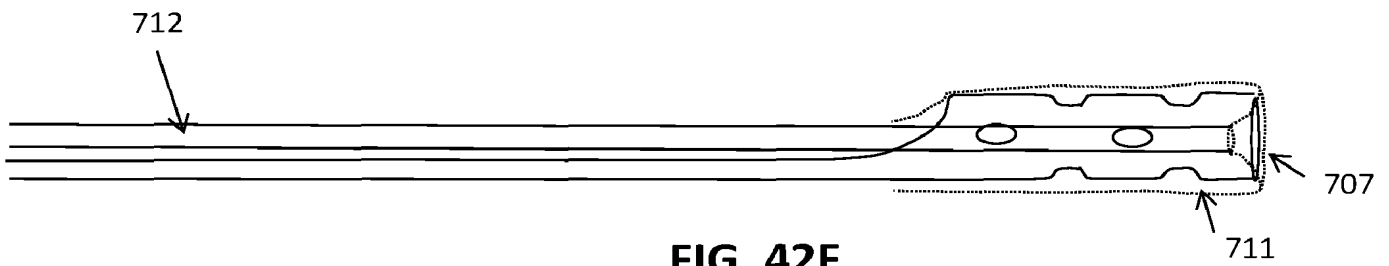


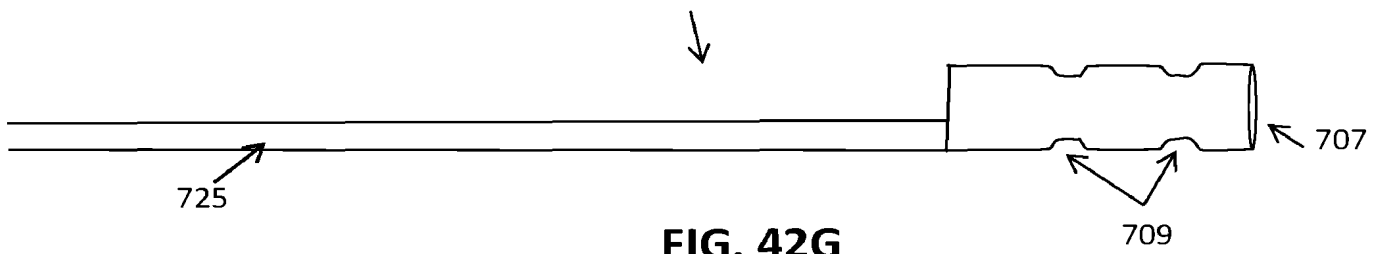
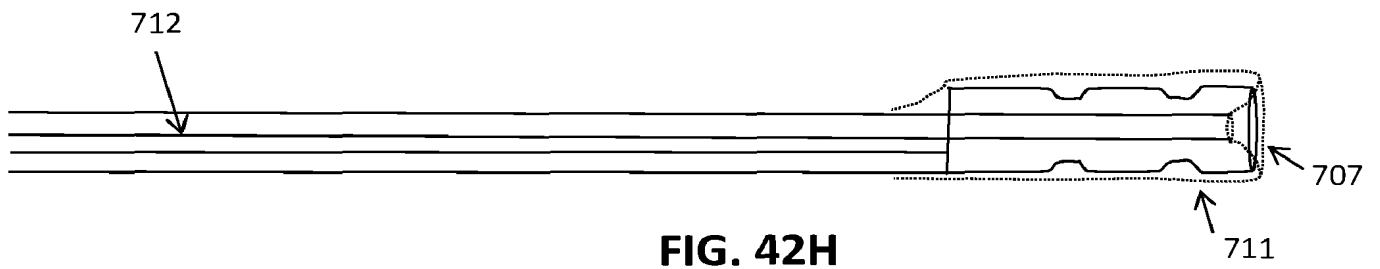
FIG. 41B

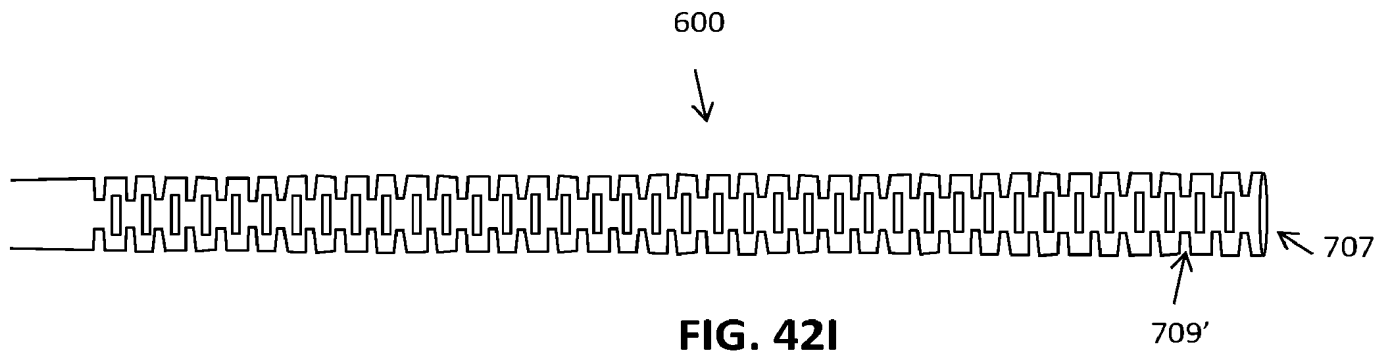
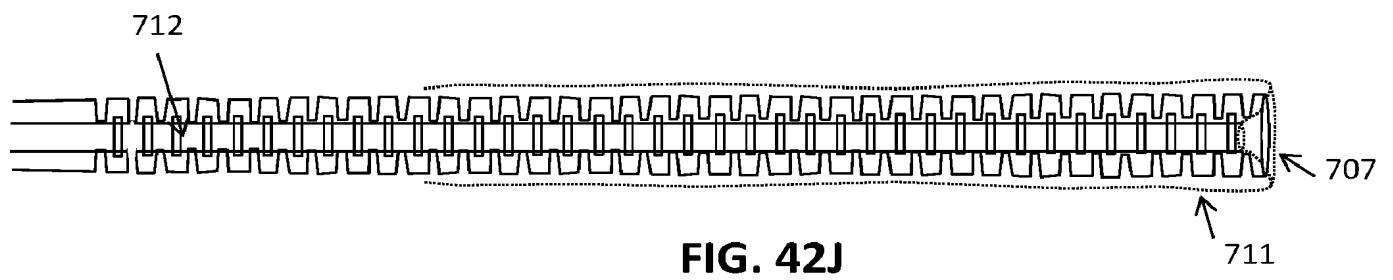
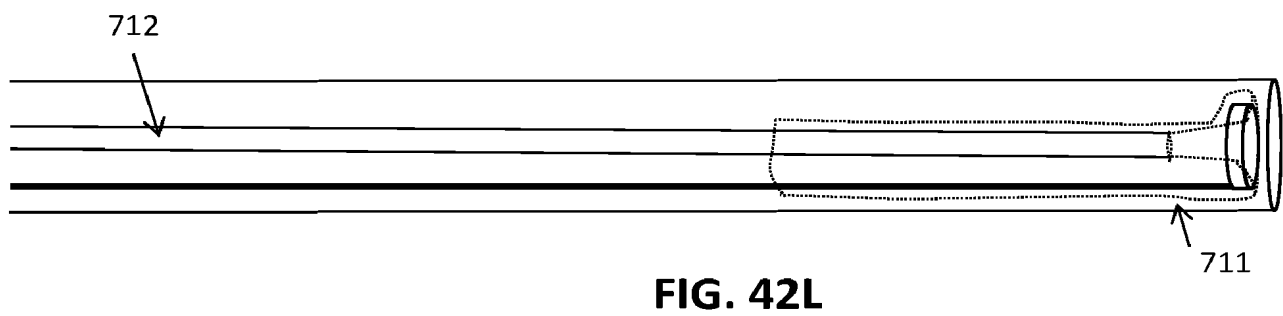


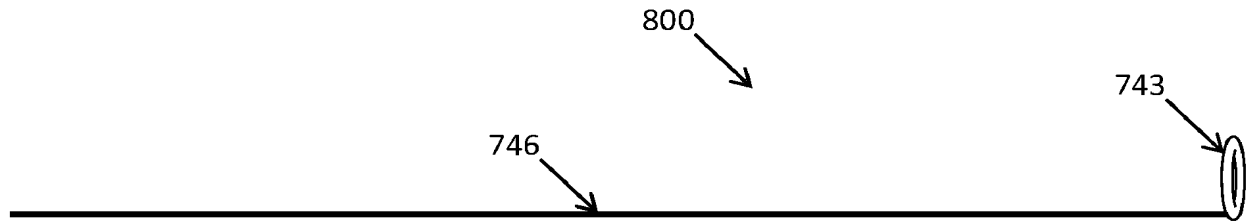
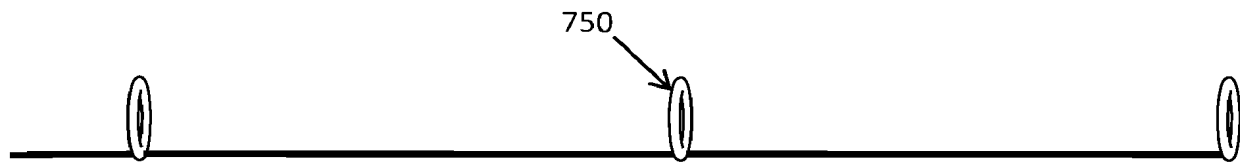
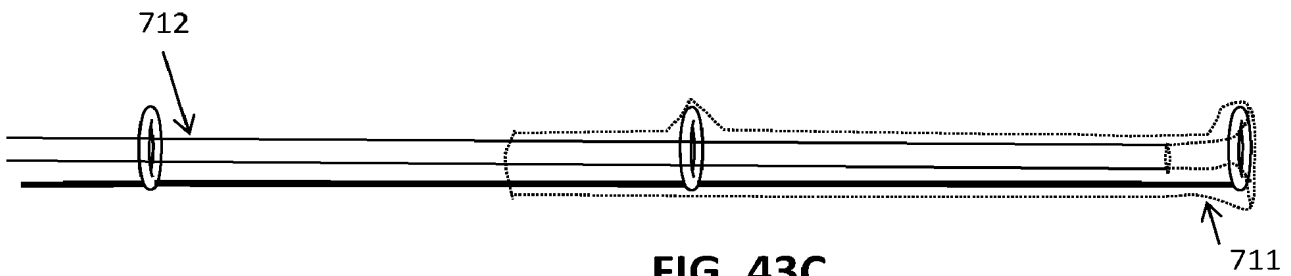
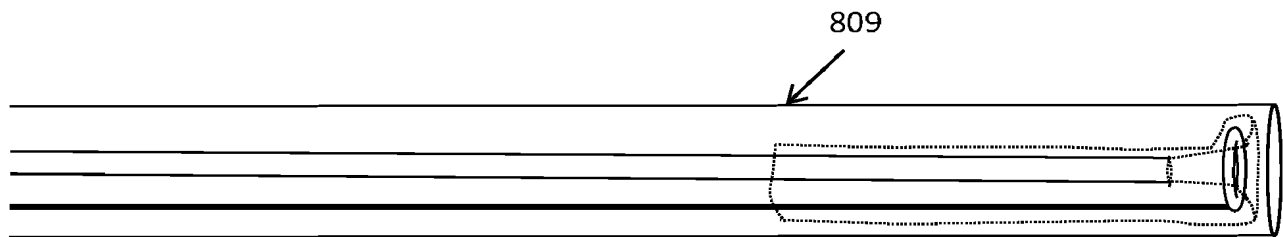
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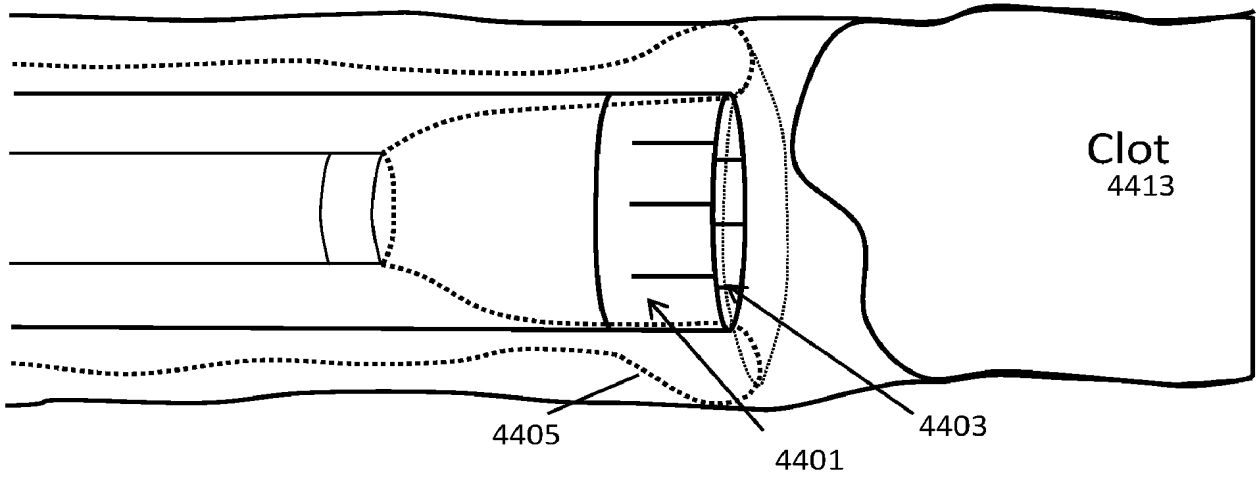
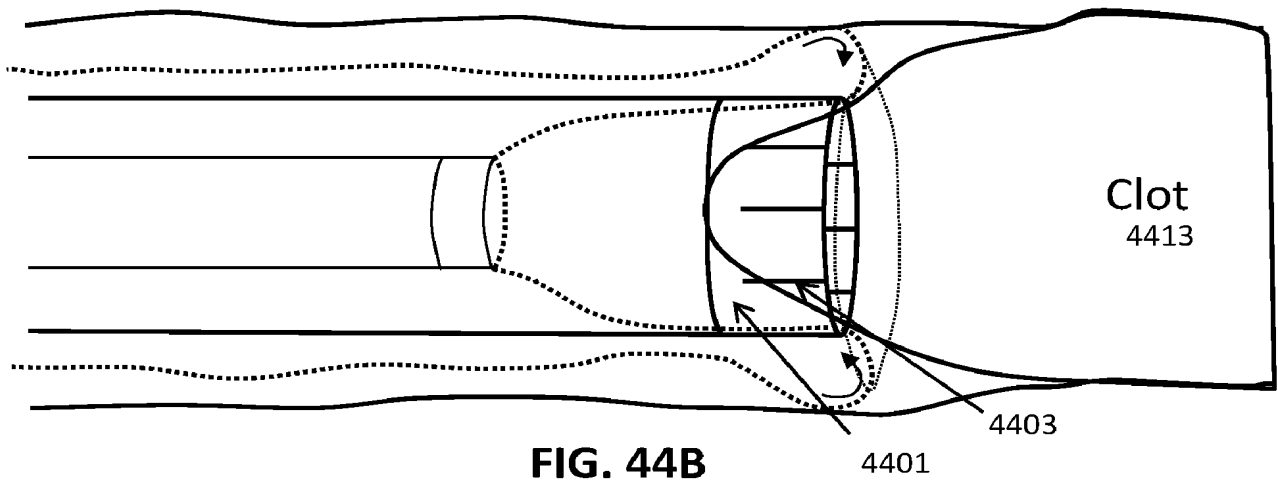
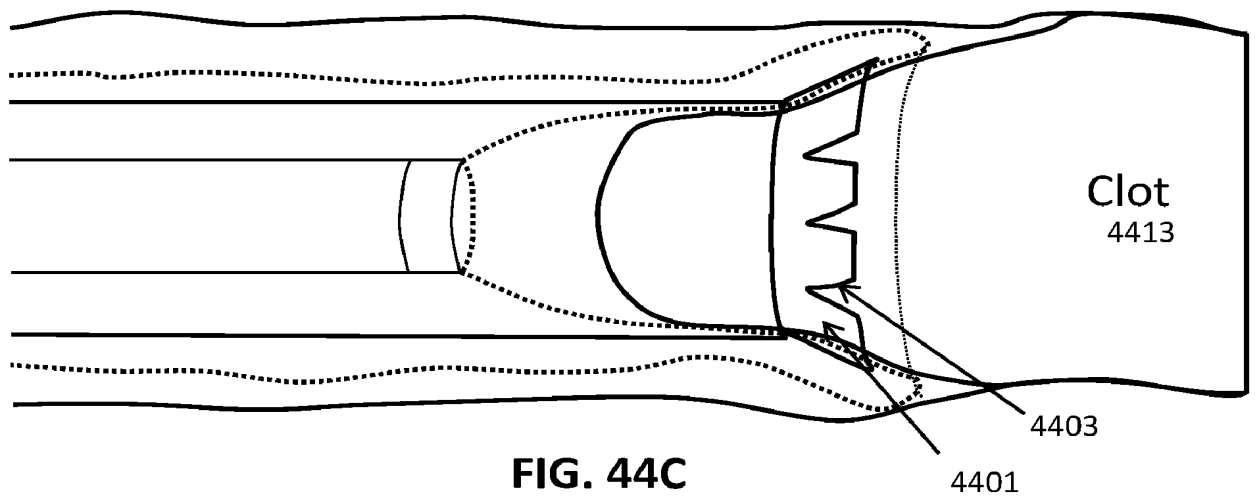


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**FIG. 43A****FIG. 43B****FIG. 43C****FIG. 43D**





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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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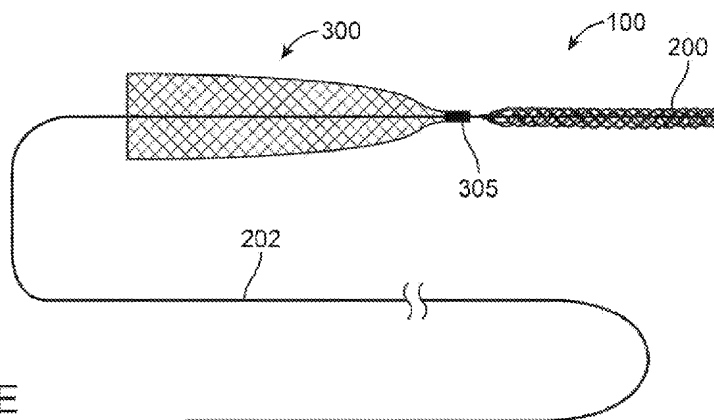


FIG. 2E

(57) Abstract: The devices and methods described herein relate to improved structures for removing obstructions from body lumens. Such devices have applicability in through-out the body, including clearing of blockages within the vasculature, by addressing the frictional resistance on the obstruction prior to attempting to translate and/or mobilize the obstruction within the body lumen.

RETRIEVAL SYSTEMS AND METHODS FOR USE THEREOF

RELATED APPLICATIONS

- [0001] This application is a non-provisional of U.S. Provisional Application Nos. 61/489,183 filed May 23, 2012 entitled RETRIEVAL SYSTEMS AND METHODS FOR USE THEROF, and 61/489,254 filed May 24, 2012 entitled STENT RETRIEVER WITH INTEGRATED PROTECTION the entirety of each of which is incorporated by reference.

FIELD OF THE INVENTION

- [0002] The devices described herein are intended to retrieve obstructions from the body. Such devices have applicability throughout the body, including clearing of blockages within body lumens and providing passive protection of such, such as the vasculature, by providing a capturing portion that can translate and/or mobilize the obstruction within the body lumen.

BACKGROUND OF THE INVENTION

- [0003] A large number of medical procedures require the use of medical device(s) to remove an obstruction from a body lumen, vessel, or other organ. An inherent risk in such procedures is that mobilizing or otherwise disturbing the obstruction can potentially create further harm if the obstruction or a fragment thereof dislodges from the retrieval device. If a particle or the obstruction breaks free from the device and flows downstream, it is highly likely that the particle or obstruction will become trapped in smaller and more tortuous anatomy. In many cases, the physician will no longer be able to use the same retrieval device to again remove the obstruction because the size of the device may prevent advancing the device to the site of the new obstruction.
- [0004] Even in successful procedures, a physician must proceed with caution to prevent the walls of the vessel or body lumen from imparting undesired forces to shear or dislodge the obstruction as it is translated through the body during removal. These forces have the potential of breaking portions or fragments of the obstruction away. In some cases, the obstruction can simply break free from the retrieval device and can lodge in a new area causing more concern than the original blockage.
- [0005] Procedures for restoring flow within the cerebral vasculature as a result of ischemic stroke are one example of where these issues present a concern. The brain relies on its arteries and veins to supply oxygenated blood from the heart and lungs and to remove carbon dioxide

and cellular waste from brain tissue. Blockages that interfere with this supply eventually cause the brain tissue to stop functioning. If the disruption in supply occurs for a sufficient amount of time, the continued lack of nutrients and oxygen causes irreversible cell death (infarction). Accordingly, immediate medical treatment of an ischemic stroke is critical for the recovery of a patient. To access the cerebral vasculature a physician typically advances a catheter from a remote part of the body (typically a leg) through the vasculature and into the cerebral region of the vasculature. Once within the cerebral region, the physician deploys a device for retrieval of the obstruction causing the blockage. Concerns about dislodged obstructions or the migration of dislodged fragments increases the duration of the procedure at time when restoration of blood flow is paramount. Furthermore, a physician might be unaware of one or more fragments that dislodge from the initial obstruction and cause blockage of smaller more distal vessels.

[0006] Many physicians currently use stents to perform thrombectomy (i.e. clot removal) to resolve ischemic stroke. Typically, the physician deploys the stent into the clot, in an attempt to push the clot to the side of the vessel and re-establish blood to flow. Tissue plasminogen activator (“Tpa”) is often injected into the bloodstream through an intravenous line. The TPA must travel in the blood stream until it reaches the clot that is causing the blockage. Once the Tpa contacts the clot, it begins to break up the clot with the hope of restoring blood flow to the affected areas. Tpa is also often administered to supplement the effectiveness of the stent. Yet, if attempts at clot dissolution are ineffective or incomplete, the physician can attempt to remove the stent while it is expanded against or enmeshed within the clot. In doing so, the physician must effectively drag the clot from the vessel, in a proximal direction, into a guide catheter located within vessels in the patients neck (typically the carotid artery). While this procedure has been shown to be effective in the clinic and easy for the physician to perform, there remain some distinct disadvantages using this approach.

[0007] The stent may not sufficiently hold onto the clot as it drags the clot to the catheter. In such a case, the clot might not move from the vessel. Another risk is that use of the stent might mobilize the clot from the original blockage site, but the clot might not adhere to the stent during translation toward the catheter. This is a particular risk when translating through bifurcations and tortuous anatomy. Furthermore, blood flow can migrate the clot (or fragments of the clot) into a branching vessel at a bifurcation. If the clot is successfully brought to the guide catheter in the carotid artery, yet another risk is that the clot may be “stripped” or “sheared” from the stent as the stent enters the guide catheter. Regardless, simply dragging an expanded stent (either fully or partially expanded) can result in undesired

trauma to the vessel. In most cases, the stent is oversized compared to the vessel. Dragging a fixed metallic (or other) structure can pull the arteries and/or strip the cellular lining from the vessel, causing further trauma such as a hemorrhagic stroke (leakage of blood from a cerebral vessel). Also, the stent can become lodged on plaque on the vessel walls resulting in further vascular damage.

[0008] In view of the above, there remains a need for improved devices and methods that can remove occlusions from body lumens and/or vessels. While the discussion focuses on applications in the cerebral vasculature, the improved devices and methods described below have applications outside of the area of ischemic stroke.

SUMMARY OF THE INVENTION

[0009] The examples discussed herein show the inventive device in a form that is suitable to retrieve obstructions or clots within the vasculature. The term obstructions may include blood clot, plaque, cholesterol, thrombus, naturally occurring foreign bodies (i.e., a part of the body that is lodged within the lumen), a non-naturally occurring foreign body (i.e., a portion of a medical device or other non-naturally occurring substance lodged within the lumen.) However, the devices are not limited to such applications and can apply to any number of medical applications where elimination or reduction of the number of connection points is desired.

[0010] The devices discussed herein include interventional medical devices for retrieving and securing an obstruction within a vessel lumen. In one example the device comprises a shaft having a flexibility to navigate through tortuous anatomy, the shaft a distal portion and a proximal portion; a capturing structure located at a distal portion of the shaft comprising a plurality of struts, the capturing structure having a reduced profile for positioning in or adjacent to the obstruction and an expanded profile, such that when expanded into the obstruction, the struts at least partially enmesh with the obstruction such that subsequent movement of the capturing structure permits dislocation of at least a portion of the obstruction from the lumen; an eversible cover having a fixed section affixed relative to a proximal end of the capturing structure, a free section extending in a proximal direction from the distal section and a cover wall extending from the fixed section to the free section, where the eversible cover is expandable such that at least a portion of the eversible cover has a diameter equal to or greater than the capturing structure, the eversible cover being axially compliant such that when the shaft is moved proximally within the lumen, in some cases friction between the cover wall and the lumen resists proximal movement of the cover wall to cause the eversible

cover to evert over the capturing structure allowing for the free section of the cover to be distal to the fixed end of the capturing portion. Evert or eversible generally includes movement of the device within the cover causing the cover to turn inside out as it protects and covers the retrieval device. The covers disclosed herein can be expandable through self-expanding configurations, or via actuated expansion (e.g., a shape memory alloy, spring expansion, or other actuation).

[0011] In one example, the device includes a configuration where the eversible cover, capturing structure, and shaft are a unitary structure. The device can also be configured so that each wire located at an end of the free section loops back to the cover causing the wires at the end of the free section to be continuous.

[0012] In another variation at least a portion of the cover wall adjacent to the distal end has a set shape that is everted upon expansion. The device can also optionally include a catheter body, where in a delivery configuration, the shaft, capturing structure and eversible cover are located within the catheter body and where the capturing structure is advanceable in and out of a distal end of the catheter body.

[0013] The device can also be configured so that the fixed section of the eversible cover comprises a pre-set shape to reduce a force required to evert the evertable cover.

[0014] The retrieval devices can comprise any number of capturing or retrieval device such as a filter, an artherectomy device, a rotational cutter, an aspiration device, stent based retrievers and retrieval baskets.

[0015] The methods described herein can include methods of securing an obstruction within a vessel. In one example, the method can comprise: positioning a catheter within a vessel; advancing a shaft having a retrieval device affixed thereto out of the catheter; advancing an eversible cover out of the catheter such that a fixed end of the eversible cover is affixed adjacent to a proximal end of the retrieval device and a free end of the eversible cover is moveable relative to the shaft and retrieval device; expanding a at least a portion of the eversible cover against a portion of a wall of the vessel; manipulating the retrieval device to become at least partially enmeshed with the obstruction; and proximally translating the shaft and retrieval device with at least a portion of the obstruction affixed thereto such that resistance of the eversible cover against the vessel resists movement of the eversible cover causing the free section of the eversible cover to evert over the proximally translated retrieval device.

[0016] In another variation, the methods can include further withdrawing the shaft from the vessel such that during withdrawal the eversible cover forms a protective barrier over the

obstruction to lessen shearing forces caused by the vessel and reduce dislodging portions of the obstruction from the retrieval device.

[0017] Another variation of a method includes a method of preparing a retrieval device comprising: providing a retrieval device having been previously removed from a body of a patient where the retrieval device includes a protective cover where a fixed end of the protective cover is affixed adjacent to a proximal end of the retrieval device and where a free end is located distally to the fixed end covering the retrieval device and is moveable relative to the second end; reversing the protective cover by moving the free end proximally of the fixed while the fixed end remains affixed adjacent to the proximal end of the retrieval device; inserting the retrieval device and cover into a catheter where the free end of the cover is proximal to the fixed end of the cover and retrieval device such that upon deployment from the catheter, the free end of the cover deploys proximally to the fixed end of the cover.

[0018] In another example, the devices described herein can include medical device retrieval systems for securing an obstruction within a vessel lumen and for use with a catheter configured to be navigated through the vasculature. In one variation, the device comprises an elongated stent comprising a plurality of struts, the stent being collapsible for positioning in the catheter during delivery and having an expanded profile such that when expanded the struts are configured to engage the obstruction; a shaft fixedly attached to the elongated stent and having a flexibility to navigate through tortuous anatomy; a fluid permeable cover having a distal end coupled to a proximal end of the elongated stent a cover wall defining a cavity and extending along the shaft, and a proximal end being moveable relative to the shaft, where the fluid permeable cover is collapsible for positioning in the catheter during delivery and is expandable upon deployment from the catheter such that at least a portion of the fluid permeable cover is expandable; where the fluid permeable cover is axially pliable such that when the device is deployed in the vessel the frictional forces between the vessel and the fluid permeable cover permit proximal movement of the shaft and elongated stent to cause inversion of the fluid permeable cover wall such that the fluid permeable cover wall everts over the elongated stent.

[0019] Another variation of a device includes an interventional medical device for use with a catheter configured for delivery through vasculature for securing an obstruction within a vessel lumen. For example, the device can comprise a shaft having a flexibility to navigate through tortuous anatomy, the shaft having a distal portion and a proximal portion; a capturing device comprising a sidewall, the capturing device fixedly located at a distal portion of the shaft and having a reduced profile for positioning in the catheter and an expanded

profile, such that upon deployment from the catheter, the capturing device expands to force a portion of the sidewall into the obstruction to at least partially attach to the obstruction; a cover having a distal end coupled adjacent to a proximal end of the capturing structure, a proximal end and a cover wall extending therebetween, where the proximal end of the cover is slidable relative to the distal end, where the cover is expandable such that when located in the catheter the cover is in a reduced delivery state and upon advancement from the catheter the cover expands with the proximal end located proximally of the distal end, where the cover wall is compliant such that when deployed from the catheter and the shaft is pulled in a proximal direction frictional forces between the vessel and the cover wall or proximal end cause the cover to invert as the cover wall inverts over the capturing device to surround the capturing device.

[0020] Another variation of the device include an interventional medical device for securing a retrieval device having one or more obstructions located therein for removal from a body. In one such example the medical device includes a sheath having a flexibility to navigate through tortuous anatomy, the sheath a distal portion and a proximal portion and a lumen extending therethrough; an eversible cover having a fixed section affixed to the distal portion of the sheath, a free section extending in a proximal direction from the fixed section and a cover wall extending from the fixed section to the free section, where the eversible cover is expandable, the eversible cover being axially compliant such that when the retrieval device is positioned through the sheath lumen moved in a proximal direction against the eversible cover, the eversible cover everts over the retrieval device allowing for the free section of the cover to be distal to the retrieval device.

[0021] Another variation of the method includes advancing a shaft having a retrieval device affixed thereto to the obstruction; advancing a protective device over the shaft, the protective device comprising a sheath having an eversible cover, where a fixed end of the eversible cover is affixed to a distal portion of the sheath and a free end of the eversible cover is located proximal to the fixed end; positioning the fixed end of the eversible cover adjacent to the retrieval device and expanding at least a portion of the eversible cover against a portion of a wall of the vessel; proximally translating the shaft and retrieval device with at least a portion of the obstruction affixed thereto such that resistance of the eversible cover against the vessel resists movement of the eversible cover causing the free section of the eversible cover to evert over the proximally translated retrieval device.

[0022] The capturing portions described herein can include a stent retrieval device for expanding against one or more occlusive bodies in a vasculature. In one example, the stent

retrieval device includes an elongate shaft having a flexibility to navigate through tortuous anatomy, the elongate shaft having a distal portion and a proximal portion; a plurality of filaments that diverge from the distal portion of the elongate shaft to form an expandable elongated stent body having an open distal end and a fluid permeable closed proximal end and a cavity therebetween, where divergence of the filaments at the distal portion of the elongate shaft forms the fluid permeable closed proximal end; where the plurality of filaments extending along the shaft are free of any connection joints in the distal portion to permit increased flexibility of the distal portion as it navigates through tortuous anatomy; and one or more connection joints proximal to the distal portion where the connection joints secure the plurality of filaments to the shaft.

[0023] The stent retrieval can also include at least one of the plurality of filaments that comprise at least two wires twisted together, the elongated stent body further comprising at least one intersection of filaments, where the wires of each filament are interwoven to provide increased outward radial strength of the elongated stent body and such that the wires slide relative to each other as the elongated stent body expands or compresses in diameter to reduce a force required to linearize the elongated stent body.

[0024] The stent retrieval device can have an exterior surface of the elongated stent body that comprises an irregular surface formed by intersection of filaments.

[0025] The stent retrieval device can also have intersection of filaments comprising a barb or knuckle and where a plurality of barbs or knuckles are radially spaced about the elongated stent body. The stent retrieval device can also have an intersection of filaments that comprises a barb or knuckle and where a plurality of barbs or knuckles are aligned with an axis of the elongated stent body.

[0026] In one variation of the devices described herein, the device comprises a main bundle or group of wires that diverge to form a device having various shapes but few or no connections points or joints (where fabrication of such a construction is referred to as "jointless"). Clearly, the inventive devices described herein are not limited to such a jointless construction. Additional variation includes one or more leading wires that are attached to a capturing portion as described below.

[0027] Devices of the present invention can incorporate any number of wires of different characteristics including, but not limited to, materials, shapes, sizes and/or diameters. Clearly, the number of permutations of device configurations is significant. Providing devices with such a composite construction allows for the manipulation of the device's properties to suite the intended application.

[0028] As noted herein, the joint-less construction improves the flexibility and strength of the device by eliminating joints, connection points, or other attachment points. In addition, the joint-less construction improves the ability of the device to be delivered through a small microcatheter. As a result, the device and microcatheter are able to access remote regions of the vasculature.

[0029] The devices may be fabricated to be self-expanding upon deployment from a catheter. Alternatively, the devices can be constructed from shape-memory alloys such that they automatically deploy upon reaching a pre-determined transition temperature.

[0030] It should be noted that in some variations of the invention, all or some of the device can be designed to increase their ability to adhere to the obstruction. For example, the wires may be coupled to an energy source (e.g., RF, ultrasonic, or thermal energy) to “weld” to the obstruction. Application of energy to the device can allow the surrounding portion to deform into the obstruction and “embed” within the obstruction. Alternatively, the device can impart a positive charge to the obstruction to partially liquefy the obstruction sufficiently to allow for easier removal. In another variation, a negative charge could be applied to further build thrombus and nest the device for better pulling force. The wires can be made stickier by use of a hydrophilic substance(s), or by chemicals that would generate a chemical bond to the surface of the obstruction. Alternatively, the filaments may reduce the temperature of the obstruction to congeal or adhere to the obstruction.

[0031] Additional devices and methods for treating ischemic stroke are discussed in commonly assigned U.S. Patent application nos.: 11/671,450 filed February 5, 2007; 11/684,521 filed March 9, 2007; 11/684,535 filed March 9, 2007; 11/684,541 filed March 9, 2007; 11/684,546 filed March 9, 2007; 11/684,982 filed March 12, 2007, 11/736,526 filed April 17, 2007, 11/736,537 filed April 17, 2007, 11/825,975 filed September 10, 2007; 12/344,378 filed 12/26/2008, 13/012,727 filed 1/24/2011, and 13/226,222 filed 9/6/2011; the entirety of each of which is incorporated by reference. The principles of the invention as discussed herein may be applied to the above referenced cases to produce devices useful in treating ischemic stroke. In other words, the wire-shaped construction of devices according to present invention may assume the shapes disclosed in the above-referenced cases when such a combination is not inconsistent with the features described herein.

BRIEF DESCRIPTION OF THE DRAWINGS

- [0032] Each of the following figures diagrammatically illustrates aspects of the invention. Variation of the invention from the aspects shown in the figures is contemplated.
- [0033] Fig. 1 illustrates an example of a device according to the present invention when used in a system for removing obstructions from body lumens.
- [0034] Figs. 2A to 2C illustrate working ends of various coverable retrieval devices.
- [0035] Figs. 2D and 2E show variations of retrieval devices.
- [0036] Fig. 2F shows an independent eversible cover on a delivery sheath.
- [0037] Figs. 3A to 3C illustrate an example of a coverable retrieval device where the cover everts about the retrieval structure.
- [0038] Fig. 4A to 4I illustrates an example where an improved retrieval device with passive protection retrieves a clot from tortuous anatomy.
- [0039] Figs. 4J and 4K illustrate examples of an obstruction or other material captured within a retrieval device with a cover further protecting the loaded retrieval device.
- [0040] Fig. 5A illustrates a retrieval device having a retrieval structure adjacent to a double layer cover.
- [0041] Fig. 5B shows a funnel with a free end that tapers down about the delivery wire.
- [0042] Figs. 5C and 5D show a fixed end of a cover that is pre-shaped to reduce the force required to evert the cover wall.
- [0043] Fig. 5E shows alternate variation of a passive cover integrated into a retrieval device.
- [0044] Fig. 5F illustrates a cover having a pre-set flattened cover wall at a fixed end of the retrieval structure.
- [0045] Figs. 5G to 5I illustrate various layered covers.
- [0046] Fig. 5J shows a cover that is constructed directly onto the retrieval structure rather than the delivery shaft.
- [0047] Figs. 5K and 5L show a variation of a cover and retrieval device where the cover is first mounted in a distal direction and then inverted in a proximal direction.
- [0048] Figs. 6A to 6L illustrate a variation of covers for use as describe herein.
- [0049] Figs. 7A to 7C show additional variations of covers.
- [0050] Fig. 8 illustrates a variation of a proximal and distal end of an additional retrieval device.
- [0051] Figs. 9A to 9C illustrate wires of different constructions within a delivery wire or shaft.

- [0052] Figs. 10A to 10E illustrate additional variations of covers for use as described above.
- [0053] Figs. 11A to 11C illustrate additional variations of covers for use with the devices and methods described herein.
- [0054] Figs. 12A to 12E illustrate various stent designs for increasing the ability of a stent to adhere to an occlusion within a vessel.
- [0055] Fig. 12G illustrates a proximal end of the stent structure.

DETAILED DESCRIPTION

- [0056] It is understood that the examples below discuss uses in the cerebral vasculature (namely the arteries). However, unless specifically noted, variations of the device and method are not limited to use in the cerebral vasculature. Instead, the invention may have applicability in various parts of the body. Moreover, the invention may be used in various procedures where the benefits of the method and/or device are desired.
- [0057] Fig. 1 illustrates a system **10** for removing obstructions from body lumens as described herein. In the illustrated example, this variation of the system **10** is suited for removal of an obstruction in the cerebral vasculature. As stated herein, the present devices and methods are useful in other regions of the body including the vasculature and other body lumens or organs. For exemplary purposes, the discussion shall focus on uses of these devices and method in the vasculature.
- [0058] It is noted that any number of catheters or microcatheters may be used to locate the catheter/microcatheter **12** carrying the obstruction removal device **200** at the desired target site. Such techniques are well understood standard interventional catheterization techniques. Furthermore, the catheter **12** may be coupled to auxiliary or support components **14**, **16** (e.g., energy controllers, power supplies, actuators for movement of the device(s), vacuum sources, inflation sources, sources for therapeutic substances, pressure monitoring, flow monitoring, various bio-chemical sensors, bio-chemical substance, etc.) Again, such components are within the scope of the system **10** described herein.
- [0059] In addition, devices of the present invention may be packaged in kits including the components discussed above along with guiding catheters, various devices that assist in the stabilization or removal of the obstruction (e.g., proximal-assist devices that holds the proximal end of the obstruction in place preventing it from straying during removal or assisting in the removal of the obstruction), balloon-tipped guide catheters, dilators, etc.

[0060] Fig. 2A illustrates a working end of a coverable retrieval device **100**. Typically, the device includes a capturing or retrieval structure **200**. In the illustrated example, the retrieval structure **200** comprises an elongated stent structure. However, unless specifically noted, the capturing structure can comprise any number of devices, including but not limited to a filter, an artherectomy device, a rotational cutter, an aspiration catheter.

[0061] The retrieval structure **200** is located at a distal end of a delivery wire **202**. In one variation, the retrieval structure **200** can be permanently affixed to the delivery wire **200** by such methods including, but not limited to adhesive bonding, soldering, welding, polymer joining, or any other conventional method. In some variations, the retrieval device **200** can be formed from one or more wires forming the delivery wire **202** or shaft **202**. The delivery wire **202** can have sufficient column strength such that it can axially advance and retract the device **100** within the vasculature as the physician manipulates a non-working end of the delivery wire **202** outside of the body. Accordingly, the delivery wire **202** should have a length that is sufficient to extend from the target area, e.g., the cerebral vasculature, to the entry point on the body. Alternatively, additional variations of the device **100** can allow for the use of a support member or catheter that positions the retrieval structure **200** as needed. Additional features of the retrieval structure **200** can be found in the commonly assigned patents and applications cited herein an incorporated by reference.

[0062] The coverable retrieval device **100** further includes a cover **300** (also referred to as a funnel or sheath) affixed relative to a proximal end **206** of the retrieval structure **200**. By being affixed relative to a proximal end **206**, a distal end **204** of the retrieval structure **200** can move relative to the cover **300** so that the cover **300** everts over the proximal end **206** of the structure **200** when the cover **300** is expanded within a vessel and as the structure **200** is withdrawn into the distal end **302** of the cover **300**. This mechanism is discussed in detail below.

[0063] Figs. 2B and 2C illustrate alternative variations of a coverable retrieval device **100**. As shown in Fig. 2B and 2C, the distal end **302** of the cover **300** can be spaced from the proximal end **206** of the retrieval structure **200**. Alternatively, the distal end **302** of the cover **300** can extend over a portion of the retrieval structure **200**. In some variations, at least a section of the cover **300** expands to a greater diameter than a diameter of the retrieval structure **200**. This allows the cover **300** to expand to a vessel wall where the vessel holds the cover stationary while the device is pulled proximally through the cover to evert the cover. In alternate variations, the cover **300** expands to the same or lesser diameter than the retrieval structure **200** or other device.

- [0064] Fig. 2D shows a retrieval device **100** with a catheter **112** (usually a microcatheter). The retrieval device **100** can comprise a single unitary device of a cover **300** and retrieval structure **200** (in this case the retrieval structure is an elongated stent structure). One benefit of a unitary device is that additional devices complicates the procedure and can increase the duration of what is ordinarily a time sensitive procedure. The retrieval device **100** can be positioned through the catheter **112** that includes a hub **114**. As a result, the physician only needs to manipulate the unitary retrieval device **100** and the catheter/microcatheter **112**. The retrieval device **100** is loaded into the catheter **112** for placement at the target site. In addition, the retrieval device can be reloaded if the procedure must be repeated. The cover **300** and retrieval structure **200** described herein can comprise any construction described herein or as known by those skilled in the art.
- [0065] Fig. 2E shows a retrieval device **100** with a cover **300** and retrieval device **200** with a radiopaque marker **305** therebetween. As shown, variations of the device **100** do not require a catheter or microcatheter.
- [0066] Fig. 2F illustrates an eversible cover **300** located on a sheath **330** having a lumen **332** extending therethrough. A separable retrieval device **200** can be coupled to the cover **300** and sheath **330** by inserting the wire **202** of the cover retrieval device **200** through the lumen **332** of the sheath **330**. In this variation, the eversible cover **300** can be used with any number of different interventional tools. The separate devices can be assembled prior to delivery into the patient. Alternatively, the devices can be positioned within the body and subsequently joined once the retrieval device **200** engages the target area.
- [0067] Fig. 3A illustrates an example of a coverable retrieval device **100** where the cover **300** is in the process of everting about the retrieval structure **200**. As shown, arrow **50** illustrates a force applied on the wire **202** in a proximal direction. Arrows **52** illustrate a resistance force applied by the friction of the expanded cover **300** against a vessel or similar wall. This friction force **52** prevents or resists proximal movement of the free end **304** of the cover **300** while the fixed end **302** moves in a proximal direction with the proximal end **206** of the retrieval structure **200**. This action causes a wall **306** of the cover **300** to evert over the retrieval structure **200**. Ultimately, and as shown in Fig. 3B, the free end **304** of the cover **300** ends up distally over the fixed end **302**. As shown, the wall of the everted cover **300** provides a safety type cover for the retrieval device **200**. In additional variations, the fixed end **302** of the cover can actually be slidable or moveable along the delivery wire **202**. However, the similar principle as discussed above shall apply to cause everting of the cover **300** over the retrieval structure **200**.

[0068] Fig. 3C illustrates another variation of a coverable retrieval device **100** after the cover **300** is everted about the retrieval structure **200**. In this variation, the free end **304** of the cover **300** ends up distally of the fixed end **302** and tapers or collapses towards the free end **304**. The cover **300** can be shape set so that prior to eversion the cover is as shown above where the forces acting on the cover wall **306** expand outwards, but after eversion the forces on the cover wall **306** cause the tapering or collapsing as shown in Fig. 3C.

[0069] In accordance with the illustrations discussed above, the cover **300** can be made so that the cover wall **306** is atraumatic when dragged across a lumen wall. The cover can be manufactured from any number of materials including a fabric, a reinforced fabric, a braid, weave, or any such material that allows for expansion against a wall of the body lumen or vessel as well as to allow everting of a wall **306** of the cover over the retrieval device **200**. The cover wall **306** can also comprise combinations of these materials such as braids of polymer material with metal fibers, soft braids with coil reinforcements or various other combinations.

[0070] The cover wall can comprise a mesh that can include any medically acceptable materials such as a Nitinol braid. Furthermore, the mesh allows for flow through the vessel or lumen while expanded. However, additional variations of the device can include a solid layer of material substituted for the mesh. Moreover the cover can comprise any number of configurations. For example, the cover can comprise a single layer wall or a multi layer wall, the open end of the cover could be made to have terminated ends such as by using continuous wire loops formed during the braiding process. Alternatively, the ends can be cut and then terminated by encasing in polymer, laser welds, or by folding inward for a discreet length and then terminating

[0071] In one example, the cover **300** comprises a continuous wire construction as described in earlier commonly assigned patent applications incorporated by reference. In one variation the cover **300** comprises a finely braided wire, such as 48-96 wires of .0005" to 0.002" diameter fine Nitinol wire or similar. Additionally, the wire can comprise cobalt chromium, stainless steel, or similar, or drawn filled tube (dft) with platinum core. In additional variations, a flat wire or oval wire can be used. The wire does not need to be uniform. Instead, a number of different types of wires can be used. Some of the individual wires could be platinum alloys for added radiopacity.

[0072] Fig. 4A to 4I illustrates an example where an improved retrieval device **100** with passive protection retrieves a clot **2** from tortuous anatomy. Fig. 4A illustrates a clot **2** that obstructs blood flow in a vessel **6**. As noted herein, the vessel **6** can comprise any vessel in

cerebral vasculature, coronary or peripheral vasculature. Alternatively, the device and methods for use are not limited to use in the vasculature. Variations of the principles, concepts, method and devices described herein can be applicable wherever a retrieval device can be used. Fig. 4A also illustrates a guide sheath or access catheter **108** that is advanced within the vessel. During a procedure, the physician will advance the access catheter **108** as far distally as possible. However, due to the size of the access catheter **108**, a physician typically positions it a distance away from the obstruction **2**. As shown, there can be any number of bifurcations **8** in the vessel **6** located between the access catheter **108** and the obstruction **2**. As discussed herein, in some variations, the access catheter **108** can be used to remove the obstruction **2** from the body once the obstruction is captured by a retrieval device. However, the greater the distance between the initial location of the obstruction **2** and the location of the access catheter **108**, the greater the risk that the obstruction **2** can break free from the retrieval device or become dislodged due to anatomic or environmental features, including but not limited to bifurcations, the wall of the lumen, the tortuosity of the anatomy, vessel wall plaque, etc.

[0073] Fig. 4B illustrates an optional catheter **112** that advances from the access catheter **108** to the site of the obstruction **2**. Once at the site, the catheter **112** can deploy a retrieval device (not shown in Fig. 4B) so that the retrieval device can engage the clot **2**. Alternatively, the catheter **112** can traverse the obstruction **2** as shown in Fig. 4C and deploy a portion of the retrieval device **100** distally to the obstruction **2**. The physician then manipulates the retrieval device **100** to secure the obstruction **2**. For example, the physician can deploy the retrieval structure **200** distally to the obstruction **6** and withdraw the retrieval structure **200** proximally to secure the obstruction **2**. In another variation, the physician can position the retrieval structure **200** within the catheter **2** while the catheter **112** is through or adjacent to the obstruction **2**. Then, the physician can withdraw the catheter **112** to expose the retrieval structure **200** so that it secures to the obstruction **2** after expansion. In the illustrated example, the retrieval structure **200** comprises an elongated stent type structure that expands (or is expanded) to enmesh or secure to the obstruction. Although not illustrated, the system can include a distal capture filter or basket as described in any of the commonly assigned applications incorporated by reference herein.

[0074] Next, as shown in Fig. 4E, the physician can further withdraw the catheter **112** to expose a cover **300** as described above. In many cases, the physician exposes the cove **300** once the retrieval structure **200** is engaged with the obstruction **2**. This sequential process allows for easier repositioning of the retrieval structure **200** if necessary. Alternatively, the

cover 300 can be deployed prior to engaging the retrieval structure 200 with the obstruction 2. If necessary, the physician can apply a proximal force on the delivery wire 202 while withdrawing the catheter 112 to prevent inadvertent movement of the obstruction 2 and retrieval device 200.

[0075] Fig. 4F illustrates the stage with a fully exposed the cover 300 and a catheter 112 moved closer towards the access sheath 108. As shown, the free end 304 of the cover 300 is proximal to fixed end 302 of the cover 300. As also noted above, the cover 300 can be a shape memory alloy that expands against the walls of the vessel 6 upon reaching body temperature. Alternatively, the cover 300 can be self expanding upon deployment into the vessel 6. In some variations, the cover wall 306 comprises a porous material or construction that allows blood to continue to flow through the cover 300.

[0076] In addition, some variations of the retrieval device 100 include a cover 300 that has at least a section that expands to a greater diameter or dimension than the retrieval structure 200. This allows for expansion of the cover 300 against the wall of the vessel 6. In most variation, expansion of the cover 300 provides sufficient friction against the walls of the vessel to overcome column strength of the cover walls 306 allowing for everting of the cover walls 306 over the retrieval structure 200 and obstruction 2 as discussed herein. As noted above, in alternate variations the cover 300 can expand a diameter or dimension that is equal to or less than the retrieval structure 200.

[0077] Figs. 4G illustrates proximal movement of the delivery wire 202, which causes proximal translation of the obstruction 2 and retrieval structure 200. Because the cover 300 is expanded against the walls of the vessel 6 the free end 304 of the cover 300 does not move or moves less than the fixed end 306 of the cover 300. The fixed end 306 moves with the obstruction 2 and retrieval structure 200 in a proximal direction causing the cover walls 306 to evert over the obstruction 2 and retrieval structure 200. Unlike a conventional funnel, the everting cover functions similar to a conveyor belt type movement as the obstruction and retrieval structure move together. This action allows for a passive type of protection since cover 300 does not need to be actuated over the obstruction 2 and retrieval structure 200 and can be performed in a quick manner by simply withdrawing the deployed retrieval device 100.

[0078] Fig. 4H illustrates a stage where the fixed end 306 of the cover 300 is now proximal to the free end 304. As shown, the everted cover 300 forms a protective sheath or cover over the obstruction 2 and the retrieval structure 200. Fig. 4H also illustrates how the cover 300 protects the obstruction 2 and retrieval structure 200 as they are pulled along the vessel and navigate the tortuous anatomy, walls of the vessel, as well as bifurcations 8. The cover 300

and cover wall 306 also protects the vasculature from the surface of the retrieval structure 200 and obstruction 2.

[0079] Fig. 4I shows the obstruction 2 and retrieval structure 200 protected by the cover 300 as the retrieval device 100 is positioned against or within the access catheter 108 in preparation for removal from the body. The retrieval device 100 can remain outside of the access catheter 108 as the physician removes both devices from the body. Alternatively, the cover 300 can assist in pulling the retrieval device 100 and obstruction 2 into the access catheter 108 by compressing the obstruction 2 as it is pulled into the access catheter 108.

[0080] Figs. 4J and 4K illustrate examples of an obstruction or other material 2 captured within a retrieval device 2 with a cover 300 further protecting the loaded retrieval device 200.

[0081] Figs. 5A to 5K show a variety of cover configurations. Fig. 5A illustrates a retrieval device 100 having a retrieval structure 200 adjacent to a double layer cover 300 with an exterior wall 306 and an interior wall 308.

[0082] Fig. 5B shows a cover 300 with a free end 304 that tapers down about the delivery wire 202 where the cover 300 will eventually form a double wall configuration when the cover 300 everts over the retrieval structure 200. The tapered free end 304 limits the cover 304 from moving once the retrieval structure 200 reaches the free end 304 thereby forming double wall protection over the retrieval structure 200.

[0083] Figs. 5C and 5D show how a fixed end 302 of a cover 300 can be pre-shaped to reduce the force required to evert the cover wall 306 or to lower the threshold to trigger passive covering of the retrieval structure by the cover.

[0084] Fig. 5E shows alternate variation of a passive cover 300 integrated into a retrieval device 100. In this variation, the retrieval device 100 includes a control shaft or wire 202 to manipulate the working end of the retrieval device 100. The cover 300 floats along the shaft 202 between two fixed anchors or nodes 220, 222. The cover 300 can float or slide between the fixed nodes 220, 222. The nodes 220, 222 can comprise radiopaque marker bands, glue joints, or any other mechanical obstructions capable of stopping the translation of cover 300. When the device 100 advances through a microcatheter, the rear or proximal node 220 limits rearward movement of the cover 300. When positioned appropriately, the microcatheter can be withdrawn to expose the retrieval device 200 and cover 300 as described herein. When the retrieval structure 200 engages the obstruction (not shown) the retrieval device 100 can be withdrawn by pulling on the delivery shaft 202. While this occurs, the cover 300, being expanded against the vessel remains stationary (or moves at a slower rate than the obstruction and retrieval structure 200 due to the friction against the vessel wall). The retrieval structure

200 and clot enter the cover 300, causing the distal node 222 to make contact with the near end 320 of the cover 300. This contact causes the retrieval structure 200 and cover 300 to translate as an integrated unit. It should be appreciated that the cover could be a single layer or double layer cover, and could have any of the wire design variables and termination variables described herein.

[0085] Fig. 5F illustrates a cover having a pre-set flattened cover wall 304 at a fixed end 302 that is spaced from a proximal end of the retrieval structure 200. Figs. 5G to 5I illustrate various layered covers 300. The layered covers allow for shortening the axial length of the cover and therefore shortens the required translation length. Layering of the cover wall 306 allows for a shortened deployed length of the cover 300 when deployed in the vessel or body structure. As the cover 300 everts over the retrieval structure 200 the layered wall 306 extends. As a result, shortening the length reduces the length that the cover 300 extends into the proximal vessels and reduces the length of that the retrieval structure 200 must travel to become protected by the cover 300. This also helps shorten the distance required to move the device 100 to complete eversion of the cover 300.

[0086] Fig. 5J shows a cover 300 that is constructed directly onto the retrieval structure 200 rather than the delivery shaft 202. This construction also assists in reducing the distance necessary to complete passive protection of the retrieval structure by the cover.

[0087] Fig. 5K show a variation of a cover 300 that is mounted in a distal direction over the retrieval device 200 and then everted in a proximal direction over the wires or shaft 202 as shown by arrows 230. Once everted, as shown by Fig. 5L, the device 100 is ready for deployment as discussed herein.

[0088] Figs. 6A to 6B illustrate a variation of a cover 350 for use as describe herein. Additionally, the cover 350 can be used with any obstruction retrieval device not limited to the retrieval baskets and stents described herein. The covers 350 disclosed herein can be used where the physician desires to shield the obstruction being removed from the frictional effects of the arteries or from the local anatomy (e.g., branching vessels, tortuous anatomy, or other substances on the vessel walls). In use, the covers can be sized for use with guide catheters, micro-catheters, and/or distal access catheters. The covers can include any number of radiopaque marker bands to allow non-invasive imaging of the device (see marker 390 affixed between cover 350 and shaft 212 in Fig. 7B as one example). In any case, once the retrieval device captures a clot or obstruction, as described above, the device and clot are protected by the cover so that the cover eliminates or reduces direct contact between the interior of the wall of the vessel and the clot.

[0089] Figs. 6A to 6C show a variation in which a cover is created from one or more mesh tubes 372. Fig. 6B illustrates inversion of the tube 372 so that a first end 374 is drawn over the tube 372 towards a second end 376. As shown in Fig. 6C, this creates a double walled cover having an exterior wall 378 separated from an interior wall 380. In one example, such a spacing or gap could range between 0.001 inches to 0.100 inches. However, any range is contemplated within alternative variations of the device. In some variations the inverted cover 350 is heat set to maintain a separation between layers or walls 378 380 of the cover 350. Typically, if the cover 350 is not created from a radiopaque material, a marker band will be placed on the proximal end 376 and adjacent to a shaft or catheter to which the cover 350 is attached. In some variations the construction of the mesh material is compliant to allow for movement of a first part of the mesh relative to a second part of the mesh through compression and expansion of the mesh material. In such a case, the individual strands forming the mesh are moveable relative to one another to cause the mesh to be naturally compliant. Accordingly, this construction permits the inner wall 380 to move or deflect with the retrieval device and/or obstruction as the device is withdrawn into the cover 350. In some variations, both ends of the mesh 374 and 376 are affixed to the catheter, shaft or wire.

[0090] In many variations, the cover mesh is selected to minimize friction when the interior layer 380 moves against the exterior layer 378. For example, the braid pattern, wire, wire diameter, angle of the braid and or other features can be selected to reduce friction between the outer layer 378 and inner layer 380. This permits the inner layer 380 to move proximally with a retrieval device while the outer layer remains stationary. Again, as discussed above, the construction of the mesh permits compression and expansion of the mesh layer to permit movement of the inner layer while the outer layer remains affixed when engaged against the vessel wall. In certain variations, the cover is heat set so that the inner layer has cushioning and the ability to deflect to assist in movement of the inner layer. Fig. 5C also illustrates a cover 350 having a tapered design.

[0091] Figs. 6D to 6L illustrate additional variations of cover construction to produce covers having more than two walls. For example, a mesh tube 372 is everted or drawn over a second end 376 in the direction 420. As shown in Fig. 6E this produces a dual layer cover having a open ends 422 and 424 and a folded end 426. The dual layer tube is then folded over again in the direction 420. This creates a cover construction with an exterior layer 378 and an interior layer 380 as well as a first intermediate layer 381 and a second intermediate layer 383. As shown in Fig. 6F, the cover can be set to assume the tapered shape having an opening at the

first end 374 that is flared with the ends of the mesh at the second end 372, which are ultimately affixed to a shaft, wire or other catheter device as described herein.

[0092] Fig. 6G illustrates another example of a cover construction. As shown, a first mesh tube 372 is placed coaxially with a second tube 372. The concentric tubes are then everted in direction 420 to produce a four layer cover. As shown in Fig. 6H, the cover can comprise an interior mesh layer 380, and exterior mesh layer 378 as well as any number of intermediate layers 381, 383 depending on the number of tubes that are initially used. The second end 372 of the cover 350 includes four unconnected ends of the mesh tubes that can be affixed to a shaft or tube as discussed herein, while the first end 374 of the cover 350 can be shape set to taper from the opening.

[0093] Figs. 6I to 6L illustrate another example of the construction of a multi-wall cover. As shown in Fig. 6I, a first end 374 of a mesh tube 372 is everted over and beyond a second end 376 in direction 420 to produce the configuration of Fig. 6J. Next, the first end 374 is everted or folded back in direction 420 to produce the configuration of Fig. 6K. Finally, the first end 374 is folded again in direction 420 so that the ends 374 and 376 are even to produce the cover configuration shown in Fig. 6K. Again, one end of the cover 350 can be set to form the tapered shape while the other respective end can be affixed to a catheter or shaft.

[0094] Although the covers of the present disclosure are presented without additional structures, it should be noted that these covers are coupled with a shaft or other member so that the cover can be advanced within the target anatomy to assist in removal of a device, structure, or debris from the site.

[0095] Figs. 7A to 7C show additional variations of covers 350. Fig. 7A illustrates a cover in which the cover wall as defined by the inner layer 380 and outer layer 378 is set in a shape that varies along a length of the cover. For example, the end adjacent to the cover opening 382 can be set to a bulbous shape. Such a configuration assists in maintaining separation of layers 378 and 380, which aids in re-entry of the retrieval device. Additional configurations of cover walls that vary in thickness are within the scope of this disclosure.

[0096] One of the benefits of using a cover 350 as described herein is that the cover reduces flow through the vessel when deployed so that the retrieval device can remove the obstruction without the full force of the flow of blood opposing the obstruction. Typically, conventional devices relied upon the use of an inflated balloon to obstruct flow. However, use of a cover eliminates the need for total occlusion of blood flow. Fig. 7B illustrates a further improvement on a cover 350 that aids in flow reduction. As shown, the cover 350 includes a dense region 386 and a relatively less dense region 384. This configuration permits greater

blood flow through the region **385** while region **386** reduces or prevents blood flow. Furthermore, the distal section of the cover is more flexible and conformable. Additional mesh layers can be added to any of the cover designs to alter flow characteristics or even provide reinforcement to the cover. Alternatively, or in combination, the braid density can be altered to adjust the porosity of the braid at different sections. Furthermore, additional braid layers can also be used to affect porosity of portions of the cover or even the entire cover. Deployment of a cover can reduce blood flow by 30% to 40%. Adding additional layers or coatings can additionally reduce flow.

[0097] Fig. 7C shows another variation of a cover **350** in which the mesh partially or totally is obscured using a polymeric coating **388** that reduces the permeability of the mesh design. Furthermore, drugs or other substances can be placed within the cover wall of any of the covers or can be deposited on the cover using the polymeric coatings. In some examples, the covers described herein can range from a length of 10 mm up to 50 mm. The OD at the opening of the cover can range from 7 mm and could range between 4 mm to 10 mm. Again, any range of dimensions is contemplated within the disclosure.

[0098] The covers described herein can further be stacked on a device. For example, two or more covers can be placed on a device to provide added protection.

[0099] The cover/reentry devices described herein can be constructed of any material currently used in vascular applications, including those discussed above. Furthermore, fabrication of the cover from a DFT material can provide additional benefits as the entire cover remains radiopaque and can be imaged non-invasively. Furthermore, the covers can be provided with any type of medicament or bioactive substance either in a polymer that coats the mesh or in a delivery agent within the mesh or between layers. Such substances include tpa, urokinase, IIb/IIIa inhibitors, and other clot disruptors or inhibitors.

[0100] Fig. 8 illustrates another variation of a retrieval device **400** including a distal capture portion **426** coupled to one or more leading wires in the form of a main bundle **402**. The main bundle extends through a sheath **106** that includes a proximal capture portion **460**. The configuration of the retrieval device **400** can incorporate the proximal and distal capture portions discussed herein as well as various other configurations discussed in the commonly assigned patent applications noted above.

[0101] An end **464** of the proximal capture portion **460** is affixed to a distal end of the sheath **106**. However, as noted above, other variations are within the scope of the disclosure. The main bundle **402** can optionally terminate at a handle **442**. As noted above, in certain variations, the main bundle is joined to a stiffer wire or stiffer bundle of wires. This allows

the device **400** to have a very flexible distal section with a relatively stiffer proximal section. The device **400** can have a proximal bundle **403** that comprises either the exposed wires or a covering/tube over the wires. In certain variations, the bundle or wire **402**, **403** can be encapsulated with a coating. The device also includes a cover **300** adjacent to the retrieval device.

[0102] The proximal end of the sheath **106** includes a sheath handle **444**. As discussed herein, axial movement of the bundle **402** or proximal bundle **403** (typically at the handle **442**) results in movement **126**, or translation of the bundle within the sheath **106**. This action moves the distal capture portion **426** (as shown by arrows **126**). In certain variations, the device **400** is loaded into a microcatheter (not shown but discussed above) that is delivered to the site of the obstruction and crosses the obstruction.

[0103] In some variations, the sheath hub **444** includes one or more locking hubs **446**. Where actuation (either axial or rotational) of the locking hub **446** locks the main bundle **402** relative to the sheath handle **444** and sheath **106**. It follows that such locking action also locks the distal capture portion **426** relative to the proximal capture portion **460**. A variety of methods can be employed to increase a frictional interference between the locking hub **446** and the proximal bundle **403**. As a result, when a physician determines a length of an obstruction, the physician can set a spacing between the capturing portions **426** **460** by locking the proximal bundle **403** relative to the sheath hub **444**. Accordingly, the proximal bundle **403** can include any type of incremental markings to allow the physician to readily determine a spacing of the capturing portions. As illustrated, the sheath hub **444** can include additional injection ports to deliver fluid or other substances through the sheath **106**.

[0104] As noted above, the device **400** can be used with a micro-catheter. In those variations it is important that the device **400** is loaded without damaging the distal bundle **402**, capture portions **426** **460**, and/or sheath **106**. As a result, the device **400** can include an optional cover **486** that reduces the proximal capture portion **460** (and /or the distal capture portion **426**) for loading within the microcatheter and/or sheath **106**.

[0105] Another variation of the device **400** includes an insertion tool **480** slidably affixed to the sheath **480**. Because variations of the device **400** can be extremely flexible, the insertion tool **480** can be used to provide column strength to the sheath **106**, bundle **402** or other components as the device **400** is pushed into the microcatheter. The insertion tool comprises a rigid section **482** and a frictional coupler **484**. The rigid section **282** has a column strength that supports the device **400** to prevent buckling. The frictional coupler **484** can be a flexible material that allows an operator to squeeze or grip the coupler **484** to create a temporary

frictional interface between the loading tool **480** and the device **400** (typically the sheath **106**). Such an action allows axial advancement of the device **400** as the loading tool **480** is advanced into the microcatheter. Once the rigid section **482** is fully inserted into the microcatheter, the operator releases the frictional coupler **484** and can withdraw the loading tool **480** from the catheter without withdrawing the device **400**. The insertion tool **480** can also include an optional loading tube **486** slidably coupled to the rigid section **482**. When used, the cover **486** can withdraw the proximal and distal capturing portion **226 260** within the loading tube **486**. The loading tube **486** then couples to a microcatheter allowing the capturing portions to advance therein as the rigid section **482** and frictional coupler **484** advance the device **400** relative to the loading tube **486**.

[0106] Figs. 9A to 9C show cross sectional views taken along the line 9A-9A in Fig. 2A. As shown, the wire form construction described herein allows for a number of configurations depending on the particular application. For example, the individual wires **254** (as discussed herein) may themselves comprise a bundle of smaller wires or filaments. In addition, the wires can be selected from materials such as stainless steel, titanium, platinum, gold, iridium, tantalum, Nitinol, alloys, and/or polymeric strands. In addition, the wires used in a device may comprise a heterogeneous structure by using combinations of wires of different materials to produce a device having the particular desired properties. For example, one or more wires in the device may comprise a shape memory or superelastic alloy to impart predetermined shapes or resiliency to the device. In some variations, the mechanical properties of select wires can be altered. In such a case, the select wires can be treated to alter properties including: brittleness, ductility, elasticity, hardness, malleability, plasticity, strength, and toughness.

[0107] The device may include a number of radiopaque wires, such as gold and platinum for improved visibility under fluoroscopic imaging. In other words, any combination of materials may be incorporated into the device. In addition to the materials, the size of the wires may vary as needed. For example, the diameters of the wires may be the same or may vary as needed.

[0108] In addition, the individual wires may have cross-sectional shapes ranging from circular, oval, d-shaped, rectangular shape, etc. Fig. 9A illustrates one possible variation in which a number of circular wires **254** are included around another larger wire **256**. Moreover, the device is not limited to having wires having the same cross-sectional shape or size. Instead, the device can have wires having different cross-sectional shapes. For example, as shown in Fig. 9B, one or more wires **256** can have a different cross-sectional shape or size

than a reminder of the wires **254**. Clearly, any number of variations is within the scope of this disclosure. This construction can apply to the retrieval portion, capturing portion and/or the covering portion of the device.

[0109] To illustrate one such example, a device can have 8-12 wires made of .003" round superelastic material (e.g., Nitinol). The device may additionally have 2-4 wires made from .002" platinum for fluoroscopy. Of the 8-12 Nitinol wires, 1-4 of these wires can be made of a larger diameter or different cross-section to increase the overall strength of the device. Finally, a couple of polymer fibers can be added where the fibers have a desired surface property for clot adherence, etc. Such a combination of wires provides a composite device with properties not conventionally possible in view of other formation means (such as laser cutting or etching the shape from a tube or joining materials with welds, etc.). Clearly, any number of permutations is possible given the principles of the invention.

[0110] In another example, the device may be fabricated from wires formed from a polymeric material or composite blend of polymeric materials. The polymeric composite can be selected such that it is very floppy until it is exposed to either the body fluids and or some other delivered activator that causes the polymer to further polymerize or stiffen for strength. Various coatings could protect the polymer from further polymerizing before the device is properly placed. The coatings could provide a specific duration for placement (e.g., 5 minutes) after which the covering degrades or is activated with an agent (that doesn't affect the surrounding tissues) allowing the device to increase in stiffness so that it doesn't stretch as the thrombus is pulled out. For example, shape memory polymers would allow the device to increase in stiffness.

[0111] In another variation, one or more of the wires used in the device may comprise a Drawn Filled Tube (DFT) such as those provided by Fort Wayne Metals, Fort Wayne, Indiana. As shown in Fig. 9C, such a DFT wire **252** comprises a first material or shell **258** over a second material **260** having properties different from the outer shell. While a variety of materials can be used, one variation under the present devices includes a DFT wire having a superelastic (e.g., Nitinol) outer tube with a radiopaque material within the super-elastic outer shell. For example, the radiopaque material can include any commercially used radiopaque material, including but not limited to platinum, iridium, gold, tantalum, or similar alloy. One benefit of making a capturing portion from the DFT wire noted above, is that rather than having one or more markers over the capturing portion, the entire capturing portion can be fabricated from a super-elastic material while, at the same time, the super-elastic capturing portion is made radiopaque given the core of radiopaque material within the super-elastic

shell. Clearly, any composite DFT wire 252 can be incorporated into the system and capturing portions described herein.

[0112] Another aspect applicable to all variations of the devices is to configure the devices or portions thereof that engage the obstruction to improve adherence to the obstruction. One such mode includes the use of coatings that bond to certain clots (or other materials causing the obstruction.) For example, the wires may be coated with a hydrogel or adhesive that bonds to a thrombus. Accordingly, as the device secures about a clot, the combination of the additive and the mechanical structure of the device may improve the effectiveness of the device in removing the obstruction. Coatings may also be combined with the capturing portions or catheter to improve the ability of the device to encapsulate and remove the obstruction (e.g., a hydrophilic coating).

[0113] Such improvements may also be mechanical or structural. Any portion of the capturing portion can have hooks, fibers, or barbs that grip into the obstruction as the device surrounds the obstruction. The hooks, fibers, or barbs 370 can be incorporated into any portion of the device. However, it will be important that such features do not hinder the ability of the practitioner to remove the device from the body.

[0114] In addition to additives, the device can be coupled to an RF or other power source (such as 14 or 16 in Fig. 1), to allow current, ultrasound or RF energy to transmit through the device and induce clotting or cause additional coagulation of a clot or other the obstruction.

[0115] Figs. 10A to 10E illustrate additional variations of covers 300 for use as described above. For example, as show in Fig. 10A, a cover 300 can comprise a single wire, coil, or laser cut tube 350. Alternatively, as shown in Fig. 10B, the cover 300 can comprises two or more 350, 352 wires or coils. Fig. 10C shows a cover 300 comprising a coil 350 inside a mesh structure 354. A variation of the device shown in Fig. 10C can include a compliant atraumatic mesh 354 that is radially supported by the coil (whether interior or exterior to the mesh). The coil 350 provides the outward force against the vessel. Fig. 10D illustrates a polymeric film or membrane 356 coupled to a coil 350. The polymeric film 356 can be permeable to fluid flow or impermeable. Fig. 10E illustrates a dual layer braid construction having an inner braid 358 and an outer braid 360. The braids can be constructed to have unique properties. For example, the inner braid 358 can be composed of fewer wires or larger diameter wires, such that it provides an expansion force against the vessel wall. The outer braid 360 can comprise a softer construction and increased compliance. Accordingly, it can be comprised of a number of smaller diameter wires having a denser pattern to provide increased surface area to protect the obstruction as it is removed from the body. Alternatively,

these two constructional elements (e.g., braids of varying diameters) can be combined into a single layer or even multiple layers for the cover.

[0116] Fig. 11A illustrates yet another variation of a device 100 having a retrieval structure 200 and cover 300 where the cover is simply fabricated from the same material as the retrieval structure so long as it functions as described herein. The variation can optionally include one or more barbs 370 to increase resistance against a vessel wall.

[0117] Fig. 11B and 11C illustrate a variation where the cover 300 comprises a balloon material. Fig. 11B illustrates the balloon cover 370 prior to deployment. Fig. 11C illustrates the balloon cover 370 once deployed.

[0118] The retrieval devices described herein can optionally comprise elongated stents 400 as shown in Figs. 12A to 12E. These stents 400 can include any number of features to better assist the stent 400 in becoming enmeshed into the obstruction. For example, Fig. 12A illustrates a variation of a stent 400 affixed to a shaft 412. As noted herein, the shaft 412 can include a lumen extending therethrough. Alternatively, the shaft 412 can include a solid member with the stent 400 affixed to a distal end thereof. The variation shown in Fig. 12A includes a stent where a distal end 414 that is “closed off” by intersecting elements or wires 402 403. Accordingly, any of the variations of the stents disclosed herein can include an open lumen type stent or a closed lumen type stent as shown in Fig. 12A. As noted herein, the wires forming the stent 400 can comprise a single wire that is wound from a first direction (e.g., from proximal to distal) and then wound back in a second direction (e.g., from distal to proximal).

[0119] Fig. 12A also illustrates a stent 400 comprised of twisted wires 402 or elements. For example, Fig. 12B shows a magnified view of the section 12B in Fig. 12A. As illustrated, the elements 402 403 are twisted to increase the surface area at the exterior perimeter of the stent 400. The twisting or spiraling of the elements 402 403 creates additional surface area to increase the ability of the stent 400 to capture debris, thrombus, foreign body, etc. as the stent is expanded against the debris. The twisting elements 402 403 can twist along the entire length of the stent 400 or along one or more portions of the stent. In certain variations, the twisting of the elements 402 403 is sufficiently loose such that as the stent expands into a clot or obstruction, the twisted pairs slightly separate to allow material to become trapped between the elements making up the pairs. The construction shown in Figs. 12A and 12B also provide an additional benefit to a retrieval stent. In the illustrated variation, the twisted or spiraling elements interlock with crossing elements to form intersections 405 that provided added radial expansive force. As shown, a first twisted element 407 passes in between elements 402 403 of

an intersecting element 409. When in an expanded state, the element on the interior of the intersection 405 (in this case element 403) provides an added outward radial force against the intersection 405. However, since the elements are not affixed but instead are slidable at the intersection 405, the force required to linearize and compress the stent 400 is reduced due to the fact that the intersections are not affixed but slidable over the adjacent elements. This reduced linearization force allows the stent to be compressed to a small diameter for positioning within a microcatheter but allow for a significant radial expansive force once removed from the microcatheter. This design allows for a reduction in radial force of the stent against the vessel wall when the stent is pulled and removed from the vessel. However, this design also provides a high degree of radial force due to the interweaving of elements when the stent is deployed in the vessel prior to withdrawal of the stent.

[0120] Figs. 12C to 12F illustrate another variation of types of stents 400 that have an irregular surface at an exterior of the stent 400 that is formed by an intersection of elements 402 403. The intersection or crossing of the elements forms a type of barb or knuckle 416 that creates an irregular surface on the exterior of the stent 400. Fig. 12C illustrates a variation of a stent 400 having a plurality of knuckles 52 that are radially spaced about an axis 390 of the stent 400. Fig. 12E shows another variation of a stent 400 with knuckles 416 aligned with an axis 390 of the stent 400 as shown in Fig. 12D. Although the figures show the axial and radial aligned knuckles 416 on separate devices, both types of knuckles 416 can be incorporated into a single stent structure. Varying the alignment of knuckles can permit increased radial force as the stent expands into the obstruction or increased flexibility as the stent navigates through tortuous anatomy.

[0121] Fig. 12G illustrates a proximal end of the stent structure 400 as shown, a plurality of elements 402 and 403 extend along the shaft 412 and diverge to form the fluid permeable closed proximal end of the stent structure 400. The elements 402 and 403 that extend along the shaft 412 can be covered by a sheath, tube, spiral cut tube, or any structure 418 that prevents separation of the elements 402 403. A variation of the stent structure 402 includes a construction where the elements 402 403 are not glued, welded, or have any similar type of joint in the distal portion 420 of the shaft 412. Instead, the joint 411 is located proximal to the distal section of the shaft 412 in an intermediate section 422. Because joints or other similar features reduce flexibility of the joined structure, positioning the joints 411 in a proximal area allows the the distal portion 420 of the shaft to remain flexible.

[0122] The methods described herein may also include treating the obstruction prior to attempting to remove the obstruction. Such a treatment can include applying a chemical or

pharmaceutical agent with the goal of making the occlusion shrink or to make it more rigid for easier removal. Such agents include, but are not limited to chemotherapy drugs, or solutions, a mild formalin, or aldehyde solution.

[0123] As for other details of the present invention, materials and manufacturing techniques may be employed as within the level of those with skill in the relevant art. The same may hold true with respect to method-based aspects of the invention in terms of additional acts that are commonly or logically employed. In addition, though the invention has been described in reference to several examples, optionally incorporating various features, the invention is not to be limited to that which is described or indicated as contemplated with respect to each variation of the invention.

[0124] Various changes may be made to the invention described and equivalents (whether recited herein or not included for the sake of some brevity) may be substituted without departing from the true spirit and scope of the invention. Also, any optional feature of the inventive variations may be set forth and claimed independently, or in combination with any one or more of the features described herein. Accordingly, the invention contemplates combinations of various aspects of the embodiments or combinations of the embodiments themselves, where possible. Reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in the appended claims, the singular forms “a,” “and,” “said,” and “the” include plural references unless the context clearly dictates otherwise.

[0125] It is important to note that where possible, aspects of the various described embodiments, or the embodiments themselves can be combined. Where such combinations are intended to be within the scope of this disclosure.

CLAIMS

We claim

1. An interventional medical device for retrieving and securing an obstruction within a vessel lumen, the device comprising:
 - a shaft having a flexibility to navigate through tortuous anatomy, the shaft a distal portion and a proximal portion;
 - a capturing structure located at a distal portion of the shaft comprising a plurality of struts, the capturing structure having a reduced profile for positioning in or adjacent to the obstruction and an expanded profile, such that when expanded into the obstruction, the struts at least partially enmesh with the obstruction such that subsequent movement of the capturing structure permits dislocation of at least a portion of the obstruction from the lumen;
 - an eversible cover having a fixed section affixed relative to a proximal end of the capturing structure, a free section extending in a proximal direction from the fixed section and a cover wall extending from the fixed section to the free section, where the eversible cover is expandable, the eversible cover being axially compliant such that when the shaft is moved proximally within the lumen, the eversible cover everts over the capturing structure allowing for the free section of the cover to be distal to the fixed end of the capturing portion.
2. The medical device of claim 1, where the eversible cover, capturing structure, and shaft are a unitary structure.
3. The medical device of claim 1, where each wire located at an end of the free section loops back to the cover causing the wires at the end of the free section to be continuous.
4. The medical device of claim 1, where at least a portion of the cover wall adjacent to the distal end has a set shape that is everted upon expansion.
5. The medical device of claim 1, further comprising a catheter body, where in a delivery configuration, the shaft, capturing structure and eversible cover are located within the catheter body and where the capturing structure is advanceable in and out of a distal end of the catheter body.

6. The medical device of claim 1, where the eversible cover comprises a plurality of layers forming the cover wall.
7. The medical device of claim 1, where the free section of the eversible cover partially restricts about the shaft without being attached to the shaft.
8. The medical device of claim 1, where a portion of the cover wall extends distally beyond the fixed section when the eversible cover is expanded.
9. The medical device of claim 1, where the fixed section of the eversible cover comprises a pre-set shape to reduce a force required to evert the evertable cover.
10. The medical device of claim 1, where the cover wall is layered in an undulating pattern upon deployment.
11. The medical device of claim 1, where the capturing structure comprises an elongated stent structure.
12. The medical device of claim 1, where the capturing structure comprises a device selected from a group consisting of a filter, an artherectomy device, a rotational cutter, an aspiration device, stent based retrievers and retrieval baskets.
13. The medical device of claim 1, where the cover is self expanding.
14. The medical device of claim 1, where a portion of the cover at or adjacent to the distal opening comprises a bulbous shape.
15. The medical device of claim 1, where the cover comprises a first porous section having a first porosity and at least a second porous section having a second porosity, where the first and second porosity are different such that the ability of fluid to flow through the first porous section and second porous section differs.
16. The medical device of claim 15, where the first porous section comprises a first braid density and the second porous section comprises a second braid density.
17. The medical device of claim 15, where the first porous section comprises an additional braid layer.

18. The medical device of claim 15, where the first porous section prevents fluid from flowing therethrough.
19. The medical device of claim 15, where the first porous section is distal to the second porous section and where the first porosity is greater than the second porosity.
20. The medical device of claim 15, where the first porous section comprises a circumferential area of the cover.
21. The medical device of claim 1, further comprising at least one polymeric layer on or adjacent to a region of the cover.
22. The medical device of claim 21, further comprising at least one medicament on or in the polymeric layer.
23. The medical device of claim 1, further comprising at least one radiopaque marker on a distal end of the shaft.
24. The medical device of claim 1, where the cover comprises a mesh material
25. The medical device of claim 24, where the mesh material comprises a single continuous wire.
26. The medical device of claim 24, where at least a portion of the mesh material is fabricated from a drawn filled tube material.
27. The medical device of claim 24, where at least a portion of the mesh material is fabricated from a radiopaque material.
28. The medical device of claim 1, where the eversible cover comprises at least one wire coiled such that turns of the coil form the cover wall.
29. The medical device of claim 28, where the cover further comprises a braid adjacent to the coil.
30. The medical device of claim 28, where the cover further comprises a film coupled to the coil.

31. The medical device of claim 1, where the eversible cover comprises at least one barb or knuckle at an exterior surface of the cover wall.
32. The medical device of claim 1, where the eversible cover comprises an inner braided layer and an outer braided layer, where the outer braided layer is relatively more compliant than the inner braided layer.
33. A method of securing an obstruction within a vessel, the method comprising:
 positioning a catheter within a vessel;
 advancing a shaft having a retrieval device affixed thereto out of the catheter;
 advancing an eversible cover out of the catheter such that a fixed end of the eversible cover is adjacent to a proximal end of the retrieval device and a free end of the eversible cover is moveable relative to the shaft and retrieval device;
 expanding at least a portion of the eversible cover against a portion of a wall of the vessel;
 manipulating the retrieval device to become at least partially enmeshed with the obstruction; and
 proximally translating the shaft and retrieval device with at least a portion of the obstruction affixed thereto such that resistance of the eversible cover against the vessel resists movement of the eversible cover causing the free section of the eversible cover to evert over the proximally translated retrieval device.
34. The method of claim 33, further comprising further withdrawing the shaft from the vessel such that during withdrawal the eversible cover forms a protective barrier over the obstruction to lessen shearing forces caused by the vessel and reduce dislodging portions of the obstruction from the retrieval device.
35. A method of preparing a retrieval device comprising:
 providing a retrieval device *having been previously removed from a body of a patient* where the retrieval device includes a protective cover where a fixed end of the protective cover is affixed adjacent to a proximal end of the retrieval device and where a free end is located distally to the fixed end covering the retrieval device and is moveable relative to the second end;
 reversing the protective cover by moving the free end proximally of the fixed while the fixed end remains affixed adjacent to the proximal end of the retrieval device;

inserting the retrieval device and cover into a catheter where the free end of the cover is proximal to the fixed end of the cover and retrieval device such that upon deployment from the catheter, the free end of the cover deploys proximally to the fixed end of the cover.

36. A method of securing an obstruction within a vessel, the method comprising:
- advancing a shaft having a retrieval device affixed thereto to the obstruction;
 - advancing a protective device over the shaft, the protective device comprising a sheath having an eversible cover, where a fixed end of the eversible cover is affixed to a distal portion of the sheath and a free end of the eversible cover is located proximal to the fixed end;
 - positioning the fixed end of the eversible cover adjacent to the retrieval device and expanding at least a portion of the eversible cover against a portion of a wall of the vessel;
 - proximally translating the shaft and retrieval device with at least a portion of the obstruction affixed thereto such that resistance of the eversible cover against the vessel resists movement of the eversible cover causing the free section of the eversible cover to evert over the proximally translated retrieval device.
37. A medical device retrieval system for securing an obstruction within a vessel lumen and for use with a catheter configured to be navigated through the vasculature, the device comprising:
- an elongated stent comprising a plurality of struts, the stent being collapsible for positioning in the catheter during delivery and having an expanded profile such that when expanded the struts are configured to engage the obstruction;
 - a shaft fixedly attached to the elongated stent and having a flexibility to navigate through tortuous anatomy;
 - a fluid permeable cover having a distal end coupled to a proximal end of the elongated stent a cover wall defining a cavity and extending along the shaft, and a proximal end being moveable relative to the shaft, where the fluid permeable cover is collapsible for positioning in the catheter during delivery and is expandable upon deployment from the catheter such that a portion of the fluid permeable cover is expandable;
 - where the fluid permeable cover is axially pliable such that when the device is deployed in the vessel and frictional forces are applied against the fluid permeable cover, proximal movement of the shaft and elongated stent cause inversion of the fluid

permeable cover wall such that the fluid permeable cover wall everts over the elongated stent.

38. An interventional medical device for use with a catheter configured for delivery through vasculature and for securing an obstruction within a vessel lumen, the device comprising:
- a shaft having a flexibility to navigate through tortuous anatomy, the shaft having a distal portion and a proximal portion;

- a capturing device comprising a sidewall, the capturing device fixedly located at a distal portion of the shaft and having a reduced profile for positioning in the catheter and an expanded profile, such that upon deployment from the catheter, the capturing device expands to force a portion of the sidewall into the obstruction to at least partially attach to the obstruction;

- a cover having a distal end coupled adjacent to a proximal end of the capturing structure, a proximal end and a cover wall extending therebetween, where the proximal end of the cover is slidable relative to the distal end, where the cover is expandable such that when located in the catheter the cover is in a reduced delivery state and upon advancement from the catheter the cover expands with the proximal end located proximally of the distal end, where the cover wall is compliant such that when deployed from the catheter and the shaft is pulled in a proximal direction frictional forces between the vessel and the cover wall or proximal end cause the cover to invert as the cover wall inverts over the capturing device to surround the capturing device.

39. An interventional medical device for securing a retrieval device having one or more obstructions located therein for removal from a body, the medical device comprising:

- a sheath having a flexibility to navigate through tortuous anatomy, the sheath a distal portion and a proximal portion and a lumen extending therethrough;

- an eversible cover having a fixed section affixed to the distal portion of the sheath, a free section extending in a proximal direction from the fixed section and a cover wall extending from the fixed section to the free section, where the eversible cover is expandable, the eversible cover being axially compliant such that when the retrieval device is positioned through the sheath lumen and moved in a proximal direction against the eversible cover, the eversible cover everts over the retrieval device allowing for the free section of the cover to be distal to the retrieval device.

40. A stent retrieval device for expanding against one or more occlusive bodies in a vasculature, the stent retrieval device comprising:
- an elongate shaft having a flexibility to navigate through tortuous anatomy, the elongate shaft having a distal portion and a proximal portion;
 - a plurality of filaments that diverge from the distal portion of the elongate shaft to form an expandable elongated stent body having an open distal end and a fluid permeable closed proximal end and a cavity therebetween, where divergence of the filaments at the distal portion of the elongate shaft forms the fluid permeable closed proximal end;
 - where the plurality of filaments extending along the shaft are free of any connection joints in the distal portion to permit increased flexibility of the distal portion as it navigates through tortuous anatomy; and
 - one or more connection joints proximal to the distal portion where the connection joints secure the plurality of filaments to the shaft.
41. The stent retrieval device of claim 40, wherein at least one of the plurality of filaments comprise at least two wires twisted together, the elongated stent body further comprising at least one intersection of filaments, where the wires of each filament are interwoven to provide increased outward radial strength of the elongated stent body and such that the wires slide relative to each other as the elongated stent body expands or compresses in diameter to reduce a force required to linearize the elongated stent body.
42. The stent retrieval device of claim 40, where the exterior surface of the elongated stent body comprises an irregular surface formed by intersection of filaments.
43. The stent retrieval device of claim 42, where the intersection of filaments comprises a barb or knuckle and where a plurality of barbs or knuckles are radially spaced about the elongated stent body.
44. The stent retrieval device of claim 42, where the intersection of filaments comprises a barb or knuckle and where a plurality of barbs or knuckles are aligned with an axis of the elongated stent body.
45. The stent retrieval device of claim 42, where the elongated stent body comprises a plurality of barbs or knuckles radially spaced about the elongated stent body and a plurality of barbs or knuckles axially aligned with an axis of the elongated stent body.

46. The stent retrieval device of claim 40, where at least one filament comprises a drawn filled tube material.
47. The stent retrieval device of claim 40, where at least one filament comprises at least one wire comprised of a first material and at least a second wire comprised of at least a second material different from the first material.
48. The stent retrieval device of claim 40, where at least one filament comprises at least one wire comprised of a first material and at least a second filament having at least one wire comprised of at least a second material different from the first material.

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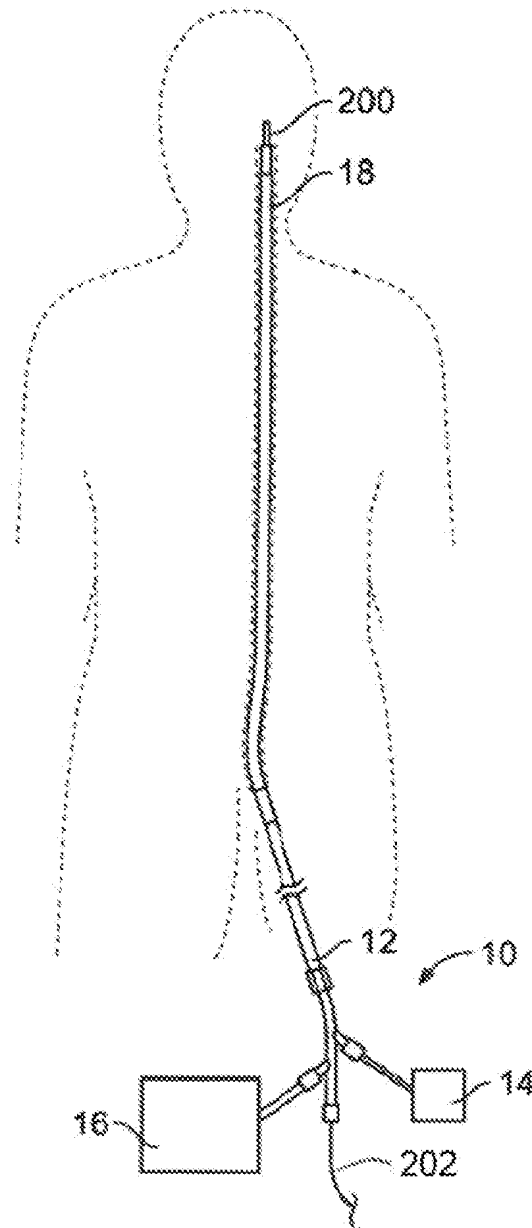


FIG. 1

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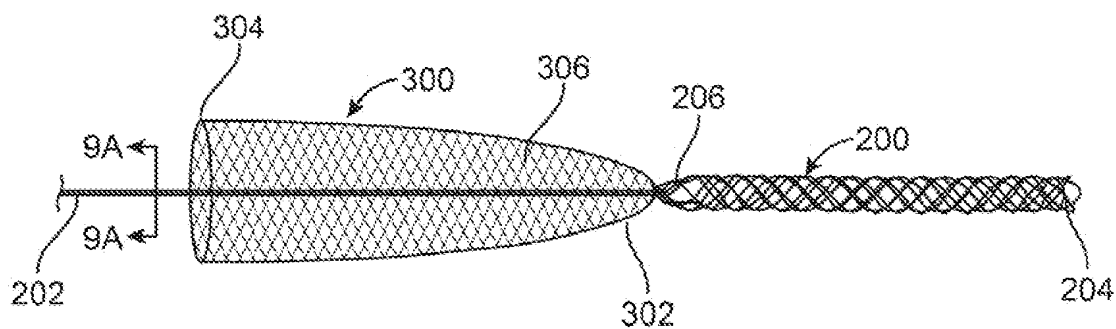


FIG. 2A

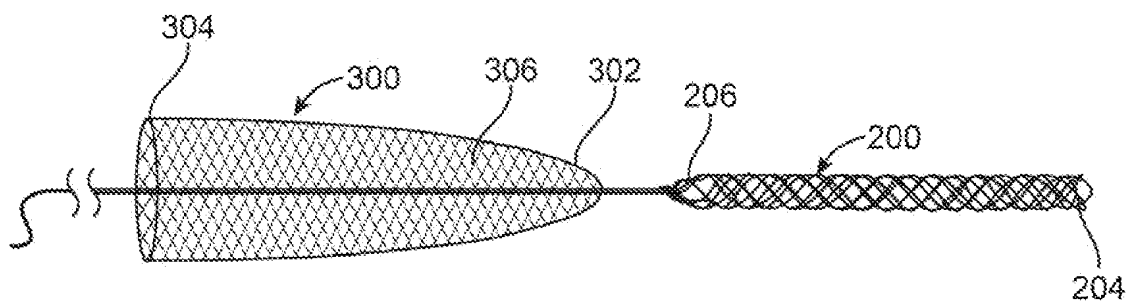


FIG. 2B

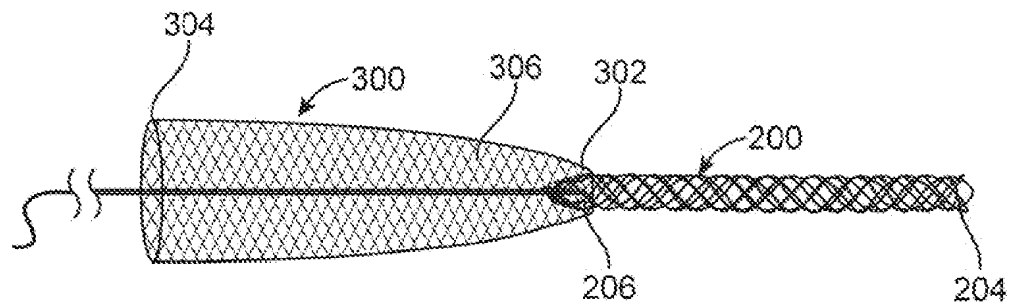


FIG. 2C

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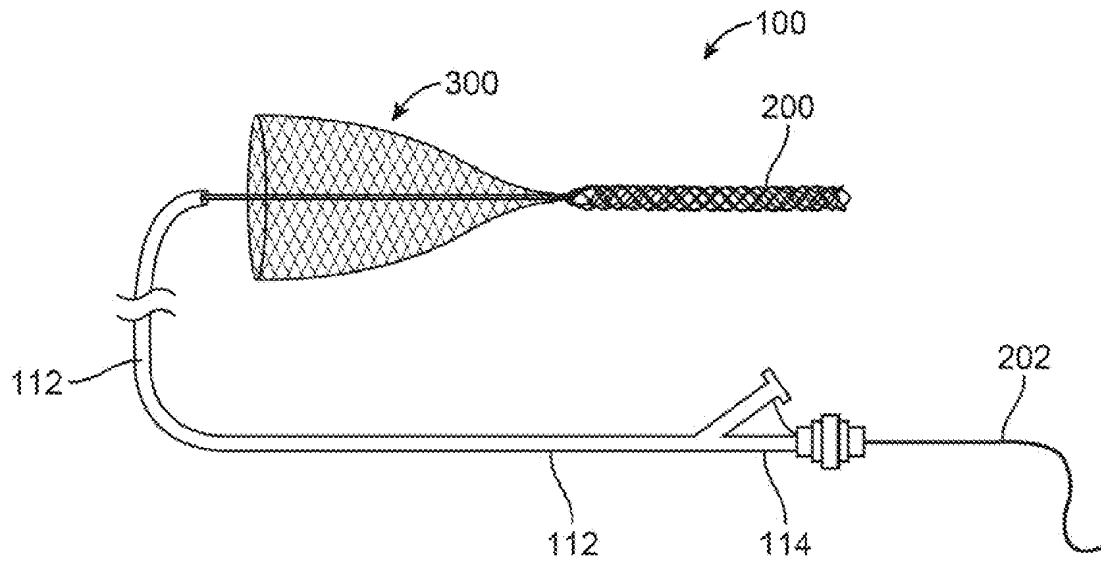


FIG. 2D

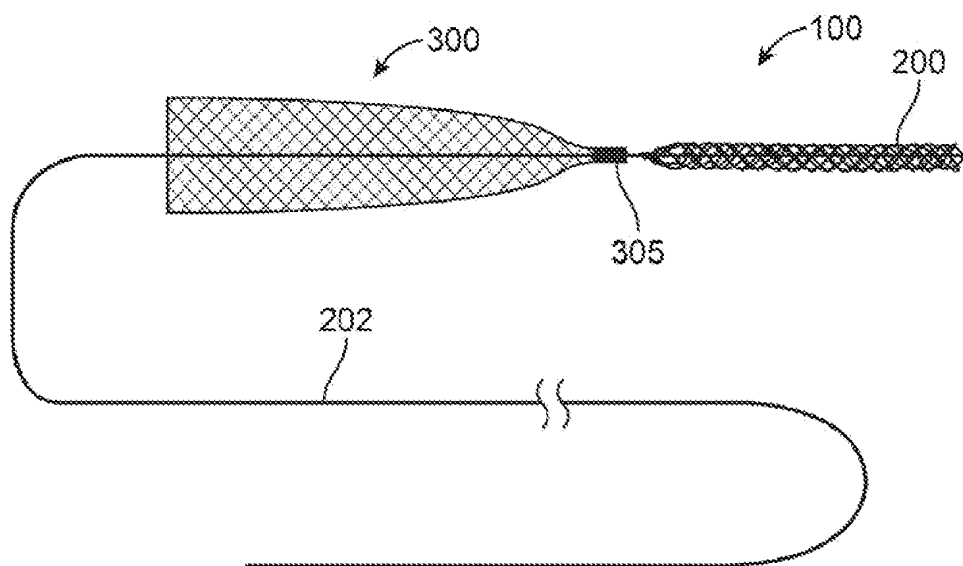


FIG. 2E

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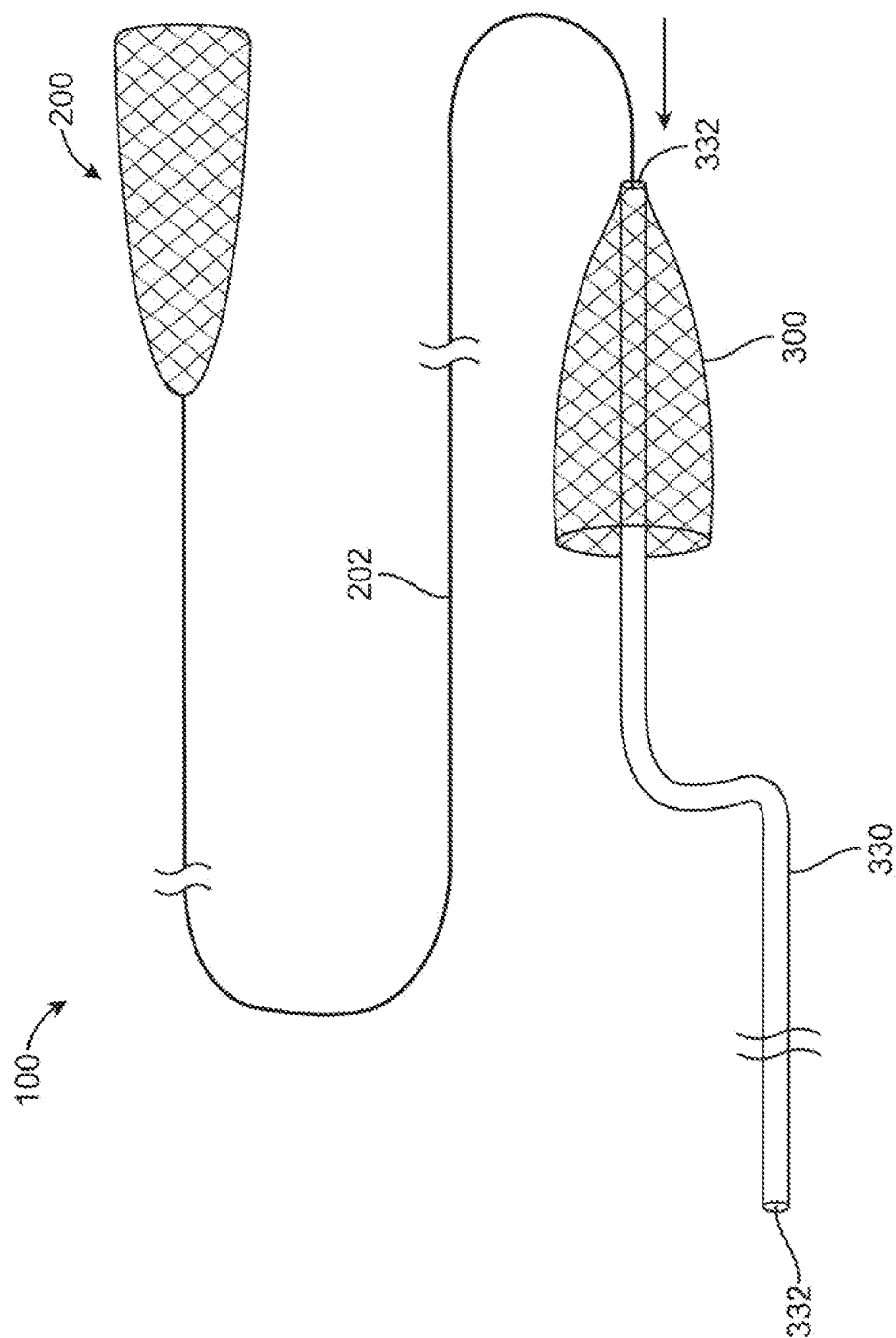


FIG. 2F

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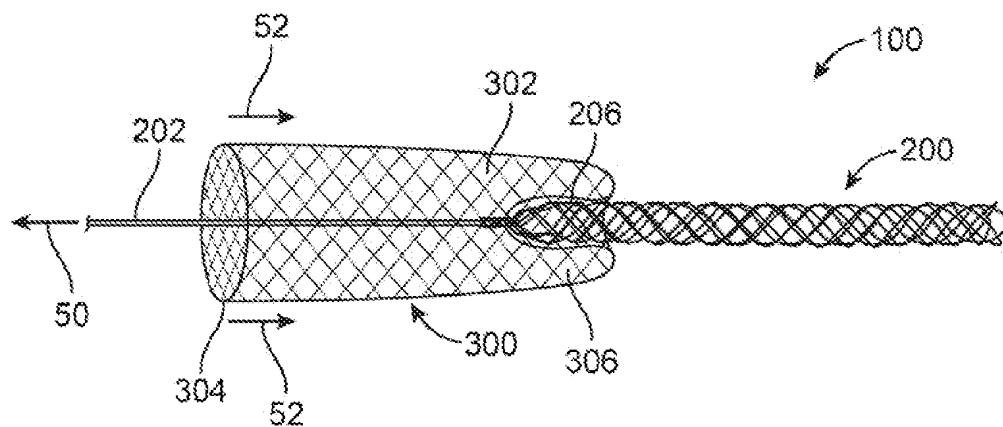


FIG. 3A

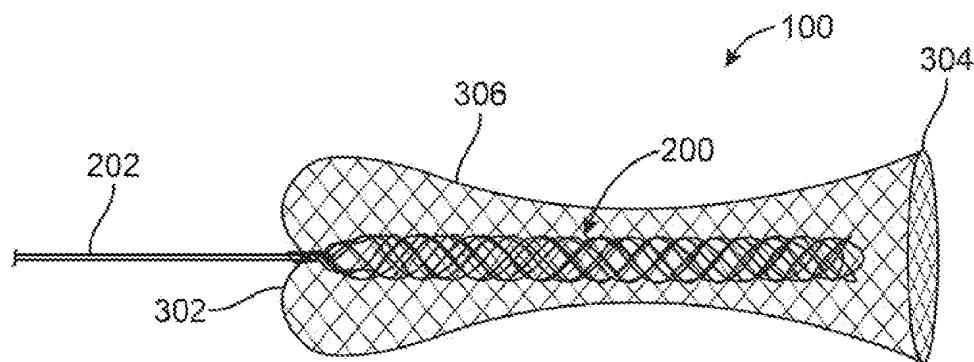


FIG. 3B

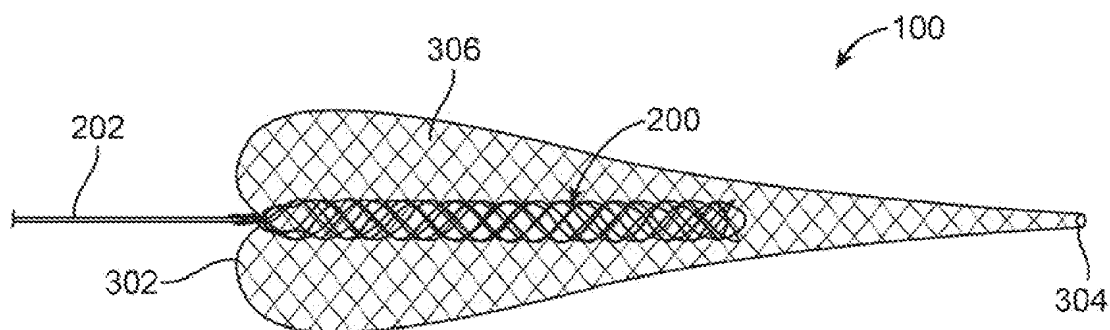


FIG. 3C

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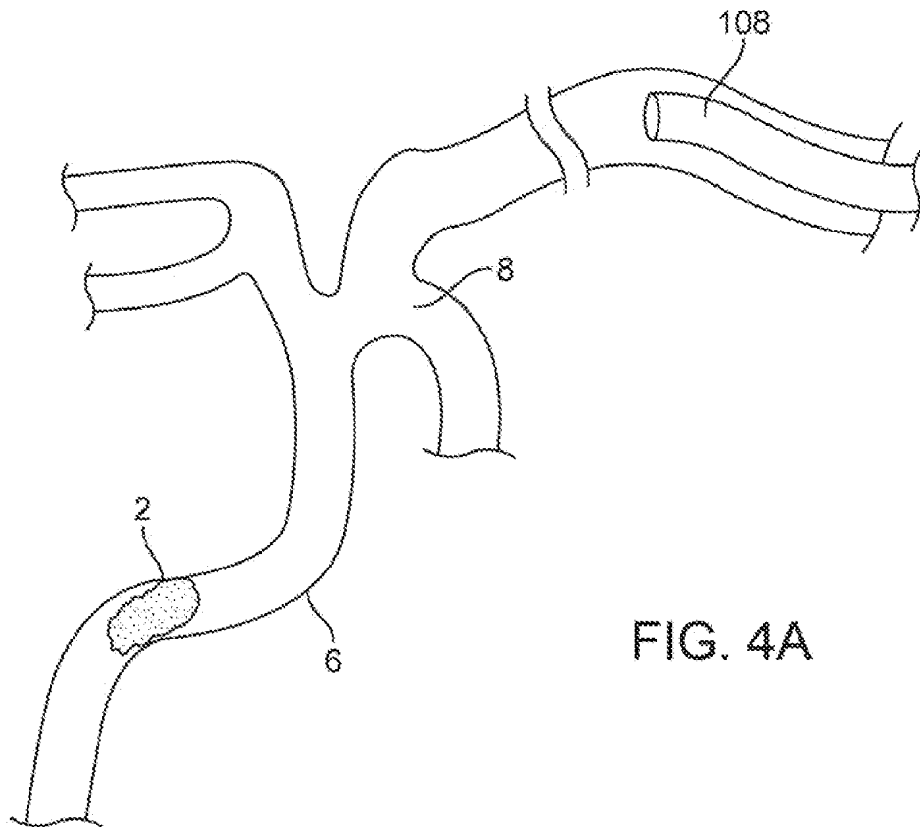


FIG. 4A

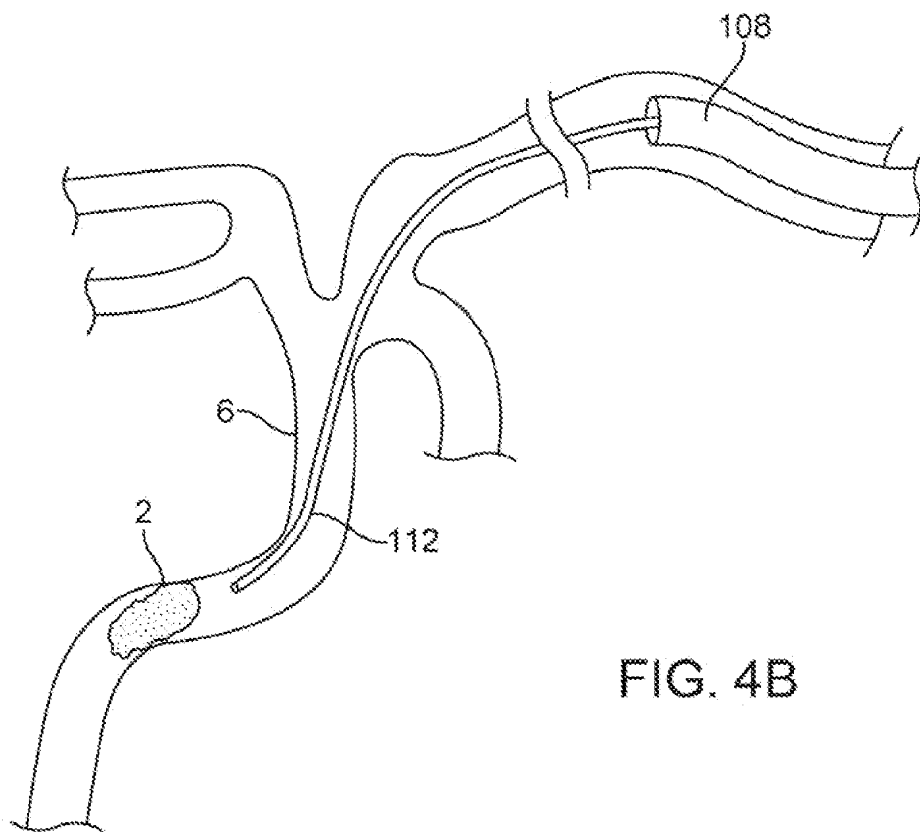
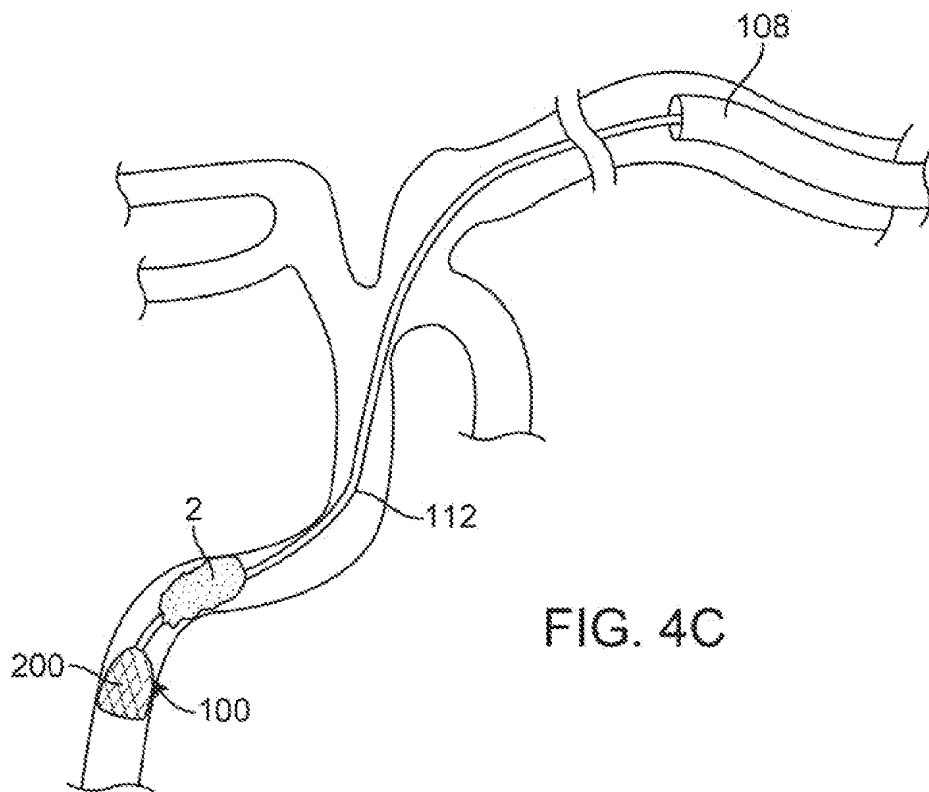
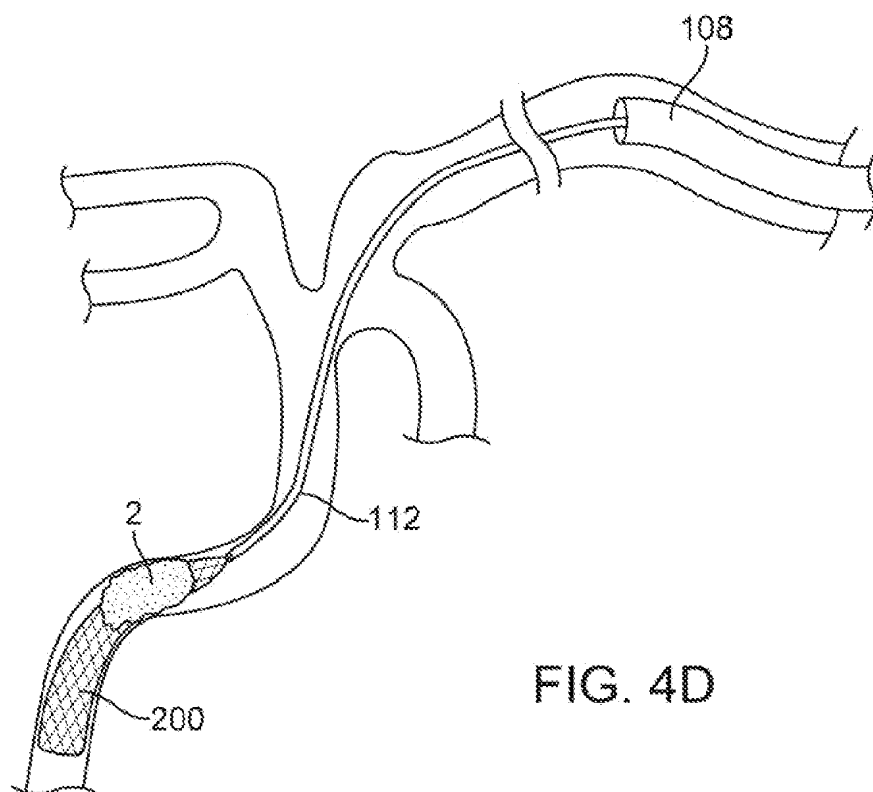


FIG. 4B

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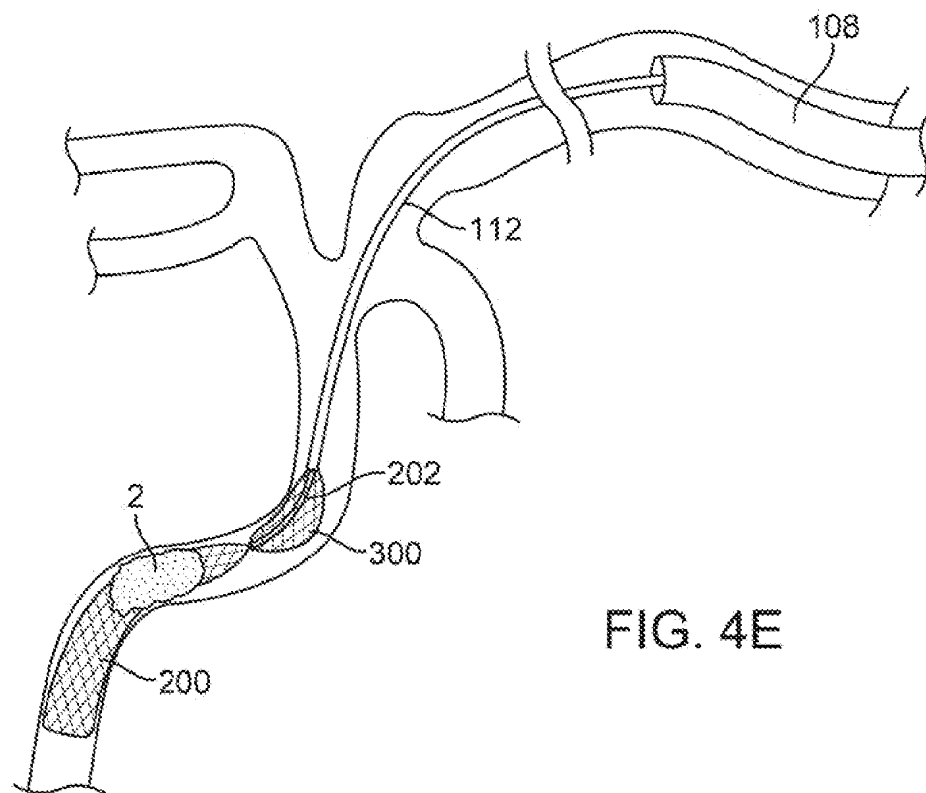


FIG. 4E

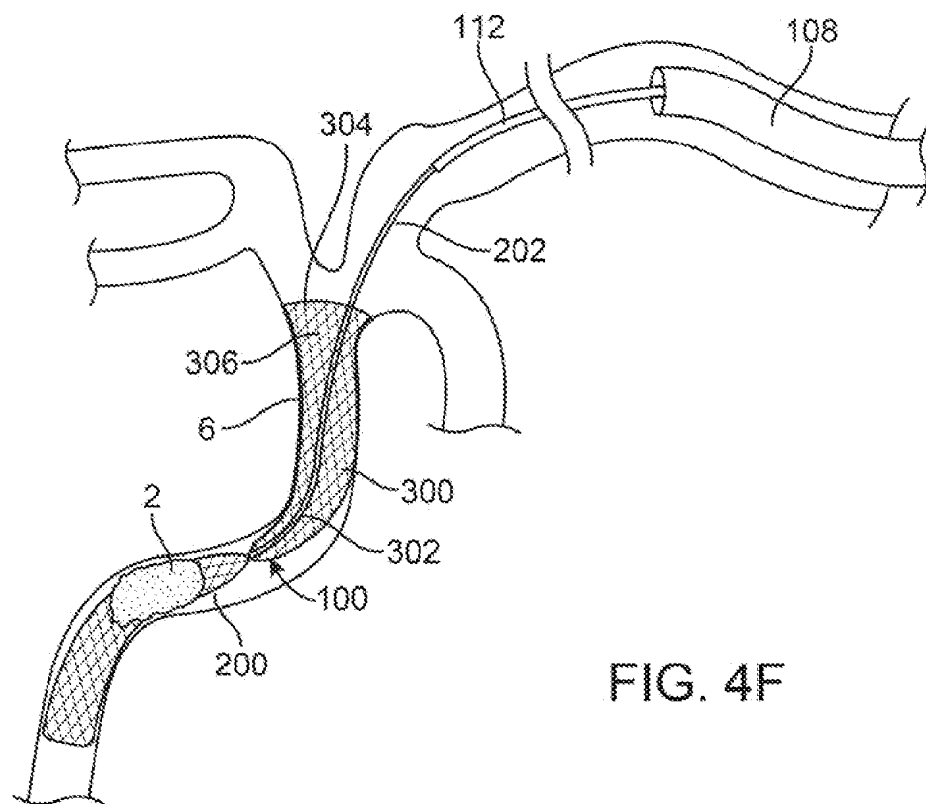


FIG. 4F

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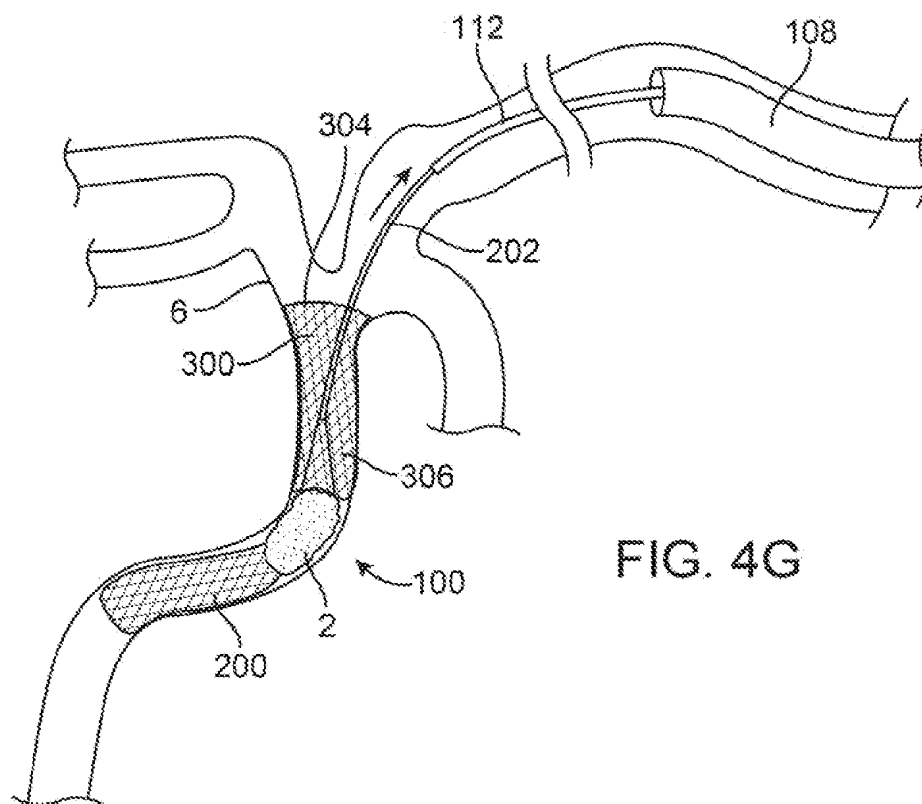


FIG. 4G

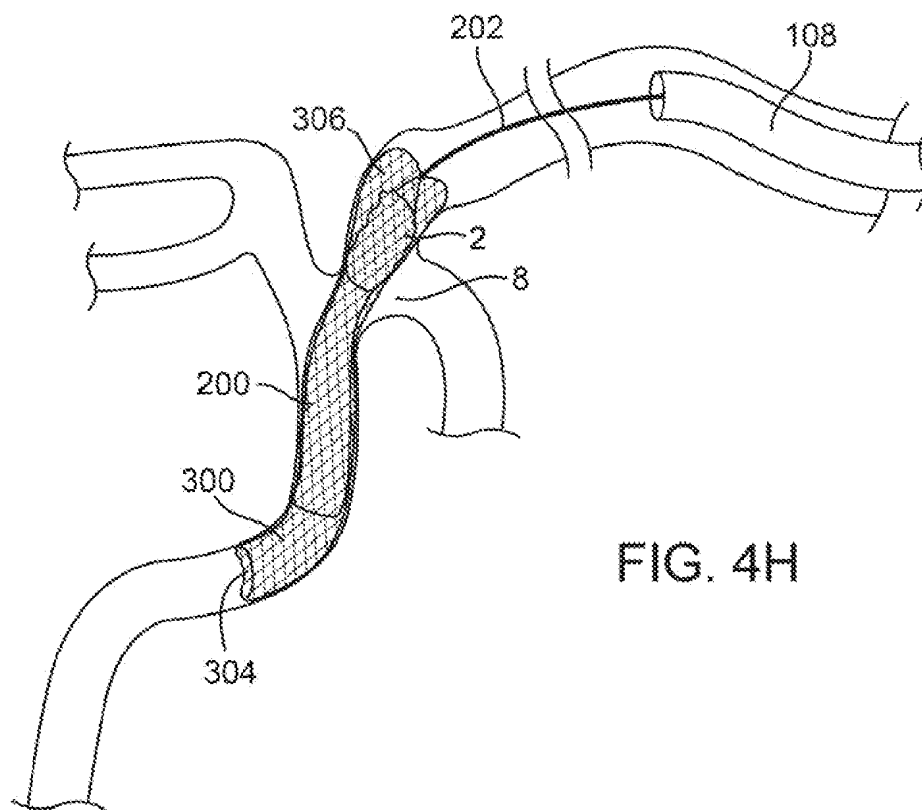
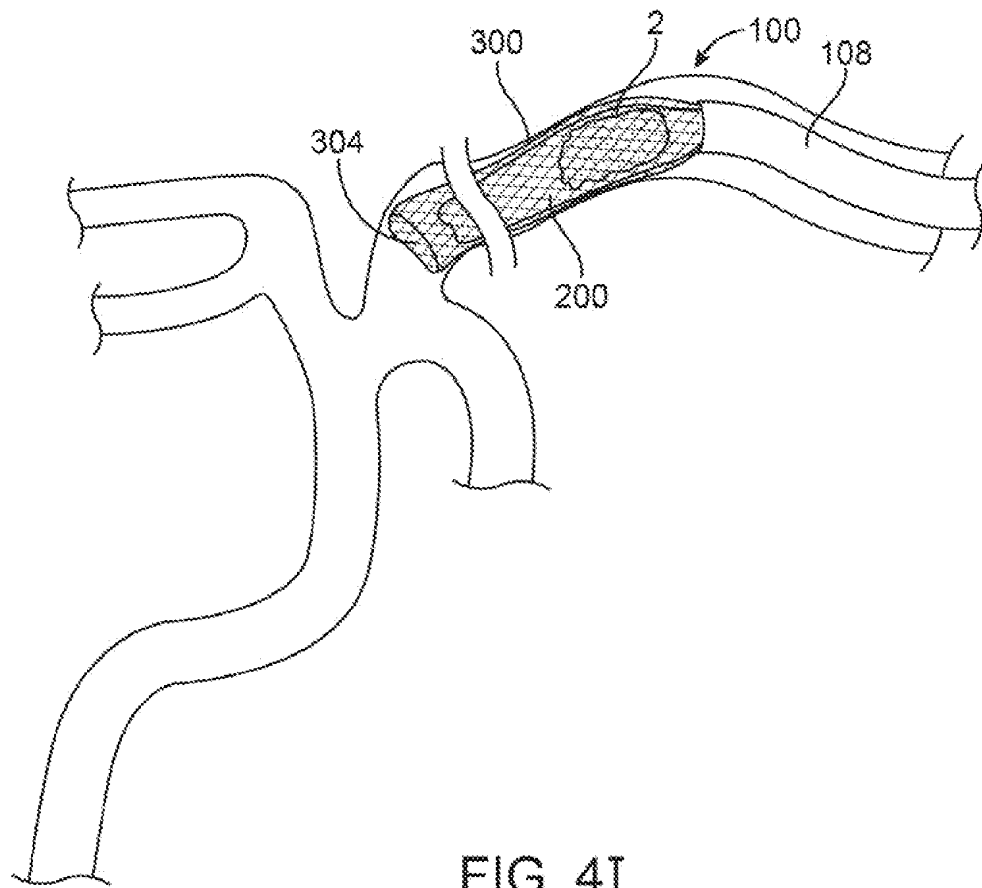


FIG. 4H

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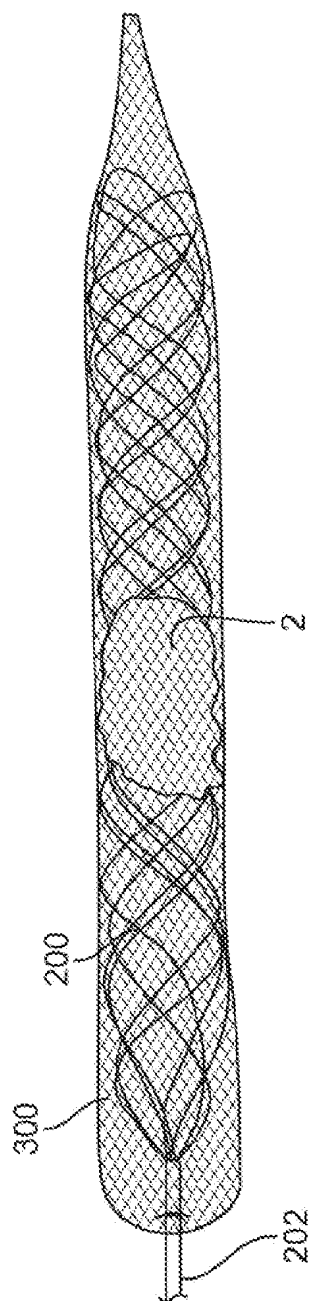


FIG. 4J

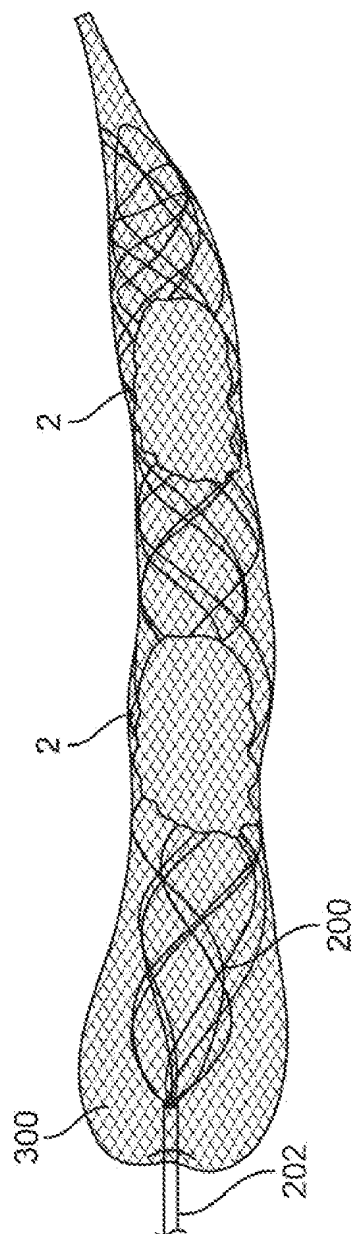


FIG. 4K

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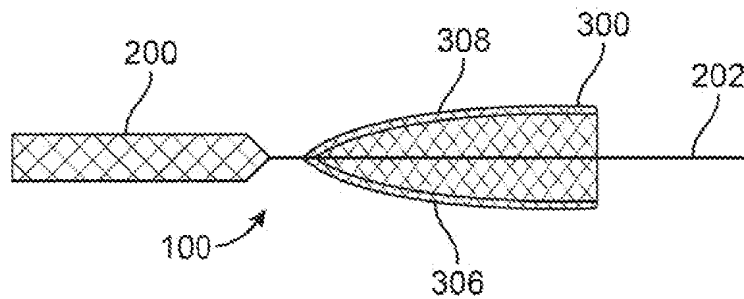


FIG. 5A

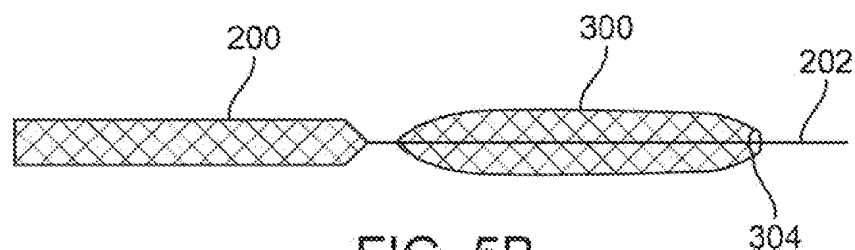


FIG. 5B

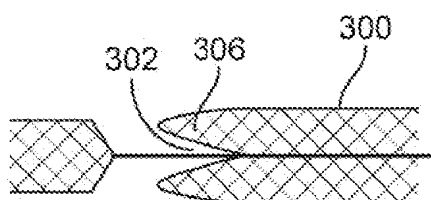


FIG. 5C

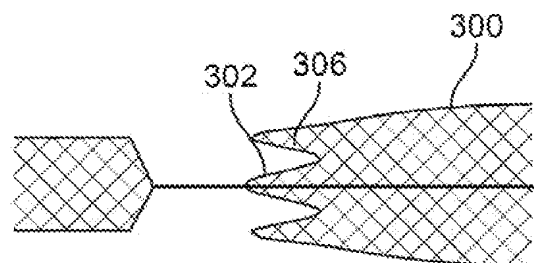


FIG. 5D

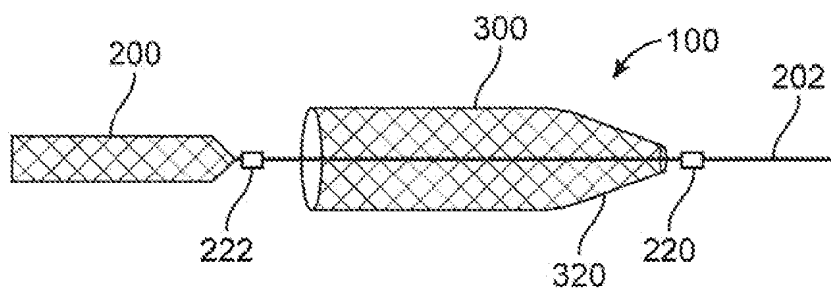


FIG. 5E

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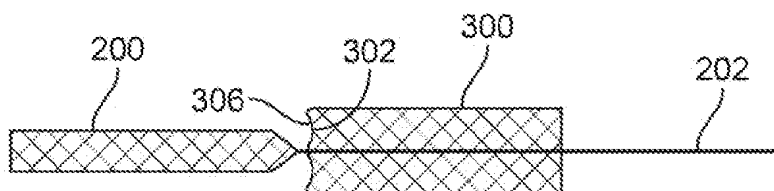


FIG. 5F

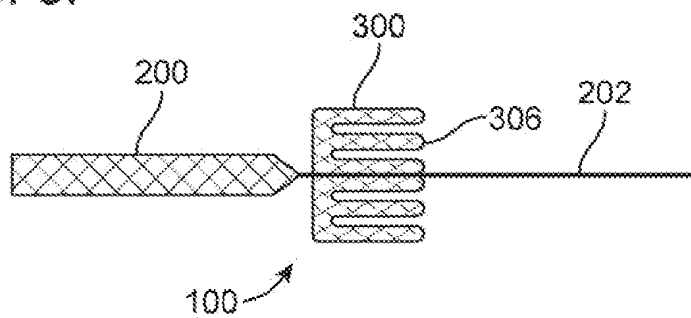


FIG. 5G

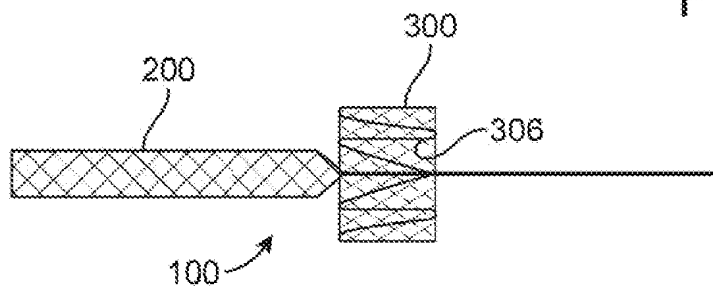


FIG. 5H

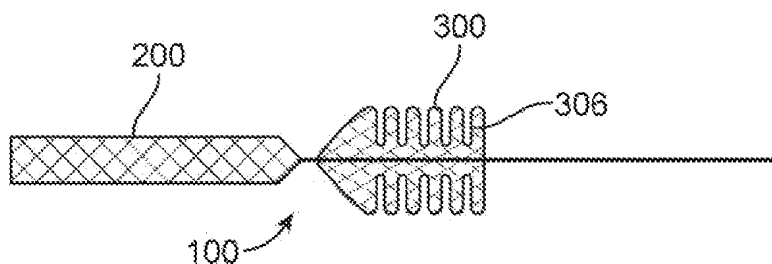


FIG. 5I

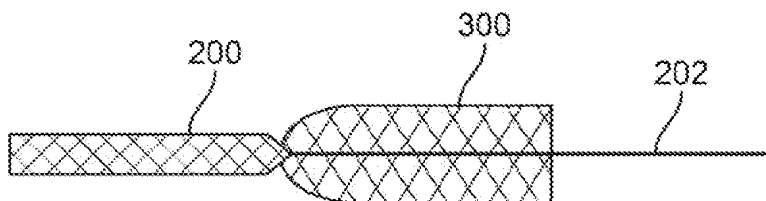


FIG. 5J

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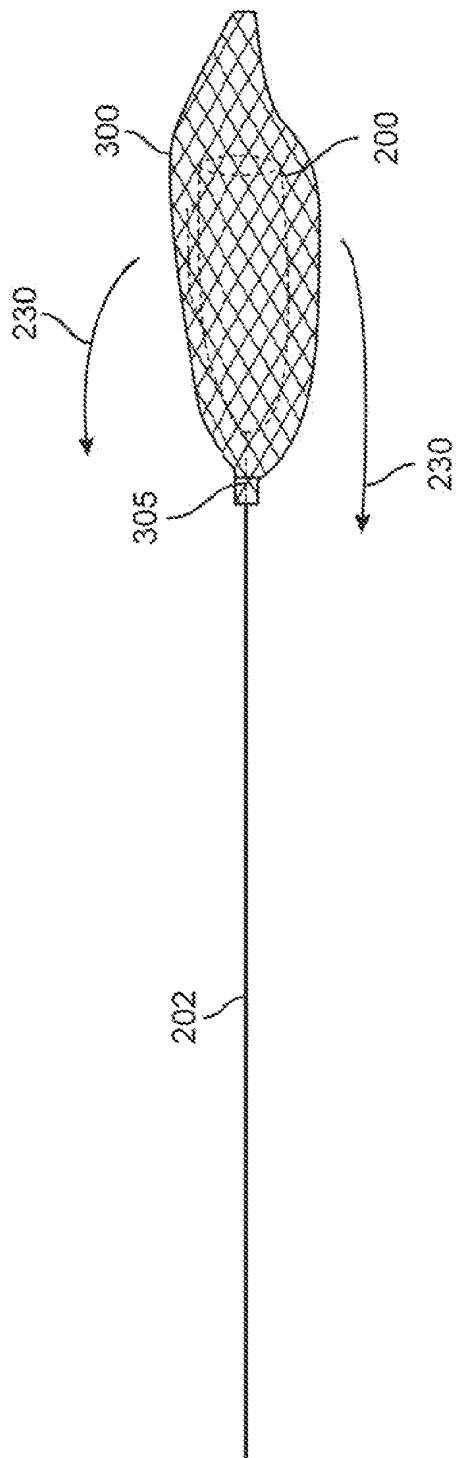


FIG. 5K

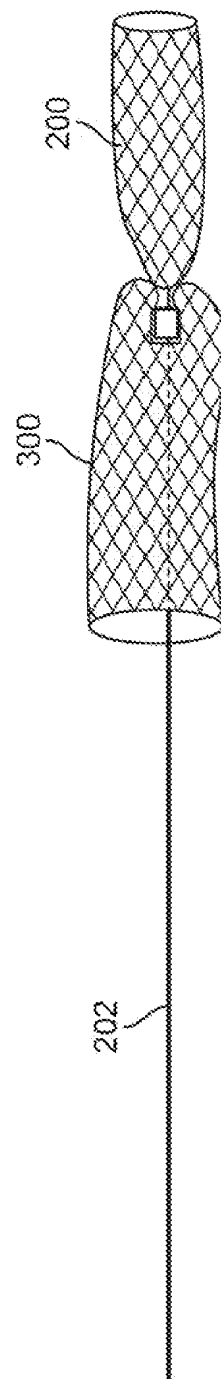


FIG. 5L

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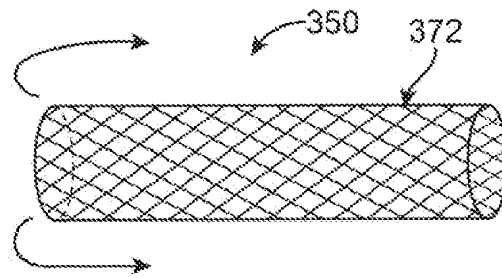


FIG. 6A

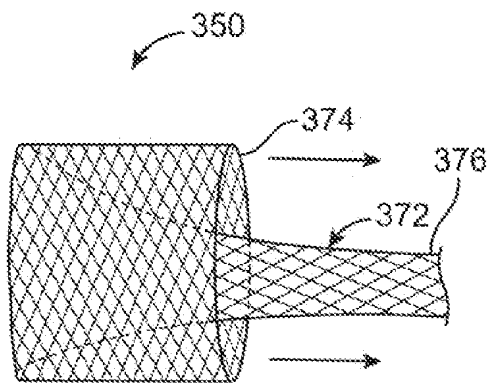


FIG. 6B

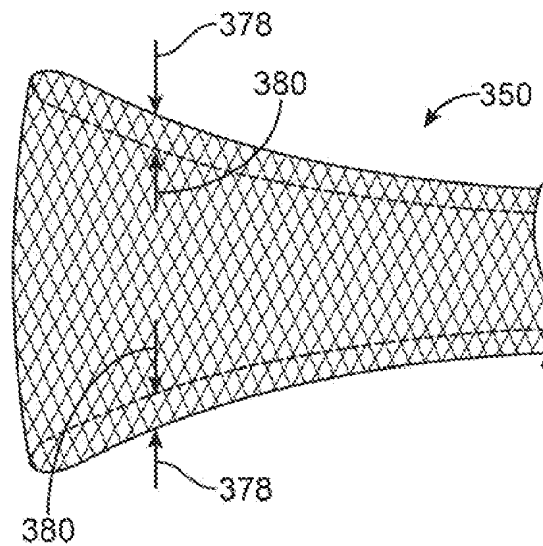
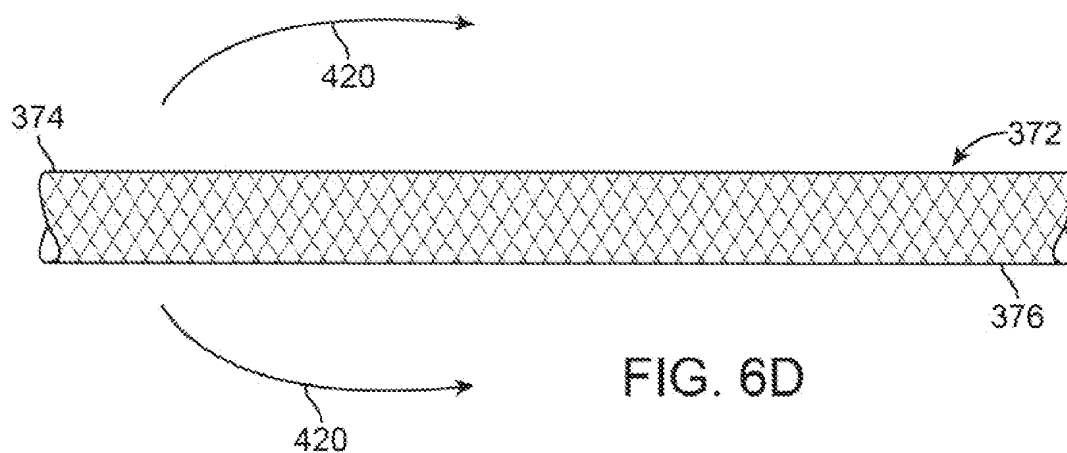
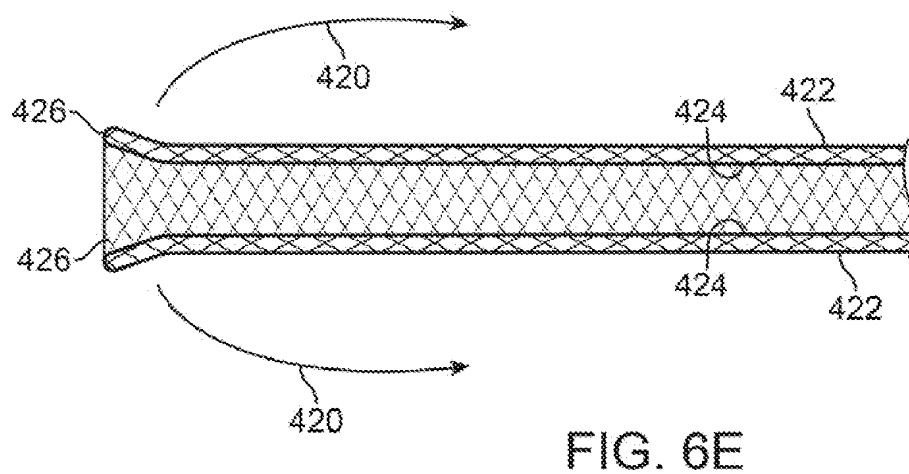
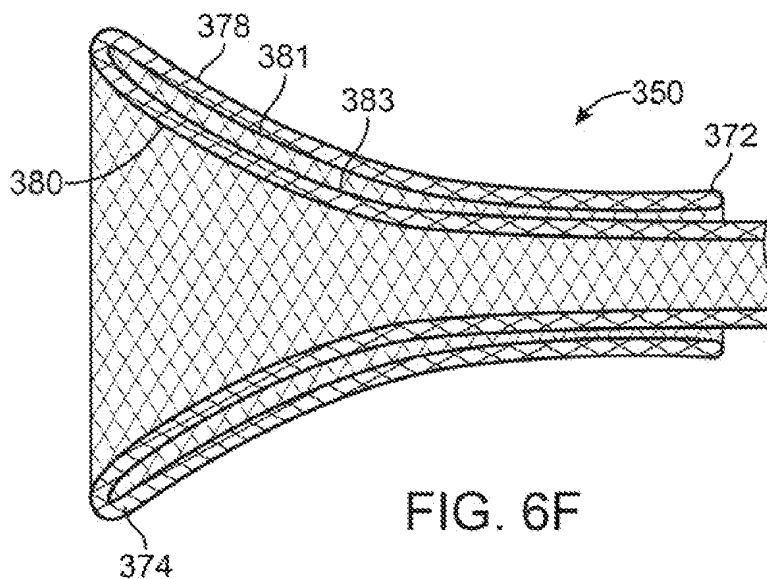


FIG. 6C

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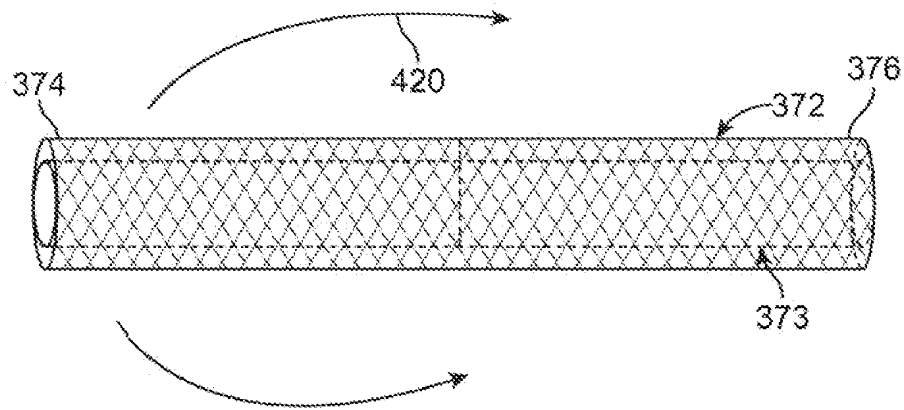


FIG. 6G

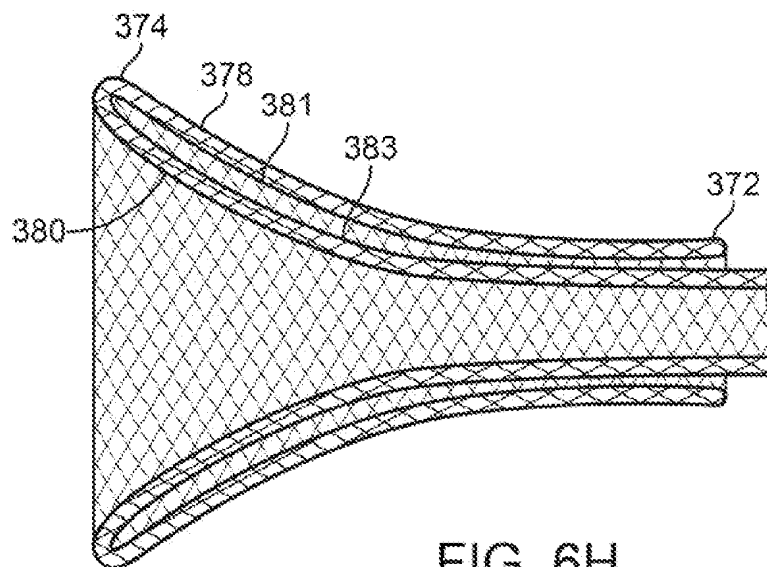


FIG. 6H

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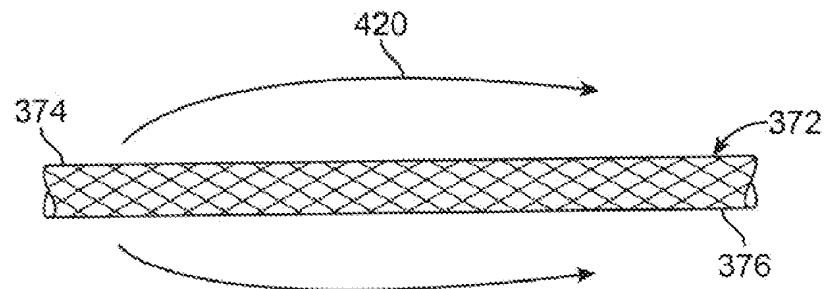


FIG. 6I

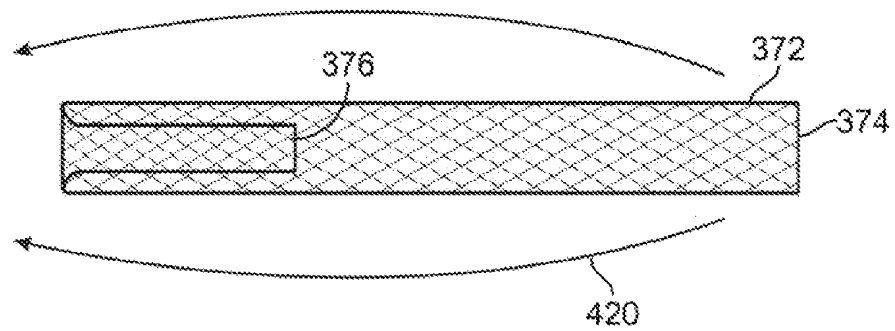


FIG. 6J

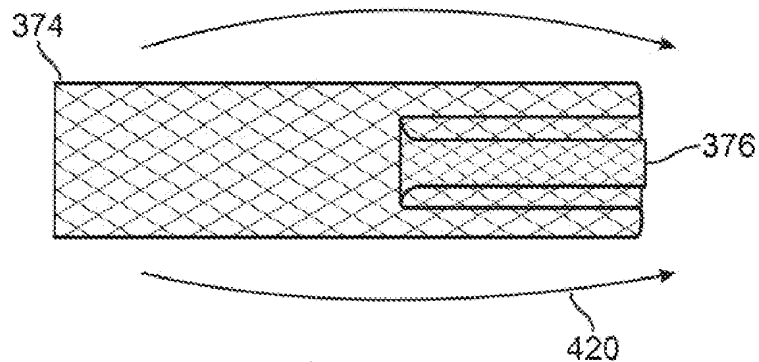


FIG. 6K

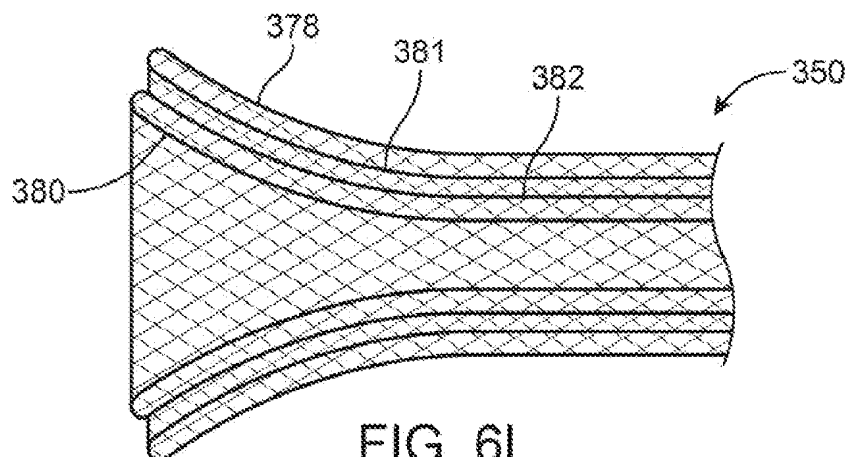


FIG. 6L

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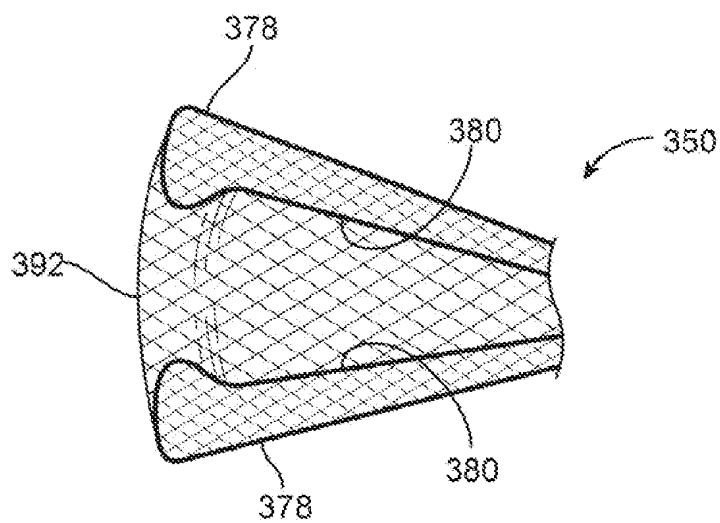


FIG. 7A

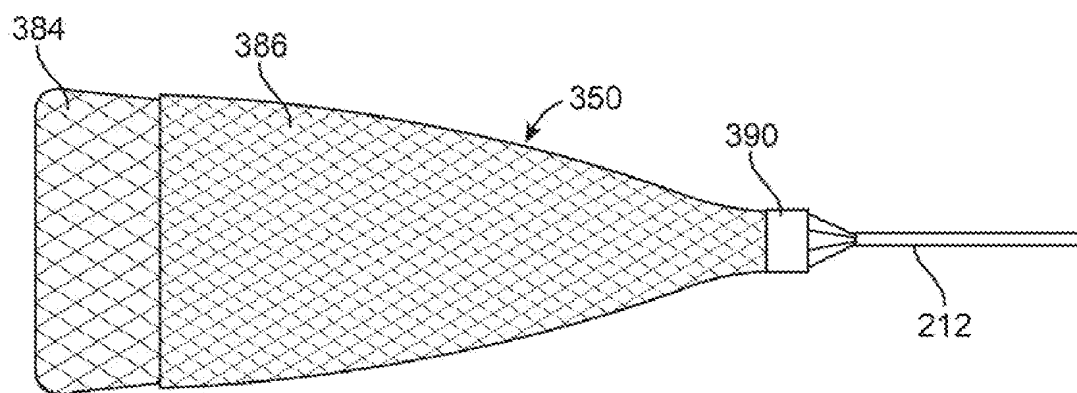


FIG. 7B

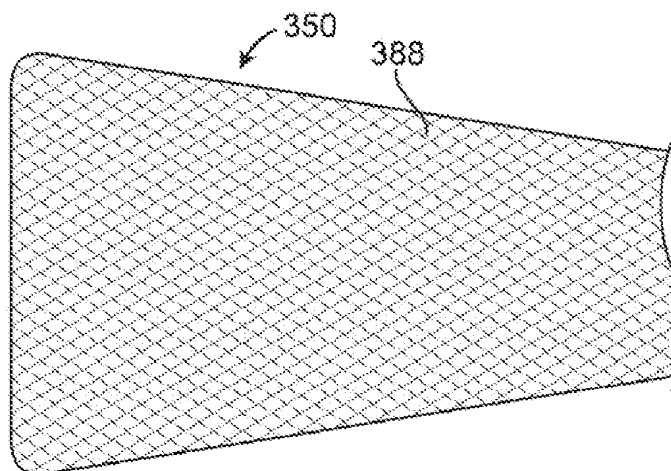
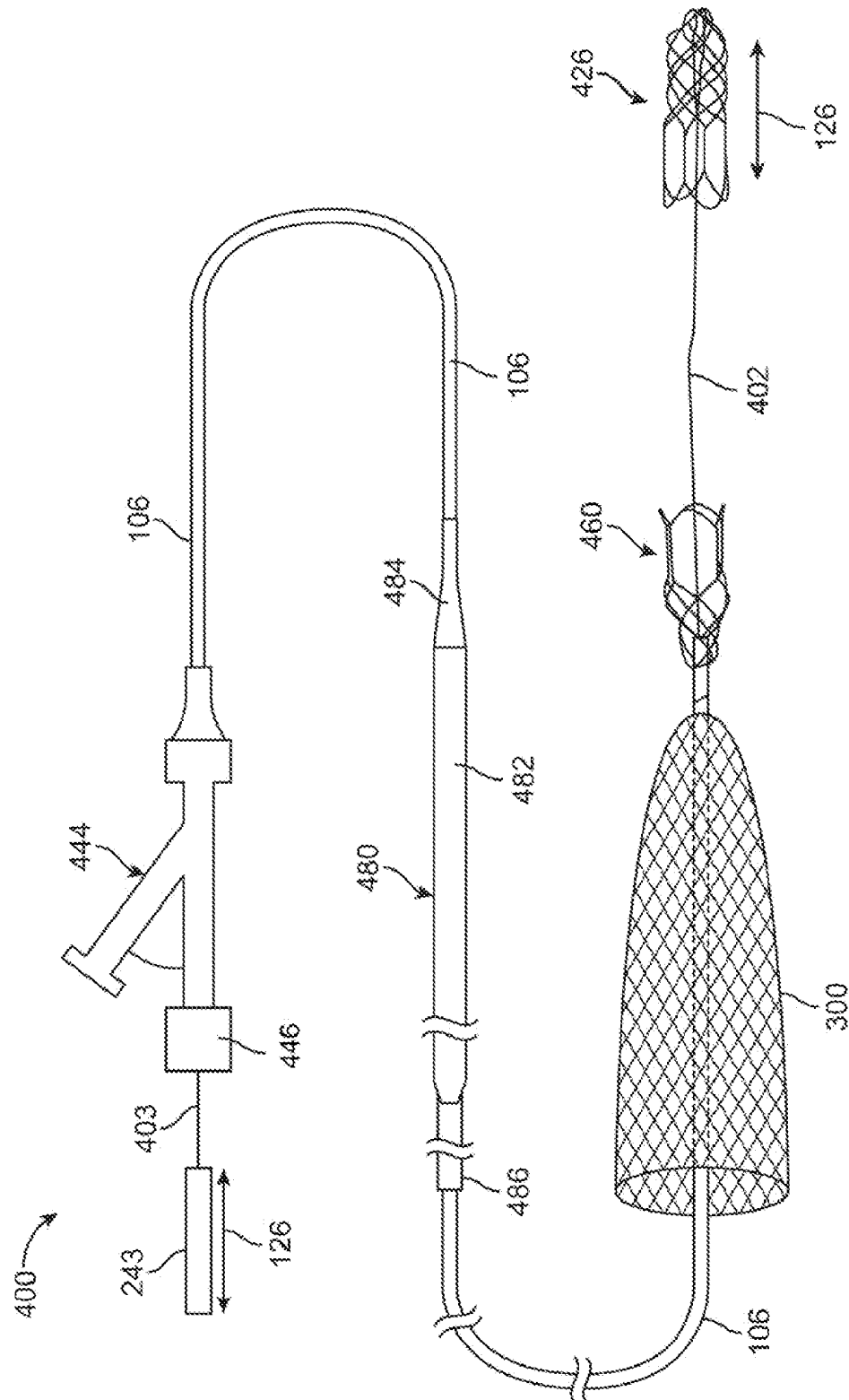


FIG. 7C

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9
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11

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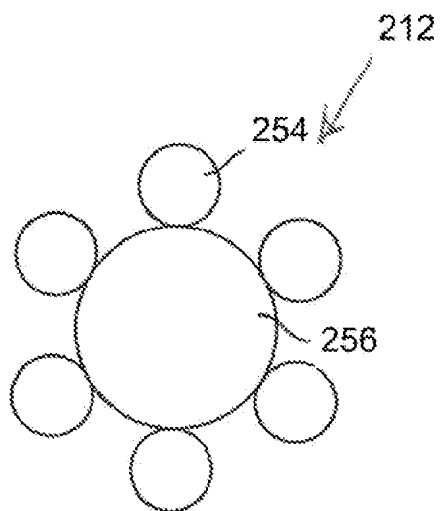


FIG. 9A

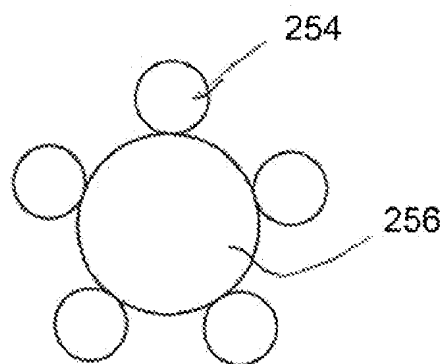


FIG. 9B

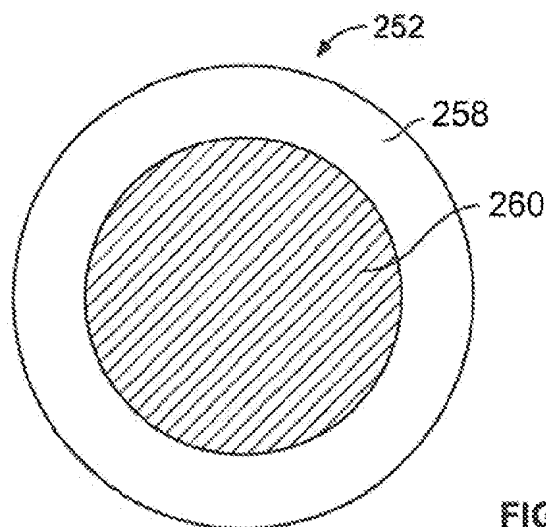


FIG. 9C

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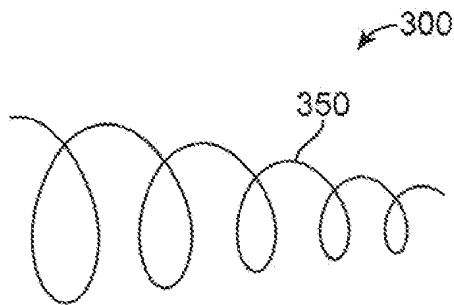


FIG. 10A

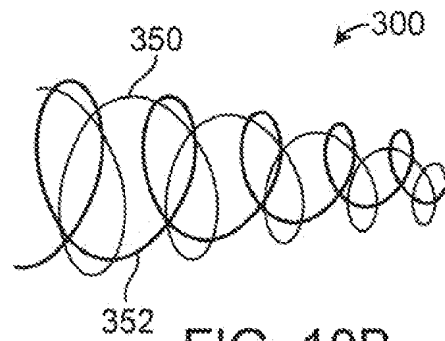


FIG. 10B

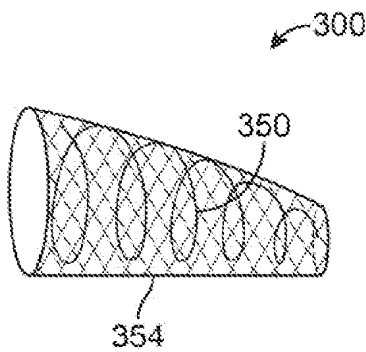


FIG. 10C

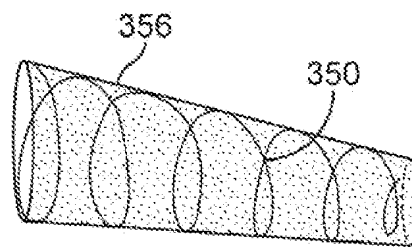


FIG. 10D

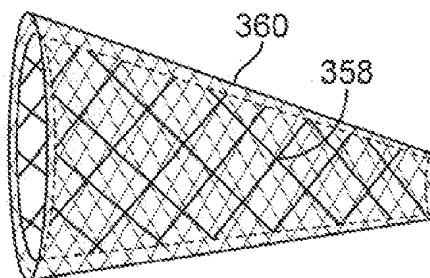


FIG. 10E

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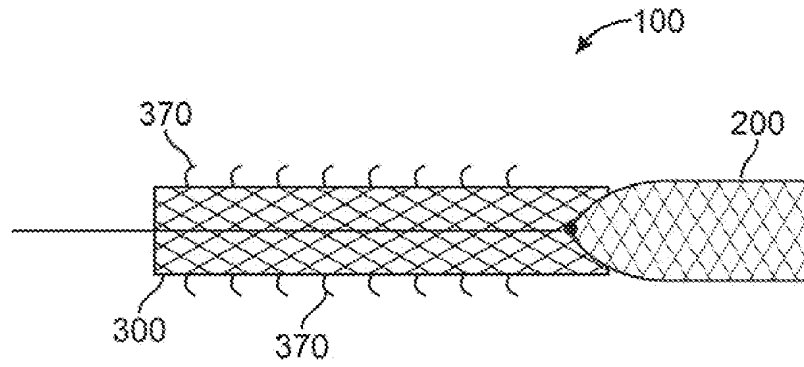


FIG. 11A

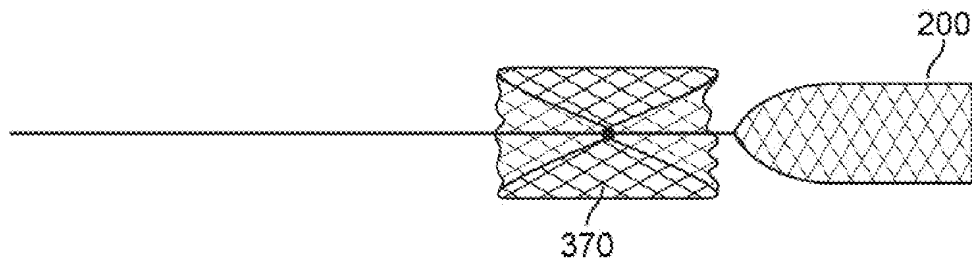


FIG. 11B

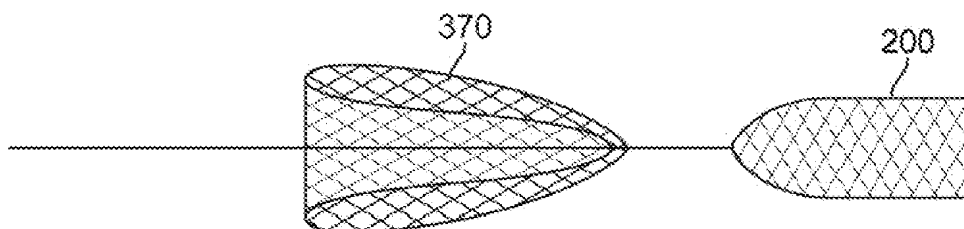


FIG. 11C

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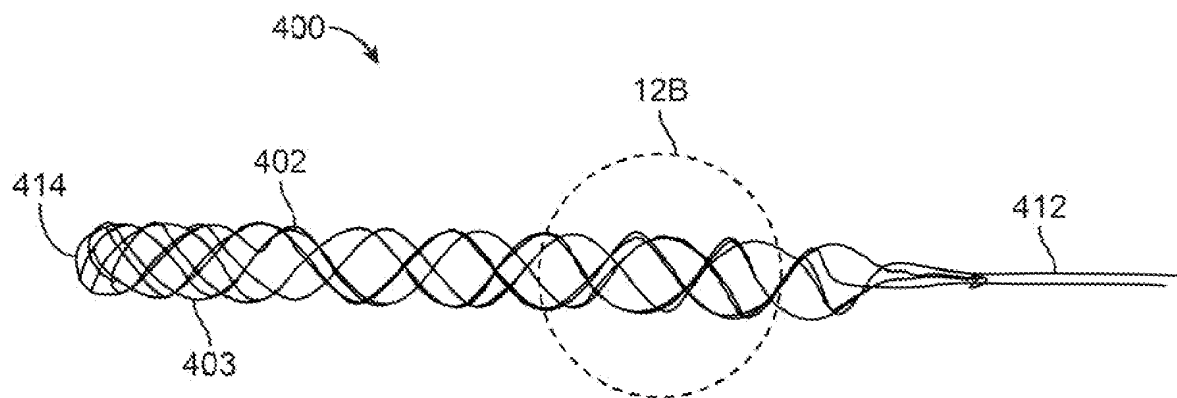


FIG. 12A

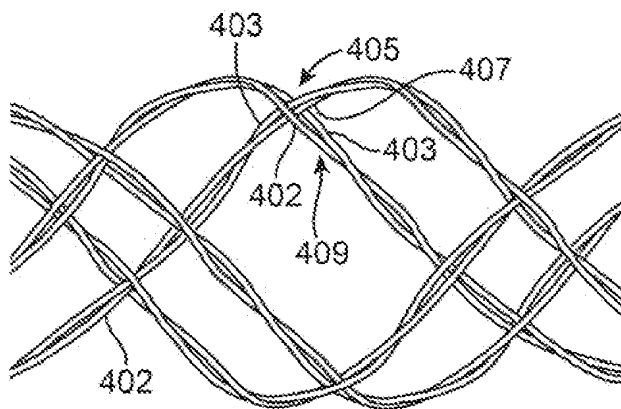


FIG. 12B

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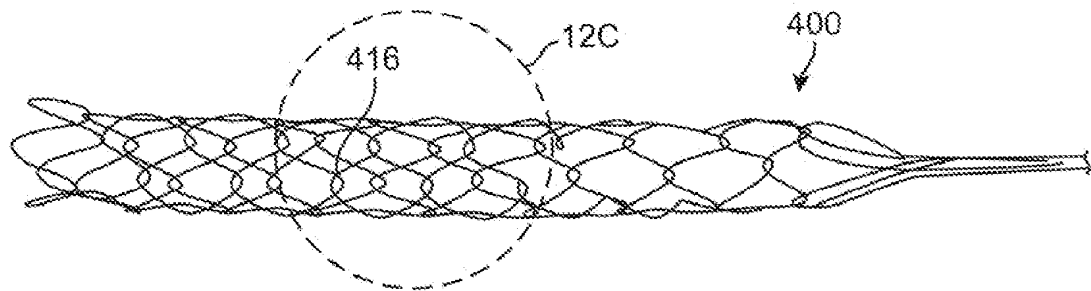


FIG. 12C

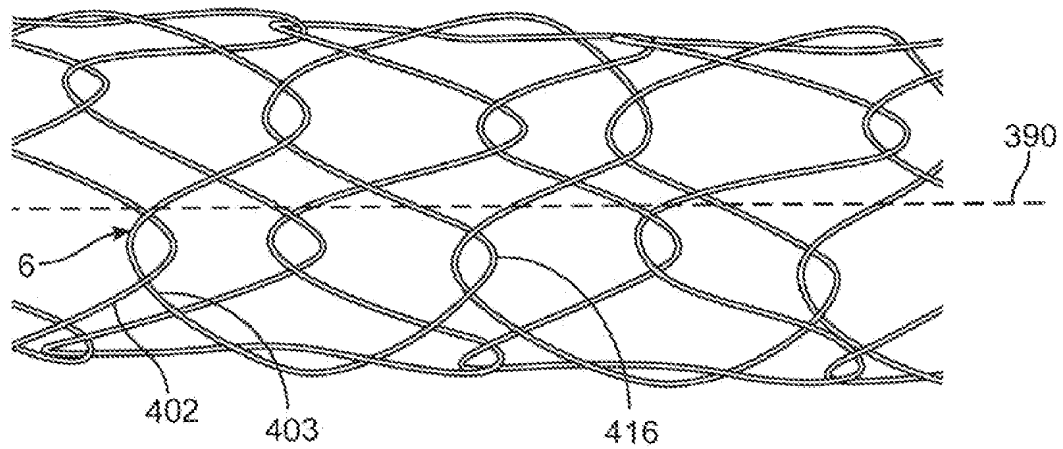


FIG. 12D

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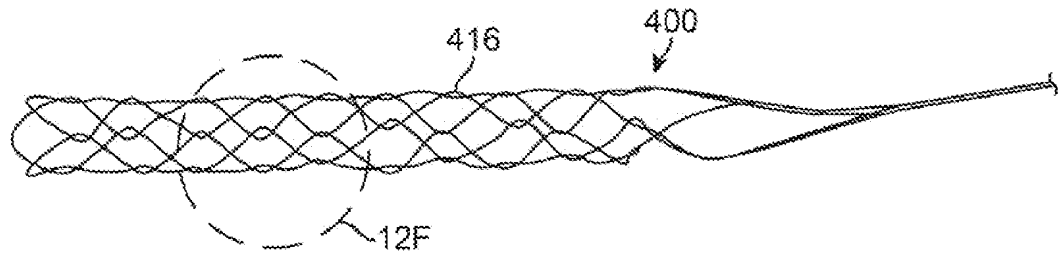


FIG. 12E

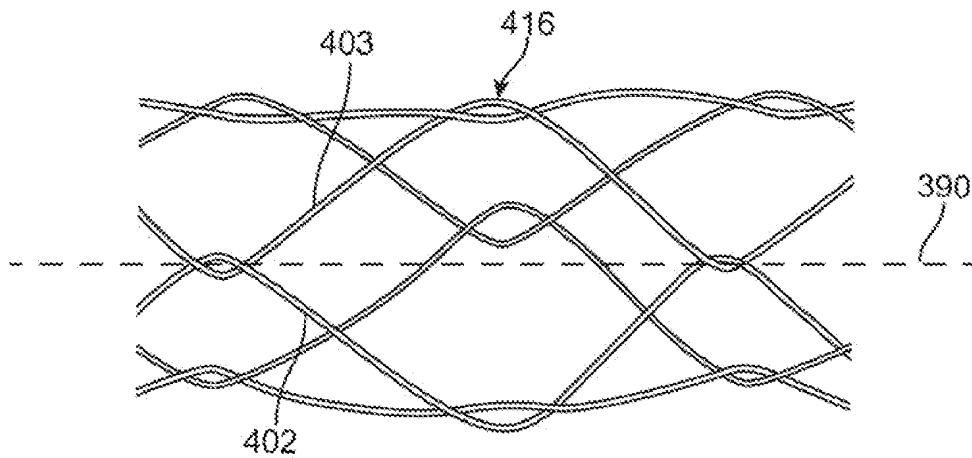


FIG. 12F

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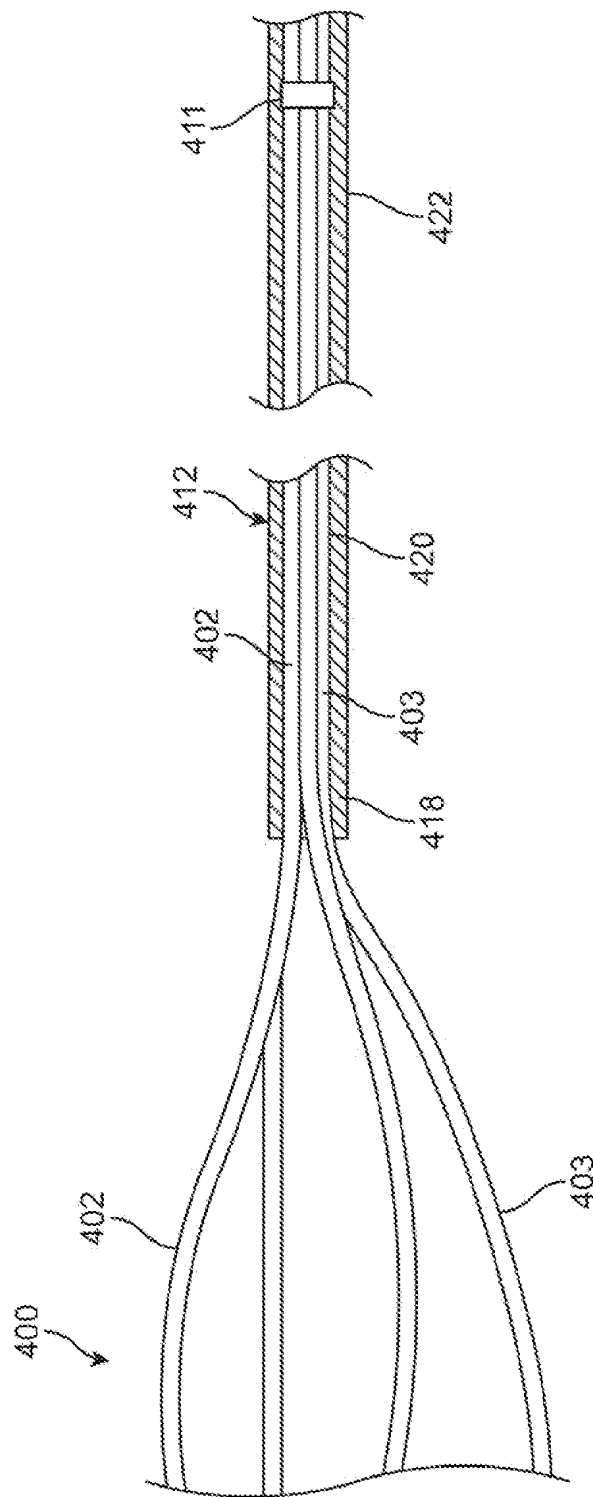


FIG. 12G

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/39216

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/22 (2012.01)

USPC - 606/159

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC: 606/159Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 606/170, 1, 180, 200 (keyword limited; terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PubWEST(PGPB, USPT, EPAB, JPAB); Google

Search Terms Used: drug, medication, medicament, film, coat\$3, layer, inner, outer, braid\$3, polymer\$2, inver\$4, ever\$4, sheath, sleeve, cover, stent, strut, remov\$3, retriev\$3, radiopaque, plaque, obstruction, clot, thromb\$2, reus\$4, basket, reposition\$3, net\$4, web\$4

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y	US 2009/0299393 A1 (MARTIN et al) 03 December 2009 (03.12.2009) fig 3H, 5B, para [0017], [0072]-[0073], [0108]-[0109], [0141]	40-48 ----- 3, 11-12, 25-26, 31, 33-34, 36-38
X	US 2005/0085826 A1 (NAIR et al.) 21 April 2005 (21.04.2005) Entire document, especially para[0034]- para[0039] and figs. 1, 4-9.	39
X ----- Y	US 2010/0076452 A1 (SEPETKA et al) 25 March 2010 (25.03.2010) fig 13, 14, 15, 16, 17, 18, 22, 26, 52, para [0089]-[0091], [0095], [0100], [0116]	1-2, 4-5, 7-8, 14, 23-24 ----- 3, 6, 9-13, 15-22, 25-34, 36-38
Y	US 2005/0283186 A1 (BERRADA et al) 22 December 2005 (22.12.2005) fig 3A, 3B, 20A, para [0081], [0128], [0142], [0149]	6, 9-10, 13, 15-22, 27-30, 32
Y	US 2005/0234505 A1 (DIAZ et al) 20 October 2005 (20.10.2005) para [0054]	35
Y	US 2009/0287291 A1 (BECKING et al) 21 April 2009 (21.04.2009) para [0095]	17, 32
Y	US 2010/0185210 A1 (HAUSER et al) 22 July 2010 (22.07.2010) para [0053]	22

☐ Further documents are listed in the continuation of Box C.

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"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

06 August 2012 (06.08.2012)

Date of mailing of the international search report

06 SEP 2012

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P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)



- (51) **International Patent Classification:**
A61M 5/32 (2006.01) *A61M 5/315* (2006.01)
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PCT/US2021/045072
- (22) **International Filing Date:**
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- (25) **Filing Language:** English
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- (30) **Priority Data:**
63/061,902 06 August 2020 (06.08.2020) US
- (71) **Applicant: INARI MEDICAL, INC.** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US).
- (72) **Inventors; and**
(71) **Applicants: RUGGLES, Kendall Anne** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US). **MERRITT, Benjamin Edward** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US). **STRAUSS, Brian Michael** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US).
- (72) **Inventors: THRESS, John Coleman**; 9 Parker, Suite #100, Irvine, California 92618 (US). **HUNTER, Evan Stuart**; 9 Parker, Suite #100, Irvine, California 92618

(US). **ZIKRY, Christopher Andrew**; 9 Parker, Suite #100, Irvine, California 92618 (US).

(74) **Agent: WILLIAMS, Matthew S.** et al.; PERKINS COIE LLP, P.O. Box 1247, Seattle, Washington 98111-1247 (US).

(81) **Designated States** (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) **Designated States** (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,

(54) **Title:** AUTOMATICALLY-LOCKING VACUUM SYRINGES, AND ASSOCIATED SYSTEMS AND METHODS

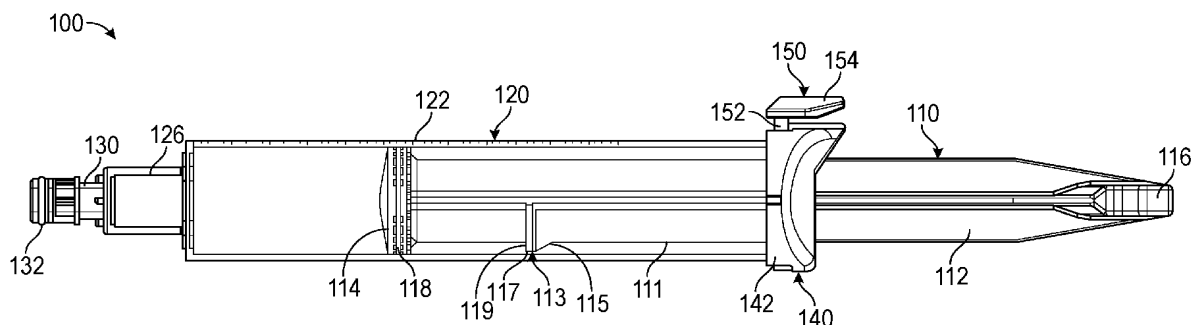


FIG. 1B

(57) **Abstract:** Automatically-locking syringes are disclosed herein. A syringe in accordance with embodiments of the present technology can include (i) a barrel, (ii) a plunger slidably positioned within the barrel, and (iii) a lock plate coupled to the barrel. The plunger also extends through an opening in the lock plate, and a biasing member is configured to bias the lock plate to a locking position. When the plunger is moved from a depressed position to a withdrawn position, the lock feature engages the lock plate to drive the lock plate away from the locking position to thereby permit the lock feature to pass through the opening in the lock plate. After the lock feature passes through the opening, the biasing member drives the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.

TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

Published:

- *with international search report (Art. 21(3))*
- *before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments (Rule 48.2(h))*

AUTOMATICALLY-LOCKING VACUUM SYRINGES, AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/061,902, filed August 6, 2020, and titled "AUTOMATICALLY-LOCKING VACUUM SYRINGES, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology relates generally to systems, methods, and devices for the intravascular treatment of emboli and/or thrombi within a blood vessel of a human patient. In particular, some embodiments of the present technology relate to automatically-locking syringes for generating and releasing stored vacuum pressure to aspirate clot material from a blood vessel.

BACKGROUND

[0003] Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

[0004] When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. However, infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can accordingly lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

[0005] In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT commonly occurs where there is a propensity for stagnated blood (e.g., long distance air travel, immobility) and clotting (e.g., cancer, recent surgery such as orthopedic surgery,). DVT can obstruct drainage of venous blood from the legs leading to swelling, ulcers, pain and infection. DVT can also create a reservoir in which blood clots can collect and then travel to other parts of the body including the heart, lungs, brain (stroke), abdominal organs, and/or extremities.

[0006] In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs, and therefore the entire body. This can result in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting in low blood oxygen and buildup of blood carbon dioxide.

[0007] There are many existing techniques to reestablish blood flow through an occluded vessel. Embolectomies, for example, are a surgical technique involving incising a blood vessel and placing a balloon-tipped device (such as the Fogarty catheter) at the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to withdraw the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Although such surgical techniques have been useful, exposing a patient to surgery may be traumatic and best avoided when possible. Additionally, the use of a Fogarty catheter may be problematic due to the possible risk of damaging the interior lining of the vessel as the catheter is being withdrawn.

[0008] Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating vessel stenosis, but it is generally not effective for treating acute thromboembolisms as none of the occlusive material is removed and restenosis regularly occurs after dilation. Another percutaneous technique involves placing a catheter near the clot and infusing streptokinase, urokinase, or other thrombolytic agents to dissolve the clot. Unfortunately, thrombolysis typically takes hours to days to be successful. Additionally, thrombolytic agents can cause hemorrhaging, and in many patients the thrombolytic agents cannot be used at all.

[0009] Various devices exist for performing a thrombectomy or removing other foreign material. However, such devices have been found to have structures which are either highly complex, cause trauma to the treatment vessel, or lack the ability to be appropriately fixed against the vessel. Furthermore, many of the devices have highly complex structures that lead to manufacturing and quality control difficulties as well as delivery issues when passing through

tortuous or small diameter catheters. Less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all the clot material.

[0010] Thus, there exists a need for improved systems and methods for embolic extraction.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0012] Figures 1A and 1B are an exploded isometric view and a side view, respectively, of a vacuum-pressure locking syringe in accordance with embodiments of the present technology.

[0013] Figures 2A and 2B are isometric views of the syringe of Figures 1A and 1B in a depressed position and a withdrawn position, respectively, in accordance with embodiments of the present technology.

[0014] Figure 3A is a side view, and Figures 3B and 3C are enlarged side views, of the syringe illustrating the steps of locking a plunger of the syringe to a lock member of the syringe in accordance with embodiments of the present technology.

[0015] Figure 4 is an enlarged isometric view of a portion of the syringe in accordance with additional embodiments of the present technology.

[0016] Figures 5A and 5B are an isometric view and a side view, respectively, of a syringe in a withdrawn position in accordance with additional embodiments of the present technology.

[0017] Figure 5C is an isometric of the syringe of Figures 5A and 5B in a depressed position in accordance with embodiments of the present technology.

[0018] Figure 6A is a side view of a vacuum-pressure locking syringe in accordance with additional embodiments of the present technology.

[0019] Figures 6B and 6C are enlarged side views of a locking mechanism of the syringe of Figure 6A in a first position and a second position, respectively, in accordance with embodiments of the present technology.

[0020] Figure 7 is a partially schematic side view of a clot treatment or clot removal system incorporating the syringe of Figures 1A–4, the syringe of Figures 5A–5C, and/or the syringe of Figures 6A–6C in accordance with embodiments of the present technology.

[0021] Figures 8A and 8B are enlarged, partially-schematic side views of a vacuum indicator of the clot removal system of Figure 7 in a vacuum-off position and a vacuum-on position, respectively, in accordance with embodiments of the present technology.

[0022] Figure 9 is a perspective view of a vacuum indicator in a vacuum-off position in accordance with additional embodiments of the present technology.

[0023] Figures 10A and 10B are perspective views of a vacuum indicator in a vacuum-off position and a vacuum-on position, respectively, in accordance with additional embodiments of the present technology.

[0024] Figure 11 is a side-view of the syringe of Figures 1A and 1B including a vacuum indicator in accordance with embodiments of the present technology.

[0025] Figures 12A and 12B are perspective views of a syringe including a vacuum indicator in accordance with additional embodiments of the present technology.

[0026] Figures 13A–13C are side views of a vacuum indicator in a vacuum-off position, a partial-vacuum position, and a full-vacuum position, respectively, in accordance with additional embodiments of the present technology.

[0027] Figures 14A and 14B are an isometric view and a top view of a syringe in accordance with additional embodiments of the present technology.

[0028] Figures 14C and 14D are enlarged side views of a vacuum indicator of the syringe of Figures 14A and 14B in a "vacuum-off" and a "vacuum-on" position, respectively, in accordance with embodiments of the present technology.

[0029] Figures 14E and 14F are enlarged partially transparent side views of the vacuum indicator of Figures 14A–14D in the vacuum-off and the vacuum-on position, respectively, in accordance with embodiments of the present technology.

[0030] Figure 14G is an enlarged side cross-sectional view of the vacuum indicator of Figures 14A–14F in the vacuum-off position in accordance with embodiments of the present technology.

[0031] Figures 15A and 15B are an isometric view and a side view of a syringe in accordance with additional embodiments of the present technology.

[0032] Figures 15C and 15D are enlarged side views of a vacuum indicator of the syringe of Figures 15A and 15B in a "vacuum-off" and a "vacuum-on" position, respectively, in accordance with embodiments of the present technology.

[0033] Figures 15E and 15F are enlarged partially transparent side views of the vacuum indicator of Figures 15A–15D in the vacuum-off and the vacuum-on position, respectively, in accordance with embodiments of the present technology.

[0034] Figure 15G is an enlarged side cross-sectional view of the vacuum indicator of Figures 15A–15F in the vacuum-off position in accordance with embodiments of the present technology.

[0035] Figure 16 is an enlarged side cross-sectional view of the vacuum indicator of Figures 15A–15G further including a biasing member in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0036] The present technology is generally directed to automatically-locking syringes, such as for use in clot removal systems for aspirating clot material from a blood vessel of a human patient. In some embodiments, an automatically-locking syringe can include (i) a barrel, (ii) a lock plate coupled to the barrel, and (iii) a plunger slidably positioned within the barrel and having a lock feature configured to engage the lock plate. The plunger also extends through an opening in the lock plate, and a biasing member is configured to bias the lock plate toward a locking position. When the plunger is moved through the barrel from a depressed position to a withdrawn position, the lock feature is configured to engage the lock plate to drive the lock plate away from the locking position to thereby permit the lock feature to pass through the opening in the lock plate. When the lock feature passes through the opening, the biasing member is configured to bias the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position. Accordingly, in one aspect of the present technology, the plunger is automatically locked in position via engagement of the lock plate with the lock feature when the plunger is withdrawn a selected distance.

[0037] In additional embodiments, an automatically-locking syringe can include (i) a barrel having a flange, (ii) a plunger slidably positioned within the barrel, and (iii) at least one lock

member coupled to the plunger. The lock member can include a body and a first arm hingedly coupled to the body. The first arm is configured to be biased at least partially outwardly away from a longitudinal axis of the plunger to a locking position. When the plunger is in a withdrawn position, the first arm can engage the flange of the barrel to inhibit movement of the plunger through the barrel from the withdrawn position to a depressed position. The syringe can further include an actuator that is movable between a first position and a second position. The actuator can include a second arm configured to engage the first arm in the second position to drive the first arm inwardly toward the longitudinal axis and away from the locking position. Accordingly, when the plunger is withdrawn, moving the actuator from the first position to the second position can drive the first arm radially inward away from the locking position to permit movement of the plunger through the barrel from the withdrawn position to the depressed position.

[0038] Specific details of several embodiments of the present technology are described herein with reference to Figures 1A–16. The present technology, however, may be practiced without some of these specific details. In some instances, well-known structures and techniques often associated with the disclosed syringes, clot removal systems, and the like have not been shown in detail so as not to obscure the present technology. The terminology used in the description presented below is intended to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain specific embodiments of the disclosure. Certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

[0039] The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be arbitrarily enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles, and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles, and features without departing from the spirit or scope of the present technology.

[0040] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to use in a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

[0041] The headings provided herein are for convenience only and should not be construed as limiting the subject matter disclosed.

I. Selected Embodiments of Vacuum-Pressure Locking Syringes

[0042] Figures 1A and 1B are an exploded isometric view and a side view, respectively, of a vacuum-pressure locking syringe ("syringe 100") in accordance with embodiments of the present technology. The syringe 100 is in a partially-withdrawn position in Figure 1B. Referring to Figures 1A and 1B together, the syringe 100 includes a plunger 110 slidably positioned within a barrel 120. The barrel 120 is shown as partially transparent in Figure 1B for clarity. The barrel 120 can include a barrel portion 122 (e.g., a cylindrical portion) extending between a flange 124 and a tip 126. In some embodiments, the barrel portion 122 can have a volume of about 60 cc or greater than 60 cc. The tip 126 is configured to be releasably or permanently coupled to an adaptor 130 (shown as partially transparent in Figures 1A and 1B). In some embodiments, the tip 126 can define a bore 128 having a size of about 26 French or greater. In the illustrated embodiment, the adaptor 130 is a Toomey-tip adaptor having a sealing member 132 (e.g., an O-ring) extending around an exterior surface thereof for sealingly engaging (e.g., connecting to) a Toomey fitting or Toomey adaptor. In other embodiments, the adaptor 130 can be omitted and the tip 126 of the barrel 120 can be directly coupled to another device or system (not shown), and/or the tip 126 can be another type of tip such as, for example, a Luer lock, Lock slip, and/or needle.

[0043] In the illustrated embodiment, the plunger 110 includes a shaft 112 extending between a flange 114 and a grip portion 116. The grip portion 116 is configured to be grasped by a user for withdrawing (e.g., retracting, pulling) and/or depressing (e.g., advancing, pushing) the plunger 110 through the barrel 120 during operation of the syringe 100. The plunger 110 can include a sealing member 118 positioned around the flange 114 and configured to sealingly engage an interior surface of the barrel portion 122 to define a sealed volume (e.g., of negative/vacuum

pressure) within the barrel 120. The various components of the syringe 100 can comprise metal, plastic, and/or other suitable materials.

[0044] As best seen in Figure 1B, the shaft 112 of the plunger 110 includes a lower edge or surface 111 and a lock feature 113 extending/protruding from the lower surface 111. In the illustrated embodiment, the lock feature 113 includes (i) a ramp portion 115, (ii) a plateau portion 117 extending from the ramp portion 115, and (iii) a stop surface 119 extending from the plateau portion 117. The ramp portion 115 can extend/slope at angle relative to the lower surface 111 in a direction (i) away from the lower surface 111 and (ii) toward the flange 114 of the plunger 110. The plateau portion 117 can extend away from the ramp portion 115 in a direction toward the flange 114 and generally parallel to the lower surface 111. The stop surface 119 can extend away from the plateau portion 117 in a direction generally perpendicular to the plateau portion 117 and the lower surface 111. In some embodiments, the lock feature 113 can be a tab, flat face, half disc, and/or other feature extending from the lower surface 111 of the shaft 112.

[0045] In the illustrated embodiment, the syringe 100 further includes a base 140 and a lock member 150 operably coupled to the base 140. In some embodiments, the base 140 can be coupled to the flange 124 of the barrel 120. Accordingly, the base 140 can couple the lock member 150 to the barrel 120. The base 140 can include a body 142 having an opening 143 extending therethrough and configured to slidably receive the shaft 112 of the plunger 110. The lock member 150 can include a lock plate 152 coupled to a button portion 154. The lock plate 152 can include an opening 153 (i) extending therethrough, (ii) defined by an edge portion 156, and (iii) configured to slidably receive the shaft 112 of the plunger 110. In some embodiments, the lock member 150 can be movably coupled to the base 140 via, for example, a biasing member (e.g., an arm 358 illustrated in Figures 3B and 3C, springs 460 illustrated in Figure 4, and/or another type of biasing member). As described in greater detail below with reference to Figures 3A–4, the lock plate 152 is configured to engage the lock feature 113 of the plunger 110 when the plunger 110 is withdrawn to a selected position to lock the plunger 110 in the selected position. The selected position can correspond to a pre-selected vacuum volume of the barrel 120. The button portion 154 is actuatable (e.g., depressible) by a user to release the lock plate 152 from the lock feature 113 to release the plunger 110 to, for example, permit the plunger 110 to move through the barrel 120 to expel any contents (e.g., bodily fluids such as blood and clot material) collected in the barrel 120 from the tip 126.

[0046] Figures 2A and 2B are isometric views of the syringe 100 in a depressed position (e.g., a first position, an emptied positioned, zero-vacuum position) and a withdrawn position (e.g., a second position, a vacuum-storage position, a vacuum-generation position, full-vacuum position), respectively, in accordance with embodiments of the present technology. The barrel 120 is shown as partially transparent in Figures 2A and 2B for clarity. Referring to Figures 2A and 2B together, in general, a user can move the syringe 100 from the depressed position to the withdrawn position by pulling the grip portion 116 of the plunger 110 in the direction of arrow A (Figure 2A) relative to the barrel 120 to withdraw the plunger 110 through the barrel 120, the base 140, and the lock member 150. In some embodiments, withdrawing the plunger 110 can charge a vacuum (e.g., generate negative pressure) within the barrel 120. Moreover, the lock plate 152 of the lock member 150 can engage the lock feature 113 (obscured in Figure 2B) of the plunger 110 when the plunger 110 is withdrawn past the lock plate 152 to automatically lock the plunger 110 in the withdrawn position. To move the syringe 100 from the withdrawn position to the depressed position, the user can (i) actuate the button portion 154 of the lock member 150 (e.g., depress the button portion 154 in the direction of arrow B in Figure 2B) to disengage the lock plate 152 from the lock feature 113 to unlock the plunger 110 from the lock member 150 and then (ii) push the plunger 110 in the direction of arrow C (Figure 2B) relative to the barrel 120.

[0047] Figure 3A is a side view, and Figures 3B and 3C are enlarged side views, of the syringe 100 illustrating the process of locking the plunger 110 to the lock member 150 in accordance with embodiments of the present technology. The syringe 100 is in a partially-withdrawn position in Figures 3A and 3B. More specifically, Figures 3A and 3B illustrate the syringe 100 as the lock feature 113 passes through the opening 153 (Figure 1A) in the lock member 150 during withdrawal of the plunger 110 from the depressed position to the withdrawn position. Figure 3C illustrates the syringe 100 after the lock feature 113 has been withdrawn through the opening 153 past the lock plate 152. The barrel 120 is shown as partially transparent in Figures 3A–3C, and the base 140 is shown as partially transparent in Figures 3B and 3C for clarity.

[0048] Referring to first to Figures 3B and 3C together, the lock member 150 further includes an arm 358 (e.g., a biasing member) operably coupling the lock member 150 to the base 140. In the illustrated embodiment, for example, the arm 358 projects away from (e.g., perpendicular) to the lock plate 152 and presses against (e.g., engages, attaches to) the base 140. The arm 358 can be a spring arm, living hinge, lever arm, or other member that is (i) hingedly/movably coupled to the lock member 150 and (ii) configured to bias the lock plate 152

upward to a locking position (e.g., a first position) as shown in Figures 3C and 1B (e.g., in an upward direction indicated by arrow D in Figure 3C). As the lock feature 113 is withdrawn past the lock plate 152, the lock feature 113 can engage the lock plate 152 and drive the lock plate 152 against the biasing force of the arm 358 away from the locking position (e.g., toward a second position) as shown in Figure 3B (e.g., in a downward direction indicated by arrow E in Figure 3B).

[0049] More specifically, referring to Figures 3A and 3B together, as the plunger 110 is withdrawn toward the lock member 150 in the direction of the arrow A, the ramp portion 115 of the lock feature 113 first engages the edge portion 156 (Figure 1A) of the lock plate 152 at a first side 357a of the lock plate 152 opposite a second side 357b. As the plunger is withdrawn farther, the angled ramp portion 115 drives the lock plate 152 (and the button portion 154) downward in the direction of the arrow E against the biasing force of the arm 358 (e.g., away from the locking position) until the lock plate 152 reaches the plateau portion 117 of the lock feature 113. That is, the ramp portion 115 of the lock feature 113 translates the longitudinal force of the plunger 110 into radial movement of the lock plate 152. Continued withdrawal of the plunger 110 slides the lock plate 152 over/against the plateau portion 117 until the lock feature 113 reaches the stop surface 119. Referring to Figure 3C, when the lock plate 152 passes the end of the plateau portion 117, the arm 358 can drive the lock plate 152 upward in the direction of arrow D to the locking position. The plunger 110 is then inhibited from moving/advancing past the lock plate 152 toward the depressed position (e.g., in the direction of the arrow C shown in Figure 2B). Specifically, the second side 357b of the lock plate 152 can engage/contact the stop surface 119 of the lock feature 113 to inhibit advancement of the plunger 110. In other embodiments, the lock feature 113 and/or the lock plate 152 can have different configurations/arrangements that facilitate locking of the plunger 110 in the withdrawn position. For example, in some embodiments the plateau portion 117 of the lock feature 113 can be omitted.

[0050] To unlock the plunger 110 from the lock member 150, the user can actuate the button portion 154 of the lock member 150 by, for example, pressing the button portion 154 downward in the direction of arrow E. The movement of the button portion 154 drives the lock plate 152 downward relative to the lock feature 113 until the edge portion 156 (Figure 1A) of the lock plate 152 fully passes the stop surface 119 of lock feature 113, thereby permitting movement of the lock feature 113 through the opening 153 (Figure 1A) of the lock plate 152. The user can then advance the plunger 110 through the barrel 120 to expel any contents collected in the barrel 120.

[0051] Accordingly, in one aspect of the present technology, the plunger 110 is automatically locked in position—via the lock plate 152 and lock feature 113—when the plunger 110 is withdrawn a selected distance. In contrast, many conventional locking syringes require the user to rotate the plunger relative to the barrel to facilitate locking of the plunger. Such rotation can be difficult when the syringe has a large volume—for example, 60 cc or greater—and thus requires a relatively significant retraction force to withdraw the plunger. Therefore, the syringe 100 of the present technology has improved usability compared to conventional locking syringes, especially during procedures that require multiple withdrawals of the plunger 110 over the course of the procedure. In some embodiments, the lock member 150 and the lock feature 113 can be configured (e.g., shaped, positioned) such that the syringe 100 automatically locks at a selected position corresponding to a selected volume of the barrel 120. In some embodiments, the selected volume can be about 60 cc or greater.

[0052] In another aspect of the present technology, the syringe 100 is lockable at only a single position. This can be particularly useful where the syringe 100 is used in procedures in which a single operational volume is preselected/desired, such as during a clot removal procedure that includes aspirating clot material from a vessel, as described in greater detail below with reference to Figure 6.

[0053] Figure 4 is an enlarged isometric view of a portion of the syringe 100 in accordance with additional embodiments of the present technology. The barrel 120 is shown as partially transparent in Figure 4 for clarity. In the illustrated embodiment, the lock plate 152 of the lock member 150 is operably coupled to the base 140 via a pair of springs 460 (only one of the springs 460 is visible in Figure 4). The springs 460 are configured to bias the lock plate 152 to the first position shown in Figures 4 and 1B, and can replace or supplement the arm 358 described in detail above with reference to Figures 3A–3C. More particularly, each of the springs 460 can be a compression spring operably coupled between a first spring mount 462 of the lock plate 152 and a second spring mount 464 of the body 142 of the base 140. In a similar manner as described in detail above with reference to Figures 3A–3C, (i) the lock feature 113 can engage the lock plate 152 and drive the lock plate 152 against the biasing force of the springs 460 during withdrawal of the plunger 110, and (ii) the springs 460 can drive the lock plate 152 upward after the lock feature 113 passes through the lock plate 152 to automatically lock the plunger 110 in the withdrawn position.

[0054] Figures 5A–5C are an isometric view, a side view, and another isometric view, respectively, of a syringe 500 in accordance with additional embodiments of the present technology. The syringe 500 is in a withdrawn/retracted position in Figures 5A and 5B, and in a depressed/advanced position in Figure 5C. Referring to Figures 5A–5C together, the syringe 500 can include several features generally similar or identical to the syringe 100 described in detail above with reference to Figures 1A–4. In the illustrated embodiment, for example, the syringe 500 includes a plunger 510 configured to be slidably positioned within a barrel 520. The barrel 520 is shown as partially transparent in Figures 5A–5C for clarity. The barrel 520 can include a barrel portion 522 extending between a flange 524 and a tip 526. In some embodiments, the tip 526 is configured to be releasably or permanently coupled to an adaptor 530 (e.g., a Toomey tip adaptor; shown as partially transparent in Figures 5A–5C). The plunger 510 can include a shaft 512 extending between a flange 514 and a grip portion 516. The plunger 510 can include a sealing member 518 positioned around the flange 514 and configured to sealingly engage an interior surface of the barrel portion 522 to define a sealed volume (e.g., of negative/vacuum pressure) within the barrel 520.

[0055] In the illustrated embodiment, the syringe 500 further includes a pair of lock members 570 (identified individually as a first lock member 570a and a second lock member 570b) operably coupled to an actuator 580. In some embodiments, the shaft 512 of the plunger 510 includes a spline 511 (e.g., a wall portion), and the lock members 570 can be positioned on opposite sides of the spline 511. The lock members 570 can each include a body 572 and an arm 574 hingedly/movably attached to the body 572. The arms 574 can be spring arms, living hinges, lever arms, or other members configured to be biased outwardly away from a longitudinal axis L (Figure 5A) of the syringe 500. The bodies 572 can each include a first end portion 573 and a second end portion 575 opposite the first end portion 573, and can each include/define an elongate opening 576 extending between the first and second end portions 573, 575. The lock members 570 can be formed of plastic, metal, and/or other suitable materials and can be single integral parts (e.g., injected molded parts) or can be formed of discrete parts coupled together.

[0056] In the illustrated embodiment, the actuator 580 includes a push portion 582 and a pair of elongate arms 584 (identified individually as a first arm 584a and a second arm 584b) extending away from the push portion 582. In some embodiments, the push portion 582 is slidably coupled to the spline 511 of the shaft 512 and configured to slide at least partially between (i) a first position in which the push portion 582 abuts and/or is adjacent to the grip portion 516 of the

plunger 510 and (ii) a second position in which the push portion 582 abuts and/or is adjacent to the second end portions 575 of the arms 574. The plunger 580 is shown in the second position in Figures 5A–5C. The first arm 584a can extend at least partially through the opening 576 in the first body 570a, and the second arm 584b can extend at least partially through the opening 576 in the second body 570b. In some embodiments, the arms 584 are slidably positioned within the openings 576 such that movement of the push portion 582 between the first and second positions advances/retracts the arms 584 through the openings 576. In some embodiments, in the first position, the arms 584 of the actuator 580 do not extend over the arms 574 of the lock members 570. In the second position, the arms 584 of the actuator 580 can extend over/around all or a portion of the arms 574 of the lock members 570 to move (e.g., pinch) the arms 574 inwardly toward the longitudinal axis L—counter to the biasing force of the arms 574 (e.g., in the direction of arrows F in Figure 5B). The actuator 580 can be formed of plastic, metal, and/or other suitable materials and can be a single integral part or can be formed of discrete parts coupled together.

[0057] In the withdrawn position shown in Figures 5A and 5B, the arms 574 of the lock members 570 are biased outwardly such that end portions of the arms 574 engage the flange 524 of the barrel 520. Accordingly, the arms 574 inhibit/lock the plunger 110 from advancing farther into the barrel 520 toward the depressed position. To unlock the plunger 510, a user can push the push portion 582 of the actuator to move the push portion 582 at least partially from the first position to the second position (e.g., toward the barrel 520 and the lock members 570). The movement of the push portion 582 drives the arms 584 through the openings 576 in the bodies 572 and over/around the arms 574 of the lock members 570 to move the arms 574 inward toward the longitudinal axis L and out of engagement with the flange 524. The user can then advance the plunger 510 toward the depressed position (Figure 5C) to expel any contents collected in the barrel 520.

[0058] To subsequently withdraw the plunger 510 from the depressed position to the retracted position, the user can first move the actuator 580 to the first position to free the arms 574 of the lock members 570 from the arms 584 of the actuator 580. Accordingly, the arms 574 of the lock members 570 can return to their outwardly-biased position and, in some embodiments, can contact an inner surface of the barrel portion 522. Then, as the plunger 510 is withdrawn through the barrel 520, the arms 574 of the of lock members 570 can spring (i) outward as they are withdrawn from the barrel 520 (e.g., after they past the flange 524) and (ii) into engagement with the flange 524. Accordingly, in one aspect of the present technology, the plunger 510 is

automatically locked in position—via the arms 574 of the lock members 570—when the plunger 510 is withdrawn a selected distance.

[0059] In some embodiments, the lock members 570 can be configured (e.g., shaped, positioned) such that the syringe 500 automatically locks at a selected position corresponding to a selected volume of the barrel 520. In some embodiments, the selected volume can be about 60 cc or greater. In some embodiments, the syringe 500 can include only one of the lock members 570, or more than two of the lock members 570.

[0060] Figure 6A is a side view of a vacuum-pressure locking syringe ("syringe 600") in accordance with additional embodiments of the present technology. The syringe 600 is in a depressed position in Figure 6A. The syringe 600 can include several features generally similar or identical to the syringe 100 described in detail above with reference to Figures 1A–3C. In the illustrated embodiment, for example, the syringe 600 includes a plunger 610 slidably positioned within a barrel 620. The barrel 620 is shown as partially transparent in Figure 6A for clarity. The syringe 600 further includes a base 640 and a lock member 650 operably coupled to the base 640. The lock member 650 includes a lock plate 652 coupled to a button portion 654. The plunger 610 includes a lower edge or surface 611 including a plurality of lock features 613 extending/protruding from the lower surface 611. Each of the lock features 613 can include (i) a ramp portion 615, (ii) a plateau portion 617 extending from the ramp portion 115, and (iii) a stop surface 619 extending from the plateau portion 617.

[0061] When the plunger 610 is withdrawn through the barrel 620, the lock features 613 are configured to engage the lock plate 652 to automatically lock the plunger 110 in a withdrawn position corresponding to the position of the lock feature 613. More specifically, a user can withdraw the plunger 610 to a desired location/volume and the lock feature 613 nearest the lock plate 652 can engage the lock plate 652 to automatically lock the plunger 610 in position. To move the syringe 600 from the withdrawn position to the depressed position, the user can (i) actuate the button portion 654 of the lock member 650 to disengage the lock plate 652 from the lock feature 613 to unlock the plunger 610 from the lock member 650 and then (ii) push the plunger 610 relative to the barrel 620. In one aspect of the present technology, the syringe 600 includes multiple ones of the lock features 613 that permit the syringe 600 to be automatically locked at multiple different positions. In the illustrated embodiment, the plunger 610 includes 12 locking features while, in other embodiments, the syringe 600 can include any number of lock

features 613 to facilitate locking of the syringe 600 at any desired position/volume. Moreover, the location of the lock features 613 can be selected to provide refined volume and vacuum control.

[0062] In the illustrated embodiment, the syringe 600 further includes a locking mechanism 690 that is actuatable to enable/disable the auto-locking functionality of the syringe 600. More specifically, Figures 6B and 6C are enlarged side views of the locking mechanism 690 of the syringe 600 in a first position and a second position, respectively, in accordance with embodiments of the present technology. Referring to Figures 6B and 6C together, the locking mechanism 690 can include a pin 692 operably coupled to the base 650 via a biasing member 694. In the illustrated embodiment, the pin 692 includes a head portion 693 and an engagement portion 695. The biasing member 694 can be operably coupled between the head portion 693 and the base 640, and the engagement portion 695 can at least partially extend through a channel 696 in the base 640. The lock member 650 can include an opening 698 configured to receive the engagement portion 695 of the pin 692 in the first position shown in Figure 6B.

[0063] In the first position shown in Figure 6B, the biasing member 694 (e.g., a tension spring) biases the lock pin 692 toward the lock member 650 such that the engagement portion 695 is positioned in the opening 698. Referring to Figures 6A and 6B together, in the first position the lock member 650 is partially depressed such that the lock features 613 are free to slide past the lock plate 652 without engaging the lock plate 652. Accordingly, the plunger 610 can be withdrawn/depressed through the barrel 620 without the lock features 613 automatically locking the syringe 600—and thus the syringe 600 functions similar to a conventional syringe when the locking mechanism 690 is in the first position. To enable to the auto-locking functionality of the syringe 600, a user can pull the pin 692 (e.g., the head portion 693) away from the lock member 650 (e.g., against the biasing force of the biasing member 694) to withdraw the engagement portion 695 from the opening 698 and disengage the engagement portion 695 from the lock member 650. Accordingly, in the second position, the lock member 650 is operable to engage the lock features 613 to auto-lock the syringe 600 (e.g., the lock member 650 can be biased towards as described with reference to Figures 3A–4). In other embodiments, the pin 692 can be operably coupled to the lock member 650 and configured to engage the base 640. In some embodiments, the syringe 100 and/or the syringe 500 described in detail with reference to Figures 1A–5C can include an identical or similar locking mechanism for enabling/disabling the autolocking functionality.

II. Selected Embodiments of Clot Treatment Systems

[0064] Figure 7 is a partially schematic side view of a clot treatment or clot removal system comprising an aspiration assembly 700 ("assembly 700") incorporating the syringe 100, the syringe 500, and/or the syringe 600 in accordance with embodiments of the present technology. In the illustrated embodiment, the assembly 700 includes a catheter subsystem 710 fluidly coupled to a tubing subsystem 720. In general, the assembly 700 (i) can include features generally similar or identical to those of the aspiration assemblies described in detail in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety, and/or (ii) can be used to treat/remove clot material from a patient (e.g., a human patient) using any of the methods described in detail therein.

[0065] In the illustrated embodiment, the catheter subsystem 710 includes a catheter 702 (e.g., an aspiration catheter) comprising an elongated shaft defining a lumen 704 and having a distal portion 703 and a proximal portion 705. The catheter subsystem 710 further includes a valve 706 that can be integral with or coupled to the proximal portion 705 of the catheter 702. In some embodiments, the valve is a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in the proximal direction through the valve 706 as various components such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and so on are inserted through the valve 706 to be delivered through the catheter 702 to a treatment site in a blood vessel. The valve 706 includes a branch or side port 708 configured to fluidly couple the lumen 704 of the catheter 702 to the tubing subsystem 720. In some embodiments, the valve 706 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety.

[0066] The tubing subsystem 720 fluidly couples the catheter subsystem 710 to the syringe 100, the syringe 500, and/or the syringe 600 (collectively the "syringe 100/500/600"). More specifically, the tubing subsystem 720 can include one or more tubing sections 724 (individually labeled as a first tubing section 724a and a second tubing section 724b), at least one fluid control device 726 (e.g., a valve), and at least one connector 728 (e.g., a Toomey tip connector) for fluidly coupling the tubing subsystem 720 to the syringe 100/500/600 and/or other suitable components. More specifically, in the illustrated embodiment the fluid control device 726 is a stopcock that is

fluidly coupled to (i) the side port 708 of the valve 706 via the first tubing section 724a and (ii) the connector 728 via the second tubing section 724b.

[0067] The fluid control device 726 is externally operable by a user to regulate the flow of fluid therethrough and, specifically, from the lumen 704 of the catheter 702 to the syringe 100/500. In some embodiments, the connector 728 is a quick-release connector (e.g., a quick disconnect fitting) that enables rapid coupling/decoupling of the catheter 702 and the fluid control device 726 to/from the syringe 100/500/600.

[0068] With reference to Figures 1A–7 together, the syringe 100/500/600 is configured to generate (e.g., form, create, charge, build-up) a vacuum (e.g., negative relative pressure) and store the vacuum for subsequent application to the catheter subsystem 710. For example, during operation of the assembly 700, a user can first close the fluid control device 726 before (i) withdrawing the plunger 110 of the syringe 100 until the plunger 110 automatically locks to build up vacuum pressure within the barrel 120 of the syringe 100, (ii) withdrawing the plunger 510 of the syringe 500 until the plunger 510 automatically locks to build up vacuum pressure within the barrel 520 of the syringe 500, and/or (iii) withdrawing the plunger 610 of the syringe 600 until the plunger 610 automatically locks at a location corresponding to one of the lock features 613. In this manner, a vacuum is charged within the syringe 100/500/600 (e.g., a negative pressure is maintained) before the syringe 100/500/600 is fluidly connected to the catheter subsystem 710. To aspirate the lumen 704 of the catheter 702, the user can open the fluid control device 726 to fluidly connect the syringe 100/500/600 to the catheter subsystem 710 and thereby apply or release the vacuum stored in the syringe 100/500/600 to the lumen 704 of the catheter 702.

[0069] Opening of the fluid control device 726 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing subsystem 720 and the catheter 702, thereby generating a suction pulse throughout the catheter 702. In particular, the suction is applied at the distal portion 703 of the catheter 702. In one aspect of the present technology, pre-charging or storing the vacuum in the syringe 100/500/600 before applying the vacuum to the lumen 704 of the catheter 702 is expected to generate greater suction forces and corresponding fluid flow velocities at and/or near the distal portion 703 of the catheter 702 compared to simply activating the syringe 100/500/600 while it is fluidly connected to the catheter 702. When the distal portion 703 is intravascularly positioned near clot material within a patient (e.g., a human patient), the suction forces generated by application of the stored vacuum can be used to aspirate or otherwise remove clot material from within a blood vessel of the patient.

III. Selected Embodiments of Vacuum Indicators

[0070] Referring to Figure 7, in some embodiments the assembly 700 can include a vacuum indicator 730 (shown schematically) operably coupled to the tubing subsystem 720. As described in greater detail below with reference to Figures 8A and 8B, the vacuum indicator 730 can provide an indication, such as a visual indication, of whether the assembly 700 is under vacuum pressure. In the illustrated embodiment, the vacuum indicator 730 is operably coupled to the tubing subsystem 720 between the fluid control device 726 and the valve 706 (e.g., to the first tubing section 724a, between separate portions of the first tubing section 724a). In other embodiments, the vacuum indicator 730 can be operably coupled to the tubing subsystem 720 between the fluid control device 726 and the connector 728 (e.g., to the second tubing section 724b, between separate portions of the second tubing section 724b).

[0071] Figures 8A and 8B are enlarged, partially-schematic side views of the vacuum indicator 730 in a vacuum-off position and a vacuum-on position, respectively, in accordance with embodiments of the present technology. Referring to Figures 8A and 8B together, the vacuum indicator 730 includes a body 832 and a flexible member 834 operably coupled to the body 832. The flexible member 834 is shown as partially transparent in Figures 8A and 8B for clarity. In some embodiments, the body 832 is an integral or one-piece member of plastic, metal, or another suitably rigid material. The body 832 can include a first connector portion 836a (e.g., a first barb), a second connector portion 836b (e.g., a second barb), and a central portion 838 extending between the first and second connector portions 836a, b. The body 832 can further define a lumen 837 extending therethrough between the first and second connector portions 836a, b. The first connector portion 836a can be coupled to a first tube 825a and the second connector portion 836b can be coupled to a second tube 825b. In some embodiments, the first and second tubes 825a, b can together form the first tubing section 724a (Figure 7) such that the vacuum indicator 730 is fluidly coupled between the fluid control device 726 and the valve 706.

[0072] In the illustrated embodiment, the central portion 838 of the body 832 includes/defines (i) a recess 840 extending circumferentially thereabout (ii) and an opening 842 positioned in the recess 840 and extending through the central portion 838 to the lumen 837. In some embodiments, the recess 840 can have a different shape and/or can extend only partially around the central portion 838, and/or the body 832 can include more than one of the openings 842 positioned in the recess 840. The flexible member 834 can be a thin compliant tube that is positioned over the recess 840 and the opening 842. In some embodiments, opposing end portions

of the flexible member 834 are secured to the body 832 via a first attachment member 844a and a second attachment member 844b. The first and second attachment members 844a, b can comprise adhesives, welds, fasteners, collars, or other components that mechanically secure the flexible member 834 over the recess 840 such that the flexible member 834 forms a seal over the recess 840. In some embodiments, the flexible member 834 can have a thickness of between about 0.005 inch to about 0.100 inch.

[0073] With additional reference to Figure 7, when the assembly 700 is not under vacuum, the flexible member 834 is positioned over the recess 840 in a relaxed state such that the flexible member 834 has a generally cylindrical shape as shown in Figure 8A. When a vacuum is generated in the assembly 700, the vacuum is applied to the flexible member 834 via the opening 842 and pulls/sucks the flexible member 834 into the recess 840 as shown in Figure 8B. The deformation of the flexible member 834 provides a visual indication to a user of the assembly 700 that the assembly 700 is under vacuum. When the vacuum is released, the flexible member 834 returns/rebounds to the vacuum-off position shown in Figure 8A to provide a visual indication that the assembly 700 is not under vacuum.

[0074] In some embodiments, the thickness of the flexible member 834, the size of the opening 842, and/or the number of openings 842 can be selected such that the flexible member 834 deforms to the vacuum-on position (Figure 8B) and returns to the vacuum-off position (Figure 8A) at a selected level of vacuum. For example, making the flexible member 834 thinner will cause it to indent under less vacuum while making the flexible member 834 thicker will require more vacuum to indent. Likewise, a thinner flexible member 834 will be less likely to rebound to the vacuum-off position (Figure 8A) and therefore require more pressure (e.g., positive pressure) to rebound, while a thicker flexible member 834 will rebound with little to no pressure.

[0075] In some embodiments, the vacuum indicator 730 can include a housing 846 (shown schematically) at least partially surrounding the flexible member 834. The housing 846 can be formed of a rigid material (e.g., plastic, metal) and can be coupled to the body 832. In some embodiments, the housing 846 is configured to inhibit or even prevent excessive deformation of the flexible member 834 when the assembly 700 is under positive pressure. For example, when positive pressure is applied to the assembly 700, the flexible member 834 can flex outwardly away from the body 832 and contact the housing 846. The housing 846 can therefore inhibit the flexible member 834 from flexing further outwardly, which could damage or rupture the flexible member 834.

[0076] In some aspects of the present technology, the vacuum indicator 730 can aid the user during a clot removal procedure on a patient using the assembly 700. Sometimes, for example, after applying the vacuum stored in the syringe 100/500/600 to the lumen 704 of the catheter 702, clot material can at least partially clog the distal portion 703 of the catheter 702—causing the assembly 700 to cavitate. In such instances, it is often desirable to remove the assembly 700 from the patient to thereby remove the clot material clogging and/or attached to the distal portion 703 of the catheter 702. However, user error and/or leakage of the assembly 700 (e.g., out of the valve 706) can dissipate the vacuum in the assembly 700, thereby releasing and/or decreasing the force holding the clot material to the catheter 702. The vacuum indicator 730 can provide a fast and easy visual indication to the user of whether the assembly 700 is maintaining vacuum. Thus, based on the position of the vacuum indicator 730, the user can determine how to proceed with the procedure—for example, whether to continue withdrawing the assembly 700 from the patient.

[0077] In some aspects of the present technology, the vacuum indicator 730 is a passive device that adds no or very little volume to the flow path of the assembly 700. Adding volume to the flow path of the assembly 700 can reduce the amount of aspirational force that can be generated at the distal portion 703 of the catheter 702. Accordingly, the vacuum indicator 730 can provide an indication of vacuum (e.g., on or off) without negatively affecting the clot removal capabilities of the assembly 700. In contrast, for example, a vacuum gauge coupled along the flow path of the assembly 702 would increase the volume thereof and reduce the aspirational force of the assembly 700. Moreover, the recess 840 can have a relatively small volume such that the vacuum indicator 730 is not prone to clogging during use of the assembly 700 (e.g., clogging with blood clots during a thrombectomy procedure using the assembly 700). In contrast, a vacuum gauge or similar mechanism would be more prone to clogging, possibly rendering them non-functional.

[0078] Figure 9 is a perspective view of a vacuum indicator 930 in a vacuum-off position in accordance with additional embodiments of the present technology. The vacuum indicator 930 can include some features, functions, and/or advantages that are generally similar or identical to the vacuum indicator 730 described in detail above with reference to Figures 8A and 8B. For example, in the illustrated embodiment the vacuum indicator 930 includes a body 932 and a flexible member 934 operably coupled to the body 932. The flexible member 934 is shown as partially transparent in Figure 9 for clarity. The body 932 can include a first connector portion 936a (e.g., a first barb), a second connector portion 936b (e.g., a second barb), and a central portion 938 extending between the first and second connector portions 936a, b. The body 932 can further

define a lumen 937 extending therethrough between the first and second connector portions 936a, b. The first and second connector portions 936a, b can be coupled to, for example, various tubes of the first tubing section 724a and/or the second tubing section 724b (Figure 7).

[0079] In the illustrated embodiment, the central portion 938 of the body 932 includes/defines a plurality of longitudinal openings 950 extending through the central portion 938 to the lumen 937. In some embodiments, the openings 950 can be equally spaced about the body 932. In other embodiments, the central portion 938 can include more or fewer of the openings 950 and/or the openings 950 can be positioned differently about the central portion 938. The flexible member 934 can be a thin compliant tube that is sealingly secured to the body 932 over the openings 950 via a first attachment member 944a and a second attachment member 944b.

[0080] With additional reference to Figure 7, when the assembly 700 is not under vacuum, the flexible member 934 is positioned over the openings 950 in a relaxed state such that the flexible member 934 has a generally cylindrical shape as shown in Figure 9. When a vacuum is generated in the assembly 700, the vacuum is applied to the flexible member 934 via the openings 950 and pulls the flexible member 934 at least partially into one or more of the openings 950. The deformation of the flexible member 934 provides a visual indication to a user of the assembly 700 that the assembly 700 is under vacuum. When the vacuum is released, the flexible member 934 can return to the position vacuum-off shown in Figure 9 to provide a visual indication that the assembly 700 is not under vacuum. In some embodiments, the vacuum indicator 930 can include a housing (not shown) at least partially surrounding the flexible member 934 and configured to inhibit or even prevent excessive deformation of the flexible member 934 when the assembly 700 is under positive pressure.

[0081] Figures 10A and 10B are perspective views of a vacuum indicator 1030 in a vacuum-off position and a vacuum-on position, respectively, in accordance with additional embodiments of the present technology. The vacuum indicator 1030 can include some features, functions, and/or advantages that are generally similar or identical to the vacuum indicator 730 and/or the vacuum indicator 930 described in detail above with reference to Figures 8A–9. For example, referring to Figures 10A and 10B together, the vacuum indicator 930 includes a flexible member 934 fluidly coupled to a tube 1025. In some embodiments, the tube 925 is a portion of the first tubing section 724a or the second tubing section 724b (Figure 7).

[0082] In the illustrated embodiment, however, the flexible member 1034 is directly attached to the tube 1025 over a hole or opening 1027 (obscured in Figure 10A and shown

schematically) in the tube 1025. In some embodiments, opposing end portions of the flexible member 1034 are secured to the tube 1029 via a first attachment member 1044a and a second attachment member 1044b. The first and second attachment members 1044a, b can be clamps, collars, or other mechanical components that mechanically secure the flexible member 1034 over the opening 1027 such that the flexible member 1034 forms a seal over the opening 1027. The first and second attachment members 1044a, b can be secured to the tube 1025 via compression, adhesives, fasteners, and/or other suitable means of connection. In some embodiments, the opening 1027 can have a diameter of about 0.100 inch to about 0.300 inch.

[0083] With additional reference to Figure 7, when the assembly 700 is not under vacuum, the flexible member 1034 is positioned over the opening 1027 in a relaxed state such that the flexible member 1034 has a generally cylindrical shape as shown in Figure 10A. When a vacuum is generated in the assembly 700, the vacuum is applied to the flexible member 1034 via the opening 1027 and pulls the flexible member 1034 into the opening 1027 as shown in Figure 10B. The deformation of the flexible member 1034 provides a visual indication to a user of the assembly 700 that the assembly is under vacuum. When the vacuum is released, the flexible member 1034 returns to the vacuum-off position shown in Figure 10A to provide a visual indication that the assembly 700 is not under vacuum.

[0084] In some embodiments, a syringe configured in accordance with the present technology can include a vacuum indicator integrated therewith. For example, Figure 11 is a side-view of the syringe 100 of Figures 1A and 1B including a vacuum indicator 1130 formed in the adaptor 130 in accordance with embodiments of the present technology. In the illustrated embodiment, the vacuum indicator 1130 includes a flexible member 1134 sealingly positioned over an opening 1152 in the adaptor 130. The flexible member 1134 can be formed from a compliant material, such as silicone, and can have a dome-like shape in a vacuum-off position shown in Figure 11. With additional reference to Figure 7, when the syringe 100 is coupled to the system 700 (e.g., to the connector 728) and the plunger 110 is drawn to pull a vacuum in the barrel 120, the vacuum is applied to the flexible member 1134 via the opening 1152 and pulls the flexible member 1134 into/toward the opening 1152. For example, the flexible member 1134 can invert when the assembly 700 is under vacuum. The inversion/deformation of the flexible member 1134 provides a visual indication to a user of the assembly 700 that the assembly 700 is under vacuum. When the vacuum is released, the flexible member 1134 can passively return to the vacuum-off

position shown in Figure 11 to provide a visual indication that the assembly 700 is not under vacuum.

[0085] Figures 12A and 12B are perspective views of a syringe 1200 including a vacuum indicator 1230 in accordance with additional embodiments of the present technology. The syringe 1200 is in a withdrawn position in Figure 12B. Referring to Figures 12A and 12B together, the syringe 1200 includes a plunger 1210 slidably positioned within a barrel 1220. The barrel 1220 is shown as partially transparent in Figure 1B for clarity. The plunger 1210 includes a flange 1214 configured to sealingly engage an inner surface of the barrel 1220 to define a sealed volume 1217 (Figure 12B: e.g., of negative/vacuum pressure) within the barrel 1220.

[0086] In the illustrated embodiment, the vacuum indicator 1230 includes a housing 1260 (shown as partially transparent in Figures 12A and 12B) coupled to the plunger 110 and defining a lumen 1262. The flange 1214 can include a through-hole 1264 fluidly coupling the lumen 1262 of the housing 1260 to the sealed volume 1217 within the barrel 1220. The vacuum indicator 1230 can further include an indication member 1266 slidably positioned within the lumen 1262. The indication member 1266 can be an elongate member and, in some embodiments, can have a color (e.g., a relatively bright color) that contrasts with a color of the housing 1260. In some embodiments, the indication member 1266 is configured to sealingly engage the housing 1260. For example, the housing 1260 can include one or more sealing members (e.g., O-rings; not shown) on an inner surface thereof and/or the indication member 1266 can include one or more sealing members (e.g. O-rings; not shown) on an outer surface thereof to provide a dynamic seal between the housing 1260 and the indication member 1266. In the illustrated embodiment, the indication member 1266 is operably coupled to the flange 1214 via a biasing member 1268 that extends through the lumen 1262. The biasing member 1268 (e.g., a compression spring) is configured to bias the indication member 1266 through the lumen 1262 in a direction away from the flange 1214 (e.g., as indicated by arrow F in Figure 12A).

[0087] With additional reference to Figure 7, when the syringe 1200 is coupled to the system 700 (e.g., to the connector 728) and the plunger 1210 is drawn to pull a vacuum in the sealed volume 1217 of the barrel 1220, the vacuum is applied to the indication member 1266 via the through-hole 1264 in the flange 1214 and the lumen 1262 of the housing 1260. The vacuum pulls the indication member 1266 through the lumen 1262 against the biasing force of the biasing member 1268 as indicated by arrow G in Figure 12B. The positioning of the indication member 1266 relative to the housing 1260 can provide a visual indication to a user of the assembly 700

that the assembly 700 is under vacuum. In some embodiments, for example, when the plunger 1210 is fully withdrawn, the indication member 1266 can be positioned entirely within the lumen 1262 and thus obscured by the housing 1260 as shown in Figure 12B. When the vacuum is released, the biasing member 1268 drives the indication member 1266 through the lumen 1262 in the direction of arrow F at least partially outside the housing 1260 (e.g., as shown in Figure 12A) to provide a visual indication that the assembly 700 is not under vacuum. In some aspects of the present technology, the position of the indication member 1266 relative to the housing 1260 can provide an indication of a varying level of vacuum in the assembly 700 (e.g., in contrast to a binary on/off indication).

[0088] In some embodiments, the plunger 1210 includes a grip portion 1216 configured to engage the indication member 1266, as shown in Figure 12A, to inhibit further movement of the indication member 1266 in the direction of arrow F when the assembly 700 is under positive pressure. In some embodiments, any of the vacuum-pressure locking syringes 100/500/600 described in detail above with reference to Figures 1A–6C can include the vacuum indicator 1230.

[0089] Figures 13A–13C are side views of a vacuum indication device or vacuum indicator 1330 in a vacuum-off position, a partial-vacuum position, and a full-vacuum position, respectively, in accordance with additional embodiments of the present technology. Referring to Figures 13A–13C together, the vacuum indicator 1330 includes a sealing indicator 1370 slidably positioned within a barrel 1320. The barrel 1320 includes a cap 1371 (e.g., a sealed cap), and a tip 1326 (e.g., a Luer connector) that can be directly coupled to another device or system, such as the fluid control device 726 (e.g., stopcock) of Figure 7, as shown in Figures 13B and 13C.

[0090] In some embodiments, the sealing indicator 1370 is configured to sealingly engage the barrel 1320 to define a first volume or chamber 1372 and a second volume or chamber 1374 within the barrel 1320. For example, the sealing indicator 1370 can include one or more sealing members (e.g. O-rings; not shown) on an outer surface thereof to provide a dynamic seal between the barrel 1320 and the sealing indicator 1370. In some embodiments, the one or more sealing members can engage the barrel 1320 with low friction to facilitate sliding movement of the sealing indicator 1370 within the barrel 1320. The first chamber 1372 can be a sealed volume with no outlet, while the second chamber 1374 can be open to the tip 1326.

[0091] With additional reference to Figure 7, when the assembly 700 is not under vacuum pressure, the sealing indicator 1370 can be positioned near an upper portion of the barrel 1320 proximate the cap 1371. When the syringe 100/500/600 is used to generate a vacuum in the

assembly 700, vacuum pressure is generated in the second chamber 1374. The vacuum pressure in the second chamber 1374 pulls the sealing indicator 1370 downward toward the tip 1326 of the barrel 1320 as shown in Figure 13B. As the sealing indicator 1370 moves downward away from the cap 1371, the volume of the first chamber 1372 increases, thereby generating vacuum pressure in the first chamber 1372. The vacuum pressure generated in the first chamber 1372 provides a resistive force that acts against the vacuum force in the second chamber 1374 to urge the sealing indicator 1370 upward toward the cap 1371. The vacuum force in second chamber 1374 must overcome the resistive vacuum force in first chamber 1372 to cause the sealing indicator 1370 to travel downward through the barrel 1320. In some embodiments, the vacuum indicator 1370 is configured (e.g., shaped, sized) such that the sealing indicator 1370 abuts the tip 1326 of the barrel 1320 in the full-vacuum position, as shown in Figure 13C, to indicate that a maximum vacuum level has been generated in the assembly 700. If vacuum force dissipates or is lost in the assembly 700, the resistive vacuum force in the first chamber 1372 can return the sealing indicator 1370 toward the vacuum-off position shown in Figure 13A.

[0092] In general, the opposing vacuum forces in the first and second volumes 1372, 1374, along with the friction forces between the barrel 1320 and the sealing indicator 1370, dictate the travel speed and location of the sealing indicator 1370 along the barrel 1320. In some aspects of the present technology, the vacuum indicator 1330 can provide a continuous resolution of the vacuum level at higher vacuum levels (e.g., greater than 25 inHg). That is, the position of the sealing indicator 1370 in the barrel 1320 can indicate a specific level of vacuum in the assembly 700.

[0093] Figures 14A and 14B are an isometric view and a top view of a syringe 1400 in accordance with additional embodiments of the present technology. The syringe 1400 is in a depressed/advanced position in Figures 14A and 14B. Referring to Figures 14A and 14B together, the syringe 1400 can include several features generally similar or identical to the syringe 100 described in detail above with reference to Figures 1A–4, and can be coupled to the assembly 700 of Figure 7 for use in a clot removal procedure. In the illustrated embodiment, for example, the syringe 1400 includes a plunger 1410 configured to be slidably positioned within a barrel 1420. The barrel 1420 is shown as partially transparent in Figures 14A and 14B for clarity. The barrel 1420 can include a barrel portion 1422 and a tip 1426. The plunger 1410 can include a shaft 1412 and a grip portion 1416. The syringe 1400 further includes a base 1440 and a lock member 1450 having a lock plate 1452 (obscured in Figure 14B and partially obscured in Figure 14A) and a

button portion 1454. The lock member 1450 is configured to automatically engage the base 1440 when the plunger 1410 is withdrawn to automatically lock the plunger 1410 in a withdrawn position, as described in detail above. The button portion 1454 can be actuatable (e.g., depressible) by a user to release the lock plate 1452 from the base 1440 to release the plunger 1410 to, for example, permit the plunger 1410 to move through the barrel 1420 to expel any contents (e.g., bodily fluids such as blood and clot material) collected in the barrel 1420 from the tip 1426. In the illustrated embodiment, however, the button portion 1454 extends generally parallel to the grip portion 1416 of the plunger 1410.

[0094] Moreover, in the illustrated embodiment the syringe 1400 further includes a vacuum indicator 1430 formed in and/or coupled to the tip 1426. Figures 14C and 14D are enlarged side views of the vacuum indicator 1430 in a "vacuum-off" and a "vacuum-on" position, respectively, in accordance with embodiments of the present technology. Figures 14E and 14F are enlarged partially transparent side views of the vacuum indicator 1430 in the vacuum-off and the vacuum-on position, respectively, in accordance with embodiments of the present technology. Figure 14G is an enlarged side cross-sectional view of the vacuum indicator in the vacuum-off position in accordance with embodiments of the present technology. Referring to Figures 14E–14G together, the vacuum indicator 1430 can include a flexible member 1434 (e.g., a diaphragm, a rolling diaphragm) sealingly positioned over an opening 1461 in the tip 1426. The flexible member 1434 can be formed from a compliant material, such as silicone.

[0095] Referring to Figures 14C–14G together, in the illustrated embodiment the vacuum indicator 1430 further includes (i) a non-transparent (e.g., opaque) bonnet or base 1435 positioned around and/or coupled to the flexible member 1434, (ii) a transparent tube 1437 coupled to and extending from the base 1435, and (iii) a non-transparent cap 1439 coupled to and positioned above the tube 1437. The base 1435, the tube 1437, and/or the cap 1439 can be integrally formed or can be separate components coupled together. The vacuum indicator 1430 can further include an indicator 1460 movably positioned within the tube 1437 and the cap 1439. The indicator 1460 can include a first indicator region 1462 and a second indicator region 1464 each having at least one different visual characteristic (e.g., color, pattern, size, thickness, shape) from one another. For example, in some embodiments the first indicator region 1462 can be a first color (e.g., red) while the second indicator region 1464 can be a different second color (e.g., green). In some embodiments, a first end portion of the indicator 1460 (e.g., a lower end of the first indicator region 1462) can be coupled to the flexible member 1434 and a second end portion of the indicator

1460 (e.g., an upper end of the second indicator region 1464) can be coupled to the cap 1439 via a biasing member 1466 (Figures 14F and 14G), such as a spring. As best seen in Figure 14G, in some embodiments the biasing member 1466 can extend at least partially through an internal channel 1469 of the indicator 1460.

[0096] When the tip 1426 of the syringe 1400 is not under vacuum, the vacuum indicator 1430 is in the vacuum-off position in which the biasing member 1466 biases the indicator 1460 toward the cap 1439 such that the first indicator region 1462 is positioned adjacent the transparent tube 1437—and thus visible to the user—as shown in Figures 14C and 14E. At the same time, the second indicator region 1464 is obscured by the non-transparent cap 1439 in the vacuum-off position. When the tip 1426 of the syringe 1400 is under vacuum, the vacuum indicator 1430 is in the vacuum-on position in which the vacuum pulls the flexible member 1434 into/toward the opening 1461, thereby pulling the indicator 1460 toward the opening 1461 against the biasing force of the biasing member 1466 such that the second indicator region 1464 is positioned adjacent the transparent tube 1437—and thus visible to the user—as shown in Figures 14D and 14F. At the same time, the first indicator region 1462 is obscured by the non-transparent base 1435 in the vacuum-on position. In this manner, the first and second indicator regions 1462, 1464 are configured to provide a visual indication to the user of whether the syringe 1400 (and the coupled assembly 700 of Figure 7) is under vacuum or not.

[0097] Figures 15A and 15B are an isometric view and a side view of a syringe 1500 in accordance with additional embodiments of the present technology. The syringe 1500 is in a depressed/advanced position in Figures 15A and 15B. Referring to Figures 15A and 15B together, in some embodiments the syringe 1500 can be generally identical to the syringe 1400 described in detail above with reference to Figures 14A and 14B (e.g., including the plunger 1410, the barrel 1420, the 1426, the base 1440, and the lock member 1450). In the illustrated embodiment however, the syringe 1500 includes a different vacuum indicator 1530 formed in and/or coupled to the tip 1426.

[0098] Figures 15C and 15D are enlarged side views of the vacuum indicator 1530 in a "vacuum-off" and a "vacuum-on" position, respectively, in accordance with embodiments of the present technology. Figures 15E and 15F are enlarged partially transparent side views of the vacuum indicator 1530 in the vacuum-off and the vacuum-on position, respectively, in accordance with embodiments of the present technology. Figure 15G is an enlarged side cross-sectional view of the vacuum indicator in the vacuum-off position in accordance with embodiments of the present

technology. The vacuum indicator 1530 can include several features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the vacuum indicator 1430 described in detail above with reference to Figures 14C–14G, and can operate in a generally similar or identical manner to the vacuum indicator 1430.

[0099] For example, referring to Figures 15E–15G together, the vacuum indicator 1530 can include a flexible member 1534 (e.g., a diaphragm, a rolling diaphragm) sealingly positioned over the opening 1461 in the tip 1426. The flexible member 1534 can be biased to a first (e.g., preconvoluted) position in the vacuum-off position and can be pulled downward toward the opening 1461 to a second position in the vacuum-on position. Referring to Figures 15C–15G together, the vacuum indicator 1530 can further include (i) a non-transparent (e.g., opaque) base 1535 positioned around and/or coupled to the flexible member 1534, (ii) a transparent tube 1537 coupled to and extending from the base 1535, and (iii) a non-transparent cap 1539 coupled to and positioned above the tube 1537. The base 1535, the tube 1537, and/or the cap 1539 can be integrally formed or can be separate components coupled together. The vacuum indicator 1530 further includes an indicator 1560 positioned within the tube 1537 and the cap 1539. In the illustrated embodiment, the indicator 1560 includes a first indicator region or portion 1562 and a second indicator region or portion 1564 each having at least one different visual characteristic from one another. For example, in some embodiments the first indicator portion 1562 can be a first color (e.g., red) while the second indicator portion 1564 can be a different second color (e.g., green). In some embodiments, the second indicator portion 1564 is at least partially nested within the first indicator portion 1562 in the vacuum-off position (e.g., as best seen in Figure 15G). The first indicator portion 1562 (e.g., a lower end portion thereof) can be coupled to the flexible member 1534 while the second indicator portion 1564 (e.g., an upper end portion thereof) can be coupled to the cap 1539.

[0100] When the tip 1426 of the syringe 1500 is not under vacuum, the vacuum indicator 1530 is in the vacuum-off position in which the flexible member 1534 is in the first position and biases the first indicator portion 1562 upward toward the cap 1539 such that the second indicator portion 1564 is positioned adjacent the transparent tube 1537—and thus visible to the user—as shown in Figures 15C and 15E. At the same time, the first indicator portion 1562 at least partially surrounds the second indicator portion 1564 such that the second indicator portion 1564 is obscured and not visible to the user in the vacuum-off position. When the tip 1426 of the syringe 1500 is under vacuum, the vacuum indicator 1530 is in the vacuum-on position in which the

vacuum pulls the flexible member 1534 into/toward the opening 1461, thereby pulling the first indicator portion 1562 downward away from the cap 1539 and the second indicator portion 1564 such that the second indicator portion 1564 is visible through the transparent tube 1537, as shown in Figures 15D and 15F. At the same time, the first indicator portion 1562 is obscured by the non-transparent base 1535 in the vacuum-on position. In this manner, the first and second indicator portions 1562, 1564 are configured to provide a visual indication to the user of whether the syringe 1500 (and the coupled assembly 700 of Figure 7) is under vacuum or not.

[0101] In some embodiments, alternatively to or in addition to using the flexible member 1534 to bias the first indicator portion 1562 to the vacuum-off position, the vacuum indicator 1530 can include a biasing member configured to bias the first indicator portion 1562 to the vacuum-off position. Figure 16, for example, is an enlarged side cross-sectional view of the vacuum indicator 1530 further including a biasing member 1666, such as a spring, operably coupled between the cap 1539 and the first indicator portion 1562 in accordance with embodiments of the present technology. In the illustrated embodiment, the biasing member 1666 has an upper end portion 1667 coupled to the cap 1539 (e.g., a spring-mount thereof) and a lower end portion 1668 coupled to the first indicator portion 1562 (e.g., a spring mount thereof). In some embodiments the biasing member 1666 can extend at least partially through an internal channel 1669 of the second indicator portion 1564. When the tip 1426 of the syringe 1500 is not under vacuum, the biasing member 1666 can bias the first indicator portion 1562 toward the cap 1539 to the vacuum-off position. When the tip 1426 of the syringe 1500 is under vacuum, the flexible member 1534 can pull the first indicator portion 1562 toward the opening 1461 against the biasing force of the biasing member 1666 to the vacuum-on position.

IV. Further Examples

[0102] The following examples are illustrative of several embodiments of the present technology:

1. An automatically-locking syringe, comprising:
a barrel;
a plunger slidably positioned within the barrel, wherein the plunger is movable between a depressed position and a withdrawn position, and wherein the plunger includes a lock feature; and

a lock plate coupled to the barrel and having an opening extending therethrough, wherein the plunger is slidably positioned in the opening, wherein the lock plate includes a biasing member configured to bias the lock plate to a locking position, and wherein—

when the plunger is moved from the depressed position to the withdrawn position, the lock feature is configured to engage the lock plate to drive the lock plate to a position away from the locking position to thereby permit the lock feature to pass through the opening, and

after the lock feature passes through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.

2. The syringe of example 1 wherein the lock feature includes a stop surface extending generally perpendicular to a longitudinal axis of the syringe, and wherein the lock plate is configured to engage the stop surface when (a) the lock plate is in the locking position and (b) the plunger is in the withdrawn position.

3. The syringe of example 1 or example 2, further comprising a button coupled to the lock plate, wherein the button is actuatable to move the lock plate away from the locking position to permit movement of the plunger from the withdrawn position to the depressed position.

4. The syringe of any one of examples 1–3 wherein the biasing member includes at least one of a spring and a living hinge.

5. The syringe of any one of examples 1–3 wherein the biasing member is an arm hingedly coupled to the locking plate.

6. The syringe of any one of examples 1–5 wherein the lock feature is one of a plurality of lock features positioned along a longitudinal axis of the plunger.

7. The syringe of example 6 wherein—

when the plunger is moved from the depressed position to the withdrawn position, individual ones of the lock features are configured to sequentially engage the lock

plate to drive the lock plate to the position away from the locking position to thereby permit the lock feature to pass through the opening, and after the individual ones of the lock features sequentially pass through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.

8. The syringe of example 6 or example 7, further comprising a locking mechanism configured to engage the lock plate to lock the lock plate in the position away from the locking position.

9. The syringe of any one of examples 1–8 wherein the barrel has a volume of about 60 cc or greater.

10. An automatically-locking syringe, comprising:
a barrel including a flange;
a plunger slidably positioned within the barrel, wherein the plunger is aligned along a longitudinal axis, and wherein the plunger is movable along the longitudinal axis between a depressed position and a withdrawn position;
a lock member coupled to the plunger, wherein the lock member includes a body and a first arm hingedly coupled to the body, and wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position; and
an actuator including a second arm, wherein the actuator is movable between a first position and a second position, and wherein the second arm is configured to engage the first arm in the second position to drive the first arm inwardly toward the longitudinal axis away from the locking position.

11. The syringe of example 10 wherein the first arm is configured to engage the flange of the barrel to inhibit movement of the plunger from the withdrawn position to the depressed position when (a) the actuator is in the first position and (b) the plunger is in the withdrawn position.

12. The syringe of example 10 or example 11 wherein the lock member includes a third arm hingedly coupled to the body, wherein the third arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position, wherein the actuator includes a fourth arm, and wherein the fourth arm is configured to engage the third arm in the second position to drive the third arm inwardly toward the longitudinal axis away from the locking position.

13. The syringe of example 12 wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis in a first direction, and wherein the third arm is configured to be biased at least partially outwardly away from the longitudinal axis in a second direction opposite the first direction.

14. The syringe of example 12 or example 13 wherein the first arm and the third arm have an identical size and shape, and wherein the second arm and the fourth arm have an identical size and shape.

15. The syringe of any one of examples 12–14 wherein the third arm is configured to engage the flange of the barrel to inhibit movement of the plunger from the withdrawn position to the depressed position when (a) the actuator is in the first position and (b) the plunger is in the withdrawn position.

16. A clot treatment system, comprising:
a catheter;
a pressure source configured to generate vacuum pressure; and
a tubing subsystem configured to fluidly connect the catheter to the pressure source,
wherein the tubing subsystem includes a vacuum indicator configured to provide
an indication that the catheter is under vacuum pressure.

17. The clot treatment system of example 16 wherein the tubing subsystem includes an aperture, wherein the vacuum indicator includes a flexible member positioned over the aperture, and wherein the flexible member is configured to deform about the opening when the catheter is under vacuum pressure to provide the indication that the catheter is under vacuum pressure.

18. The clot treatment system of example 17 wherein the vacuum indicator includes a housing positioned around the flexible member and configured to inhibit excessive deformation of the flexible member when the catheter is under positive pressure.

19. The clot treatment device of any one of examples 16–18, wherein the pressure source is an automatically-locking syringe.

20. The clot treatment device of claim 16 wherein—
the tubing subsystem includes a valve, a first tubing section, a fluid control device, and a second tubing subsystem,
the valve fluidly connects the catheter to the first tubing section,
the first tubing section is fluidly connected between the valve and the fluid control device,
the second tubing system fluidly connects the fluid control device to the pressure source,
and
the vacuum indicator is fluidly connected between the valve and the fluid control device.

21. A syringe, comprising:
a barrel having a tip, wherein the tip includes an opening;
a plunger movable through the barrel to generate vacuum pressure within the barrel; and
a vacuum indicator positioned over the opening in the tip, wherein the vacuum indicator includes a transparent tube and an indicator movably positioned within the tube, wherein the indicator includes a first region having a first visual characteristic and a second region having a second visual characteristic different than the first visual characteristic, and wherein—
when the barrel is not under vacuum pressure, the first region is configured to be positioned adjacent the tube; and
when the barrel is under vacuum pressure, the second region is configured to be positioned adjacent the tube.

22. The syringe of example 21 wherein the vacuum indicator further includes an opaque cap over the tube, wherein the indicator is movably positioned within the cap and the tube, and wherein—

when the barrel is not under vacuum pressure, the second region is configured to be positioned adjacent the cap; and

when the barrel is under vacuum pressure, the first region is configured to be positioned adjacent the cap.

23. The syringe of example 22 wherein the vacuum indicator further includes a biasing member coupled between the indicator and the cap, wherein the biasing member is configured to bias the indicator to position the first region adjacent the tube when the barrel is not under vacuum pressure.

24. The syringe of any one of examples 21–23 wherein the vacuum indicator further includes a flexible member positioned over the opening in the tip and coupled to the indicator.

25. The syringe of example 24 wherein the flexible member is configured to deform about the opening when the catheter is under vacuum pressure.

26. The syringe of example 24 or example 25 wherein the vacuum indicator further includes an opaque cap over the tube, wherein the first portion of the indicator is coupled to the flexible member, and wherein the second portion of the indicator is coupled to the cap.

27. The syringe of any one of examples 21–26 wherein the vacuum indicator further includes a flexible member positioned over the opening in the tip and a biasing member, wherein the first portion of the indicator is coupled to the biasing member, and wherein the second portion of the indicator is coupled to the flexible member.

28. The syringe of any one of examples 21–27 wherein the first and second portions of the indicator are movable relative to one another, and wherein the second indicator is at least partially nested within the second indicator.

V. Conclusion

[0103] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0104] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0105] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. An automatically-locking syringe, comprising:
a barrel;
a plunger slidably positioned within the barrel, wherein the plunger is movable between a depressed position and a withdrawn position, and wherein the plunger includes a lock feature; and
a lock plate coupled to the barrel and having an opening extending therethrough, wherein the plunger is slidably positioned in the opening, wherein the lock plate includes a biasing member configured to bias the lock plate to a locking position, and wherein—
when the plunger is moved from the depressed position to the withdrawn position, the lock feature is configured to engage the lock plate to drive the lock plate to a position away from the locking position to thereby permit the lock feature to pass through the opening, and
after the lock feature passes through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.
2. The syringe of claim 1 wherein the lock feature includes a stop surface extending generally perpendicular to a longitudinal axis of the syringe, and wherein the lock plate is configured to engage the stop surface when (a) the lock plate is in the locking position and (b) the plunger is in the withdrawn position.
3. The syringe of claim 1, further comprising a button coupled to the lock plate, wherein the button is actuatable to move the lock plate away from the locking position to permit movement of the plunger from the withdrawn position to the depressed position.
4. The syringe of claim 1 wherein the biasing member includes at least one of a spring and a living hinge.

5. The syringe of claim 1 wherein the biasing member is an arm hingedly coupled to the locking plate.
6. The syringe of claim 1 wherein the lock feature is one of a plurality of lock features positioned along a longitudinal axis of the plunger.
7. The syringe of claim 6 wherein—
when the plunger is moved from the depressed position to the withdrawn position, individual ones of the lock features are configured to sequentially engage the lock plate to drive the lock plate to the position away from the locking position to thereby permit the lock feature to pass through the opening, and
after the individual ones of the lock features sequentially pass through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.
8. The syringe of claim 6, further comprising a locking mechanism configured to engage the lock plate to lock the lock plate in the position away from the locking position.
9. The syringe of claim 1 wherein the barrel has a volume of about 60 cc or greater.
10. An automatically-locking syringe, comprising:
a barrel including a flange;
a plunger slidably positioned within the barrel, wherein the plunger is aligned along a longitudinal axis, and wherein the plunger is movable along the longitudinal axis between a depressed position and a withdrawn position;
a lock member coupled to the plunger, wherein the lock member includes a body and a first arm hingedly coupled to the body, and wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position; and
an actuator including a second arm, wherein the actuator is movable between a first position and a second position, and wherein the second arm is configured to engage

the first arm in the second position to drive the first arm inwardly toward the longitudinal axis away from the locking position.

11. The syringe of claim 10 wherein the first arm is configured to engage the flange of the barrel to inhibit movement of the plunger from the withdrawn position to the depressed position when (a) the actuator is in the first position and (b) the plunger is in the withdrawn position.

12. The syringe of claim 10 wherein the lock member includes a third arm hingedly coupled to the body, wherein the third arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position, wherein the actuator includes a fourth arm, and wherein the fourth arm is configured to engage the third arm in the second position to drive the third arm inwardly toward the longitudinal axis away from the locking position.

13. The syringe of claim 12 wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis in a first direction, and wherein the third arm is configured to be biased at least partially outwardly away from the longitudinal axis in a second direction opposite the first direction.

14. The syringe of claim 12 wherein the first arm and the third arm have an identical size and shape, and wherein the second arm and the fourth arm have an identical size and shape.

15. The syringe of claim 12 wherein the third arm is configured to engage the flange of the barrel to inhibit movement of the plunger from the withdrawn position to the depressed position when (a) the actuator is in the first position and (b) the plunger is in the withdrawn position.

16. A clot treatment system, comprising:
a catheter;
a pressure source configured to generate vacuum pressure; and

a tubing subsystem configured to fluidly connect the catheter to the pressure source, wherein the tubing subsystem includes a vacuum indicator configured to provide an indication that the catheter is under vacuum pressure.

17. The clot treatment system of claim 16 wherein the tubing subsystem includes an aperture, wherein the vacuum indicator includes a flexible member positioned over the aperture, and wherein the flexible member is configured to deform about the opening when the catheter is under vacuum pressure to provide the indication that the catheter is under vacuum pressure.

18. The clot treatment system of claim 17 wherein the vacuum indicator includes a housing positioned around the flexible member and configured to inhibit excessive deformation of the flexible member when the catheter is under positive pressure.

19. The clot treatment device of claim 16, wherein the pressure source is an automatically-locking syringe.

20. The clot treatment device of claim 16 wherein—
the tubing subsystem includes a valve, a first tubing section, a fluid control device, and a second tubing subsystem,
the valve fluidly connects the catheter to the first tubing section,
the first tubing section is fluidly connected between the valve and the fluid control device,
the second tubing system fluidly connects the fluid control device to the pressure source,
and
the vacuum indicator is fluidly connected between the valve and the fluid control device.

21. A syringe, comprising:
a barrel having a tip, wherein the tip includes an opening;
a plunger movable through the barrel to generate vacuum pressure within the barrel; and
a vacuum indicator positioned over the opening in the tip, wherein the vacuum indicator includes a transparent tube and an indicator movably positioned within the tube, wherein the indicator includes a first portion having a first visual characteristic and a second portion having a second visual characteristic different than the first visual characteristic, and wherein—

when the barrel is not under vacuum pressure, the first portion is configured to be positioned adjacent the tube; and
when the barrel is under vacuum pressure, the second portion is configured to be positioned adjacent the tube.

22. The syringe of claim 21 wherein the vacuum indicator further includes an opaque cap over the tube, wherein the indicator is movably positioned within the cap and the tube, and wherein—

when the barrel is not under vacuum pressure, the second portion is configured to be positioned adjacent the cap; and
when the barrel is under vacuum pressure, the first portion is configured to be positioned adjacent the cap.

23. The syringe of claim 22 wherein the vacuum indicator further includes a biasing member coupled between the indicator and the cap, wherein the biasing member is configured to bias the indicator to position the first portion adjacent the tube when the barrel is not under vacuum pressure.

24. The syringe of claim 21 wherein the vacuum indicator further includes a flexible member positioned over the opening in the tip and coupled to the indicator.

25. The syringe of claim 24 wherein the flexible member is configured to deform about the opening when the catheter is under vacuum pressure.

26. The syringe of claim 24 wherein the vacuum indicator further includes an opaque cap over the tube, wherein the first portion of the indicator is coupled to the flexible member, and wherein the second portion of the indicator is coupled to the cap.

27. The syringe of claim 21 wherein the vacuum indicator further includes a flexible member positioned over the opening in the tip and a biasing member, wherein the first portion of the indicator is coupled to the biasing member, and wherein the second portion of the indicator is coupled to the flexible member.

28. The syringe of claim 21 wherein the first and second portions of the indicator are movable relative to one another, and wherein the second indicator is at least partially nested within the second indicator.

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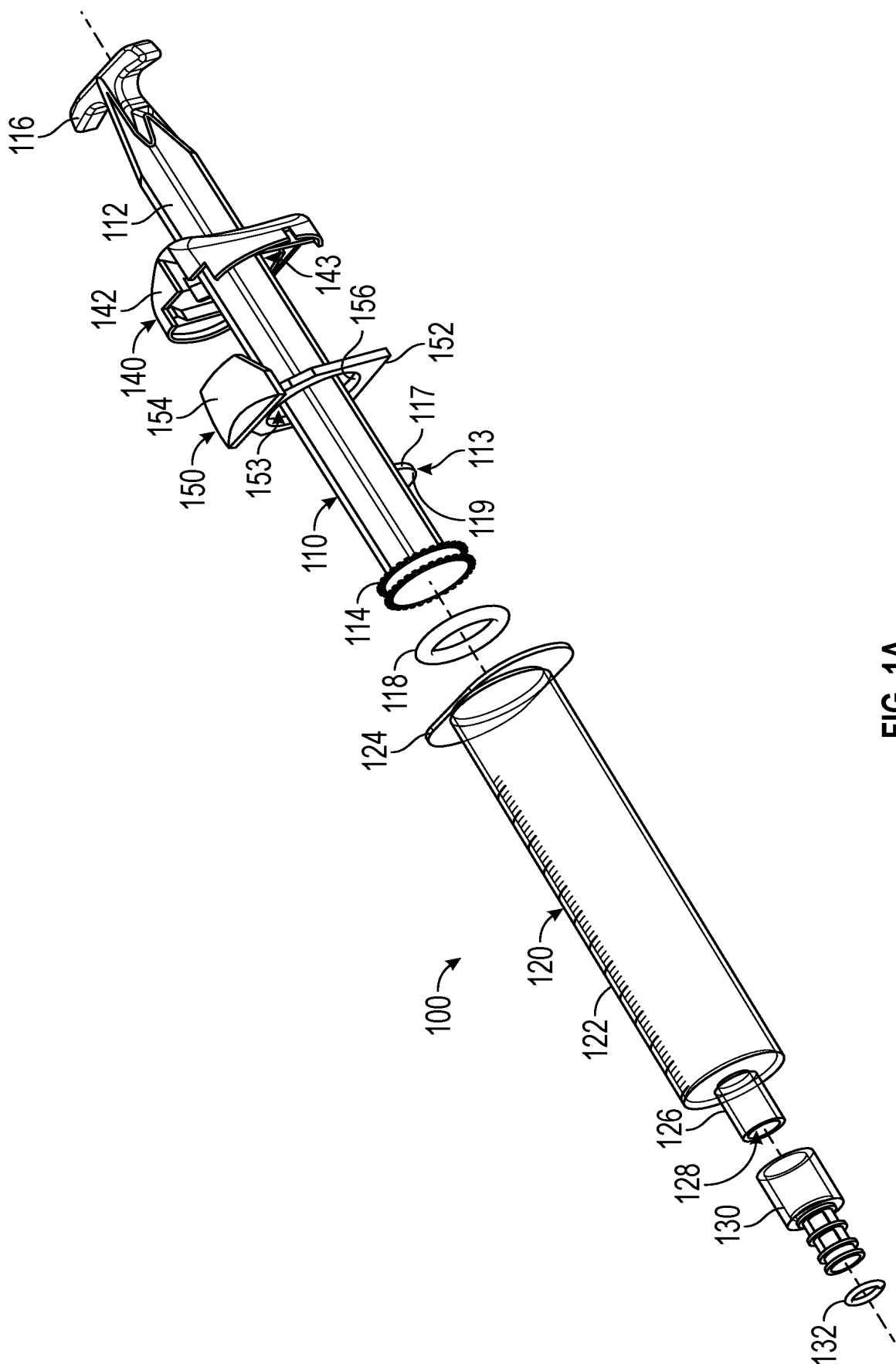


FIG. 1A

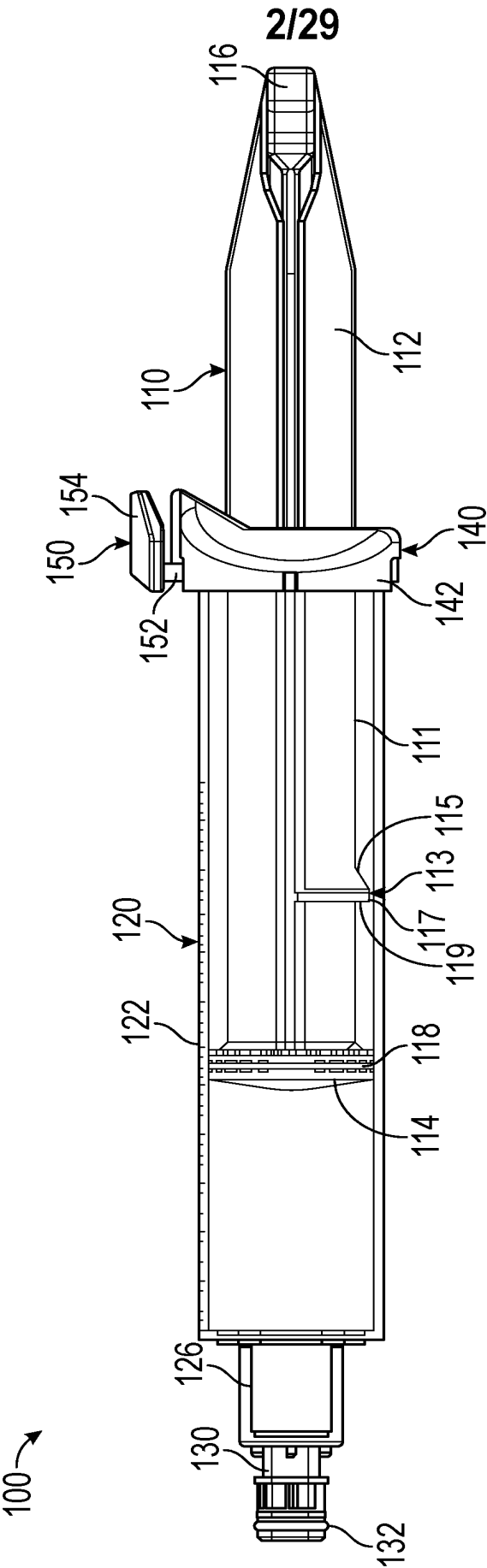


FIG. 1B

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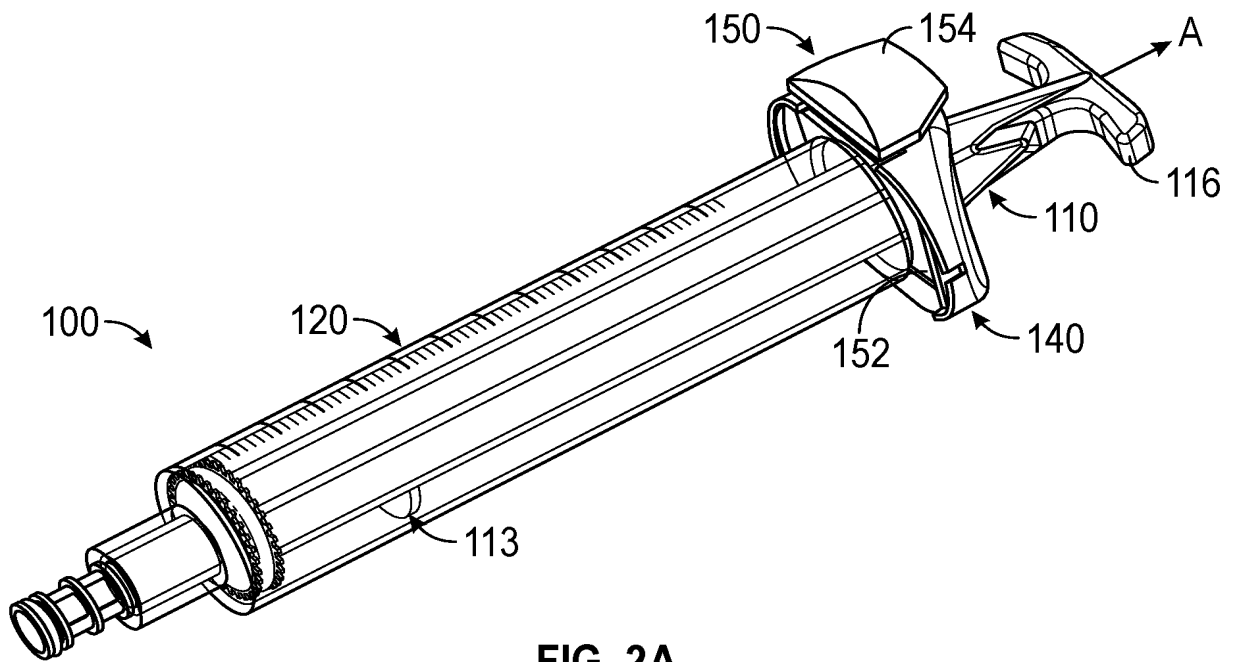


FIG. 2A

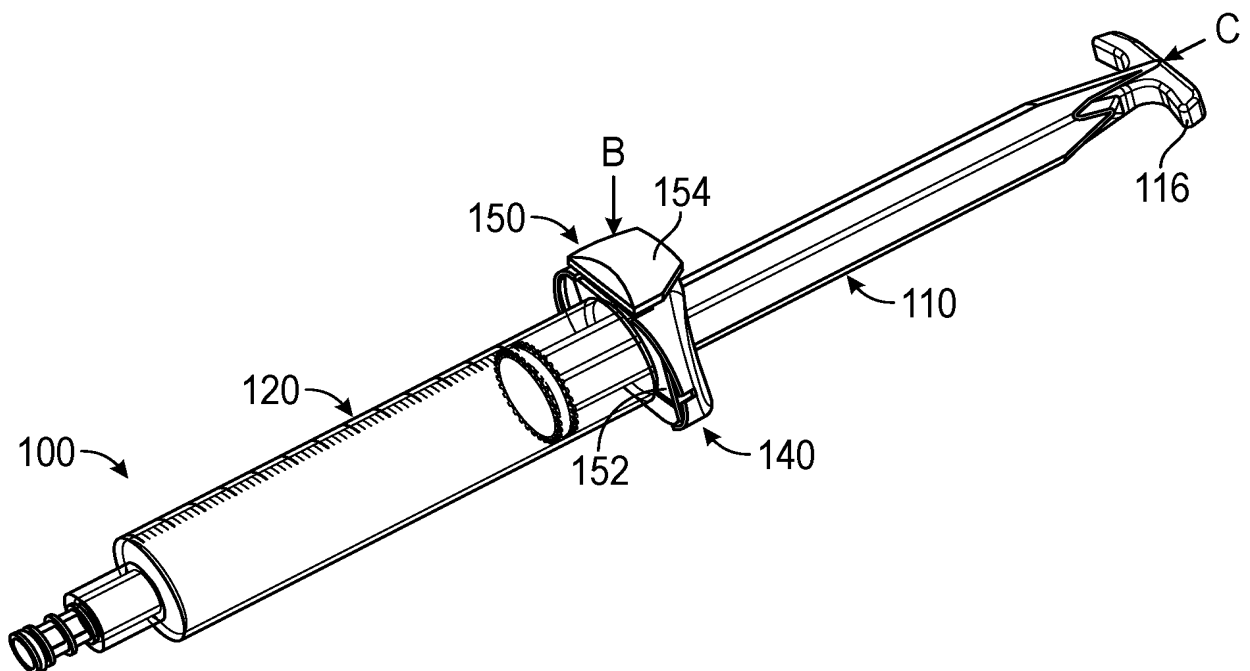


FIG. 2B

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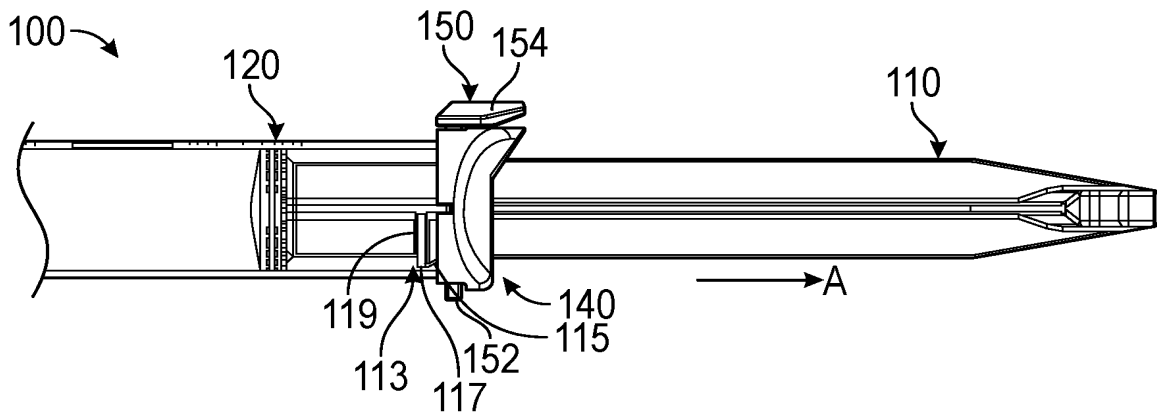


FIG. 3A

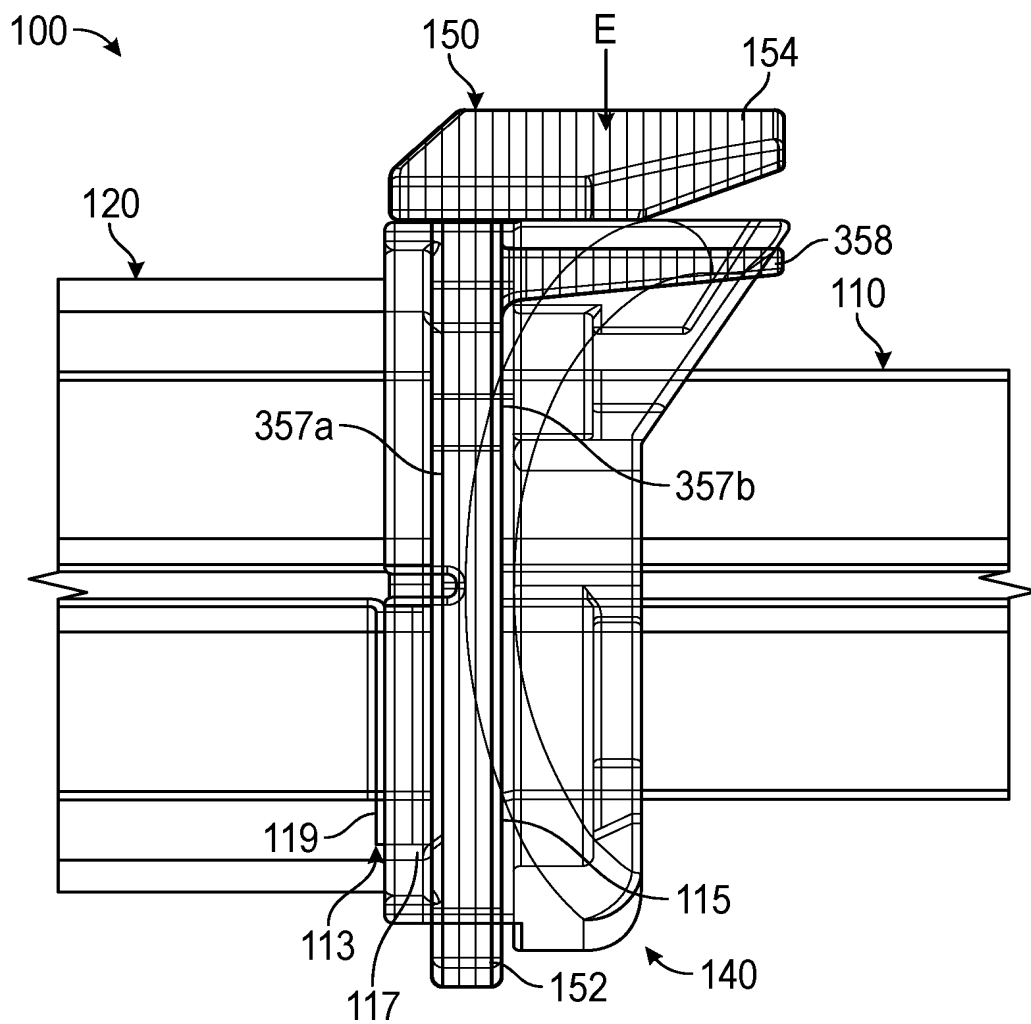


FIG. 3B

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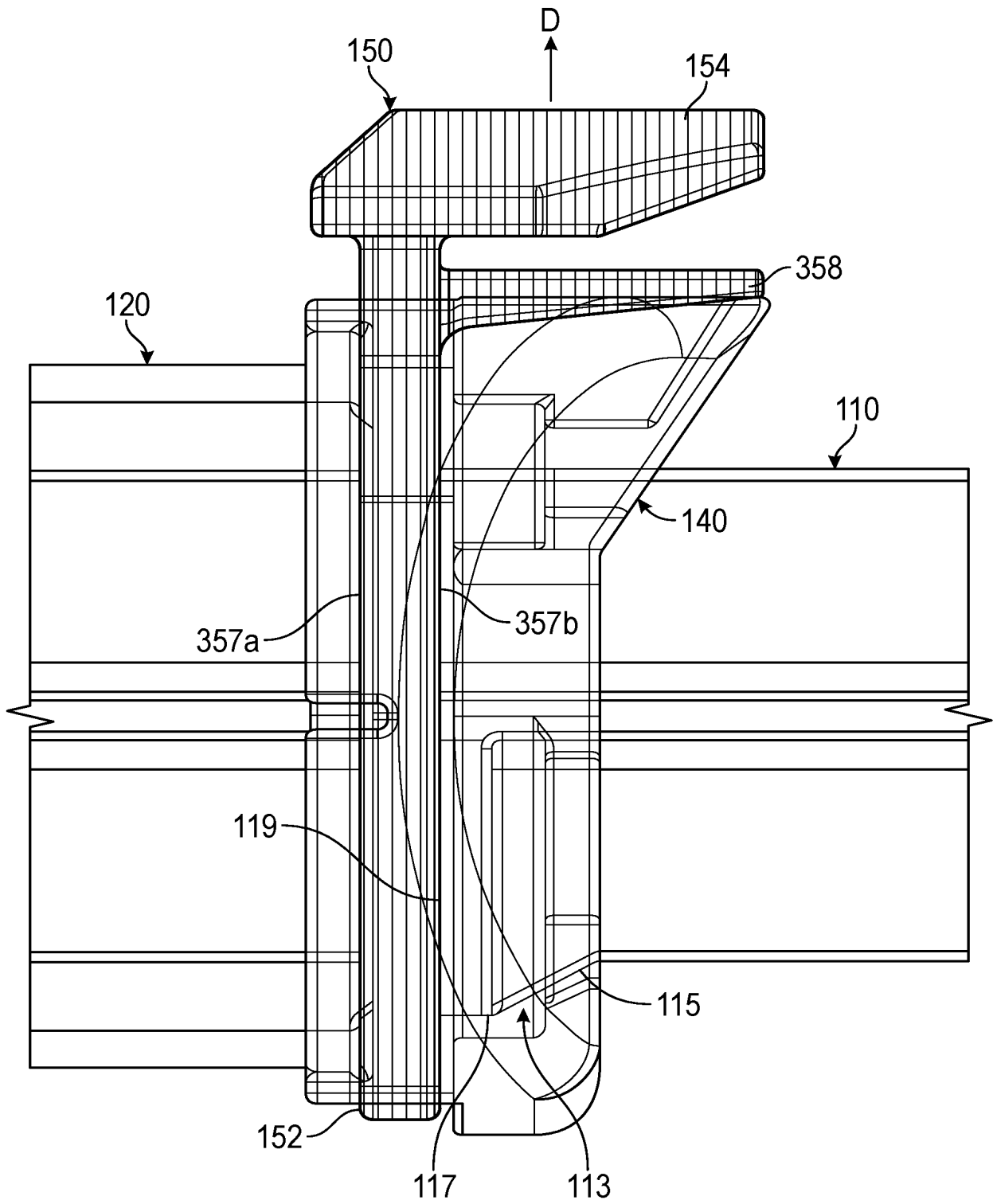


FIG. 3C

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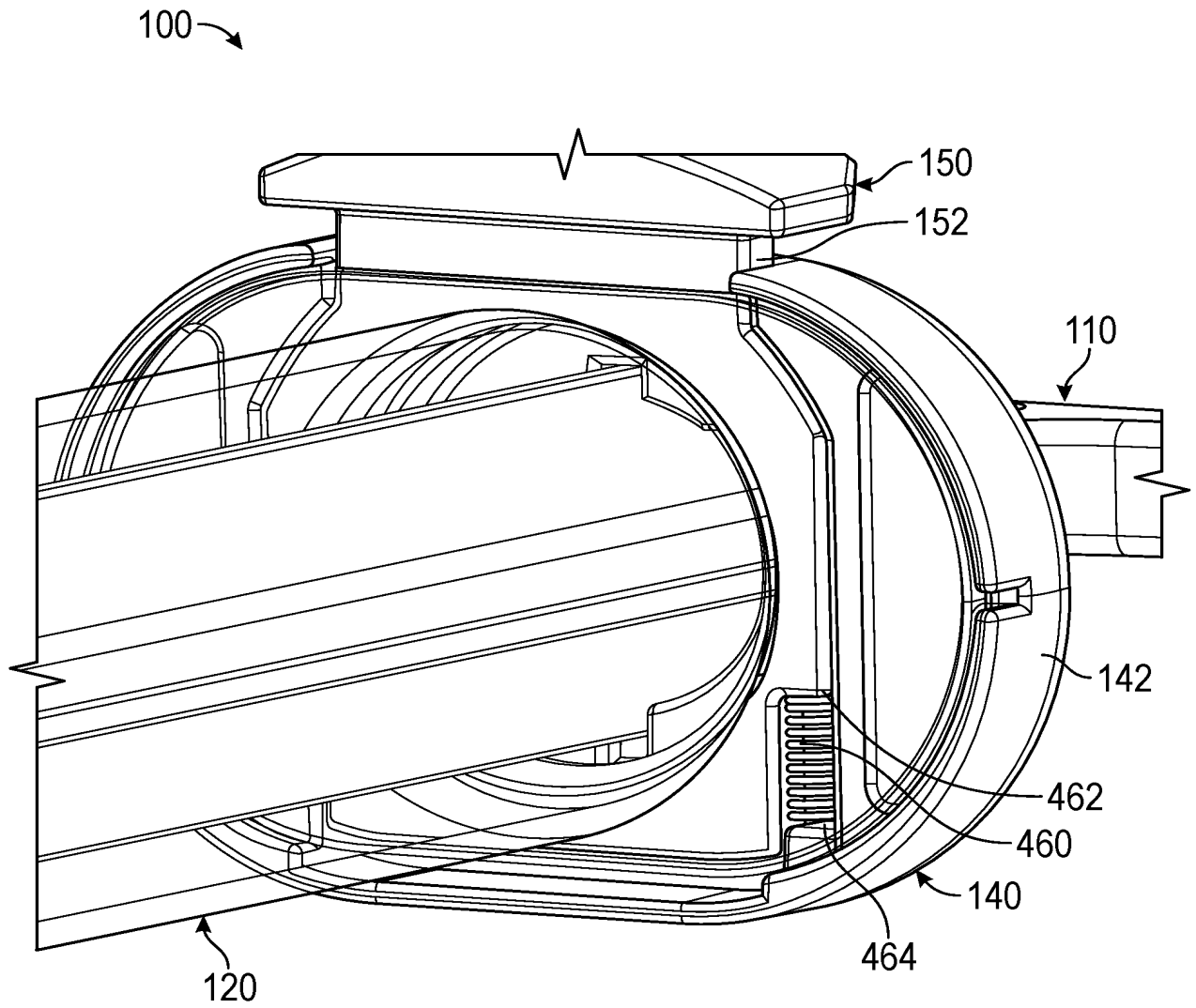


FIG. 4

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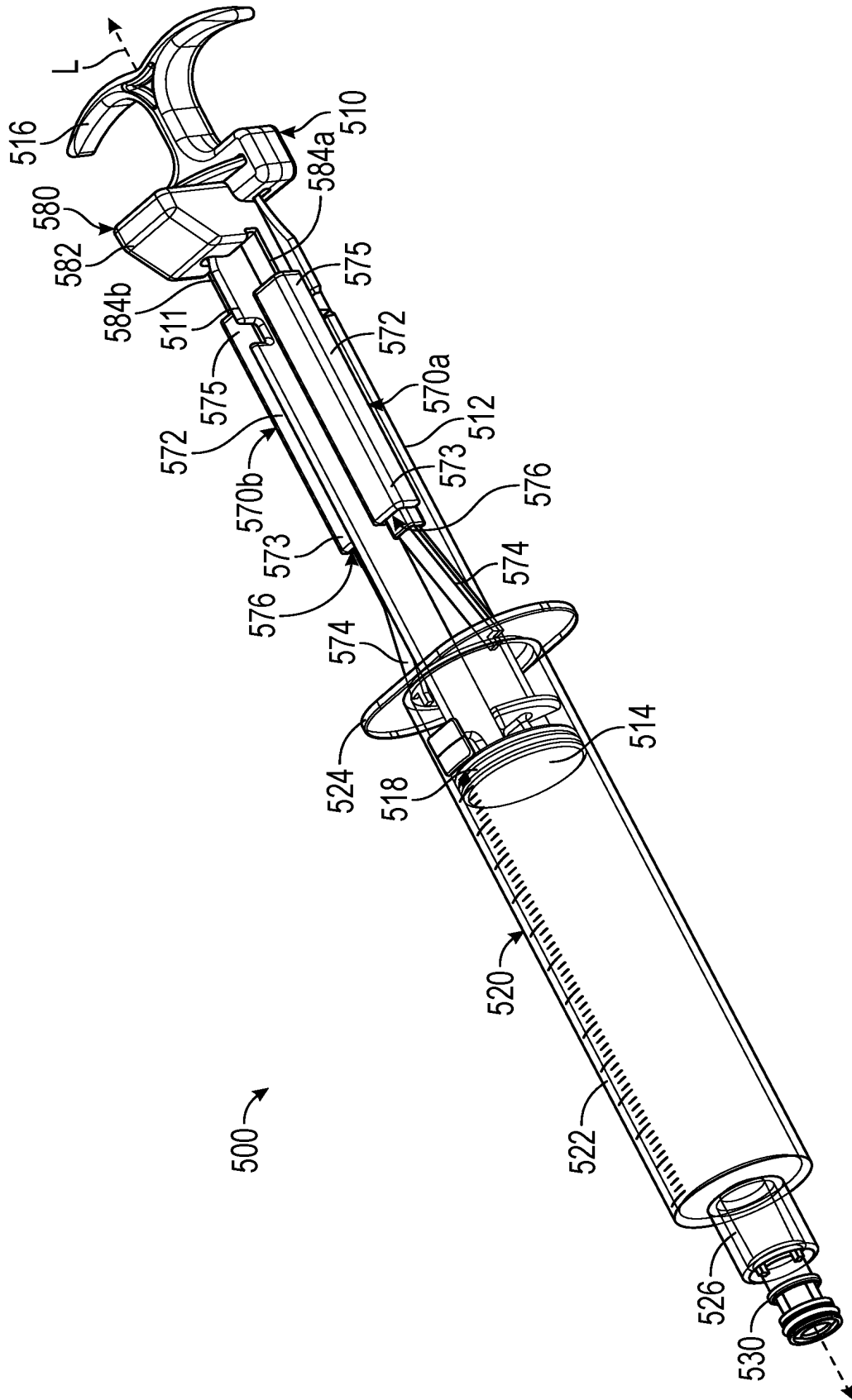


FIG. 5A

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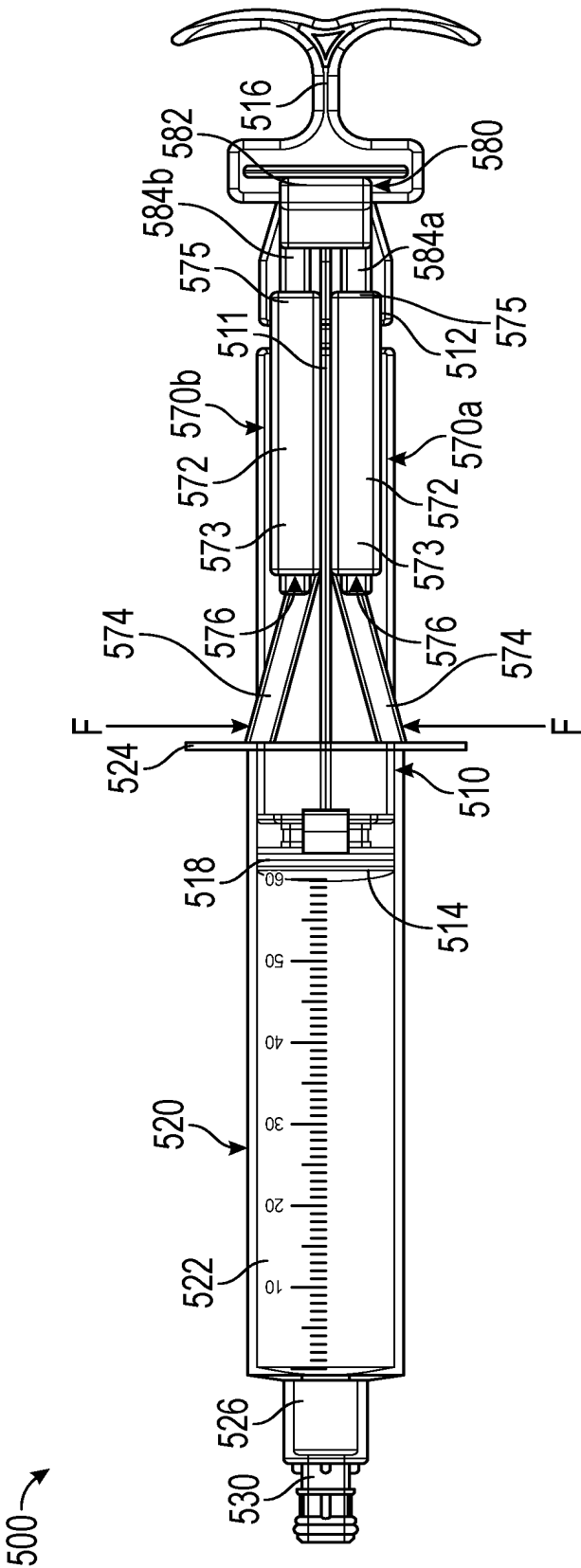


FIG. 5B

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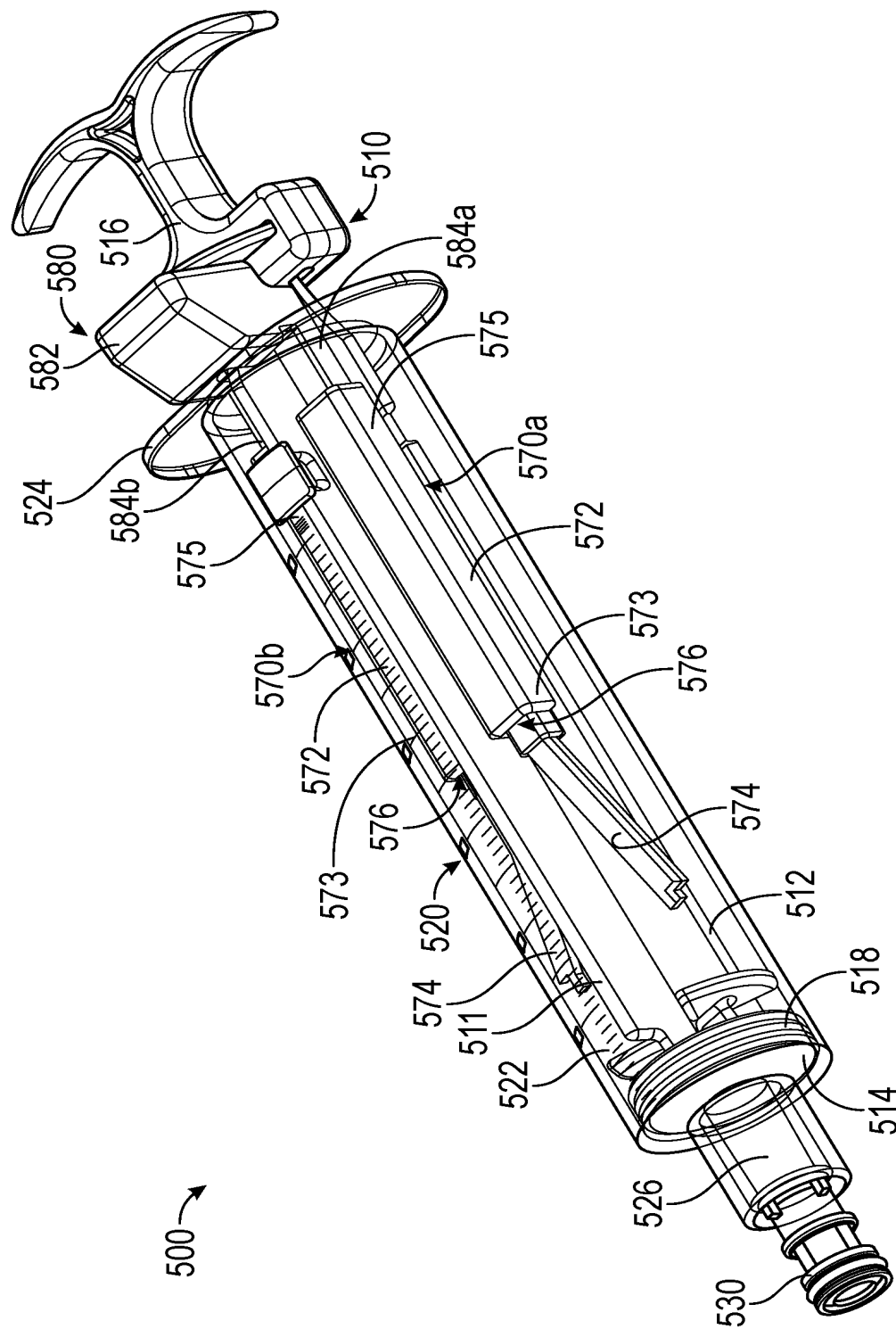


FIG. 5C

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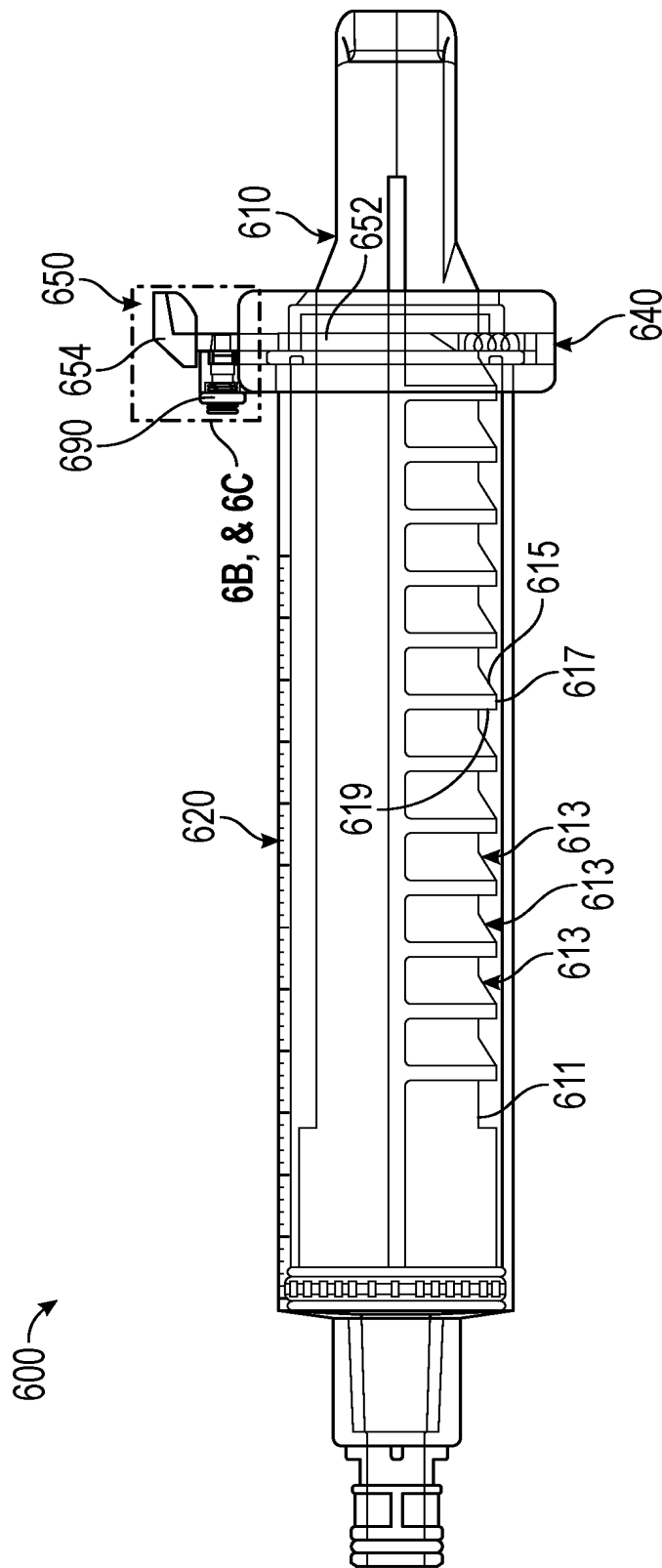


FIG. 6A

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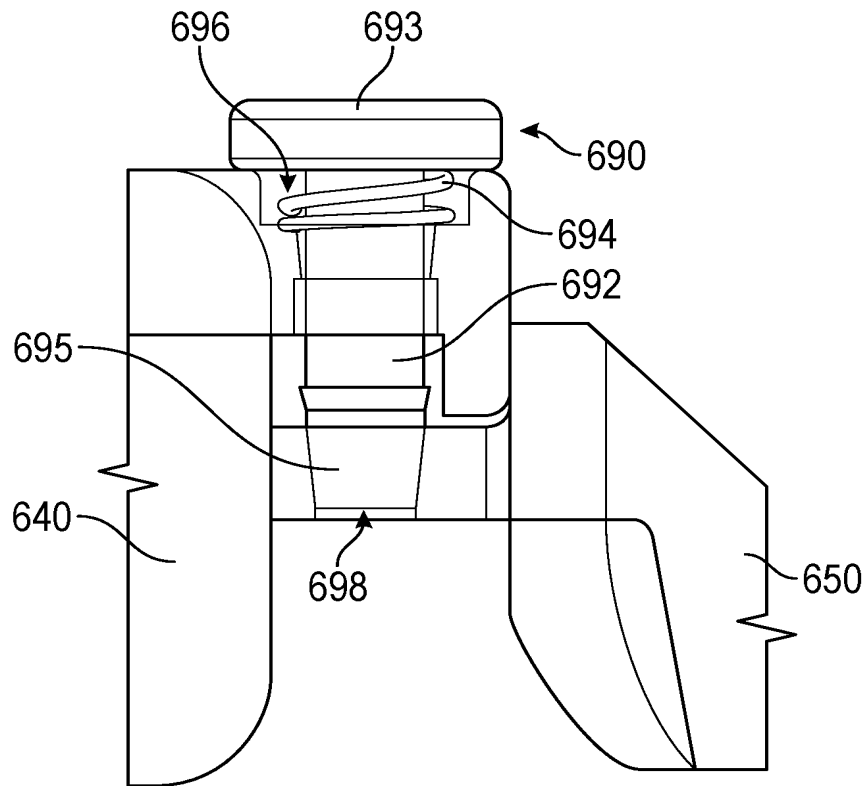


FIG. 6B

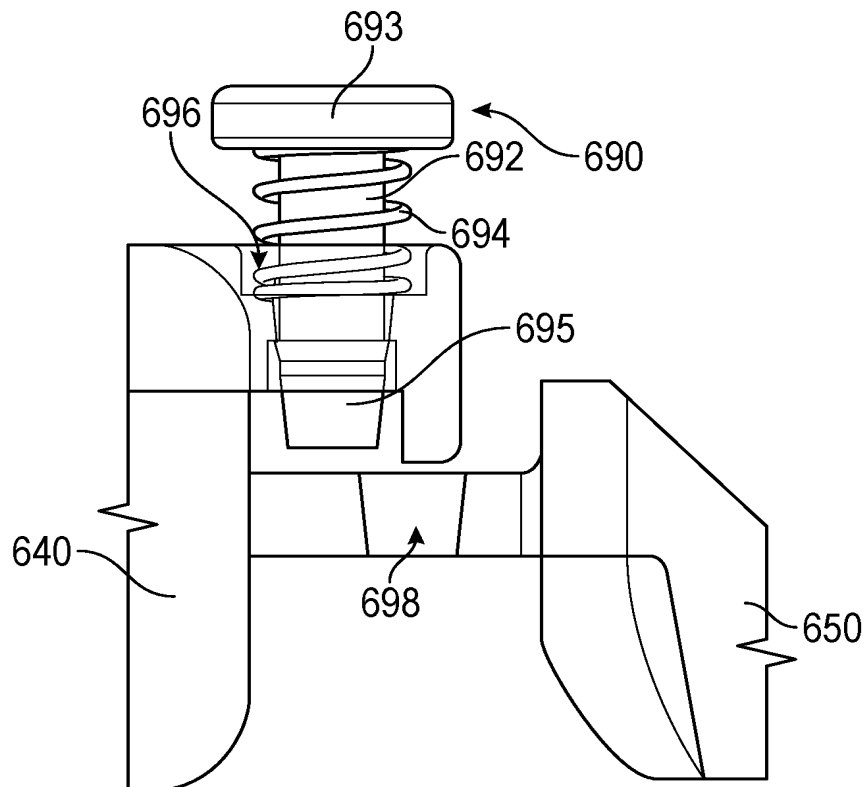


FIG. 6C

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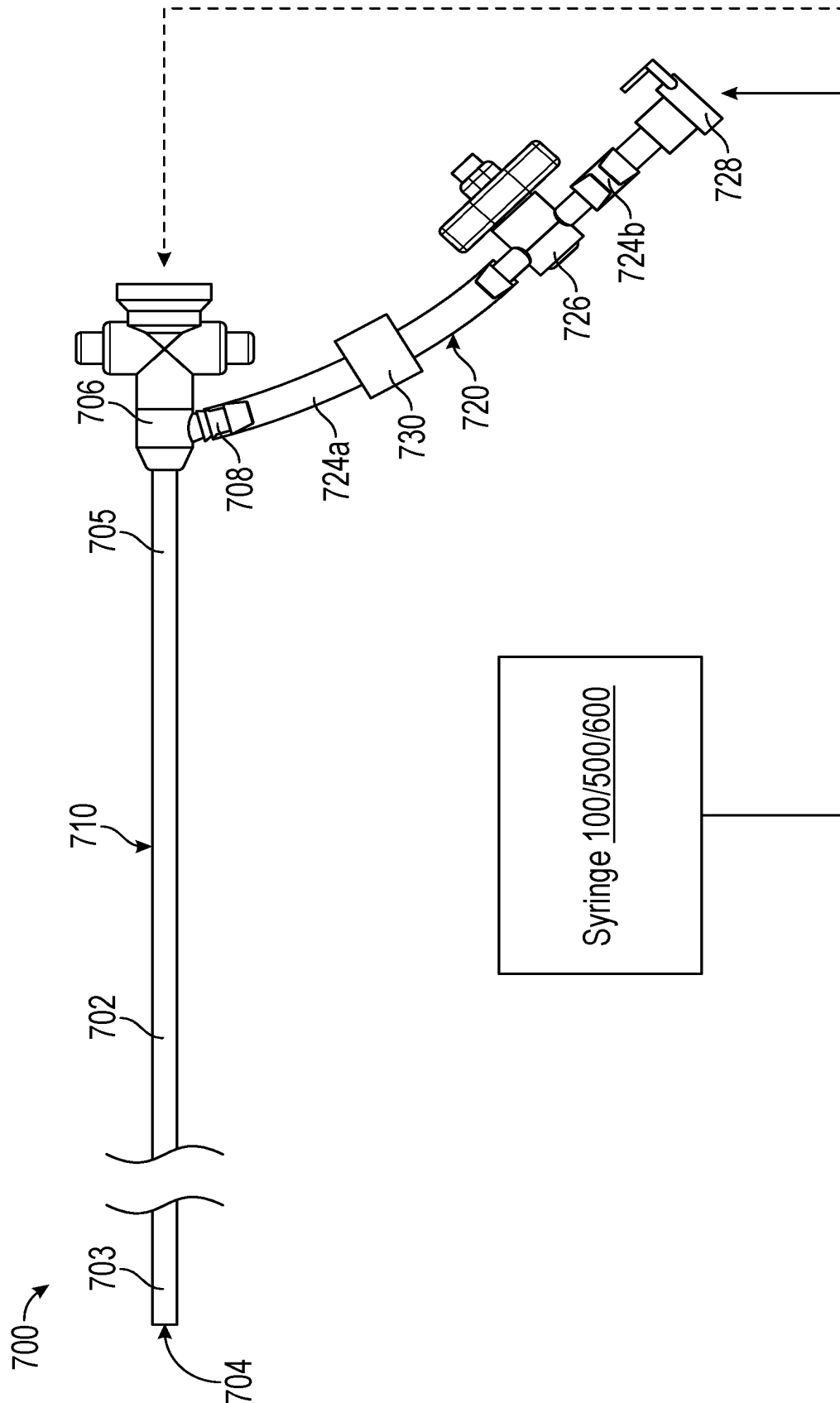


FIG. 7

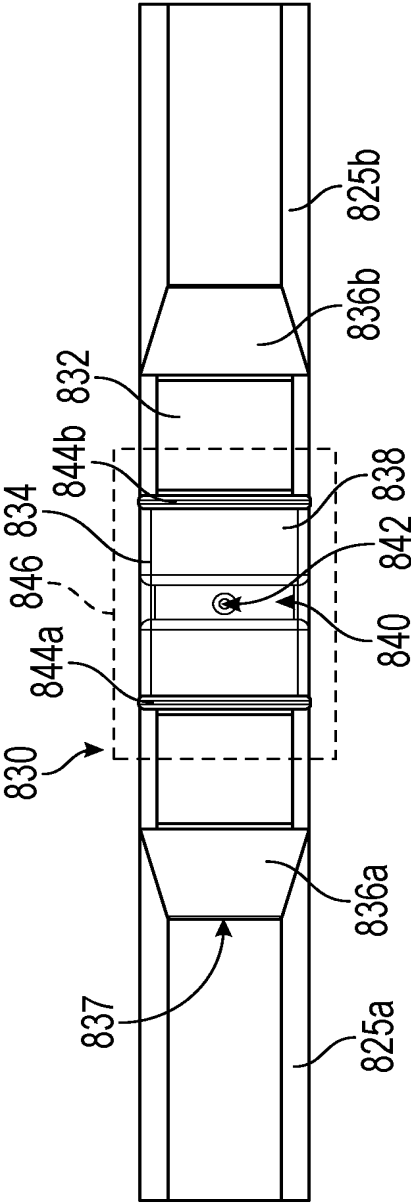


FIG. 8A

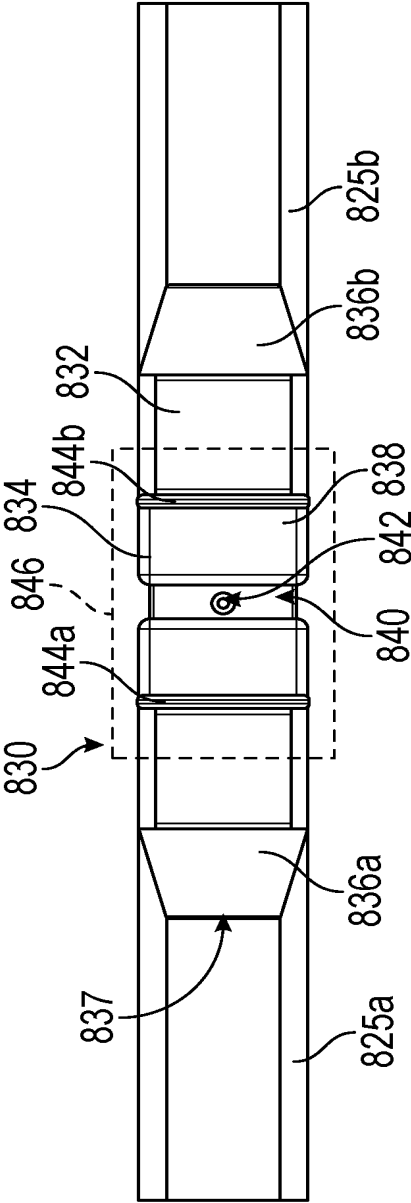


FIG. 8B

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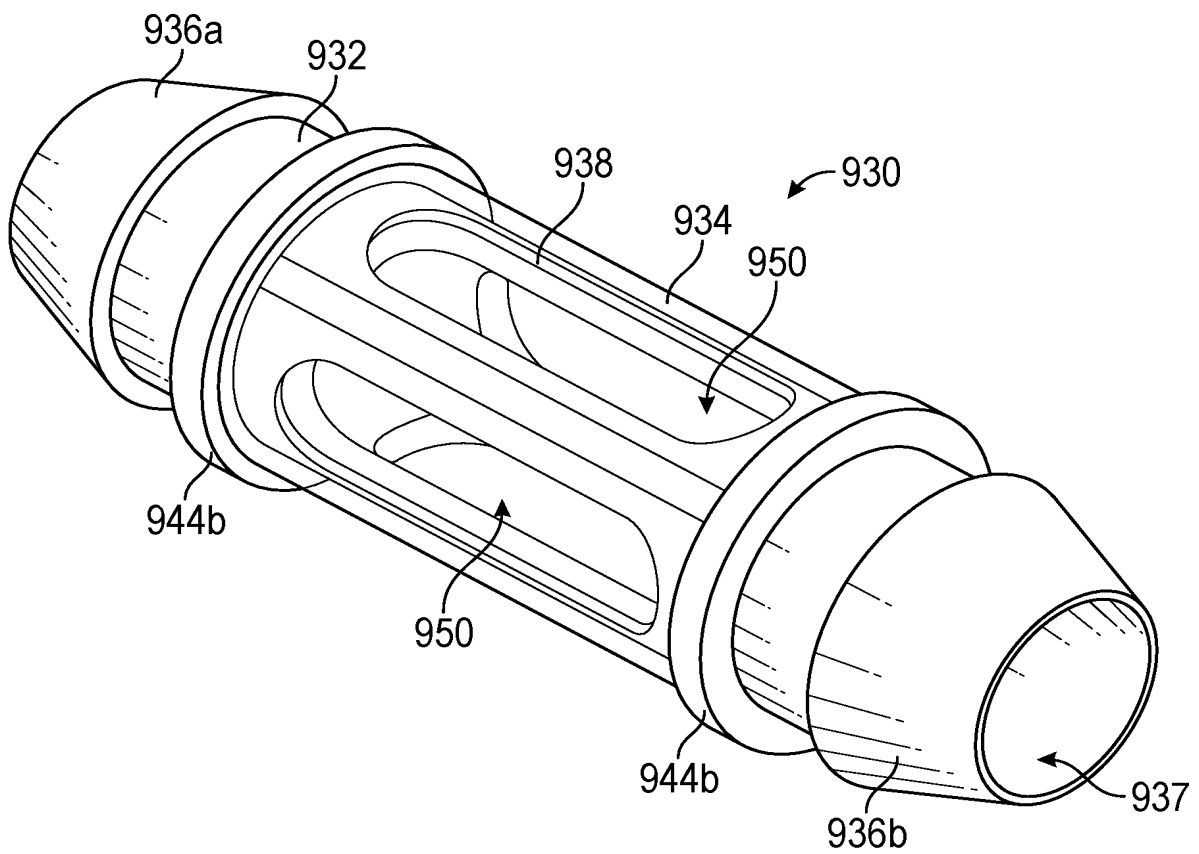


FIG. 9

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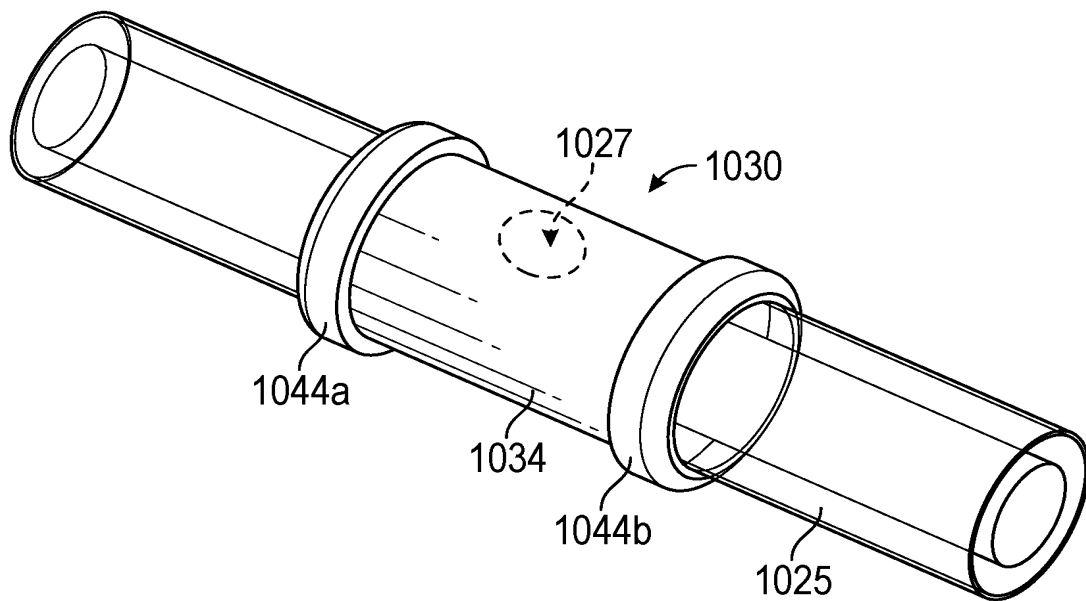


FIG. 10A

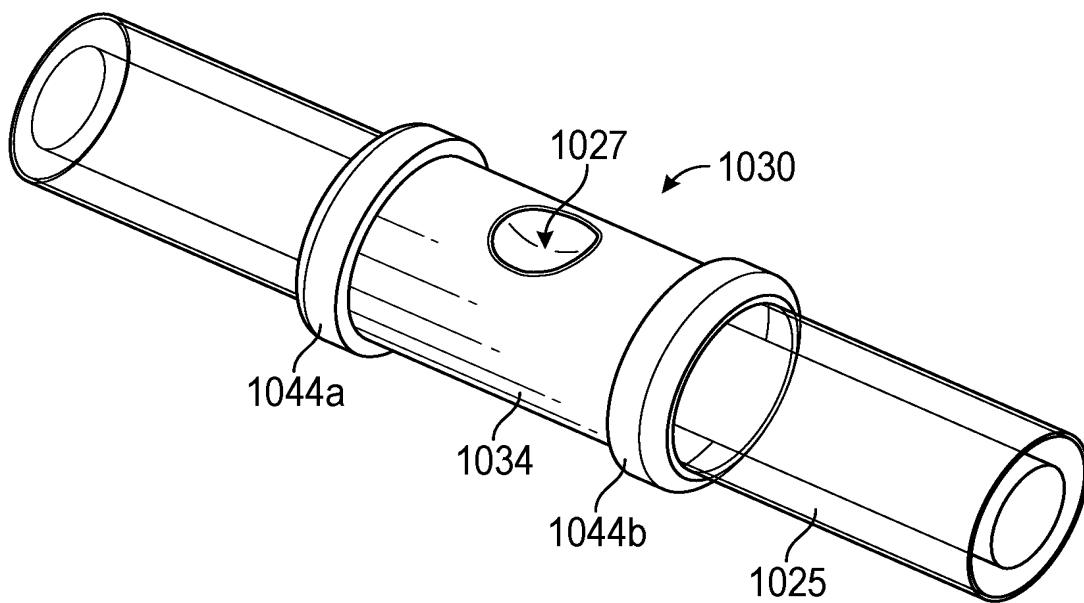


FIG. 10B

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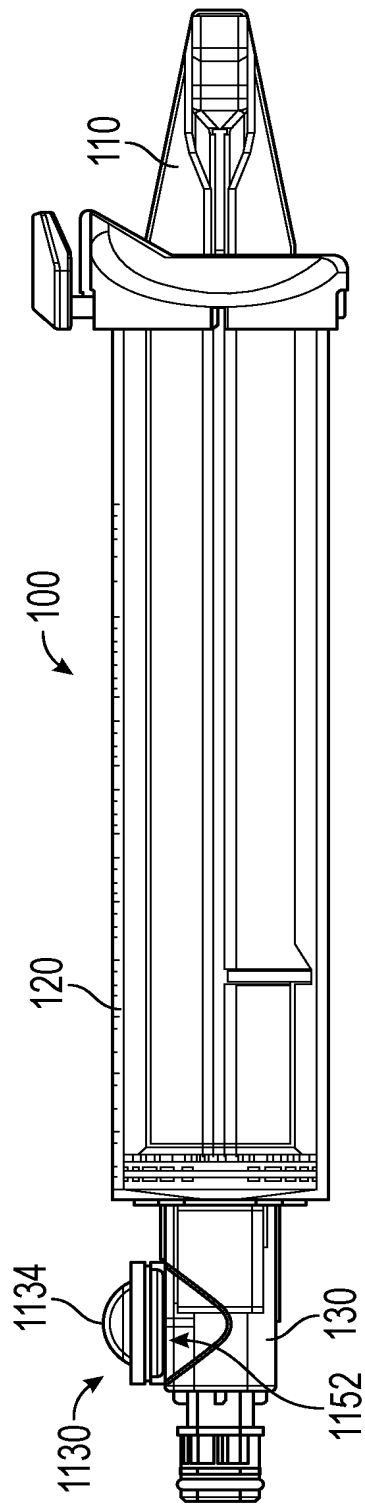


FIG. 11

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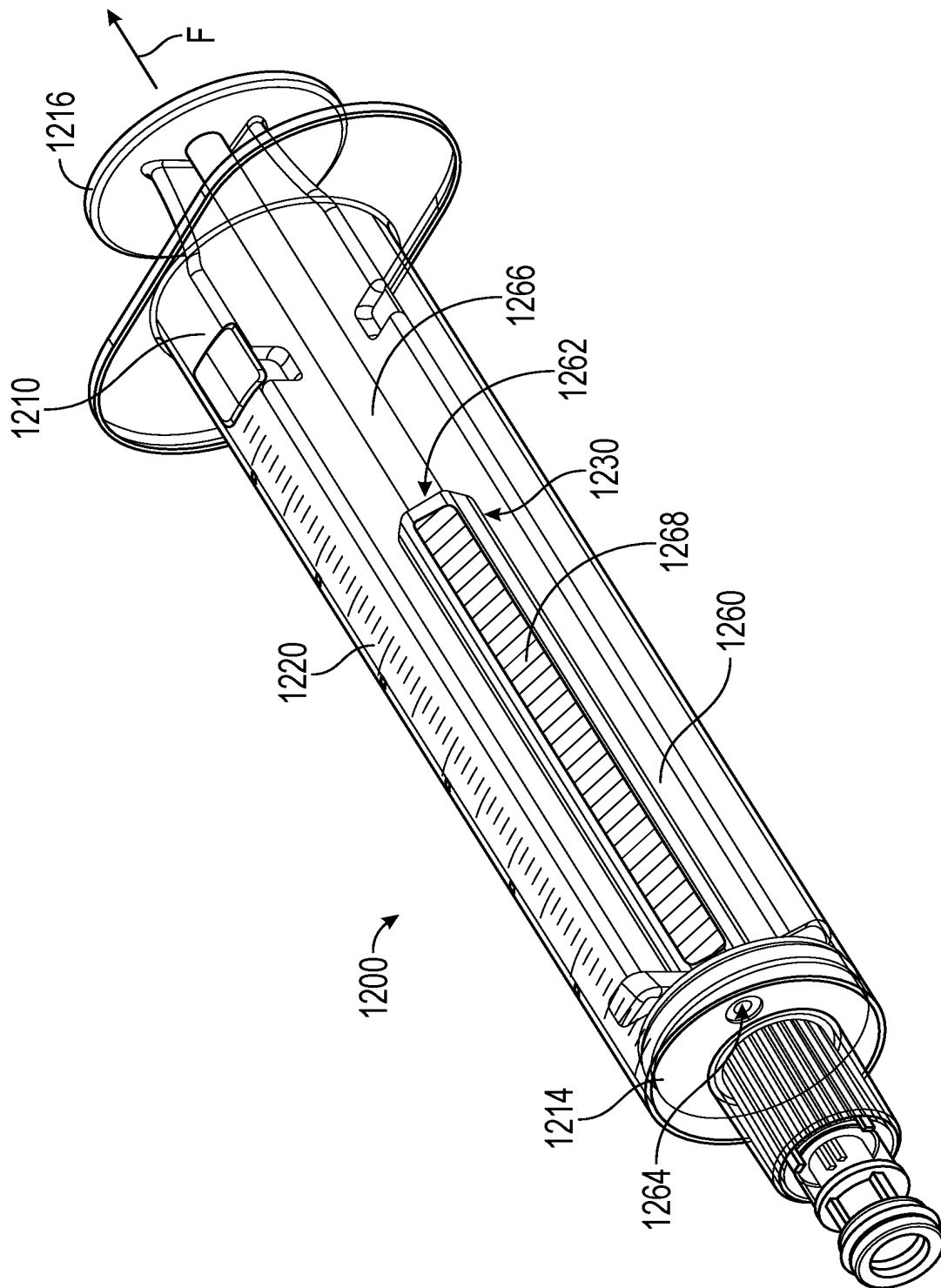


FIG. 12A

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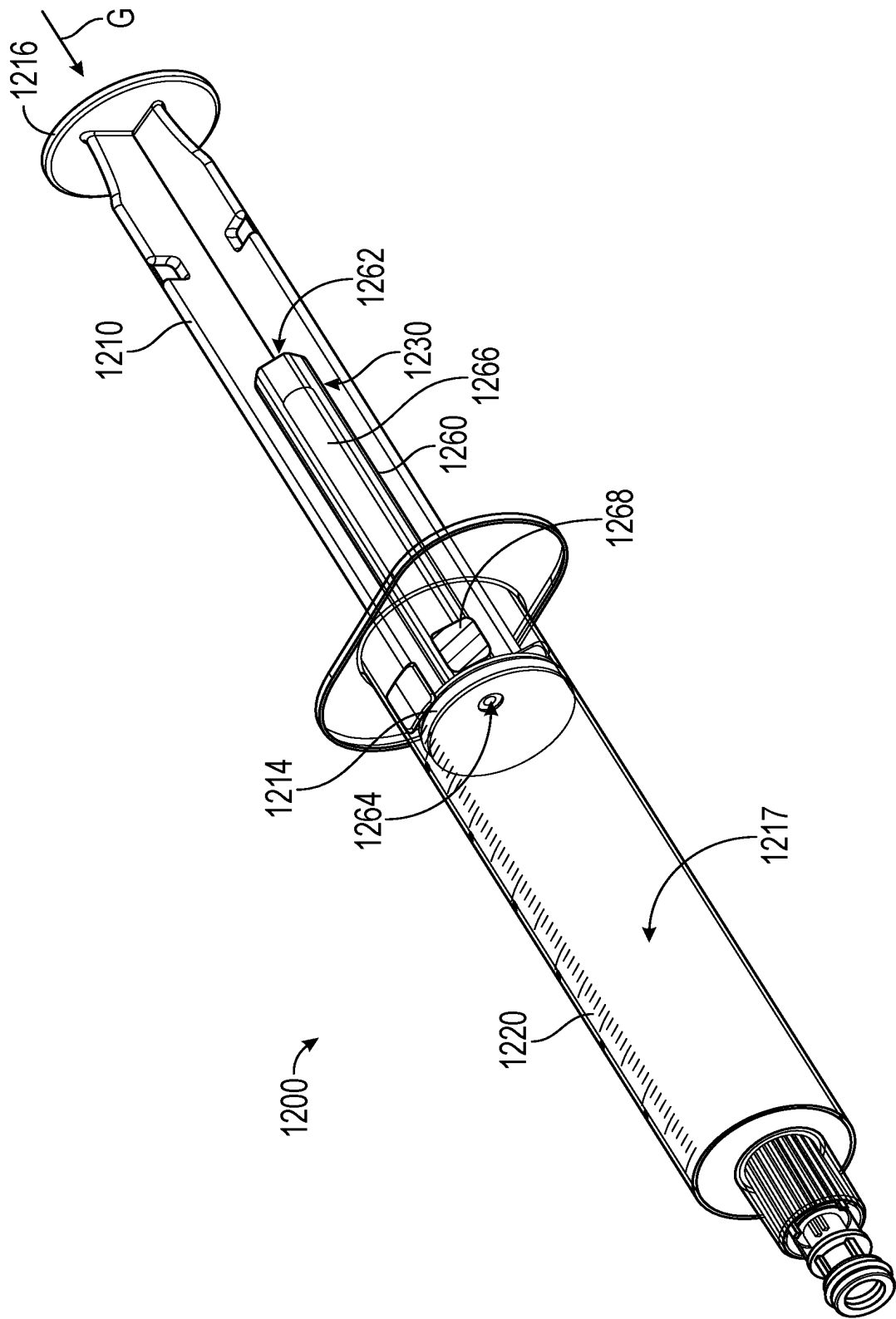


FIG. 12B

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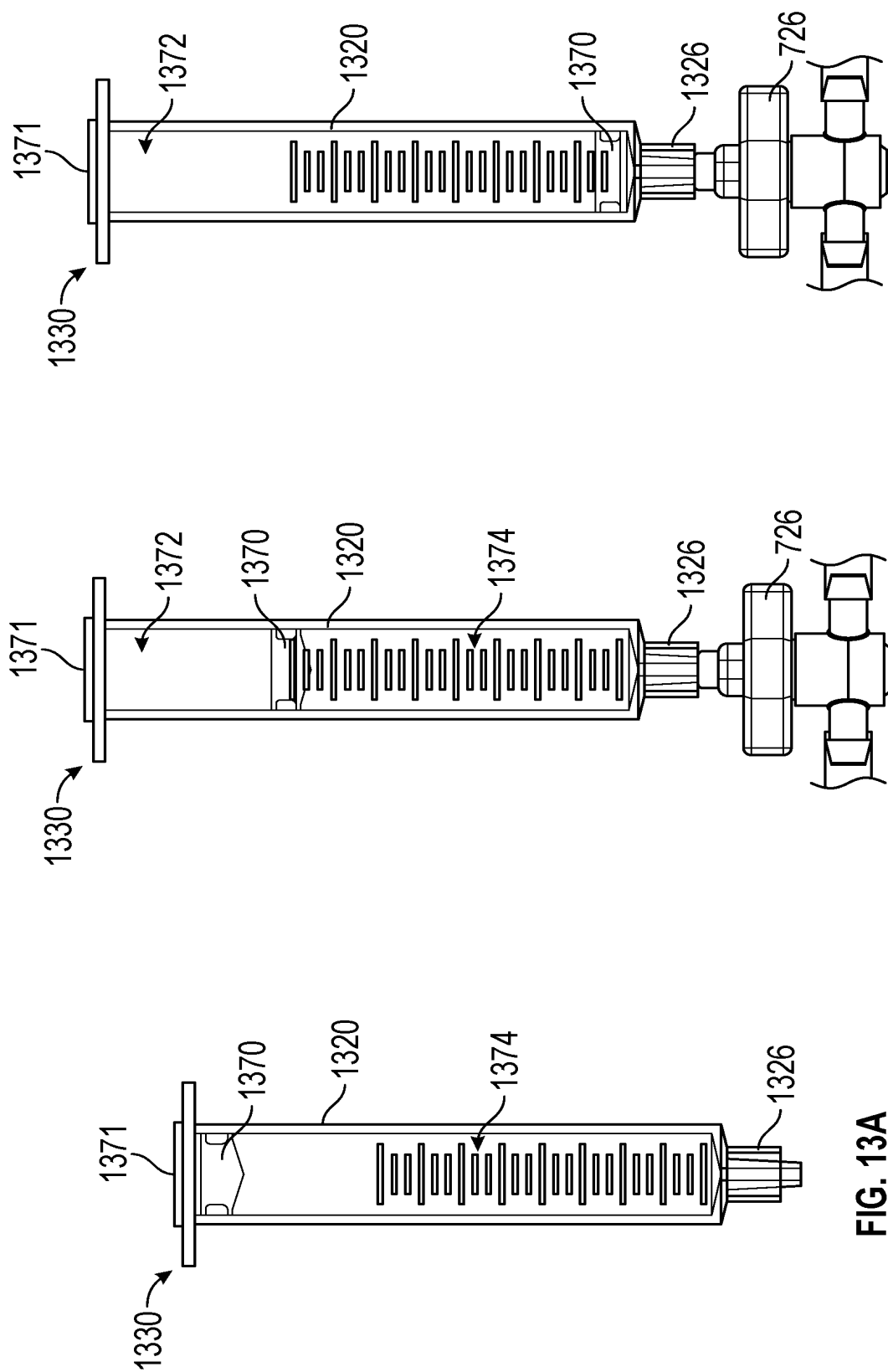


FIG. 13C

FIG. 13B

FIG. 13A

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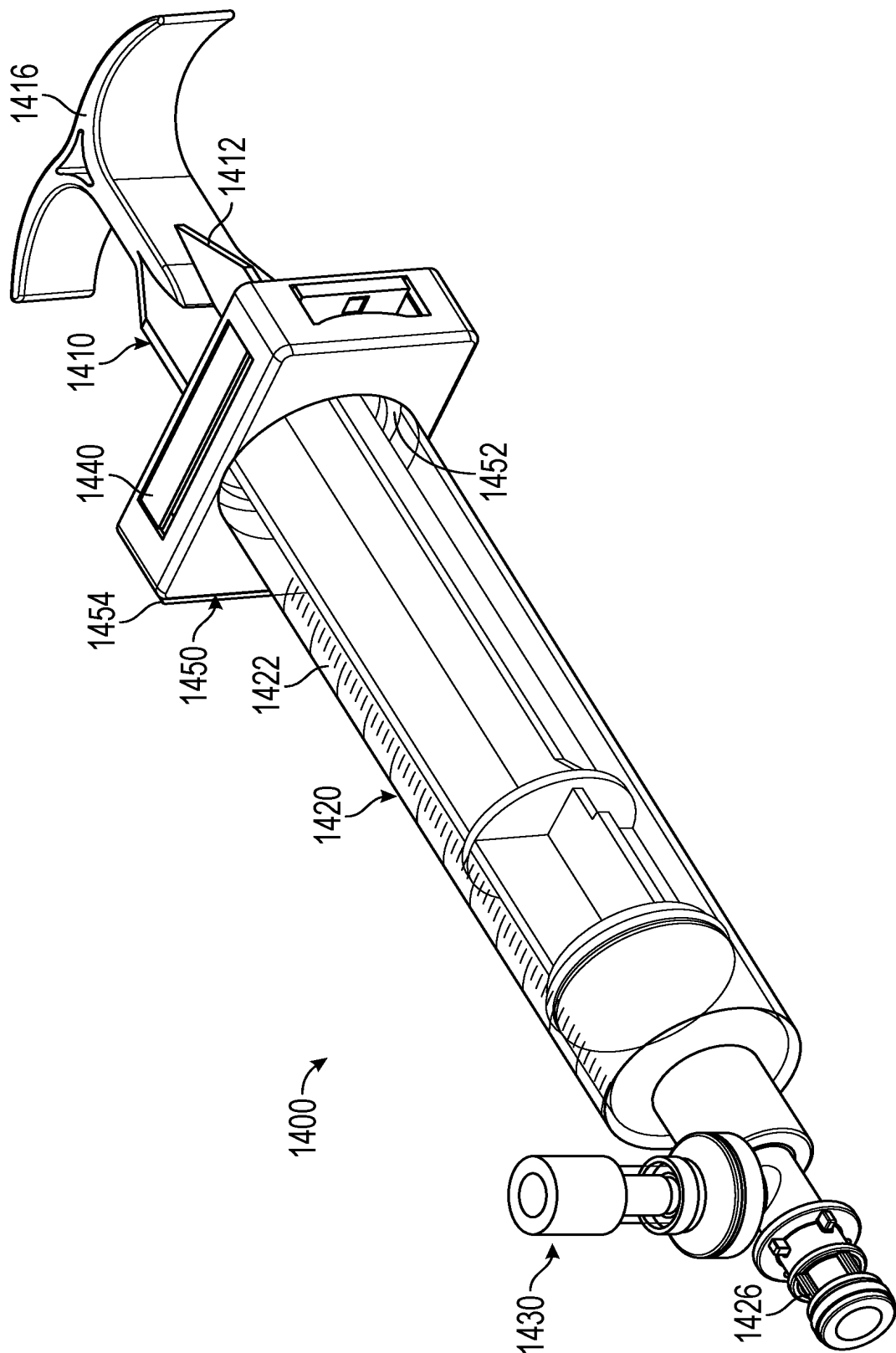


FIG. 14A

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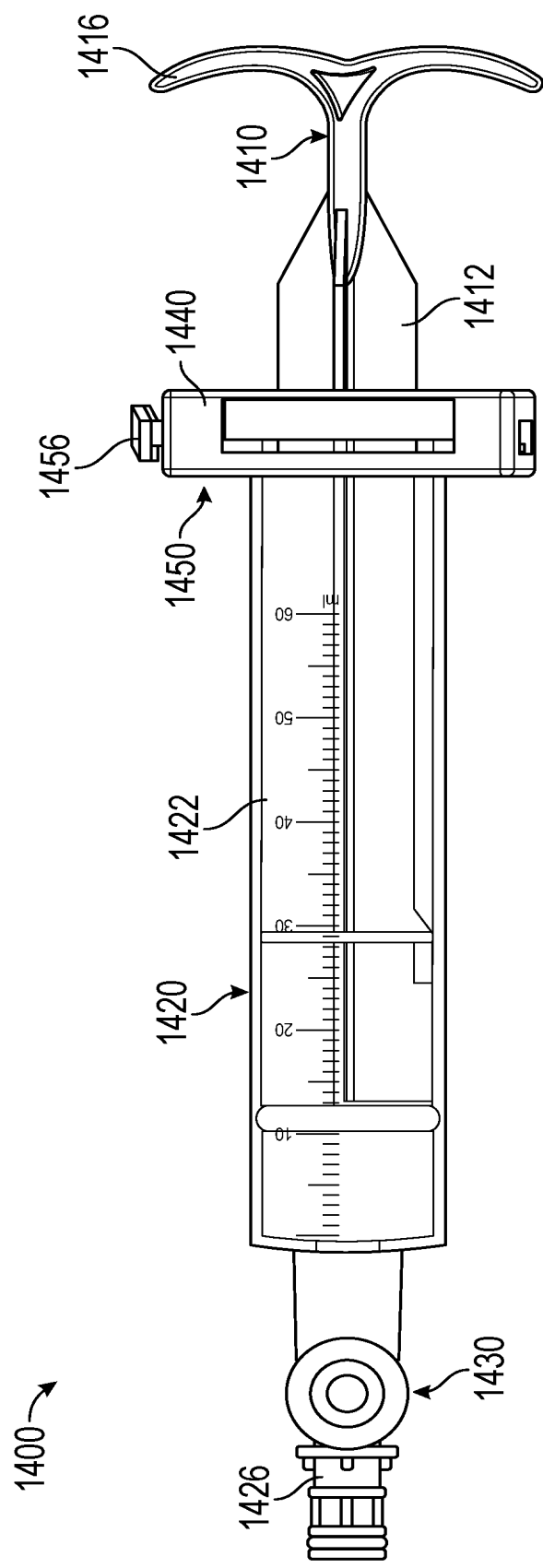


FIG. 14B

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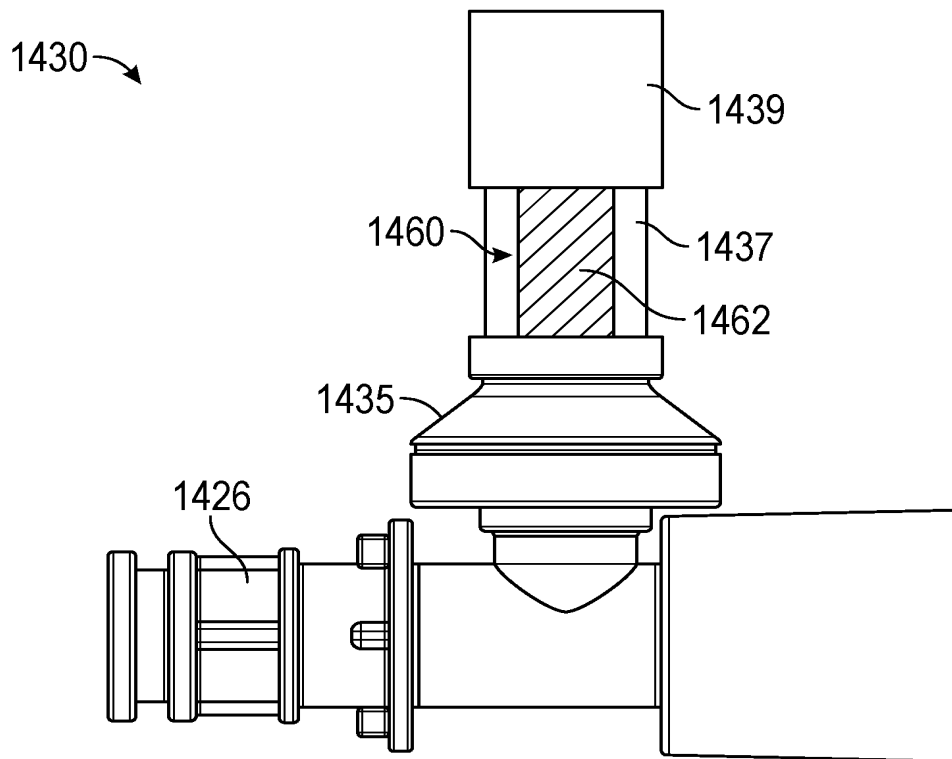


FIG. 14C

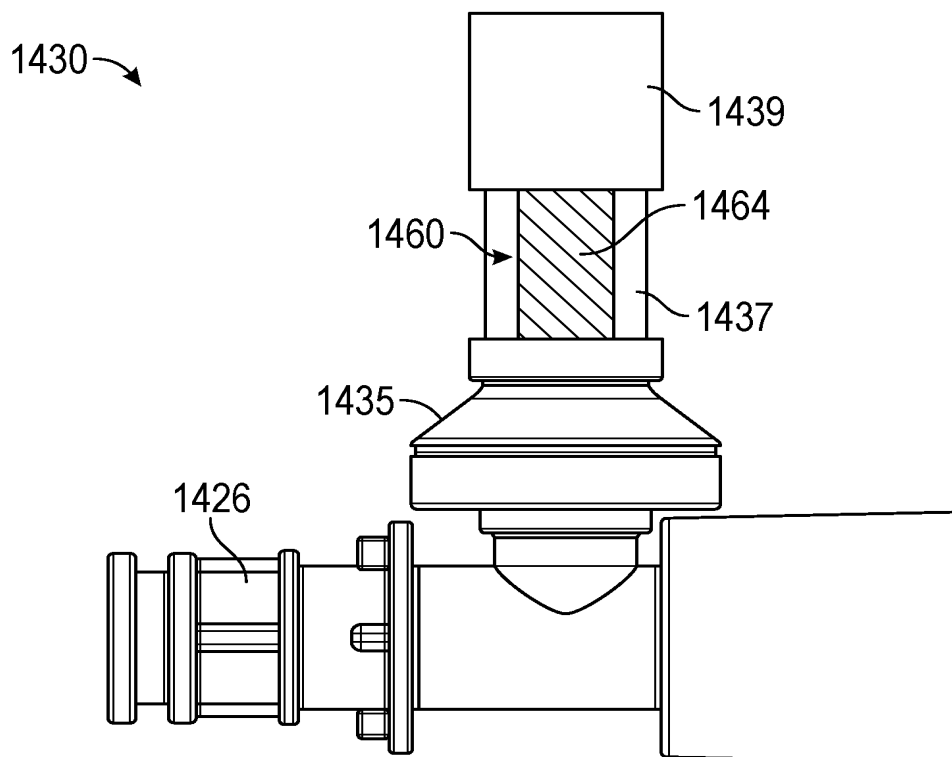


FIG. 14D

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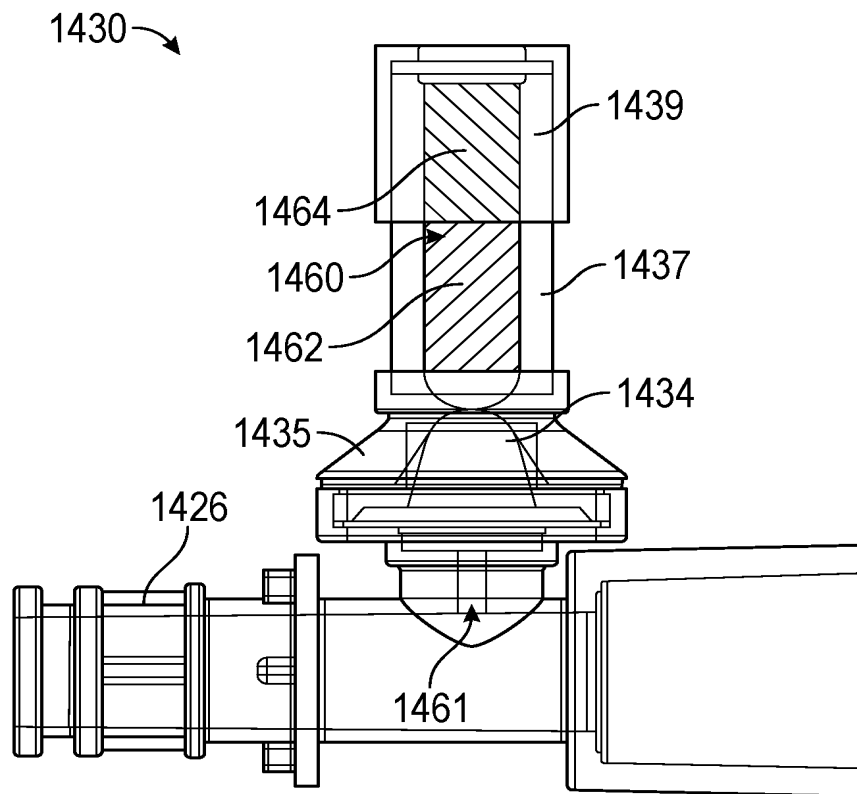


FIG. 14E

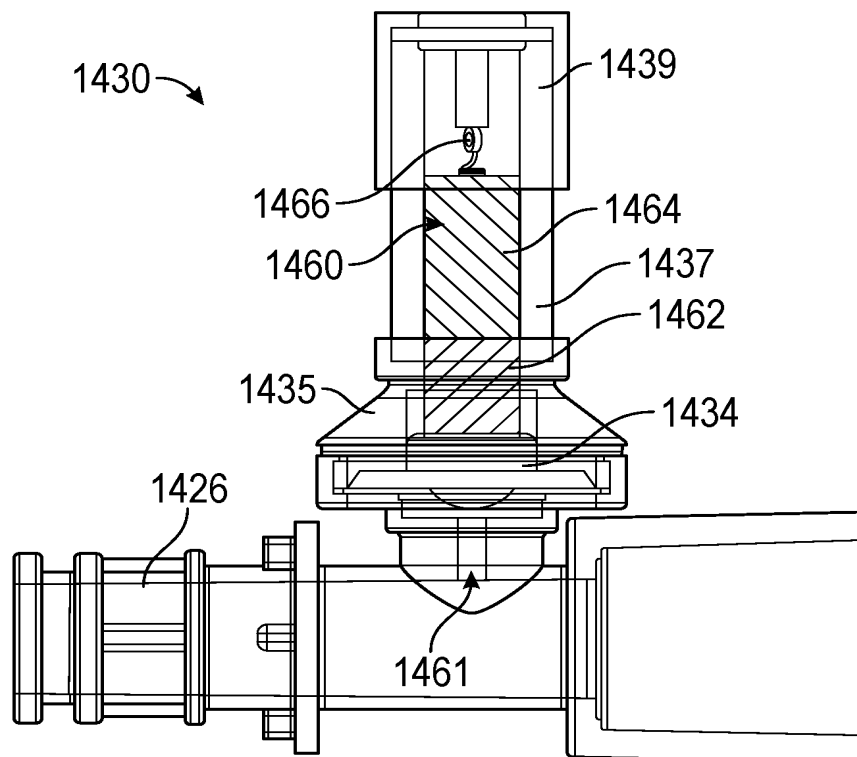


FIG. 14F

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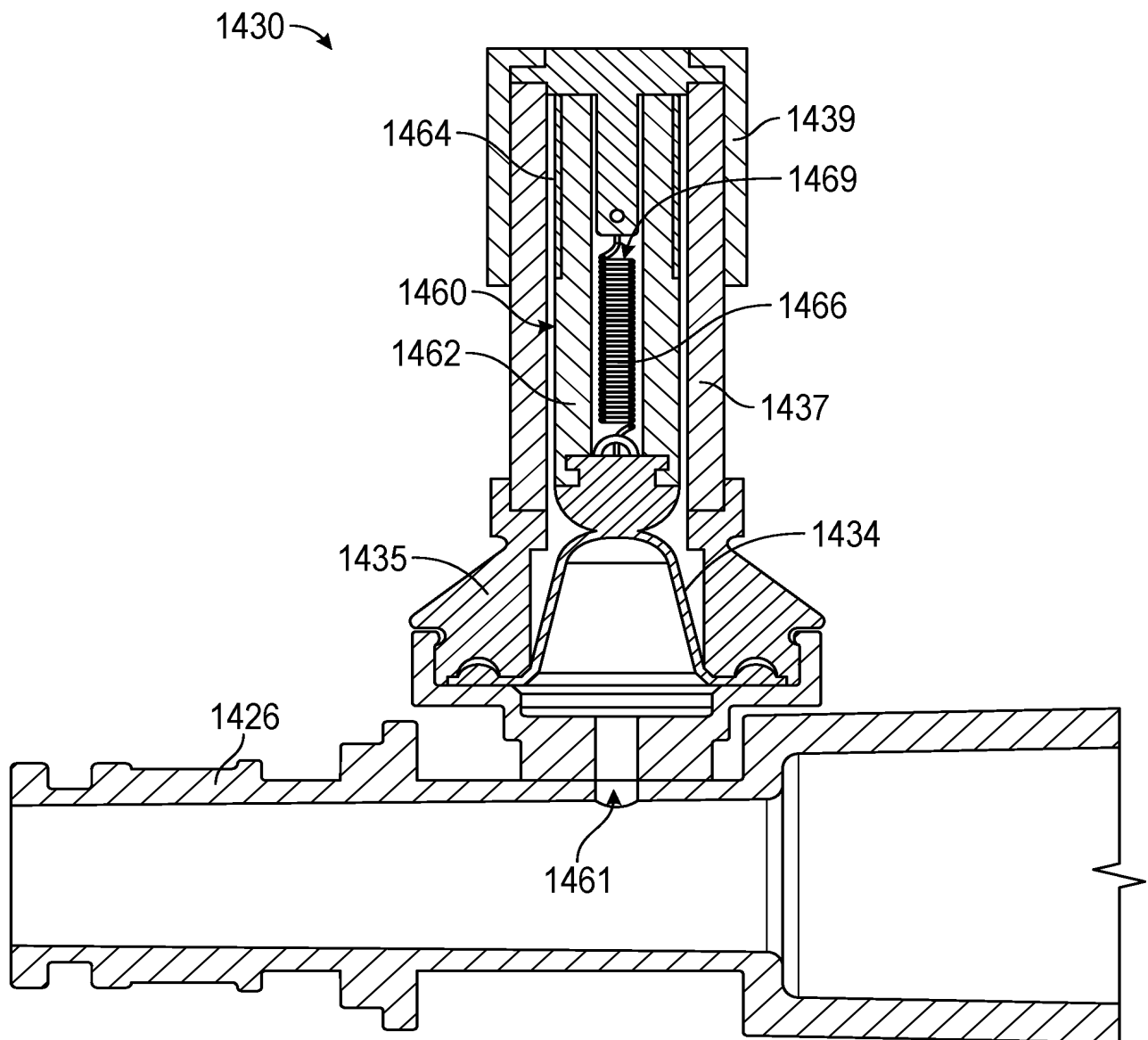


FIG.14G

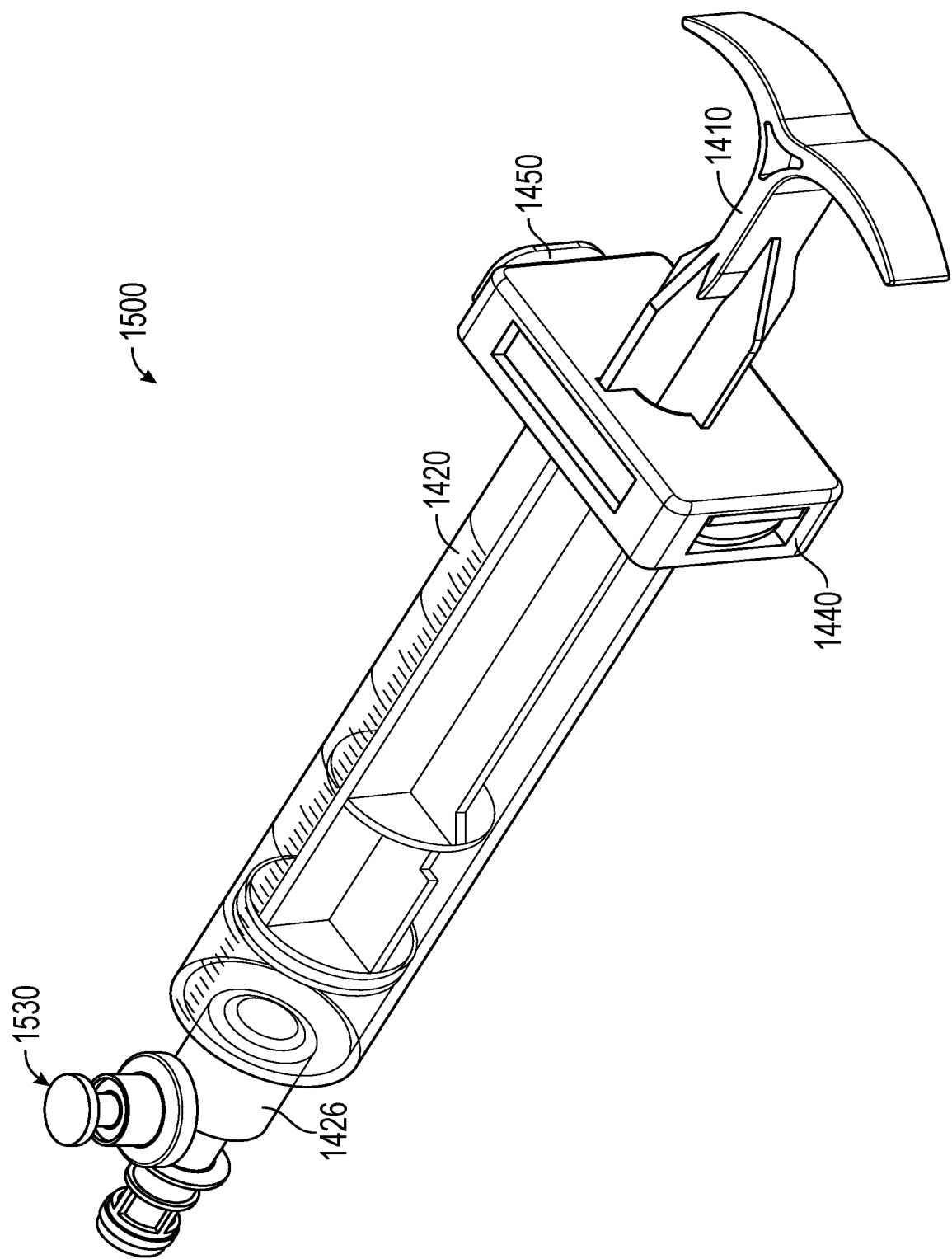


FIG. 15A

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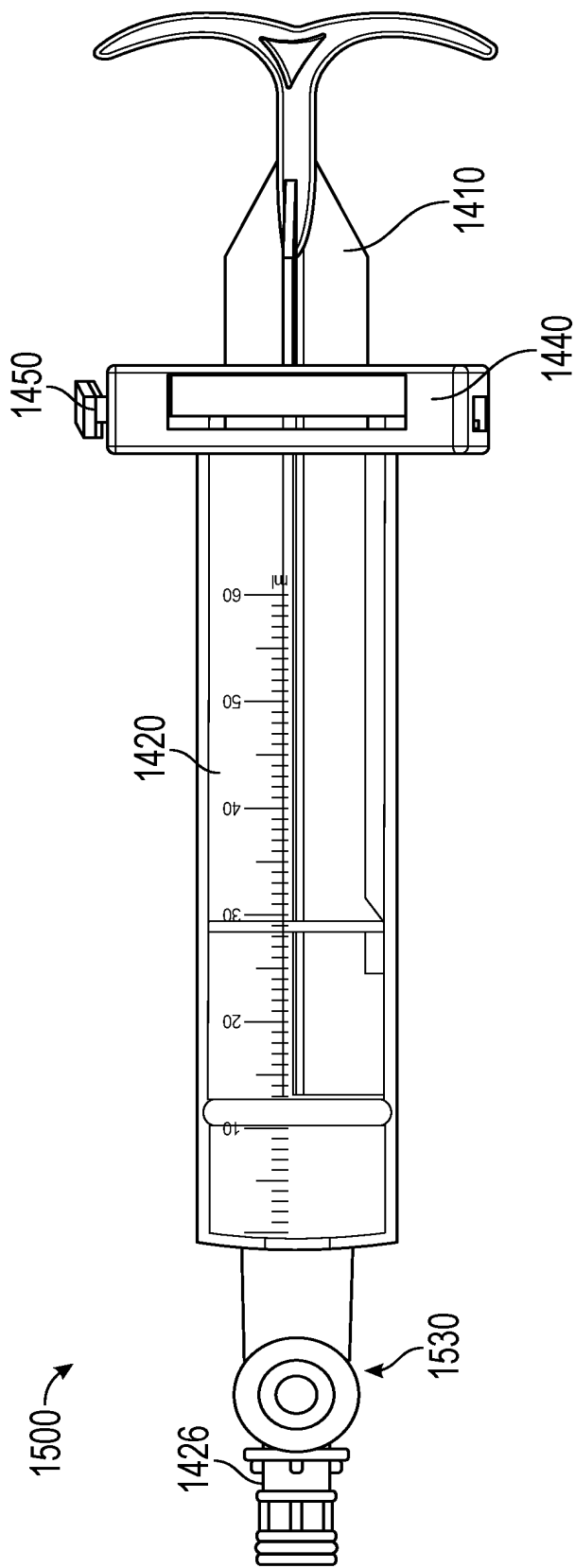


FIG. 15B

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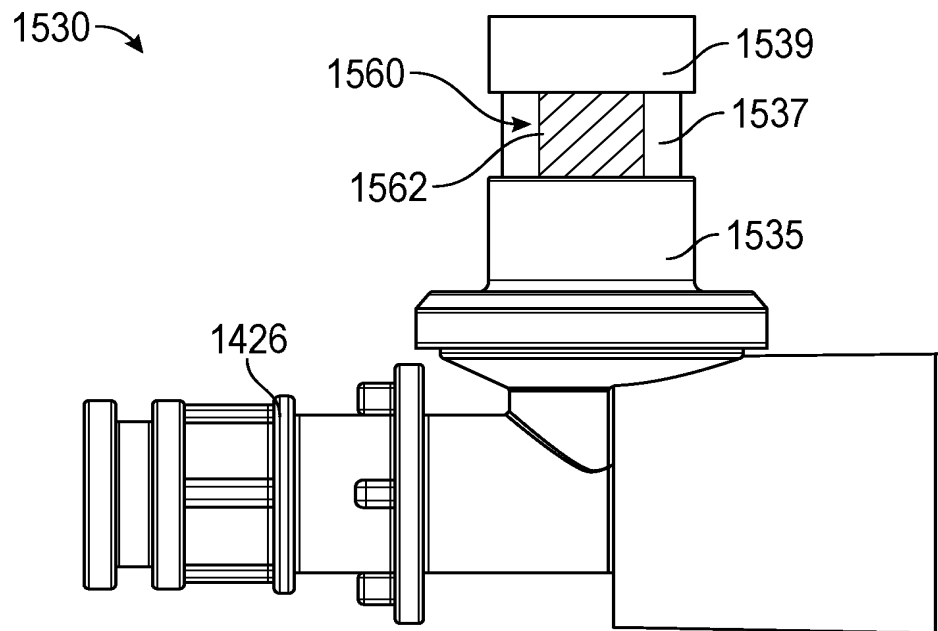


FIG. 15C

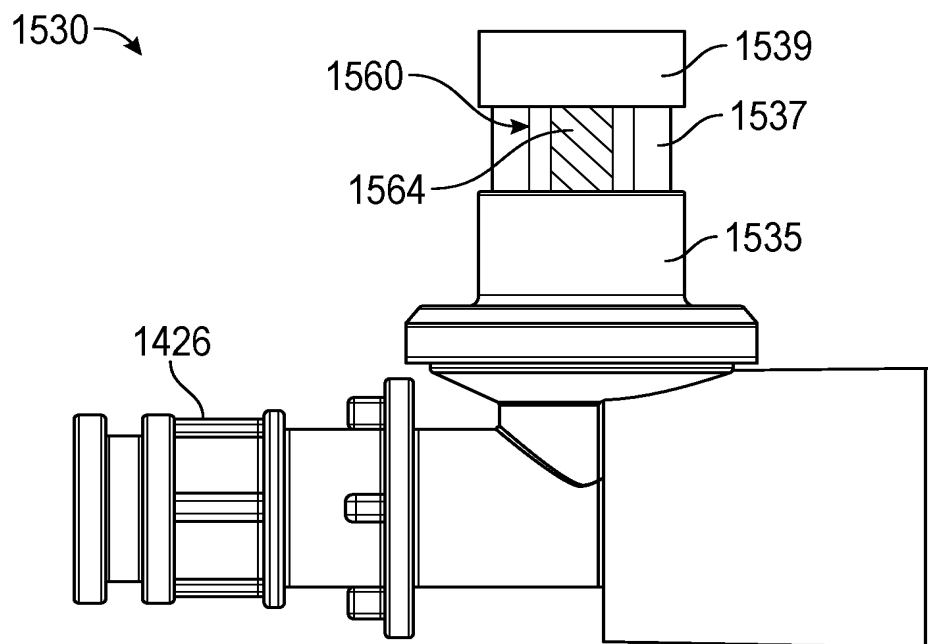


FIG. 15D

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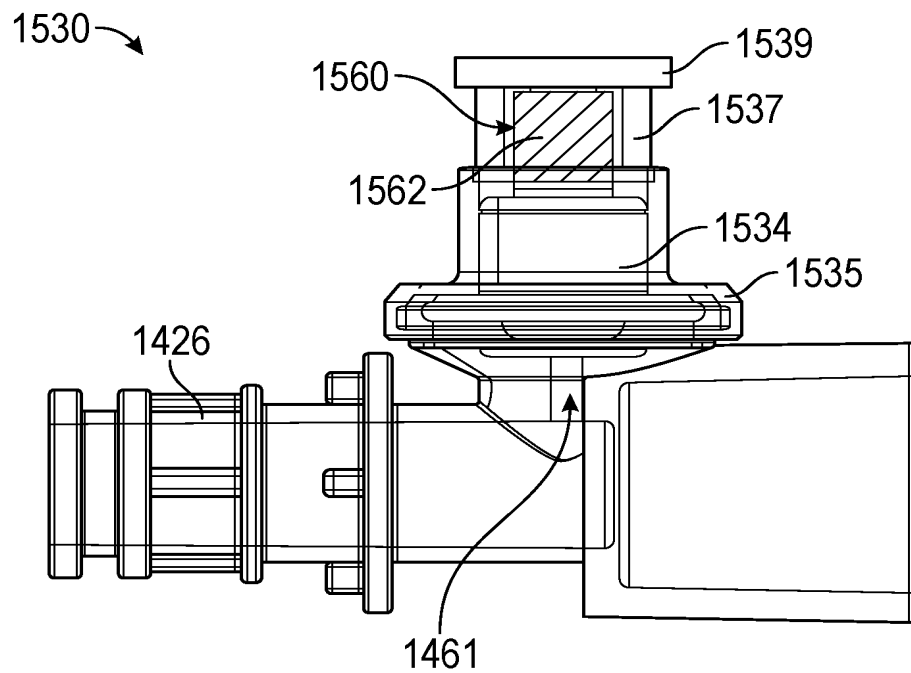


FIG. 15E

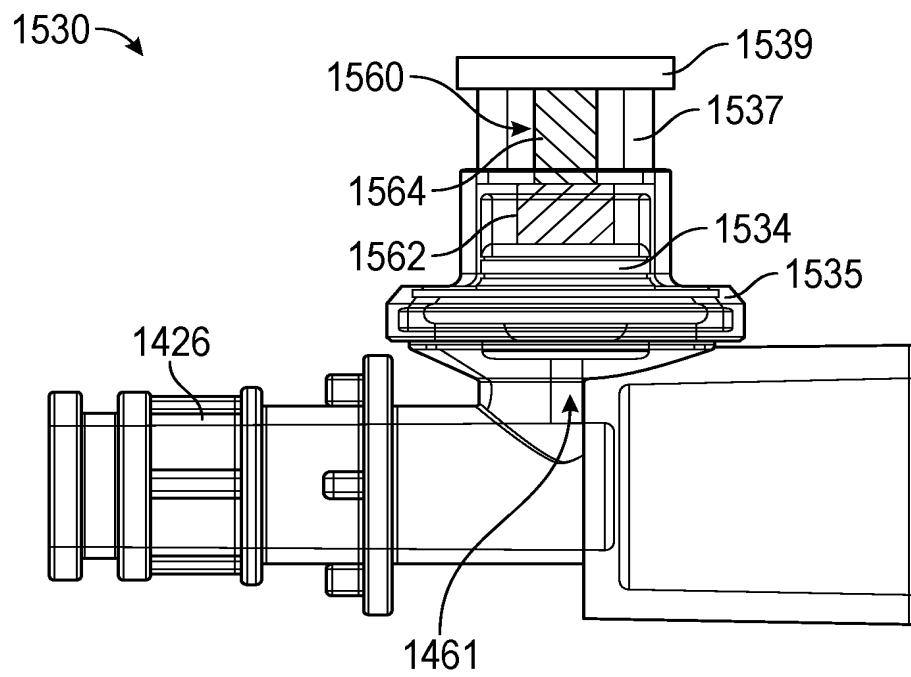


FIG. 15F

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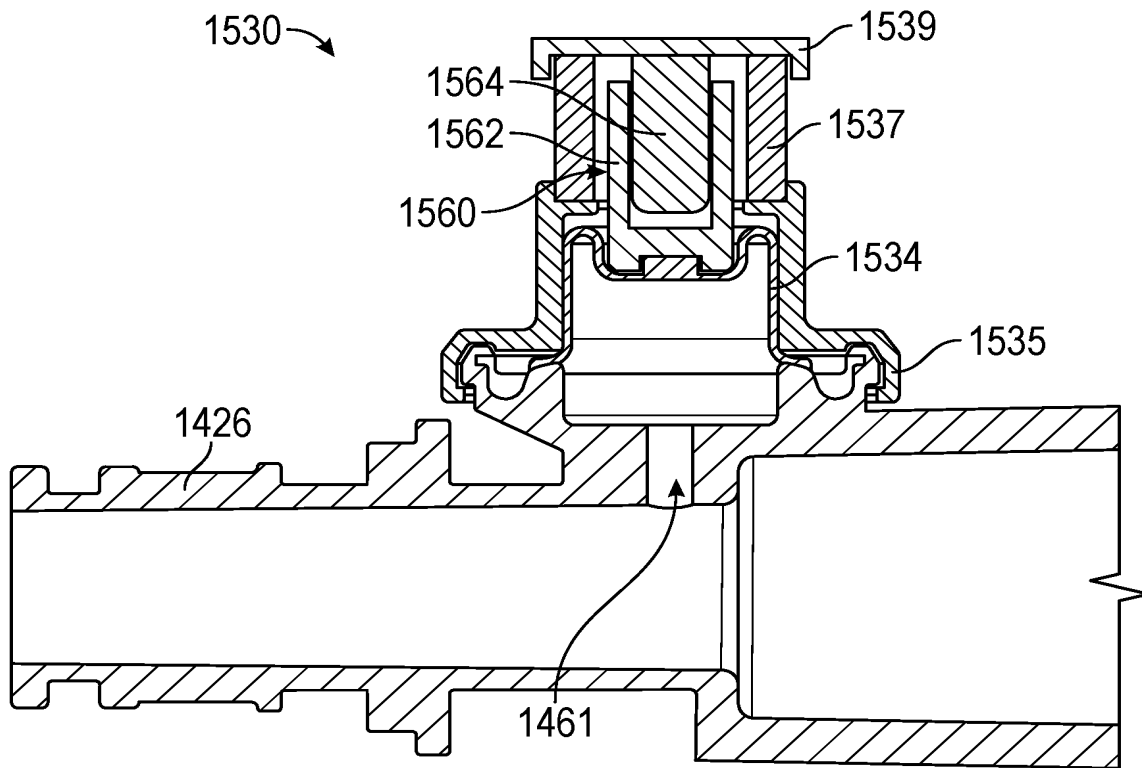


FIG. 15G

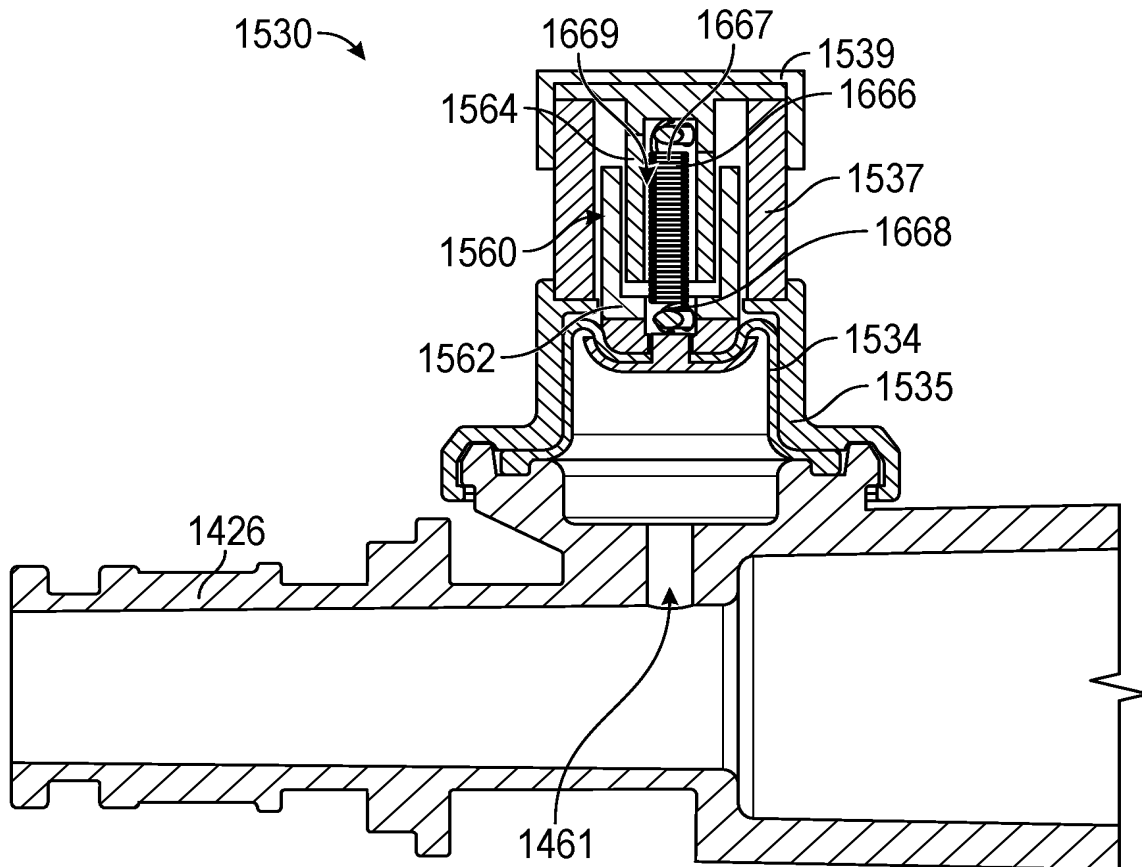


FIG. 16

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/45072

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61M 5/32; A61M 5/315 (2021.01)

CPC - A61M 5/32; A61M 5/502; A61M 5/3243; A61M 5/150641; A61M 5/3234; A61M 5/3232; A61M 5/5013; A61M 2005/5026; A61M 2005/3247; A61M 2005/3223; A61M 5/315

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2013/0126559 A1 (COWAN et al.) 23 May 2013 (23.05.2013); entire document, especially para [0028], and Fig. 1-2.	1-10
A	US 2004/0122359 A1 (WENZ et al.) 24 June 2004 (24.06.2004); entire document, especially para [0063]-[0066], and Fig. 7.	1-15
A	WO 2011/073176 A1 (NOVARTIS AG) 23 June 2011 (23.06.2011); especially pg 6 ln 33 to pg 7 ln 2, and Fig. 1-3.	10-15
A, P	WO 2021/067134 A1 (BECTON, DICKINSON AND COMPANY) 8 April 2021 (08.04.2021); entire document.	1-15
A	US 2004/0267272 A1 (HENNIGES et al.) 30 December 2004 (30.12.2004); entire document.	1-15

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search

2 December 2021

Date of mailing of the international search report

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Form PCT/ISA/210 (second sheet) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/45072

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-15 directed to an automatically-locking syringe.

Group II: Claims 16-20 directed to a clot treatment system.

Group III: Claims 21-28 directed to a syringe having a barrel and a vacuum indicator having a transparent tube and an indicator with a visual characteristic.

-*- See Supplemental Box -*-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-15

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/US 21/45072

-*- Box III.0 - Explanations where unity of invention is lacking

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a lock plate, not required by the claims of Groups II-III.

The invention of Group II includes the special technical feature of a catheter, not required by the claims of Groups I or III.

The invention of Group III includes the special technical feature of a transparent tube and an indicator movably positioned within the tube, not required by the claims of Groups I-II.

COMMON TECHNICAL FEATURES

Groups I and III share the common technical feature of a syringe having a barrel and a plunger movable through the barrel. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 5,788,463 A (CHAN) (hereinafter Chan), which discloses a syringe (10; Fig. 1-10; col 4 ln 66 to col 5 ln 20) having a barrel (50; Fig. 1-10; col 5 ln 21-23) and a plunger movable through the barrel (60; Fig. 1-10; col 5 ln 21-23).

Groups II-III share the common technical feature of a vacuum indicator. However, this shared technical feature does not represent a contribution over prior art as being anticipated by Chan, which discloses a vacuum indicator (15; Fig. 1-10; col 8 ln 36-50).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.



(12) 发明专利申请

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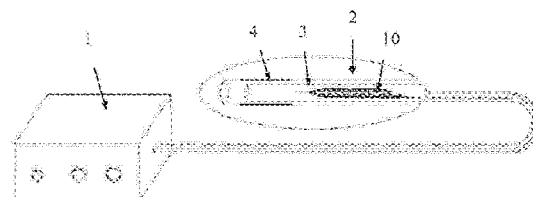
权利要求书1页 说明书4页 附图5页

(54) 发明名称

血管取栓系统

(57) 摘要

本发明提供一种血管取栓系统。所述取栓系统包括导引导丝、推拉导丝、外鞘管、能够相对于外鞘管移动的内管和取栓器，导引导丝穿过内管，内管则被套在外鞘管内，且内管能够沿着导引导丝移动，该取栓器与推拉导丝相连，安装好的推拉导丝和取栓器被压握入内管内，且所述取栓器能够通过推拉导丝推拉而在收回位置和展开位置之间转换，在收回位置，取栓器被回收到内管内，在展开位置，取栓器被推出内管。所述取栓系统还包括抽吸装置，该抽吸装置与内管相连通，且内管上设有抽吸孔。根据本发明的取栓系统，既可以方便的捕捉大块血栓，又可以通过抽吸防止小块血栓的脱落，解决了血管远端血管再次栓塞的问题，同时有效减少了取栓后并发症的概率。



1. 一种取栓系统,其特征在于,其包括导引导丝、推拉导丝、外鞘管、能够相对于外鞘管移动的内管和取栓器,导引导丝穿过内管,内管则被套在外鞘管内,且内管能够沿着导引导丝移动,该取栓器与推拉导丝相连,安装好的推拉导丝和取栓器被压握入内管内,且所述取栓器能够通过推拉导丝推拉而在收回位置和展开位置之间转换,在收回位置,取栓器被回收到内管内,在展开位置,取栓器被推出内管,所述取栓系统还包括抽吸装置,该抽吸装置与内管相连通,且内管上设有抽吸孔。
2. 根据权利要求 1 所述的取栓系统,其中取栓器包括外层支架和内层支架,内外层支架均构成为网状,且外层支架包覆在内层支架外,两者之间形成间隙。
3. 根据权利要求 2 所述的取栓系统,其中外层支架与内层支架在近端相连接或在近端和远端均相连接。
4. 根据权利要求 2 或 3 所述的取栓系统,其中内外层支架的近端和 / 或远端具有椭圆形开口或圆形开口,或为封闭的。
5. 根据权利要求 1-3 中任一项所述的取栓系统,其中推拉导丝与取栓器的牵引连接点布置成在展开位置贴近血管壁。
6. 根据权利要求 1-3 中任一项所述的取栓系统,其中取栓器在展开位置整体呈近似圆柱形。
7. 根据权利要求 1-3 中任一项所述的取栓系统,其中取栓器被构造有内凹和 / 或外凸的结构。

血管取栓系统

技术领域

[0001] 本发明涉及医疗器械,具体涉及一种介入血管的医疗器械,特别涉及一种血管取栓系统。

背景技术

[0002] 血管内血栓是临床上的常见病和多发病,而颅内血栓又是重中之重,它造成脑栓塞,具有发病率高、致残率高、死亡率高和复发率高的特点,是中老年人致死和致残的主要疾病。而随着老年人口的不断增加和生活水平的提高,脑血管病的发病率在不断升高。根据调查,我国目前每年有 300 万的新增脑血栓群体,而急性脑血栓占脑卒中的比例也由 55.8% 上升到 81.6%,成为脑部第一大疾病。

[0003] 血管的再通是治疗急性缺血性脑卒中的关键。目前颅内血栓的治疗方法主要有两种:药物溶栓和机械取栓。

[0004] 药物溶栓治疗是把溶栓剂注入病变所在的血管内的病灶附近,在病灶局部瞬间地形成很高的溶栓剂浓度,加快血栓溶解速度,进而增加血管再通的机会。但是,根据美国国立神经疾病与卒中研究院(NINDS)的研究结果,静脉溶栓应在发病 3 小时内进行,动脉溶栓时间窗为 6 小时之内。由于药物溶栓治疗时间窗较短,而且溶栓治疗只适用于体积较小的血栓,其对大体积血栓栓塞的治疗效果并不理想,所以最终大约只有 3~5% 的患者适合做药物溶栓治疗。

[0005] 机械取栓是将取栓器输送至病变位置,然后通过鞘管将血栓取出至体外。机械取栓包括以下几种方法:捕捉取栓、抽吸取栓、旋切取栓等。捕捉取栓在取大块血栓时效果最好,但是容易造成血管壁上的斑块和破碎的血栓块脱落后流向远端血管造成新的栓塞;抽吸取栓在取小块栓子时效果较好,在取大块血栓时为了防止堵塞抽吸管需要反复捣碎血栓后再抽吸,过程麻烦而且很容易伤到血管;旋切取栓对血管壁造成的损伤较大,很容易引起并发症。

[0006] 中国实用新型专利 CN201020104685.1 公开了一种用于人体血管内血栓抽吸导管,其包括依次连接的管座、加强管、单腔管、双腔管、尖端管和显影标记。该取栓系统在抽吸腔的远端有 1-4 个开孔,增加了导管的通过性和血栓抽吸能力,并减小在手术过程中对人体血管的损伤,同时提高导管的跟踪性和推送性。

[0007] 中国发明专利申请 CN201110222609.X 和中国实用新型专利 CN201120281795.X 公开了一种血栓抽吸导管,其包括抽吸管,所述抽吸管包括管座,所述管座连接导管,所述抽吸管的外壁上可活动的套设有套管,所述套管包括 Y 型连接头、双腔管及球囊,所述 Y 型连接头连接双腔管,球囊设置于双腔管的远端外壁上,所述抽吸管内可插入干扰金属丝,所述干扰金属丝的远端可伸出抽吸管的远端外。该取栓系统可以快速清除散布在血管广泛区域的血栓及处理冠脉末梢微血管的栓塞,而且当遇到体积大及高黏稠的血栓时,可利用干扰金属丝打散血栓后再进行抽吸。

[0008] 美国专利申请 US2010/0049147A1 公开了另外一种血栓抽吸导管。美国专利申请

US2007/0161963A1 也公开了一种血栓切除术抽吸导管系统。

[0009] 上述抽吸取栓系统在取小块栓子时效果较好,但是在取大块血栓时为了防止堵塞抽吸管需要反复捣碎血栓后再抽吸,过程麻烦而且很容易伤到血管。

[0010] 中国发明专利申请 01114889.6 公开了一种可用于颅内血管的可回收血栓临时过滤器,其由过滤器、导向头、导引杆、连接件和外鞘组成,其中过滤器由形状记忆合金丝编织而成。美国专利申请 2011/0160763 也公开了一种可用于颅内血管的取栓装置,其包括骨架,骨架可由形状记忆合金丝编织而成,以捕获血栓。

[0011] 上述取栓系统在捕获血栓之后回收时,血栓固定不牢固、容易脱落,而且结构复杂。

[0012] 此外,利用目前的取栓装置,在取栓过程中血管壁上的斑块和破碎的血栓块很容易脱落,流向远端血管,造成新的栓塞。据报道,约有 70% 的血管介入取栓手术中观察到了有血栓碎片和碎块流向远端血管,这增加了患者血管再栓塞的风险。

[0013] 因此,需要一种改进的血管取栓装置,这种装置应满足以下几个条件:1)取栓过程简单、方便;2)柔顺性好,捕获率高,支撑力适中,取栓过程中不会损伤血管内壁;3)在捕获血栓之后回收时,血栓固定牢固、不易脱落。总之,既要具有良好的取栓效果,又要能够有效防止小血栓的脱落同时又不会损伤血管造成严重的并发症。

发明内容

[0014] 有鉴于此,本发明提供了一种改进的取栓系统,该系统解决了现有技术中存在的血管壁斑块和碎血栓块容易脱落而造成远端血管再次栓塞的问题,而且柔顺性好、捕获率高。

[0015] 根据本发明的一方面,本发明提出一种血管取栓系统,其包括导引导丝、推拉导丝、外鞘管、能够相对于外鞘管移动的内管和网状取栓器,导引导丝穿过内管,内管则被套在外鞘管内,且内管能够沿着导引导丝移动,该取栓器与推拉导丝相连,安装好的推拉导丝和取栓器被压握入内管内,且所述取栓器能够通过推拉导丝推拉而在收回位置和展开位置之间转换,在收回位置,取栓器被回收入内管内,在展开位置,取栓器被推出内管,所示取栓系统还包括抽吸装置,该抽吸装置与内管相连通,且内管上设有抽吸孔。本发明的取栓系统将捕捉取栓与抽吸取栓相结合,既可以方便的捕捉大块血栓,又可以通过抽吸防止小块血栓的脱落,解决了血管远端血管再次栓塞的问题,同时有效减少了取栓后并发症的概率。

[0016] 根据本发明的优选实施例,外鞘管在远端还设有可膨胀封堵球囊。

[0017] 根据本发明的优选实施例,内管上设有 1~4 个抽吸孔,这些抽吸孔可以是导管远端的开口,也可以是导管侧壁上的开孔。开口和开孔的形状可以是圆形、椭圆形或其他形状。开孔可以对称分布、间隔分布或随机分布。

[0018] 根据本发明的优选实施例,取栓器既可以通过激光切割金属管材、片材而获得,也可以通过金属丝编织而获得,其中金属管、片、丝材可以是镍钛合金、钴镍合金、不锈钢等。这样使取栓器的柔顺性和贴壁性良好。

[0019] 另外,优选地,取栓器的近端和远端均可以是开口的或封闭的。取栓器整体还可以是近似圆柱状、内凹状或外凸状等。取栓器还可以是单层结构,或是双层或多层结构。

[0020] 根据本发明的优选实施例,取栓器整体长度为 15~60mm,直径为 2~6mm,壁厚为

0.04 ~ 0.12mm。

[0021] 优选地, 推拉导丝与取栓器的牵引连接点布置成在展开位置贴近血管壁。这样可以提高大体积血栓的有效捕获率。

[0022] 优选地, 取栓器在展开位置整体呈近似圆柱形。这样使取栓器具有良好的径向支撑力, 从内管中释放到血管后具有较好的血管贴壁性。

[0023] 取栓时, 通过血管造影确定血栓的位置, 然后把内管输送至栓塞处远端, 回撤内管, 将取栓器从血栓中间释放, 利用封堵球囊在远端封堵住血管, 然后先回撤取栓器进入内管中, 之后再打开抽吸装置进行抽吸。然后, 关闭抽吸装置, 将内管向远端移动 5 ~ 20mm, 之后再次打开抽吸装置抽吸剩余小块血栓, 然后关闭抽吸装置。最后, 将内管收进外鞘管内, 撤出体外。

[0024] 根据本发明的血管取栓系统, 可以有效捕获斑块和血栓碎片, 增加了血栓捕获稳定性, 防止了血栓脱落, 从而降低再栓塞的风险。另外, 本发明的血管取栓系统结构简单, 取栓过程方便容易。

附图说明

[0025] 通过下面参照附图对本发明实施例进行的详细描述, 本发明的特征及其优点将是显而易见的。在图中:

[0026] 图 1 是本发明实施例的取栓系统的总体示意图。

[0027] 图 2-9 是本发明的内管的实施例的示意图。

[0028] 图 10-20 显示了本发明的取栓器的实施例的示意图。

具体实施方式

[0029] 下面参照图 1-20 详细描述本发明的实施例。

[0030] 为了便于描述, 以下描述使用了术语“近端”和“远端”, 其中“近端”指的是离操作端近的一端, 远端指的是远离操作端的一端。

[0031] 如图 1 所示, 取栓系统包括抽吸装置 1、外鞘管 2、内管 3 和取栓器 10 组成。取栓器 10 为网状并与取栓系统的推拉导丝(未示出)相连, 安装好的推拉导丝和取栓器 10 被压握入内管 3 内。取栓器 10 可通过推拉导丝的推拉而在收回位置和展开位置之间转换, 在收回位置, 取栓器 10 收回到内管 3 内, 在展开位置, 取栓器 10 被推出到内管 3 外。另外, 取栓系统还包括导引导丝(未示出), 导引导丝穿过内管 3, 用以在血管内引导取栓系统。外鞘管 2 在远端处设有可膨胀封堵球囊 4。

[0032] 此外, 取栓器 10 上还设有显影标记(未示出), 以帮助定位取栓器 10。可以理解的是, 内管 3 和外鞘管 2 上也可以设有显影标记。

[0033] 内管上设有 1 ~ 4 个抽吸孔, 这些抽吸孔可以仅是内管远端的开口, 如图 2 和 6 所示, 也可以是在远端开口基础上在导管侧壁上再开一些抽吸孔, 如图 3 ~ 5 和图 7 ~ 9 所示。开口和开孔可以是圆形、椭圆形或其他形状, 可以单独、对称、间隔或随机分布。

[0034] 取栓器可以是单层结构, 如图 10 ~ 14 的取栓器 10 所示。取栓器 10 的近端和远端均可以是封闭的或开口的。另外, 如图 14 所示, 取栓器 10 可以构造有外凸和内凹结构。

[0035] 取栓器也可以是双层结构。如图 15 ~ 20 所示。取栓器 10' 为支架套支架结构,

整体呈近似圆柱形,其包括两部分,即内层支架 20 和外层支架 30,其中内外层支架均构成网状,外层支架包覆在内层支架外,且两者之间留有间隙。取栓器 10' 的内外层的近端远端可以是只近端连接,如图 16、17、19 和 20 所示,也可以是近远端都连接,如图 15 和 18 所示。连接可以是焊接连接、利用金属套管连接或利用金属丝缠绕连接等。

[0036] 当然,取栓器也可以是多层结构。

[0037] 取栓器通过激光切割具有形状记忆效应的金属管材(如镍铁合金等)而形成并经热处理定型。当然,取栓器也可以通过切割具有形状记忆效应的金属片材,然后卷曲,热处理定型而形成。取栓器的合适尺寸如下:长度为 15~60mm,直径为 2~6mm,壁厚为 0.04~0.12mm。也可以用高弹性的高分子材料来代替金属材料。上述合适的材料是本领域技术人员所熟知的,在此不再详细描述。

[0038] 推拉导丝与取栓器的牵引连接点布置为在展开位置贴近血管壁。这样可提高大体积血栓的有效捕获率。

[0039] 本发明的取栓系统的使用方法如下。

[0040] 介入治疗时,首先通过血管造影确定血管病变位置,然后将取栓装置 1 导入血管内,使导引导丝穿过病变位置,再使内管 3 沿导引导丝穿过病变位置并通过内管 3 上的显影标记(未示出)定位,期间取栓器 10 一直位于内管 3 内,处于收回位置。然后,回撤导引导丝,通过推拉导丝将取栓器 10 推到内管 3 远端,回撤内管 3 至病变位置,将取栓器 10 释放,通过取栓器 10 上的显影标记可定位取栓器 10。由于形状记忆金属的形状记忆效应或高弹性高分子材料的弹性作用,取栓器 10 在血液温度的作用下转换到展开位置,贴靠血管壁。然后,利用封堵球囊 4 在远端封堵住血管,拉动推拉导丝,回撤取栓器 10 捕获血栓,直至将取栓器 10 收回到内管 3 内。然后,打开抽吸装置 1 进行抽吸,之后关闭抽吸装置,接着将内管向远端移动 5~20mm,之后再次打开抽吸装置抽吸剩余小块血栓,然后关闭抽吸装置。再将内管 3 收回到外鞘管 2 中。最后,将取栓装置 1 整体撤出人体外,完成取栓过程。

[0041] 采用目前的取栓系统取栓时,血管壁上的斑块和破碎的血栓块很容易因外力作用破碎脱落,流向远端血管而造成新的栓塞,增加患者的手术风险。本发明的设计将捕捉取栓与抽吸取栓这两种方式相结合,在取栓时可以通过抽吸将脱落的小块血栓吸入抽吸管,同时通过捕获可以将大体积的血栓拉入抽吸管,避免了捕获取栓时小块血栓易脱落和抽吸取栓时不易捕获大块血栓的缺点,且操作方便,再通率高。

[0042] 本发明的取栓系统可适合于颅内血管取栓,也可以适合于其它血管内取栓。本领域技术人员可以理解,以上描述只是示例性的。在不背离本发明的思想和范围的情况下,本领域技术人员仍可以对本发明作出多种修改和变化。

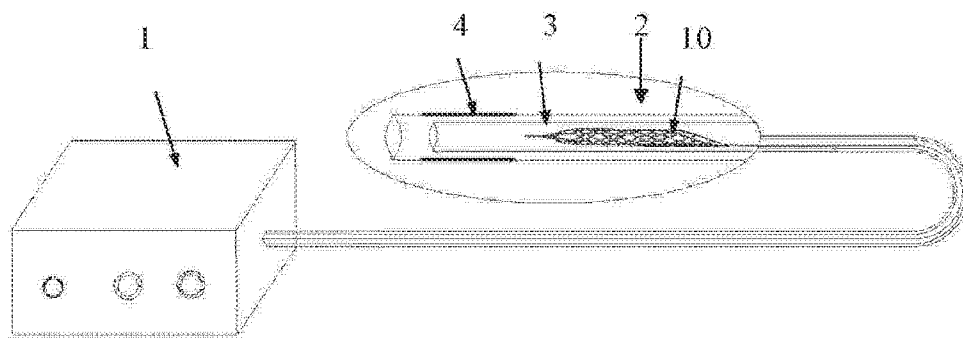


图 1



图 2

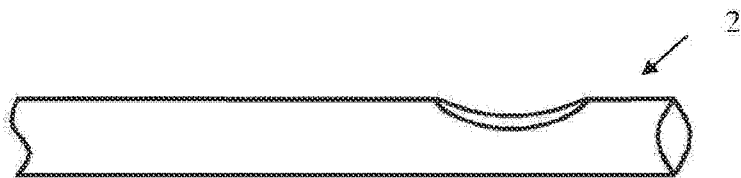


图 3



图 4

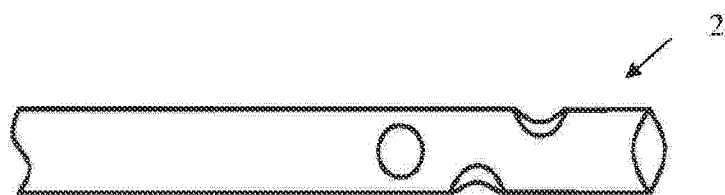


图 5

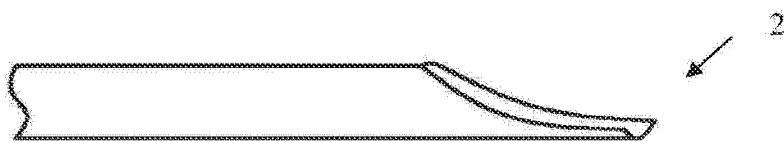


图 6



图 7

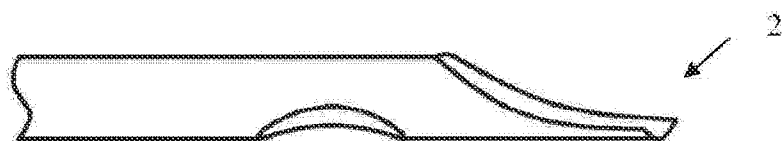


图 8

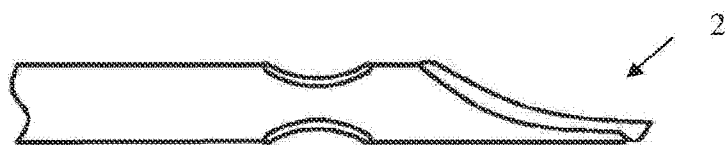


图 9

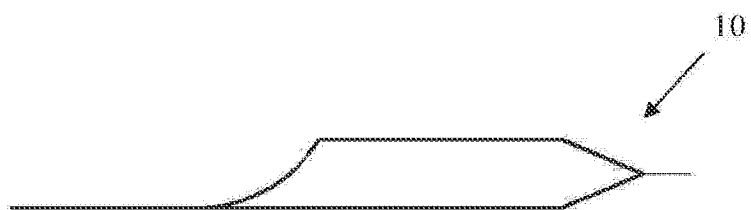


图 10

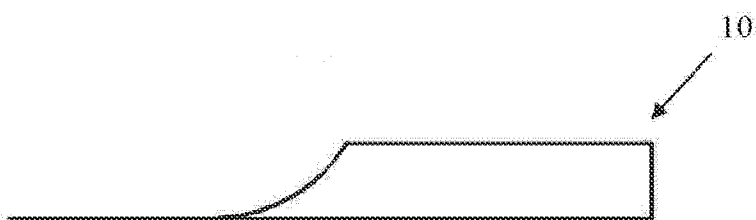


图 11

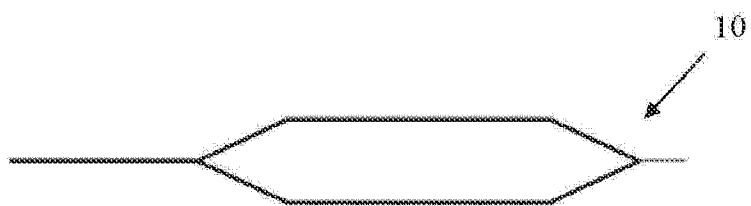


图 12

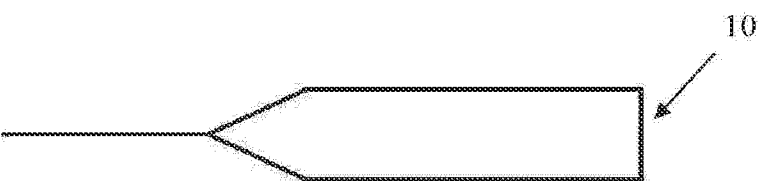


图 13

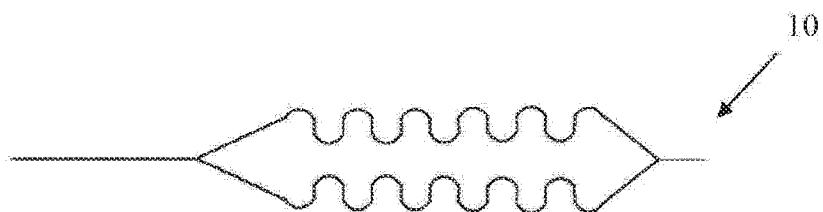


图 14

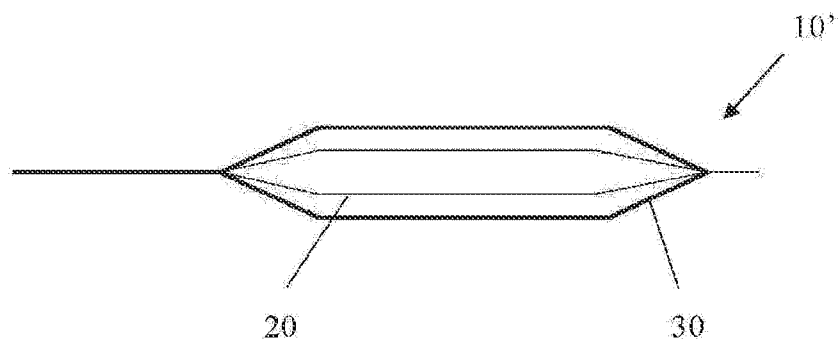


图 15



图 16

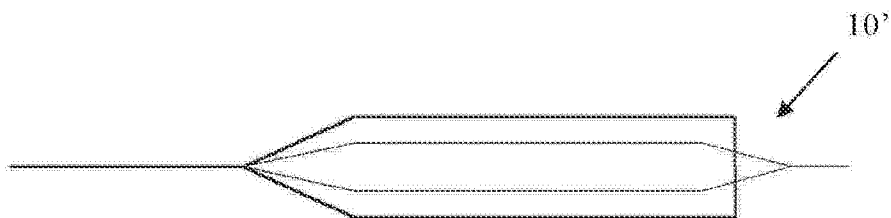


图 17

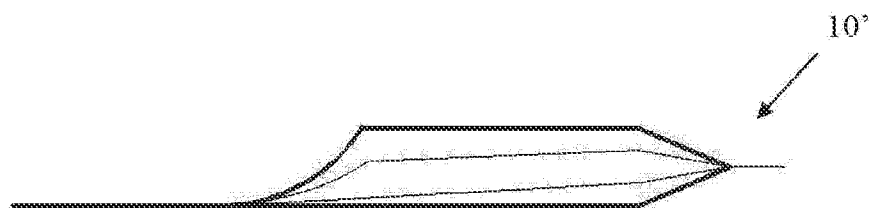


图 18

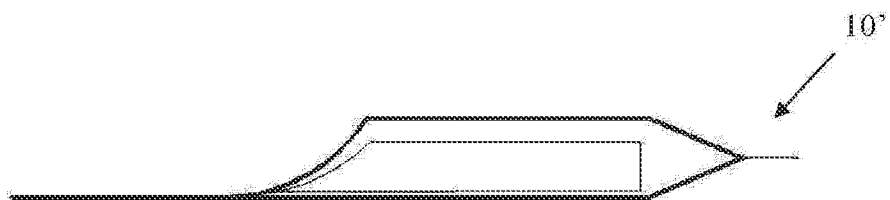


图 19

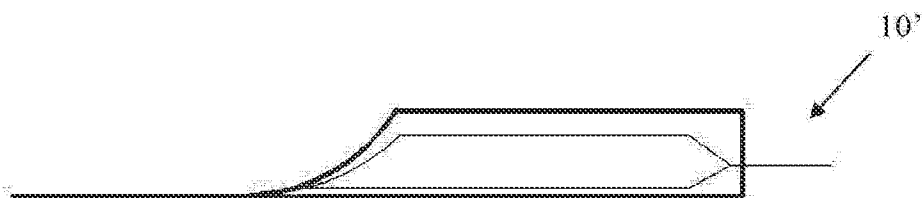


图 20

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To: MATTHEW S. WILLIAMS PERKINS COIE LLP P.O. BOX 1247 SEATTLE, WA 98111-1247
RECEIVED PATENT DOCKETING JAN 25 2022 PERKINS COIE LLP

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 111552-8025WO00	Date of mailing (day/month/year) JAN 20 2022
International application No. PCT/US 21/45072	International filing date (day/month/year) 06 August 2021 (06.08.2021)
Applicant INARI MEDICAL, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

How? Directly to the International Bureau preferably through ePCT, or on paper to:
The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland

For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 - 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to any protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
 - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices. In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Within 22 months from the priority date, the applicant may request that a supplementary international search be carried out by a different International Searching Authority that offers this service (Rule 45bis.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer <div style="text-align: center; font-weight: bold;">Kari Rodriguez</div> Telephone No. PCT Helpdesk: 571-272-4300
---	--

Form PCT/ISA/220 (revised January 2020)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 111552-8025WO00		FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US 21/45072	International filing date (<i>day/month/year</i>) 06 August 2021 (06.08.2021)	(Earliest) Priority Date (<i>day/month/year</i>) 06 August 2020 (06.08.2020)	
Applicant INARI MEDICAL, INC.			

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (see Box No. II).

3. ☒ Unity of invention is lacking (see Box No. III).

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 1B
☒ as suggested by the applicant.
☐ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/45072

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-15 directed to an automatically-locking syringe.

Group II: Claims 16-20 directed to a clot treatment system.

Group III: Claims 21-28 directed to a syringe having a barrel and a vacuum indicator having a transparent tube and an indicator with a visual characteristic.

.*- See Supplemental Box -*.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos. 1-15

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/45072

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61M 5/32; A61M 5/315 (2021.01)

CPC - A61M 5/32; A61M 5/502; A61M 5/3243; A61M 5/150641; A61M 5/3234; A61M 5/3232; A61M 5/5013; A61M 2005/5026; A61M 2005/3247; A61M 2005/3223; A61M 5/315

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History documentDocumentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History documentElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2013/0126559 A1 (COWAN et al.) 23 May 2013 (23.05.2013); entire document, especially para [0028], and Fig. 1-2.	1-10
A	US 2004/0122359 A1 (WENZ et al.) 24 June 2004 (24.06.2004); entire document, especially para [0063]-[0066], and Fig. 7.	1-15
A	WO 2011/073176 A1 (NOVARTIS AG) 23 June 2011 (23.06.2011); especially pg 6 ln 33 to pg 7 ln 2, and Fig. 1-3.	10-15
A, P	WO 2021/067134 A1 (BECTON, DICKINSON AND COMPANY) 8 April 2021 (08.04.2021); entire document.	1-15
A	US 2004/0267272 A1 (HENNIGES et al.) 30 December 2004 (30.12.2004); entire document.	1-15

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

2 December 2021

Date of mailing of the international search report

JAN 20 2022

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Kari Rodriguez

Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/US 21/45072

Box III.0 - Explanations where unity of invention is lacking -A-

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a lock plate, not required by the claims of Groups II-III.

The invention of Group II includes the special technical feature of a catheter, not required by the claims of Groups I or III.

The invention of Group III includes the special technical feature of a transparent tube and an indicator movably positioned within the tube, not required by the claims of Groups I-II.

COMMON TECHNICAL FEATURES

Groups I and III share the common technical feature of a syringe having a barrel and a plunger movable through the barrel. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 6,788,463 A (CHAN) (hereinafter Chan), which discloses a syringe (10; Fig. 1-10; col 4 in 66 to col 5 in 20) having a barrel (50; Fig. 1-10; col 5 in 21-23) and a plunger movable through the barrel (60; Fig. 1-10; col 5 in 21-23).

Groups II-III share the common technical feature of a vacuum indicator. However, this shared technical feature does not represent a contribution over prior art as being anticipated by Chan, which discloses a vacuum indicator (15; Fig. 1-10; col 6 in 36-50).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: MATTHEW S. WILLIAMS PERKINS COIE LLP P.O. BOX 1247 SEATTLE, WA 98111-1247
RECEIVED PATENT DOCKETING JAN 25 2022 PERKINS COIE LLP

Date of mailing (day/month/year)	JAN 20 2022
-------------------------------------	--------------------

Applicant's or agent's file reference 111552-8025WO00		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US 21/45072	International filing date (day/month/year) 06 August 2021 (06.08.2021)	Priority date (day/month/year) 06 August 2020 (06.08.2020)	
International Patent Classification (IPC) or both national classification and IPC IPC - A61M 5/32; A61M 5/315 (2021.01) CPC - A61M 5/32; A61M 5/502; A61M 5/3243; A61M 5/150641; A61M 5/3234; A61M 5/3232; A61M 5/5013; A61M 2005/5026; A61M 2005/3247; A61M 2005/3223; A61M 5/315			
Applicant INARI MEDICAL, INC.			

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Date of completion of this opinion 2 December 2021	Authorized officer Kari Rodriguez PCT Help Desk Telephone No. 571-272-4300
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Form PCT/ISA/237 (cover sheet) (revised January 2019)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 21/45072

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(b)).
3. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. ☐ forming part of the international application as filed:
 - ☐ in the form of an Annex C/ST.25 text file.
 - ☐ on paper or in the form of an image file.
 - b. ☐ furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
 - ☐ in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
 - ☐ on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest and, where applicable, the protest fee.
 - ☐ paid additional fees under protest but the applicable protest fee was not paid.
 - ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-15 directed to an automatically-locking syringe.

Group II: Claims 16-20 directed to a clot treatment system.

Group III: Claims 21-28 directed to a syringe having a barrel and a vacuum indicator having a transparent tube and an indicator with a visual characteristic.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a lock plate, not required by the claims of Groups II-III.

The invention of Group II includes the special technical feature of a catheter, not required by the claims of Groups I or III.

The invention of Group III includes the special technical feature of a transparent tube and an indicator movably positioned within the tube, not required by the claims of Groups I-II.

COMMON TECHNICAL FEATURES

Groups I and III share the common technical feature of a syringe having a barrel and a plunger movable through the barrel. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 5,788,463 A (CHAN) (hereinafter Chan), which discloses a syringe (10; Fig. 1-10; col 4 ln 66 to col 5 ln 20) having a barrel (50; Fig. 1-10; col 5 ln 21-23) and a plunger movable through the barrel (60; Fig. 1-10; col 5 ln 21-23).

Groups II-III share the common technical feature of a vacuum indicator. However, this shared technical feature does not represent a contribution over prior art as being anticipated by Chan, which discloses a vacuum indicator (15; Fig. 1-10; col 8 ln 36-50).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

☐ all parts.

☒ the parts relating to claims Nos. 1-15

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Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement			
1. Statement				
Novelty (N)	Claims	1-15	YES	
	Claims	None	NO	
Inventive step (IS)	Claims	1-15	YES	
	Claims	None	NO	
Industrial applicability (IA)	Claims	1-15	YES	
	Claims	None	NO	
2. Citations and explanations:				
<p>Claims 1-15 meet the criteria of PCT Article 33(2)-(3) because as will be shown, the prior art does not teach nor fairly suggest the claimed limitations.</p> <p>The prior art is exemplified by (1) US 2013/0126559 A1 (COWAN et al.) (hereinafter Cowan); (2) US 2004/0122359 A1 (WENZ et al.) (hereinafter Wenz); and (3) WO 2011/073176 A1 (NOVARTIS AG) (hereinafter Novartis).</p> <p>(1) Cowan teaches an automatically-locking syringe (8; Fig. 1-2; para [0028]), comprising: a barrel (10; Fig. 1-2; para [0028]); a plunger slidably positioned within the barrel (16; Fig. 1-2; para [0028]), wherein the plunger is movable between a depressed position and a withdrawn position (depression and withdrawing action of 16 within 10; Fig. 1-2; para [0028]), and wherein the plunger includes a lock feature (ratchet teeth upon 16; Fig. 1-2; para [0028]); and a lock plate coupled to the barrel (18; Fig. 1-2; para [0028]), wherein the lock plate includes a biasing member configured to bias the lock plate to a locking position (30; Fig. 1-2; para [0035]).</p> <p>(2) Wenz teaches a syringe (Fig. 7; para [0063]-[0066]), comprising: a barrel (unlabeled barrel through which 5 extends; Fig. 7; para [0064]), a plunger (5; Fig. 7; para [0064]), a lock plate (31, 32, 33, 34; Fig. 7; para [0064]-[0066]), said lock plate having an opening extending therethrough (opening of 31, 32, 33, 34 through which 5 extends; Fig. 7), wherein the plunger is slidably positioned in the opening (5 extending through opening of 31, 32, 33, 34; Fig. 7).</p> <p>(3) Novartis teaches a syringe (2; Fig. 1-3; pg 6 in 33 to pg 7 in 2), comprising: a first arm (22; Fig. 1-3; pg 7 in 20-28), a second arm (24; Fig. 1-3; pg 7 in 20-28), wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position (outward bias of 22 away from 18; Fig. 1-3; pg 8 in 25 to pg 9 in 3).</p> <p>-*- See Supplemental Box -*-</p>				

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

*- Box V.2 - Citations and explanations *-

As pertaining to claim 1, Cowan teaches an automatically-locking syringe (8; Fig. 1-2; para [0028]), comprising:

a barrel (10; Fig. 1-2; para [0028]);

a plunger slidably positioned within the barrel (16; Fig. 1-2; para [0028]),

wherein the plunger is movable between a depressed position and a withdrawn position (depression and withdrawing action of 16 within 10; Fig. 1-2; para [0028]), and

wherein the plunger includes a lock feature (ratchet teeth upon 16; Fig. 1-2; para [0028]); and

a lock plate coupled to the barrel (18; Fig. 1-2; para [0028]),

wherein the lock plate includes a biasing member configured to bias the lock plate to a locking position (30; Fig. 1-2; para [0035]);

but is silent wherein comprising:

said lock plate having an opening extending therethrough,

wherein the plunger is slidably positioned in the opening,

wherein-

when the plunger is moved from the depressed position to the withdrawn position, the lock feature is configured to engage the lock plate to drive the lock plate to a position away from the locking position to thereby permit the lock feature to pass through the opening, and after the lock feature passes through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.

Further, Wenz teaches a syringe (Fig. 7; para [0063]-[0066]), comprising:

a barrel (unlabeled barrel through which 5 extends; Fig. 7; para [0064]),

a plunger (5; Fig. 7; para [0064]),

a lock plate (31, 32, 33, 34; Fig. 7; para [0064]-[0066]),

said lock plate having an opening extending therethrough (opening of 31, 32, 33, 34 through which 5 extends; Fig. 7),

wherein the plunger is slidably positioned in the opening (5 extending through opening of 31, 32, 33, 34; Fig. 7),

but the prior art does not teach nor fairly suggest: when the plunger is moved from the depressed position to the withdrawn position, the lock feature is configured to engage the lock plate to drive the lock plate to a position away from the locking position to thereby permit the lock feature to pass through the opening, and

after the lock feature passes through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.

The lock plate as claimed by the Applicant is driven away to prevent depression movement of the plunger through the barrel. There exists no motivation without benefit of hindsight for modification of the syringe of Cowan as modified by Wenz such the plunger is inhibited from depression movement as opposed to withdrawing movement, such that the claimed limitations are met.

As pertaining to claims 2-9, the prior art does not teach nor fairly suggest the claimed limitations, because claims 2-9 depend from claim 1.

As pertaining to claim 10, Wenz teaches an automatically-locking syringe (Fig. 7; para [0063]-[0066]), comprising:

a barrel (unlabeled barrel through which 5 extends; Fig. 7; para [0064]) including a flange (14; Fig. 7; para [0064]);

a plunger slidably positioned within the barrel (5; Fig. 7; para [0064]),

wherein the plunger is aligned along a longitudinal axis (longitudinal alignment of 5; Fig. 7), and

wherein the plunger is movable along the longitudinal axis between a depressed position and a withdrawn position (movement of 5 through unlabeled barrel; Fig. 7; para [0064]);

a lock member coupled to the plunger (31, 32, 33, 34; Fig. 7; para [0064]-[0066]),

wherein the lock member includes a body (body of 31; Fig. 7; para [0064]);

but is silent wherein:

the lock member includes a first arm hingedly coupled to the body,

wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position; and

an actuator including a second arm,

wherein the actuator is movable between a first position and a second position, and

wherein the second arm is configured to engage the first arm in the second position to drive the first arm inwardly toward the longitudinal axis away from the locking position.

Further, Novartis teaches a syringe (2; Fig. 1-3; pg 6 in 33 to pg 7 in 2), comprising:

a first arm (22; Fig. 1-3; pg 7 in 20-28),

a second arm (24; Fig. 1-3; pg 7 in 20-28),

wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position (outward bias of 22 away from 18; Fig. 1-3; pg 8 in 25 to pg 9 in 3),

but the prior art does not teach nor fairly suggest employment of the elements of Novartis upon the syringe of Wenz such that the claimed limitations are met.

There exists no motivation without benefit of hindsight for employment of the first arm and second arm of Novartis upon the syringe of Wenz, such that the second arm engages directly with the first arm in order to unlock the plunger for withdrawing.

As pertaining to claims 11-15, the prior art does not teach nor fairly suggest the claimed limitations, because claims 11-15 depend from claim 10.

Claims 1-15 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.



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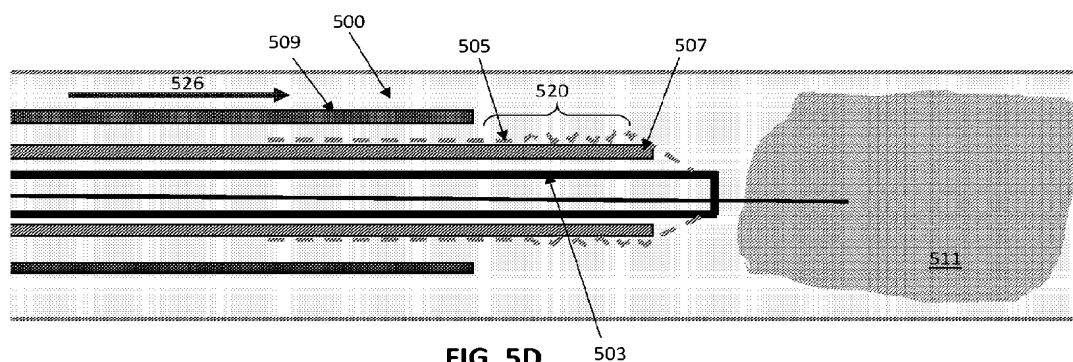


FIG. 5D

(57) **Abstract:** Inverting tube thrombectomy apparatus for removing clot that are configured to prevent compression of the apparatus that may separate the distal end of the apparatus from the clot and may make it difficult to advance the apparatus to engage with the clot, particularly in a tortuous vessel. The apparatuses and methods of using them described herein may be adapted to prevent tension in the flexible tube that is rolling and inverting over the distal end of the inversion support catheter when capturing a clot. Also described herein are inverting tube thrombectomy apparatus that are configured to reload either automatically or manually within the vessel to capture additional clot material.

INVERTING THROMBECTOMY APPARATUSES AND METHODS OF USE

FIELD

[0001] The apparatuses and methods described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses and methods.

BACKGROUND

[0002] Many vascular problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery. It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue, such as blood clots, from within a patient's vasculature may improve patient conditions and quality of life.

[0003] Mechanical thrombectomy devices may be particularly advantageous. There is a definite need for thrombectomy devices, and particularly a mechanical thrombectomy devices that can be easily and accurately delivered through the often tortious anatomy in the peripheral and central vasculature, then reliably deployed to remove clot material. Further, there is a need for devices that are easy and intuitive to operate. Described herein are apparatuses (devices, systems and kit) and methods of using them that may address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[0004] Described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and methods of using and making them. These apparatuses may also be referred to as inverting mechanical thrombectomy apparatuses and/or inverting tube thrombectomy apparatuses.

[0005] In particular, described herein are inverting tube thrombectomy apparatuses that may be deployed within even the most tortious vessels of the anatomy and may maintain their proximity to the clot during operation. Generally, the inverting tube thrombectomy

apparatuses described herein may include an inner puller (which may be configured as a puller catheter), an inverting flexible tube attached at a distal end region of the puller, and an outer inversion support catheter; the flexible tube may initially extend over an external region at the distal end of the inversion support catheter. All or a portion of the inversion support catheter, flexible tube and puller may be housed within an intermediate (e.g., delivery) catheter. In operation, the puller may be pulled to roll and invert the flexible tube over the open distal end of the inversion support catheter. This rolling and inversion of the flexible tube may capture a material, such as a clot, and pull it into the inner lumen of the inversion support catheter as the flexible tube is rolled and inverted.

[0006] Specifically, the inverting tube thrombectomy apparatuses and methods of operating them may prevent or reduce compression of the distal end of the inversion support catheter that may otherwise separate the end of the apparatus from the clot (e.g., kick back) and make further tracking of the apparatus within a tortious vessel difficult. Thus, in some variations of inverting tube thrombectomy apparatuses, pulling on the inverting tube (e.g., woven/braided/etc. tractor) compresses the distal end of the inversion support catheter (particularly in tortious anatomy), and causes it to separate from the clot and make additional tracking difficult within the tortious vessel.

[0007] Thus, any of the apparatuses described herein may be configured to prevent tension in the external portion of the flexible tube that is on the outer surface of the inversion support catheter before and/or during rolling and inverting the flexible tube over the distal end of the inversion support catheter.

[0008] Also described herein are methods for removing a clot (or multiple portions of a clot, or multiple clots) from a vessel. For example, a method of removing a clot from a vessel may include: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an inversion support catheter, a puller catheter slideable within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller catheter and a second end coupled to the inversion support catheter; applying aspiration through a lumen in the puller catheter to hold the clot on a distal end of the puller catheter; pushing the inversion support catheter distally to form slack in the flexible tube; and pulling the puller catheter proximally relative to the inversion support catheter to roll and invert the inversion support catheter over the distal end of the inversion support catheter and pull the clot into the inversion support

catheter. This process may be repeated multiple times without removing the apparatus from the vessel.

[0009] For example, described herein are methods of removing a clot from a vessel, the method comprising: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an inversion support catheter, a puller catheter slideable within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller catheter and a second end coupled to the inversion support catheter; applying aspiration through a lumen of the puller catheter to hold the clot on a distal end of the puller catheter; pushing the inversion support catheter distally to expand the flexible tube radially outward; pulling the puller catheter proximally while advancing the inversion support catheter distally to roll and invert the inversion support catheter over the distal end of the inversion support catheter and pull the clot into the inversion support catheter; and pulling the clot proximally through the lumen of the puller catheter.

[00010] Thus, pushing the inversion support catheter distally to form slack in the flexible tube may include expanding the flexible tube radially outward from the puller catheter.

[00011] Any of these methods may include pulling the clot proximally through the lumen of the puller catheter. For example, pulling the clot proximally through the lumen of the puller catheter may comprise aspirating the clot through the puller catheter, and/or using a wire to draw the clot proximally through the lumen of the puller catheter.

[00012] Any of these methods may include reloading the inverting tube thrombectomy apparatus while still in the vessel so that additional clot may be removed with the same device. Thus, any of these methods may include removing a second clot with the inverting tube thrombectomy apparatus. Reloading the inverting tube thrombectomy apparatus may comprise advancing the puller catheter distally relative to the inversion support catheter. Reloading may be done automatically or manually. For example, advancing the puller catheter distally may releasing the puller catheter so that a bias advances the puller catheter distally (e.g., automatically or semi-automatically).

[00013] In any of these methods, pulling the puller catheter proximally may comprise applying vacuum through the lumen of the puller catheter. Vacuum may be applied through the entire procedure (e.g., continuously) or through just a portion of the procedure, e.g., when drawing the clot proximally through the lumen of the puller catheter.

[00014] Any of these methods may include the use of an inverting tube thrombectomy apparatus that includes an intermediate catheter; the inversion support catheter and the puller catheter may be held (slidably held) within the intermediate catheter for delivery and may be extended from the intermediate catheter when the distal end is near the clot.

[00015] For example, in some variations, the apparatus and/or method of using it may be configured to form slack in an external portion of the flexible tube on the outer surface of the inversion support catheter. Slack may be formed by driving the second end of the flexible tube (that may not be attached to anything, including the intermediate catheter or the inversion support catheter) distally over the inversion support catheter. In some variations the second end of the flexible tube may be held between the inversion support catheter outer surface and the intermediate catheter. For example, in an un-deployed state, the inverting tube thrombectomy apparatus may be tracked through the vasculature with most of the flexible tube, inversion support catheter and puller housed within the intermediate catheter. This assembly may be tracked through the vasculature over a guidewire, for example, in some variations, the puller and the attached first end of the flexible tube may be extended slightly out of the distal end of the intermediate catheter. Once deployed at the clot, the intermediate catheter may be withdrawn proximally (or the pusher, flexible tube and/or inversion support catheter extended distally out of the intermediate catheter) but leaving a portion of the second end of the flexible tractor between the intermediate catheter and the inversion support catheter; advancing the intermediate catheter distally may then bunch up (form slack) the flexible tube. The pusher may be held fixed, advanced distally or (in the variation described below, pulled proximally). Alternatively, in some variations the intermediate catheter may be fully removed from over the flexible tube and advancing it distally may push on the end of the flexible tube (which may include a cuff), to drive the flexible tube distally. The second end of the flexible tube may be adapted so that it may be pushed by the intermediate catheter. As mentioned, the second end of the flexible tube may include a cuff, which may be a region of relative stiffness compared to the adjacent region of the flexible tube.

[00016] In some variations, apparatus and method are configured to both push on the second end of the flexible tube distally, and pull on the first end by pulling the puller (e.g., puller catheter) proximally. This may limit or reduce tension on the outside portion of the tractor. Thus, in any of these methods, the intermediate catheter may be pushed distally at the same time the puller is pulled proximally (at the same, or different rates) to reduce tension on the outside portion of the flexible tube, thereby reducing the compressive force applied to the distal end of the inversion support catheter.

[00017] For example, described herein are method of removing a clot from a vessel that may include: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; positioning the puller and inversion support catheter adjacent to the clot; and pushing a proximal end region of the external portion of the flexible tube distally over the inversion support catheter during one or both of: before or while pulling the puller proximally so that the external portion of the flexible tube rolls and inverts over the distal end of the inversion support catheter.

[00018] Pushing the proximal end region of the external portion of the flexible tube may include pushing the proximal end region of the external portion of the flexible tube by advancing the intermediate catheter distally. Alternatively or additionally, the proximal end region of the external portion of the flexible tube (which may be referred to as the second end of the flexible tube) may be pushed by a different member, such as a push wire or rod.

[00019] In some variations, pushing the proximal end region of the external portion of the flexible tube comprises pushing the proximal end region of the external portion of the flexible tube before pulling the puller proximally to form slack in the external portion of the flexible tube. Slack may refer to a region in which the flexible tube is not under tension, and may be loose; in some variations the slack region may be bunched up on itself. In some variations the slack region may be compressed, so that it expands (e.g., when pulled from the first end) easily.

[00020] In some variations, pushing the proximal end region of the external portion of the flexible tube comprises pushing the intermediate catheter distally to push the proximal end region of the external portion of the flexible tube distally while pulling the puller proximally, wherein the flexible tube is not attached to the intermediate catheter.

[00021] In any of the apparatuses and methods described herein, the flexible tube may be unattached to the intermediate catheter. For example, the second end of the flexible tube may be loose.

[00022] In any of the methods and apparatuses described herein, a vacuum may be applied through the puller. Thus, the apparatus, and particularly the puller, may be adapted to include

a lumen or passage for applying suction. This suction may be used to pull the clot out from the flexible tube once it has been all or partially engulfed, e.g., by the flexible tube.

[00023] In general, any of the methods described herein may include capturing the clot within the flexible tube as the puller is pulled proximally.

[00024] For example, a method of removing a clot from a vessel may include: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; positioning the puller and inversion support catheter adjacent to the clot; forming slack in the external portion of the flexible tube; and pulling the puller proximally so that the external portion of the flexible tube rolls and inverts over the distal end of the inversion support catheter so that the slack in the external portion of the flexible tube is withdrawn into the inversion support catheter.

[00025] In any of these methods pulling the puller proximally may comprise withdrawing all or a majority of the slack into the inversion support catheter before a second end of the flexible tube is moved distally over the inversion support catheter. For example, pulling the puller proximally may comprise withdrawing the slack into the inversion support catheter while applying 1 pound or less of force (e.g., applying 0.75 or less pounds of force, applying 0.5 pounds or less of force, applying 0.4 pounds or less of force, applying 0.3 pounds or less of force, applying 0.25 pounds or less of force, applying 0.2 pounds or less of force, applying 0.1 pound or less of force, etc.) proximally against the distal end of the inversion support catheter.

[00026] In any of the methods described herein, pulling the puller proximally may comprise withdrawing the slack into the inversion support catheter without causing the distal end of the inversion support catheter to withdraw from the clot within the vessel. Thus, the methods described herein may prevent the kickback (e.g., separation from the clot) described above.

[00027] Forming slack may comprise advancing the intermediate tube distally to push at least part of the external portion of the flexible tube distally to form slack in the external portion of the flexible tube over the inversion support catheter. For example, forming slack

may comprise axially compressing the external portion of the flexible tube on the inversion support catheter by driving the second end of the flexible tube distally. Forming slack may include driving a second end of the flexible tube distally without moving the puller proximally.

[00028] For example, a method of removing a clot from a vessel may include: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; positioning the puller and inversion support catheter adjacent to the clot; advancing the intermediate tube distally relative to the pusher to push at least part of the external portion of the flexible tube distally to form slack in the external portion of the flexible tube over the inversion support catheter; pulling the puller proximally so that the external portion of the flexible tube rolls and inverts over the distal end of the inversion support catheter so that the slack in the external portion of the flexible tube is withdrawn into the inversion support catheter; and capturing the clot with the rolling flexible tube to draw the clot into the inversion support catheter.

[00029] Any of the methods described herein may include reducing the tension on the flexible tube (and particularly the portion of the flexible tube that rolls and inverts over the distal end of the inversion support catheter). For example, a method of removing a clot from a vessel may include: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; and positioning the puller and inversion support catheter adjacent to the clot; and pushing a proximal end region of the external portion of the flexible tube distally over the inversion support catheter while pulling the puller proximally so that the

external portion of the flexible tube rolls and inverts over the distal end of the inversion support catheter.

[00030] In some variations, pushing the proximal end region of the external portion may comprise pushing the intermediate catheter distally to drive the proximal end region of the external portion distally.

[00031] Also described herein are apparatuses, including in systems, for removing a clot. For example the apparatus comprising: an intermediate catheter; an inversion support catheter within a lumen of the intermediate catheter; a puller within a lumen of the inversion support catheter; a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; and a handle coupled to the intermediate catheter and the puller, wherein the handle is configured to, when activated by a control on the handle, automatically advance the intermediate catheter while one or more of: holding the puller fixed or withdrawing the puller proximally as the intermediate catheter is advanced.

[00032] The methods and apparatuses described herein may alternatively or additionally include automatic reloading. For example, described herein are apparatuses and methods of using them that automatically reload the flexible tube after it has been inverted and rolled into the inversion support catheter, so that additional (or a different) clot may be captured. Clot that has already been captured within the inverted flexible tube may be removed proximally through the puller (e.g., puller catheter), using a vacuum and/or a wire within the puller. This may allow the device to be repeatedly used to remove clot without requiring the device to be removed from the body. Thus, the apparatus may repeated peck or bite at a clot by repeatedly rolling and inverting the flexible tube into the inversion support catheter, clearing the portion of the clot captured from the flexible tube into the puller, then automatically and/or manually everting the flexible tube back over the distal end and out of the inversion support catheter. In some variations the inversion support catheter may include a narrower inner diameter region near the distal end than more proximal regions, so that the flexible tube within the inversion support catheter may expand outwards slightly more proximally within the inversion support catheter, which may help release the compressed clot from the flexible tube. In some variations, the flexible tube may be lubricious (e.g., coated, etc.) within the inverted configuration (e.g., within the inversion support catheter). The suction through the puller be applied continuously or intermittently. The suction pressure may be monitored to confirm removal of the clot from the flexible tube before re-setting.

[00033] For example, described herein are methods of removing clot from a vessel, the method comprising: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; and positioning the puller and inversion support catheter adjacent to the clot; pulling the puller proximally to roll the external portion of the flexible tube over a distal end of the inversion support catheter so that it inverts and is drawn into the inversion support catheter, capturing clot and pulling clot material into the inversion support catheter; applying a vacuum through the puller to suction the clot proximally through the puller; and pulling a second end of the flexible tube proximally to roll and evert the external portion of the flexible tube over the distal end of the inversion support catheter so that it extends proximally over the inversion support catheter.

[00034] In some variations, the method may repeat the step to remove additional clot. For example, the method may include repeating (e.g., cycling) one or more times, the steps of pulling the puller, applying the vacuum and pulling the second end of the flexible tube to remove additional clot material.

[00035] In any of these methods, applying the vacuum may comprise turning the vacuum on while or after the puller is pulled proximally. Pulling the second end of the flexible tube may comprise releasing the puller to allow a bias force to pull the second end of the flexible tube proximally.

BRIEF DESCRIPTION OF THE DRAWINGS

[00036] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00037] FIG. 1A illustrates one example of an intermediate catheter (“delivery catheter” or I.C.) that may be used with a mechanical thrombectomy apparatus as described herein.

[00038] FIGS. 1B-1C2 illustrate components of a mechanical thrombectomy apparatus (also referred to herein as an inverting tube thrombectomy apparatus); FIG. 1B shows an example of an elongate inversion support catheter that is configured to include a plurality of slots (shown here as transverse slots) arranged along the catheter in order to enhance flexibility of the elongate inversion support catheter while providing sufficient column strength to resist buckling as the tractor tube is drawn proximally to invert. The slot pattern of FIG. 1B is intended as a single example only. Other slot/cut-out patterns may be used. FIGS. 1C1 and 1C2 show a flexible tubes attached to a puller (e.g., puller catheter in FIG. 1C1, or puller wire in FIG. 1C2). The flexible tubes are shown attached at a first end to a distal end region of the puller; in FIG. 1C1 the puller is a puller catheter (PMC) while in FIG. 1C2 the puller is a guidewire. The flexible tube is shown schematically and may be a knitted, woven, or braided material.

[00039] FIGS. 2A-2C illustrate the operation of an inverting tractor mechanical thrombectomy apparatus (e.g., inverting tube thrombectomy apparatus) as described above. FIG. 2A shows the assembled apparatus in which the flexible tube is coupled to the puller and within the elongate inversion support catheter with the flexible tube inverting over the distal end of the elongate inversion support catheter. FIG. 2B shows the apparatus of FIG. 2A delivered within a vessel near a clot. FIG. 2C shows the operation of the apparatus to withdraw the clot by pulling proximally on the flexible tube from within the elongate inversion support catheter so that the flexible tube is pulled to roll over and evert from the inverted configuration on the outside of the distal end of the elongate inversion support catheter into the un-inverted configuration within the elongate inversion support catheter, pulling the clot with it.

[00040] FIG. 3A is an example of a preloaded assembly of an inverting tube thrombectomy apparatus including an intermediate catheter that may be used as described in order to the apparatus through a tortuous vessel to a clot location. In this example, all of the other components of the inverting tube thrombectomy apparatus (elongate inversion support catheter) may be held within the intermediate catheter (and may be locked in this position) until deployed, while the pusher (e.g., PMC) and flexible tube are partially extending distally. A guidewire may also be used.

[00041] FIG. 3B shows the inverting tube thrombectomy apparatus of FIG. 3A with the inversion support catheter advanced distally.

[00042] FIGS. 4A-4B illustrate one example of an inverting tube thrombectomy apparatus within a tortuous anatomy that may pull away from the clot when deploying the flexible tube

(e.g., when rolling the flexible tube over the distal end and into the inversion support catheter. In FIG. 4A, the inverting tube thrombectomy apparatus is positioned adjacent to the clot. In FIG. 4, in the tortuous anatomy, once the puller is pulled proximally to invert the flexible tube (also referred to herein as the tractor tube) over the distal end of the inversion support catheter, the inverting tube thrombectomy apparatus, and particularly the inversion support catheter, may compress, causing the distal face of the flexible tube and the elongate support catheter to pull away from the clot. In a tortuous anatomy, such as shown in FIGS. 4A-4B, it may be particularly difficult to advance the apparatus back to the clot (and forward), particularly while the puller pulling the flexible tube over the distal end of the inversion support catheter applies a proximal force against the inversion support catheter.

[00043] FIGS. 4C and 4D illustrate another example of the ‘kickback’ that may occur in an inverting tube thrombectomy apparatus which may be difficult to correct for in a tortuous vessel. In FIG. 4C the inverting tube thrombectomy apparatus (e.g., the distal face of the puller, attached flexible tube and/or inversion support catheter) is positioned adjacent to the clot. In FIG. 4D the puller is withdrawn proximally, rolling the flexible tube over the distal end of the inversion support catheter and into the lumen of the inversion support catheter. In this example, pulling the flexible tube over the distal end moves the distal end away from the clot.

[00044] FIGS. 5A-5L illustrate one example of a method of operating an inverting tube thrombectomy apparatus to remove a clot that alleviates the tension (compressive force) applied by pulling the flexible tube over the distal end opening of the inversion support catheter, preventing the separation of the inverting tube thrombectomy apparatus from the clot. In this example, the method includes forming slack in an external portion of the flexible tube prior to pulling the puller proximally to roll the flexible tube and invert it over the distal end face of the inversion support catheter.

[00045] FIGS. 6A-6C illustrate an example of a method for removing a clot using an inverting tube thrombectomy apparatus that prevents pull back of the end of the inverting tube thrombectomy apparatus from the clot. In this example, the method includes reducing tension in flexible tube as it is rolled and inverted over the distal end of the inversion support catheter by introducing slack (in this example, compressing the flexible tube) prior to rolling and inverting the flexible tube over the distal end face of the inversion support catheter.

[00046] FIGS. 7A-7B illustrate an example of a method of removing a clot using an inverting tube thrombectomy apparatus that prevents pull back of the end of the inverting tube thrombectomy apparatus from the clot. In this example, the method includes

coordinating pushing the second (unattached) end of the flexible tube distally (e.g., by pushing on the intermediate catheter) and pulling the puller proximally.

[00047] FIG. 8 is an example of an inverting tube thrombectomy apparatus that is configured to automatically reload to remove multiple ‘bites’ of clot without needing to be removed from within the vessel. In FIG. 8, the inverting tube thrombectomy apparatus includes the flexible tube (e.g., a woven tube) a puller, and an inversion support catheter; a return bias (e.g., in this example, a coil spring) is attached to the second end of the flexible tube to reset the flexible tube on the outside of the inversion support catheter after it is rolled and inverted into the inversion support catheter and released.

[00048] FIGS. 9A-9D illustrate a method of removing a clot including automatically reloading the flexible tube without having to remove it from the vessel.

[00049] FIGS. 10A-10B show another example of an inverting tube thrombectomy apparatus that is configured to automatically reload to remove multiple ‘bites’ of clot without needing to be removed from within the vessel. FIG. 10A schematically illustrates an example of an inverting tube thrombectomy apparatus that includes a self-biased flexible tube that is coupled to an outer region of the inversion support catheter. FIG. 10B shows an example of an embodiment of the inverting tube thrombectomy apparatus including a self-biased flexible tube configured as a stacked braid.

[00050] FIGS. 11A-11F illustrate an example of a method of removing clot and automatically reloading the flexible tube without having to remove it from the vessel.

[00051] FIG. 12 is a schematic illustration (not to scale) of one variation of an apparatus for removing one or more clot(s) from a vessel. This apparatus may be configured to remove multiple clots by repeatedly withdrawing clot and resetting to an initial position; clot material may be withdrawn through the lumen of the puller catheter (e.g., inner catheter).

DETAILED DESCRIPTION

[00052] In general, described herein are inverting tube thrombectomy apparatus having a flexible tube, configured as an inverting flexible tube or an inverting tractor tube (“tractor tube”) that may be pulled proximally to invert over and into the distal end of an elongate inversion support catheter. An end of the tractor tube may be coupled to a puller (e.g., pull wire, pull catheter, etc.) to provide the proximal pulling force. In particular, described herein are apparatuses and methods of using them that improve or enhance the ease of use, including tracking of the apparatus within a tortuous vessel to remove a clot by rolling the flexible tube into the elongate inversion support catheter and grabbing the clot.

[00053] In general, the apparatus described herein may be configured to prevent compression of the apparatus (e.g., the inversion support catheter) when pulling the puller to roll and invert the flexible tube into the inversion support catheter, which may separate the distal end of the apparatus from the clot and may make it difficult to advance the apparatus to engage with the clot, particularly in a tortuous vessel. Any of the apparatuses described herein (and methods of using them) may be adapted to prevent tension in the flexible tube in the region of the flexible tube that is rolling and inverting over the distal end of the inversion support catheter. For example, tension may be reduced in the region of the flexible tube (the external portion of the flexible tube) by pushing from the second, usually loose or unattached, end of the flexible tube on the outside of the inversion support catheter. The flexible tube may be pushed by a member, including a dedicated wire, rod, etc., or by an outer or intermediate catheter. In some variations, the method may include pushing the end (e.g., the second end, opposite from the first end attached to the puller) of the flexible tube distally to form a slack region.

[00054] FIGS. 1A-C2 and 2A-2C illustrate examples of inverting tube thrombectomy apparatus and methods of operating them to remove a clot, respectively.

[00055] An inverting tube thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an inversion support catheter having a distal end and a distal annulus (distal end opening), and a flexible tube assembly (which may be referred to as a tractor tube or tractor tube assembly) including a flexible tube coupled to an elongate puller that is positioned within the elongate inversion support catheter. The flexible tube is configured to roll and invert over the distal end opening of the elongate inversion support catheter when pulled proximally by the puller. Knitted tractor tubes are of particular interest and described herein, although it should be understood that other tractor tubes, e.g., woven, braided, etc., may be used.

[00056] Tracking of any of the inverting tractor mechanical thrombectomy apparatus described herein may include an intermediate catheter (I.C.) as a delivery catheter along with a guidewire. For example, FIG. 1A illustrates an example of a typical intermediate catheter 101. Note that in some variations an intermediate catheter is not needed or used and the inverting tractor mechanical thrombectomy apparatus may be delivered to the deployment site near the clot to be removed without the need for an intermediate catheter.

[00057] FIG. 1B illustrates one example of an inversion support catheter. In this example, the elongated inversion support catheter 103 is formed of a normally high column-strength material (such as a metal, e.g. Nitinol) having a number openings (e.g., cut-out regions) or

slots along the length to provide enhanced flexibility. The distal end of the elongate inversion support catheter is open 105. Either the entire length or a portion of the length may be cut/slotted as described. The elongate inversion support catheter includes a catheter body having a distal end region that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing hardness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1 mm, 0.8 mm, 0.5 mm, 0.3 mm, 0.2 mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00058] In FIG. 1B, the elongate inversion support catheter is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of compressive force is applied (e.g., able to withstand at least about 500g, at least about 700 g, at least about 600 g, at least about 500 g, at least about 400 g, at least about 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include an elongate inversion support catheter that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like. In FIG. 1B the catheter 103 of the elongate inversion support catheter may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00059] The inversion support catheter may be solid (e.g., may not include the cuts/slots shown in FIG. 1B).

[00060] In some variations the distal end 105 of the elongate inversion support catheter is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in

some variations the distal tip (end) may be curved or radiused, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[00061] FIG. 1C1 shows an example of a flexible tube 111 coupled to a puller 113, forming a pullable tractor assembly 140. In this example, the tractor tube 111 is shown integrated with the puller 113 and extending back over the puller. The puller in this example is a catheter (e.g. a micro catheter, also referred to herein as a PMC or pull micro catheter). In this example, the opposite end of the flexible tractor tube 111 is open and free (e.g., not connected to the puller or catheter, e.g. elongate inversion support catheter, intermediate catheter, etc.). This open, free, end may be adapted to be expanded and held open, e.g., by shape setting back on itself and/or by including an annular bias, to enhance deployment and positioning of the catheter between the flexible tractor tube and the puller. In FIGS. 1C1 and 1C2, the tractor tube is formed of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The flexible tube 111 is shown extended from the puller in a first configuration. The relaxed outer diameter of the flexible tractor in this first configuration may have a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting, or it may be approximately the same. The flexible and tubular tractor 111 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The tractor 111 may be configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first configuration to a radial diameter that is between 1.1 and 10 times (e.g., between 1.1x and 5x, between 1.1x and 4x, etc.) the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained. In FIG. 1C2, the tractor tube 111 is shown coupled to a guidewire (non-hollow structure) 115. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00062] The flexible tubes (e.g., tractor tubes) described herein generally comprises a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support. The flexible tube may be formed of a knitted material, and may be configured (e.g., sized, oriented, etc.) to roll smoothly over the distal end opening of the elongate inversion support catheter. The flexible tube may be configured so that it is doubly biased, in order to prevent jamming and to grab and compress relatively large clots as it rolls and inverts into the elongate inversion support catheter at the distal end opening of the elongate inversion support catheter; the flexible tube may be biased so that it has an expanded (e.g., relaxed) un-inverted configuration having an outer diameter that is approximately the

same or slightly larger than the inner diameter of the elongate inversion support catheter, which may be referred to as a second configuration of the flexible tube. The flexible tube may also be further biased so that it has an expanded (e.g., relaxed) inverted configuration (which may be referred to as a first configuration) having an inner and outer diameter that is larger than the outer diameter of the elongate inversion support catheter. The inner diameter in this first configuration may be greater than 1.2x (e.g., between 1.2x and 10x, between 1.2x and 8x, between 1.2x and 6x, between 1.2x and 5x, between 1.2x and 3x, etc.) the outer diameter of the inversion support catheter. Thus, when the flexible tube is placed in and over the distal end of the inversion support catheter, a first (inner) portion of the tractor tube is within the distal end of the elongate inversion support catheter in the un-inverted configuration and it is biased to expand towards (and in some configuration against) the inner diameter of the inversion support catheter; the region of the flexible tube that is inverted over the distal end opening of the inversion support catheter and extends proximally down the outside of the inversion support catheter is in an inverted configuration in which the inner diameter of the flexible tube is biased to be larger than the outer diameter of the inversion support catheter. This double-biased configuration may be a result of the weave pattern (e.g., knitting), and/or a shape setting of the material forming the tractor tube, which may be a shape memory material. As a result, the inverting portion of the flexible tube, where it rolls and inverts over itself at the distal end of the inversion support catheter may be prevented from collapsing on itself as the tractor tube is rolled and pulled into the inversion support catheter. In some variations this configuration may also result in a somewhat flattened (e.g., and in some cases “trumpet shaped”) distal end face that is rolling over the distal end opening of the elongate inversion support catheter. The trumpet-shaped distal end may have a teardrop-shaped cross-section. In some variations, the distal end face of the flexible tube may be T-shaped.

[00063] Also described herein are variations in which the first configuration of the flexible tube on the outside of the inversion support catheter (which may be referred to herein as an elongate inversion support catheter) may be flush or nearly flush with the outer diameter of the inversion support catheter, e.g., within 50%, 40%, 30%, 20%, etc. of the outer diameter of the inversion support catheter.

[00064] The flexible tube may be coupled to a puller that is within the lumen of the inversion support. The puller may be a wire, filament, rod or more preferably a catheter or tube (and may be referred to herein as a pull micro catheter or “PMC” for convenience). A

guidewire may be passed through the flexible tube, and therefore through the inversion support and the tractor tube. As will be described herein, this may be used for positioning.

[00065] The inversion support catheter may be configured as a catheter having a distal end opening into which the tractor inverts. The flexible tube may invert and rolls back into itself and may be drawn into the inversion support in a conveyor-like motion; the outward-facing region rolls around to become an inward-facing region, e.g., within the lumen of the inversion support catheter. The rolling motion may thus draw a clot or other object within a vessel into the inversion support. The inversion support catheter may be shaped or configured to have a sufficient column strength to withstand the compressive pulling force of the flexible tube as it is drawn (and rolled, inverting) into the distal end of the inversion support catheter. The inversion support catheter may be slotted (e.g., may include a plurality of slots or openings) to provide increased flexibility as well as column strength. However, as will be described herein, many inversion support catheters may become less flexible (e.g., more rigid) when a compressive force is applied to the flexible tube, either as a result of pulling the flexible tube proximally, either from within the inversion support catheter, or from the outside of the inversion support catheter as the flexible tube brushes against the vessel and/or a delivery catheter when being driven distally towards a clot.

[00066] The methods and apparatuses described herein may be used with any of the apparatuses and methods described, for example, in U.S. app. no. 15/291,015, filed on 10/11/2016 (“Mechanical Thrombectomy Apparatuses and Methods”) and U.S. app. no. 15/496570, filed on 4/25/2017 (“Anti-Jamming and Macerating Thrombectomy Apparatuses and methods”), previously incorporated by reference in their entirety.

[00067] The inverting tube thrombectomy apparatus (e.g., a mechanical thrombectomy apparatus) may be inserted through a vessel such as a blood vessel, artery, etc., until a distal end, or a distal-most end, of the inverting tube thrombectomy apparatus is proximate to a clot. The clot may be immediately adjacent to the end of the apparatus, or it may be within a few cm (e.g., within 1 cm, within 2 cm, within 3 cm, within 4 cm, etc.). This may be detected by visualization, such as fluoroscopy. Thus the apparatuses described herein may include one or more markers for visualization. Contrast may be used to visualize the clot and/or may be released from the apparatus. The apparatus may be deployed in a pre-loaded/pre-assembled configuration, as will be described in more detail below.

[00068] In any of these methods described herein, the flexible tube may be knitted and/or the apparatus may be configured with the opening into the vacuum lumen (e.g., through the puller catheter) at the distal-most end of the device, so that the flexible tube extends behind

(proximal) the distal-facing end of the puller catheter. For example, the method of removing a clot from a vessel may include: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to a clot, wherein the inverting tube thrombectomy apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller catheter within a lumen of the elongate support catheter, and a knitted tube having a first end coupled at a distal end region of the puller catheter, wherein knitted tube inverts over a distal end of the inversion support catheter and extends proximally between the intermediate catheter and the inversion support catheter, further wherein the knitted tube comprises a filament that is knitted to form a plurality of interlocking loop stitches; advancing the puller catheter distally so that a distal face of puller catheter extends distally from the inverting tube thrombectomy apparatus further than the knitted tube; applying a vacuum through the puller catheter to engage the clot with the distal face of the puller catheter; and pulling the puller catheter proximally to roll the knitted tube over a distal end of the inversion support catheter so that the knitted tube inverts over the distal end of the inversion support catheter, captures the clot, and pulls the clot proximally into the inversion support catheter.

[00069] The second end of the flexible tube may comprise a cuff that is less flexible than a region of the tube adjacent to the cuff. As will be described in more detail below, the cuff may be formed as a material attached to or applied onto/over the end of the flexible tube. For example, the second end of the flexible tube may comprise a cuff formed of a polymeric material applied onto/over the knitted tube. The cuff may be slit or cut (e.g., all or partially along its length) to provide some flexibility when pulling over or around the end of the tube. For example, the cuff may include longitudinal slits along its length. The cuff may have a durometer that is greater than the durometer of the flexible tube (e.g., knitted tube). The cuff, in some variations, is thicker than the flexible tube. In any of the variations described herein, the cuff may be radiopaque (e.g., by including a radiopaque material, such as platinum) on or within the cuff.

[00070] FIG. 2A illustrates an example of a deployed inverting tube thrombectomy apparatus 200. In FIG. 2B the inverting tractor mechanical thrombectomy apparatus is shown deployed near a clot 209 within a vessel. In the deployed configuration the puller 201 (shown here as a puller micro catheter) is held within the elongate inversion support catheter so that the flexible tube 203 extends from the end of the puller and expands toward the inner radius of the elongate inversion support catheter 207; at the distal end opening of the elongate inversion support catheter the flexible tube inverts over itself and extends proximally in an

inverted configuration over the distal end of the elongate inversion support catheter. As shown in FIG. 2C, by pulling the puller proximally, the flexible tube may roll and invert over the distal end opening of the elongate inversion support catheter, drawing the adjacent clot into the elongate inversion support catheter, as shown.

[00071] FIG. 2A the inversion support catheter is positioned between the flexible tube and the puller so that the flexible tube can be pulled proximally by pulling on the puller and rolling the flexible tube into the elongate inversion support catheter so that it inverts. The portion of the flexible tube that is inverted over the distal end of the elongate inversion support catheter has an outer diameter that is greater than the outer diameter of the elongate inversion support catheter. In some variations the diameter (e.g., inner diameter) of the external portion of the flexible tube outside of the inversion support catheter may be approximately the same diameter (e.g., within 1.01x and 1.3x) of the outer diameter of the inversion support catheter. In some variations, the flexible tube may be biased so that it has a relaxed expanded configuration with a diameter that is greater than the outer diameter (OD) of the elongate inversion support catheter; in addition, the flexible tube may also be configured (e.g., by heat setting, etc.) so that when the flexible tube is inverted and rolled over the distal end opening into the elongate inversion support catheter, the inverted flexible tube within the elongate inversion support catheter has an outer diameter that is greater than the inner diameter of the elongate inversion support catheter (e.g., greater than 0.1x, 0.5x 0.6x, 0.7x, 0.75x, 0.8x, 0.9x, 1x, etc. the inner diameter, ID, of the elongate inversion support catheter. This combination of an un-inverted diameter of the flexible tube of greater than the diameter of the OD of the elongate inversion support catheter and an inverted diameter of the flexible tube of greater than about 0.7x the ID of the elongate inversion support catheter is surprisingly helpful for preventing jamming of the apparatus, both when deploying the apparatus and when rolling the flexible tube over the distal end opening of the elongate inversion support catheter to grab a clot. The flexible tube may be expandable and may be coupled to the puller as shown. In some variations the flexible tube and the puller may comprise the same material but the flexible tube may be more flexible and/or expandable, or may be connected to elongate puller (e.g., a push/pull wire or catheter).

[00072] In FIG. 2C the clot may be drawn into the elongate inversion support catheter by pulling the flexible tube proximally into the distal end of the elongate inversion support catheter, as indicated by the arrows 211, 211' showing pulling of the inner portion of the flexible tube, resulting in rolling the flexible tube over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled

into the catheter, shown by arrows. The end (e.g., the second end) of the flexible tube outside of the catheter may be “loose” relative to the outer wall of the catheter.

[00073] In general the inverting tube thrombectomy apparatuses described herein may be highly flexible, both before actuating and during operation. For example, the flexible tube may not increase the stiffness/flexibility of the catheter or the elongate inversion support, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortuous vessels of the neurovasculature. Described herein are flexible tube portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[00074] As mentioned, the flexible tubes may be woven, braided and/or knitted materials. For woven and braided materials, which may include a plurality of fibers that are woven or braided to form the inverting tube, these structures may be tuned to prevent jamming and/or to reduce the force necessary to pull the flexible tube and invert over the catheter tip. For example, the mechanical atherectomy apparatus may include a braid-type flexible tube that can roll freely around the tip of catheter even in a tortuous anatomy and when grabbing clot by tuning one or more of the braid structure; minimizing the braid angle; including a hydrophilic coating on the distal aspect of the catheter outer diameter (OD) or the inner diameter (ID) of the braid (e.g., flexible tube); including a radiused wall on the catheter; and/or increasing the stiffness of the distal tip region relative to adjacent proximal regions. Alternatively it may be advantages to have a hydrophilic coating on 1, 3, 5, 10, or 15 cm of the distal ID or the entire catheter ID. This may even enhance aspiration of the clot without a tracking element.

[00075] As mentioned, the flexible tube (e.g., braided, woven, knitted, etc.) may be configured to collapse down into the inner diameter (ID) of the catheter as little as possible. For example the flexible tube may collapse to an ID that is greater than, equal to, or within 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter inner diameter (ID)/Catheter Tip OD, since, when the flexible tube is being pulled around catheter tip it may create axial tension on the flexible tube (e.g., braid, knit, etc.) that can inadvertently cause the flexible

tube to jam on the catheter tip. When flexible tube is pulled around catheter tip, the flexible tube is being pulled in the axial orientation creating axial tension on flexible tube structure as the flexible tube is being pulled through the catheter ID. By having the flexible tube elements jam at an ID greater than or equal to 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter ID (or in some variations, OD), when being axially tensioned, the flexible tube is less likely to grab/synch down onto the catheter tip, helping the braid roll around the catheter tip with less axial force applied by the user. If less axial force is required by the user to pull the flexible tube structure around the tip then the catheter tip is less likely to buckle or deflect when retracting the flexible tube. It may be advantageous to minimize the chance the catheter tip will buckle. The flexible tube can be tuned to "jam" at a specific ID by controlling any of the following variables and in any combination: selecting a specific number of braid ends, selecting the size/diameter of the braid ends; selecting the braid material (e.g., multifilament or monofilament); heat setting the bias on the braid (e.g., braid diameter); and selecting a braid pattern, e.g., 1x2, 1x1 or any other pattern.

[00076] The braid angle may be minimized to prevent locking up of the rolling of the flexible tube over the catheter end opening. Typically, the lower the braid angle (e.g., 45 degrees or less, 40 degrees or less, 35 degrees or less, 30 degrees or less, 25 degrees or less, 20 degrees or less, etc.) the less likely it is to have the braid cross over points catch on the catheter tip.

[00077] In any of the variations described herein, the catheter and/or a surface of the flexible tube may be coated to enhance rolling over the distal end region of the catheter. It may be helpful to have a hydrophilic coating on the distal aspect of the catheter OD or the ID of the flexible tube so the flexible tube can more easily slide over the catheter's distal end and around the tip of the catheter when pulled through the inside of the catheter.

[00078] The radius wall of the catheter tip may be chosen/set to within a range that allows sliding. For example, it may be helpful for the tip of the catheter to have the largest radius possible but at least 0.0025" radius wall on the catheter, ideally approximately 0.005" radius wall.

[00079] The stiffness of the distal of the elongate inversion support catheter may be sufficiently stiff to prevent collapse as the flexible tube is pulled; it may also be lubricious (e.g., by a coating or material property). The distal most section of the elongate inversion support catheter tip (e.g., the last 5mm) may be fabricated of a material which is stiff enough and lubricious enough so the distal tip of the catheter does not collapse or buckle inwardward.

when the braid structure is rolling around the catheter tip. Thus, the distal tip may have a stiffness that is greater than the more proximal region at the distal end of the catheter.

[00080] It may be helpful or desirable to have pores in the flexible tube. A lack of gaps or small pore size may limit the ability of the braid to grab clot. Alternatively or additionally, it may be desirable to form a braid structure with texture. One example is to braid two or more different diameter braid ends into the same structure: the difference in braid end diameters will help form a texture to the braid structures outer surface, aiding the grabbing of the clot when rolling the braid-dozer around the catheter tip.

[00081] As an alternative (or in addition) the flexible tube may be configured to lock so it does not compress in diameter during axial load by adding a coating, laminate or adhesive to the braid at a desired diameter. Adding a thin coating, laminate or adhesive can inhibit the braid elements from sliding with respect to each other, thereby locking the braid to a specific diameter. The coating can be applied while leaving the majority of the pores and pore area substantially open. Examples of thin coatings include urethanes and silicones with and without hydrophilic coatings and hydrophilic coatings with no tie layer.

[00082] FIG. 3A shows one example of a pre-loaded inverting tube thrombectomy apparatus for removing a clot from a vessel that may be delivered through a tortious anatomy. In this example, the apparatus may include an intermediate catheter 303 having a distal end 305. The intermediate catheter (I.C.) may be considered part of the inverting mechanical thrombectomy apparatus, although in other variations it may be considered a separate component that is used with the inverting mechanical thrombectomy apparatus. The apparatus also includes an elongate inversion support catheter 307 within the lumen of the intermediate catheter. The elongate inversion support catheter 307 has a distal end 311 and a distal end opening. The apparatus also includes a puller 319 extending distally within the elongate inversion support catheter and a flexible tube 315 extending proximally from a distal end region of the puller. The puller extends from the distal end of the intermediate catheter and the distal end opening of the elongate inversion support catheter.

[00083] In the configuration shown in FIG. 3A, the elongate inversion support catheter is held within the lumen of the intermediate catheter so that the distal end opening of the elongate inversion support catheter is proximal to the distal end opening of the intermediate catheter by a first distance 325. This distance may be between about 1 mm and about 10 cm (e.g., between about 2 mm and about 10 mm, between about 2 mm and about 20 mm, between about 2mm and about 30 mm, etc.). The elongate inversion support catheter may be fixed in position relative to the intermediate catheter, so that as the two move together, until

released. For example, the proximal ends of the intermediate catheter and the elongate inversion support catheter may be removably coupled.

[00084] The flexible tube in the pre-assembled apparatus of FIG. 3 extends between the elongate inversion support catheter and the intermediate catheter for some second distance along the length 323 of the elongate inversion support catheter. Securing the end of the flexible tube between the I.C. and the distal end of the elongate inversion support catheter may help both hold it in place, so that the flexible tube may be pushed formed (e.g., in compression). For example, the second length 323 may be between about 1 mm and about 50 cm (e.g., between about 5 cm and about 10 cm, between about 1 cm and about 20 cm, between about 1 cm and about 10 cm, between about 2 cm and about 20 cm, between about 2 cm and about 10 cm, etc.).

[00085] The portion of the flexible tube 315 and puller 319 (e.g., pull micro catheter, or pmc) in this pre-loaded example may extend distally and ride over the guidewire 317. The flexible tube and puller may also be longitudinally fixed relative to the intermediate catheter 303 (e.g., by releasably locking, e.g., at the distal end region) or they may be somewhat longitudinally slideable (and, in some variations, prevented from exceeding a range of, e.g., between about 1 mm and 20 cm from the distal end opening 305 of the intermediate catheter.

[00086] In this example, the portion 327 of the flexible tube 315 that extends outside of the intermediate catheter 303 may be between about 1 mm and about 20 cm (e.g., between about 1 cm and about 7cm, between about 1 cm and about 10 cm, between about 1 cm and about 15 cm, between about 2 cm and about 10 cm, between about 2 cm and about 7 cm, etc.). As mentioned, this distance may be fixed (e.g., by fixing the puller with respect to the push catheter and/or I.C.), or variable. In any of these variations, the puller may extend some distance 329 beyond the distal attachment site for the flexible tube, or the flexible tube may be attached at the distal end of the puller. The distance from the attachment site of the flexible tube and the distal end of the puller may be between about 0 mm and about 10 cm, for example (e.g., between about 1 mm and about 10 cm, between about 1 mm and about 5 cm, etc.).

[00087] FIG. 3B shows the apparatus of FIG. 3A, but with the inversion support catheter 307 advanced distally. In this example, the distal opening 311 of the inversion support catheter 307 has been pushed distally toward the attachment site of the flexible tube, and any clot. Once in position, the puller may be pulled proximally to invert the flexible tube into the inversion support catheter.

FLEXIBLE TUBES HAVING SLACK

[00088] FIGS. 4A-4B and 4C-4D illustrate kickback when using an inverting tube thrombectomy apparatus. For example, in FIG. 4A, a model of a tortuous vessel 403 (e.g., a neurovascular region) is shown; the vessel is transparent to show a clot 411 and an inverting tube thrombectomy apparatus 400 that has been positioned with the distal end 401 adjacent to the clot. This example of an inverting tube thrombectomy apparatus includes a puller with a flexible tube attached near the distal end, and an inversion support catheter. The puller extends within the lumen of the inversion support catheter and the flexible tube extends from within the lumen of the inversion support catheter, out of the distal end of the inversion support catheter where it everts over itself to extend proximally along the outside from the distal end of the inversion support catheter. The second end of the flexible tube may be held between the outer surface of the inversion support catheter and an inner surface of an intermediate catheter, or it may be fully released from intermediate catheter. When positioned next to the clot 411 in FIG. 4A, the distal end of the catheter and therefore the inverting face of the flexible tube, may be positioned next to the clot. Pulling the puller proximally will roll and invert the flexible tube (the outer portion of the flexible tube) over the distal end of the inversion support catheter. However, as shown in FIG. 4B, the force applied by the flexible tube pulling proximally against the inversion support catheter (even a high column-strength inversion support catheter as shown in FIG. 1B) may compresses the distal end of the inversion support catheter slightly, and/or may causes it to separate from the clot. In FIG. 4B, the same device after pulling the puller proximally is shown with the distal end separated slightly from the clot (space 422). This compressive force may also make additional distal tracking of the deployed device difficult within the tortuous vessel.

[00089] FIGS. 4C and 4D illustrate another example of this. In FIG. 4C the distal end 401 of the inverting tube thrombectomy apparatus 400 is adjacent to the clot 411. Pulling the puller proximally to roll and invert the flexible tube into the inversion support catheter may pull the distal end of the inverting tube thrombectomy apparatus 400 away from the clot 411, as shown in FIG. 4D, introducing a gap 422.

[00090] In order to prevent this kickback, the tension on the flexible tube may be reduced or eliminated. For example, FIGS. 5A-5L illustrate one example of a method of removing a clot that reduces or eliminates the tension on the portion of the flexible tube that is rolling and inverting over the distal end of the apparatus. In FIG. 5A, a sectional view through an inverting tube thrombectomy apparatus is shown. The inverting tube thrombectomy

apparatus includes a puller 503 (shown as a puller catheter) with a flexible tube 505 (e.g., a woven tube, knitted tube, etc.) attached near the distal end, and an inversion support catheter 507. The puller extends within the lumen of the inversion support catheter and the flexible tube extend from within the lumen of the inversion support catheter, out of the distal end of the inversion support catheter where it everts over itself to extend proximally along the outside from the distal end of the inversion support catheter. The second end of the flexible tube may be held between the outer surface of the inversion support catheter and an inner surface of an intermediate catheter 509, as shown. In FIG. 5A, the apparatus may be tracked over a guidewire 513 to be positioned adjacent to a clot 511. Thus, the apparatus may be pre-loaded with an intermediate catheter to the face of a clot. In FIG. 5B, the inversion support catheter 507 may be advanced distally towards the clot, as shown by arrow 521. The intermediate catheter 509 may then be pulled back, as shown by the arrow 524 in FIG. 5C to completely or partially unsheath the flexible tube 505, exposing the outer portion of the flexible tube over the inversion support catheter 507. For example, in some variations the intermediate catheter may be pulled back is 30-95% of the length of the flexible tube 505.

[00091] To prevent kickback when inverting the flexible tube, slack 520 may be added to the outer portion of the flexible tube, as shown in FIG. 5D. In this example, slack 520 (shown as a bunching up of the flexible tube on the outside of the inversion support catheter before the distal end) may be added to the flexible tube by pushing the intermediate catheter distally 526 (e.g., approximately 50% of the exposed length of the flexible tube, e.g., the outer flexible tube region). In woven flexible tubes, this may compress the weave. Thereafter, the device may be operated, e.g., by pulling the puller, to roll and invert the flexible tube and grab clot. For example in FIG. 5E, the guidewire is first removed, and aspiration (e.g., vacuum) may be applied through the lumen of the puller (and/or the inversion support catheter) to connect to the clot. The apparatus may also be additionally tracked distally slightly, to capture the clot 511 as shown in FIG. 5F. For example, when aspiration is being applied, the apparatus 500 may be advanced 527 (the intermediate catheter, inversion support catheter and/or puller, all or some of which may be locked together proximally) distally until flow through the puller stops, indicating that the clot is on the puller (e.g., “corked”), as shown in FIG. 5F.

[00092] Once positioned, the puller may be pulled proximally 532 while advancing the inversion support catheter and intermediate catheter (together), as shown in FIGS. 5G-5J, to capture clot. Additional slack may be added during this process by, for example, advancing the intermediate catheter independently of the rest of the device; alternatively or additionally,

the flexible tube may be released from between the intermediate catheter and the inversion support catheter, as shown in FIG. 5I. As shown in FIGS. 5K and 5L, the clot may be removed fully into the inversion support catheter and/or the intermediate catheter (as shown in FIG. 5L) by withdrawing first the puller and then the rest of the apparatus proximally, while applying aspiration (e.g., suction) through the intermediate catheter.

[00093] FIGS. 6A-6C illustrate another example of a method of removing a clot while preventing kickback by releasing tension on the flexible tube. In FIG. 6A, an example of an apparatus 600 (similar to that shown in FIG. 5A, above) is positioned adjacent to a clot 603. As described above, before pulling the puller to roll and invert the flexible tube into the inversion support catheter, the outside region of the flexible tube may be compressed to form slack, for example, by advancing the intermediate catheter distally, after partially or completely removing from over the flexible tube, to push the flexible tube distally. Thereafter, in FIG. 6B, the puller may be pulled proximally while advancing the intermediate catheter to capture clot. In FIG. 6C, the intermediate catheter may be fully unsheathed from over the flexible tube, and more of the clot may be ingested by the rolling, inverting flexible tube.

[00094] FIGS. 7A-7B illustrate an alternative variation in which the tension on the flexible tube may be reduced or eliminated when rolling and inverting the outer portion of the flexible tube by coordinating the application of both a distal pushing force on the second end of the flexible and a pulling force on the first end of the flexible tube when pulling the puller proximally. In FIG. 7A, the apparatus 700 includes a puller 703 to which the flexible tube 705 is attached near the distal end of the puller. An inversion support catheter 707 is between the puller and the flexible tube, and an intermediate catheter 709 extends over the majority of the length of the apparatus. In FIG. 7A, the apparatus is shown deployed, but prior to rolling/inverting the flexible tube 705. In FIG. 7B, tension that may otherwise apply a compressive force on the distal end of the inversion support catheter may be reduced or eliminated by applying a distal force (e.g., by advancing the intermediate catheter distally 721 in this example) before or while pulling 723 the puller proximally to roll and invert the flexible tube over the distal end. The puller may be pulled slightly faster than the rate at which the intermediate catheter is advanced distally, as the flexible tube may extend slightly within the inversion support catheter.

AUTOMATIC RELAOADING

[00095] FIGS. 8-11F illustrate apparatuses and methods that automatically reload the flexible tube after grabbing all or a portion of clot. For example, in FIG. 8, the apparatus includes a bias (an external bias) for pulling the flexible tube from within the inversion support catheter back outside of the inversion support catheter (rolling and everting). In FIG. 8, the apparatus 800 includes a puller 803 and a flexible tube (e.g., woven, knitted, etc.). A first end of the flexible tube 805 is attached near the distal end region of the puller. The puller is within the lumen of an inversion support catheter 807, and the flexible tube extends over the outer surface of the inversion support catheter. A region 806 of the flexible tube extends on the outside of the inversion support catheter. The second end (or a region at the second end) of the flexible tube is connected to a bias 811, shown here as a spring element. The spring may be heat set in a compressed configuration, as shown. A distal end of the bias 815 is attached to the second end of the flexible tube (or a cuff, not shown, on the flexible tube). Another, e.g., a proximal end 817, of the spring may be attached to the inversion support catheter 807, as shown.

[00096] FIGS. 9A-9D illustrate the operation of an apparatus such as that shown in FIG. 8, which is biased to return the flexible tube to the outside of the inversion support catheter. The amount of bias may be set so that the force applied is relatively low (e.g., pushing the puller distally may allow the flexible tube to reset (e.g., evert and roll back) the flexible tube to the outside of the inversion support catheter; alternatively the bias may be higher, so that the bias resets the flexible tube after just releasing the puller.

[00097] In FIG. 9A, the apparatus 900 may be approximated near the clot and aspiration (e.g., suction) applied through the lumen of the puller 903, as shown, until the clot is attached to the puller ("corked"). The puller 903 may then be pulled proximally, as shown in FIG. 9B, to roll 933 the flexible tube 905 and invert it into the inversion support catheter 907, capturing the clot. Pulling the puller proximally also pulls against the bias 911. The puller may be pulled until it reaches a stop, which may be set by the bias (spring 911) or by a mechanical stop, or both. Once The clot or portion of the clot within the inversion support catheter that has been engulfed by the flexible tube may then be aspirated proximally down the puller, as shown in FIG. 9C. Once cleared from the flexible tube, which may be detected by monitoring the suction through the puller (e.g., showing a drop in suction pressure when the clot is removed proximally from the flexible tube), the flexible tube may be reset outside of the inversion support catheter as shown in FIG. 9D, by applying a small force driving the

puller distally, allowing the spring (bias) to evert and roll the flexible tube back out of the inversion support catheter and over the outside surface, as shown. This processes may be repeated 915 as many times as desired; large clots may be removed by taking multiple bites in this manner, or multiple different clots may be removed with the same apparatus. The apparatus shown in FIGS. 8 and 9A-9D may include an intermediate catheter (not shown).

[00098] The flexible tube, as described above, may be any appropriate flexible tube. For example, the flexible tube may be a braid (e.g., braid structure). In some variations the flexible tube may be a braid of a flat or round wire that is braided and heat set (as described above, it may be heat set to have an inner diameter in tension that is greater than the outer diameter of the inversion support catheter). For example the flexible tube may be formed as a braid of 144 strands of 0.001" NiTi filaments that are braided at large braid angle (e.g., having a very smooth surface). In some variations, the braid may include a low durometer polymer laminate or covering, on all or braid part of braid length. In some variations, the braid may be configured as a knit structure. The knit may be formed of a round or flat wire having a circular knit structure. The apparatus may be heat set so that the ID of the flexible tube when tensioned is greater than the outer diameter of the inversion support catheter. A knit may include a low durometer polymer laminate or covering, on all or braid part of braid length.

[00099] Any appropriate bias may be used. For example, the bias may be a spring such as a metallic or polymeric spring. The spring may be heat set in a closed pitch form. For example, the spring may be a metal or metallic material such as NiTi, Cobalt Cr, stainless steel, etc. The spring may be, e.g., a polymeric tubing spring, such as a spring formed of a silicone, urethane, latex or other elastic material.

[000100] In some variations, an additional element, such as a wire, may be used to assist the clot in removing/releasing from the flexible tube. For example, a wire have a bent or bendable distal end may be used to help pull the clot out of the distal end of the puller.

[000101] FIGS. 10A-11F illustrate another example of an apparatus including a bias to restore the flexible tube to the outside of the apparatus. In this variations, the flexible tube is biased to return to the outside of the inversion support catheter. For example, in FIG. 10A, the apparatus 1000 includes a puller 1003 to which a flexible tube 1005 is attached at a first end to the distal end region of the puller. The puller has a relatively large outer diameter (in both this example and the example shown above in FIG. 8), but is slidably held within the inner lumen of the inversion support catheter 1007. In addition, the flexible tube 1005 is attached at the second end to the outside of the inversion support catheter at an attachment

region 1009. In FIG. 10A, the flexible tube is biased to spring back to this configuration (e.g., a loading or insertion configuration), in which the flexible tube is outside of the inversion support catheter. In this example the flexible tube is attached proximal to the distal end of the puller; any appropriate distance from the distal end of the puller may be used (e.g., more than 0.1 mm, 0.2 mm, 0.3 mm, 0.5 mm, 1 mm, 2 mm, 3 mm, etc. and/or less than about 0.1 mm, 0.2 mm, 0.3 mm, 0.5 mm, 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, etc.). Alternatively the flexible tube may be attached to the distal end of the puller (e.g., flush with the distal end).

[000102] In some variations, the flexible tube is configured as a braid that has a stacked configuration when attached to the outside of the inversion support catheter with the puller distal end aligned with the end of the inversion support catheter. In FIG. 10B, for example, a flexible tube shown as a weave formed of a Nitinol material having a stacked braid configuration is illustrated.

[000103] FIGS. 11A-11F illustrate the operation of an apparatus such as the one shown in FIG. 10A. In FIG. 11A, the apparatus is deployed near the clot 1109 with the puller 1103 extended distally ahead of the rest of the apparatus. In FIG. 11B, aspiration may be used to attach the clot 1109 to the puller (shown with the clot “corked” on the distal end of the puller). Thereafter, the inversion support catheter 1107 may be advanced 1131 distally to compress 1133 the weave of the flexible tube 1105, causing it to stack up as shown in FIG. 11C into a stacked configuration. This configuration is equivalent to forming slack in the flexible tube as described above. While (optionally, but preferably) still applying aspiration through the puller, the inversion support catheter 1107 may be advanced distally 1137 (as shown in FIG. 11D), against the clot, and at least partially over it. The inversion support catheter (e.g., the outer catheter) may be advanced distally so that the distal end of the inversion support catheter extends to or past the end of the puller, which may advance the flexible tube over the clot. The inversion support catheter may then be advanced distally while pulling the puller proximally, to roll and invert the flexible tube, as shown in FIG. 11E, to further ingest the clot, as shown. Alternatively the inversion support catheter may be held still while pulling the puller proximally; in some variations the inversion support catheter and puller are moved in a coordinated manner, either together simultaneously or incrementally and alternately.

[000104] The clot within the puller may be removed proximally (e.g., by aspiration and/or mechanically, such as using a wire), as shown in FIG. 11F. In addition, the puller may be advanced distally to evert and roll the flexible tube back out of the inversion support catheter.

This process may then be repeated (shown by dashed arrow 1139) to remove additional clot material. In any of these variations, the clot may be cut after a certain amount of it has entered into the device, e.g., by a separate or integrated cutter (such as a wire, etc.). This may allow repeated bites of clot to be removed using the same device.

[000105] Although not shown explicitly in FIG. 11C, the apparatus shown may also include an intermediate catheter, e.g., within which the inversion support catheter (outer catheter) and the puller (pull catheter, inner pull catheter or inner catheter) may move into and/or out of, as shown in FIGS. 5K-5L, above).

[000106] FIG. 12 illustrates one example of an apparatus (e.g., a system) for removing a clot, a series of clots and/or multiple clots, as described herein. The schematic shown in FIG. 12 is not to scale. For example, in FIG. 12, the apparatus includes an inversion support catheter 1211 and a puller catheter 1215 within a lumen of the inversion support catheter 1211. The puller catheter, as described above, may have a large inner diameter to allow removal of clot through the puller catheter inner lumen. For example, the inner diameter of the puller catheter may be about 75% (or about 80% or about 85% or about 90% or about 95%) or more than the inner diameter of the inversion support catheter. In some variations the outer diameter of the puller catheter is within 15% or less of the inner diameter of the inversion support catheter (e.g., within 12%, within 10%, within 8%, within 7%, within 5%, etc.). Thus the puller catheter may slide within the inversion support catheter, but may maximize the inner diameter of the inversion support catheter in order to pass clot through the puller catheter.

[000107] A flexible tube 1217 is connected to the distal end region of the puller catheter and to an outer surface of the distal end region (or distal end) of the inversion support catheter, as shown. Thus, the flexible tube has a first end coupled at a distal end region of the puller catheter, and a second end coupled at an outer surface of a distal end region of the inversion support catheter. As mentioned above, the flexible tube may be any appropriate material for grabbing clot, such as a woven, knitted or braided material, including metallic woven, knitted and/or braided materials. The flexible tube may be biased or may include a biasing element that is pre-biased to drive the flexible tube to the initial (delivery) configuration, such as shown in FIG. 10A. For example, in some variation the flexible tube includes a shape memory material, such as Nitinol, that is biased to return to the predetermined shape.

[000108] In FIG. 12, an intermediate catheter is not shown, but may be included and the inversion support catheter, puller catheter and flexible tube may be passed through the intermediate catheter.

[000109] The apparatus shown in FIG. 12 also includes a handle 1205 coupled to the inversion support catheter and the puller catheter. The handle is shown schematically in FIG. 12, but may be shaped for held-held use; alternatively the handle may be part of a base unit that is not hand-held. As shown, the handle includes a vacuum port 1219 that couples to a vacuum 1225, and may couple the vacuum line to a lumen of the puller catheter.

[000110] The handle may include one or more controls 1203, 1207, 1209 that may control the operation of the apparatus and particular the relative movement of the puller catheter and the inversion support catheter. The proximal end regions of the puller catheter and the inversion support catheters may be coupled to one or more actuators within the handle (not visible) to drive axial movement (distal/proximal movement) of these members. For example the handle may be configured to, when activated by one or more controls on the handle, advance the inversion support catheter distally before concurrently advancing the inversion support catheter distally while withdrawing the puller catheter proximally, as described in the methods illustrated in FIGS. 11A-11F (and particularly FIG. 11C and FIG. 11D-11E described above). In any of these variations, the handle may be configured to reset the inversion support catheter proximally and the puller catheter distally, e.g., to reset the puller catheter and the inversion support catheter to the delivery configuration. For example, the apparatus may include a control 1209 that may release the inner and/or outer catheters (e.g., the puller catheter and/or inversion control catheter) to allow the device to return to the delivery catheter; alternatively the control may actively move the inner and outer catheters to the delivery configuration.

[000111] The handle may be further configured to apply vacuum through the puller catheter while advancing the inversion support catheter distally before concurrently advancing the inversion support catheter distally while withdrawing the puller catheter proximally. For example, the handle may include control logic that applies the negative pressure (e.g., vacuum from the vacuum device 1225) when the actuators within the handle move the inversion support catheter distally while moving the puller catheter proximally. The control logic within the handle may be software, hardware or firmware, and may coordinate operation of the handle. For example the handle may be configured to separately and/or jointly move the inner catheter (puller catheter) and the outer catheter (inversion support

catheter), as mentioned above, and/or to coordinate the application of suction (e.g., vacuum) through the puller catheter.

[000112] Separate controls on the handle may control the movements involved in the different stages of the operation. For example, the handle may include a first control to advance the inversion support catheter distally and a second control to advance the inversion support catheter distally while withdrawing the puller catheter proximally. Alternatively or additionally, the first control may advance the inversion support catheter distally and may separately advance the inversion support catheter distally while withdrawing the puller catheter proximally. In some variations, the handle is configured to advance the inversion support catheter distally to a predetermined distance (e.g., 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 1 cm, 1.5 cm, 2 cm, 3 cm, etc.) before advancing the inversion support catheter distally while withdrawing the puller catheter proximally to a variable distance and/or to a second predetermined distance (e.g., 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 1 cm, 1.5 cm, 2 cm, 3 cm, 4 cm, 5 cm, 6 cm, 7 cm, 8 cm, 9 cm, etc.).

[000113] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[000114] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof.

As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[000115] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[000116] Although the terms "first" and "second" may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[000117] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising" means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term "comprising" will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

[000118] In general, any of the apparatuses and methods described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may alternatively be exclusive, and may be expressed as "consisting of" or alternatively "consisting essentially of" the various components, steps, sub-components or sub-steps.

[000119] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or "approximately," even if the term does not expressly appear. The phrase "about"

or “approximately” may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is $\pm 0.1\%$ of the stated value (or range of values), $\pm 1\%$ of the stated value (or range of values), $\pm 2\%$ of the stated value (or range of values), $\pm 5\%$ of the stated value (or range of values), $\pm 10\%$ of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For example, if the value “10” is disclosed, then “about 10” is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that “less than or equal to” the value, “greater than or equal to the value” and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value “X” is disclosed the “less than or equal to X” as well as “greater than or equal to X” (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point “10” and a particular data point “15” are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[000120] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[000121] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this

disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term “invention” merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

1. A system for removing a clot, the system comprising:

an inversion support catheter;

a puller catheter within a lumen of the inversion support catheter;

a flexible tube having a first end coupled at a distal end region of the puller catheter, and a second end coupled at an outer surface of a distal end region of the inversion support catheter; and

a handle coupled to the inversion support catheter and the puller catheter, the handle comprising a vacuum port configured to couple a lumen of the puller catheter to a vacuum, further wherein the handle is configured to, when activated by one or more controls on the handle, advance the inversion support catheter distally before concurrently advancing the inversion support catheter distally while withdrawing the puller catheter proximally.

2. The apparatus of claim 1, wherein the first end of the flexible tube is coupled proximal to the distal end of the puller catheter by greater than 0.5 mm.

3. The apparatus of claim 1 or 2, wherein the handle is further configured to reset the inversion support catheter proximally and the puller catheter distally.

4. The apparatus of any of claims 1-3, further wherein the flexible tube further comprises a bias configured to extend the puller catheter distally relative to the inversion support catheter.

5. The apparatus of any of claims 1-4, wherein the flexible tube comprises a woven or knitted material.

6. The apparatus of any of claims 1-4, wherein the flexible tube comprises a braided material.

7. The apparatus of any of claims 1-6, wherein the handle is further configured to apply vacuum through the puller catheter while advancing the inversion support catheter distally before concurrently advancing the inversion support catheter distally while withdrawing the puller catheter proximally.

8. The apparatus of any of claims 1-7, wherein the handle comprises a first control to advance the inversion support catheter distally and a second control to advance the inversion support catheter distally while withdrawing the puller catheter proximally.

9. The apparatus of any of claims 1-7, wherein the handle comprises a first control to advance the inversion support catheter distally and to separately advance the inversion support catheter distally while withdrawing the puller catheter proximally.

10. The apparatus of any of claims 1-7, wherein the handle is configured to advance the inversion support catheter distally to a predetermined distance before advancing the inversion support catheter distally while withdrawing the puller catheter proximally.

11. The apparatus of any of claims 1-10, wherein the outer diameter of the puller catheter is within about 10% of the inner diameter of the inversion support catheter.

12. A system for removing a clot, the system comprising:

an intermediate catheter;

an inversion support catheter within a lumen of the intermediate catheter;

a puller within a lumen of the inversion support catheter;

a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; and

a handle coupled to the intermediate catheter and the puller, wherein the handle is configured to, when activated by a control on the handle, automatically advance the intermediate catheter while one or more of: holding the puller fixed or withdrawing the puller proximally as the intermediate catheter is advanced.

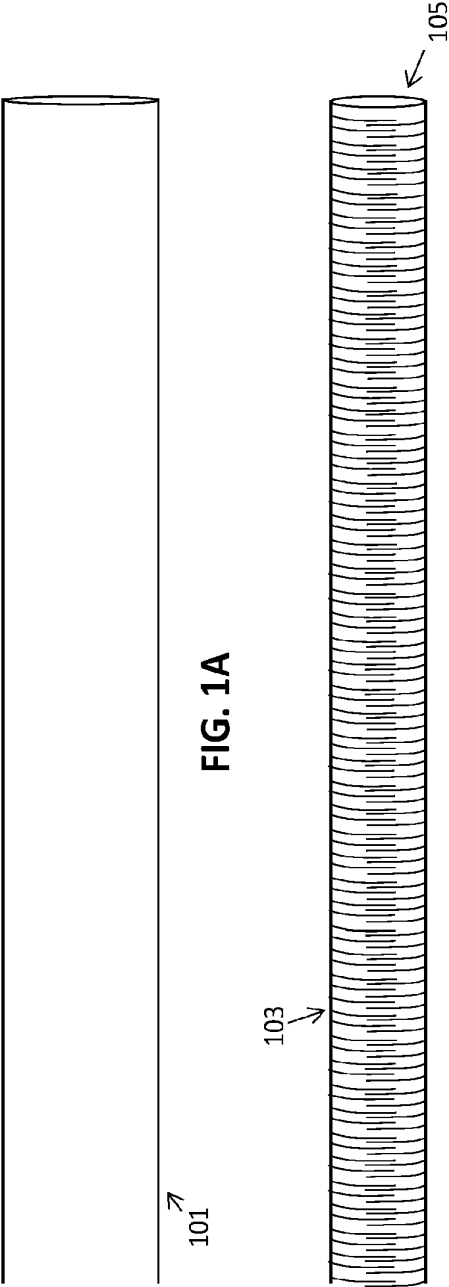
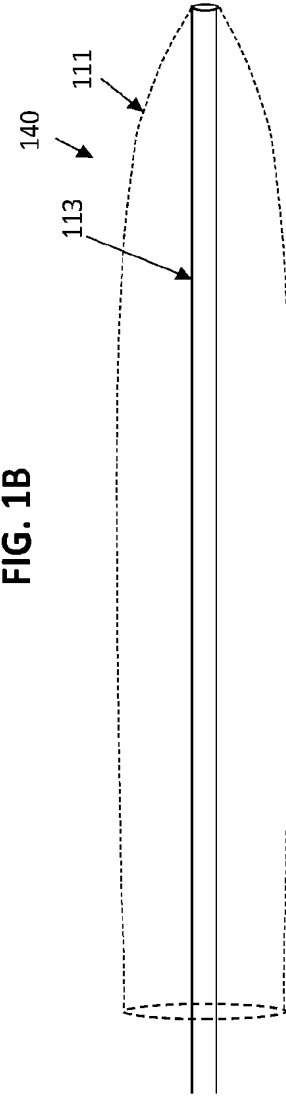
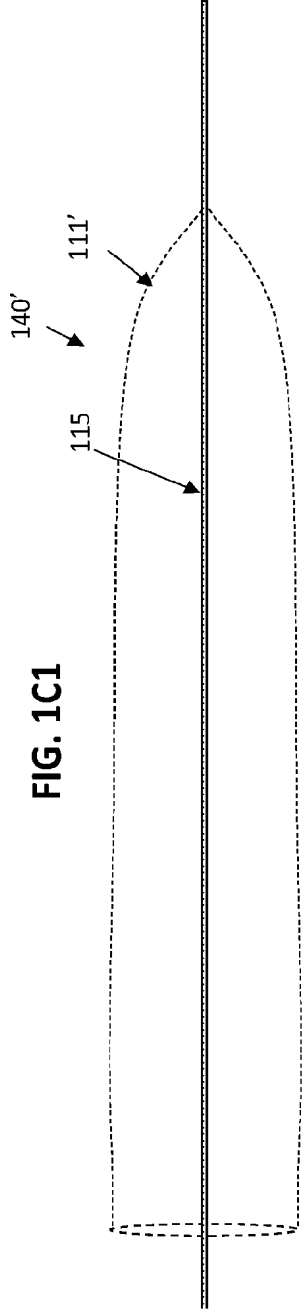


FIG. 1C2

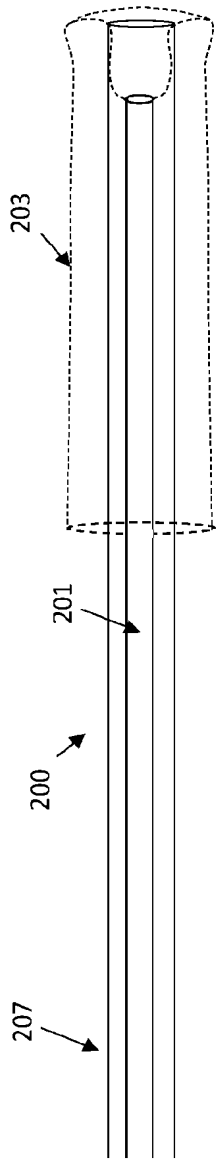


FIG. 2A

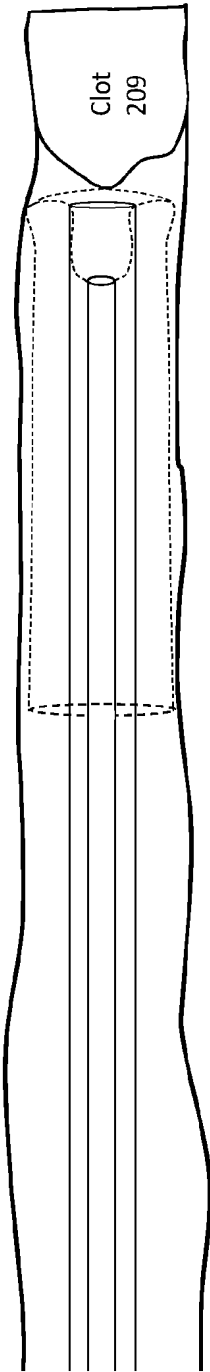


FIG. 2B

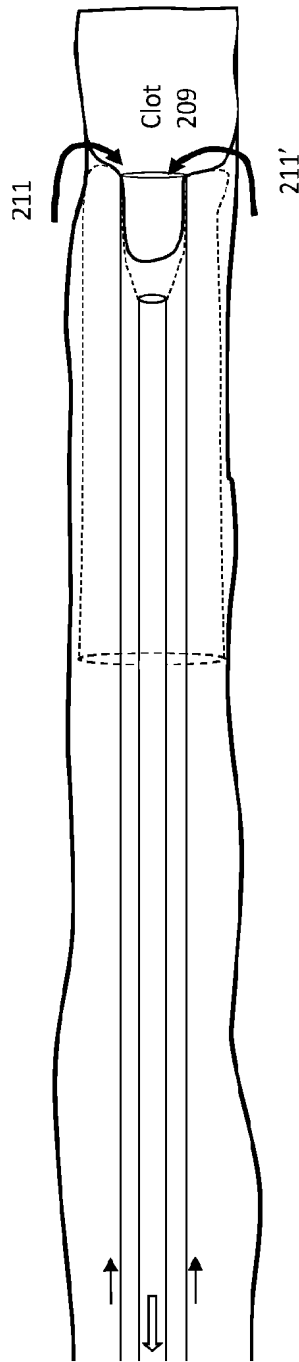


FIG. 2C

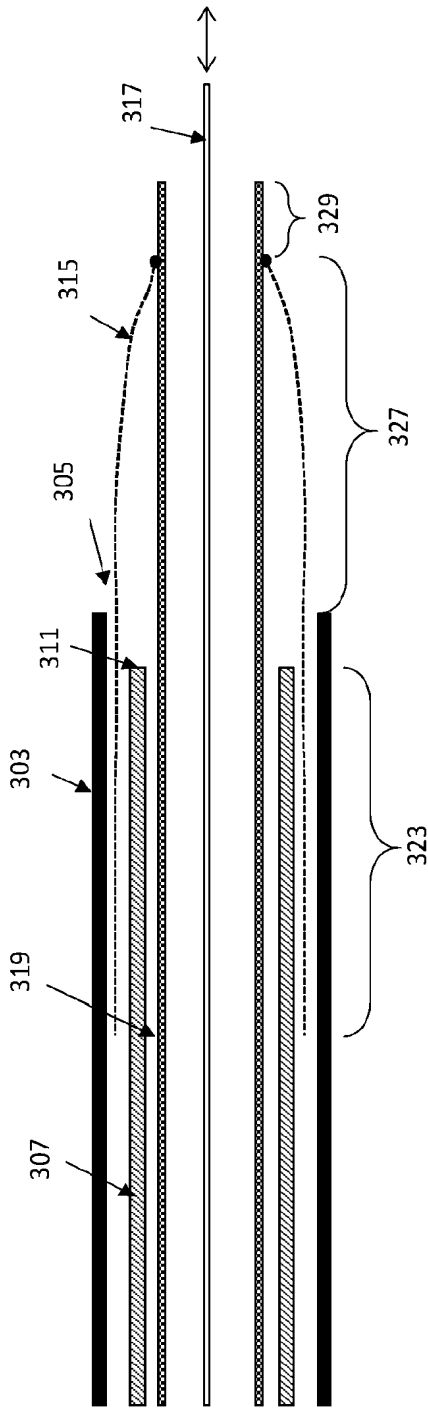


FIG. 3A

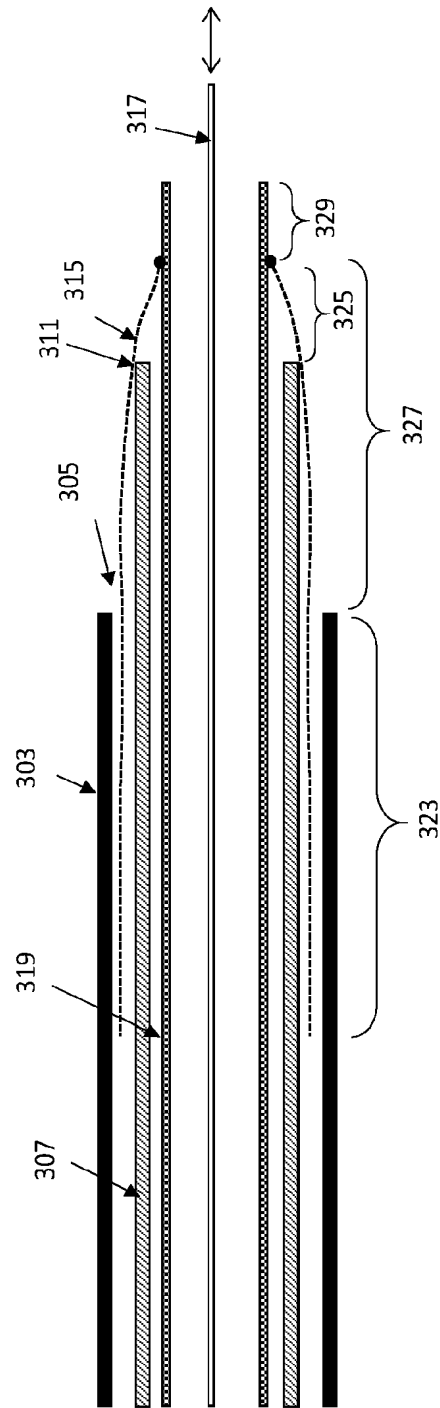


FIG. 3B

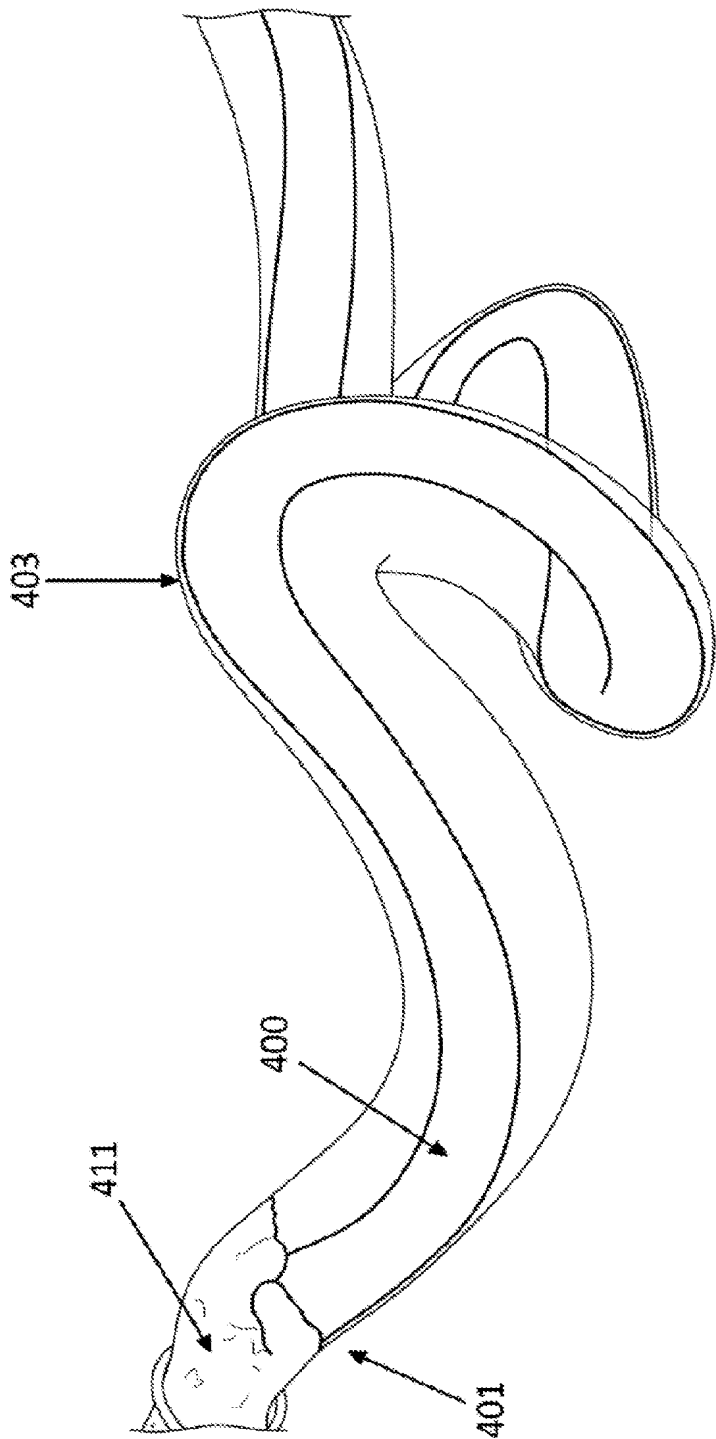


FIG. 4A

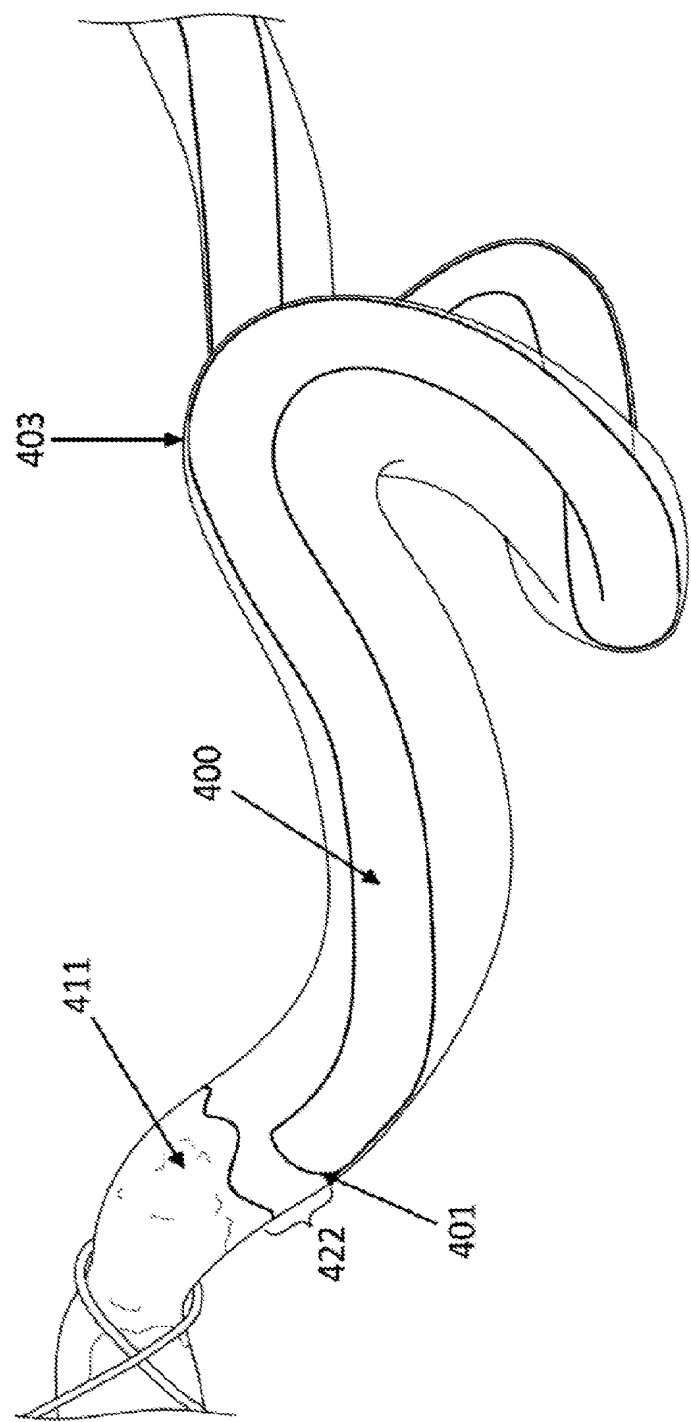


FIG. 4B

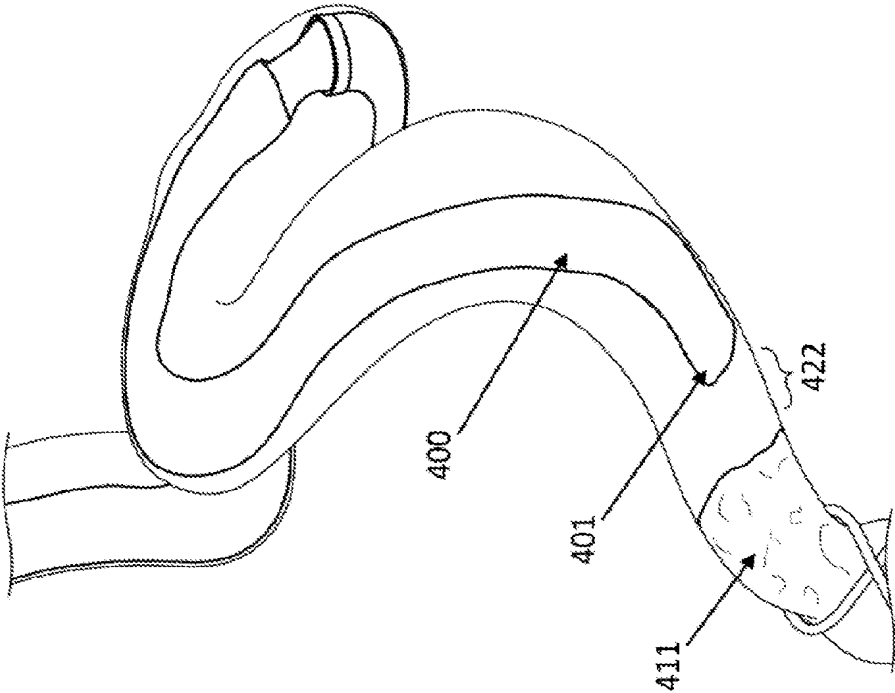


FIG. 4D

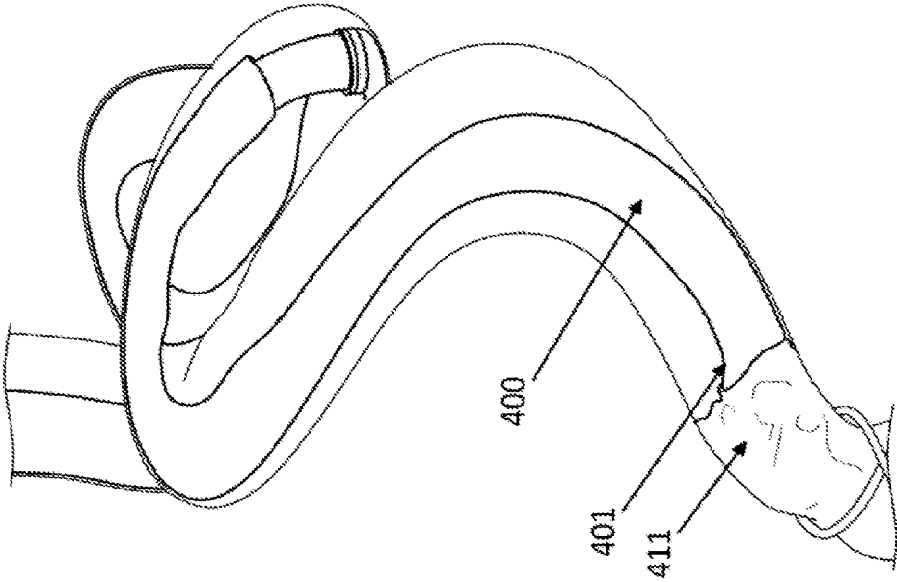


FIG. 4C

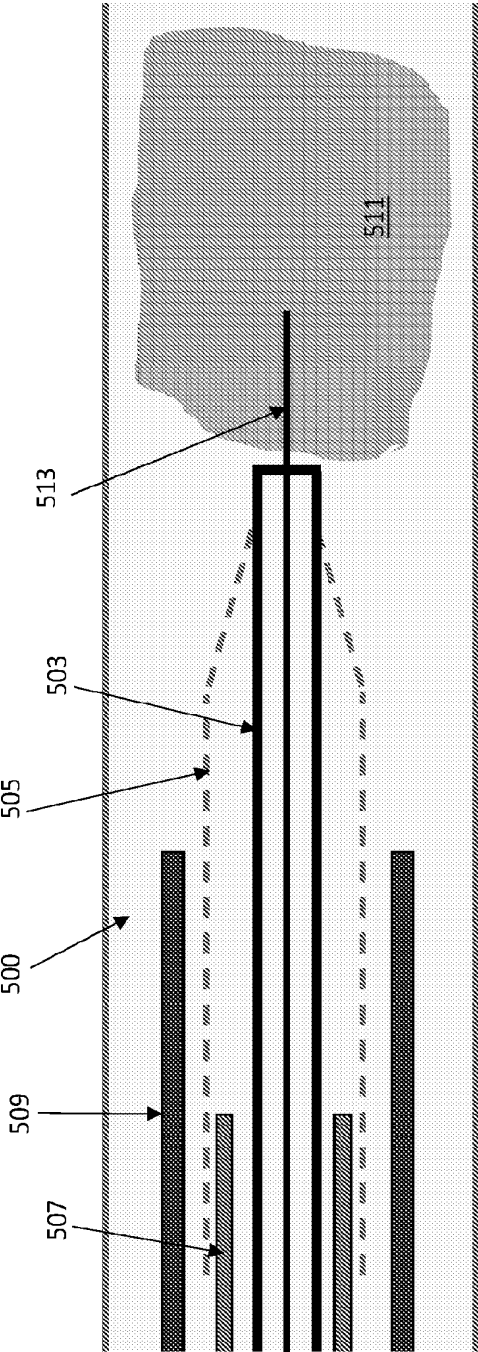


FIG. 5A

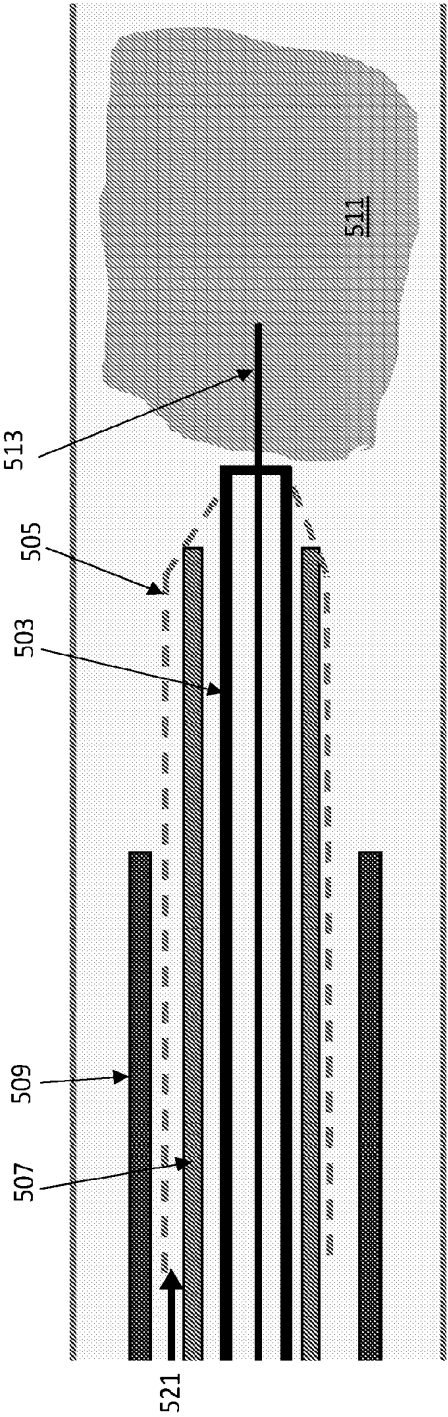


FIG. 5B

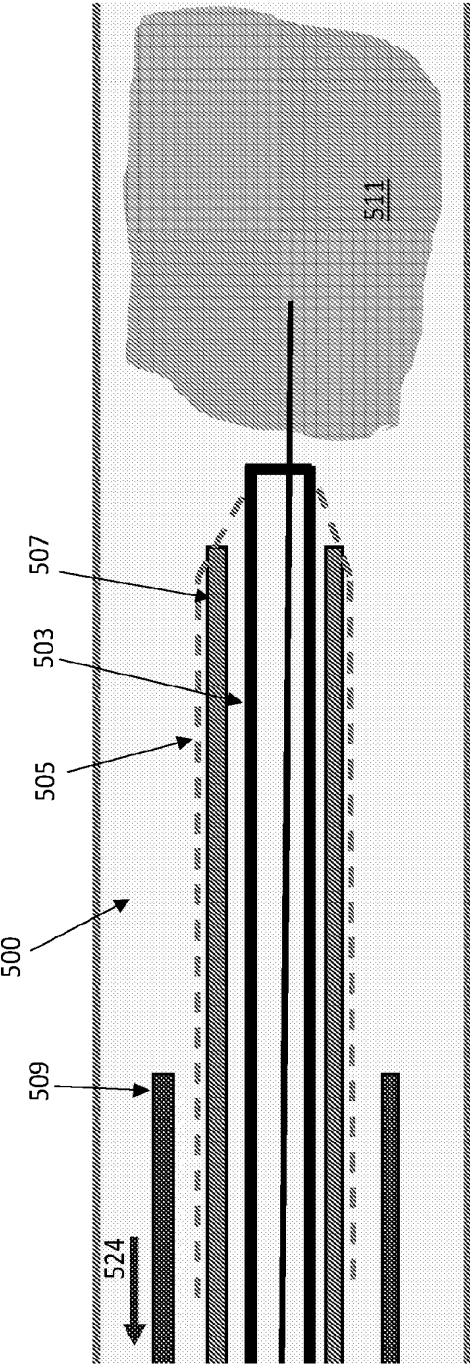


FIG. 5C

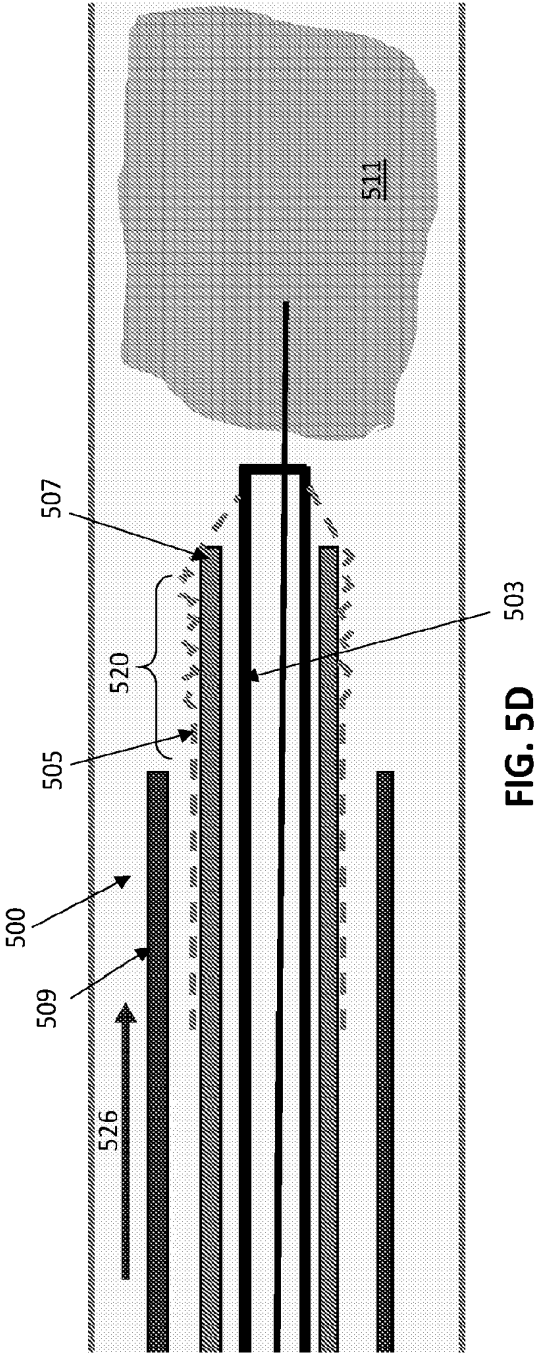
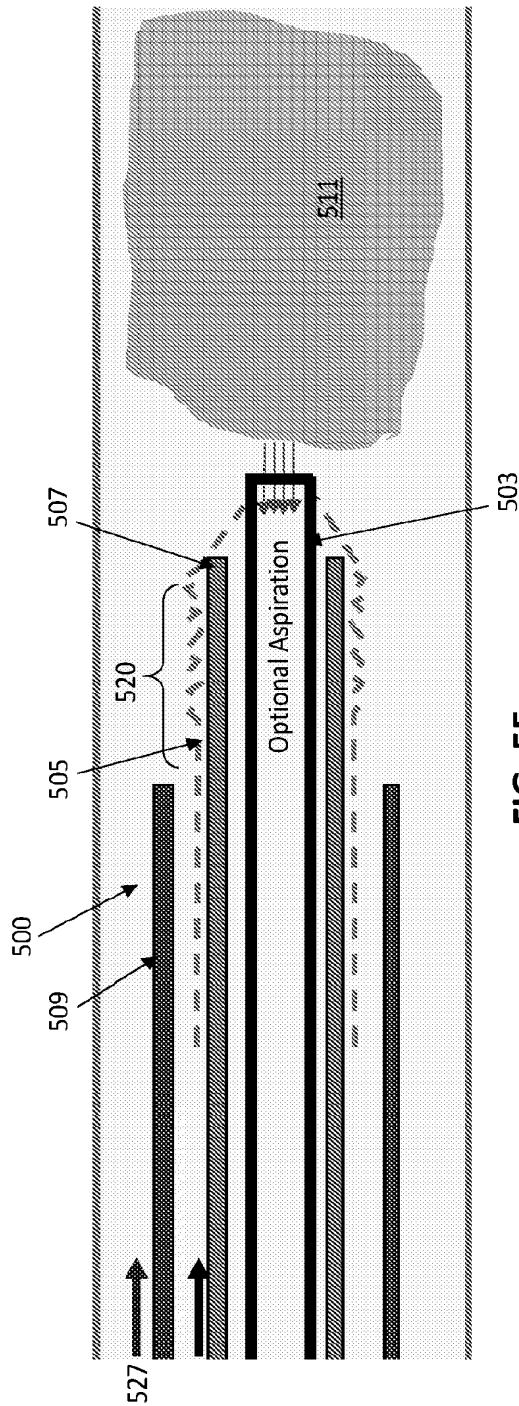
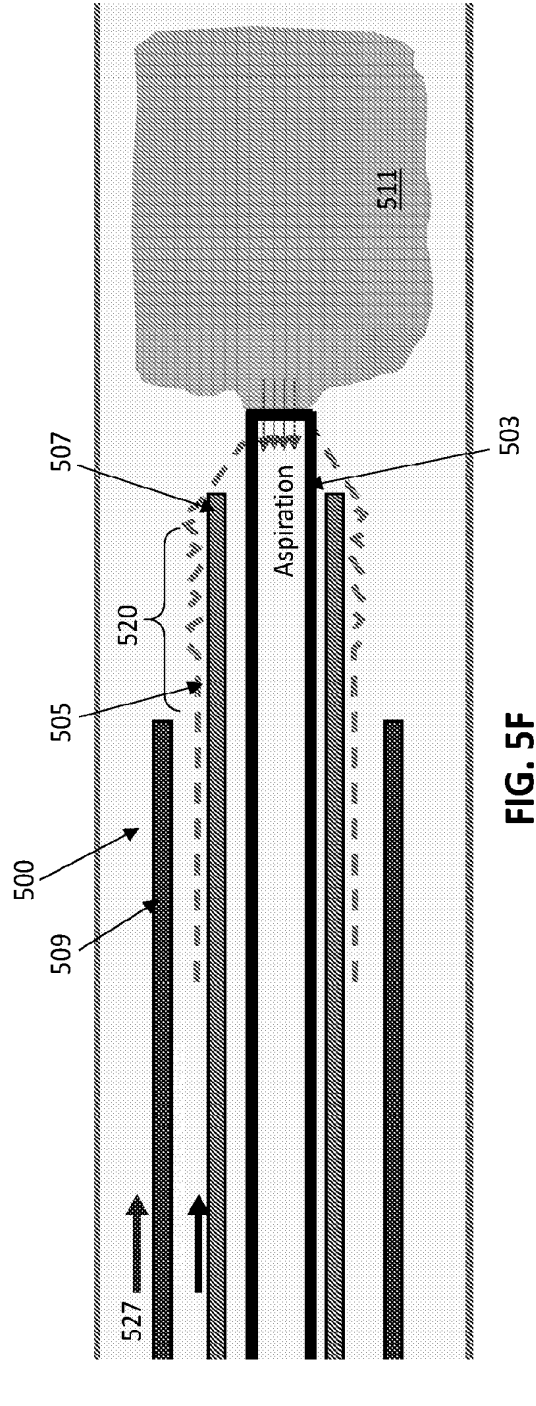
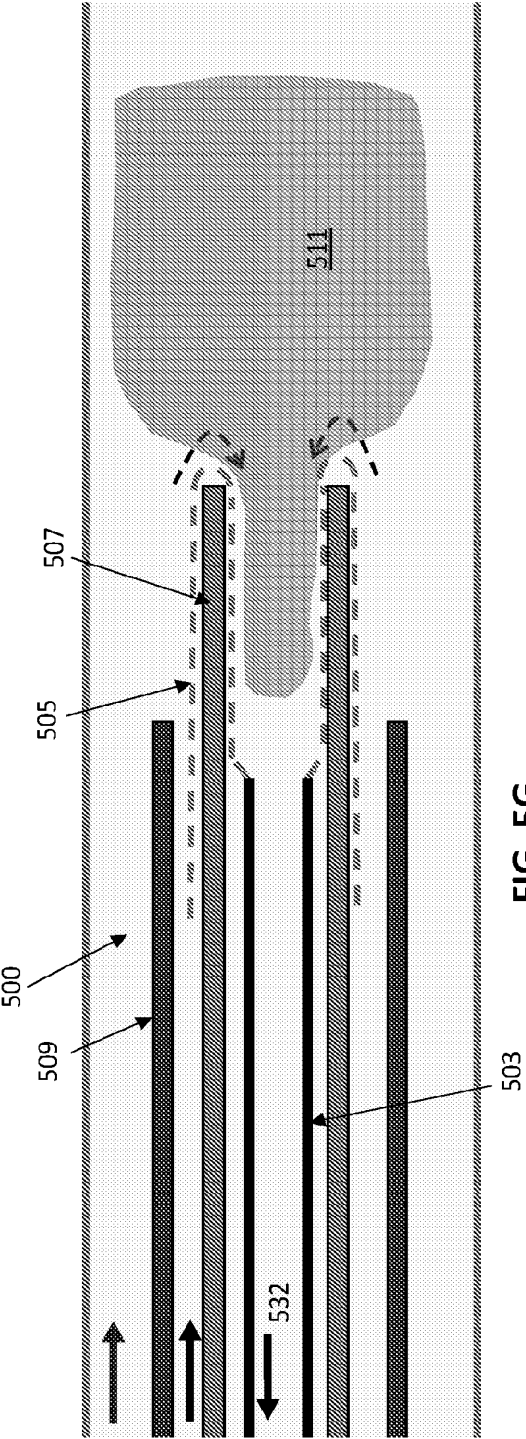
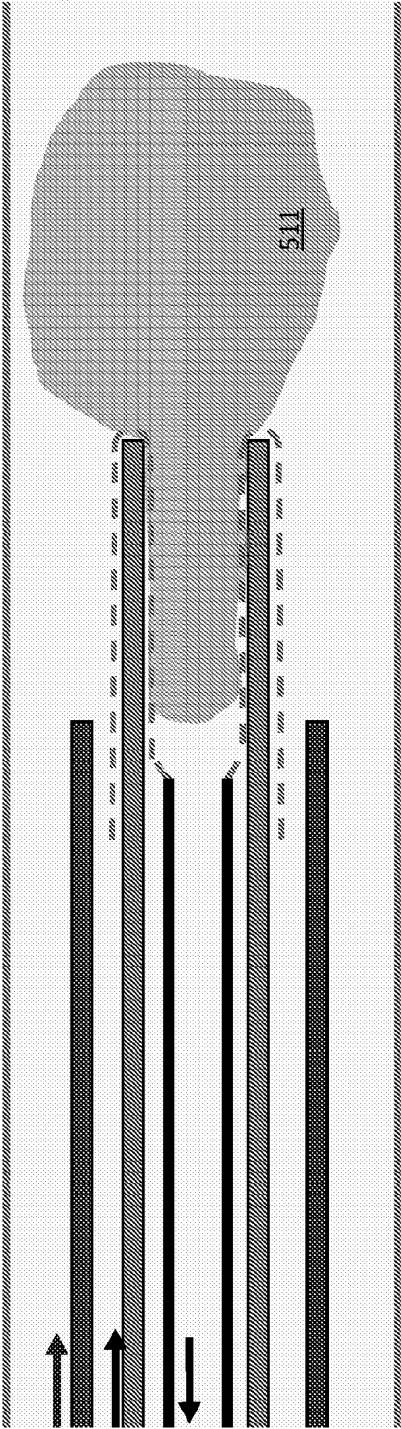


FIG. 5D





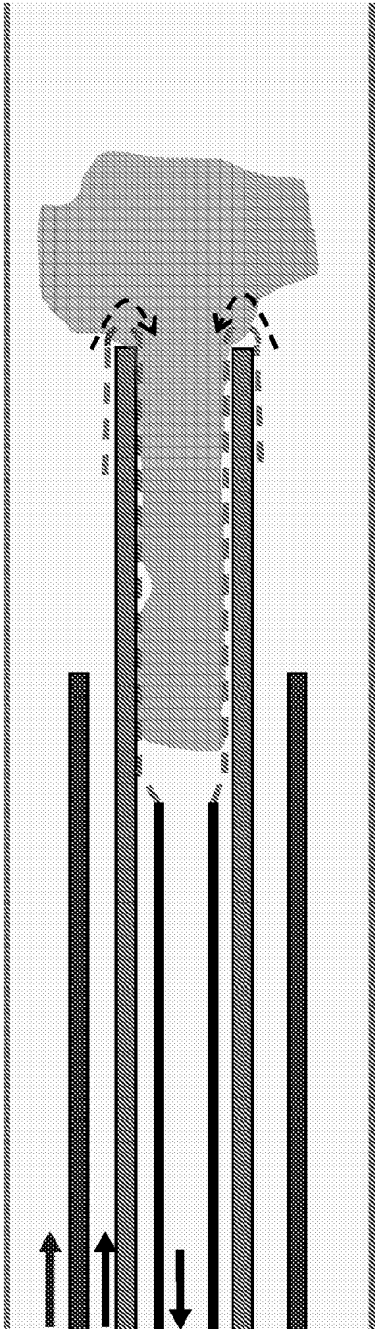


FIG. 5I

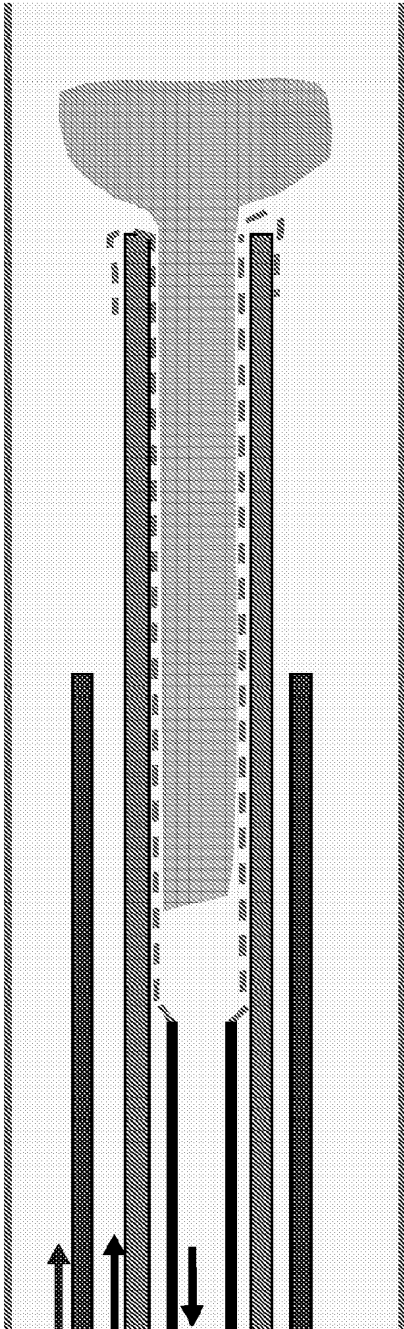


FIG. 5J

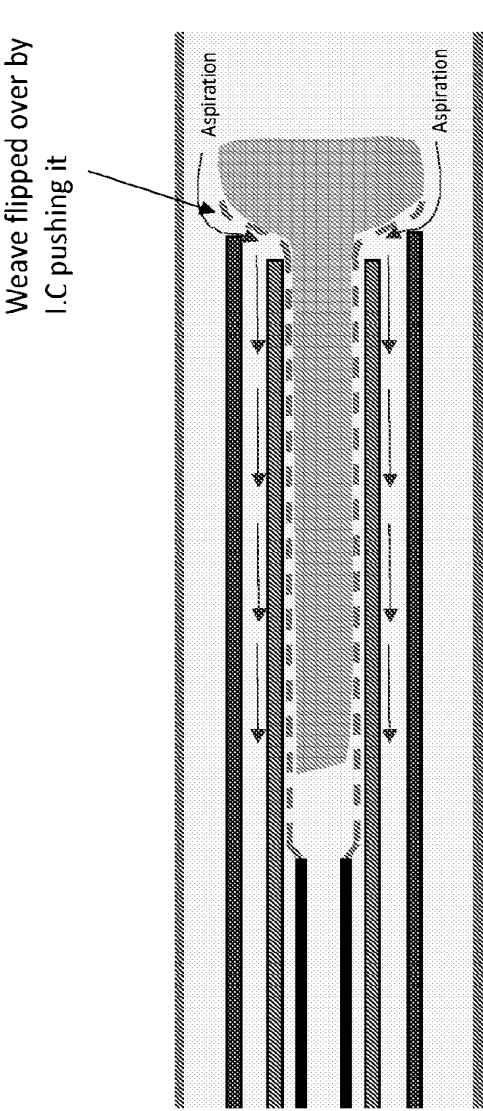


FIG. 5K

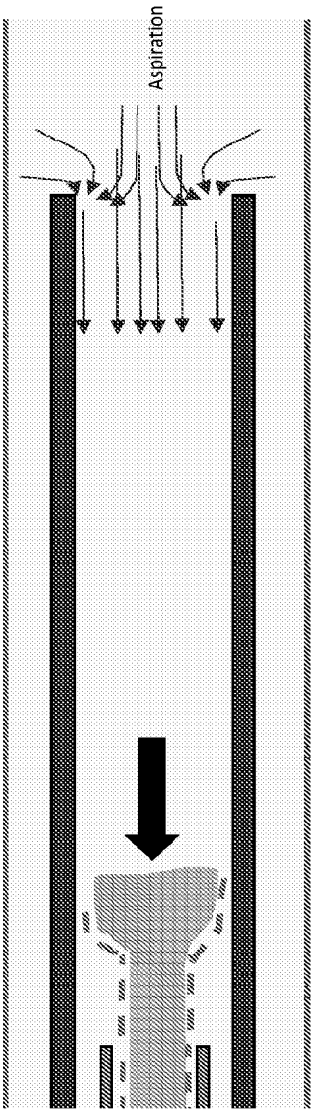


FIG. 5L

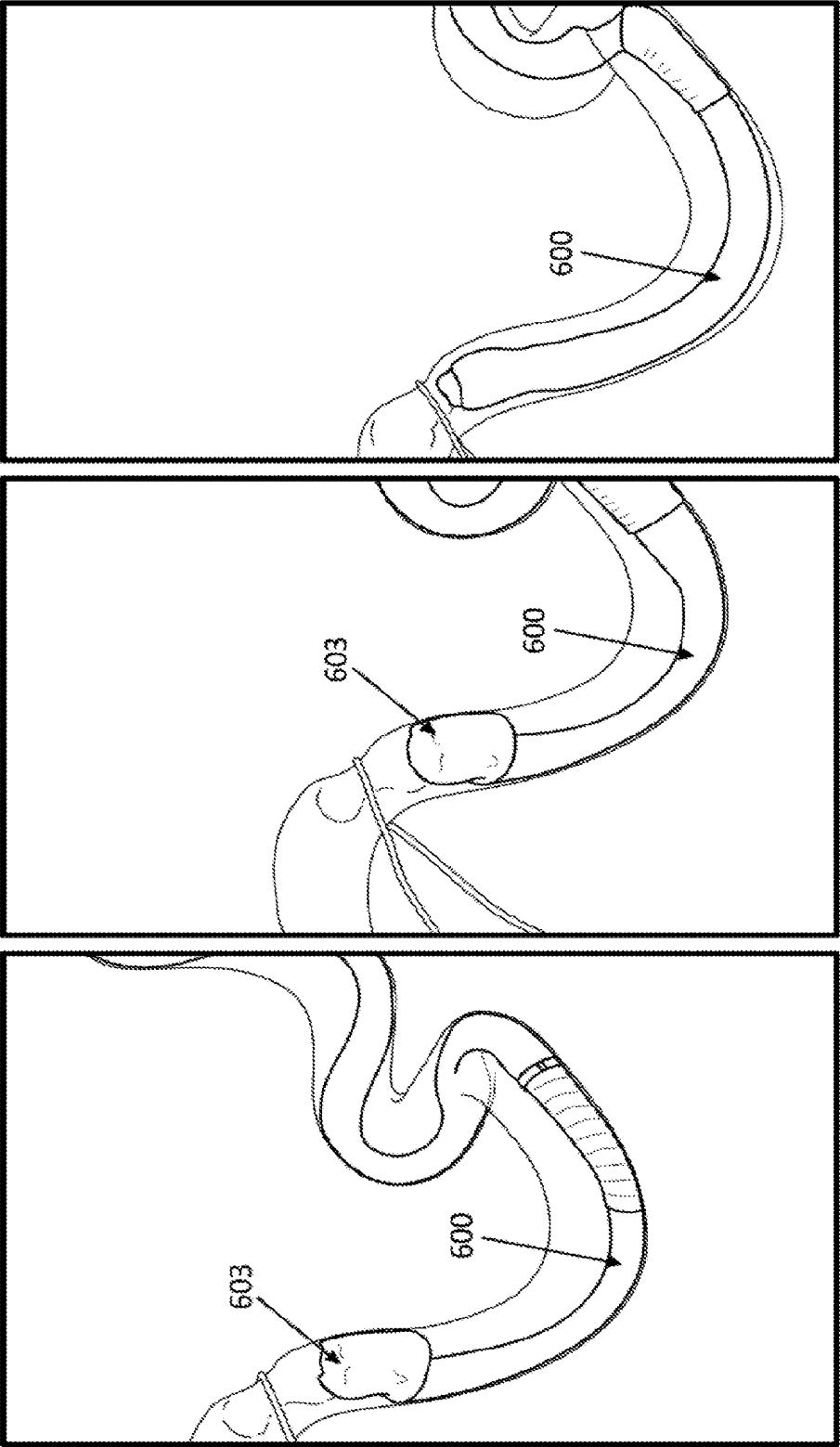


FIG. 6C

FIG. 6B

FIG. 6A

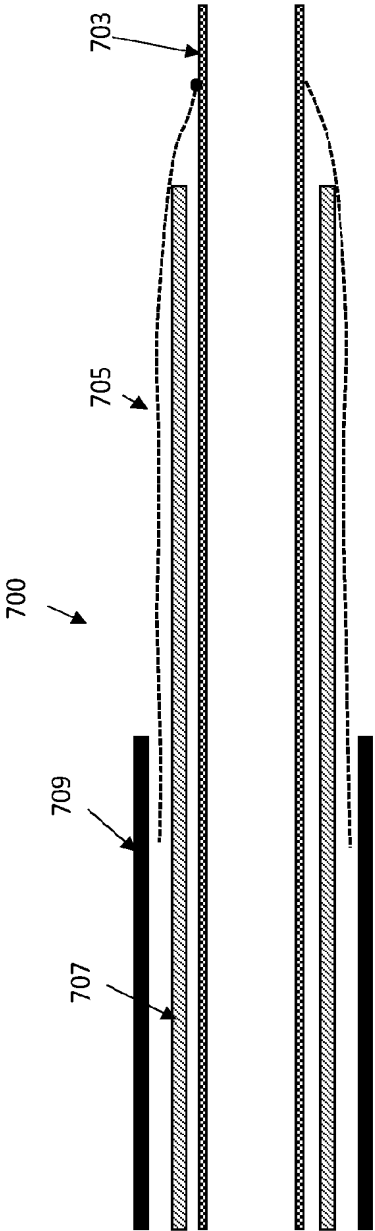


FIG. 7A

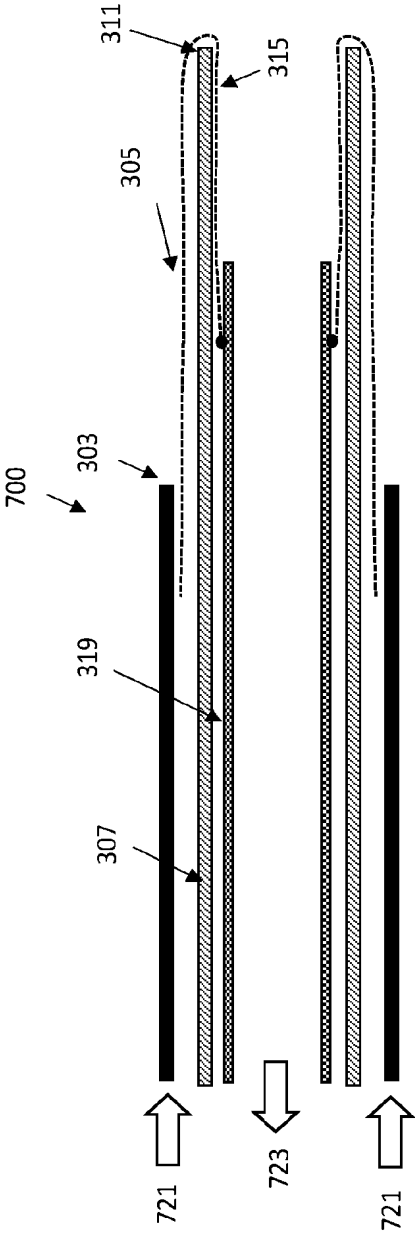


FIG. 7B

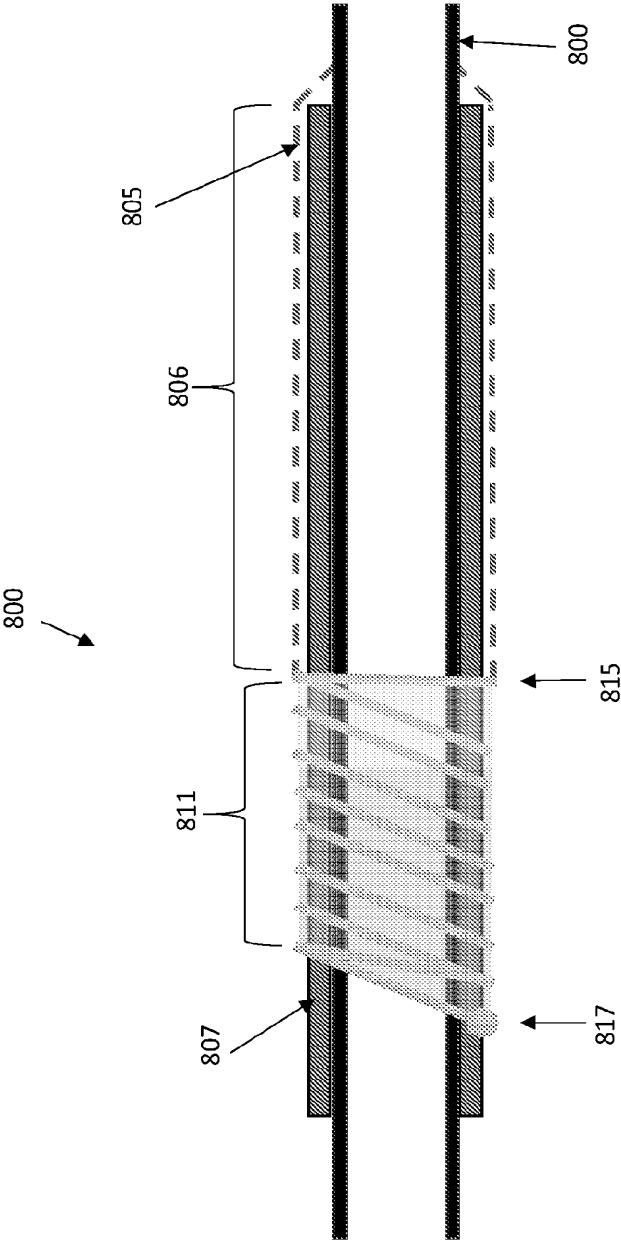
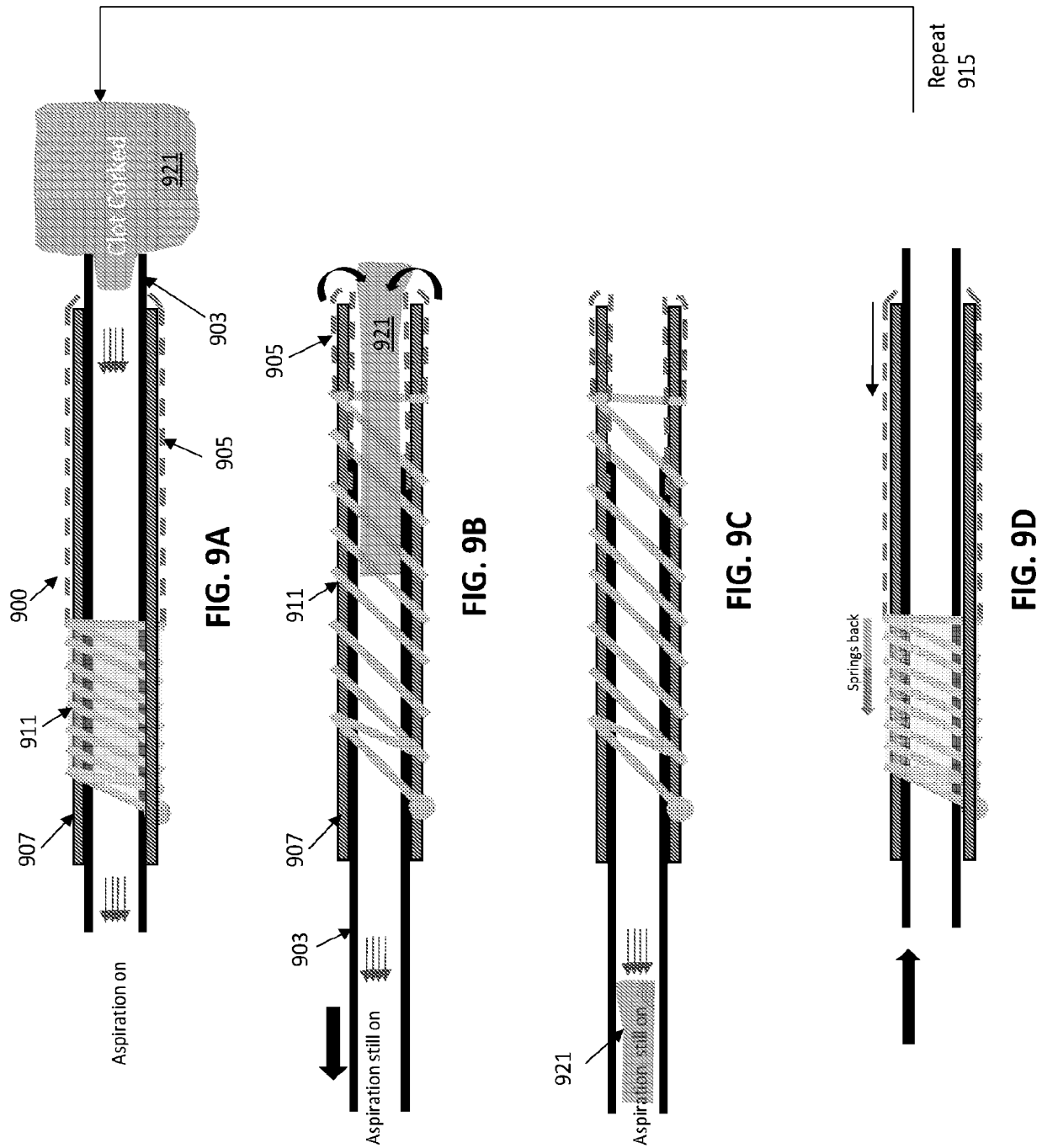


FIG. 8



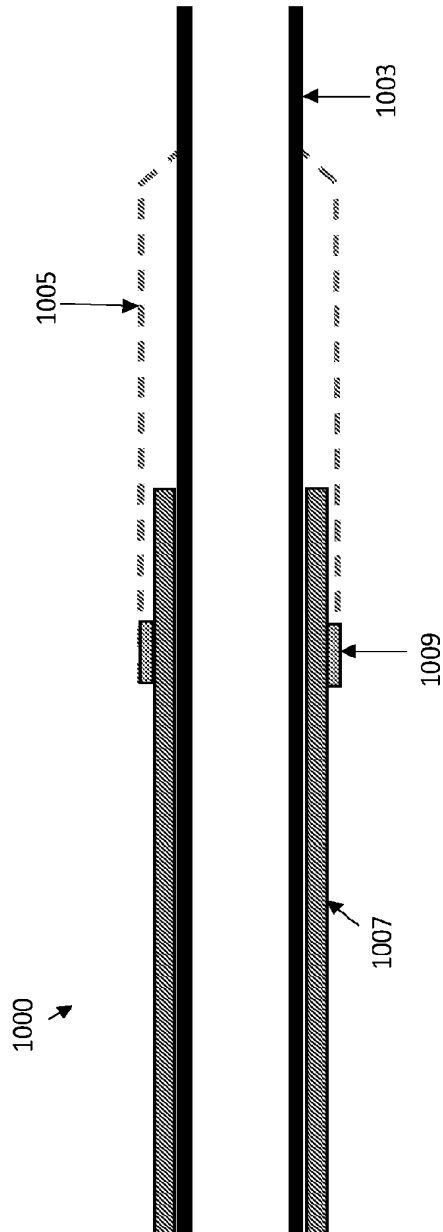


FIG. 10A

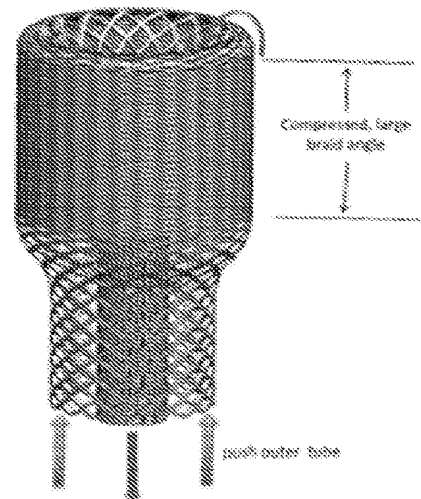
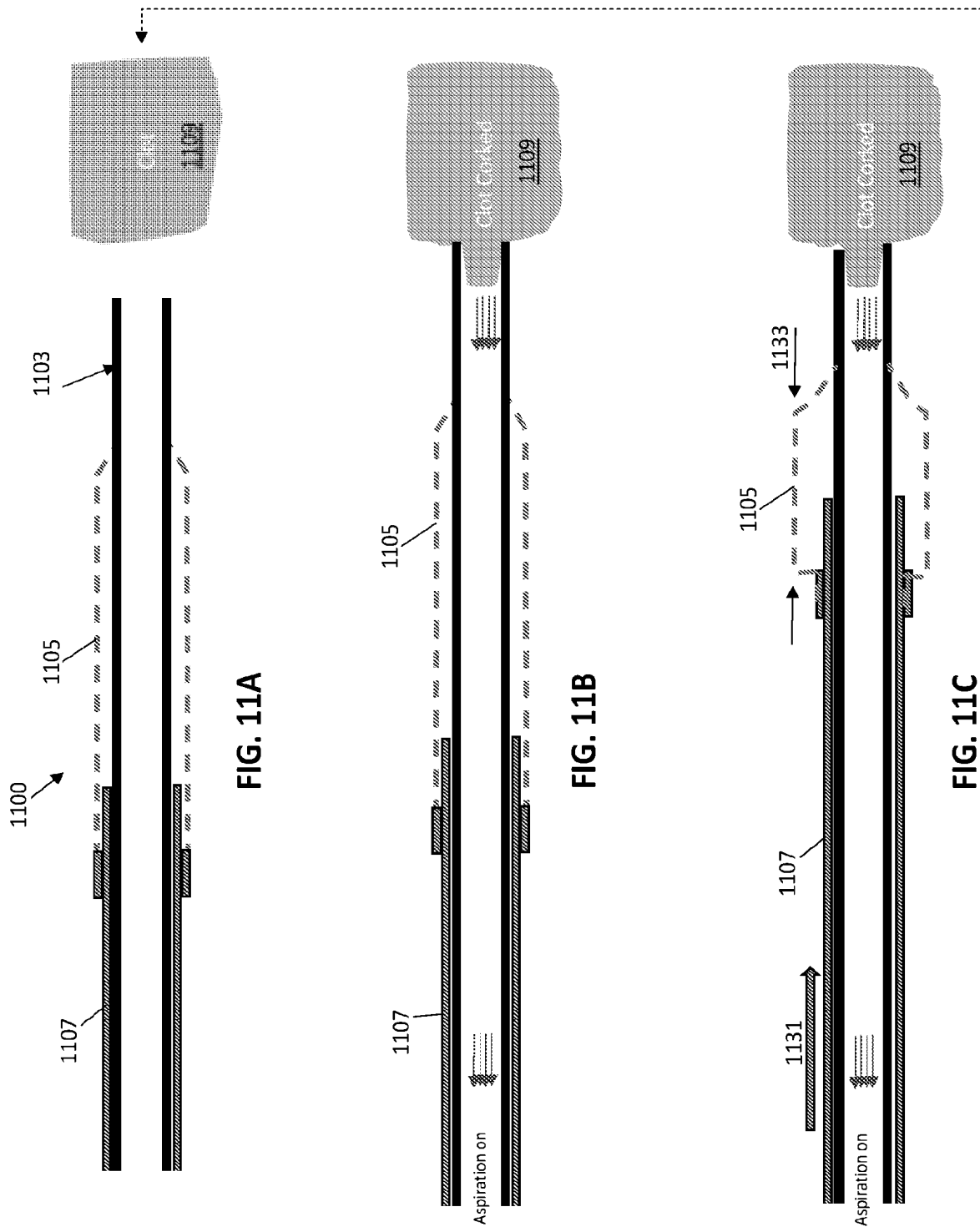


FIG. 10B



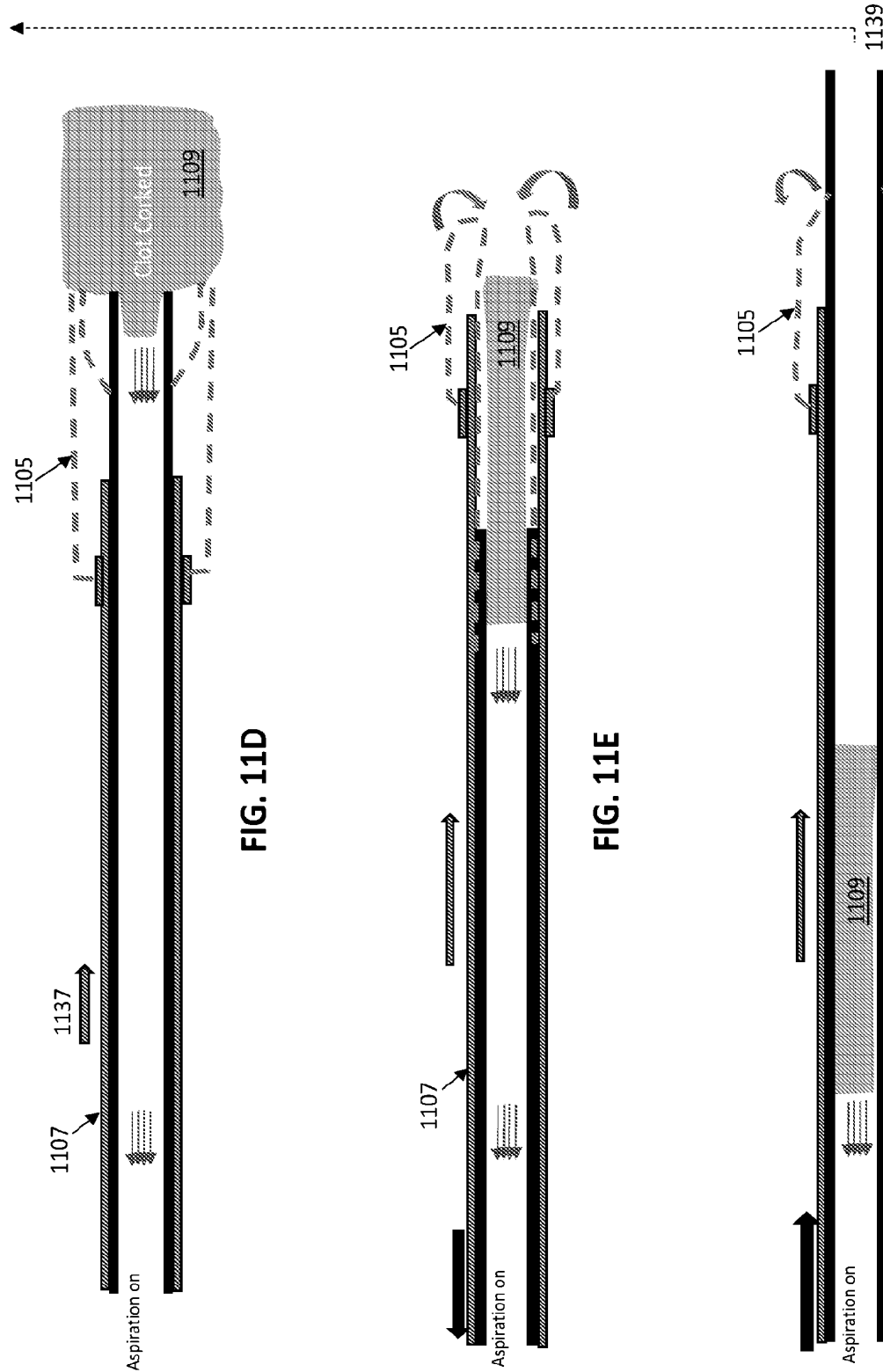


FIG. 11D

FIG. 11E

FIG. 11F

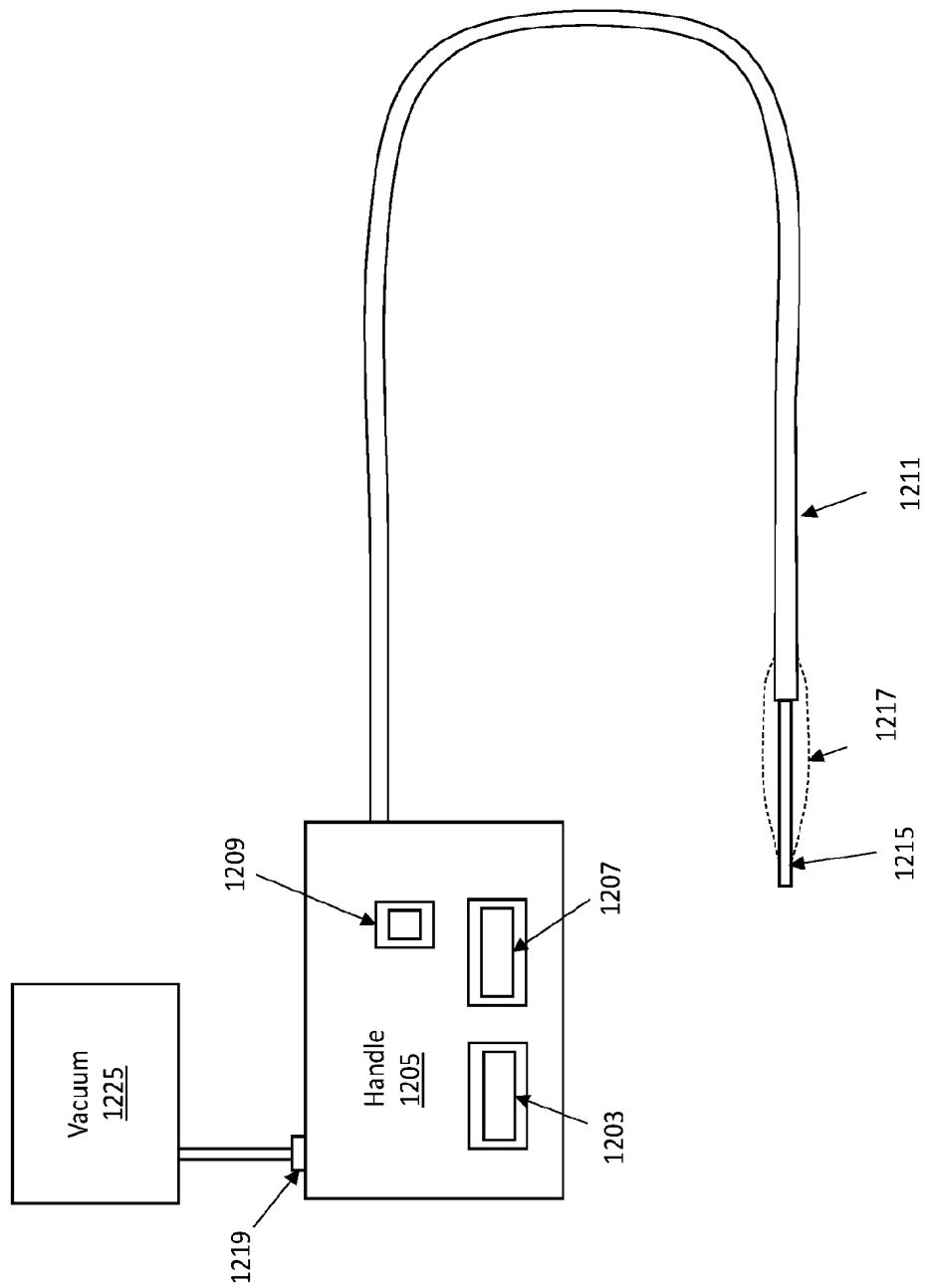


FIG. 12
(not to scale)

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2019/032061

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/22 A61B17/221 A61B17/34
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>US 2017/086864 A1 (GREENHALGH E SKOTT [US] ET AL) 30 March 2017 (2017-03-30) cited in the application figure 6A figure 8 figure 10A figure 36 paragraph [0134] - paragraph [0136] paragraph [0141] - paragraph [0142] paragraph [0158] paragraph [0188] paragraph [0193]</p> <p style="text-align: center;">----- -/-</p>	1-12



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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Date of the actual completion of the international search

10 July 2019

Date of mailing of the international search report

23/07/2019

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Biegler, Marcel

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2019/032061

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2017/303948 A1 (WALLACE MICHAEL P [US] ET AL) 26 October 2017 (2017-10-26) cited in the application figures 2A-C figures 41A-B figures 38A-B figures 39A-C paragraph [0125] - paragraph [0126] paragraph [0130] - paragraph [0132] paragraph [0210] paragraph [0213] paragraph [0218] -----	1,12
A	US 5 389 100 A (BACICH STEVEN R [US] ET AL) 14 February 1995 (1995-02-14) figure 2 column 1, line 15 - line 68 -----	1
A	US 2013/116721 A1 (TAKAGI TOSHIAKI [JP] ET AL) 9 May 2013 (2013-05-09) paragraph [0088]; figures 9A-C -----	1-12

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2019/032061

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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			JP 2012010880 A 19-01-2012
			US 2013116721 A1 09-05-2013
			WO 2012001826 A1 05-01-2012



(51) International Patent Classification:

A61B 17/22 (2006.01) A61B 17/221 (2006.01)

(21) International Application Number:

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(22) International Filing Date:

01 June 2017 (01.06.2017)

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English

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(30) Priority Data:

62/345,152 03 June 2016 (03.06.2016) US

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(74) Agent: **BURSE, David, T.** et al.; Vista IP Law Group LLP,
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nia 95014 (US).

(81) Designated States (*unless otherwise indicated, for every
kind of national protection available*): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,
HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR,
KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG,
MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM,
PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC,

SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR,
TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every
kind of regional protection available*): ARIPO (BW, GH,
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UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
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TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: INVERTING THROMBECTOMY APPARATUSES

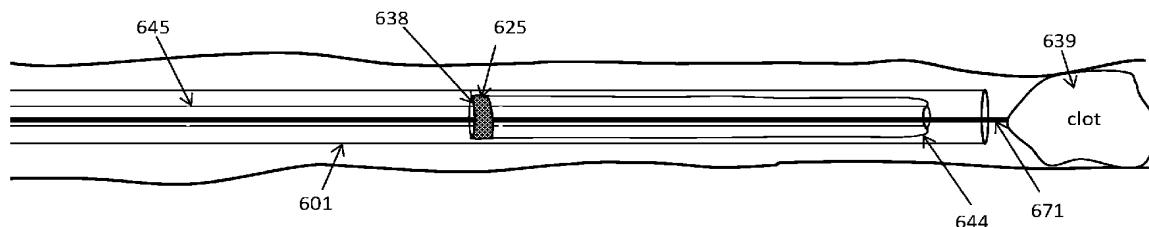


FIG. 6B

(57) Abstract: Rolling tractor tube mechanical thrombectomy apparatuses that may be deployed from out of a catheter *in situ* are described herein. These apparatuses may be delivered out of a catheter from a collapsed delivery configuration within the catheter to a deployed configuration out of the catheter, in which the same catheter is re-inserted between a tubular tractor and an elongate puller. In particular, any of these methods and apparatuses may be adapted to work with a tractor tube having an open end that is biased open, including using an annular bias.

INVERTING THROMBECTOMY APPARATUSES

FIELD

5 [0001] The apparatuses described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses.

BACKGROUND

[0002] Many vascular problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery. It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue, such as blood clots, from within a patient's vasculature may improve patient conditions and quality of life.

[0003] When a thrombus forms, it may effectively stop the flow of blood through the zone of formation. If the thrombus extends across the interior diameter of an artery, it may cut off the flow of blood through the artery. If one of the coronary arteries is 100% thrombosed, the flow of blood is stopped in that artery, resulting in a shortage of oxygen carrying red blood cells, e.g., to supply the muscle (myocardium) of the heart wall. Such a thrombosis is unnecessary to prevent loss of blood but can be undesirably triggered within an artery by damage to the arterial wall from atherosclerotic disease. Thus, the underlying disease of atherosclerosis may not cause acute oxygen deficiency (ischemia) but can trigger acute ischemia via induced thrombosis. Similarly, thrombosis of one of the carotid arteries can lead to stroke because of insufficient oxygen supply to vital nerve centers in the cranium. Oxygen deficiency reduces or prohibits muscular activity, can cause chest pain (angina pectoris), and can lead to death of myocardium which permanently disables the heart to some extent. If the myocardial cell death is extensive, the heart will be unable to pump sufficient blood to supply the body's life sustaining needs. The extent of ischemia is affected by many factors, including the existence of collateral blood vessels and flow which can provide the necessary oxygen.

[0004] Clinical data indicates that clot removal may be beneficial or even necessary to improve outcomes. For example, in the peripheral vasculature, inventions and procedures can reduce the need for an amputation by 80 percent. The ultimate goal of any modality to treat these conditions of the arterial or venous system is to remove the blockage or restore patency, quickly, safely, and cost effectively. This may be achieved by thrombus dissolution, fragmentation, thrombus aspiration or a combination of these methods.

[0005] Mechanical thrombectomy devices may be particularly advantageous. Depending on the size, location and extent of a clot, it may also be particularly advantageous to mechanically retrieve and break apart the clot in a manner that is both safe and effective. There is a definite need for a thrombectomy device, and particularly a mechanical thrombectomy device that can be more effective in removing tissue such as clots from within a body. Described herein are apparatuses (devices, systems and kit) and illustrative methods of using them that may address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[0006] Described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and illustrative methods of using and making them. These apparatuses may be configured for reliable operation in particular in narrow regions of the body, including peripheral vascular and neurovascular regions. Typically, the mechanical thrombectomy apparatuses described herein are inverting tractor thrombectomy apparatuses that include a tractor (e.g., tractor region, tractor portion, etc.) comprising a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support. The elongate inversion support typically comprises a catheter having a distal end opening into which the tractor inverts. The flexible tractor inverts and rolls back into itself and may be drawn into the elongate inversion support in a conveyor-like motion; the outward-facing region rolls around to become an inward-facing region, e.g., within the lumen of the elongate inversion support. The rolling motion may thus draw a clot or other object within a vessel into the elongate inversion support.

[0007] The apparatus may be deployed from a collapsed configuration using an in situ deployment, wherein the tractor is folded over an elongate puller/pusher member (which may be a hollow tube, wire or the like), and is collapsed down into a compact form for positioning within the vessel. Once the distal end of the tractor is in position within the vessel, the tractor may be expanded open and the distal end of the catheter over which the tractor is to be rolled or inverted is advanced distally between the tractor and the puller/pusher member, so the

distal end opening of the catheter is positioned distally and the tractor can roll over the distal end and invert when the puller/pusher is pulled proximally.

[0008] In practice, it is beneficial to provide a tractor that is able to be radially compacted to a large degree (e.g., to less than 0.7x the diameter, 0.6x the diameter, 0.5x the diameter, 0.4x the diameter, 0.3x the diameter 0.2x the diameter, 0.1x the diameter, etc.) while still maintaining high degree of flexibility for ease in rolling and inverting over the distal end. Further, the tractor may be advantageously biased so that it has an outer diameter when collapsed into the catheter (after being rolled and inverted into the catheter) that is greater than 0.7x the inner diameter of the catheter (e.g., greater than 0.7x, 0.75x, 0.8x, 0.85x, 0.9x, 0.95x, etc.). In some variations, it may be particularly beneficial if the outer diameter of the portion of the tractor that extends along the outer diameter of the catheter is biased to have an inner diameter that is between 1.1x and 2x the outer diameter of the catheter (e.g., between 1.1x and 1.9x, between 1.1x and 1.8x, between 1.1x and 1.7x, between 1.1x and 1.6x, between 1.1x and 1.5x, etc.).

[0009] Unfortunately, when performing an in situ deployment, it has proven particularly difficult to provide a tractor having an open end region into which the distal end of the catheter may be easily, reliably and robustly inserted between the expanded tractor and the inner puller/pusher, particularly when the apparatus is deployed within a curved, bent, or tortuous portion of the body. If the catheter distal end does not clearly and cleanly enter between the outer end of the tractor and the puller/pusher, it may get caught on the tractor and may prevent successful operation.

[00010] Described herein are apparatuses for improving and enhancing deployment, and particularly in situ deployment, of the apparatus so that the distal end (tip) of the catheter can be deployed distally between the free tractor end and a puller/pusher to which the other end of the tractor is attached and inverted.

[00011] For example, described herein are mechanical thrombectomy apparatuses to be used for removing a clot from a vessel. Any of these apparatuses may include an annular bias that holds the flexible tractor tube open so that an elongate inversion support catheter can be inserted through the annular bias and between the flexible tractor tube and the elongate puller/pusher (“elongate puller”) to prepare the apparatus for rolling the flexible tractor tube over the distal end opening of the elongate inversion support catheter, even where the flexible tractor tube is expanding from a collapsed configuration within the elongate inversion support catheter.

[00012] For example, an apparatus as described herein may include: an elongate inversion support catheter having a distal end and a distal end opening; an elongate puller extending within the elongate inversion support catheter; a flexible tractor tube having a free first end and a second end that is attached to a distal end region of the elongate puller, wherein the flexible tractor tube is inverted over the elongate puller and is held within the elongate inversion support catheter in a collapsed first configuration; and an annular bias around the free first end of the flexible tractor tube, wherein the flexible tractor tube is configured to be extended from the distal end opening of the elongate inversion support catheter and to expand into an expanded second configuration, wherein the annular bias has a diameter that is larger than an outer diameter of the elongate inversion support catheter in the expanded second configuration (e.g., between 1.1 and 10 times the OD of the elongate inversion support catheter in the expanded second configuration, between 1.1x and 10x, etc.).

[00013] For example, a mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate inversion support catheter having a distal end and a distal end opening; an elongate puller extending within the elongate inversion support catheter, wherein the elongate puller comprises a central lumen; a flexible tractor tube having a free first end and a second end that is attached to a distal end region of the elongate puller, wherein the flexible tractor tube comprises a woven, braided, mesh or knitted material and is inverted over the elongate puller and is held within the elongate inversion support catheter in a collapsed first configuration; further wherein the flexible tractor tube is biased to expand to between 1.1 and 4 times an outer diameter of the elongate inversion support catheter in an uninverted configuration and is further biased to expand to greater than 0.5x an inner diameter of the elongate inversion support catheter in an inverted configuration; and an annular bias around the free first end of the flexible tractor tube, wherein the flexible tractor tube is configured to be extended from the distal end opening of the elongate inversion support catheter and to expand into an expanded second configuration, wherein the annular bias has a diameter that is larger than (e.g., greater than 1.1 times, etc.) the outer diameter of the elongate inversion support catheter in the expanded second configuration so that the elongate inversion support catheter may be pushed through the annular bias and between the flexible tractor tube and an outer diameter of the elongate puller.

[00014] The annular bias may be any appropriate bias, including a ring, a stent (e.g., a stent having a zig-zag strut pattern), a lobed bias, etc. The annular bias may be attached the free, open end of the flexible tractor tube. The annual bias may be attached by stitching,

adhesive, etc. Alternatively or additionally, the annular bias may be formed by shape-setting the open end of the flexible tractor tube.

[00015] In particular, the flexible tractor tube may be biased to expand to between 1.1 and 4 times the outer diameter of the elongate inversion support catheter in an un-inverted configuration and may further be biased to expand to greater than 0.5x an inner diameter of the elongate inversion support catheter in an inverted configuration.

[00016] The elongate inversion support catheter may be configured to be pushed through the annular bias and between the flexible tractor tube and an outer diameter of the elongate puller when the flexible tractor tube is in the expanded second configuration.

[00017] In general, the flexible tractor tube may comprise a woven, braided, mesh or knitted material. For example, the flexible tractor tube may be a knitted material. The flexible tractor tube is typically formed of a soft material that may readily roll over the distal open end of the elongate inversion support catheter. For example, the flexible tractor tube may be sufficiently soft such that without support, it collapses radially under an axial compression of less than 200g of force. The flexible tractor tube may comprise steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric.

[00018] Any of these apparatuses may be configured for use with a guidewire. For example, any of these apparatuses may be configured to include a guidewire lumen extending through the elongate puller that is configured to pass a guidewire.

[00019] Although any appropriate elongate inversion support catheter may be used, in particular, the elongate inversion support catheter may have a harness profile such that this distal end is generally soft, until the very distal end, which may be harder than the more proximal region (e.g., the distal most 5 mm, distal most 4 mm, distal most 3 mm, distal-most 2 mm, distal most 1mm, etc. has a hardness that is greater than the region immediately proximal, which otherwise gradually becomes softer along the distal length). For example, the material hardness of the elongate inversion support catheter may generally decrease over the distal end of the catheter until the distal end opening, wherein the distal end opening may have a material hardness that is greater than a material hardness of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile.

[00020] The elongate puller may comprise a hypotube. The flexible tractor tube may be any appropriate length. For example, the flexible tractor tube may be between 3 cm to 50 cm long.

[00021] The elongate inversion support catheter of the any of the apparatuses described herein may be or may include (particularly at its distal end) any appropriate catheter, e.g., a

flexible tube that can be inserted into a body vessel (e.g., blood vessel) into which the more flexible tractor portion can be withdrawn by pulling against the elongate inversion support. The elongate inversion support catheter may, in some variations, also be referred to as an outer catheter (e.g., when the puller for the tractor is referred to as an inner catheter) and/or inversion catheters and/or support catheter, as it may support the inversion of the tractor around the distal end opening of the catheter. The elongate inversion support catheter may include a braided or woven portion, a spiral or coiled portion, etc. (e.g., having a braided shaft), may have a single layer or multiple layers, and may be formed of biocompatible materials, including polymers, metals, etc. (e.g., PTFE). Examples of vascular catheters that may form the elongate inversion support include micro catheters.

[00022] The flexible tractor tube may be referred to as simply a tractor or as a tractor region, and may be configured to prevent jamming, while still able to efficiently “grab” a clot from within a vessel. For example, described herein are mechanical thrombectomy apparatuses that may be configured to grab or grasp a clot as it is mechanically drawn into the apparatus for removal. Although suction may be used in addition to the mechanical grabbing of the clot, in some variations suction is not used.

[00023] The flexible tractor tube may include projections that extend from the tractor region, particularly or exclusively as it bends around during inverting (e.g., at the distal end of the device). These projections may remain flat or non-extending when the tractor is held in parallel with the elongate inversion support. Alternatively, the projections may extend at all times. In general, the tractor may be formed of a woven materials, knitted material, or laser-cut sheet of material. The knitted and/or woven materials may be fibrous materials (including natural fibers, synthetic fibers, etc.), polymeric materials, or the like. For example, the material (e.g., strands) forming the woven or knitted material may be one or more of: monofilament polymer, multifilament polymer, NiTi filament, NiTi tube with radiopaque metallic center, Cobalt chromium alloy filament, Cobalt chromium alloy tube with radiopaque metallic center, Nylon, Polyester, Polyethylene terephthalate, and Polypropylene. The sheets of material (e.g. a solid sheet of material) formed into the tractor region may be one or more of: polymeric material (e.g., PTFE), silicone materials, polyurethanes, shape memory alloys, stainless steels, etc. The sheets may be extruded, glued, or the like. The sheets may be cut to form pores and/or projections. For example, the sheets may include one or more laser-cut projections. Any of these apparatuses may be coated with a hydrophilic and/or hydrophobic coating, and/or may include pores. The tractor may have a

porosity of greater than >60% (greater than 70%, greater than 75%, greater than 80%, greater than 85%, etc., between 60-95, 65-95, 70-95%, etc.).

[00024] In any of the apparatuses described herein, the elongate inversion support catheter may be adapted to enhance rolling of the tractor region (inverting) over the distal end. For example, in any of the apparatuses described herein, the catheter may be configured so that the material hardness of the catheter decreases over the distal end of the catheter until the distal end opening, wherein the distal end opening has a material hardness that is greater than a material hardness of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile. The catheter distal end may be stiffer because it is thicker (e.g., it may be formed by inverting the distal end of the catheter back over itself, and/or it may be formed of a stiffer material than the adjacent more proximal region (including by including a reinforcing material).

[00025] In any of the apparatuses described herein, the flexible tractor tube may include one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating. In particular the tractor may include a uniform or non-uniform lubricious (e.g., hydrophilic) coating.

[00026] As mentioned, any of these apparatuses may include a puller, e.g., an elongate puller coupled to a distal end of the tractor. Any of these apparatuses may include an elongate puller within the catheter coupled to a distal end of the tractor. The elongate puller may comprise a hypotube having an inner lumen that is continuous with the guidewire lumen through the flexible tube.

[00027] In general, the tractor may be any appropriate length. For example, the tractor may be between 3 to 100 cm long (e.g., between 3 and 50 cm, between 3 and 40 cm, between 3 and 30 cm, between 3 and 20 cm, between 10 and 100 cm, between 10 and 50 cm, between 20 and 100 cm, between 20 and 50 cm, etc.).

[00028] In any of these apparatuses, the apparatus may be configured so that the tractor may be inverted and rolled into the catheter by applying less than 300 grams of force (e.g., less than 400 g of force, less than 300 g of force, less than 200 g of force, less than 100 g of force, less than 90 g of force, less 80 g of force, less than 70 g of force, less than 60 g of force, less than 50 g of force, less than 10 g of force, etc.) to a distal end of the flexible tube, e.g., by pulling the elongate puller. For example, as mentioned above, the apparatus may include a hydrophilic coating, a lubricant on the catheter and/or tractor, a sleeve between the tractor and catheter, etc. This force required to retract the tractor into the catheter typically refers to the force required to roll the tractor over the distal end of the tractor.

[00029] Any of the apparatuses described herein may be configured so that the tractor is highly soft, and therefore rolls around the distal end of the catheter forming the elongate inversion support easily without jamming and/or requiring a large force to roll the tractor over the distal end opening of the catheter. In particular, tractors having a low axial compression strength, that would, but for the elongate inversion support, typically buckle, have been found to prevent jamming of the elongate inversion support as the tractor inverts. In particular, unsupported tractors (e.g., tractor that are not rolling over a catheter supported annular opening) that are configured to collapse radially under an axial compression of less than about 500g of force (e.g., less than: about 500g force, about 400g force, about 300g force, about 200g force, about 150 g force, about 100 g force, about 50 g force, etc.) may be particularly helpful in preventing jamming. For most knitted, woven, and braided tractors, including those described herein, when the tractor is configured to withstand greater than this amount of axial compression force, the tractor may jam, and/or may require excessive force to invert. Thus, in any of the apparatuses and methods described herein, the tractor may be sufficiently soft such that without support from the catheter, the tractor collapses radially under an axial compression of less than 200g of force when inverting (and may instead buckle).

[00030] Further, in any of the apparatuses described herein, the tractor may be biased to expand to greater than the outer diameter of the catheter in a second configuration (that is inverted relative to the first configuration) where the tractor is extending over the outer diameter of the catheter. The same tractor may be biased to expand to greater than the inner diameter of the catheter of the elongate inversion support in the first (e.g., un-inverted), configuration where the tractor is within the catheter of the elongate inversion support. Thus, in relaxed configuration, prior to assembling with the elongate inversion support, the tractor may be oversized compared to the catheter of the elongate inversion support; the portion of the tractor that extends within the catheter of the elongate inversion support, referred to as “un-inverted,” may have an inner diameter that is greater than the inner diameter of the catheter, which may tend to drive the tractor toward the walls of the inner diameter of the catheter without collapsing down into the catheter. Further, the inner diameter of the tractor in the “inverted” configuration, e.g., the configuration of the portion that is doubled back over and along the catheter of the elongate inversion support, may be greater than the outer diameter of the catheter of the elongate inversion support. This arrangement may prevent jamming and an increased resistance between the tractor and the outside of the catheter of the elongate inversion support. The catheter may be biased to expand in both the inverted and

un-inverted configurations by, e.g., heat setting. The tractor may be inverted to transition between the first and second configurations by rolling over the distal end of the catheter; the terms “inverted” and “un-inverted” are therefore relative terms.

5 [00031] The annular bias may be biased to have an expanded, open configuration that has a slightly larger (e.g., greater than 5%, greater than 10%, greater than 15%, greater than 20%, greater than 25%, etc., larger than the expanded diameter of the flexible tractor tube. In addition, the annular bias may be relatively “stiffer” than the open (free) end of the flexible tractor tube, to prevent buckling, collapse, etc. In some variations, the annular bias has a smooth and/or curved edge to prevent getting caught on the elongate inversion support
10 catheter when it is inserted into the annular bias.

BRIEF DESCRIPTION OF THE DRAWINGS

[00032] The novel features of embodiments of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the
15 present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00033] FIGS. 1A-1H illustrate an example of an apparatus for mechanically removing an object such as a clot from a body region. FIG. 1A shows an example of an elongate inversion support catheter portion of an apparatus. At least the distal end of the elongate inversion support is configured as a catheter. FIG. 1B shows an enlarged view of a partial section of a distal end (opening) of the catheter of the elongate inversion support of FIG. 1A, showing the aperture formed by the distal end opening; FIG. 1C shows an example of a flexible tractor tube attached over a puller (the puller in this example is configured as a catheter). The tractor is shown in a first configuration. In some variations, the flexible tractor tube may be biased open, e.g., by heat setting, to have an outer diameter that is greater than the inner diameter of the catheter of the elongate inversion support, as shown in FIG. 1D. FIG. 1D shows the same distal tractor region of FIG. 1C with the expandable first end region expanded. This first configuration may be compressed down into the elongate inversion support and the distal end inverted over the catheter portion of the elongate inversion support, as shown in FIG. 1E. In FIG. 1E, the assembled mechanical thrombectomy apparatus includes an elongate inversion support catheter having a distal end and a distal end opening; the elongate puller extends within the elongate inversion support catheter and a flexible tractor tube is connected at one end to the elongate puller. The flexible tractor tube and puller may be extended through the

elongate inversion support catheter, including extended out of the distal end (e.g., by pulling the elongate inversion support catheter proximally and/or by pushing the elongate puller distally). The flexible tractor tube may initially be held in a collapsed first configuration (as shown in FIG. 1E) for positioning within a vessel; it may be deployed and expanded, as shown in FIG. 1F, with the elongate inversion support catheter positioned between the flexible tractor tube and the elongate puller. The flexible tractor tube may be biased so that in the second configuration (inverted over the distal end of the catheter), the tractor has a 'relaxed' outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support.

[00034] FIGS. 1G and 1H illustrate the use of the an apparatus such as the one shown in FIGS. 1E and 1F to remove a clot by drawing the flexible tractor tube proximally and/or advancing the catheter distally towards the clot so that the expandable first end region inverts as it is drawn into the distal end of the catheter, pulling the clot into the catheter.

[00035] FIG. 1I illustrates an alternative variation of a tractor and puller. In FIG. 1I, the tractor is shown attached to the distal end of a tapered or narrow puller; the distal end region is tapered, and includes a radiopaque marker at or near the attachment site to the tractor; the tractor may be knitted, braided, woven, etc. Thus, in some variations the distal end region of the puller may have a greater flexibility than the proximal end of the puller. The puller may be hollow (e.g., a catheter or hypotube) or solid (e.g., like a wire).

[00036] FIGS. 2A -2F illustrate an exemplary (in situ) method of deploying a mechanical thrombectomy apparatus designed in accordance with the disclosed embodiments. In FIG. 2A the elongate inversion support catheter (either alone or with a guidewire) is positioned within the vessel, near a clot. In some variations the flexible tractor tube and elongate puller may already be positioned within the elongate inversion support catheter, e.g., near the distal end, or it may be moved into position thereafter, as shown in FIG. 2B. In FIG. 2C, the flexible tractor tube is deployed out of the elongate inversion support catheter and allowed to expand. Thereafter, the elongate inversion support catheter is moved distally between the flexible tractor tube and the elongate puller, as shown in FIG. 2D. Once the elongate inversion support catheter is positioned distally between the flexible tractor tube and elongate puller, as shown in FIG. 2E, the flexible tractor tube may be rolled and inverted into the elongate inversion support catheter, as shown in FIG. 2F. In this example, the inverting flexible tractor tube is shown grabbing a clot may as it is inverted into the elongate inversion support catheter. The flexible tractor tube extends from the distal end opening of the elongate inversion support catheter and expands into an expanded second configuration; the flexible

tractor tube is biased to expand to between 1.1 and 4 times an outer diameter of the elongate inversion support catheter in an un-inverted configuration (e.g., FIG. 2D) and is further biased to expand to greater than 0.5x an inner diameter of the elongate inversion support catheter in an inverted configuration (when drawn into the catheter as shown in FIG. 2F).

[00037] FIGS. 3A-3B illustrate a first variation of an apparatus having an elongate puller with a stepped outer diameter into which the flexible tractor tube may be compressed. This configuration may provide improved mobility within the elongate inversion support catheter. This variation may also be readily adapted for application to a vacuum through the hollow elongate puller. In FIG. 3A the flexible tractor tube is collapsed. In FIG. 3B the flexible tractor tube is expanded, as shown.

[00038] FIGS. 4A-4C illustrate deployment of the elongate puller with a stepped outer diameter shown in FIGS. 3A-3B. In FIG. 4A the elongate puller is positioned at the distal end of the elongate inversion support catheter, and extended from the distal end opening of the catheter until the collapsed flexible tractor tube is expanded at least slightly, as shown in FIG. 4B. An annular bias, described in greater detail below, may be used in this variation as well. As shown in FIG. 4C, the elongate inversion support catheter may then be positioned between the flexible tractor tube and the elongate puller, so that the elongate inversion support catheter can support the flexible tractor tube until it can be pulled proximally by pulling the elongate puller to invert into the elongate inversion support catheter.

[00039] FIG. 5A-5F illustrate the use of the apparatus of FIG. 3A-3B, including an annular bias, to remove a thrombus (clot) from within a vessel. In FIG. 5A the elongate inversion support catheter is positioned near the clot in the vessel. The elongate pusher to which a flexible tractor tube is attached at a first end, with an annular bias on an open, free second end, is extended distally through the catheter and out of the distal end of the elongate inversion support catheter, as shown in FIG. 5B. In FIG. 5C, the annular bias holds the free end of the flexible tractor tube open. In some variations the flexible tractor tube is biased to expand to diameter that is slightly greater than the outer diameter of the catheter (e.g., greater than 1.1x the outer diameter of the elongate inversion support catheter), however the annular bias may be open even slightly more, and may be more rigid when expanded open, as shown. The elongate inversion support catheter may then be inserted distally through the annular bias and between the flexible tractor tube and the elongate puller, as shown in FIGS. 5D-5E. A vacuum may be applied through the elongate puller and/or elongate inversion support catheter, as shown in FIG. 5E. In FIG. 5F, withdrawing the elongate puller proximally (with or without a vacuum) to roll the flexible tractor over the distal end of the

elongate inversion support catheter so that it inverts into the elongate inversion support catheter may draw the clot into the elongate inversion support catheter, as shown.

[00040] FIGS. 6A-6F illustrate another variation of an apparatus including an annular bias on an open, free, end of the flexible tractor tube. In FIG. 6A, the elongate inversion support catheter is positioned, shown here with the optional use of a guidewire, within the lumen of the vessel. In FIG. 6B, the elongate puller and flexible tractor tube are positioned distally within the elongate inversion support catheter, also over the guidewire; the flexible tractor tube is attached at one end of the flexible tractor tube, with the other end of the flexible tractor tube attached to an annular bias at a free (loose) end. The guidewire may be removed or left in position when deploying the flexible tractor tube from the distal end of the elongate inversion support catheter. In FIG. 6C, the distal end of the puller including the entire flexible tractor tube is extended distally from the elongate inversion support catheter and the annular bias expands to a diameter that is greater than the outer diameter of the elongate inversion support catheter. In FIG. 6D and 6E, the elongate inversion support catheter is advanced distally within the annular bias and between the flexible tractor tube and the elongate puller, so that the elongate inversion support catheter may support the flexible tractor tube as it is pulled proximally by the elongate puller to invert over the distal end opening of the elongate inversion support catheter. The apparatus may be advanced (e.g., while pulling the elongate puller proximally) to grab and remove a clot from the vessel, as shown in FIG. 6E.

[00041] FIGS. 7A-7D illustrate four variations of annular biases that may be used to support the expanded open (free) end of the flexible tractor tube in any of the variations described herein. The vertical columns illustrate an expanded end view, an expanded side view, a collapsed end view (e.g., within the elongate inversion support catheter) and a side view shown attached to a flexible tractor tube, respectively, from left to right. In FIG. 7A, a ring-shaped annular bias is shown. In FIG. 7B the annular bias is a member having lobes or petals, which may predictably collapse when compressed (e.g., see the collapsed end view). In FIG. 7C the annular bias is a stent-like structure having a plurality of zig-zagging struts (members).

[00042] FIGS. 8A-8C illustrate an example of an apparatus including a flexible tractor tube having a stent-like annular bias (formed of a loop of a sinusoidally arranged strut(s) having a 0.002" thickness attached to the open end of a 144 end 0.00075" NiTi braid flexible tractor tube). FIGS. 8A shows the expanded annular bias, shown attached to the flexible

tractor tube in FIG. 8B. The flexible tractor tube with the annular bias of FIG. 8A is shown attached to an elongate puller in FIG. 8C.

[00043] FIG. 9A shows another example of a flexible tractor tube (144 end 0.00075" NiTi) having an annular bias. FIG. 9B shows the open end of the flexible tractor tube rolling over the open distal end of the elongate inversion support catheter. FIG. 9C shows a schematic of the stent-like annular bias including lead-in arms that may help it roll over the elongate inversion support catheter.

[00044] FIG. 10 illustrates an example of a flexible tractor tube that is heat-set at the open end to have an inverted shape to allow for ease of insertion of the elongate inversion support catheter. In FIG. 10, the open (loose) end of the flexible tractor tube folds back under itself which may help guide the elongate inversion support catheter into the space between the flexible tractor tube and the elongate puller. In this example, the flexible tractor tube may not require an additional annular bias.

DETAILED DESCRIPTION

[00045] In general, described herein are mechanical thrombectomy apparatuses having an inverting flexible tractor tube that is configured to be deployed in situ (e.g., within a catheter) without jamming. Any of these apparatuses may include an elongate elongate inversion support catheter over which the flexible tractor tube inverts at the distal end. In the deployment configuration, the flexible tractor tube may comprise a flexible tube that doubles back (e.g., inverts) over the distal end opening of the elongate inverting support catheter so that the tractor tube extends into the opening of the elongate inverting support catheter when the tractor tube is pulled proximally. The tractor tube may be attached at one end to an elongate puller. Pulling the elongate puller proximally will roll and invert the tractor over the distal end opening of the elongate inverting support catheter which may capture a clot and pull it into the elongate inversion support catheter.

[00046] Any of the apparatuses may include a coating (e.g., hydrophilic, lubricious coating, etc.) or the like to enhance the sliding and inverting of the tractor over the distal end. Further, any of these apparatuses may include one or more projections that are configured to enhance grabbing and/or maceration of a clot.

[00047] In general, a mechanical thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an elongate inversion support catheter having a distal end and a distal annulus (distal end opening), and a flexible tractor assembly

including a flexible tractor tube coupled to an elongate puller. The flexible tractor tube is configured to roll and invert over the distal end opening of the elongate inverting support catheter.

[00048] In many of the examples described herein, the tractor assembly is configured to extend within the elongate inversion support catheter when deployed. Any of these apparatuses may switch between a delivery configuration, e.g., in which the entire tractor assembly may be held within the elongate inversion support catheter prior to deployment, and a deployed configuration, e.g., in which the elongate inversion support catheter is positioned between the flexible tractor tube and the elongate pusher to support the flexible tractor tube as it is pulled into the elongate inversion support catheter distal end opening to roll and invert into the elongate inversion support catheter. In particular, the apparatuses may be configured so that the transition between the delivery configuration and the deployed configuration is robust. For example, as will be described in greater detail herein, any of the apparatuses described herein may include an annular bias that enhances the ability of the elongate inversion support catheter to be inserted between the flexible tractor tube and the elongate puller.

[00049] FIGS. 1A to 1I illustrate various components of a mechanical thrombectomy apparatus that may include any of the features described herein. For example, FIG. 1A shows a catheter (e.g., an elongate inversion support catheter) that may form part of the apparatuses described herein. In this example, the elongate inversion support catheter includes a catheter body 100 having a distal end region 103 that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing hardness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00050] In FIG. 1A, the elongate inversion support catheter is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled

over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include an elongate inversion support catheter that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like. In FIG. 1A the catheter 100 of the elongate inversion support catheter may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00051] In some variations the distal end 105 of the elongate inversion support is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in some variations the distal tip (end) may be curved or radiused 109 as shown in FIG. 1B, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[00052] FIG. 1C shows an example of a flexible tractor tube 144 coupled to an elongate puller 146, forming a pullable tractor assembly 140. In this example, the tractor tube is shown integrated with the puller and extending back over the puller, forming the assembly. The opposite end of the flexible tractor tube 147 is open and free (e.g., not connected to the puller or catheter). As will be described in greater detail below, this open, free, end may be adapted to be expanded and held open, e.g., by shape setting back on itself and/or by including an annular bias, to enhance deployment and positioning of the catheter between the flexible tractor tube and the puller. In FIG. 1C, the tractor tube is formed of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The tractor is shown extended from the puller in a first configuration. It may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 144 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The puller 146 may typically be a less-expandable (or non-expandable) structure (tube, puller, etc.). For example, the tractor 144 may be configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first

configuration to a radial diameter that is between 1.1 and 10 times (e.g., between 1.1x and 5x, between 1.1x and 4x, etc.) the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained. In FIG. 1D, the tractor tube has a larger expanded diameter than the variation shown in FIG. 1C in a relaxed configuration. In any of these variations, the expandable tractor may be biased to expand open. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00053] In FIGS. 1C and 1D the tractor and puller have two portions, a tractor tube 144 and a less expandable (or non-expandable) proximal portion comprising the elongate puller 146. The puller may be a separate region, such as a wire, catheter or hypotube, which is connected to an end region of the tractor (e.g., a flexible mesh, woven, braided, etc.), e.g., the distal end or near the distal end. The inverting region of the tractor, where it rolls and inverts over the distal end opening of the catheter may be referred to as the distal-facing region of the tractor, which may actively grab clot when rolling.

[00054] In FIG. 1E, the tractor assembly (flexible tractor tube 144 and puller 146 of FIG. 1D) are shown within an elongate inversion support catheter 100. The tractor is collapsed down 101, e.g., onto the puller, and may be held collapsed within the elongate inversion support catheter. Thus, FIG. 1E shows the pre-deployment (e.g., delivery) configuration. The tractor assembly may be axially movable (slidable) within the catheter so that it can be positioned within the catheter and within the vessel.

[00055] FIG. 1F shows a fully deployed apparatus. In FIG. 1F, the tractor tube is in an unconstrained or deployed configuration, and the elongate inversion support catheter is positioned between the tractor tube and the puller so that the tractor tube can be pulled proximally by pulling on the puller and rolling the tractor tube into the elongate inversion support catheter so that it inverts. In FIG. 1F, the tractor in this deployed configuration (e.g., the portion that is inverted over the distal end of the catheter) has an outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. Thus, the tractor 144 may be biased so that it has a relaxed expanded configuration with a diameter that is greater than the outer diameter (OD) of the elongate inversion support catheter; in addition, as will be described in relation to FIGS. 1G and 1H, below, the tractor tube may also be configured (e.g., by heat setting, etc.) so that when the tractor tube is inverted and pulled into the elongate inversion support catheter, the outer diameter of the inverted tractor tube has an outer diameter that is greater than 0.5x (e.g., greater than 0.6x, greater than 0.7x, greater than 0.75x, greater than 0.8x, greater than 0.9x, greater than 1x, etc.) the inner diameter (ID) of the

elongate inversion support catheter. This combination of an un-inverted diameter of the tractor tube of greater than the diameter of the OD of the elongate inversion support catheter and an inverted diameter of the tractor tube of greater than 0.7x the ID of the elongate inversion support catheter is surprisingly helpful for preventing jamming of the apparatus, both when deploying the apparatus and when rolling the tractor over the distal end opening of the elongate inversion support catheter to grab a clot. The tractor may be expandable and may be coupled to the puller as shown. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to elongate puller (e.g., a push/pull wire or catheter).

[00056] FIGS. 1G and 1H illustrate the removal of a clot using an apparatus such as the apparatus components of FIGS. 1A and 1E. The apparatus 10 is shown in a deployed state. In this example the thrombectomy apparatus 10 is configured as a thrombectomy apparatus including an elongate inversion support catheter 100 and a flexible tractor tube 144 that extends over the distal end region of the catheter and doubles-over itself at the distal end of the catheter to invert so that the external tractor end region is continuous with an inner, less-expandable (in this example, less-expandable includes non-expandable) second distal end region 146 (puller) that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The pusher/puller member that may be a rod or other member that is continuous with the distal end region of the tractor. In FIG. 1G the apparatus is shown positioned and deployed within the vessel 160 near a clot 155. The clot may be drawn into the catheter by pulling the tractor 140 proximally into the catheter 101, as indicated by the arrow 180 showing pulling of the inner portion of the flexible tractor (e.g., using a handle, not shown) resulting in rolling the tractor over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled into the catheter, shown by arrows 182. The end of the tractor outside of the catheter may be “loose” relative to the outer wall of the catheter. FIG. 1I illustrates another example of a tractor assembly 154 including a tractor tube 144 that is coupled to a puller 156. The puller in this example is tapered (having tapering region 161) and may therefore have a different flexibility of the distal end region than the proximal end region. For example the proximal end region may be less flexible than the narrower-diameter distal end region 195 to which the tractor is coupled. The assembly includes a radiopaque marker 165. The tractor may be attached to the puller by any appropriate means. For example, the tractor may be crimped, glued, fused, or otherwise attached to the puller, typically permanently.

[00057] In general the mechanical thrombectomy apparatuses described herein may be highly flexible, both before actuating and during operation. For example, the flexible tractor may not increase the stiffness/flexibility of the catheter of the elongate inversion support, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortuous vessels of the neurovasculature. Described herein are flexible tractor tube portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[00058] The tractors may be woven, braided and/or knitted materials. For woven and braided materials, which may include a plurality of fibers that are woven or braided to form the inverting tube, these structures may be tuned to prevent jamming and/or to reduce the force necessary to pull the tractor and invert over the catheter tip. For example, the mechanical atherectomy apparatus may include a braid-type tractor that can roll freely around the tip of catheter even in a tortuous anatomy and when grabbing clot by tuning one or more of the braid structure; minimizing the braid angle; including a hydrophilic coating on the distal aspect of the catheter outer diameter (OD) or the inner diameter (ID) of the braid (e.g., tractor); including a radiused wall on the catheter; and/or increasing the stiffness of the distal tip region relative to adjacent proximal regions.

[00059] As mentioned, the tractor (e.g., braided, woven, knitted, etc.) may be configured to collapse down into the inner diameter (ID) of the catheter as little as possible. For example the tractor may collapse to an ID that is greater than, equal to, or within 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter inner diameter (ID)/Catheter Tip OD, since, when the tractor is being pulled around catheter tip it may create axial tension on the tractor (e.g., braid, knit, etc.) that can inadvertently cause the tractor to jam on the catheter tip. When tractor is pulled around catheter tip, the tractor is being pulled in the axial orientation creating axial tension on tractor structure as the tractor is being pulled through the catheter ID. By having the tractor elements jam at an ID greater than or equal to 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter ID (or in some variations, OD), when being axially tensioned, the tractor is less likely to grab/synch down onto the catheter tip, helping the braid roll around

the catheter tip with less axial force applied by the user. If less axial force is required by the user to pull the tractor structure around the tip then the catheter tip is less likely to buckle or deflect when retracting the tractor. It may be advantageous to minimize the chance the catheter tip will buckle. The tractor can be tuned to "jam" at a specific ID by controlling any of the following variables and in any combination: selecting a specific number of braid ends, selecting the size/diameter of the braid ends; selecting the braid material (e.g., multifilament or monofilament); heat setting the bias on the braid (e.g., braid diameter); and selecting a braid pattern, e.g., 1x2, 1x1 or any other pattern.

[00060] The braid angle may be minimized to prevent locking up of the rolling of the tractor over the catheter end opening. Typically, the lower the braid angle (e.g., 45 degrees or less, 40 degrees or less, 35 degrees or less, 30 degrees or less, 25 degrees or less, 20 degrees or less, etc.) the less likely it is to have the braid cross over points catch on the catheter tip.

[00061] In any of the variations described herein, the catheter and/or a surface of the tractor may be coated to enhance rolling over the distal end region of the catheter. It may be helpful to have a hydrophilic coating on the distal aspect of the catheter OD or the ID of the tractor so the tractor can more easily slide over the catheter's distal end and around the tip of the catheter when pulled through the inside of the catheter.

[00062] The radius wall of the catheter tip may be chosen/set to within a range that allows sliding. For example, it may be helpful for the tip of the catheter to have the largest radius possible but at least 0.0025" radius wall on the catheter, ideally approximately 0.005" radius wall.

[00063] The stiffness of the distal of the catheter may be sufficiently stiff to prevent collapse as the tractor is pulled; it may also be lubricious (e.g., by a coating or material property). The distal most section of the catheter tip (e.g., the last 5mm) may be fabricated of a material which is stiff enough and lubricious enough so the distal tip of the catheter does not collapse or buckle inwardward when the braid structure is rolling around the catheter tip. Thus, the distal tip may have a stiffness that is greater than the more proximal region at the distal end of the catheter.

[00064] It may be helpful or desirable to have pores in the tractor. A lack of gaps or small pore size may limit the ability of the braid to grab clot. Alternatively or additionally, it may be desirable to form a braid structure with texture. One example is to braid two or more different diameter braid ends into the same structure: the difference in braid end diameters

will help form a texture to the braid structures outer surface, aiding the grabbing of the clot when rolling the braid-dozer around the catheter tip.

[00065] As an alternative (or in addition) the tractor may be configured to lock so it does not compress in diameter during axial load by adding a coating, laminate or adhesive to the braid at a desired diameter. Adding a thin coating, laminate or adhesive can inhibit the braid elements from sliding with respect to each other, thereby locking the braid to a specific diameter. The coating can be applied while leaving the majority of the pores and pore area substantially open. Examples of thin coatings include urethanes and silicones with and without hydrophilic coatings and hydrophilic coatings with no tie layer.

[00066] Reducing the sliding friction of tractor to outer catheter wall, improving tractor to tip rolling, and/or enhancing tractor to inner catheter sliding may also be achieved by including a sliding skin or sleeve. For example, a thin (e.g., ultrathin) sleeve may be used. The sleeve would be made from low friction polymer (PET, PE, PP, PTFE, ePTFE, pebax, urethanes) by braiding, knitting, weaving, extrusion, melt blown, melt spinning, etc. The sleeve could be made from laser slotted tubing, chemical etching, micro machining. The sleeve could be also coated with a lubricious coating such as a hydrophilic coating. Lubricious coatings can be located on the outside and/or inside surfaces. The sleeve may be placed between the dozer element and the catheter wall and attached to the puller element. The sleeve may be less than 0.002" thick, ideally, less than 0.001" wall thickness. The sleeve may decouple the tractor clot grabbing system from the catheter wall, tip rolling and inner catheter dragging friction. The sleeve could be totally free from the tractor, connected to the tractor in discrete locations or connected fully to the tractor. This may allow the tractor to be designed to grab clot (larger wires: 0.001" to 0.002" for neuro, and 0.002" to 0.007" for other applications) and the skin to minimized in thickness and structure to reduce friction and skin bending stiffness.

[00067] In some variations, the tractor region may be formed of with a mixed or hybrid structure, combining one or more of interwoven or knitted braid polymer filaments with metallic filaments. The mixed structure (hybrid structure) may leverage both metallic elements interwoven with low friction polymer elements. The metallic filaments may create stiffness elements that may grip/grab a clot. The polymer filaments may aid in grabbing clot but may provide surface friction reduction to the outer catheter wall, the catheter tip and the inner catheter wall once around the tip.

[00068] Any of the apparatuses described herein may include a tractor having a hydrophilic/lubricous coating on the inside surface, e.g., for braided/knitted tractors, on the

inside surface (contacting the outer and inner diameter of the catheter) of the braid/knit, which is in contact with the outside of the catheter. Examples of lubricous coatings include hydrophilic coatings (e.g., hydrogels) and hydrophobic coatings (e.g., fluorine coating such as PTFE & FEP, parylene, silicone, siloxane (silicone additive) added to various polymers including pebax to make any material more lubricious, Polyethylene, polypropylene, FEP)

5 [00069] As mentioned above, any of these apparatuses may include a distal tip that is less rigid (e.g., 'softer') than the more proximal regions of the distal tip. This may be achieved by having a structural supporting member reinforcing the distal tip, or by modifying the material forming the distal tip.

10 [00070] Any of the tractors described herein may include a marker or markers (e.g., radiopaque markers, such as gold, Pt, etc.).

[00071] For purposes of illustration and to better understand the disclosed apparatuses, FIGS. 2A-2F illustrate an in situ method of deploying a mechanical thrombectomy apparatus constructed according to embodiments of the present invention. In FIG. 2A the elongate inversion support catheter 201 is positioned within the vessel, near a clot 239, e.g., by moving the elongate inversion support catheter distally 210 towards the clot. The elongate inversion support catheter may be positioned with a guidewire (not shown), or without a guidewire. The tractor assembly portion of the apparatus, e.g., a flexible tractor tube 244 and elongate puller 245 may be positioned with the catheter, or it may be moved through the catheter once it is in position within the vessel. In FIG. 2B, the tractor assembly 240 is positioned within the elongate inversion support catheter near the distal end. Once it is in an approximate location (e.g., near the clot 239), the flexible tractor tube 244 may be extended 212 from the distal end of the elongate inversion support catheter, as shown in FIG. 2C. The flexible tractor tube may be deployed out of the elongate inversion support catheter by pulling 214 the elongate inversion support catheter proximally and/or pushing the flexible tractor tube distally; once out of the elongate inversion support catheter, the flexible tractor tube is allowed to expand into a second (expanded configuration) outside of the elongate inversion support catheter. As mentioned, the flexible tractor tube may be biased so that in this uninverted configuration the diameter of the flexible tractor tube is between 1.1x and 5x the OD of the elongate inversion support catheter (e.g., typically between 1.1x and 3x the OD of the elongate inversion support catheter, etc.). The elongate inversion support catheter may then be moved back distally, between the flexible tractor tube 244 and the elongate puller 245, as shown in FIG. 2D.

[00072] In practice, the catheter must fit into the open (free) end of the flexible tractor portion. The apparatus may be modified, e.g., by including an annular bias at or near the open end of the flexible tractor portion. Alternatively or additionally, the open end may be biased (e.g., heat set, shape set, etc.) to invert over or under itself.

5 [00073] In FIG. 2E, once the elongate inversion support catheter is positioned distally between the flexible tractor tube and elongate puller, the flexible tractor tube may be rolled and inverted 266 into the elongate inversion support catheter, as shown in FIG. 2F. In this example, the elongate puller 245 may be pulled through the elongate inversion support catheter proximally 218 to pull the flexible tractor tube proximally into the elongate inversion support catheter. In FIG. 2F, the rolling tractor is shown grabbing the clot 239, and inverting into the elongate inversion support catheter while pulling the clot into the elongate inversion support catheter. The flexible tractor tube in this example is biased to expand to between 1.1 and 4 times an outer diameter of the elongate inversion support catheter in an un-inverted configuration (e.g., FIG. 2D) and is further biased to expand to greater than 0.5x an inner diameter of the elongate inversion support catheter in an inverted configuration (when drawn into the catheter as shown in FIG. 2F).

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[00074] FIGS. 3A-3B illustrate another example of a tractor assembly including a flexible tractor tube 344 attached at one end to an elongate puller 345. In this example, similar to FIG. 1I, the elongate puller has a stepped profile. The narrower-diameter region formed in the elongate puller by the stepped profile may allow the flexible tractor tube of the tractor assembly 334 to be compressed with a smaller profile within the elongate inversion support catheter. In FIG. 3A the flexible tractor tube 344 is shown collapsed (compressed) against the elongate puller. This configuration may provide improved mobility within the elongate inversion support catheter. This variation may also be readily adapted for application to a vacuum through the hollow elongate puller. In FIG. 3A the flexible tractor tube is shown as compressed or collapsed. FIG. 3B shows the flexible tractor tube in an expanded configuration. In this example, the flexible tractor tube 244 is expanded outward from the puller. The tractor tube may be biased (e.g., heat set, shape set, etc.) in this configuration. Alternatively or additionally, the apparatus may be compressed and held within an elongate inversion support catheter.

[00075] FIGS. 4A-4C illustrate deployment of the elongate puller with a stepped outer diameter, such as the variation shown in FIGS. 3A-3B, from a delivery configuration to a deployed configuration. In FIG. 4A the elongate puller 445 is positioned at the distal end of the elongate inversion support catheter 401; the flexible tractor tube 444 is attached at one

end to the puller. In FIG. 4B, the flexible tractor tube 444 is extended from the distal end opening of the elongate inversion support catheter and expanded 449 at least slightly. In this example, the elongate inversion support catheter 401 may be withdrawn proximally 410. An annular bias, described in greater detail below, may be used in this variation as well, to hold the free, open end 433 of the tractor tube 444 open. As shown in FIG. 4C, the elongate inversion support catheter 401 may then be positioned 412 between the flexible tractor tube 444 and the elongate puller 445, so that the elongate inversion support catheter 401 can support the flexible tractor tube at the distal end so that it can roll and invert into the elongate inversion support catheter, e.g., by pulling the elongate puller to invert into the elongate inversion support catheter.

[00076] FIG. 5A-5F illustrate the use of the apparatus of FIGS. 3A-3B, including an annular bias, to remove a thrombus (clot) from within a vessel. In FIG. 5A the elongate inversion support catheter 501 is positioned near a clot 539 in the vessel 550. The elongate pusher 545, to which a flexible tractor tube 544 is attached, forming a tractor assembly, may be positioned in the elongate inversion support catheter at the distal end. In FIG. 5B the elongate pusher is attached to the first end of the tractor tube 544 at a first end, with an annular bias open and unsecured (e.g., free) at the second end. The second, open or free end 533 may include one or more annular biases 525 that may be extended distally through the catheter and out of the distal end of the elongate inversion support catheter 501, as shown in FIG. 5B. In FIG. 5C, the annular bias 525 holds the free end 533 of the flexible tractor tube open. Alternatively or additionally, the flexible tractor tube may be biased to expand to diameter that is slightly greater than the outer diameter of the catheter 501 (e.g., greater than 1.1x the outer diameter of the elongate inversion support catheter), however the annular bias 525 may be open even slightly more, and may be stiffer (e.g., more rigid) when expanded open, as shown in FIG. 5C. The elongate inversion support catheter 501 may then be inserted distally through the annular bias 525 and between the flexible tractor tube 544 and the elongate puller 545, as shown in FIGS. 5D-5E. The entire apparatus may be advanced distally 552, either before or while rolling the tractor into the elongate inversion support catheter 501. A vacuum 560 (optional) may be applied through the elongate puller 544 and/or elongate inversion support catheter and/or the puller may be drawn proximally 554, as shown in FIG. 5E. In FIG. 5F, withdrawing 556 the elongate puller proximally (with or without a vacuum) to roll the flexible tractor over the distal end of the elongate inversion support catheter so that it inverts into the elongate inversion support catheter may draw the clot into the elongate inversion support catheter, as shown.

[00077] The variations shown in FIGS. 3A-3B, 4A-4C and 5A-5F having a stepped outer diameter in the puller may maximize the inner diameter of the tractor assembly, which may aid in aspiration (mechanical or by vacuum). In any of these variations, a vacuum can be applied to the apparatus (e.g., the tractor assembly) and/or the elongate inversion support catheter. In some variations the OD of the puller along at least part of its length (e.g., proximal to the free end of the tractor tube) may be approximately the same as the ID of the elongate inversion support catheter. This may aid in forming a seal such that vacuum applied through the elongate puller may be maintained the distal end of the elongate inversion support catheter and/or puller, which may help in grabbing the clot.

[00078] FIGS. 6A-6F illustrate another variation of an apparatus including an annular bias 625 on an open, free, end 638 of the flexible tractor tube 644. In FIG. 6A, the elongate inversion support catheter 601 is positioned in the vessel. In FIG. 6A, a guidewire 671 is shown. The catheter may be advanced over the guidewire, to approach the clot 639. In FIG. 6B, the elongate puller 645 and flexible tractor tube 644 are positioned distally within the elongate inversion support catheter 601, also over the guidewire 671. The tractor assembly includes the flexible tractor tube 644 attached at one end to the elongate puller 645, with the other end of the flexible tractor tube open and free (e.g., not attached to the puller or catheter), but coupled to an annular bias 625. The guidewire 671 may be removed or left in position when deploying the flexible tractor tube from the distal end of the elongate inversion support catheter. In FIG. 6C, the tractor assembly, including the distal end of the elongate puller 645 and the entire flexible tractor tube 644 is extended distally from the elongate inversion support catheter 601. The annular bias 625 expands 674 to a diameter that is greater than the outer diameter of the elongate inversion support catheter 601 (e.g., greater than 1.1x the diameter of the elongate inversion support catheter). The annular bias may also act to stiffen or otherwise stabilize this end region of the tractor tube (which may be on or near the open end of the tractor tube) so that the elongate inversion support catheter 601 can be inserted through the annular bias, as shown in FIG. 6D.

[00079] In FIG. 6D and 6E, the elongate inversion support catheter 601 is advanced distally 671 within the annular bias and between the flexible tractor tube 644 and the elongate puller 645, so that the elongate inversion support catheter can support the flexible tractor tube 644 as it is pulled 678 proximally by the elongate puller 645 to roll 663 and invert over the distal end opening of the elongate inversion support catheter (as shown in FIG. 6F). The apparatus may be advanced (e.g., while pulling the elongate puller proximally) to grab and remove a clot 639 from the vessel, as shown in FIG. 6E.

[00080] In any of these variations, the annular bias may be configured to keep the free end of the tractor tube open when deployed. The annular bias may be welded braided, bonded, glued and/or integral to the tractor tube. The annular bias may be attached to an outside, an inside or both (e.g., may be folded over the open end of the tractor tube, or may be attached on either side of the tractor tube).

[00081] FIGS. 7A-7D illustrate four variations of annular biases that may be used to support the expanded open (free) end of the flexible tractor tube in any of the variations described herein. For example, FIG. 7A shows an annular bias forming a circular loop in the expanded end view. The loop may be formed of a shape memory material, such as Nitinol, or a polymeric material. The loop may be orthogonal to the braid or weave of the tractor tube, which may aid in compressing when rolling over the distal end opening of the elongate inversion support catheter. In some variations the annular bias may be heat set to an irregular circular shape to aid in folding or may include buckling points around the perimeter of the annular bias. In the side view shown of the annular bias of FIG. 7A the annular bias is angled relative to the long axis of the tractor tube; alternatively, the annular bias may be attached perpendicular to the long axis (similar to FIG. 7B).

[00082] In any of the variations described herein, the annular bias may be configured to include one or more predetermined collapse/expansion locations about which the annular bias is configured to collapse or expand as it transitions between an expanded and a collapsed configuration. For example, the predetermined locations may be defined by the one or more lobes or vertices forming the annular bias. FIG. 7B shows an example in which the annular bias includes folds or bends that may control the collapsed configuration. In this example, the annular bias has lobes or petals, which may predictably collapse when compressed (e.g., see the collapsed end view). The annular bias may be shaped to compress into a small diameter as the tractor tube rolls around the tip of the elongate inversion support catheter. The u-shaped features (lobes, petals, etc.) at noon, 3 o'clock, 6 o'clock, and 9 o'clock are one example. Other examples include the use of fewer (e.g., 2 lobes, 3 lobes) or more (e.g., 5 lobes, 6 lobes, etc.).

[00083] In general, the annular bias has a stiffness that is greater than the stiffness of the flexible tractor tube (e.g., greater than 1.5x the stiffness, greater than 2x the stiffness, etc.).

[00084] In FIG. 7C the annular bias is a stent-like structure having a plurality of zig-zagging struts (members). The stent-like annular bias may easily invert when rolling around the catheter tip. The length of the zig-zags may be limited to < about 5-10 mm. In some variation multiple rows of zig-zags may be used.

[00085] FIG. 7D shows an example of an annular bias that is funnel-shaped. In operation, this structure may both help the insertion of the elongate inversion support catheter between the tractor tube and the elongate puller, and may also help with inverting the end of the tractor tube and pulling it into the elongate inversion support catheter.

[00086] An example of a stent-like annular bias is shown in FIGS. 8A-8C. In this example the annular bias is formed of a sinusoidally arranged loop of wire (though multiple wires/struts may be used) having a 0.002" thickness, which is attached to the open end region of a 144 end 0.00075" NiTi braid flexible tractor tube. FIGS. 8A shows the expanded annular bias 803, shown attached to a flexible tractor tube 801 in FIG. 8B. The flexible tractor tube 801 with the annular bias 803 of FIG. 8A is shown attached to an elongate puller 805 in FIG. 8C. In the example shown in FIG. 8, the annular bias is attached near the open (free) end of the tractor tube at the distal end region, but is slightly distal to the end. In some variations the annular bias is attached at the very end (or edge) of the open end of the flexible tractor tube.

[00087] Any of the annular biases described herein may also be configured to enhance rolling of the distal end of the apparatus over the tip of the elongate inversion support catheter. For example, FIG. 9A shows another example of a flexible tractor tube (144 end 0.00075" NiTi) having an annular bias, being rolled 961 into the elongate inversion support catheter by pulling proximally on the tractor tube. In FIG. 9B the open end of the flexible tractor tube (with an attached stent-like annular bias 903) is shown rolling over the open distal end of the elongate inversion support catheter. In order to enhance this rolling, in some variations, the annular bias may also include one or more extension (e.g., lead in arms) that may extend along the long axis (length) of the flexible tractor tube. A schematic of this configuration is shown in FIG. 9C. In FIG. 9C the stent-like annular bias includes lead-in arms that may help it roll over the elongate inversion support catheter. The lead-in arms may help the annular bias to roll around the catheter tip and into the ID of the elongate inversion support catheter. One or more (e.g., 1, 2, 3, 4, 5, 6, 7, 8, etc.) lead-in arms may be used; these lead in arms may be all the same length or different lengths.

[00088] FIG. 10 illustrates an example of a flexible tractor tube 1001 that is heat-set at the open end to have an inverted shape 1003 to allow for ease of insertion of the elongate inversion support catheter. In FIG. 10, the open (loose) end of the flexible tractor tube folds back under itself which may help guide the elongate inversion support catheter into the space between the flexible tractor tube 1001 and the elongate puller 1005. In this example, the flexible tractor tube may not require an additional annular bias.

[00089] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[00090] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[00091] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[00092] Although the terms “first” and “second” may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below
5 could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[00093] Throughout this specification and the claims which follow, unless the context requires otherwise, the word “comprise”, and variations such as “comprises” and
10 “comprising” means various components can be co-jointly employed in the claimed articles (e.g., compositions and apparatuses including devices and systems). For example, the term “comprising” will be understood to imply the inclusion of any stated elements but not the exclusion of any other elements.

[00094] In general, any of the apparatuses described herein should be understood to be
15 inclusive, but all or a sub-set of the components and/or steps may alternatively be exclusive, and may be expressed as “consisting of” or alternatively “consisting essentially of” the various components, steps, sub-components or sub-steps.

[00095] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word
20 “about” or “approximately,” even if the term does not expressly appear. The phrase “about” or “approximately” may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value
25 (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For example, if the value “10” is disclosed, then “about 10” is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also
30 understood that when a value is disclosed that “less than or equal to” the value, “greater than or equal to the value” and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value “X” is disclosed the “less than or equal to X” as well as “greater than or equal to X” (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a

number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point “10” and a particular data point “15” are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[00096] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[00097] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term “invention” merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

1. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

- 5 an elongate inversion support catheter having a distal end and a distal end opening;
 an elongate puller extending within the elongate inversion support catheter;
 a flexible tractor tube having a free first end and a second end that is coupled to
 a distal end region of the elongate puller, wherein the flexible tractor
10 tube is inverted over the elongate puller and is held within the elongate inversion support catheter in a collapsed first configuration; and
 an annular bias disposed at least partially around the free first end of the flexible tractor tube,
 wherein the flexible tractor tube is configured to be extended from the distal end
15 opening of the elongate inversion support catheter and to expand into an expanded second configuration, and
 wherein the annular bias has a diameter that is larger than an outer diameter of the elongate inversion support catheter when the flexible tractor tube is in the expanded second configuration.
- 20 2. The apparatus of claim 1, wherein the annular bias comprises a ring.
3. The apparatus of claim 1, wherein the annular bias comprises a stent having a zig-zag strut pattern.
4. The apparatus of any of claims 1-3, wherein the annular bias has a diameter that is between 1.1x and 5x of the outer diameter of the elongate inversion support catheter
25 when the flexible tractor tube is in the expanded second configuration.
5. The apparatus of any of claims 1-4, wherein the annular bias comprises a plurality of pre-determined collapse locations about which the annular bias is configured to collapse or expand.
6. The apparatus of any of claims 1-4, wherein the annular bias comprises a plurality of
30 lobes, wherein the plurality of lobes comprise a respective plurality of collapse locations on the annular bias.

7. The apparatus of any of claims 1-6, wherein the annular bias is coupled to one or more of an inner side and an outer side of the flexible tractor tube.
8. The apparatus of any of claims 1-7, wherein the annular bias comprises a plurality of lead-in arms oriented along a long axis of the flexible tractor tube.
- 5 9. The apparatus of any of claims 1-8, further wherein the flexible tractor tube in an un-inverted configuration is biased to expand to between 1.1 and 4 times an outer diameter of the elongate inversion support catheter and wherein the flexible tractor tube is further biased in an inverted configuration to expand to greater than 0.5x an inner diameter of the elongate inversion support catheter.
- 10 10. The apparatus of any of claims 1-9, wherein the elongate inversion support catheter is configured to be pushed through the annular bias and between the flexible tractor tube and an outer wall of the elongate puller when the flexible tractor tube is in the expanded second configuration.
- 15 11. The apparatus of any of claims 1-10, wherein the flexible tractor tube comprises a woven, braided, mesh or knitted material.
12. The apparatus of any of claims 1-11, wherein the flexible tractor tube is sufficiently soft so as to collapse radially under an axial compression of less than 200g of force.
13. The apparatus of any of claims 1-12, further comprising a guidewire lumen extending through the elongate puller, the guidewire lumen being configured to allow passage of
20 a guidewire therethrough.
14. The apparatus of claim 11, wherein the flexible tractor tube is knitted.
15. The apparatus of any of claims 1-14, wherein the flexible tractor tube comprises one or more of steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, and a fabric.
- 25 16. The apparatus of any of claims 1-15, wherein a material hardness of the elongate inversion support catheter decreases along a length of the distal end thereof, wherein the distal end opening has a material hardness that is greater than a material hardness

of a region immediately proximal to the distal end, and wherein the distal end opening has a rounded lip profile.

17. The apparatus of any of claims 1-15, wherein the elongate puller comprises a hypotube.

5 18. The apparatus of any of claims 1-17, wherein the flexible tractor tube has a length between 3 cm to 50 cm.

19. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

10 an elongate inversion support catheter having a distal end and a distal end opening;
an elongate puller extending within the elongate inversion support catheter, wherein the elongate puller comprises a central lumen;
a flexible tractor tube having a free first end and a second end that is coupled to a distal end region of the elongate puller, wherein the flexible tractor tube
15 comprises a woven, braided, mesh and/or knitted material, is inverted over the elongate puller, and is held within the elongate inversion support catheter in a collapsed first configuration, and wherein the flexible tractor tube is biased in an un-inverted configuration to expand to between 1.1 and 4 times an outer diameter of the elongate inversion support catheter in and is further
20 biased in an inverted configuration to expand to greater than 0.5x an inner diameter of the elongate inversion support catheter; and
an annular bias disposed at least partially around the free first end of the flexible tractor tube, wherein the flexible tractor tube is configured to be extended from the distal end opening of the elongate inversion support catheter and to
25 expand into an expanded second configuration, wherein the annular bias has a diameter that is larger than an outer diameter of the elongate inversion support catheter in the expanded second configuration so that the elongate inversion support catheter may be pushed through the annular bias and between the flexible tractor tube and an outer wall of the elongate puller.

30

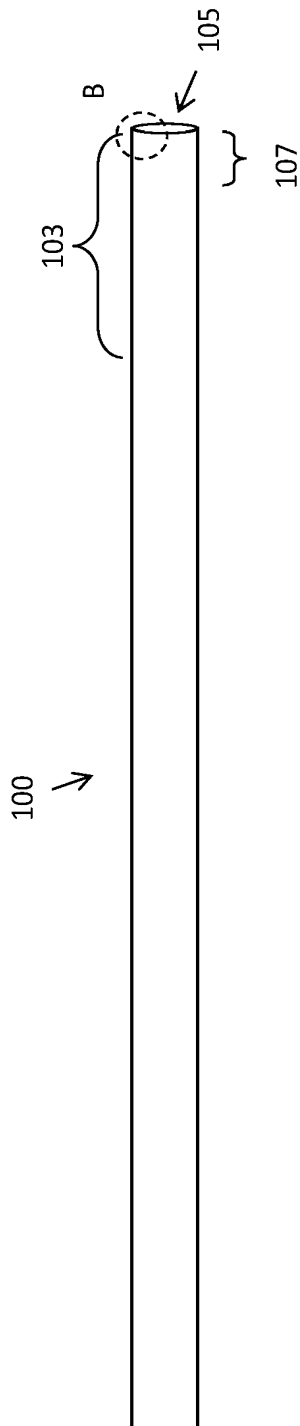


FIG. 1A

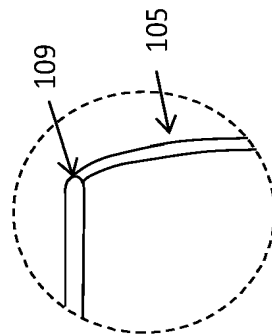


FIG. 1B

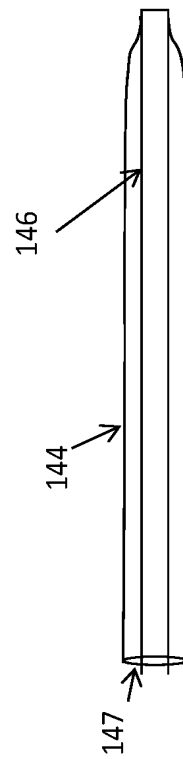


FIG. 1C

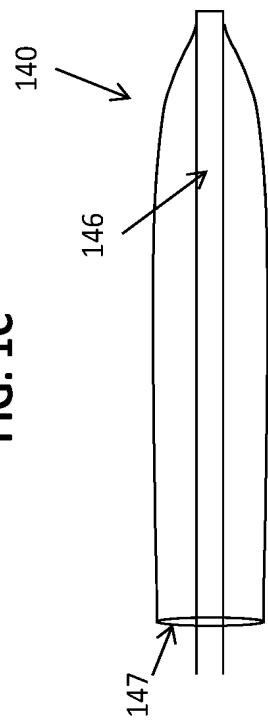


FIG. 1D

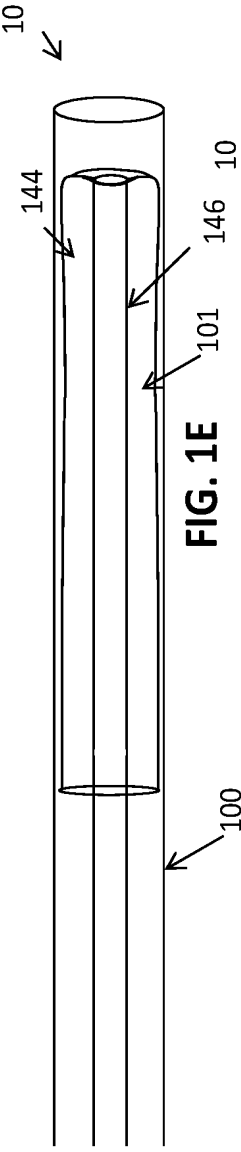


FIG. 1E

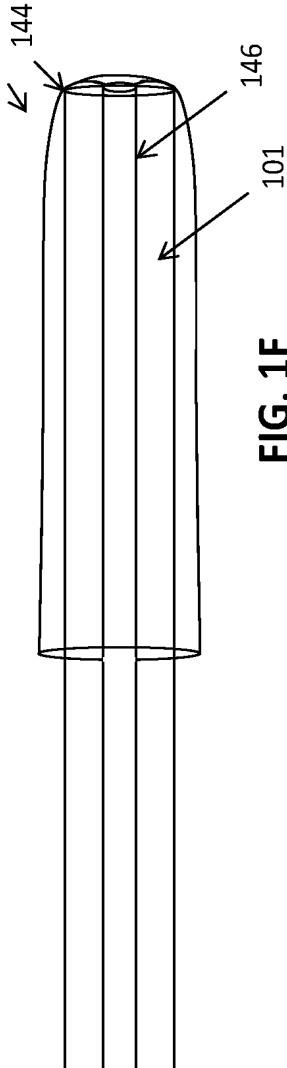


FIG. 1F

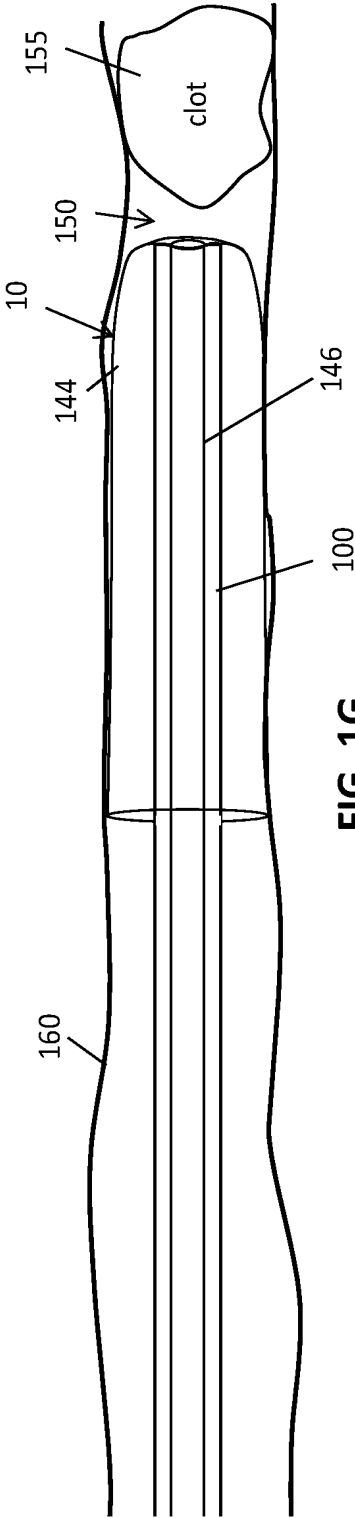


FIG. 1G

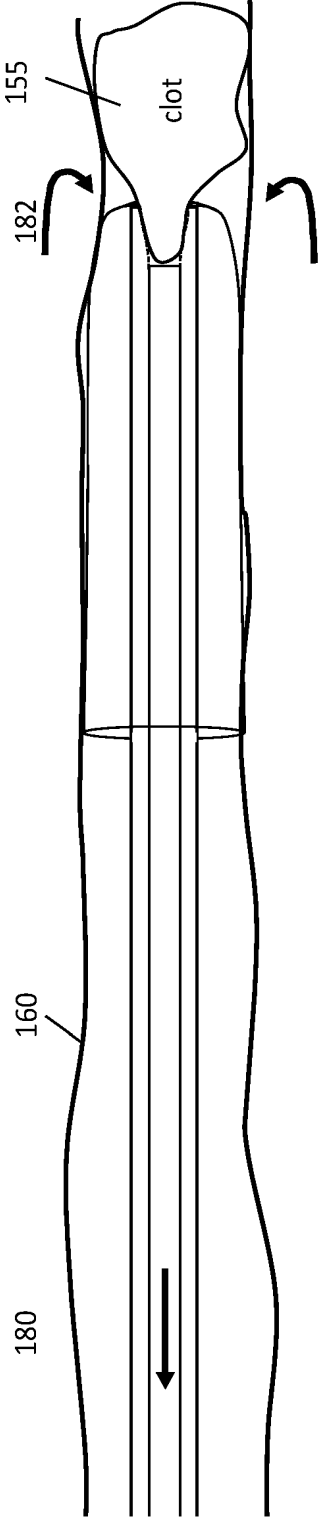


FIG. 1H

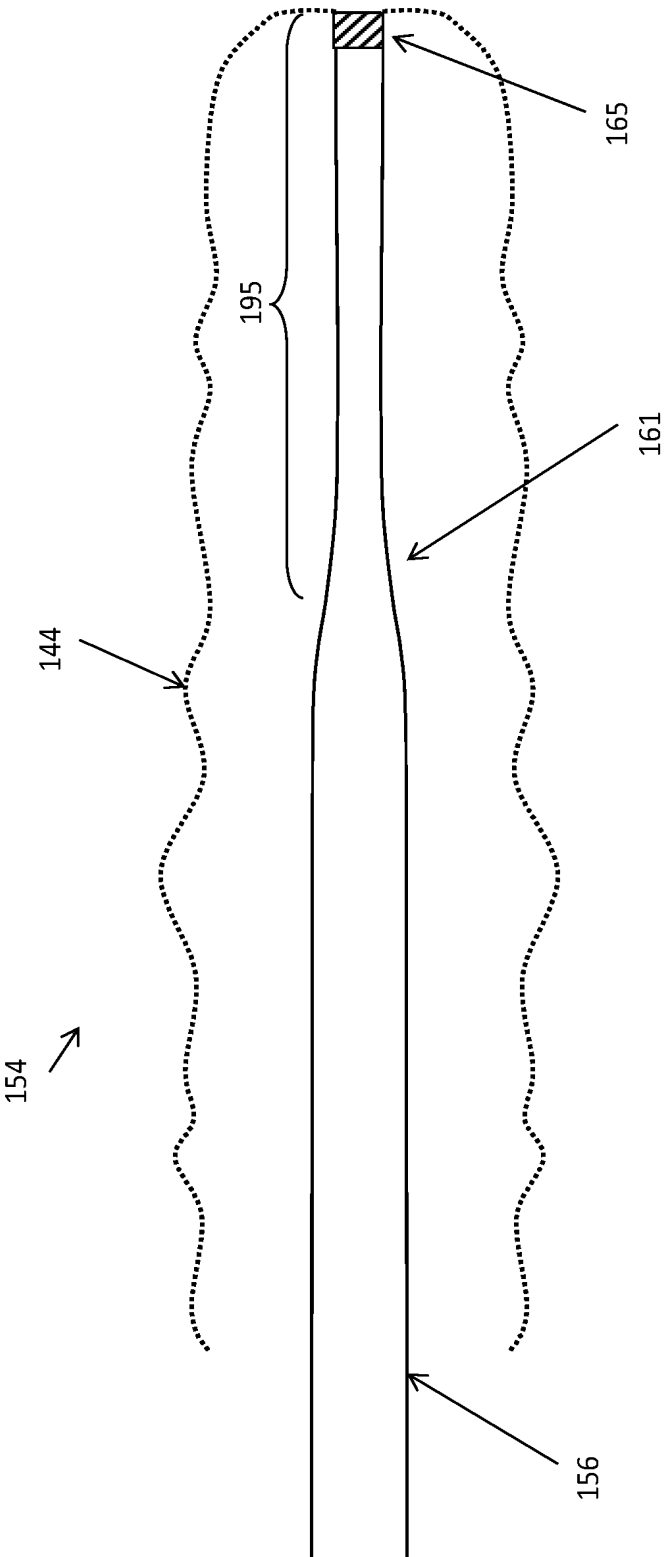


FIG. 1I

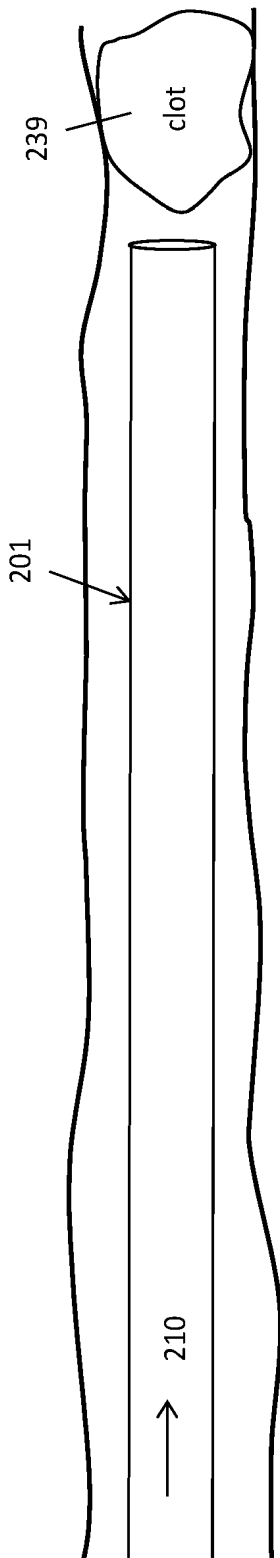


FIG. 2A

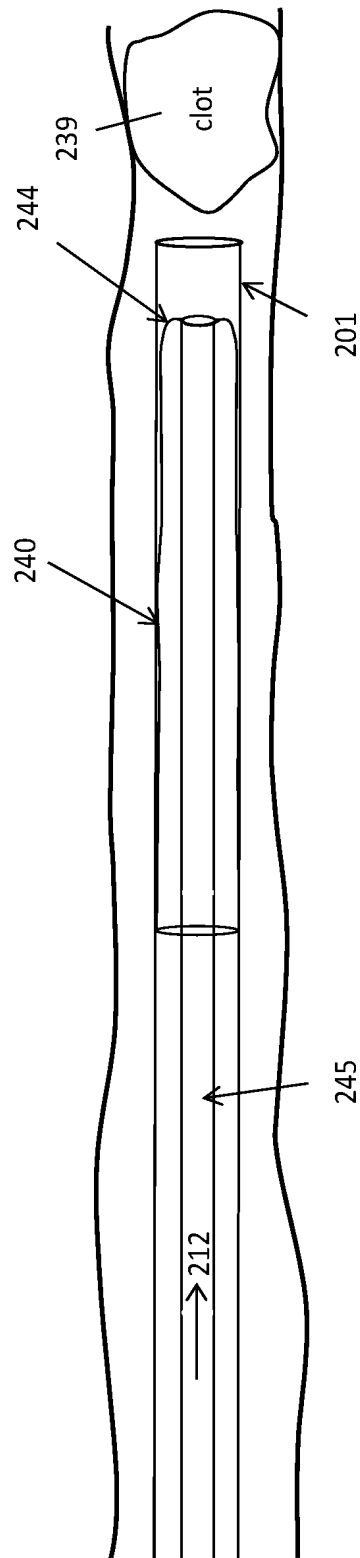


FIG. 2B

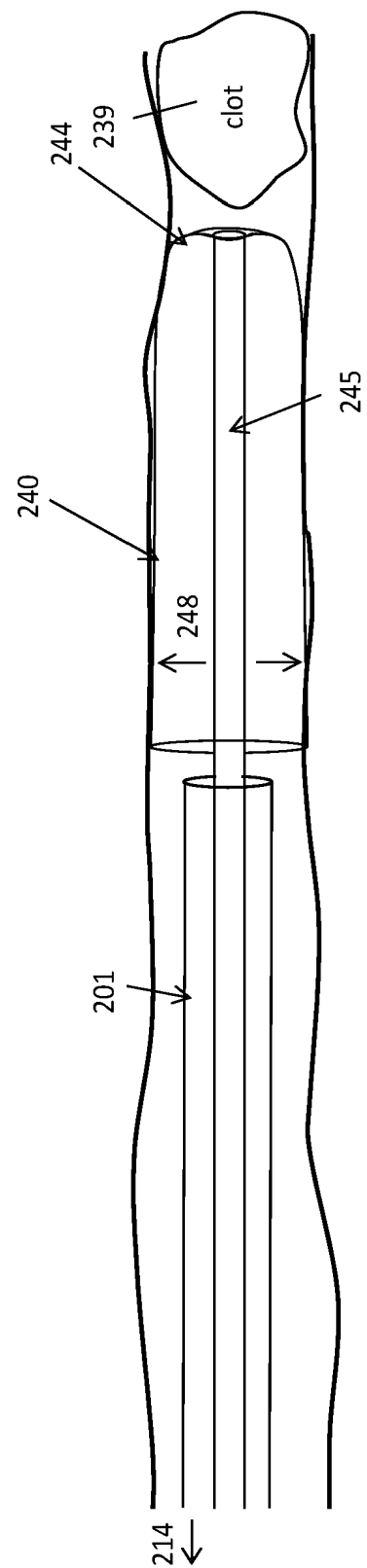


FIG. 2C

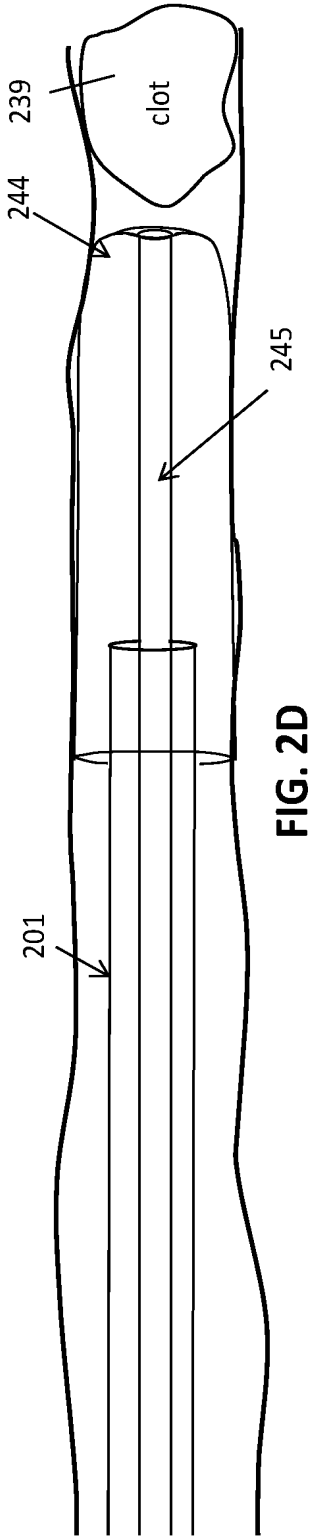


FIG. 2D

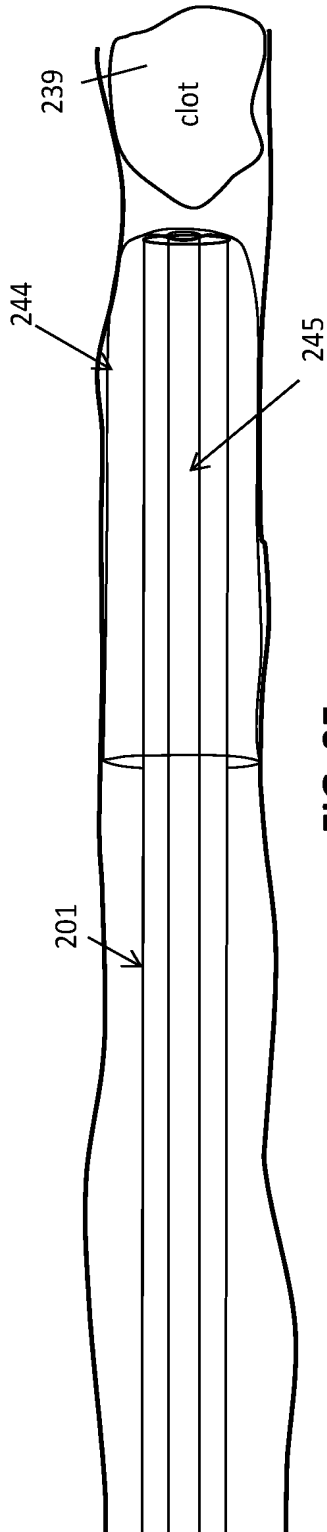


FIG. 2E

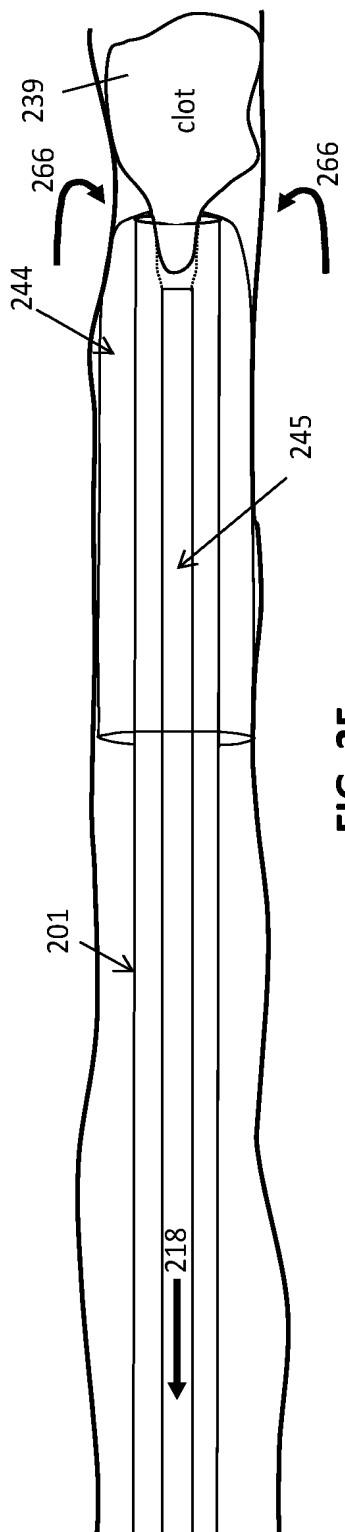


FIG. 2F

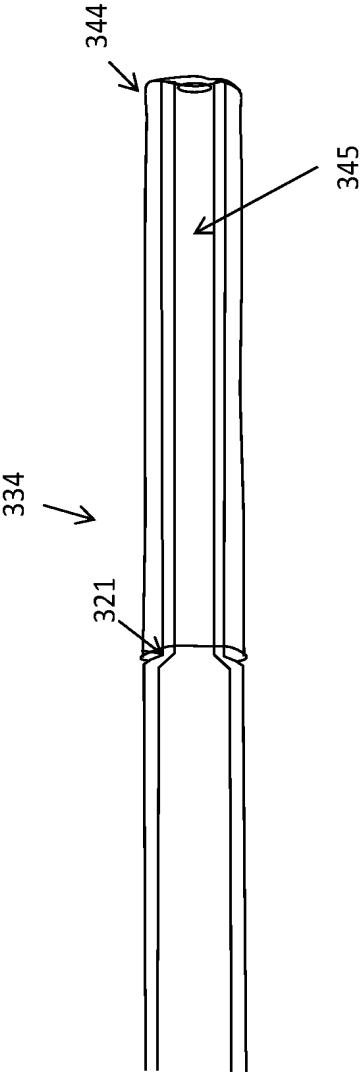


FIG. 3A

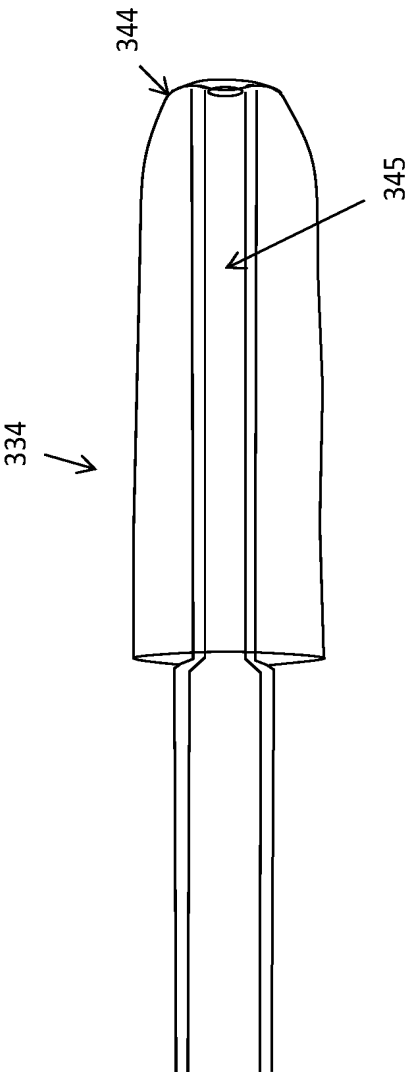


FIG. 3B

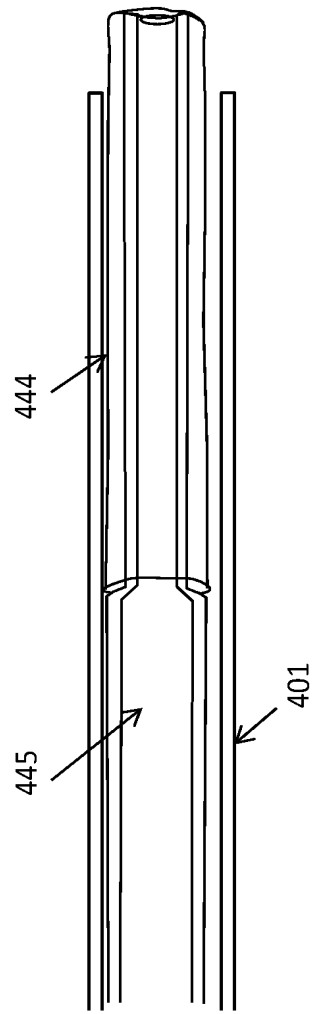


FIG. 4A

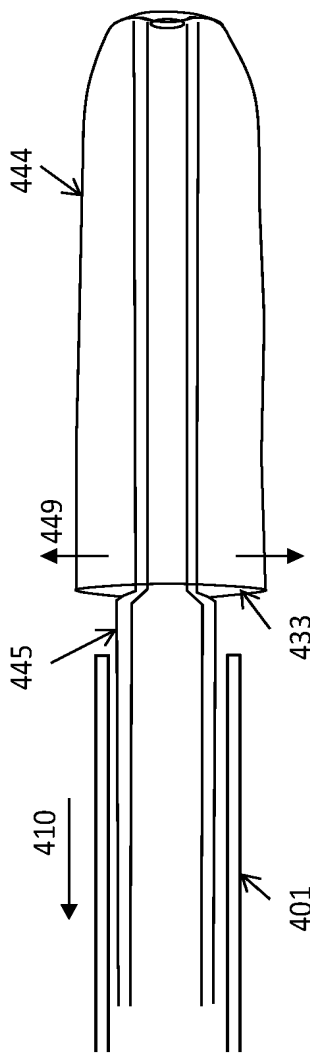


FIG. 4B

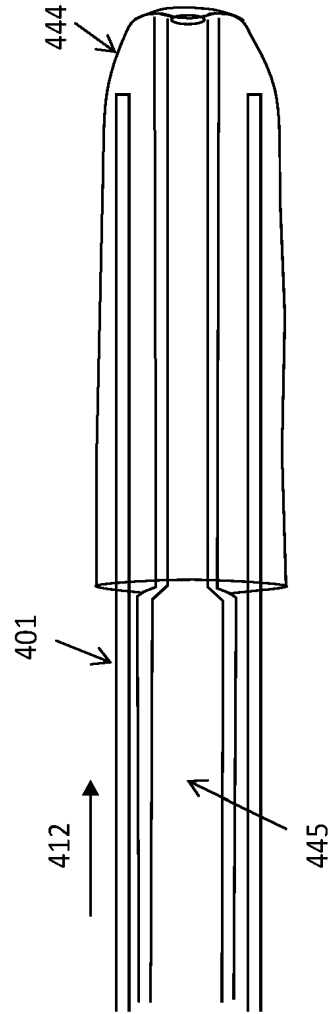


FIG. 4C

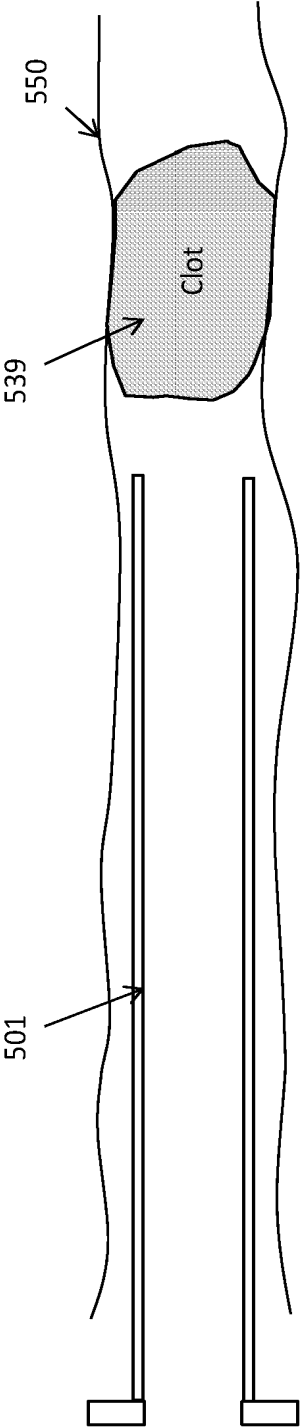


FIG. 5A

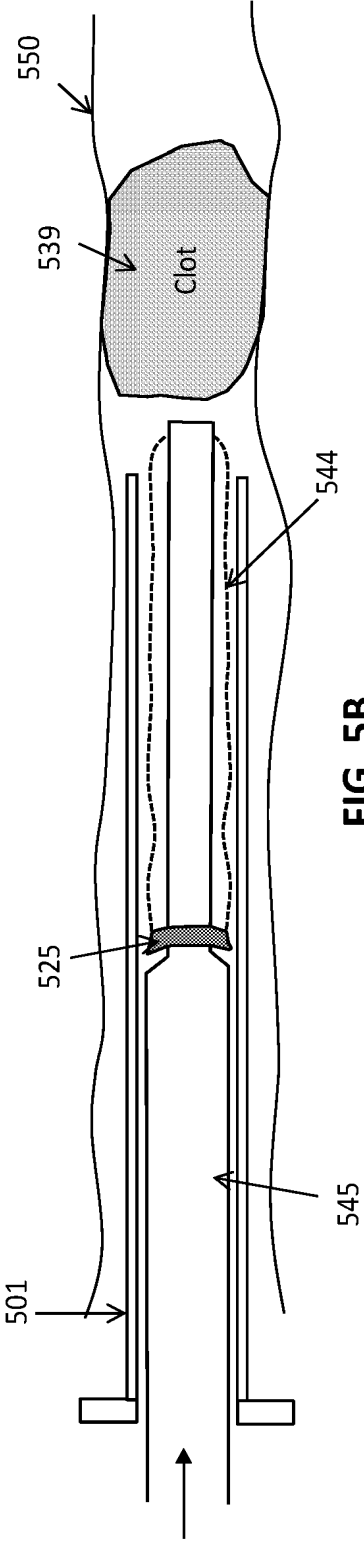


FIG. 5B

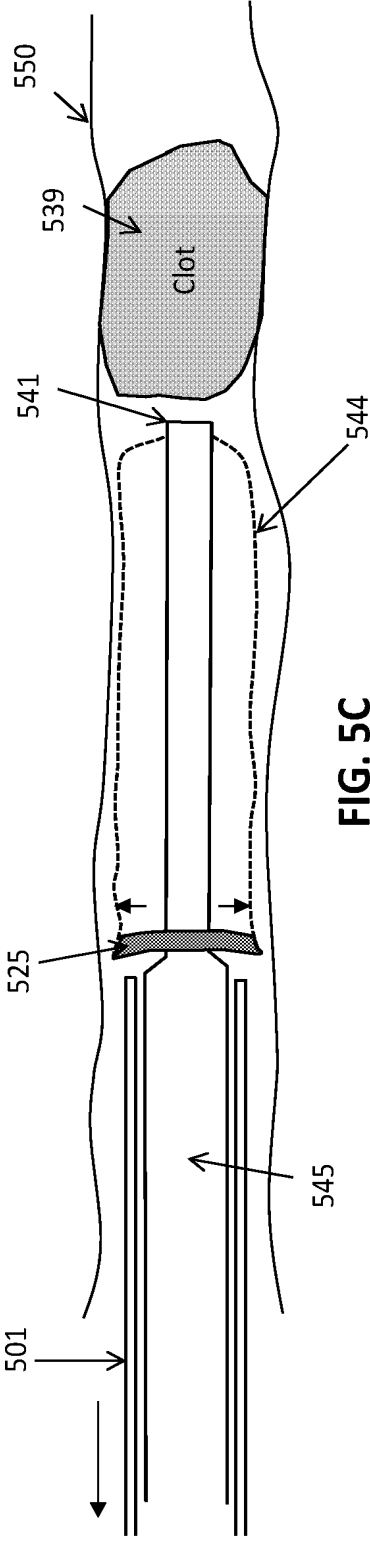
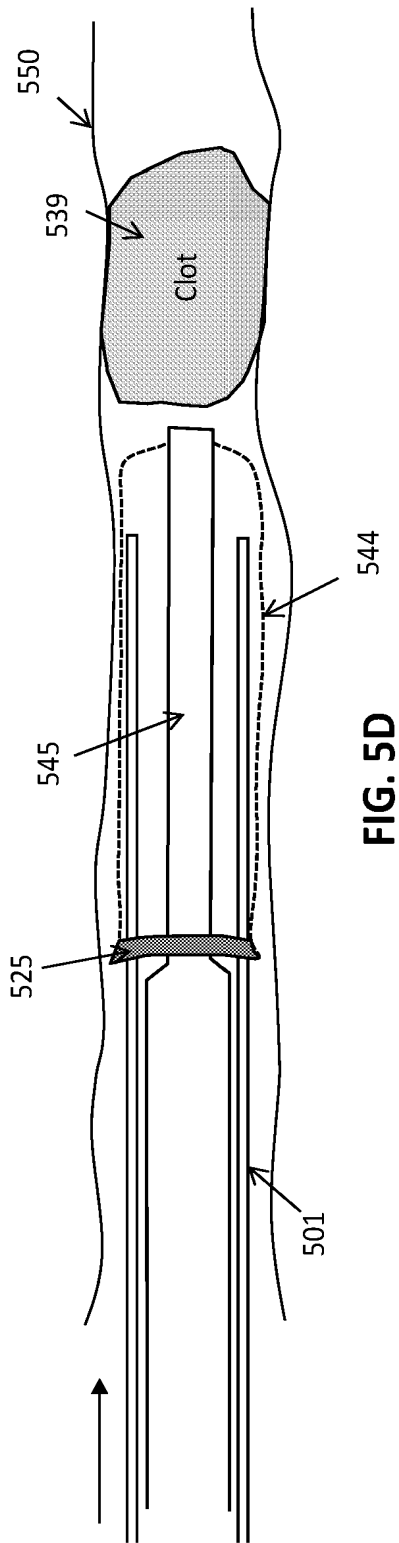
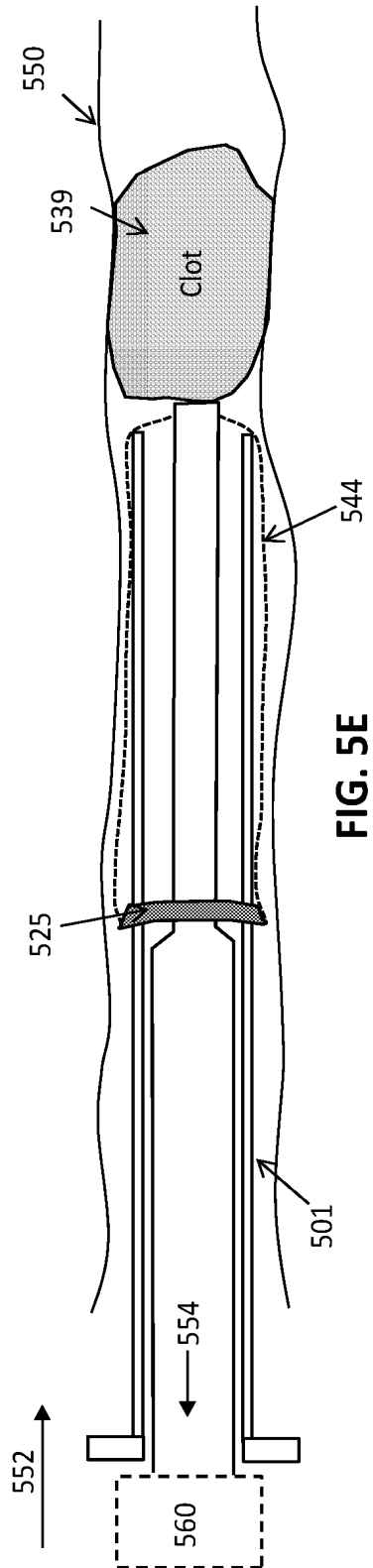
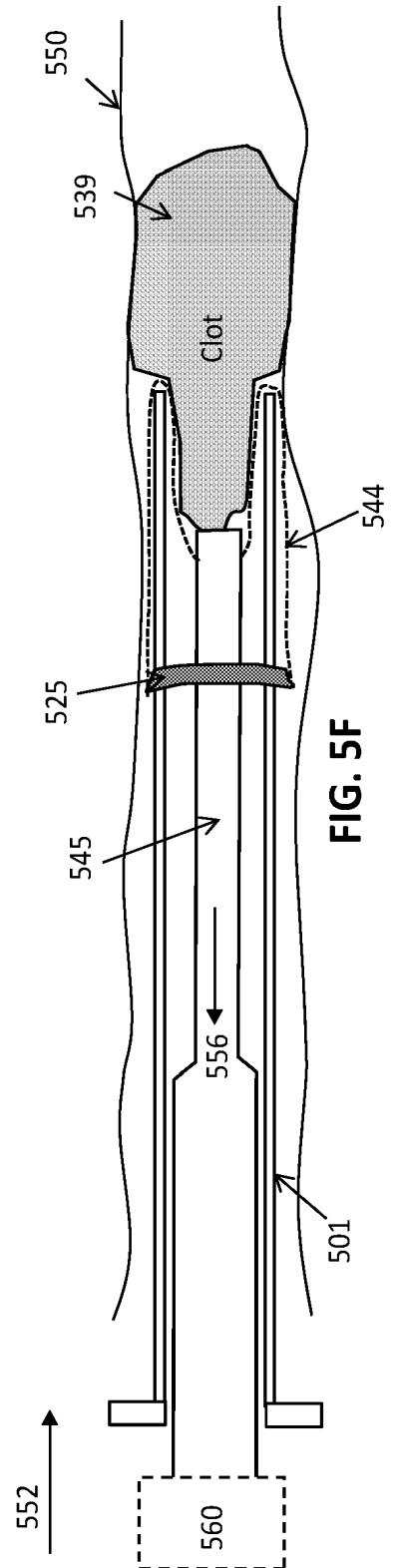
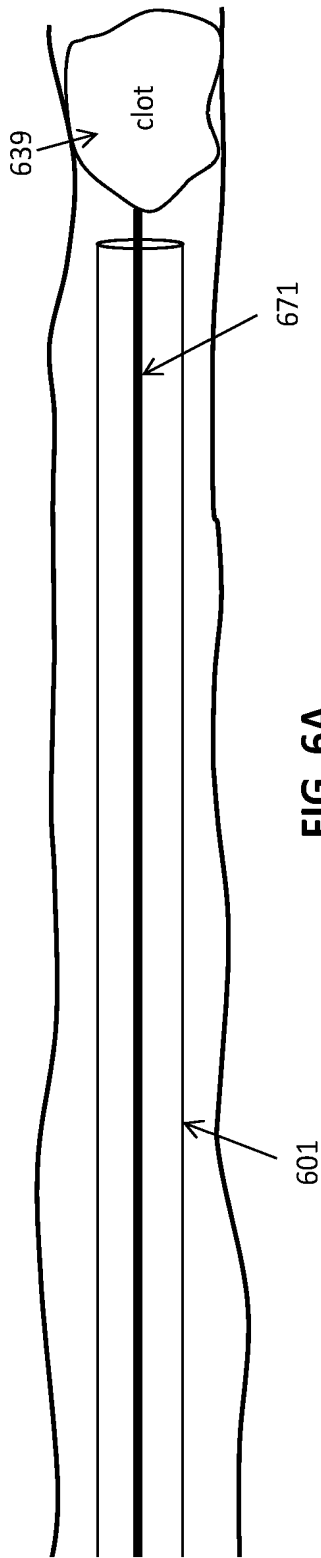
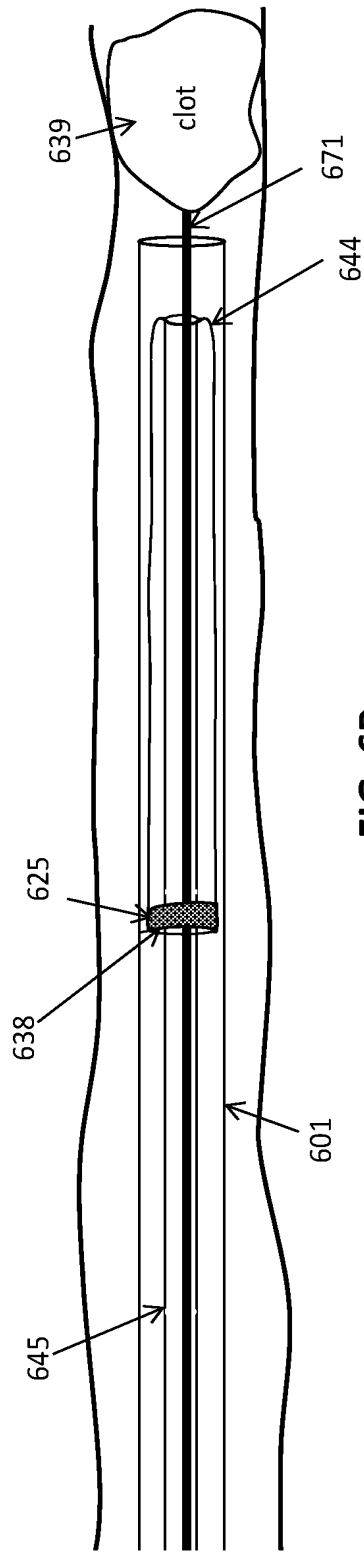
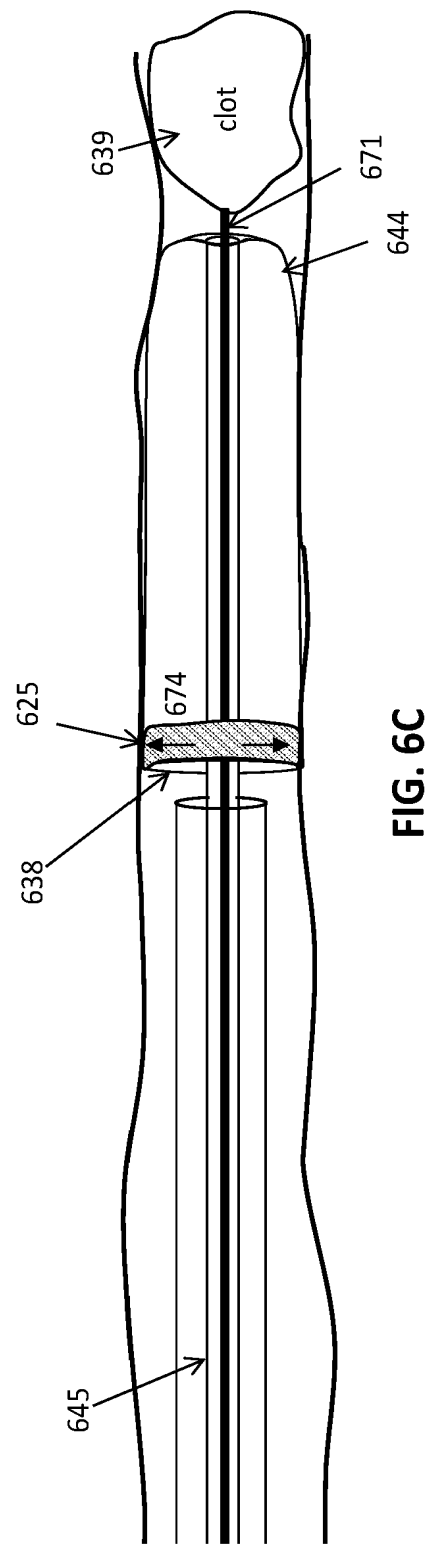
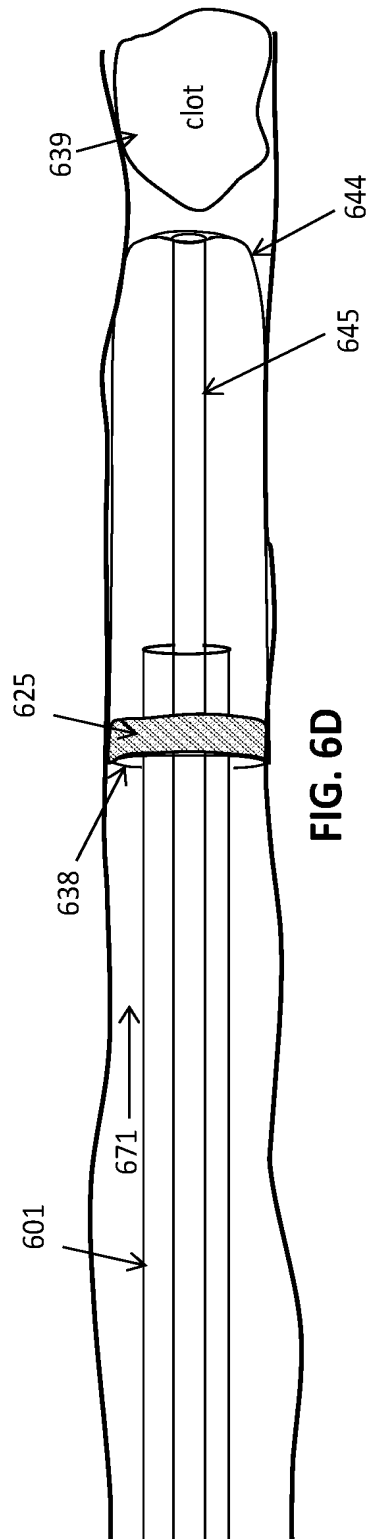
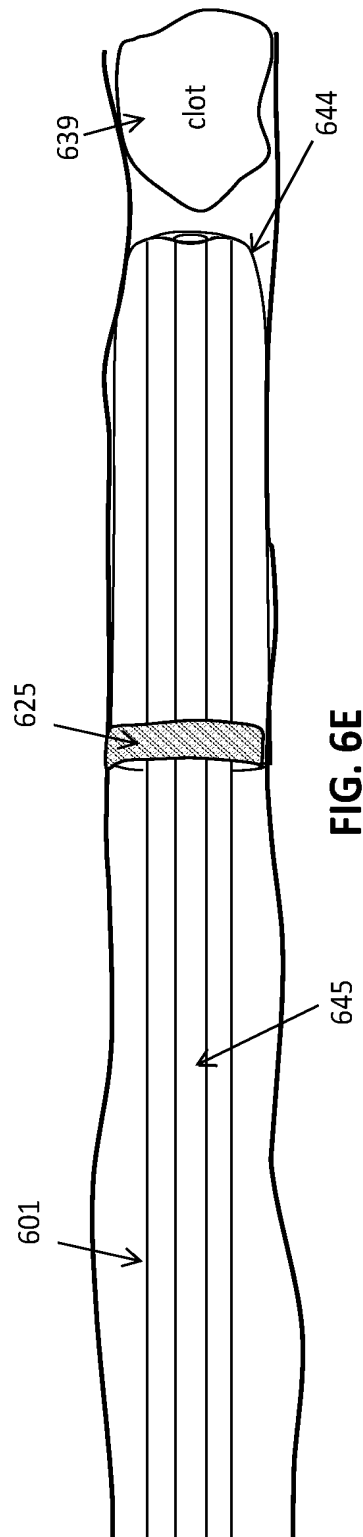
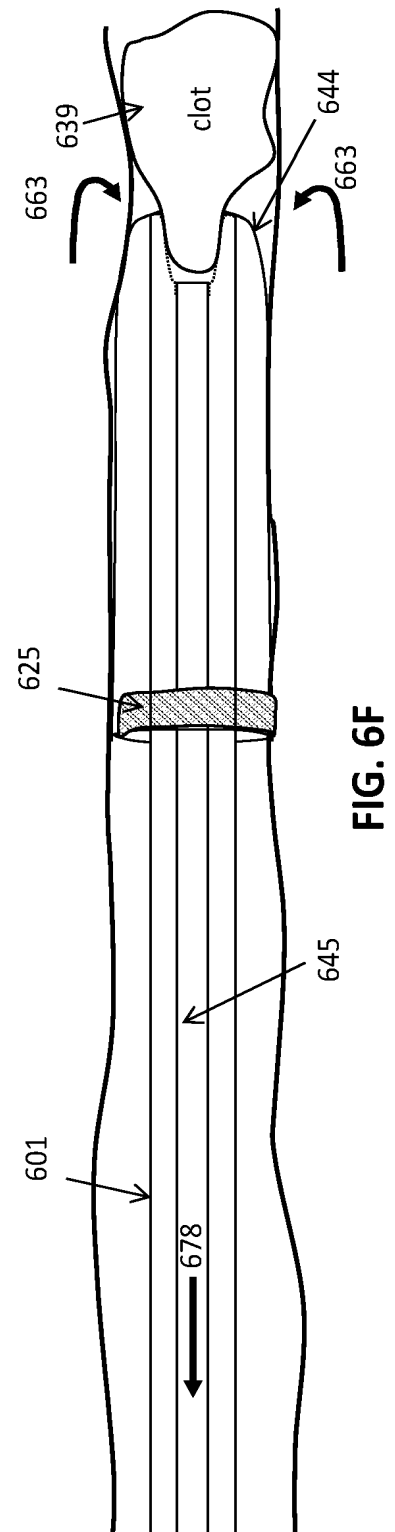


FIG. 5C







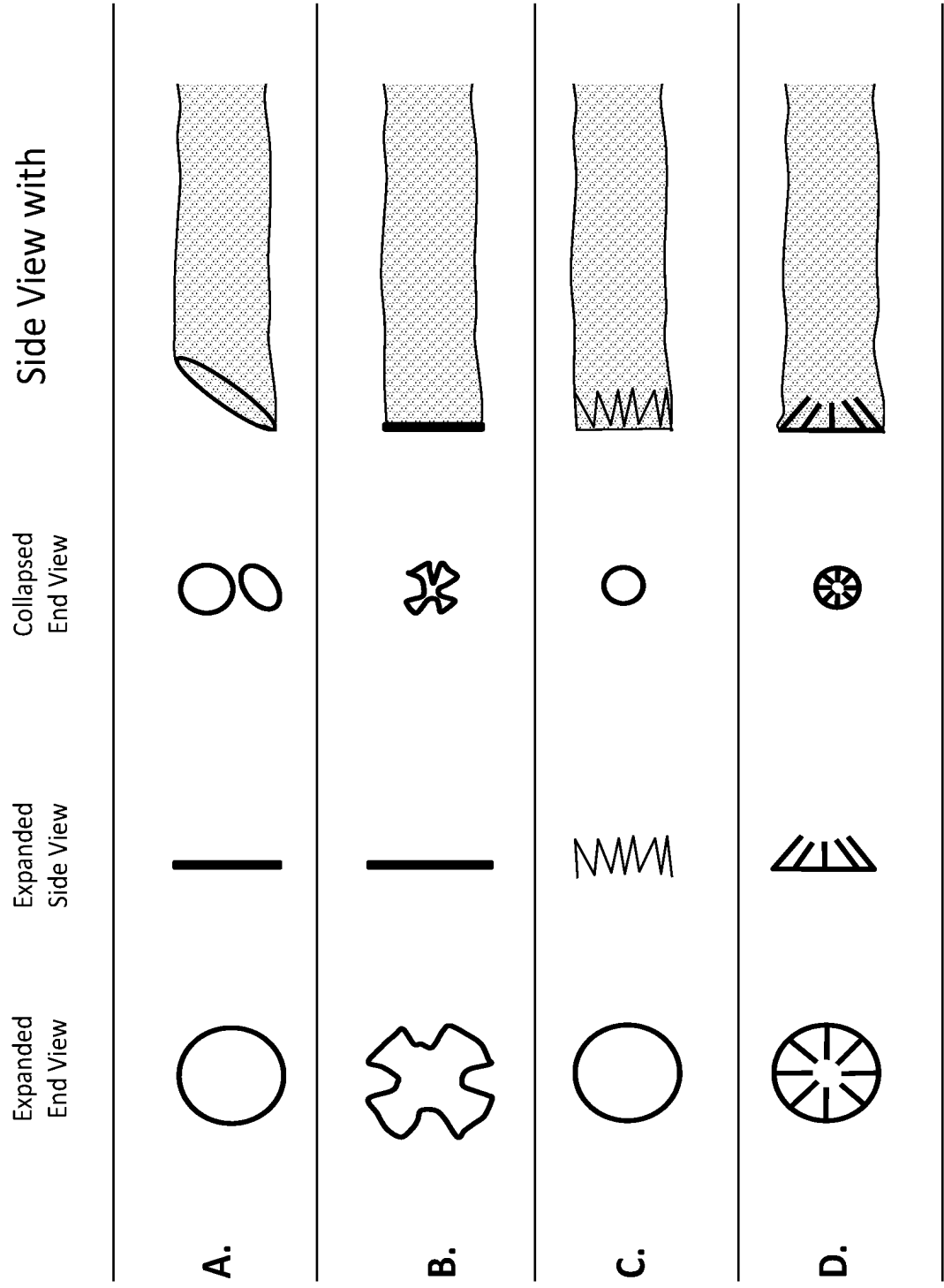


FIG. 7

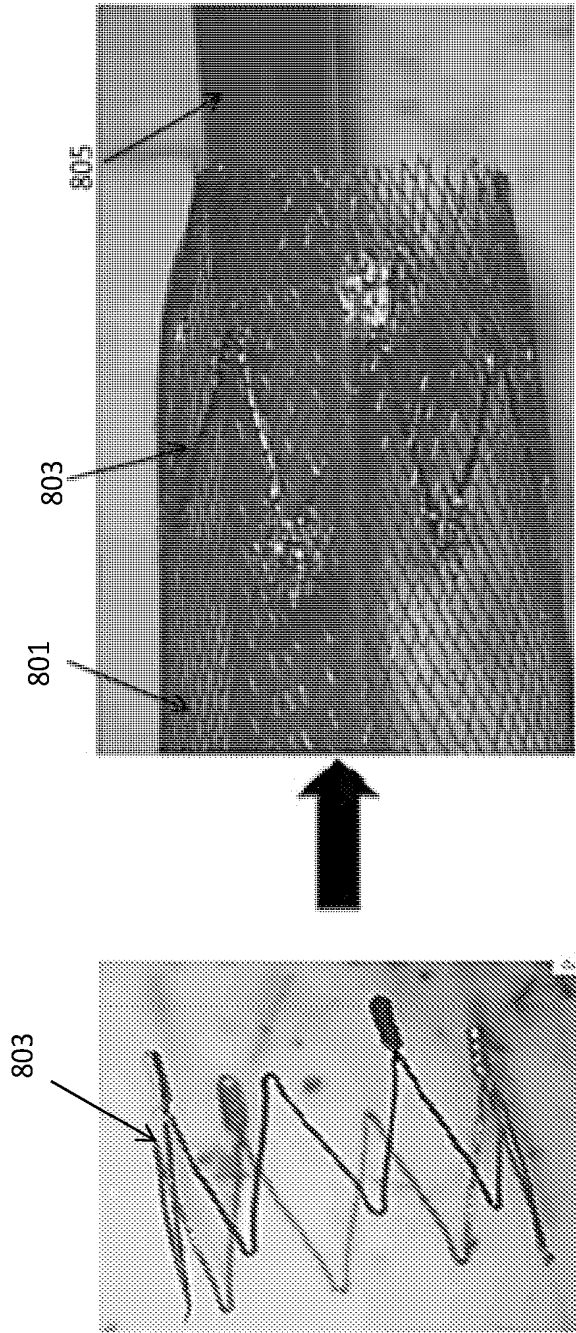


FIG. 8B

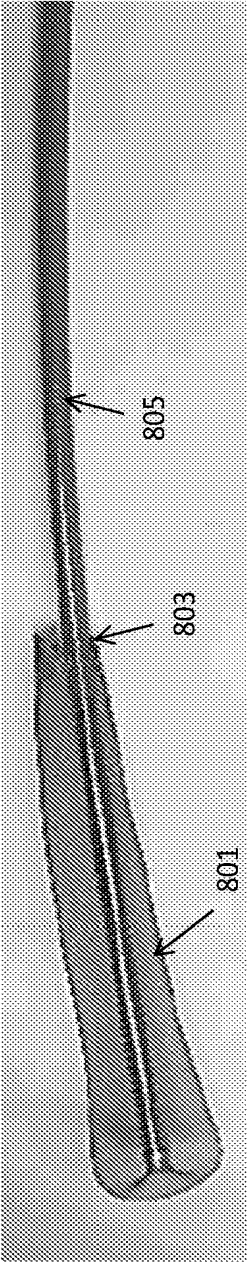


FIG. 8C

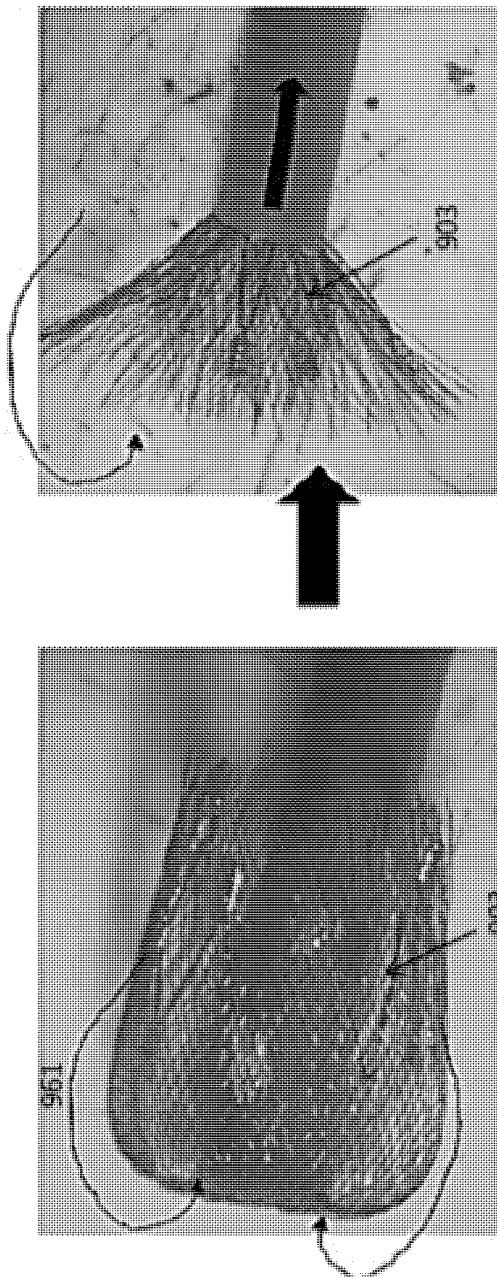


FIG. 9B

FIG. 9A

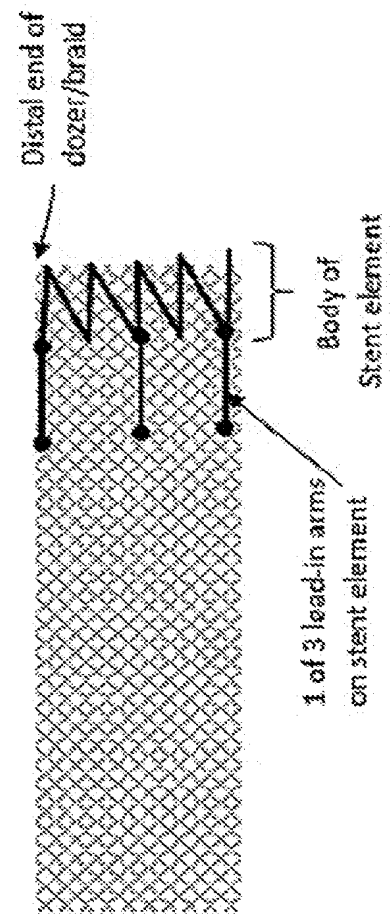


FIG. 9C

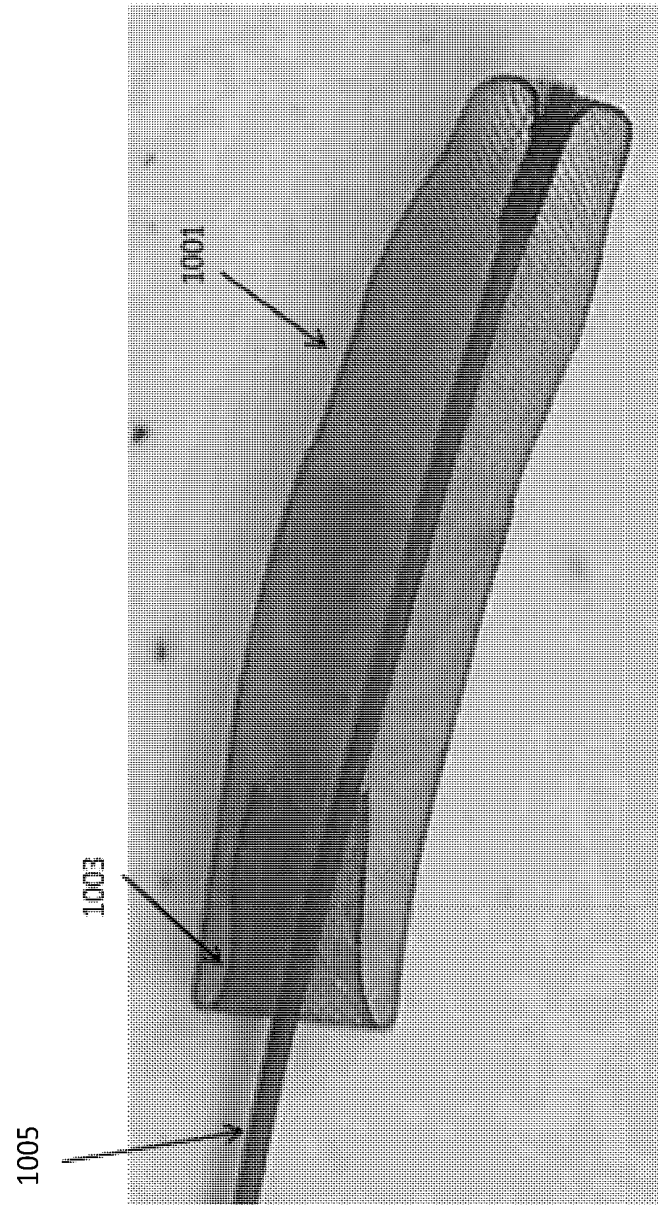


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2017/035543

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/22 A61B17/221
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; figures page 8, line 12 - page 11, line 5 -----	1-19
Y	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19) paragraphs [0152], [0153], [0167] - [0170]; figures 10, 13B -----	1-19
X,P	WO 2017/058280 A1 (GW MEDICAL LLC) 6 April 2017 (2017-04-06) the whole document -----	1-7,9-19



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

2 August 2017

Date of mailing of the international search report

14/08/2017

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Giménez Burgos, R

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2017/035543

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			US 2017086864 A1	30-03-2017
			WO 2017058280 A1	06-04-2017



(51) International Patent Classification:

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PCT/US2021/058793

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10 November 2021 (10.11.2021)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

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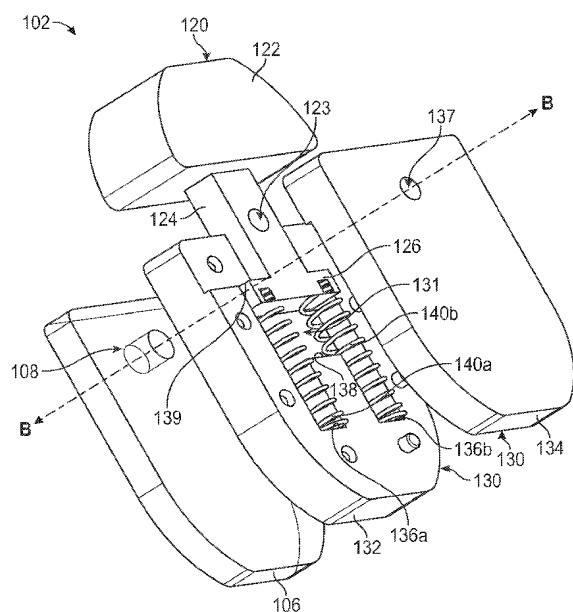


FIG. 1C

(57) Abstract: Disclosed herein are devices, systems, and methods for adjustably tensioning sutures, such as sutures used to close a catheter access site of a human patient. In some embodiments, a suture tensioning device includes a housing and an actuation member slidably coupled to the housing. The housing can include a first through-hole and a second through-hole at least partially aligned along an axis. The actuation member can include a third-through-hole. The suture tensioning device can further include a biasing member operably coupled between the actuation member and the housing. The biasing member can bias the actuation member to a first position in which the third through-hole is offset from the axis. The actuation member is movable to a second position in which the third through-hole is at least partially aligned with the first and second through-holes along the axis.

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DEVICES FOR ADJUSTABLY TENSIONING SUTURES, AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/111,774, filed November 10, 2020, and titled "DEVICES FOR ADJUSTABLY TENSIONING SUTURES, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to systems, methods, and devices for adjustably tensioning sutures, such as sutures used to close a percutaneous catheter access site of a human patient.

BACKGROUND

[0003] Percutaneous medical procedures involve accessing the inner organs, tissue, and/or vasculature of a patient via a puncture in the skin of the patient. A percutaneous approach is commonly used in intravascular procedures such as angioplasty, stenting, clot removal, and so on. More specifically, many intravascular procedures include inserting a catheter and/or medical device into a blood vessel of a patient through an access site, such as a popliteal access site, an internal jugular access site, a femoral access site, or another venous or arterial access site. For example, an introducer assembly can be positioned in the blood vessel through the access site, and one or more medical instruments can be advanced through the introducer assembly for carrying out the intravascular procedure.

[0004] After such procedures, the access site must be closed to maintain hemostasis as the patient recovers. Common techniques for closing the access site include manual compression and suturing. However, it may be difficult to successfully close the access site and achieve hemostasis when the access site is large, such as for intravascular procedures utilizing large bore catheters. Additionally, the access site closure may be uncomfortable to the patient during recovery.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0006] Figures 1A and 1B are an isometric view and a partially-exploded isometric view, respectively, of a suture tensioning device in accordance with embodiments of the present technology.

[0007] Figures 1C and 1D are exploded top and bottom isometric views, respectively, of the tensioning assembly 102 in accordance with embodiments of the present technology.

[0008] Figure 1E is an exploded isometric view of a dressing assembly of the suture tensioning device in accordance with embodiments of the present technology.

[0009] Figure 2 is an isometric view of a threading tool for use with the suture tensioning device in accordance with embodiments of the present technology.

[0010] Figure 3 is a flow diagram of a process or method for operating the suture tensioning device in accordance with embodiments of the present technology.

[0011] Figures 4A and 4B are isometric views of the suture tensioning device illustrating threading of a suture therethrough in accordance with embodiments of the present technology.

[0012] Figure 5 is an enlarged side cross-sectional view of a suture positioned within the tensioning assembly of the suture tensioning device in accordance with embodiments of the present technology.

[0013] Figure 6 is an exploded isometric view of a tensioning assembly in accordance with additional embodiments of the present technology.

[0014] Figures 7A and 7B are an exploded isometric view and an isometric view, respectively, of a suture tensioning device in accordance with additional embodiments of the present technology.

[0015] Figure 8 is an exploded isometric view of a tensioning assembly in accordance with additional embodiments of the present technology.

[0016] Figure 9 is an exploded isometric view of a suture tensioning device in accordance with additional embodiments of the present technology.

[0017] Figures 10A and 10B are isometric views of a tensioning assembly in a first position and a second position, respectively, in accordance with additional embodiments of the present technology.

[0018] Figure 11 is an isometric view of a tensioning assembly in accordance with additional embodiments of the present technology.

[0019] Figure 12 is an exploded isometric view of a tensioning assembly in accordance with additional embodiments of the present technology.

[0020] Figures 13A and 13B are isometric views of a tensioning assembly in a first position and a second position, respectively, in accordance with additional embodiments of the present technology.

DETAILED DESCRIPTION

[0021] The present technology is generally directed to devices for adjustably tensioning sutures, such as sutures used to close a catheter access site of a human patient, and associated systems and methods. In some embodiments, a suture tensioning device includes a housing and an actuation member slidably coupled to the housing. The housing can include a first through-hole and a second through-hole at least partially aligned with one another along an axis. The actuation member can include a third-through-hole. The suture tensioning device can further include a biasing member operably coupled between the actuation member and the housing. The biasing member can exert a biasing force against the actuation member that holds the actuation member in a first position in which the third through-hole is offset from the axis and therefore not aligned with the first and second through-holes of the housing. The actuation member can be movable against the biasing force of the biasing member to a second position in which the third through-hole is at least partially aligned with the first and second through-holes along the axis.

[0022] In operation, a user can thread a suture through the first, second, and third through-holes when the actuation member is in the second position. The suture can be used to close a puncture in the patient, such as a catheter access site. After adjusting the tension in the suture to a desired tension, the user can release the actuation member to permit the biasing member to drive the actuation member to the first position. In the first position, the actuation member and/or the housing engage the suture to inhibit the suture from moving through the first, second, and third through-holes. Accordingly, the suture tensioning device can maintain the desired tension

in the suture. To adjust the tension in the suture, the user can actuate (e.g., depress) the actuation member against the biasing force of the biasing member to move the actuation member to the second position. The user can then adjust the tension in the suture to another desired tension, and then release the actuation member to lock the suture in position at the selected tension. Accordingly, in one aspect of the present technology the suture tensioning device allows the tension in the suture to be easily adjusted. For example, the user can increase the tension to better close the puncture and maintain hemostasis and/or decrease the tension to accommodate patient comfort.

[0023] Certain details are set forth in the following description and in Figures 1–13B to provide a thorough understanding of various embodiments of the present technology. In other instances, well-known structures, materials, operations, and/or systems often associated with intravascular procedures, percutaneous access sites, etc., are not shown or described in detail in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. Those of ordinary skill in the art will recognize, however, that the present technology can be practiced without one or more of the details set forth herein, and/or with other structures, methods, components, and so forth.

[0024] The terminology used below is to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain examples of embodiments of the technology. Indeed, certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

[0025] The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope unless expressly indicated. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles and features without departing from the present technology. In addition, those of ordinary skill in the art will appreciate that further

embodiments of the present technology can be practiced without several of the details described below.

[0026] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," etc., are not meant to limit the referenced component to a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

[0027] Figures 1A and 1B are an isometric view and a partially-exploded isometric view, respectively, of a suture tensioning device 100 in accordance with embodiments of the present technology. Referring to Figures 1A and 1B together, the suture tensioning device 100 can include a tensioning assembly 102 (shown exploded in Figure 1B) configured to be coupled to a dressing assembly 104 via a pad 106. The dressing assembly 104 is configured to be positioned over an incision or puncture in a patient (e.g., a human patient), such as a percutaneous access site, and can be adhered to the patient (e.g., the skin of the patient) around the puncture. The tensioning assembly 102 is configured to receive and tension one or more sutures used to close the puncture. Figures 1C and 1D are exploded top and bottom isometric views, respectively, of the tensioning assembly 102 in accordance with embodiments of the present technology. The pad 106 is shown as partially transparent in Figures 1A–1D for clarity. Figure 1E is an exploded isometric view of the dressing assembly 104 in accordance with embodiments of the present technology.

[0028] Referring first to Figure 1E, in some embodiments the dressing assembly 104 includes a contact layer 110 and an adhesive portion 112 over and/or integrated with the contact layer 110. The contact layer 110 and the adhesive portion 112 are shown as partially transparent in Figure 1E for the sake of clarity. In the illustrated embodiment, the dressing assembly 104 has a generally elongate, oval-like shape while, in other embodiments, the dressing assembly 104 can have other shapes (e.g., rectangular, circular, rectilinear, polygonal, irregular). In some embodiments, the contact layer 110 includes and/or comprises an adhesive material (e.g., an acrylic and/or acrylate material) on its underside for releasably securing the dressing assembly 104 to a patient. In some embodiments, the contact layer 110 (e.g., an upper surface of the contact layer 110) can include a medical tape including, for example, a polyethylene material.

The adhesive portion 112 can comprise an acrylic, acrylate, or other suitable adhesive material. In the illustrated embodiment, the dressing assembly 104 includes a first removable protection layer 114a and a second removable protection layer 114b (collectively "protection layer 114") coupled to the contact layer 110 (e.g., a lower surface of the contact layer 110). The protection layer 114 can cover, seal, and/or protect the contact layer 110 and its adhesive before the dressing assembly 104 is used, and can be removed before placing the dressing assembly 104 on the patient. In some embodiments, the first removable protection layer 114a and the second removable protection layer 114b can be folded to facilitate their removal from the contact layer 110. In other embodiments, the dressing assembly 104 can include more or fewer layers and/or can include different materials. For example, the dressing assembly 104 can include multiple different layers laminated together.

[0029] In the illustrated embodiment, (i) the protection layer 114 includes/defines a first opening 111 (e.g., a through-hole or aperture formed between the first removable protection layer 114a and the second removable protection layer 114b), (ii) the contact layer 110 includes a second opening 113, and (iii) the adhesive portion 112 includes a third opening 115 (collectively "openings 111–115"). Referring to Figures 1A, 1B, and 1E together, the openings 111–115 are at least partially aligned to define a through-hole 118 extending entirely through the dressing assembly 104 between a first surface 117a (e.g., a lower surface) and a second surface 117b (e.g., an upper surface) thereof. The tensioning assembly 102 is configured to be secured to the adhesive portion 114 of the dressing assembly 104 over the through-hole 118. As described in greater detail below with reference to Figures 3–4B, one or more sutures can be threaded (e.g., routed, inserted) through the through-hole 118 to the tensioning assembly 102.

[0030] In operation of the suture tensioning device 100, the dressing assembly 104 can be placed against the skin of a patient with the protection layer 114 in place. After positioning the openings 111–115 over/at a desired location, such as an incision in the patient, an operator can peel back and remove the first removable protection layer 114a and the second removable protection layer 114a and then adhere the contact layer 110 to the patient.

[0031] Referring to Figures 1A–1D together, the tensioning assembly 102 can include an actuation member 120 movably (e.g., slidably) coupled to/within a housing 130 having a lower housing portion 132 and an upper housing portion 134. In the illustrated embodiment, the lower housing portion 132 and/or the upper housing portion 134 (e.g., either together or individually) define a channel 131 including a first biasing member mount 136a, a second biasing member

mount 136b, a first stop surface 138, and a second stop surface 139. The actuation member 120 can include (i) a press portion 122 extending at least partially outside the housing 130, (ii) an elongate portion 124 extending from the press portion 122 into the housing 130 past the second stop surface 139, and (iii) a flange or mount portion 126 extending from the elongate portion 124 and at least partially through the channel 131. A first biasing member 140a can be operably coupled between the first biasing member mount 136a and the mount portion 126 of the actuation member 120. Likewise, a second biasing member 140b can be operably coupled between the second biasing member mount 136b and the mount portion 126 of the actuation member 120.

[0032] The biasing members 140 are configured (e.g., shaped, sized, and/or positioned) to drive the actuation member 120 outward away from the first stop surface 138 in a direction indicated by arrow A in Figure 1A (e.g., in a horizontal or lateral direction). In some embodiments, the biasing members 140 are compression springs that extend through the channel 131 and that are directly attached to the biasing member mounts 136 and the mount portion 126 via an adhesive, fasteners (e.g., screws), welding, or another suitable attachment mechanism. In other embodiments, the tensioning assembly 102 can include more or fewer of the biasing members 140 (e.g., one, three, four or more) operably coupling the actuation member 120 to the housing 130. In some embodiments, the biasing members 140 can have a spring constant of between about 10–25 pounds per inch (e.g., between about 12–22 pounds per inch, between about 16–18 pounds per inch, about 17 pounds per inch, and so on).

[0033] In the illustrated embodiment, the lower housing portion 132 includes/defines a first through-hole 133 (Figure 1D), the elongate portion 124 of the actuation member 120 includes a second through-hole 123 (Figure 1C), and the upper housing portion 134 includes a third through-hole 137. The first through-hole 133 and the third through-hole 137 are at least partially aligned with one another (e.g., superimposed over one another) along an axis B shown in Figures 1C and 1D (e.g., a vertical axis).

[0034] The tensioning assembly 102 is in a first position (e.g., a lock position) in Figures 1A–1D in which the biasing members 140 bias the actuation member 120 outward in the direction of arrow A such that the mount portion 126 engages/contacts the second stop surface 139 of the lower housing portion 132. In the first position, the second through-hole 123 through the elongate portion 124 of the actuation member 120 is not aligned with the first and third through-holes 133, 137 of the housing 130. More specifically, the second through-hole 123 is positioned axially away from the axis B such that the second through-hole 123 is not

superimposed with the first and third through-holes 133, 137. In operation, the actuation member 120 can be actuated to move the tensioning assembly 102 from the first position to a second position (e.g., a release position; shown in Figure 4B) in which the second through-hole is aligned with the first and third through-holes 133, 137. More specifically, a user (e.g., a physician, nurse) can press the press portion 122 of the actuation member 120 to drive the actuation member 120 inward in the direction of arrow C shown in Figure 1B—against the biasing force of the biasing members 140—until the mount portion 126 engages the first stop surface 138 of the lower housing portion 132. In the second position, the second through-hole 123 is at least partially aligned with the first and third through-holes 133, 137 along the axis B. In some embodiments, the movement of the actuation member 120 in the direction of arrow C is generally orthogonal to the axis B.

[0035] Referring to Figures 1A–1E together, in some embodiments the pad 106 can be coupled to/between the lower housing portion 132 and the adhesive portion 114 of the dressing assembly 104 via an adhesive, fasteners, a snap-fit arrangement, and/or the like. In some embodiments, the pad 106 can be flexible and configured to conform to the skin of a patient during use of the suture tensioning device 100. For example, the pad 106 can be formed from a thermoplastic elastomer (TPE), rubber, silicone, and/or another flexible material. In some embodiments, the adhesive portion 114 of the dressing assembly 104, the pad 106, and the lower housing portion 132 of the housing 130 all have the same generally curved-rectangular planform shape. In other embodiments, the adhesive portion 114, the pad 106, and the lower housing portion 132 can have different shapes (e.g., rectangular, circular, rectilinear, polygonal, irregular) and/or different shapes than one another. In some embodiments, the pad 106 can be omitted and the lower housing portion 132 can be directly attached to the adhesive portion 114 of the dressing assembly 104.

[0036] In the illustrated embodiment, the pad 106 includes/defines a through-hole 108 that is aligned along the axis B with (i) the first and third through-holes 133, 137 of the tensioning assembly 102 and (ii) the through-hole 118 of the dressing assembly 104. Accordingly, when the tensioning assembly 102 is in the second position with the actuation member 120 pressed inward toward the housing 130, each of the through-holes 108, 118, 123, 133, and 137 are at least partially aligned to define a continuous path through the suture tensioning device 100 for receiving one or more sutures.

[0037] Figure 2 is an isometric view of a threading tool 250 for use with the suture tensioning device 100 in accordance with embodiments of the present technology. The threading tool 250 can include an elongate portion 252 and a loop portion 254 enclosing/defining an opening 256. In some embodiments, the elongate portion 252 and the loop portion 254 can be formed from a flexible material, such as a nylon monofilament. In some embodiments, the elongate portion 252 can be more rigid than the loop portion 254. For example, the elongate portion 252 can be formed of a different, more rigid material than the loop portion 254 and/or can be made thicker than the loop portion 254. As described in detail below with reference to Figures 4A and 4B, the threading tool 250 can be inserted and pulled through the tensioning assembly 102 when the tensioning assembly 102 is in the second position to pull/thread one or more sutures positioned in the opening 256 through the tensioning assembly 102.

[0038] Figure 3 is a flow diagram of a process or method 360 for operating the suture tensioning device 100 in accordance with embodiments of the present technology. Although some features of the method 360 are described in the context of the embodiments shown in Figures 1A–2 for the sake of illustration, one skilled in the art will readily understand that the method 360 can be carried out using other suitable systems and/or devices described herein—for example, using any of the suture tensioning devices described below with reference to Figures 6–13B.

[0039] At block 361, the method 360 includes threading one or more sutures through the suture tensioning device 100. The sutures can be used to close a puncture in a patient. Figures 4A and 4B, for example, are isometric views of the suture tensioning device 100 illustrating threading of a suture 470 therethrough before the dressing assembly 104 has been attached to the skin in accordance with embodiments of the present technology. In some embodiments, the sutures 470 have a U.S.P. size of between about #4-0 to #2. Referring first to Figure 4A, a user can insert/loop the suture 470 (e.g., end portions 472 of the suture 470) through the opening 256 of the threading tool 250. With the tensioning assembly 102 in the second position, the user can then insert the elongate portion 252 of the threading tool 250 through the through-holes in the dressing assembly 104, the pad 106, and the tensioning assembly 102. For example, the user can depress the actuation member 120 to maintain the tensioning assembly 102 in the second position. Then, referring to Figure 4B, the user can pull the threading tool 250 entirely through the through-holes in the suture tensioning device 100 to pull the suture 470 therethrough. In other embodiments, the user can thread the suture 470 through the suture tensioning device 100 without using the threading tool 250.

[0040] In some embodiments, the suture 470 can be threaded/tied in a figure eight around the puncture. In some embodiments, the suture 470 is not knotted (e.g., in a surgeon's knot) before being threaded through the suture tensioning device 100. The puncture can be an access site into the body of the patient used to carry out a percutaneous medical procedure, such as an intravascular procedure that includes inserting a catheter or medical device into a blood vessel of the patient through the access site. The access site can be a popliteal access site, an internal jugular access site, a femoral access site, or another venous or arterial access site. In some embodiments, the access site can be relatively large, such as those needed to facilitate intravascular procedures utilizing large bore catheters. In some embodiments, the access site can be used to facilitate any of the clot removal procedures described in detail in (i) U.S. Patent No. 9,700,332, filed September 16, 2016, and titled "INTRAVASCULAR TREATMENT OF VASCULAR OCCLUSION AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS," (ii) U.S. Patent No. 10,098,651, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," and/or (iii) U.S. Patent Application No. 16/536,185, titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," filed August 8, 2019, each of which is incorporated herein by reference in its entirety.

[0041] At block 362, the method 360 includes coupling the suture tensioning device 100 to the patient. For example, the user can remove the protection layer 116 from the dressing assembly 104 and press the lower layer 110 of the dressing assembly 104 against the skin of the patient around the puncture to adhere the dressing assembly 104 to the patient over/around the puncture. In some embodiments, the dressing assembly 104 can be coupled to the patient before the suture 470 is threaded through the tensioning assembly 102 and/or before the tensioning assembly 102 is coupled to the dressing assembly 104.

[0042] At block 363, the method 360 includes adjusting the suture 470 to have a desired/selected tension. For example, the user can continue depressing the actuation member 120 to move the tensioning assembly 102 to the second position, and then pull the suture 470 until a desired tension is achieved. The tension can be sufficient to close the puncture in the patient and maintain hemostasis at the puncture.

[0043] At block 364, the method 360 includes locking the suture 470 in the suture tensioning device 100 to maintain the desired tension in the suture 470. For example, after pulling the suture 470 to have the desired tension, the user can simply release the actuation

member 120 to allow the actuation member 120 to return to the first position from the second position, thereby preventing the suture 470 from moving within the tensioning assembly 102. More specifically, Figure 5 is an enlarged side cross-sectional view of the suture 470 positioned within the tensioning assembly 102 with the actuation member 120 in the first position in accordance with embodiments of the present technology.

[0044] Referring to Figures 1A–D and 5 together, releasing the actuation member 120 allows the biasing members 140 to drive the actuation member 120 away from the first stop surface 138 toward and/or into engagement with the second stop surface 139, thereby moving the second through-hole 123 out of alignment with the first and third through-holes 133, 137. As the actuation member 120 moves to the first position, a perimeter or edge 527 of the second through-hole 123 engages the suture 470 and pulls the suture 470 through the channel 131 within the housing 130 in the direction of the arrow A (Figure 1A). Thus, as shown in Figure 5, the suture 470 traverses through the tensioning assembly 102 along a serpentine path, and the friction/engagement between the suture 470 and the actuation member 120 and the housing 130 can lock/clamp the suture 470 in position—inhibiting or even preventing movement of the suture 470 through the housing 130. That is, the tensioning assembly 102 cinches the suture 470 in the first position to inhibit movement of the suture 470 therethrough.

[0045] At block 365, the method 360 optionally includes adjusting the tension of the suture 470. To adjust the tension, the user can depress the actuation member 120 to move the actuation member 120 against the biasing force of the biasing members 140 to the second position, and then advance or retract the suture 470 through the tensioning assembly 102 to decrease or increase the tension, respectively. For example, the user may wish to increase the tension of the suture 470 to increase the constriction force on the puncture to facilitate hemostasis. Conversely, the user may wish to decrease the tension of the suture 470 to accommodate the comfort of the patient. Accordingly, in one aspect of the present technology the suture tensioning device 100 permits the tension in the suture 470 to be simply adjusted by depressing/releasing the actuation member 120 and without disturbing the dressing assembly 104. In contrast, conventional techniques for closing punctures include knotting a suture used to close the puncture to maintain tension in the suture. However, knots prevent the tension in the suture from being easily adjusted—as the knot must be undone and then retied to adjust the tension.

[0046] At block 366, the method 360 includes removing the suture 470 from the suture tensioning device 100 and removing the suture tensioning device 100 from the patient. For

example, the user can depress the actuation member 120 to move the actuation member 120 to the second position, and then pull the tensioning assembly 102 and/or the dressing assembly 104 away from the patient to remove the suture 470 therefrom. In some embodiments, the tensioning assembly 102 can be decoupled from the dressing assembly 104 and removed from over the suture 470 while the dressing assembly 104 remains on the patient.

[0047] Figures 6–13B illustrate additional embodiments of suture tensioning devices and tensioning assemblies in accordance with the present technology. The suture tensioning devices described with reference to Figures 6–13B can include several features generally similar or identical to the features of one another and/or the features of the suture tensioning device 100 described in detail with reference to Figures 1A–5, and can be operated in and function in a generally similar or identical manner. Accordingly, the description of Figures 6–13B emphasizes the unique features of the various embodiments. However, one skilled in the art will appreciate that the various embodiments can be combined and/or modified. For example, each of the tensioning assemblies described with reference to Figures 6–13B can be coupled to a dressing assembly (e.g., the dressing assembly 104) and/or a flexible pad (e.g., the pad 106), even if not expressly shown.

[0048] Figure 6 is an exploded isometric view of a tensioning assembly 602 in accordance with additional embodiments of the present technology. In the illustrated embodiment, the tensioning assembly 602 includes an actuation member 620 operably coupled to a housing or base 630 via a first biasing member 640a and a second biasing member 640b. More specifically, the first biasing member 640a can be coupled in/between a first biasing member mount 629a on the actuation member 620 and a first channel 636a formed in the base 630. Similarly, the second biasing member 640b can be coupled in/between a second biasing member mount 629b on the actuation member 620 and a second channel 636b formed in the base 630. The base 630 can include a channel 631 configured to slidably receive an elongate portion 624 of the actuation member 620. The base 630 can further include a first through-hole 633 and a second through-hole 637 extending at least partially therethrough and providing access to the channel 631. The first and second through-holes 633, 637 can be at least partially aligned with one another (e.g., along an axis extending therethrough). The elongate portion 624 of the actuation member 620 can include a third through-hole 623.

[0049] The biasing members 640 are configured to bias the actuation member 620 away from the base 630 to a first position in which the third through-hole is not aligned with (e.g., is

offset from) the first and second through-holes 633, 637. A user can depress the actuation member 620 toward the base 630 against the biasing force of the biasing members 640 to drive the elongate portion 624 of the actuation member 620 through the channel 631 such that the third through-hole 623 is aligned with the first and second through-holes 633, 637. Accordingly, in operation the user can insert one or more sutures through the through-holes 623, 633, 637 when the tensioning assembly 602 is in the second position, and can then release the actuation member 620 to allow the tensioning assembly 602 to return to the first position. In the first position, the actuation member 620 and the base 630 can cinch the sutures (e.g., in the manner described with respect to Figure 5) to inhibit movement of the sutures through the tensioning assembly 602.

[0050] Figures 7A and 7B are an exploded isometric view and an isometric view, respectively, of a suture tensioning device 700 in accordance with additional embodiments of the present technology. Referring to Figures 7A and 7B together, the suture tensioning device 700 can include a tensioning assembly 702, a dressing assembly 704, and a pad 706 (e.g., a flexible pad). The pad 706 defines a through-hole 708 and is configured (e.g., sized and shaped) to be positioned in an aperture 719 in the dressing assembly 704. For example, the pad 706 can be directly coupled to the skin of a patient through the aperture 719.

[0051] In the illustrated embodiment, the tensioning assembly 702 includes a base portion 780 including/defining a channel 781 and configured to be positioned in the through-hole 708 of the pad 706. In other embodiments, the base portion 780 can be coupled to the pad 706 over the through-hole 708. The tensioning assembly 702 further includes a body portion 782 coupled to the base portion 780. The body portion 782 defines a channel 783 that is accessible via a pair of first through-holes 784 (a lower one of the first through-holes 784 is obscured in Figures 7A and 7B). The tensioning assembly 702 can further include an actuation member 786 having an elongate portion 785 rotatably positioned within the channel 783. The elongate portion 785 includes a second through-hole 787. The channel 781 of the base portion 780 and the first through-holes 784 of the body portion 782 are at least partially aligned along an axis extending therethrough. The actuation member 786 is rotatable to rotate the second through-hole 787 of the elongate portion 785 into and out of alignment with the first through-holes 784 and the channel 781.

[0052] In operation, a user can rotate the actuation member 786 such that the second through-hole 787 is aligned with the channel 781 and the first through-holes 784, and then thread one or more sutures through the channel 781, the lower one of the first through-holes 784, the

second through-hole 787, and the upper one of the first through-holes 784. Once the one or more sutures are threaded through the tensioning assembly 702, the actuation member 786 can be rotated to cinch the sutures to inhibit movement of the sutures through the tensioning assembly 702. In some embodiments, the sutures can be wound around the elongate portion 785 of the actuation member 786 to cinch the sutures via the friction between the sutures and the outer surface of the elongate portion 785. In some embodiments, the actuation member 786 can be rotated in a first direction (e.g., clockwise) to increase the tension in the sutures, and in a second direction (e.g., counterclockwise) to decrease the tension in the sutures. Accordingly, in one aspect of the technology the tensioning assembly 702 is actuatable to increase/decrease the tension in the sutures without requiring a user to manually pull/release the sutures through the tensioning assembly 702.

[0053] Figure 8 is an exploded isometric view of a tensioning assembly 802 in accordance with additional embodiments of the present technology. In the illustrated embodiment, the tensioning assembly 802 includes an actuation member 890 (e.g., a lever arm) rotatably coupled to a housing 892. More specifically, the housing 892 can include a base 893 and a sidewall 894 projecting from the base 893, and the actuation member 890 can be an elongate member extending through and supported by the sidewall 894 (e.g., extending through a pair of openings therein). The base 893 can include/define a first through-hole 895, and the actuation member 890 can include a second through-hole 896. In some embodiments, the tensioning assembly 802 can further include a cap 898 having a third through-hole 899 and configured to be coupled to the housing 892 opposite the base 893. When the cap 898 is coupled to the housing 892, the first and third through-holes 895, 899 can be at least partially aligned with one another. The actuation member 890 is rotatable to rotate the second through-hole 896 into and out of alignment with the first and third through-holes 895, 899.

[0054] In operation, a user can rotate the actuation member 890 such that the second through-hole 896 is aligned with the first and third through-holes 895, 899, and then thread one or more sutures through each of the through-holes. Once the one or more sutures are threaded through the tensioning assembly 802, the actuation member 890 can be rotated to wind the sutures around the actuation member 890 to cinch the sutures via the friction between the sutures and the outer surface of the actuation member 890. In some embodiments, the actuation member 890 can be rotated in a first direction (e.g., clockwise) to increase the tension in the sutures, and in a second direction (e.g., counterclockwise) to decrease the tension in the sutures. Accordingly, in one aspect of the technology the tensioning assembly 802 is actuatable to increase/decrease

the tension in the sutures without requiring a user to manually pull/release the sutures through the tensioning assembly 802.

[0055] Figure 9 is an exploded isometric view of a suture tensioning device 900 in accordance with additional embodiments of the present technology. In the illustrated embodiment, the suture tensioning device 900 includes a tensioning assembly 902 configured to be coupled to a dressing assembly 904. The dressing assembly 904 defines a through-hole 918 and can be applied to a patient over and/or proximate to a puncture in the skin of the patient. The tensioning assembly 902 includes a base portion 980 and a cap or lid portion 982 configured to releasably mate with and engage the base portion 980. More specifically, the base portion 980 can include/define an annular groove 983 configured (e.g., shaped, sized, and/or positioned) to receive a flange portion 986 of the lid portion 982. The lid portion 982 can be rotated by a user to rotate the flange portion 986 through the groove 983. In some embodiments, the lid portion 982 further includes a projection 987 extending radially outward from the flange portion 986 and configured to be positioned in a track 988 formed in the base portion 980 (e.g., in a sidewall of the base portion 980). Rotation of the lid portion 982 can bring the projection 987 into contact with end portions of the track 988, thereby limiting the rotation of the lid portion 982. That is, the track 988 can extend only partially around the base portion 980 such that the lid portion 982 is rotatable through an angle less than 360 degrees. In the illustrated embodiment, the base portion 980 includes a first through-hole 990 and the lid portion 982 includes a second through-hole 992 that can be rotated into and out of alignment with the first through-hole 990.

[0056] In operation, a user can rotate the lid portion 982 such that the second through-hole 992 is aligned with the first through-hole 990, and then thread one or more sutures through the through-hole 918 in the dressing assembly 904 and the first and second through-holes 992, 994. Once the one or more sutures are threaded through the tensioning assembly 902, the lid portion 982 can be rotated to cinch the sutures in the groove 983 between the flange portion 986 and the base portion 980 to inhibit movement of the sutures through the tensioning assembly 902. In some embodiments, the lid portion 982 can be rotated in a first direction (e.g., clockwise) to increase the tension in the sutures, and in a second direction (e.g., counterclockwise) to decrease the tension in the sutures. Accordingly, in one aspect of the technology the tensioning assembly 902 is actuatable to increase/decrease the tension in the sutures without requiring a user to manually pull/release the sutures through the tensioning assembly 902.

[0057] Figures 10A and 10B are isometric views of a tensioning assembly 1002 in a first position and a second position, respectively, in accordance with additional embodiments of the present technology. Referring to Figures 10A and 10B together, the tensioning assembly 1002 includes (i) a base 1080 defining a recess 1081 and (ii) a compressible member 1082 configured (e.g., shaped and sized) to be inserted into the recess 1081. In some embodiments, the compressible member 1082 can be formed from a material having a softer durometer than the base 1080. Accordingly, the compressible member 1082 can be pushed into the recess 1081 and snugly secured therein via a friction-fit or snap-fit arrangement. In the illustrated embodiment, the base 1080 defines a first through-hole 1084 and the compressible member 1082 defines a second through-hole 1086. In the first position, when the compressible member 1082 is positioned outside of the recess 1081, the second through-hole 1086 can have a first diameter D_1 . In the second position, when the compressible member 1082 is compressed inside of the recess 1081, the second through-hole 1086 can have a second diameter D_2 that is smaller than the first diameter D_1 . Moreover, the first and second through-holes 1084, 1086 can be at least generally aligned over one another in the second position.

[0058] In operation, a user can thread one or more sutures through the first and second through-holes 1084, 1086 when the tensioning assembly 1002 is in the first position. The user can then manually adjust the tension in the sutures before positioning (e.g., snapping) the compressible member 1082 into the recess 1081. The diameter D_2 of the second through-hole 1086 can be small enough that the compressible member 1082 cinches/grips the sutures in the second position to inhibit movement of the sutures through the tensioning assembly 1002. To adjust the tension in the sutures, the user can remove the compressible member 1082 from the recess 1081 and manually adjust the tension.

[0059] Figure 11 is an isometric view of a tensioning assembly 1102 in accordance with additional embodiments of the present technology. In the illustrated embodiment, the tensioning assembly 1102 includes a flexible tube 1180 and a clamp 1182 positioned around the flexible tube 1180. The flexible tube 1180 includes a first end portion 1183a, a second end portion 1183b, and a middle portion 1183c extending therebetween. The flexible tube 1180 can define a lumen 1185 extending between the first and second end portions 1183a, b. In some embodiments, a diameter of the lumen 1185 can vary. For example, in the illustrated embodiment the flexible tube 1180 is flared at the first and second end portions 1183a, b such that the diameter of the lumen 1185 is greater at and near the first and second end portions 1183a, b than at the middle portion 1183c. The clamp 1184 can include a first arm 1186a and a second

arm 1186b that are pivotally coupled together via, for example, a pin 1188. The clamp 1182 is in a first position in Figure 11 in which the arms 1186 are pivoted apart from each other. The arms 1186 can each include one or more mating/engagement features (not shown) such that the arms 1186 can be pivoted toward each other and coupled together in a second position (e.g., via a snap-fit arrangement). In the second position, the arms 1186 compress the flexible tube 1180. In the illustrated embodiment, the clamp 1182 is positioned around the middle portion 1183c of the flexible tube 1180. In some embodiments, the diameter of the flexible tube 1180 at the first and second end portions 1183a, b can be greater than a diameter of the clamp 1182 in the first position such that the clamp 1182 does not easily slide off the flexible tube 1180.

[0060] In operation, a user can thread one or more sutures through the lumen 1185 when the clamp 1182 is in the first position. The user can then manually adjust the tension in the sutures before moving the arms 1186 of the clamp 1182 to the second position to compress the flexible tube 1180 against/onto the sutures to cinch/grip the sutures to inhibit movement of the sutures through the tensioning assembly 1102. To adjust the tension in the sutures, the user can move the clamp 1182 to the first position illustrated in Figure 11 and manually adjust the tension.

[0061] Figure 12 is an exploded isometric view of a tensioning assembly 1202 in accordance with additional embodiments of the present technology. In the illustrated embodiment, the tensioning assembly 1202 includes a lower portion 1280, an upper portion 1282 coupled to the lower portion 1280 and defining a lumen 1283, and a flexible membrane 1284 positioned in the lumen 1283. The lower portion 1280 can include a first through-hole 1286, the flexible membrane 1284 can include a second through-hole 1288, and the upper portion 1282 can include a third through-hole (obscured in Figure 12). Each of the through-holes can be at least partially aligned with another. The upper portion 1282 can further include a port 1285 configured to operably/fluidly couple the flexible membrane 1284 with an external pressure source (e.g., a vacuum source such as a syringe). Applying negative pressure to the port 1285 can at least partially collapse the flexible membrane 1284.

[0062] Accordingly, in operation, a user can thread one or more sutures through the first through-hole 1286 in the lower portion 1280, the second through-hole 1288 in the flexible membrane 1284, and the third through-hole in the upper portion 1282 without applying negative pressure to the port 1285. The user can then manually adjust the tension in the sutures before applying negative pressure to the port 1285 to collapse the flexible membrane 1284 around the sutures to cinch/grip the sutures to inhibit movement of the sutures through the tensioning

assembly 1202. To adjust the tension in the sutures, the user can remove the negative pressure source and manually adjust the tension in the sutures.

[0063] Figures 13A and 13B are isometric views of a tensioning assembly 1302 in a first position and a second position, respectively, in accordance with additional embodiments of the present technology. Referring to Figures 13A and 13B together, the tensioning assembly 1302 includes an elongate flexible strap 1380 and a base 1390. In the illustrated embodiment, the base 1390 includes a first opening 1392 and a second opening 1394 extending therethrough between a first surface 1391 and a second surface 1393. The strap 1380 can include a tab portion 1382 and a ratchet surface 1384 including a plurality of ridges or ratchet portions 1386. In the illustrated embodiment, the strap 1380 is threaded through the first and second openings 1392, 1394 such that the ratchet surface 1384 faces radially-inward and the tab portion 1382 is positioned near and/or in the second opening 1394 and is accessible at the first surface 1391. In the first position shown in Figure 13A, the tab portion 1382 is separated from (e.g., disengaged from, decoupled from) the ratchet surface 1384. In the second position shown in Figure 13B, the tab portion 1382 engages the ratchet surface 1384.

[0064] In operation, with the tensioning assembly 1302 in the first position, a user can thread one or more sutures along the ratchet surface 1384 of the strap 1380 and through the first opening 1392 (e.g., in a direction from the first surface 1391 toward the second surface 1393). The user can then move the tensioning assembly 1302 to the second position by pressing the tab portion 1382 of the strap 1380 against the ratchet surface 1384 and the suture to secure the suture to the strap 1380 (e.g., against one or more of the ratchet portions 1386). In some embodiments, the user can then adjust the tensioning in the strap by pulling/pushing the strap 1380 through the base 1390, like a zip-tie, until a desired suture tension is reached. To remove the suture, the tensioning assembly 1302 can be returned to the first position and the suture removed from the first opening 1392.

[0065] In some embodiments, the tensioning assemblies described in detail herein can have other features and/or the features of the various embodiments can be combined. For example, any of the tensioning assemblies including a rotatable actuation member (e.g., the tensioning assembly 702, the tensioning assembly 802, the tensioning assembly 902, and so on) can utilize a slot rather than a hole for securing the suture to the actuation member. Specifically, for example, the elongate portion 785 of the actuation member 786 of the tensioning assembly 702 described in detail with respect to Figures 7A and 7B can include a slot extending at least

partially therethrough instead of the second through-hole 787. The slot can receive and secure the suture without requiring that the slot be fully aligned with the channel 781 of the base portion 780 or the first through-hole 784. Similarly, the second through-hole 896 of the actuation member 890 of the tensioning assembly 802 described in detail with respect to Figure 8 can be replaced with a slot, and so on. In some embodiments, the tensioning assemblies described in detail herein can have one or more locking features for inhibiting movement of the actuation members to, for example, maintain tension in a suture secured thereto/therein.

[0066] Several aspects of the present technology are set forth in the following examples:

1. A device for tensioning a suture, comprising:
a housing having a first through-hole; and
an actuator coupled to the housing and having a second through-hole, wherein the actuator is movable relative to the housing from a first position to a second position, wherein the first through-hole and the second through-hole are configured to receive a suture therethrough, and wherein—
when the first through-hole and the second through-hole receive the suture and the actuator is in the first position, the actuator and the housing cooperate to inhibit the suture from moving relative to the housing; and
when the first through-hole and the second through-hole receive the suture and the actuator is in the second position, the actuator and the housing cooperate to permit the suture to move relative to the housing.
2. The device of example 1, further comprising a flexible pad coupled to the housing.
3. The device of example 2 wherein the flexible pad is configured to be placed against skin of a patient and to conform to the skin of the patient.
4. The device of any one of examples 1–3 further comprising a biasing member operably coupled between the actuator and the housing, wherein the biasing member is configured to bias the actuator to the first position.

5. The device of any one of examples 1–4 wherein the first through-hole and the second through-hole are axially offset in the first position, and wherein the first through-hole and the second through-hole are axially aligned in the second position.

6. The device of example 5 wherein the housing and actuator engage the suture in the first position to clamp the suture relative to the housing.

7. The device of any one of examples 1–6 wherein the first through-hole and the second through-hole are aligned along an axis in the second position, and wherein the actuator is movable from the first position to the second position in a direction generally orthogonal to the axis.

8. A suture tensioning device, comprising:
a housing having a first through-hole and a second through-hole, wherein the first and second through-holes are at least partially aligned along an axis;
an actuator slidably coupled to the housing, wherein the actuator includes a third through-hole; and
a biasing member operably coupled between the actuator and the housing, wherein the biasing member is configured to bias the actuator toward a first position in which the third through-hole is offset from the axis, and wherein the actuator is movable to a second position in which the third through-hole is at least partially aligned with the first and second through-holes along the axis.

9. The suture tensioning device of example 8 wherein the first, second, and third through-holes are configured to receive a suture therethrough, and wherein the actuator and the housing engage the suture when the actuator is in the first position to inhibit the suture from moving through the first, second, and third through-holes.

10. The suture tensioning device of example 8 or example 9 wherein the first, second, and third through-holes are configured to receive a suture therethrough, and wherein the actuator and the housing engage the suture when the actuator is in the first position to maintain a tension of the suture.

11. The suture tensioning device of any one of examples 8–10 wherein the biasing member is a first biasing member, wherein the suture tensioning device further comprises a second biasing member operably coupled between the actuator and the housing, and wherein the first and second biasing members are configured to bias the actuator to the first position.

12. The suture tensioning device of any one of examples 8–11, further comprising a flexible pad coupled to a lower portion of the housing, wherein the flexible pad includes a fourth through-hole aligned with the first and second through-holes along the axis, and wherein the flexible pad is configured to be placed against skin of a patient and to conform to the skin of the patient.

13. The suture tensioning device of any one of examples 8–12, further comprising a dressing assembly configured to be attached to skin of a patient around a puncture in the skin, wherein the housing is configured to be releasably coupled to the dressing assembly.

14. The suture tensioning device of any one of examples 8–14 wherein the actuator is movable from the first position to the second position in a direction generally orthogonal to the axis.

15. A method of tensioning a suture used to close a puncture in skin of a patient, the method comprising:

- threading the suture through a suture tensioning device;
- adjusting a tension of the suture to a desired tension; and
- actuating the suture tensioning device to lock the suture in the suture tensioning device to maintain the desired tension.

16. The method of example 15 wherein actuating the suture tensioning device to lock the suture includes releasing an actuator of the suture tensioning device.

17. The method of example 16 wherein adjusting the tension of the suture includes pulling the suture while depressing the actuator.

18. The method of example 16 or example 17 wherein the method further comprises, after releasing the actuator to lock the suture, pulling the suture while depressing the actuator to adjust the tension in the suture from the desired tension to another desired tension.

19. The method of any one of examples 15–18 wherein the method further comprises adjusting the tension in the suture from the desired tension to another desired tension, wherein adjusting the tension in the suture to the other desired tension includes actuating the suture tensioning device to unlock the suture from the suture tensioning device.

20. The method of any one of examples 15–19 wherein the method further comprises positioning a flexible pad of the suture tensioning device against the skin of the patient.

[0067] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0068] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0069] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in

the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A device for tensioning a suture, comprising:
a housing having a first through-hole; and
an actuator coupled to the housing and having a second through-hole, wherein the actuator is movable relative to the housing from a first position to a second position, wherein the first through-hole and the second through-hole are configured to receive a suture therethrough, and wherein—
when the first through-hole and the second through-hole receive the suture and the actuator is in the first position, the actuator and the housing cooperate to inhibit the suture from moving relative to the housing; and
when the first through-hole and the second through-hole receive the suture and the actuator is in the second position, the actuator and the housing cooperate to permit the suture to move relative to the housing.
2. The device of claim 1, further comprising a flexible pad coupled to the housing.
3. The device of claim 2 wherein the flexible pad is configured to be placed against skin of a patient and to conform to the skin of the patient.
4. The device of claim 1 further comprising a biasing member operably coupled between the actuator and the housing, wherein the biasing member is configured to bias the actuator to the first position.
5. The device of claim 1 wherein the first through-hole and the second through-hole are axially offset in the first position, and wherein the first through-hole and the second through-hole are axially aligned in the second position.
6. The device of claim 5 wherein the housing and actuator engage the suture in the first position to clamp the suture relative to the housing.

7. The device of claim 1 wherein the first through-hole and the second through-hole are aligned along an axis in the second position, and wherein the actuator is movable from the first position to the second position in a direction generally orthogonal to the axis.

8. A suture tensioning device, comprising:
a housing having a first through-hole and a second through-hole, wherein the first and second through-holes are at least partially aligned along an axis;
an actuator slidably coupled to the housing, wherein the actuator includes a third through-hole; and
a biasing member operably coupled between the actuator and the housing, wherein the biasing member is configured to bias the actuator toward a first position in which the third through-hole is offset from the axis, and wherein the actuator is movable to a second position in which the third through-hole is at least partially aligned with the first and second through-holes along the axis.

9. The suture tensioning device of claim 8 wherein the first, second, and third through-holes are configured to receive a suture therethrough, and wherein the actuator and the housing engage the suture when the actuator is in the first position to inhibit the suture from moving through the first, second, and third through-holes.

10. The suture tensioning device of claim 8 wherein the first, second, and third through-holes are configured to receive a suture therethrough, and wherein the actuator and the housing engage the suture when the actuator is in the first position to maintain a tension of the suture.

11. The suture tensioning device of claim 8 wherein the biasing member is a first biasing member, wherein the suture tensioning device further comprises a second biasing member operably coupled between the actuator and the housing, and wherein the first and second biasing members are configured to bias the actuator to the first position.

12. The suture tensioning device of claim 8, further comprising a flexible pad coupled to a lower portion of the housing, wherein the flexible pad includes a fourth through-hole aligned

with the first and second through-holes along the axis, and wherein the flexible pad is configured to be placed against skin of a patient and to conform to the skin of the patient.

13. The suture tensioning device of claim 8, further comprising a dressing assembly configured to be attached to skin of a patient around a puncture in the skin, wherein the housing is configured to be releasably coupled to the dressing assembly.

14. The suture tensioning device of claim 8 wherein the actuator is movable from the first position to the second position in a direction generally orthogonal to the axis.

15. A method of tensioning a suture used to close a puncture in skin of a patient, the method comprising:

threading the suture through a suture tensioning device;
adjusting a tension of the suture to a desired tension; and
actuating the suture tensioning device to lock the suture in the suture tensioning device to maintain the desired tension.

16. The method of claim 15 wherein actuating the suture tensioning device to lock the suture includes releasing an actuator of the suture tensioning device.

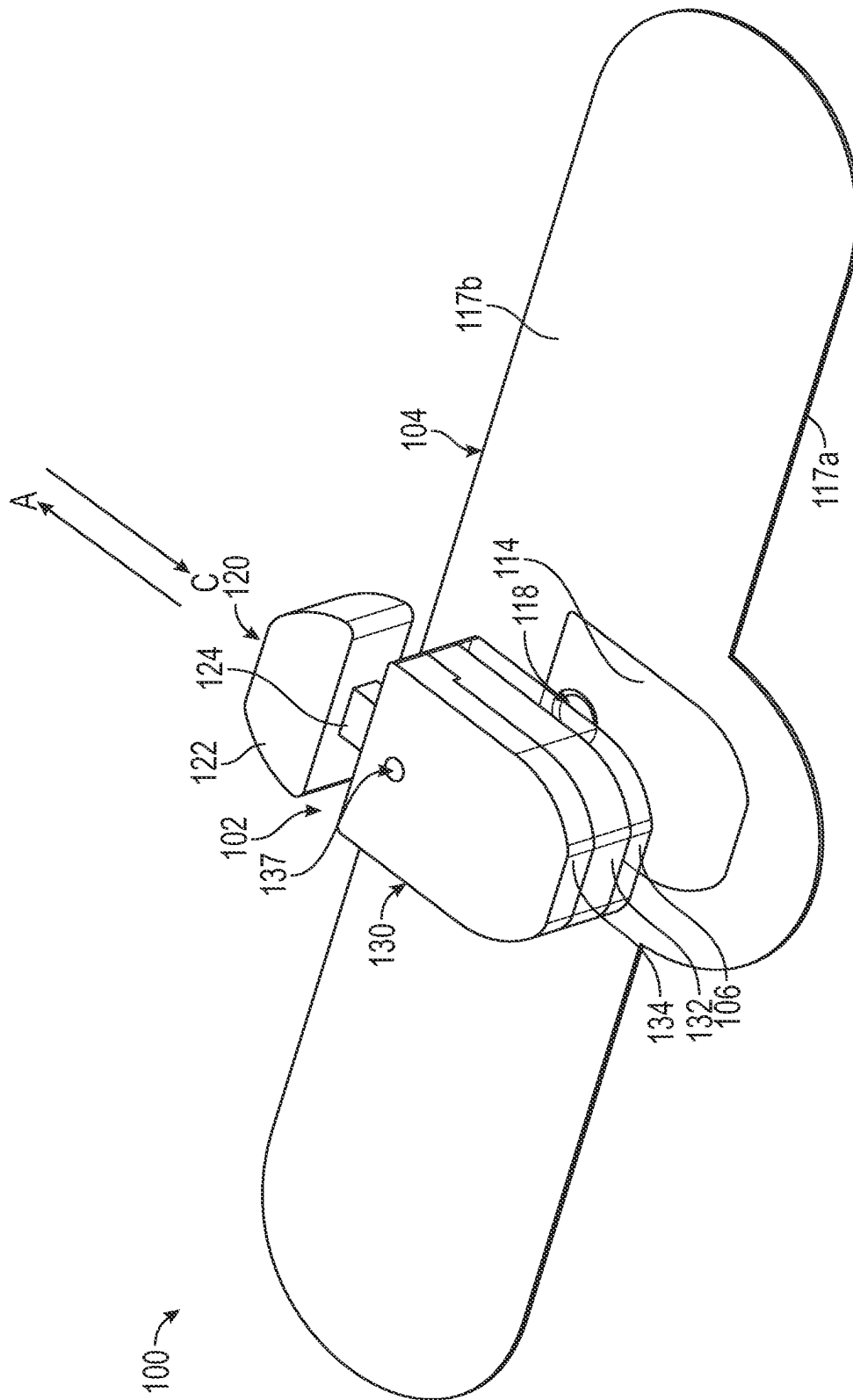
17. The method of claim 16 wherein adjusting the tension of the suture includes pulling the suture while depressing the actuator.

18. The method of claim 16 wherein the method further comprises, after releasing the actuator to lock the suture, pulling the suture while depressing the actuator to adjust the tension in the suture from the desired tension to another desired tension.

19. The method of claim 15 wherein the method further comprises adjusting the tension in the suture from the desired tension to another desired tension, wherein adjusting the tension in the suture to the other desired tension includes actuating the suture tensioning device to unlock the suture from the suture tensioning device.

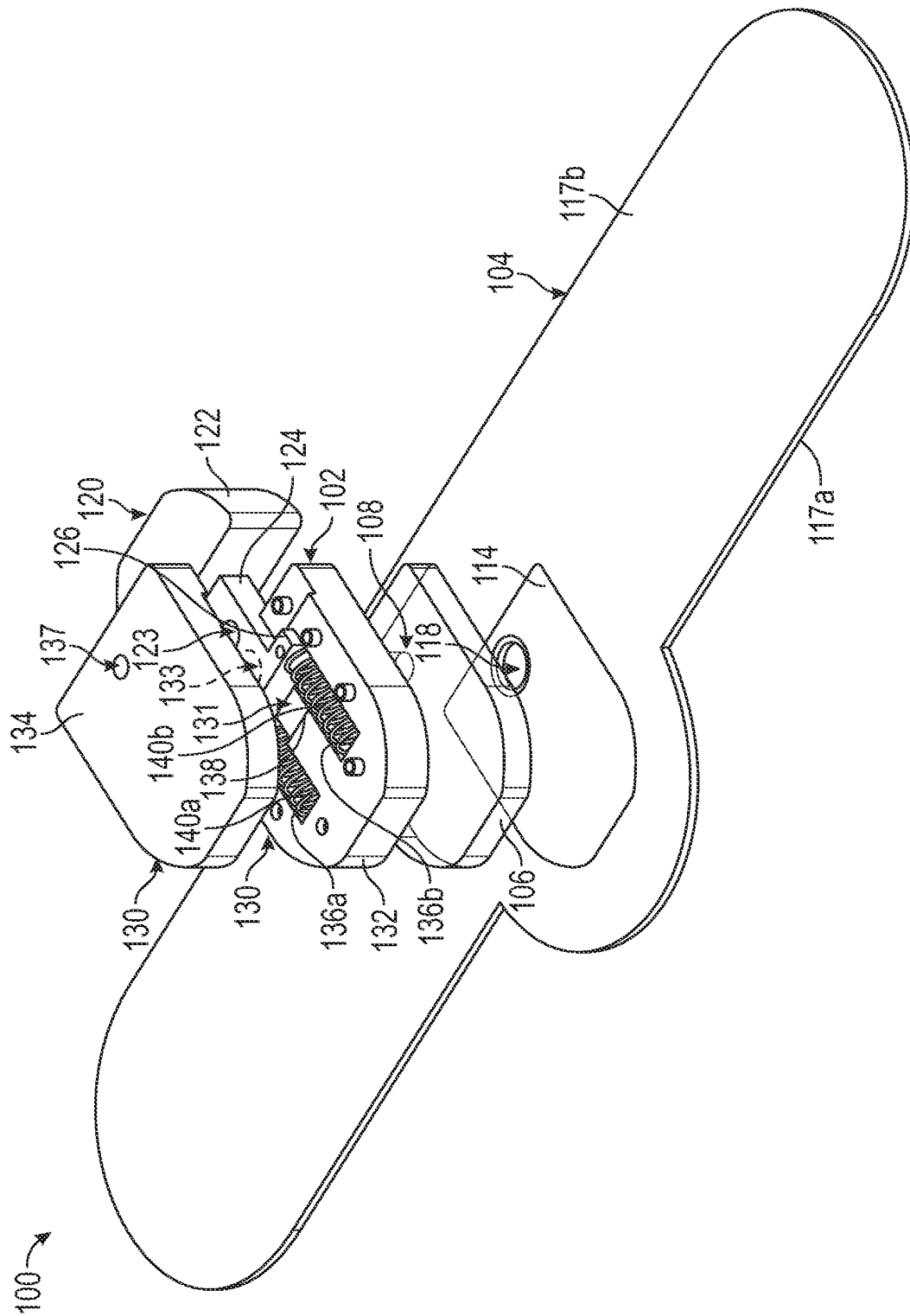
20. The method of claim 15 wherein the method further comprises positioning a flexible pad of the suture tensioning device against the skin of the patient.

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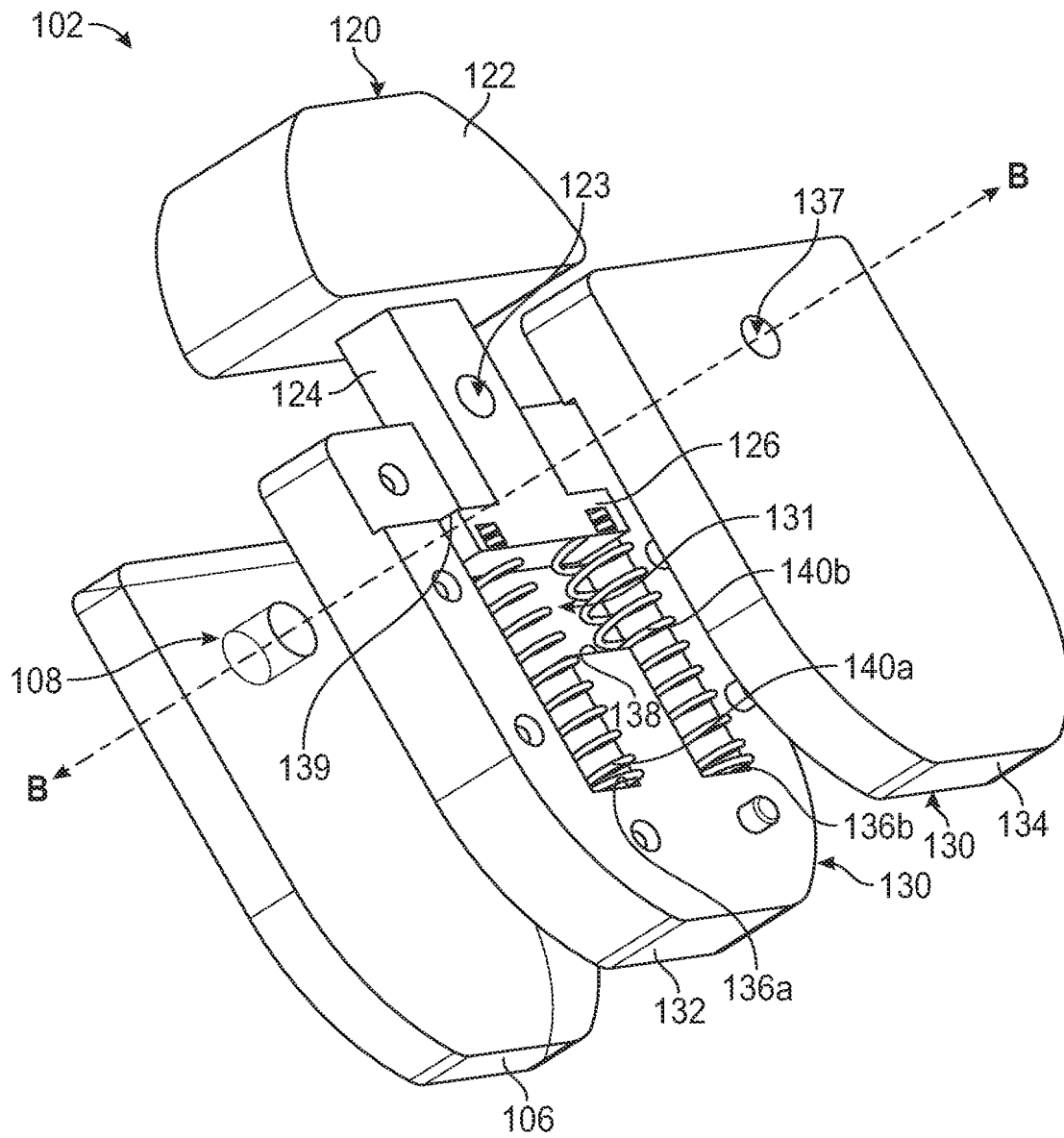


FIG. 1C

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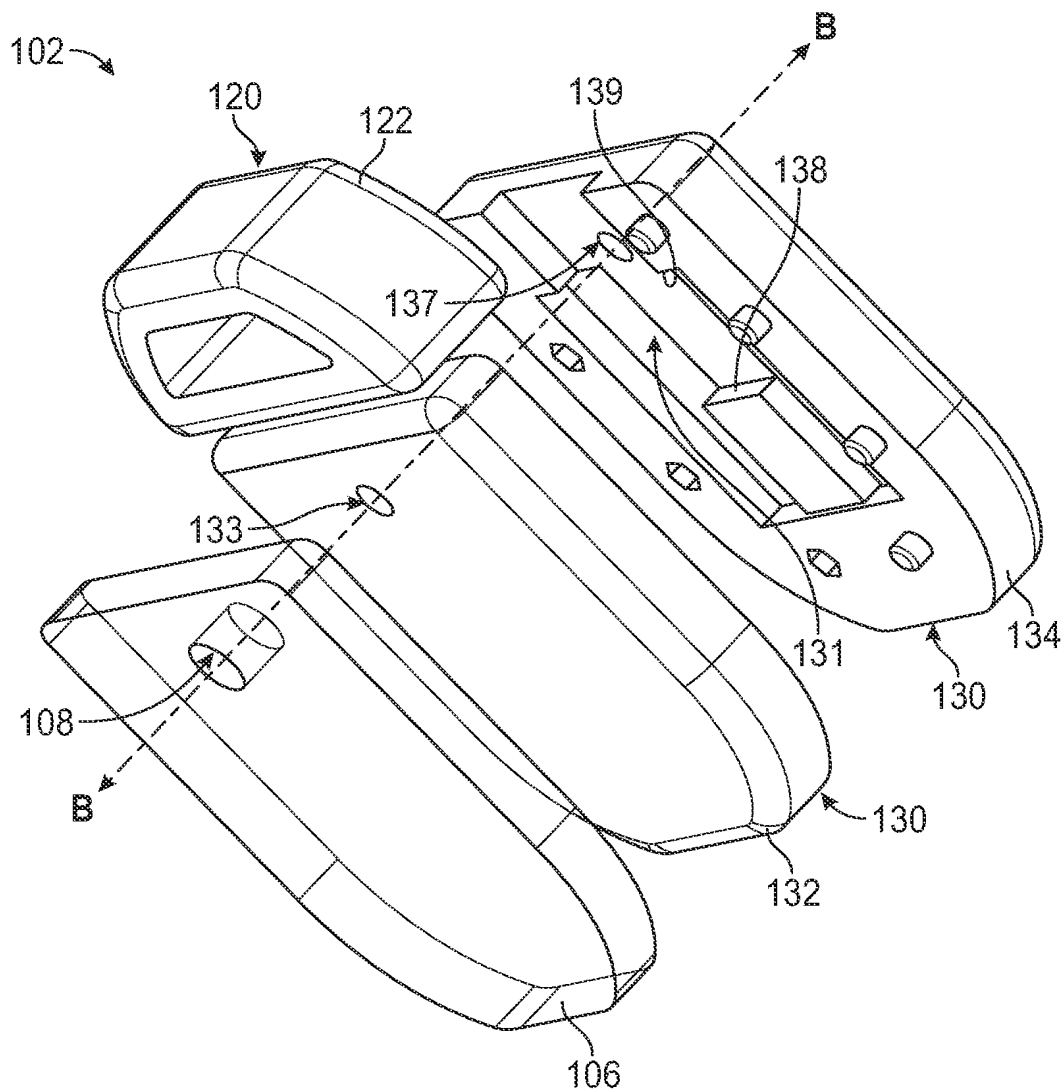


FIG. 1D

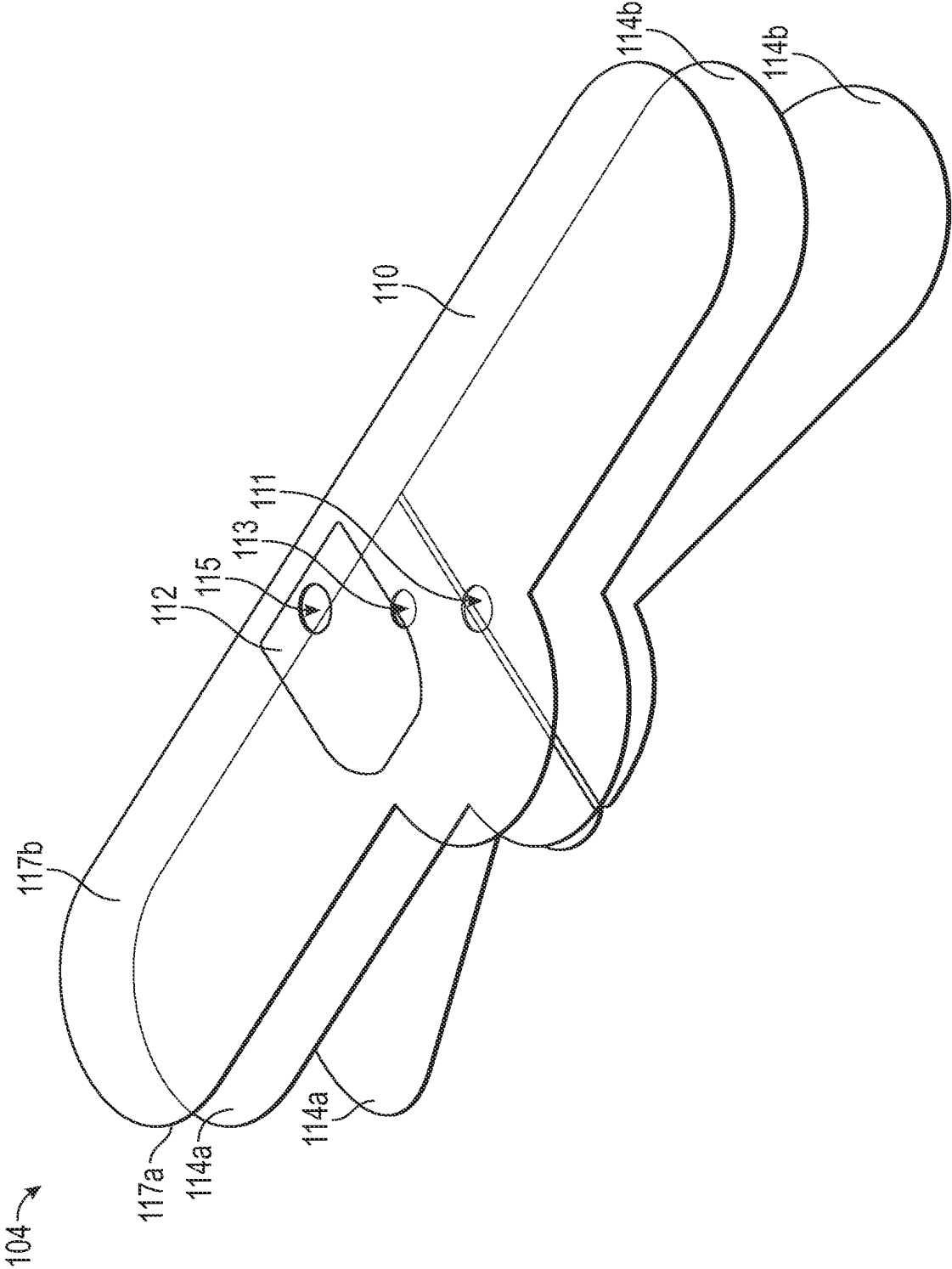


FIG. 1E

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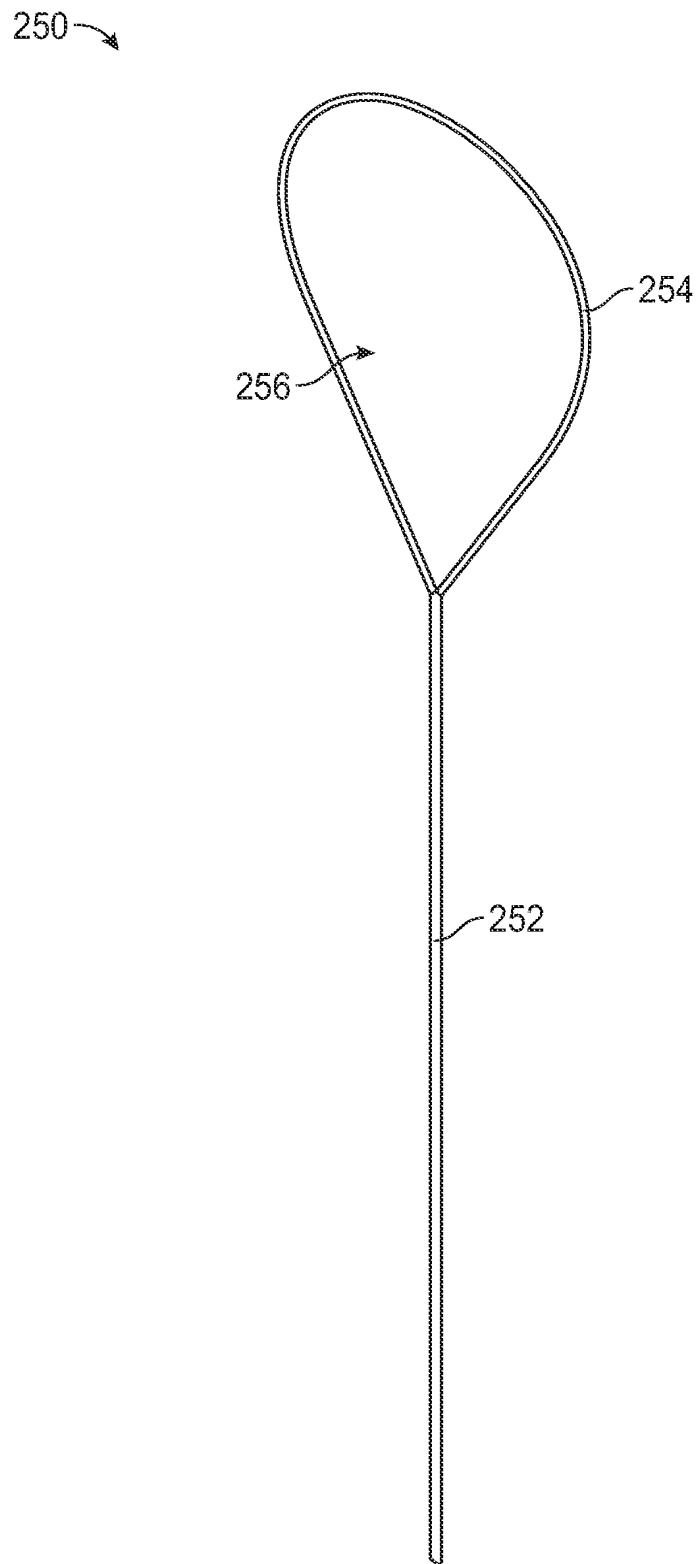


FIG. 2

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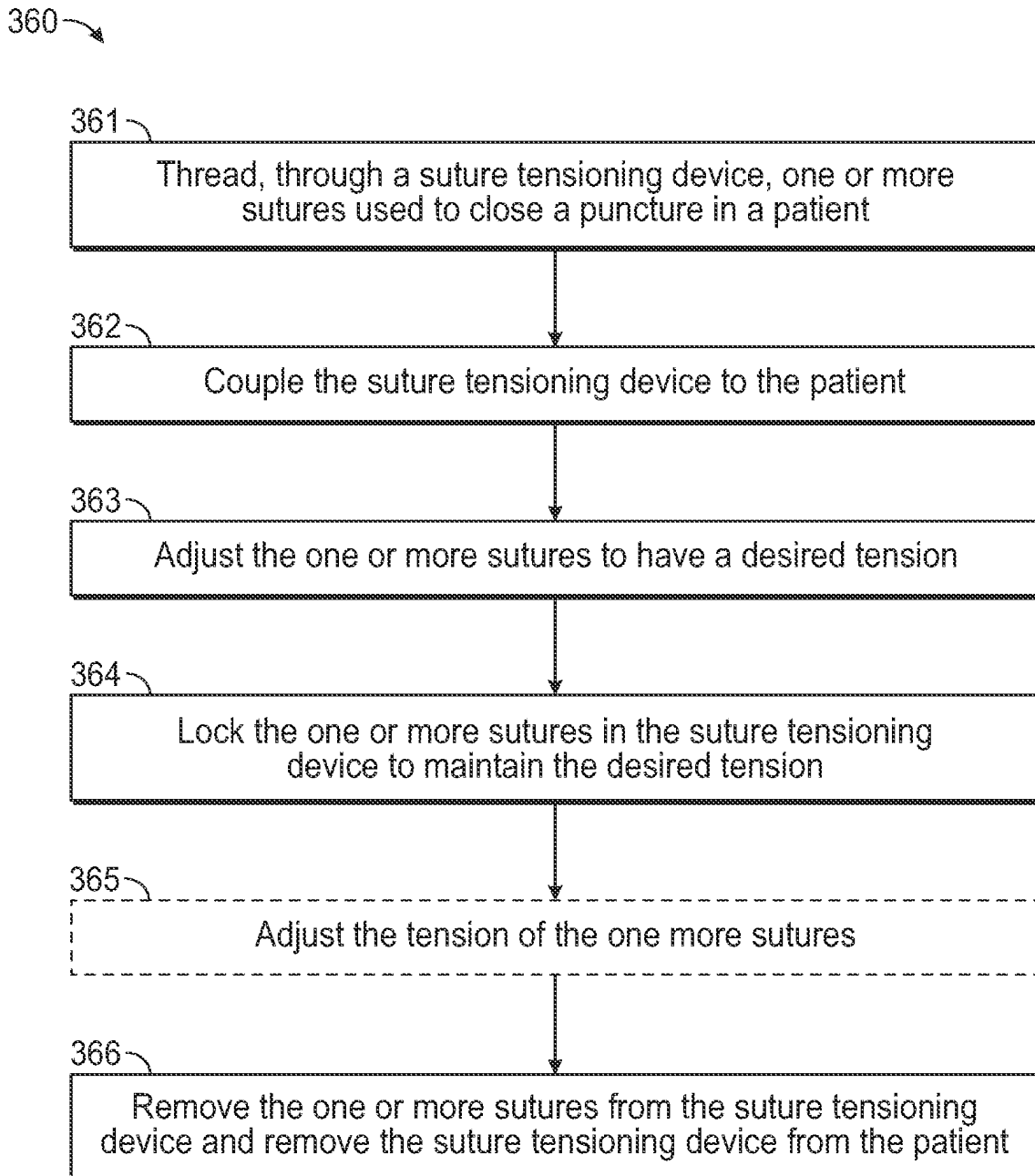


FIG. 3

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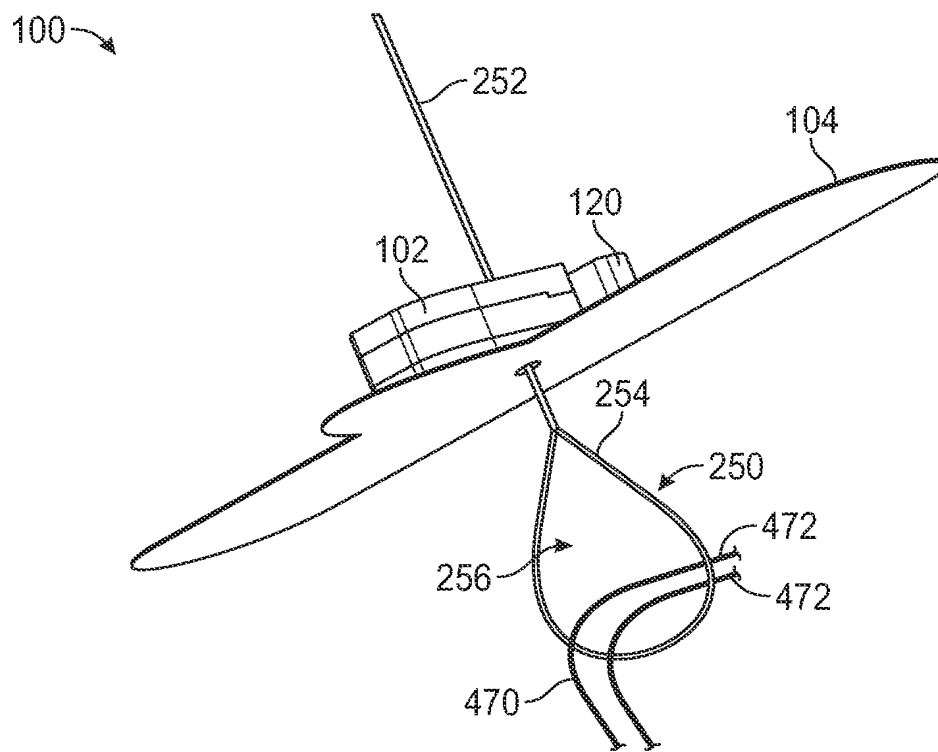


FIG. 4A

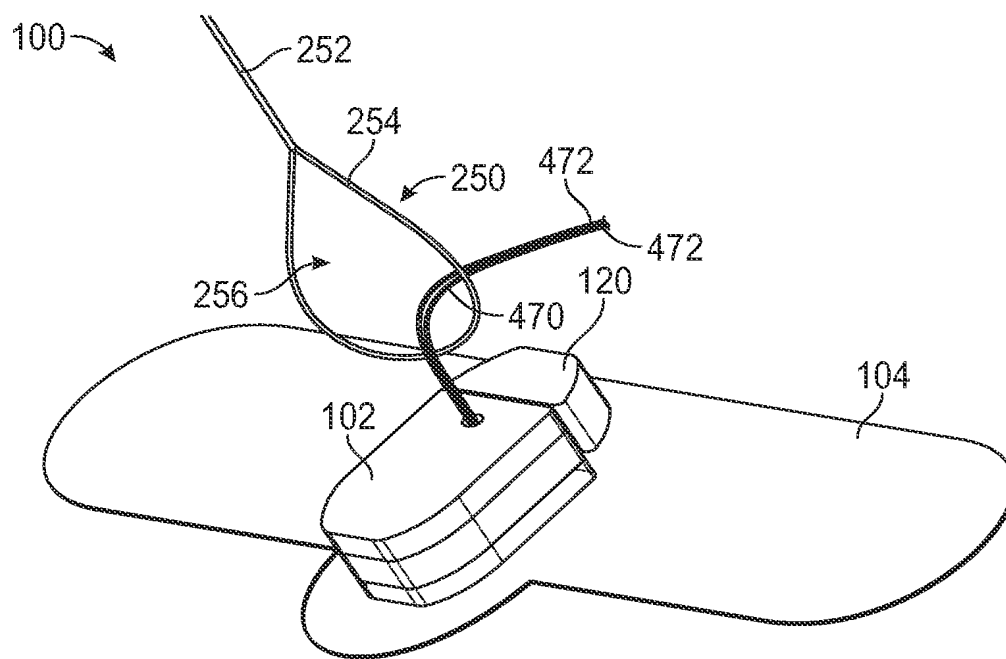


FIG. 4B

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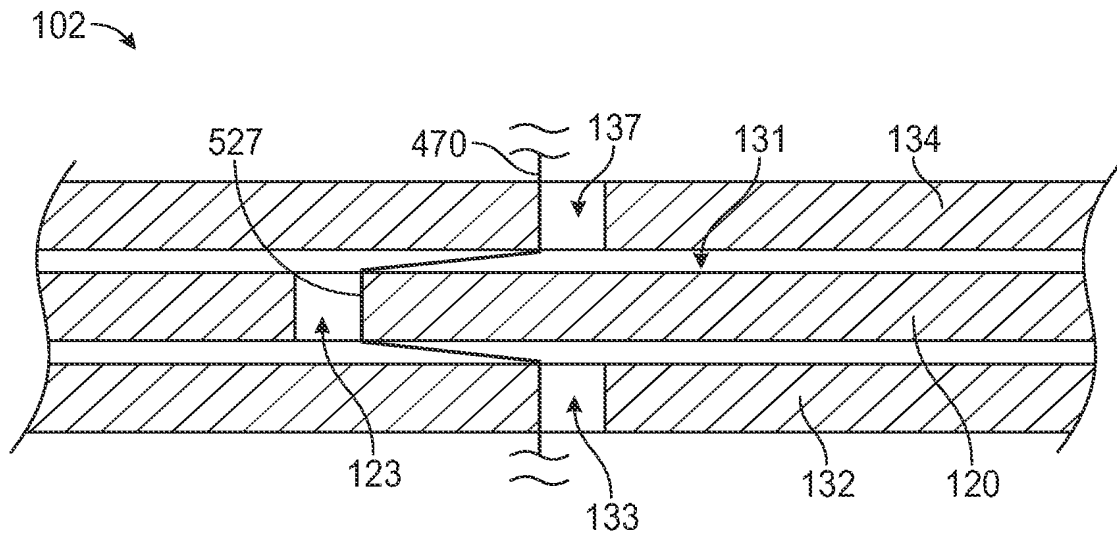


FIG. 5

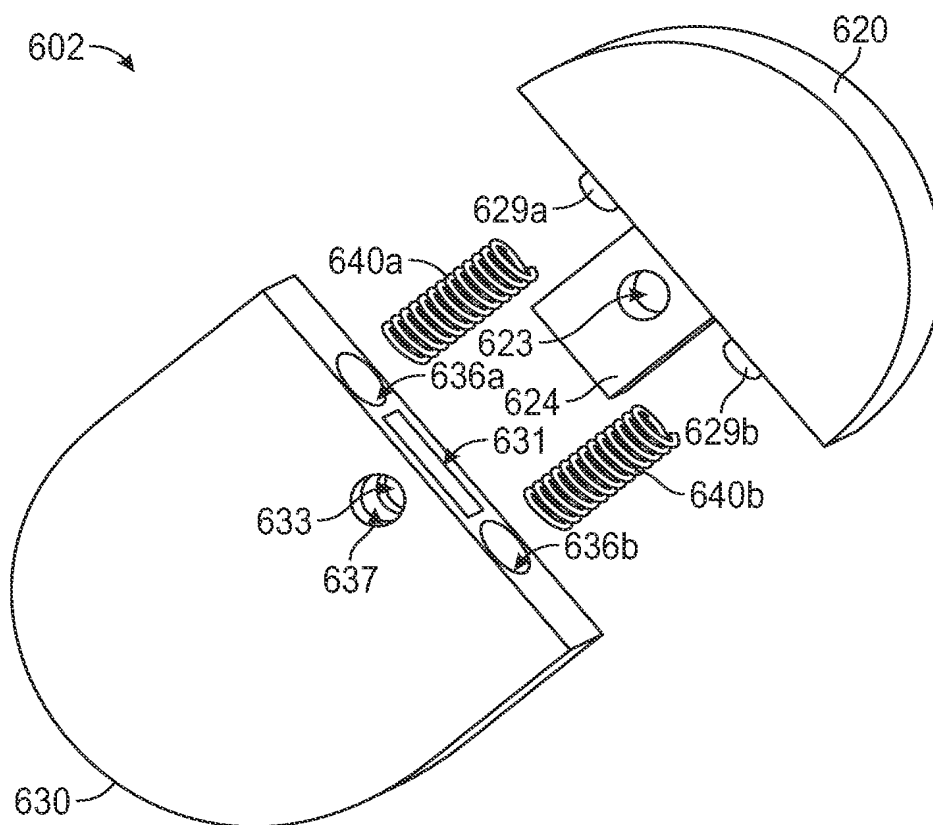


FIG. 6

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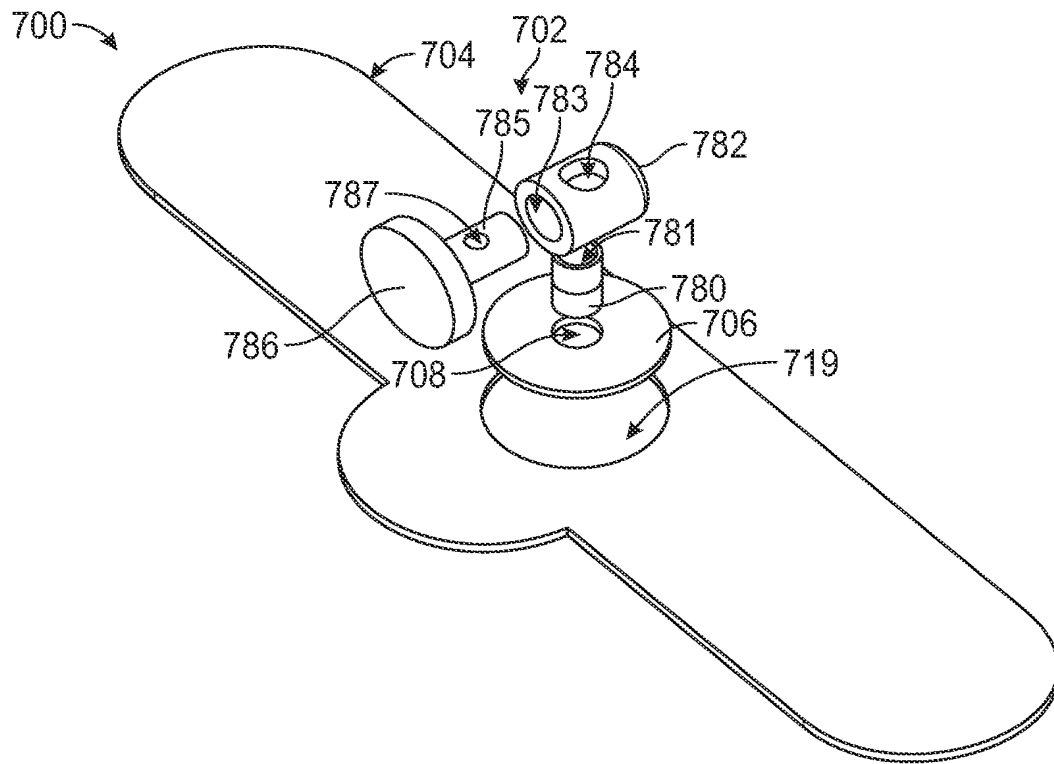


FIG. 7A

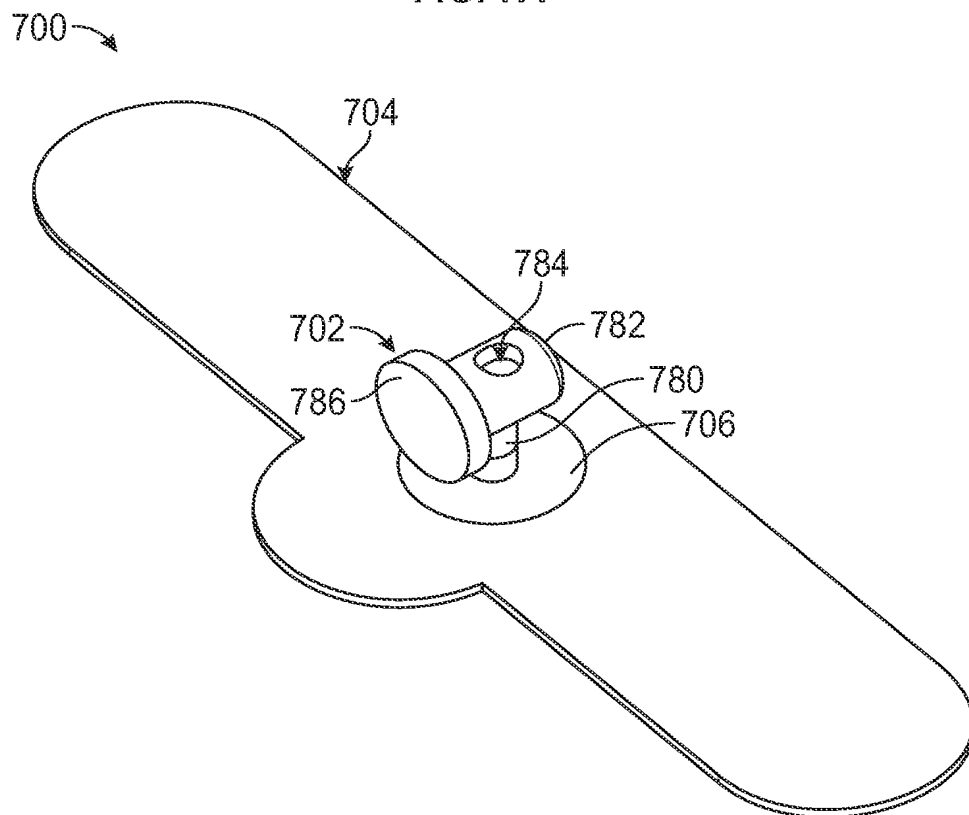


FIG. 7B

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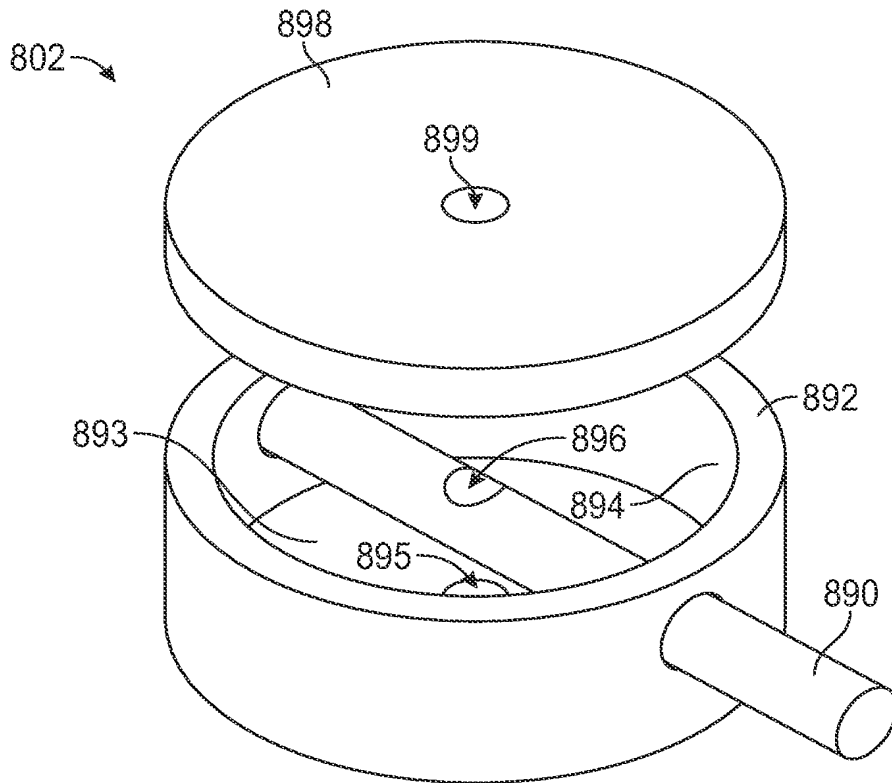


FIG. 8

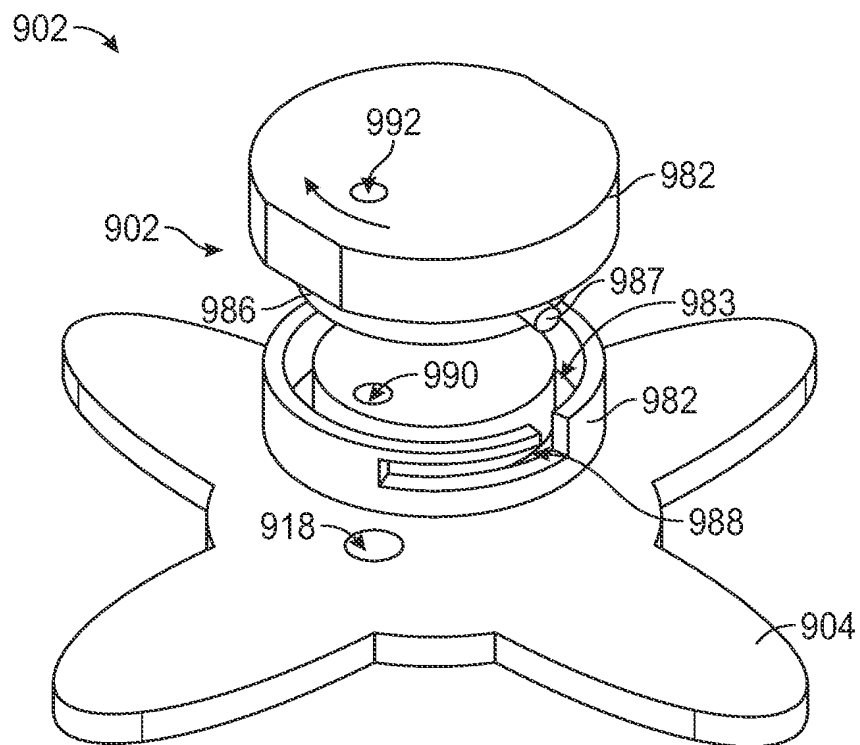


FIG. 9

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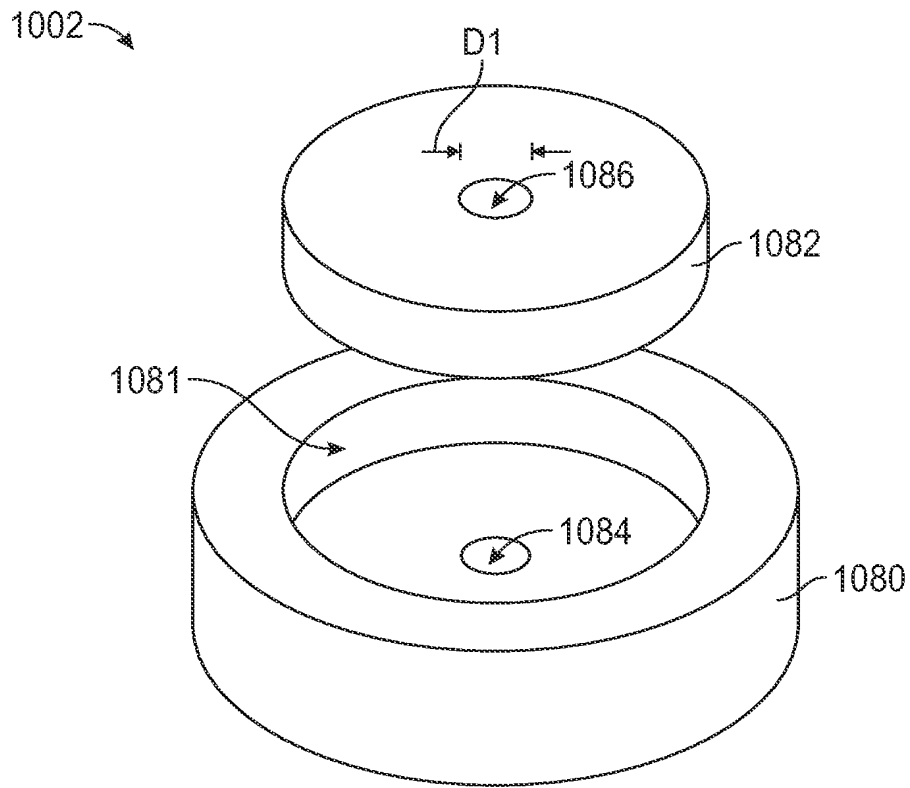


FIG. 10A

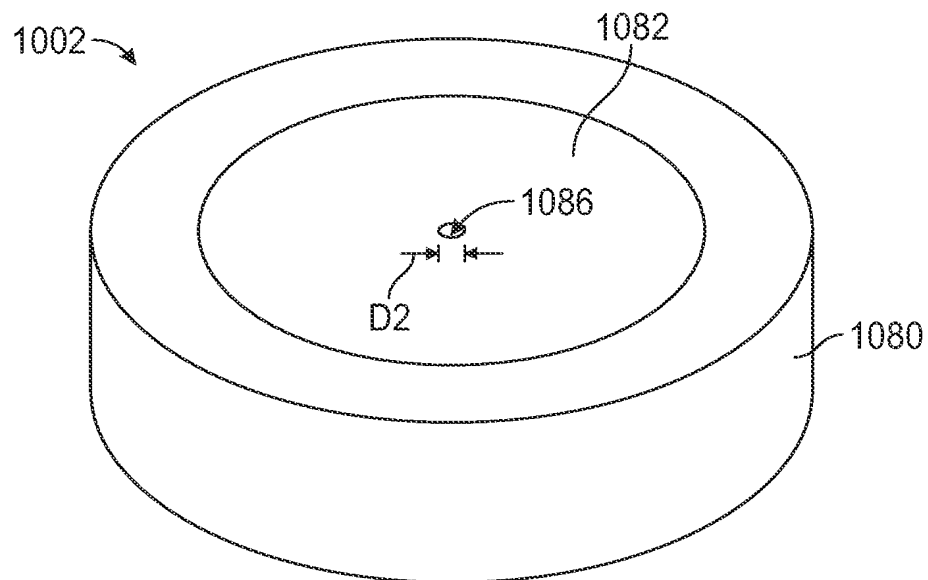


FIG. 10B

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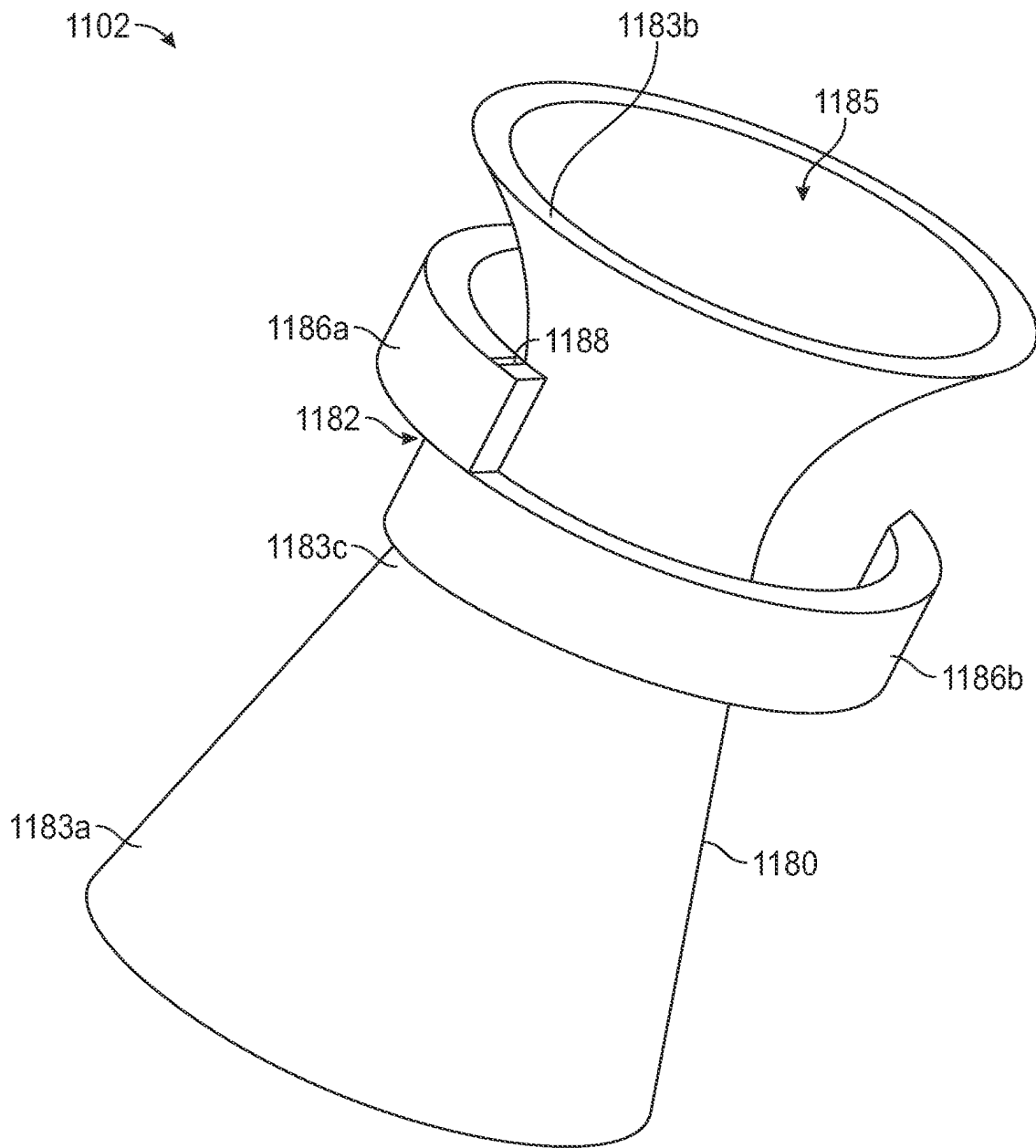


FIG. 11

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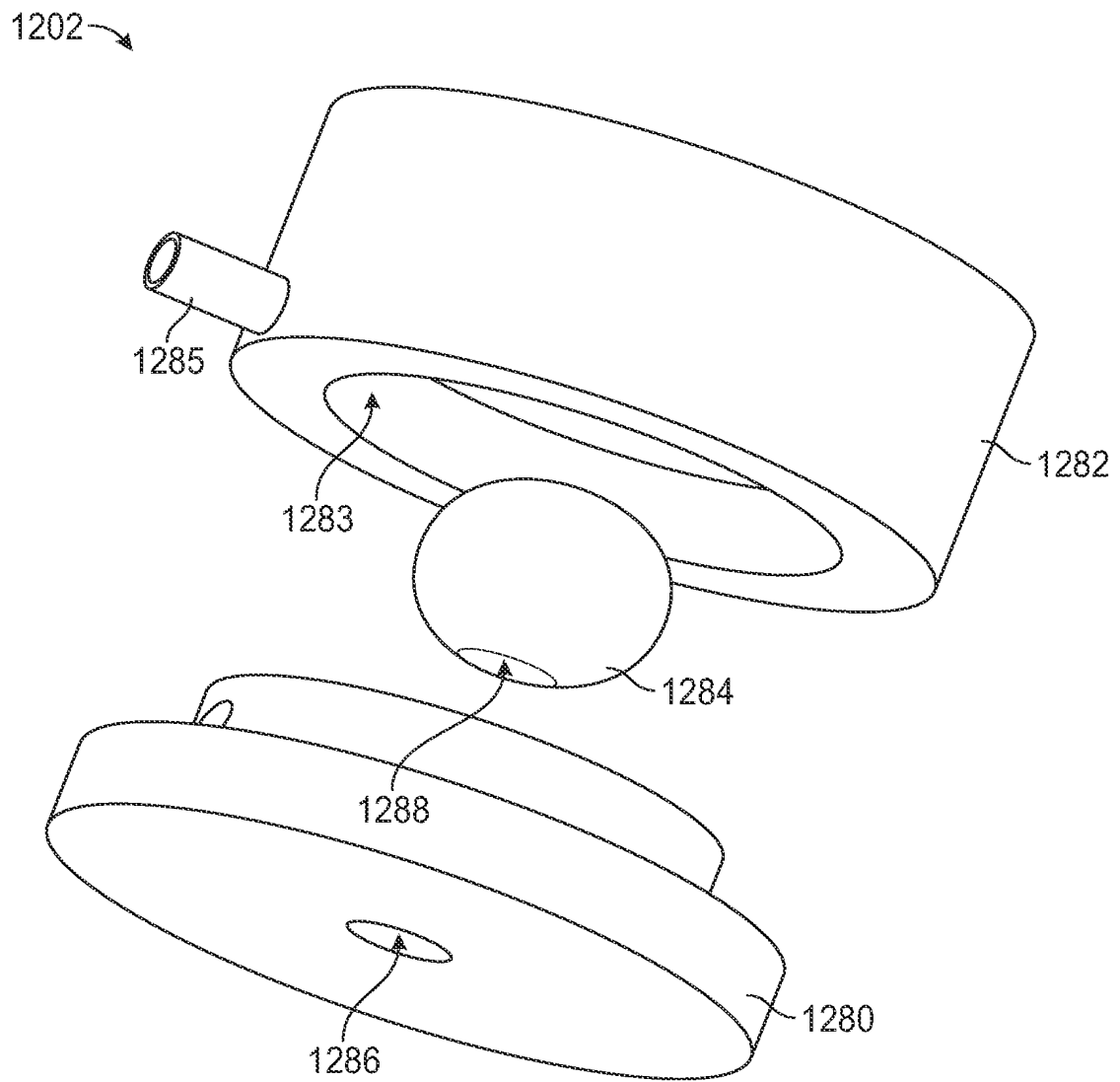


FIG. 12

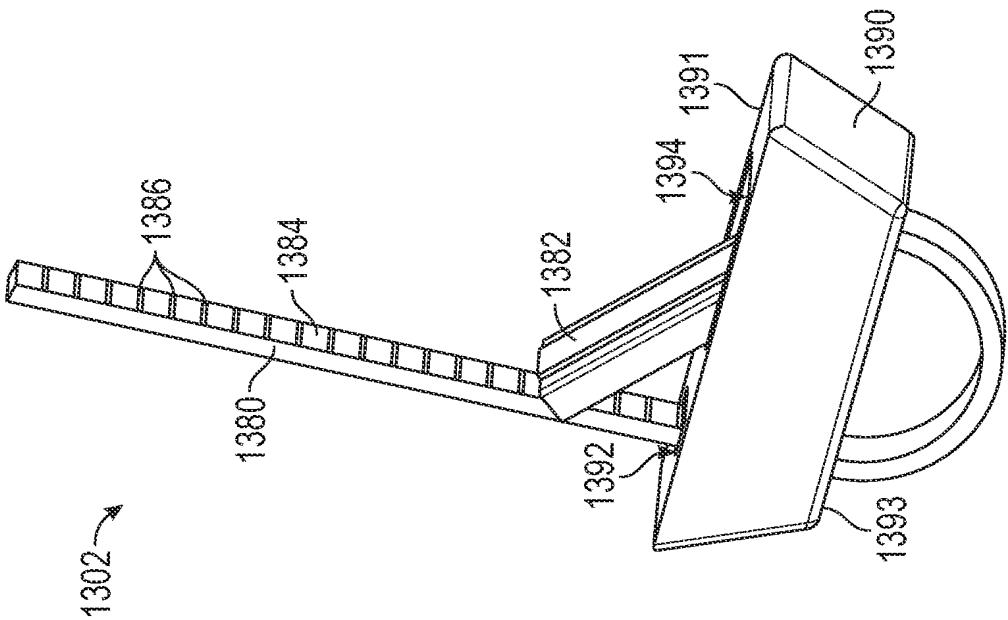


FIG. 13B

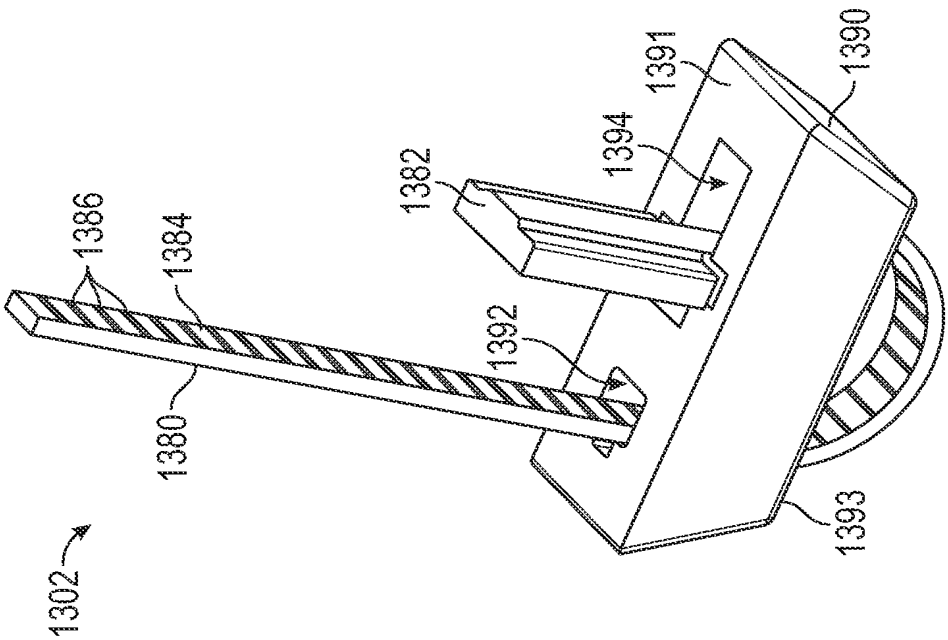


FIG. 13A

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/58793

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 17/03; A61B 17/04 (2022.01)

CPC - A61B 17/04; A61B 2017/0496; A61B 17/03; A61B 17/56; A61B 17/0467; A61B 17/8869; A61B 17/0482; A61B 17/0469

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,376,101 A (GREEN et al.) 27 December 1994 (27.12.1994); entire document, especially col 6 ln 56 to col 7 ln 17, and Fig. 15-18.	1, 5-7
Y		2-4
Y	US 5,192,274 A (BIERMAN) 9 March 1993 (09.03.1993); especially col 2 ln 21-54, and Fig. 1-2.	2-3
Y	US 2013/0116708 A1 (ZINITI et al.) 9 May 2013 (09.05.2013); especially para [0090], and Fig. 18A-B.	4
A	US 2004/0260344 A1 (LYONS et al.) 23 December 2004 (23.12.2004); entire document.	1-7

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

2 March 2022

Date of mailing of the international search report

MAR 16 2022

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US 21/58793

-*- Box III.0 - Explanations where unity of invention is lacking -*-

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of when the first through-hole and the second through-hole receive the suture and the actuator is in the second position, the actuator and the housing cooperate to permit the suture to move relative to the housing, not required by the claims of Group II-III.

The invention of Group II includes the special technical feature of a biasing member operably coupled between the actuator and the housing, not required by the claims of Group I or II.

The invention of Group III includes the special technical feature of adjusting a tension of the suture to a desired tension, not required by the claims of Group I-II.

COMMON TECHNICAL FEATURES

Groups I-III share the common technical feature of a suture tensioning device.

However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 8,888,791 B2 (JARAMILLO et al.) (hereinafter Jaramillo), which discloses a suture tensioning device (100; Fig. 1; col 5 ln 40-62).

Groups I-II share the common technical feature of a device for tensioning a suture, comprising:

a housing having a first through-hole; and

an actuator coupled to the housing and having a second through-hole,

wherein the actuator is movable relative to the housing from a first position to a second position.

However, this shared technical feature does not represent a contribution over prior art as being anticipated by Jaramillo, which discloses a device for tensioning a suture (Fig. 9; col 7 ln 41-51), comprising:

a housing (upper housing of 900; Fig. 9; col 7 ln 41-51) having a first through-hole (902; Fig. 9; col 7 ln 41-51); and

an actuator (903, unlabeled semicircular half adjacent 903; Fig. 9; col 7 ln 41-51) coupled to the housing and having a second through-hole (901; Fig. 9; col 7 ln 41-51),

wherein the actuator is movable relative to the housing from a first position (903 adjacent and flush with housing of 900; Fig. 9; col 7 ln 41-51) to a second position (position of Fig. 9 with 903 deployed rotated outward; Fig. 9; col 7 ln 41-51).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.



(12)发明专利申请



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责任公司 11240

代理人 刘凤迪

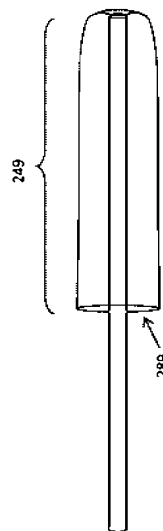
权利要求书2页 说明书31页 附图83页

(54)发明名称

机械取栓装置

(57)摘要

一种用于从血管去除凝块而没有堵塞的机械取栓装置,包括:导管,具有远侧端部区域和远侧端部开口,其中,远侧端部区域的在远侧端部开口处的硬度大于远侧端部区域的紧邻远侧端部开口的区域的硬度,进一步其中,远侧端部开口具有圆形唇缘轮廓;柔性管,在导管内延伸并且在导管的远侧端部上翻折回来,其中,柔性管被配置成当在导管内向近侧拉动柔性管的第一端部时在远侧端部开口上滑动并翻转;以及穿过导管和柔性管的导丝腔,被配置成使导丝通过。



1. 一种用于从血管去除凝块而不堵塞的机械取栓装置,所述装置包括:

导管,具有远侧端部区域和远侧端部开口,其中,所述远侧端部区域的在所述远侧端部开口处的硬度大于所述远侧端部区域的紧邻所述远侧端部开口的硬度,进一步其中,所述远侧端部开口具有圆形唇缘轮廓;

柔性管,在所述导管内延伸并且在所述导管的所述远侧端部上翻折回来,其中,所述柔性管被配置成当在所述导管内向近侧拉动所述柔性管的第一端部时在所述远侧端部开口上滑动并翻转;以及

穿过所述导管和所述柔性管的导丝腔,被配置成使导丝通过。

2. 根据权利要求1所述的装置,其中,所述柔性管具有大于5cm的长度,并且所述柔性管被配置成使得通过向所述柔性管的远侧端部施加小于1000克的力,能将所述柔性管收回到所述导管中。

3. 根据权利要求1所述的装置,其中,所述柔性管包括编织管。

4. 根据权利要求1所述的装置,其中,所述柔性管的在所述导管的所述远侧端部上翻折回来的区域形成唇缘,所述唇缘相对于所述导管的长轴线具有 5° 至 60° 之间的滚动角度(ϕ)。

5. 根据权利要求1所述的装置,其中,延伸穿过所述导管并且在所述导管的所述远侧端部上翻折回来的所述柔性管使所述导管的远侧5cm的刚度增加小于所述导管的所述远侧5cm的所述刚度的15%,而不使所述柔性管延伸穿过所述导管和在所述导管的所述远侧端部上翻折回来。

6. 根据权利要求1所述的装置,还包括位于所述柔性管上的可释放附件,所述可释放附件被配置成当以大于0.01N的预定力阈值的力拉动所述柔性管时释放。

7. 根据权利要求1所述的装置,其中,所述柔性管被配置成当所述柔性管在所述导管中被轴向地且向近侧拉动时径向地压缩5%至20%之间。

8. 根据权利要求1所述的装置,还包括在所述导管和所述柔性管上延伸的外导管。

9. 根据权利要求1所述的装置,其中,所述柔性管被配置成当在所述导管内向近侧拉动所述柔性管的第一端部时在所述远侧端部开口上翻转,其中,所述柔性管具有低泊松比,使得网状的所述柔性管当被用足够的力在所述导管内向近侧拉动时的直径大于所述导管的内径的一半,以在所述远侧端部开口上翻转。

10. 根据权利要求1所述的装置,还包括在所述导管内并耦接到所述柔性管的远侧端部的细长拉动器,其中,所述细长拉动器包括具有内腔的海波管,所述内腔与穿过所述柔性管的所述导丝腔连续。

11. 根据权利要求1所述的装置,还包括围绕所述柔性管的远侧端部区域的保持环,所述保持环被配置成将所述柔性管保持抵靠在所述导管上。

12. 根据权利要求1所述的装置,还包括真空连接件,所述真空连接件用于将所述导丝腔耦接到真空以通过所述导丝腔施加真空。

13. 根据权利要求1所述的装置,还包括外导管真空泵,所述外导管真空泵耦接到所述导管与所述柔性管之间的空间并且被配置成在所述导管的位于所述导管的内壁与所述柔性管之间的腔内施加真空。

14. 根据权利要求1所述的装置,还包括:拉动器,其中,所述柔性管的远侧端部耦接到

所述拉动器的远侧端部;以及外导管,所述外导管布置在所述导管上且邻近于所述柔性管的近侧端部,所述装置还包括具有控制器的手柄,所述控制器被配置成协调推进所述外导管以向远侧推动所述柔性管的所述近侧端部和向近侧拉动所述拉动器以将所述柔性管的所述近侧端部拉入所述导管。

15.根据权利要求1所述的装置,所述柔性管被能释放地保持,并且所述柔性管被配置成当用大于0.01N的预定力阈值的力拉动所述柔性管时释放。

机械取栓装置

[0001] 本申请是申请日为2016年2月15日、申请号为201680056752.7的中国发明专利申请“机械取栓装置和方法”的分案申请。

[0002] 相关申请的交叉引用

[0003] 本专利申请要求以下临时专利申请中的每一个的优先权，其中的每一个的全部内容通过引证结合于本文：2015年9月28日提交的美国临时专利申请第62/284,300号；2015年10月8日提交的美国临时专利申请第62/284,752号；以及2015年10月23日提交的美国临时专利申请第62/245,560号。

[0004] 本说明书中提到的所有公开和专利申请的全部内容都通过引用结合于本文，其程度如同每个单独的公开或专利申请被特定地和单独地指示通过引用结合。

技术领域

[0005] 本文所描述的装置和方法涉及从身体内机械去除物体。具体地，本文描述了机械取栓装置和方法。

背景技术

[0006] 通常希望尽可能以微创方式从身体中去除组织，以免损伤其他组织。例如，从脉管系统去除组织（例如，血凝块）可改善患者状况和生活质量。

[0007] 许多脉管系统问题源于流过血管的血液不足。造成血液流量不足或不规则的一个原因是血管内的阻塞，这被称为血凝块或血栓。出现血栓的原因很多，包括诸如手术的创伤之后或由于其他原因。例如，在美国超过120万的心脏病发作中很大一部分是由冠状动脉内形成的血凝块（血栓）引起的。

[0008] 当形成血栓时，它可以有效地阻止血液流过形成区域。如果血栓横过脉的内径延伸，则其可以切断通过动脉的血液流动。如果冠状动脉中的一个100%形成血栓，则血液流动在该动脉中停止，导致携带红血球的氧气短缺，例如用于供应心脏壁的肌肉（心肌）。此类血栓形成对于防止血液损失是不必要的，但是可能由于动脉粥样硬化疾病对动脉壁的损伤而在动脉内被不期望地引发。因此，动脉粥样硬化的潜在疾病可能不会引起急性缺氧（缺血），但可经由诱导血栓形成引发急性缺血。类似地，颈动脉中的一个的血栓形成可导致中风，这是因为颅内重要神经中枢的供氧不足。缺氧会降低或禁止肌肉活动，会引起胸痛（心绞痛），并可导致心肌死亡，这在某种程度上会永久地使心脏失去活力。如果心肌细胞死亡很广泛，则心脏将不能泵送足够的血液以供应人体的生命维持需求。局部缺血的程度受许多因素影响，包括可以提供必要氧气的侧支血管和血流的存在。

[0009] 临床数据表明，去除凝块对于改善预后可能是有益的，甚至是必要的。例如，在外周脉管系统中，发明和程序可以减少80%的截肢需求。治疗这些动脉或静脉系统状况的任何方式的最终目标是快速、安全且经济有效地去除堵塞或恢复通畅。这可以通过血栓溶解、碎裂、血栓抽吸或这些方法的组合来实现。

[0010] 导管导向取栓术和溶栓治疗通常被认为创伤小，不太可能降低与常规手术技术

相关的发病率和死亡率。近年来,将化学溶解剂直接给予冠状动脉已经显示出对具有血栓形成冠状动脉的患者有益处。在此过程中,将导管立即置于堵塞物的前方,并将链激酶滴定位成在血栓的上游侧定向。链激酶是一种能够及时溶解纤维蛋白分子的酶。该程序可能需要几个小时,并不总是成功地打破血栓。此外,其可能导致下游血栓碎片(栓子),这可能导致小直径分支的堵塞。美国专利第4,646,736号公开了一种取栓设备,其可以快速去除阻塞性血栓。然而,该装置的特征在于小的导管尖端尺寸,并因此不能对凝块施加显著的总力。而且,在旋转线材的“火线”中,未处于在血管壁上取得的良好位置的凝块不会被纤维切除。对于血流中游离的凝块尤其如此,这是因为在不存在诸如手指的限制的情况下,在这些凝块内旋转几乎是不可能的。

[0011] 该取栓设备的其它缺点包括当在旋转期间线材侧向移动时难以在所有旋转角度期间将凝块保持在线材上方的空间中,这对于扫动脉腔有时是需要的。实际上,除了最小的动脉(即直径小于1.5mm)之外,几乎不可能用旋转线材扫出整个动脉腔。附加的严重的可能的缺点是凝块的碎片可能在下游成为栓塞。

[0012] 美国专利申请2015/0005781中描述了用于捕获栓子的另一种方法。该申请描述了具有从远侧端部延伸的篮状件的导管。可以向近侧拉动诸如杆或线缆的致动器以将篮状件收回到导管中。不幸的是,篮状件阻塞腔的内部,阻止与定位和/或支撑导丝同时使用,并且篮状件必须保持在导管的远侧端部中或在其附近。取决于被去除的材料(例如凝块)的硬度,篮状件的取回通常会使导管的远侧端部收缩,阻止其使用,并且篮状件可能难以拉入导管中,特别是当保持凝块时。这可能会导致使凝块偏向。最后,在插入血管中之前,篮状件必须被预加载到导管的远侧端部中,并且预加载可能既困难又耗时,并且可能在展开之前破坏设备。

[0013] 因此,确实需要一种可以更有效地从身体内去除诸如凝块的组织的取栓设备,特别是机械取栓设备。本文所描述的是可以解决上面论述的需要和问题的装置(设备、系统和套件)以及使用它们的方法。

发明内容

[0014] 通常,本文描述了医疗装置,包括医疗设备和包括这些医疗设备的系统,以及操作这些医疗设备以用于收集对象的方法,所述对象包括但不限于血凝块(血栓)、组织(活组织检查、小肿瘤、息肉、钙化物、肾结石等)。本文所描述的装置通常包括细长导管,其具有腔和远侧端部并具有通向腔中的远侧端部开口。导管可以是具有任何适当直径(例如<1Fr、1Fr至6Fr、1Fr至9Fr等)的低轮廓神经导管(例如微导管、插入导管等)。柔性牵引器组件或部分(例如,在本文中可被称为柔性牵引器管或简单地称为柔性管)通常定位在导管内并且可在导管内纵向滑动,并且布置成使得远侧端部区域(“远侧牵引器区域”)在导管的远侧端部上翻折回来。柔性管(“牵引器管”)通常是细长和中空的,并且被配置成当在导管内向近侧拉动柔性管的第一端部时在远侧端部开口上滑动和翻转。形成远侧牵引器区域的远侧端部可以是管状的或不是管状的(例如,它可以由材料条等形成)。组合式导管和柔性牵引器组件还形成穿过导管和柔性管的导丝腔,该导丝腔被配置成使导丝穿过。

[0015] 在使用中,导丝可以被配置成滑动穿过该装置(并且可以形成装置的一部分)以允许定位并且在一些变型中支撑,通常在不干扰牵引器管的操作的情况下将诸如血凝块

的物体拉入导管的主体。

[0016] 除了具有布置在导管内并且在导管的远侧端部上翻转或翻折的柔性牵引器管的导管之外,本文所描述的装置还可以包括一个或多个特征或元件,其允许这些设备在脉管系统内操作而不收缩,特别是在其远侧端部处,尽管在优选地相当柔软的远侧端部的远侧边缘/开口上施加拉力矩。进一步地,这些装置可以适用于最小化将远侧牵引器区域取回到导管中并在导管的远侧端部开口上翻转而不损坏或减弱远侧牵引器区域所需的力,从而防止装置内的柔性牵引器管在其本身上或与导管一起破裂、束缚、堵塞或缠结。例如,如下面将更详细描述,这些装置中的任一个可以包括在导管的远侧端部处或附近的选择性润滑区域。导管端部可以被成形为允许管的远侧端部的柔性牵引器区域的翻转。另外,导管的端部轮廓(例如,最远侧5mm、4mm、3mm、2mm、1mm等)可以具有防止导管的收缩/屈曲的刚度(例如硬度)的布置。可替代地或附加地,柔性牵引器管可以适于在导管周围“扫动”血管的尽可能大部分以从血管内收集物体,同时仍然允许相对较低的力收回到导管中并且在导管的远侧端部上翻转。柔性管的牵引器部分(可指代管的在导管内的远侧部分)通常可包括邻近于第二可较少扩张(或不可扩张)的端部区域的远侧可扩张(第一)端区,其要么紧邻要么由间隔区域分开。第二端部区域靠近于第一端部区域(当第一端部区域和第二端部区域两者都被拉入导管时)。柔性牵引器管可以一直延伸穿过导管到达近侧端部和/或近侧手柄,或者其可以在导管的近侧端部之前终止并且连接到拉动器。拉动器可以是另一个可能较少柔性管,或者线材、杆、绳等。柔性牵引器管通常被配置成具有穿过其的腔(例如,中心腔或径向偏移的腔),导丝可以穿过该腔通过,穿过包括导管和柔性牵引器管的装置。当导丝位于该腔内时,通常可以操作柔性牵引器管(例如,向近侧拉动并且在一些变型中向远侧推动)。

[0017] 装置可预先加载以用于远侧牵引器区域的展开以及物体在脉管内的捕获,或者在一些变型中,装置可以在将导丝和/或导管定位在血管内之后或期间在体内加载。例如,在一些变型中,通过保持远侧牵引器区域收回到导管中直到导管位于脉管内,并且优选地在待去除的物体附近,该装置可以适于体内使用。一旦定位,柔性管的在导管内的远侧牵引器区域可以从导管向远侧延伸,扩张以形成捕获形状,其可以在向远侧推进导管或不向远侧推进导管的情况下被拉入并且在导管的远侧端部上翻转。因此,远侧牵引器部分可以被安全且可靠地输送至腔内的必要部位,而没有损坏装置或身体的风险。

[0018] 例如,执行机械取栓以从血管去除凝块的方法可以包括:将导管的远侧端部朝向凝块推进通过血管;将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露,其中,远侧牵引器区域包括可扩张的第一端部区域以及靠近于可扩张的第一端部区域的可较少扩张的第二端部区域;允许可扩张的第一端部区域在血管内扩张;将导管的远侧端部定位成使得导管的远侧端部区域位于远侧牵引器区域的可较少扩张的第二端部区域和可扩张的第一端部区域之间,同时可扩张的第一端部区域在可较少扩张的第二端部区域上翻折;以及通过将可扩张的第一端部区域在导管的远侧端部上滚动使得可扩张的第一端部区域在可扩张的第一端部区域被拉动到导管中时翻转,将凝块拉入导管。

[0019] 如上所述,将导管的远侧端部朝向凝块推进通过血管的步骤可以包括在导丝上推进。导管可以在导丝上向远侧滑动或者与导丝一起向远侧延伸(或向近侧收回)。内(牵引器)管可以被保持在导管内(例如,在远侧端部附近、中间区域或者在近侧端部附近),或

者在一些变型中,可以在将导管定位在脉管内之后插入。导管的远侧端部可以定位在待去除的物体(例如,凝块)处、附近或邻近,或者它可以分开预定的距离,例如以允许通过将远侧牵引器区域延伸出导管的远侧端部之外并且扩张以准备将物体取回到导管中来设定用于装置的空间。

[0020] 因此,一旦定位,就可以通过暴露远侧牵引器区域并且定位导管的远侧端部以及在一些变型中的导丝来展开该装置,以允许物体被捕获并被拉入导管。通过向近侧拉动导管,同时保持包括远侧牵引器区域的柔性管静止(例如相对于血管)和/或通过向远侧延伸柔性管,可以暴露远侧牵引器区域。

[0021] 如上所述,柔性管可以包括远侧牵引器区域,该远侧牵引器区域包括可扩张的第一端部区域。该端部区域通常是多孔的(例如,由网状物、针织物、机织物或其他材料形成,包括具有穿设有多个开口的固体材料)并且适于抓取待去除的物体(例如血块)。该第一端部区域通常可扩张至导管的内径的约1.3倍至约10倍之间(例如,在约1.5倍至约7倍之间、约1.5倍至约5倍之间、约1.5倍至约4倍之间、约1.5倍至约3倍等)。形成牵引器部分的该第一远侧端部区域通常邻近于可较少扩张(或基本上不可扩张的)的第二端部区域。第二区域可以使导管向近侧一直向下延伸,或者使导管部分向下延伸。通常,牵引器部分的第一端部区域暴露于导管之外并用于捕获凝块或其他物体;第二端部区域可在定位期间暴露,但在操作期间可保持在导管内。

[0022] 因此,将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露可以包括将远侧牵引器区域延伸或推出导管的远侧端部之外。在一些变型中,远侧牵引器区域被预先形成使得第一可扩张的远侧端部区域在第二远侧端部区域上翻折;在其他变型中,第一远侧端部区域与可较少扩张的第二远侧端部区域在同一直线上且远离。然后可以向远侧移动导管,使得导管的远侧端部区域(包括远侧端部)在远侧牵引器区域的扩张的可扩张的第一端部区域与可较少扩张的第二端部区域之间的径向间隙中延伸。

[0023] 在远侧牵引器区域被推出导管的远侧端部之外的任何变型中,例如在该初始体内设置阶段期间,柔性管(特别是远侧牵引器区域)可以被配置成或以其他方式适于允许推出导管之外而不束缚。如果可扩张的第一端部区域特别地被捕获在导管的内壁上,则可能发生可扩张的管的导管内的束缚,从而阻止展开。在一些变型中,可扩张的第一端部区域被配置成具有细丝(例如镍钛诺、聚合物等)的网状管状构件,该网状管状构件在具有约24至144个股线,股线在直径上的厚度为0.0005英寸至0.005英寸,其中,网状管状构件在纵向轴线上延伸,进一步其中,网状管状构件的长度大于5cm,当围绕导管的远侧端部被拉动和翻转时,在纵向轴线的方向上的交叉股线之间形成35度的编织角度,并且当不受约束时在导管的外部扩张到大于导管的内径的1.5倍的直径。在该配置下,管状构件被发现是可推动的。

[0024] 在其他变型中,当可扩张的第一远侧端部区域被推出或延伸出导管的远侧端部之外时,其可以被配置(例如,预成形、形状设定等)成在导管的远侧端部上翻转并扩张。导管可以向远侧移动,帮助将远侧牵引器区域的该可扩张的第一端部区域相对于导管的外侧向近侧推动。

[0025] 在这些方法中的任一种中,远侧牵引器区域可以包括可扩张的第一端部区域以及靠近于可扩张的第一端部区域的可较少扩张的第二端部区域,并且可扩张的第一端部

区域被允许在血管内扩张。

[0026] 因此,在展开阶段即将结束之际,导管的远侧端部通常被定位成使得导管的远侧端部区域径向地位于远侧牵引器区域的可较少扩张的第二端部区域和可扩张的第一端部区域之间,同时可扩张的第一端部区域在可较少扩张的第二端部区域上翻折。

[0027] 此后,可以通过将可扩张的第一端部区域在导管的远侧端部上滚动来将物体(例如凝块)拉入导管,使得当可扩张的第一端部区域被拉入导管中时,可扩张的第一端部区域翻转。

[0028] 如上所述,定位可以包括向远侧推进导管的远侧端部,使得导管的远侧端部区域位于远侧牵引器区域的可较少扩张的第二端部区域和可扩张的第一端部区域之间。

[0029] 导丝可以与本文所描述的任何方法一起使用。对于本文所描述的任何方法而言,可以包括将血管内的导丝推进至凝块,其中,推进导管的远侧端部包括在导丝上推进导管通过血管,直到导管的远侧端部靠近于凝块。导丝可以插入或穿过凝块,或者其可以刚好位于凝块之前。导丝可以在凝块去除期间被留下,或者其首先可以部分或完全取回。例如,这些方法中的任一种可以包括将血管内的导丝推进至凝块,其中,推进导管的远侧端部包括在导丝上推进导管穿过血管,直到导管的远侧端部靠近于凝块。进一步其中,将凝块拉入导管包括在将可扩张的第一端部区域在导管的远侧端部上滚动的同时在导丝上朝向凝块推进导管。

[0030] 将凝块拉入导管通常包括将远侧牵引器区域(例如,可扩张的第一端部区域)在导管的远侧端部上滚动。该装置也可以在远侧牵引器区域的致动期间向远侧移动。例如,将血块拉入导管可以包括向近侧取回管(以将远侧牵引器区域在远侧端部上滚动)和/或在向远侧推进导管的同时向近侧取回管。

[0031] 在这些方法中的任一种中,将凝块拉入导管可包括在向远侧推进导管的同时向近侧取回管,其中,以与推进导管不同的速率取回该管。在一些配置中,比向近侧拉管(远侧牵引器区域)更迅速地向远侧推进导管可能是有益的。在一些变型中,可以比向近侧取回管(远侧牵引器区域)更慢地推进导管。可替代地,它们以相同的速率移动。通过观察导管内的近侧运动(例如,第二端部区域的近侧运动)可以确定柔性管的运动速率。

[0032] 通常,远侧牵引器区域的可扩张的第一端部区域是可扩张的并且可以形成可以与诸如凝块的物体接合的面向远侧的嘴部或唇缘。可扩张的牵引器区域的唇缘的嘴部可相对于导管外径(OD)的长轴线形成5度至60度、并且优选地至少为10度(例如10°至60°、10°至50°、10°至45°等)范围内的切向角度或滚动角度(如下面参考图18A至图18C和图21D更详细描述)。只要滚动角度至少为10度并且管收回到导管中,则管应该不会束缚或阻塞导管尖端。网状管可以通过改变刚度以确保滚动角度大于10度而构造。可替代地或与保持最小滚动角度组合,可能期望在导管的最远侧尖端处保持导管材料ID和导管的OD之间的物理空间或间隙(如下面在图18A至图18C中更详细描述)。该间隙可能需要大于例如0.1 mm、0.2 mm、0.3 mm、0.4 mm、0.5 mm、0.7 mm、0.8 mm、0.9 mm、1.0 mm等,以确保当管被收回时管围绕导管的远侧端部滚动。扩张材料(例如网状材料、机织材料、编织材料、针织材料、穿孔材料等)可以允许其本身在血管内扩张。因此可扩张的第一区域可以是可自扩张的。远侧牵引器区域的可扩张的第一端部区域可以被预先偏置以扩张。在一些变型中,使用形

状记忆材料(例如,形状记忆合金)。在一些变型中,偏置元件被包括在可扩张的第一端部区域中或与可扩张的第一端部区域成一体以扩张使得远侧牵引器区域。可扩张的第一端部区域可以扩张至接触血管的内膜。在一些变型中,装置可以被配置(例如,设定尺寸,包括确定可扩张的第一端部区域的尺寸),使得远侧牵引器区域的最远侧端部与血管腔接触。因此,本文所描述的变型中的任一个可以附加地或可替代地包括偏置元件,诸如圈、环、支架等以推动可扩张的远侧端部区域,使得其可以通过施加增加的径向力将其扩张开来而与脉管接触。在一些变型中,该开口偏置(圈、螺旋、环等)位于远侧牵引器区域的可扩张的第一端部区域的远侧端部处或附近。

[0033] 本文所描述的变型中的任一个可以包括可扩张的导管尖端。例如,在一些变型中,导管尖端的硬度可以足够柔软以当远侧牵引器区域被向近侧拉入导管时向近侧压缩;轴向压缩远侧端部尖端可使其在远侧端部处略微扩张(例如,使得其可扩张)。

[0034] 如上所述,将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露可以包括将远侧牵引器区域推出导管的远侧端部之外。可替代地或附加地,将管的位于导管内的远侧牵引器区域暴露于导管的远侧端部之外可以包括向近侧拉动导管。例如,将管的导管内的远侧牵引器区域从导管的远侧端部暴露可以包括将远侧牵引器区域推出导管的远侧端部之外以暴露已经在可较少扩张的第二端部区域上翻转的可扩张的第一端部区域。

[0035] 在一些变型中,将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露包括将可扩张的第一端部区域延伸出导管的远侧端部之外,使得当可扩张的第一端部区域延伸时,可扩张的第一端部区域在导管的远侧端部上翻转。

[0036] 远侧牵引器区域的可扩张的第一端部区域可以是任何适当的长度,并且该长度的任何部分(全部、90%、80%、70%、60%、50%、40%等)可能在该设定时段期间暴露。例如,在一些变型中,暴露管的远侧牵引器区域可以包括暴露至少5mm的可扩张的第一端部。可扩张的第一端部区域可以是例如5mm或更大(例如,在约5mm至500mm之间的6mm、7mm、8mm、9mm、10mm、11mm、12mm、13mm、14mm、15mm、16mm、17mm、18mm、19mm、20mm、25mm、30mm、35mm、40mm、45mm、50mm、55mm、60mm、70mm、80mm、90mm、100mm、110mm、120mm、130mm、140mm、150mm、200mm、300mm、400mm、500mm等,在约5mm、6mm、7mm、8mm、9mm、10mm、11mm、12mm、13mm、14mm、15mm、16mm、17mm、18mm、19mm、20mm、25mm、30mm、35mm、40mm、45mm、50mm、55mm、60mm、70mm、80mm、90mm、100mm、110mm、120mm、130mm、140mm、150mm、200mm的任何较小值与10mm、11mm、12mm、13mm、14mm、15mm、16mm、17mm、18mm、19mm、20mm、25mm、30mm、35mm、40mm、45mm、50mm、55mm、60mm、70mm、80mm、90mm、100mm、110mm、120mm、130mm、140mm、150mm、200mm、300mm、400mm、500mm的任何较大值之间,其中较小值总是小于较大值)。在这些变型中的任一个中,当暴露远侧牵引器区域时,仅可扩张的第一远侧端部区域可以暴露出导管之外(例如,当将可扩张的远侧端部区域向远侧推出并且允许其在导管的远侧端部上翻转),或者可扩张的第一远侧端部区域和可较少扩张的第二远侧端部区域两者都可以全部或部分暴露。例如,暴露至少1cm的可扩张的第一端部区域和至少1cm的可较少扩张的第二端部区域。可扩张的第一端部区域可以在可较少扩张的第二端部区域上翻转(翻折回来)。

[0037] 如上所述,可扩张的第一端部区域可以包括既可扩张又能够抓取物体(例如凝块)的任何适当材料。例如,远侧牵引器区域的可扩张的第一端部区域可以包括邻近于可

较少扩张的第二端部区域耦接的网状物。例如,可扩张的第一端部区域可以是以下中的一种或多种:机织材料、网状编织材料、针织材料或穿设有多个开口的膜材料。可较少扩张的第二端部区域可以由相同的材料制成,或者其可以由不同的材料制成。可较少扩张的第二端部区域可以具有相同的结构(例如机织等)或者其可以具有不同的结构,包括可扩张的第一端部区域的结构的可较少扩张变型。例如,可较少扩张的第二端部区域可以是非多孔的(例如非机织的、非针织的等,或固体材料)或较少多孔的(例如,紧密机织的小空隙针织孔、紧密编织物)。在一些变型中,可较少扩张的第二端部区域可包括位于可扩张的第一端部区域(例如,具有中间可扩张性)与第二端部区域的不可扩张部分之间的过渡区域。通常,远侧牵引器区域的可较少扩张的第二端部包括不可扩张的结构和材料。

[0038] 执行机械取栓以从血管去除凝块的方法可以包括:将导管的远侧端部朝向凝块推进通过血管;将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露,其中,远侧牵引器区域包括可扩张的第一端部区域和靠近于可扩张的第一端部区域的可较少扩张的第二端部区域,并且被配置成使得可扩张的第一端部区域在可较少扩张的第二端部区域上翻转;允许可扩张的第一端部区域在血管内扩张,使得导管的远侧端部区域位于远侧牵引器区域的可较少扩张的第二端部区域与可扩张的第一端部区域之间;以及通过向远侧端部推进导管并在导管内向近侧取回导管使得可扩张的第一端部区域在导管的远侧端部上滚动并在可扩张的第一端部区域被拉动到导管中时翻转,将凝块拉入导管。

[0039] 如上所述,在暴露远侧牵引器区域之前,可扩张的第一端部区域可以在可较少扩张的第二端部区域上翻转。可替代地,暴露远侧牵引器区域可以包括当暴露远侧牵引器区域时使可扩张的远侧端部区域在可较少扩张的第二端部区域上翻转。通常,将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露可以包括将远侧牵引器区域推出导管的远侧端部之外。将管的位于导管内的远侧牵引器区域暴露在导管的远侧端部之外可包括向近侧牵拉导管。

[0040] 执行机械取栓以从血管去除凝块的方法可包括:将导管的远侧端部朝向凝块推进通过血管;将管的位于导管内的远侧牵引器区域暴露于导管的远侧端部之外,其中,远侧牵引器区域包括可扩张的第一端部区域和可较少扩张的第二端部区域,其中,暴露包括将可扩张的第一端部区域延伸导管的远侧端部之外,使得当可扩张的第一端部区域延伸时,可扩张的第一端部区域在导管的远侧端部上翻转;允许可扩张的第一端部区域当延伸出导管的远侧端部之外时在血管内扩张,使得导管的远侧端部区域位于可较少扩张的第二端部区域与可扩张的第一端部区域之间;以及通过在导管内向近侧取回管使得当可扩张的远侧端部区域被拉入导管中时可扩张的远侧端部区域在导管的远侧端部上滚动、收缩和翻转,将凝块拉动到导管中。将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露可以包括将远侧牵引器区域推出导管的远侧端部之外。可替代地或附加地,将管的位于导管内的远侧牵引器区域暴露于导管的远侧端部之外可以包括相对于管的远侧牵引器区域向近侧取回导管。

[0041] 本文还描述了用于从血管去除凝块的机械取栓设备,该设备包括:导管,其具有远侧端部和远侧端部开口,其中导管具有内径和外径;管的位于导管内的远侧牵引器区域,其中,远侧牵引器区域包括可扩张的远侧端部区域以及靠近于可扩张的远侧端部区域的可较少扩张的远侧端部区域,远侧牵引器区域被配置成使得可扩张的远侧端部区域在

可较少扩张的远侧端部区域上翻转;穿过导管和管的导丝腔,该导丝腔包括远侧牵引器区域,其中,导丝腔被配置成使导丝通过;以及近侧手柄,其耦接至管并且被配置成引起导管与管之间的相对运动,使得从导管的内径内释放远侧牵引器区域,使得可扩张的远侧端部区域可以扩张至大于外径的直径,使得可以在可扩张的远侧端部区域与可较少扩张的远侧端部区域之间推进导管,并且可以向近侧拉该管以在导管的远侧端部上拉动可扩张的远侧端部区域,使得可扩张的远侧端部区域滚动到导管的远侧端部中、翻转、收缩并被拉入导管。

[0042] 例如,用于从脉管去除凝块的机械取栓设备可以包括:导管,其具有远侧端部和远侧端部开口,其中,导管具有内径和外径;管,其具有位于导管内的远侧牵引器区域,其中,远侧牵引器区域包括可扩张的远侧端部区域和靠近于可扩张的远侧端部区域的可较少扩张的远侧端部区域,进一步其中,可扩张的远侧端部区域被偏置成当从导管的远侧端部暴露时在可较少扩张的远侧端部区域上翻转;穿过导管和管的导丝腔,该导丝腔包括远侧牵引器区域,其中,导丝腔被配置成使导丝通过;以及近侧手柄,其耦接至管并且被配置成引起导管与管之间的相对运动,使得从导管的内径内释放远侧牵引器区域,使得可扩张的远侧端部区域可以扩张至大于外径的直径,并且可以向近侧拉该管以在导管的远侧端部上拉动可扩张的远侧端部区域,使得可扩张的远侧端部区域滚动到导管的远侧端部中、翻转、收缩并被拉入导管中。

[0043] 本文还概括描述了机械取栓装置。例如,本文描述了用于从脉管去除凝块的机械取栓装置,包括:导管,其具有远侧端部和远侧端部开口;柔性管,其在导管内延伸并且在导管的远侧端部上翻折回来,其中,柔性管被配置成当在导管内向近侧拉动柔性管的第一端部时在远侧端部开口上滑动并翻转;以及穿过导管和柔性管的导丝腔,被配置成使导丝通过。

[0044] 用于从脉管中去除凝块的机械血栓装置可包括:导管,其具有远侧端部和远侧端部开口,其中远侧开口的硬度大于紧邻远侧端部的区域的硬度,进一步其中远侧端部开口具有圆形唇缘轮廓;柔性管,其在导管内延伸并且在导管的远侧端部上翻折回来,其中柔性管被配置以当柔性管的第一端部在导管内向近侧被拉动时在远侧端部开口上翻转;以及导丝腔,其穿过导管以及被配置以通过导丝的柔性管。导管远侧端部硬度可以大于60A肖氏硬度或大于40D肖氏硬度。

[0045] 用于从脉管去除凝块的机械取栓装置,其包括:内导管,其具有远侧端部和远侧端部开口;柔性管,其延伸穿过导管并且在内导管的远侧端部上翻折回来,其中,柔性管被配置成当在内导管内向近侧拉动柔性管的第一端部时在远侧端部开口上翻转;外导管,其在内导管和柔性管上延伸;柔性管的在外导管的远侧端部与内导管的远侧端部开口之间延伸的润滑区域,其中,大部分柔性管是未润滑的;以及穿过导管和柔性管的导丝腔,其被配置成使导丝通过。

[0046] 用于从脉管去除凝块的机械取栓装置可以包括:内导管,其具有远侧端部和远侧端部开口;柔性管,其延伸穿过导管并且在内导管的远侧端部上翻折回来,其中,柔性管被配置成当在内导管内向近侧拉动柔性管的第一端部时在远侧端部开口上翻转;可释放附件,其位于柔性管和导管的外表面之间,被配置成当以预定力(例如,大于0.01N)拉动柔性管时释放;以及穿过导管和柔性管的导丝腔,其被配置成使导丝通过。

[0047] 用于从脉管去除凝块的机械取栓装置可包括：导管，其具有远侧端部、远侧端部开口和内径；柔性管，其延伸穿过导管并且在导管的远侧端部上翻折回来，其中，柔性管被配置成当在导管内向近侧拉动柔性管的第一端部时在远侧端部开口上翻转，柔性管具有低泊松比，使得柔性管当被用足够的力在导管内向近侧拉动时的直径大于导管的内径的一半，以在远侧端部开口上翻转；以及穿过导管和柔性管的导丝腔，被配置成使导丝通过。具有低泊松比的柔性管可以小于0.5或者在0.05至0.5或0.1至0.3的范围内。

[0048] 如上清楚所述，柔性管通常包括远侧牵引器区域，远侧牵引器区域具有可扩张的第一端部区域以及邻近于第一端部区域的可较少(或不可)扩张的第二端部区域。因此，柔性管可以包括网状管。

[0049] 通常，形成本文所描述的装置的一部分的导管是高度灵活的，如适用于所采取的侵害路径，例如，通过神经血管导管。在一些变型中，组装装置(具有缠绕在远侧端部上并准备好操作的柔性管)的总体刚度在不具有柔性管的导管的原始刚度的预定百分比内(例如，在10%内、在12%内、在15%内、在16%内、在17%内、在18%内、在19%内、在20%内、在25%内、在30%内等)。例如，延伸穿过导管并且在导管的远侧端部上翻折回来的柔性管可以将导管的远侧5cm的刚度增加小于导管的远侧5cm的刚度的预定百分比(例如15%)，而不使柔性管延伸穿过其中和在导管的远侧端部上翻折回来。

[0050] 在本文所描述的变型中的任一个中，柔性管的远侧牵引器区域适于抓取物体，例如凝块。特别地，柔性管可以是多孔的或者具有至少一个多孔区段，所述多孔区段具有孔隙图案，所述孔隙图案在宽度小于预定距离(例如，约0.005英寸)的孔隙之间具有纵向间隔。如在该示例中所使用的，“孔隙”包括网状物(机织物等)的股线之间的窗口、开口、间隙等以及穿过固体片形成的孔隙。通常，对于机织(并且特别是编织)的可扩张的第一端部区域材料，较小的细丝在抓取时可能更好，并且因此较小的孔隙尺寸可能是优选的。最佳尺寸可以取决于材料，包括细丝尺寸、孔隙百分比、孔隙间距的尺寸、孔径等。例如，在一些变型中，孔隙率大于>60% (大于70%、大于75%、大于80%、大于85%等，在60%至95%、65%至95%、70%至95%等之间)以及纤维直径(对于机织材料)为<0.005是有利的。确保凝块或异物被抓取所需的柔性管状构件的有效孔径可以在50微米至1000微米(μm)的范围内，或者在100 μm 至200 μm 、100 μm 至300 μm 、100 μm 至500 μm 或500 μm 至1000 μm 的范围内。柔性管状构件可沿其长度具有各种孔径。

[0051] 通常，如本文所用，机织材料包括通过以交织图案(例如，交织股线、细丝、材料长度等)编织多股材料而形成的任何材料。网状物是一种机织材料。取决于形成织物的材料的弹性，机织材料通常在某些方向上(在偏置方向上)更可伸展/可扩张。机织材料通常以平行或几乎平行的路径行进。针织材料可以更柔性并且通常指的是曲折的单个路径或路线，从而形成可以对称布置和互锁的环路。机织材料可以非常可拉伸/柔性的。针织结构区域可较少拉伸，但仍然非常柔性。

[0052] 在本文所描述的装置中的任一个中，并且特别是预加载或预成形的版本中，该装置可以包括位于柔性管与导管的外表面之间的可释放附件，其被配置成当用大于预定力阈值的力拉动柔性管时释放。例如，可释放力阈值可以大于约0.001N、大于约0.005N、大于约0.01N、大于约0.03N、大于约0.05N、大于约0.08N、大于约0.1N、大于约0.3N、大于约0.5N等)。

[0053] 在本文所描述的装置中的任一个中,柔性管可以包括多个柔性材料条,其中,条被布置成与柔性管的长轴平行。可替代地或附加地,在这些变型中的任一个中,远侧端部开口可以包括多个凹口或通道,当柔性管在远侧端部开口上翻转时,形成柔性管的纤维或条被拉入该凹口或通道。

[0054] 在本文所描述的装置中的任一个中,柔性管可以包括具有穿设有多个孔的聚合物管。例如,柔性管可以包括远侧端部、近侧端部以及在远侧端部与近侧端部之间的主体区域,其中,主体区域从较柔性的远侧端部过渡到较刚性的近侧端部。

[0055] 如上所述,在本文所描述的变型中的任一个中,导管的远侧端部(例如,远侧端部开口区域)可以适于防止当在导管开口上翻转时收缩但仍然足够柔软以为神经管应用提供合适的使用。例如,本文所述的装置中的任一个在远侧端部(例如,在远侧端部开口/边缘处)处的硬度可大于紧邻远侧端部的区域的硬度。这些远侧端部开口中的任一个都可以具有圆形唇缘轮廓。通常,尽管远侧端部区域的硬度可能降低(变得“较软”),但是非常最远侧端部(开口)的硬度可能较高。这与圆形端部形状一起可以减小在将远侧牵引器区域(例如,可扩张的第一端部区域)拉入导管时使其翻转所需的力,同时防止导管的远侧端部区域收缩。

[0056] 本文所描述的装置中的任一个还可以包括适于相对于导管向近侧拉入柔性管的手柄。手柄可以附接到或可附接到导管和/或柔性管,并且可以包括用于独立地或者更优选地以协调的方式(或者在这两个模式之间切换)而致动的单独的控制。例如,这些装置中的任一个可以包括耦接到导管的近侧端部区域的驱动手柄,其中,驱动手柄包括控制器,该控制器被配置成在被致动时协调在向近侧收回柔性管的同时向远侧推进导管。

[0057] 这些装置中的任一个还可以包括在导管和柔性管上延伸的外导管。外导管可以在导管和柔性管上延伸,并且可以保持远侧牵引器区域(导管外部)的外部部分收缩,直到其已经被输送。这些装置中的任一个都可以包括在外导管的远侧端部和远侧端部开口之间延伸的柔性管的润滑区域,其中,大部分柔性管是未润滑的。该润滑区域可以减小致动该装置所需的初始力。

[0058] 在本文所描述的装置中的任一个中,柔性管可被配置成当在导管内向近侧拉动柔性管的第一端部时在远侧端部开口上翻转,并且柔性管可具有低泊松比,使得柔性管(其可以是网状管)当被用足够的力在导管内向近侧拉动时的直径大于导管的内径的一半,以在远侧端部开口上翻转。

[0059] 这些装置中的任一个可以包括位于导管内的拉动器(例如细长拉动器)并且耦接到柔性管的远侧端部。拉动器通常被配置成向近侧拉入柔性管,但是在一些变型中它可以向远侧移动柔性管。例如,这些装置中的任一个还可包括位于导管内并耦接到柔性管的远侧端部的细长拉动器,其中,细长拉动器包括具有内腔的海波管,该内腔与穿过柔性管的导丝腔连续。

[0060] 如上所述,在一些变型中,柔性管包括可推动的柔软外部网状物。例如,远侧牵引器区域(并且特别是可扩张的第一端部区域)可以由24至144个股线形成,股线在直径上具有0.0020英寸或更小的厚度,其中,网状管状构件在纵向轴线上延伸,进一步其中,网状物管状构件的长度大于5cm,网状管状构件当围绕导管的远侧端部被拉动和翻转时在纵向轴线的方向上的交叉股线之间形成约35度或更小的编织角度,并且当不受约束时在导管的

外部扩张到大于导管的内径的1.5倍的直径。

[0061] 当柔性管由股线(例如机织、编织等)形成时,股线可以由以下中的任一者形成;单丝聚合物、复丝聚合物、镍钛(NiTi)丝、具有不透射线金属中心的镍钛管、钴铬合金丝、具有不透射线金属中心的钴铬合金管、尼龙、聚酯、聚对苯二甲酸乙二醇酯和聚丙烯。

[0062] 如上所述,这些装置中的任一个都可以被配置成使得柔性管(例如可扩张的远侧端部区域)可释放地保持在导管上。例如,这些装置中的任一个可以包括围绕柔性管的远侧端部区域的保持环,该保持环被配置成将柔性管可释放地保持抵靠在导管上。

[0063] 在这些变型中的任一个中,柔性管的形状可以被设定成当在导管内被向近侧拉入导管之后时具有不同的直径。通常,柔性管可以包括多个机织丝或一个(或多个)针织丝。在一些变型中,整个(或大部分)柔性管由机织或针织细丝形成,并且柔性管的近侧端部可形成与形成拉线的细丝或细丝束相反的渐缩开口。可替代地或附加地,柔性管可以由具有小于0.020英寸的厚度的聚合物套筒形成,其中,套筒包括穿孔图案,其中,穿孔延伸穿过聚合物。穿孔图案可以包括具有由以下一个或多个构成的形状的穿孔:圆形孔、矩形孔和锯齿形状。

[0064] 这些装置中的任一个可以包括耦接到柔性管的近侧端部的一侧的拉线,该拉线被配置成被向近侧拉以将柔性管拉动到导管内。

[0065] 通常,柔性管可以是任何适当的长度。例如,柔性管可以在3cm至200cm之间(例如,3cm至150cm、3cm至100cm、3cm至50cm等)。

[0066] 在本文所描述的装置中的任一个中,装置的柔性管可被配置成使得可通过向柔性管的远侧端部施加小于预定量的力(例如500克的力、450克的力、400克的力、350克的力、300克的力、250克的力、200克的力、150克的力等)将柔性管收回到导管中。

[0067] 在这些变型中的任一个中,柔性管可以包括位于柔性管的第一端部与第二端部之间的渐缩部。在一些变型中,柔性管可以在导管的整个长度内延伸,使得柔性管的近侧端部被配置成远离导管的近侧端部向近侧被拉动以使柔性管在远侧端部开口上滑动并翻转。

[0068] 本文所描述的装置中的任一个还可以包括真空源。例如,这些装置中的任一个可以包括导丝真空泵,该导丝真空泵耦接到导丝腔的近侧端部并且被配置成通过其施加真空。例如,这些装置中的任一个可以包括外导管真空泵,该外导管真空泵耦接到导管与柔性管之间的空间并且被配置成在导管的位于导管的内壁与柔性管之间的腔内施加真空。

[0069] 如上所述,该装置可以包括拉动器,其中,柔性管的远侧端部耦接到拉动器的远侧端部。外导管可以布置在导管上且邻近于柔性管的近侧端部。这些装置中的任一个还可以包括具有控制器的手柄,该控制器被配置成协调推进外导管以向远侧推动柔性管的近侧端部和向近侧拉动拉动器以将柔性管的近侧端部拉入导管。例如,如本文所描述的装置可以包括:拉动器,其中,柔性管的远侧端部耦接到拉动器的远侧端部;外导管,其可滑动地布置在偶接到柔性管的近侧端部的导管上;以及手柄,其具有控制器,该控制器被配置成协调在向近侧拉动拉动器以将柔性管的近侧端部拉入导管的同时向远侧推进外导管以向远侧推动柔性管的近侧端部,或者在向远侧推动拉动器以将柔性管的近侧端部推出导管之外的同时向近侧拉动外导管以向近侧拉动柔性管的近侧端部。

[0070] 本文还描述了机械地去除取栓的方法,包括:将导丝至少推进到血管中的凝块的

近侧端部;在导丝上向远侧推进取栓(例如凝块去除)装置,其中,取栓装置包括具有远侧端部和远侧端部开口的导管以及沿着导管的外径且在导管的远侧端部上延伸的柔性管,使得导丝穿过导管的腔以及柔性管;从离开导管的外径向近侧拉动柔性管并将柔性管拉动到导管腔中,使得柔性管在远侧端部开口上滑动并翻转;以及当柔性管被拉入导管时将凝块拉入翻转的柔性管。

[0071] 机械地去除取栓的方法可以包括:推进导丝邻近血管中的凝块;在导丝上向远侧推进取栓装置,其中,取栓装置包括具有远侧端部和远侧端部开口的导管以及沿着导管的外径且在导管的远侧端部上延伸的柔性管,使得导丝穿过导管的腔以及柔性管;从离开导管的外径向近侧拉动柔性管并在导管的远侧端部开口的圆形唇缘上将柔性管拉动到导管腔中,使得柔性管在远侧端部开口上滑动并翻转,其中,远侧端部开口的硬度大于紧邻远侧端部的区域的硬度;以及当柔性管被拉入导管时将凝块拉入翻转的柔性管。

[0072] 机械地去除取栓术的方法可以包括:推进导丝邻近血管中的凝块;在导丝上向远侧推进取栓装置,其中,取栓装置包括具有远侧端部和远侧端部开口的内导管、沿着内导管的外径且在导管的远侧端部上延伸的柔性管,以及将柔性管的远侧端部区域固定抵靠在内导管的外径上的外导管,使得导丝穿过导管的腔和柔性管;从离开导管的外径向近侧拉动柔性管并将柔性管拉动到导管腔中,使得柔性管的润滑近侧引导区域在远侧端开口上滑动并翻转,直到柔性管的未润滑远侧区域被拉入内导管;以及当柔性管被拉入导管时将凝块拉入翻转的柔性管。

[0073] 机械地去除取栓术的方法可以包括:推进导丝邻近血管中的凝块;在导丝上向远侧推进取栓装置,其中,取栓装置包括具有远侧端部和远侧端部开口的导管以及沿着导管的外径且在导管的远侧端部上延伸的柔性管,使得导丝穿过导管的腔和柔性管;从离开导管的外径向近侧拉动柔性管并将柔性管拉动到导管腔中,使得柔性管在远侧端部开口上滑动并翻转;将柔性管向远侧拉出或推出导管的远侧端部,使得柔性管在远侧端开口上滑动并翻转;以及当柔性管被拉入导管时将凝块拉入翻转的柔性管。

[0074] 在本文所描述的方法中的任一个中,导丝可以至少部分地定位在血管中的凝块内。

附图说明

[0075] 在所附权利要求中特别阐述了本发明的新颖特征。通过参考以下详细描述来获得对本发明的特征和优点的更好理解,所述详细描述阐述了利用本发明原理的说明性实施例以及附图,附图中:

[0076] 图1A至图1H示出了用于机械地去除诸如形成身体区域的凝块的物体的装置的一个变型。图1A示出了该装置的导管部分;图1B示出了导管的远侧端部(开口)的放大视图;图1C示出了柔性管(牵引器管)的远侧牵引器区域的示例,其示出了处于收缩(未扩张)配置的柔性管的可扩张的第一端部区域,而图1D示出了具有可扩张的第一端部区域的相同的远侧牵引器区域。图1E示出了组装的机械取栓装置,其中柔性管延伸穿过导管并且在导管的远侧端部上翻折回来,使得柔性管的可扩张的第一端部区域(形成远侧牵引器区域的一部分)至少部分地位于导管外侧并处于非扩张状态。图1F示出了图1E的装置,其中可扩张的第一端部区域扩张。图1G和图1H示出了图1E和图1F的装置的使用以通过向近侧拉柔

性管和/或向远侧朝向凝块推进导管而去除凝块,使得可扩张的第一端部区域当其被拉入导管的远侧端部中时翻转,将凝块拉动到导管中。

[0077] 图2A至图2D示出了可以是本文所描述的装置的一部分的柔性管(牵引器管)的变型。图2A示出了包括远侧牵引器区域的柔性管的远侧端部,远侧牵引器区域在远侧端部处包括可扩张的第一端部区域,其邻近于可较少扩张的第二端部区域。在图2B中,可扩张的第一端部区域由多个机织纤维形成。在图2C中,可扩张的第一端部区域由整个具有多个小孔的材料片形成。在图2D中,可扩张的第一端部区域在可较少扩张的第二端部区域上翻折(doubled over,对折)。

[0078] 图3A至图3F示出了机械取栓装置的一个示例的体内展开和操作。在该示例中,在将导管定位在凝块附近之后,远侧牵引器区域被推动穿过导管,直到远侧牵引器区域从凝块的远侧端部暴露(图3A至图3D),使得可扩张的第一端部区域扩张至血管的内膜;然后在可扩张的第一端部区域与可较少扩张的第二端部区域之间推进导管(图3D至图3E),并且可扩张的第一端部区域被拉入导管中,使得其翻转并将凝块拉入导管中(图3E至图3F)。

[0079] 图4A至图4F示出了机械取栓装置的另一个示例的体内展开和操作。在该示例中,柔性(牵引器)管的可扩张的第一端部区域在通过将可扩张的第一端部区域延伸出导管的远侧端部而定位导管部分(图4A至图4B)之后被展开,使得可扩张的第一端部区域在导管的远侧端部区域上翻折回来(图4C至图4D)。一旦暴露和展开,可扩张的第一端部区域可以在向远侧推进导管或不向远侧推进导管的情况下被拉回到导管中以将凝块拉动到导管中(图4F)。

[0080] 图5A至图5E示出了机械取栓装置的另一个示例的体内展开和操作,其中可扩张的第一端部区域在定位在凝块附近的血管内之后向远侧延伸出导管的端部(图5A至图5C)。一旦可扩张的第一端部区域已经延伸并允许在脉管内扩张,则可以向远侧推进导管和导管内的柔性管的其余部分(图5D),使得可扩张的第一端部区域在远侧端部上翻折,如图所示。此后,在向远侧推进导管或不向远侧推进导管的情况下,可扩张的第一端部区域可以被拉回到导管中,以将凝块拉动到导管中(图5E)。

[0081] 图6A和图6B示出了一种机械取栓装置,其包括导管以及延伸穿过导管并在导管的远侧端部(形成远侧牵引器区域)上翻折回来的柔性管(牵引器管),以及在远侧牵引器区域上的外导管或释放保护器导管。图6A示出了定位在凝块附近的装置;图6B示出了与导丝一起使用的装置,该导丝穿过装置的导丝腔以用于定位和操作该装置。

[0082] 图7A至图7D示出了如图6A至图6B所示的取栓装置的操作,其示出了邻近凝块定位远侧端部/远侧牵引器区域(图7A),然后将凝块拉动到导管中(图7B至图7C)并且最终去除凝块和柔性牵引器管(图7D)。

[0083] 图8示出了包括可选真空源的取栓装置。

[0084] 图9A至图9D示出了本文所描述的取栓装置与导丝结合的操作。导丝可以完全或部分地经过凝块,并且该装置可以在导丝上被致动,从而提供增强的稳定性和功效。

[0085] 图10A示出了用于致动诸如本文所描述的取栓装置的装置的手柄(近侧)手柄的一个变型。手柄可以被耦接并且可以单独地或以协调的方式致动导管和柔性(牵引器)管(包括远端侧牵引器区域)的运动。

[0086] 图10B示出了用于如本文所描述的装置的近侧手柄的另一示例,其包括用于控制

(单独或一起)导管和/或内柔性牵引器管的致动的控制器。

[0087] 图11A示出了用于包括如本文所描述的取栓装置的装置的近侧手柄 的另一示例。

[0088] 图11B是示出用于如本文所描述的装置的手柄的操作的机械示意图。

[0089] 图12A和图12B示出了变型,其中装置的柔性牵引器管的可扩张的 第一端部区域可释放地固定到导管的外表面;在装置的致动使得远侧牵引 器区域可以被拉入导管的远侧端部中之前,可以分离可释放附件。在图 12A中,外管(例如,远侧牵引器区域上的外导管或释放保护器导管)至 少覆盖可扩张的远侧端部区域的端部。在图12B中,远侧牵引器区域 的可 扩张的第一端部区域可包括可释放地将可扩张的第一端部区域固定到导 管的外径的带、粘合剂、焊接件(例如,脆的粘合剂或其他附件)、卡扣 配合件、抓持件等。

[0090] 图13A和图13B示出了本文所描述的装置的柔性(例如牵引器)管 的近侧端部区域(牵引器区域)的示例。图13A示出了其中牵引器管的近 侧端部形成与管的腔径向偏离的拉线的示例;如图所示,导丝仍然可以经 过管(和导管)的腔以用于该装置的操作。图13B示出了其中拉线(或杆、构件等)由与柔性牵引器管的其余部分不同的材料形成的示例。

[0091] 图14示出了远侧牵引器区域,其包括远侧牵引器区域的可扩张的第 一端部区域的近侧端部区域附近的有限润滑区域;可扩张的第一端部区域 的其他部分可能不是润滑 的,远侧牵引器区域的其余部分也可能不是润滑 的。

[0092] 图15A至图15D示出了具有成形的可扩张的第一端部区域的柔性(牵 引器)管。特别地,这些不同的可扩张的第一端部区域可以被预先设定为 不同的直径,这可以帮助拉入和/或破坏导管内的凝块。图15A示出了第 一示例,其中可扩张的第一端部区域通过多个拉线耦接到拉动器部分。在 这些示例中,可扩张的第一端部区域被示出未在柔性管状构件 (牵引器管) 的较近侧部分上翻转。图15B示出了由不可径向扩张的多个拉线连接的多 个可扩张的端部区域。图15C示出了具有多个预先设定直径的可扩张的第 一端部区域。图15D示出了通过形成可扩张的第一端部区域的两束或多束 细丝耦接到牵引器管的较近侧拉动器部分的可扩张的第一端部区域。

[0093] 图16示出了可扩张的第一端部区域的另一示例,其包括到导管的外 径的多个可 释放附件;这些可释放附件(其可以是脆的、弹性的等)可以 通过施加足够的力而被释放, 以允许将远侧牵引器区域拉动到导管中以用 于致动该装置。

[0094] 图17示出了其中可扩张的第一端部区域在导管的远侧端部区域的外 径上被加载 (例如弹簧加载,压缩等)并且被可释放地锁定或以其他方式 (例如,通过可靠的附件)保持 在位(in place,在适当位置)的示例;该 可释放附件可以防止装置在致动之前的展开,并 且可扩张的第一端部区域 的加载可以使得远侧牵引器区域更容易在导管的远侧端部上翻 转以将凝 块拉入装置中。

[0095] 图18A至图18C示出了具有不同刚度的可扩张的第一端部区域的示 例。

[0096] 图19A和图19B示出了用于组装如本文所述的装置的组装方法。

[0097] 图20A和图20B示出了可用作本文所描述的装置的远侧牵引器区域 的一部分的可 扩张的第一端部区域的示例性轮廓。

[0098] 图21A至图21D示出了用于去除凝块的装置的示例。图21A示出了 在耦接到导管之 前的可扩张的第一端部区域的示例。图21B示出了通过拉 动柔性(牵引器)管的近侧端部而 将血管(玻璃管)内的可扩张的第一端 区域拉入导管中。图21C示出了装置的远侧端部区

域,其包括在导管的远侧端部区域上翻折的可扩张的第一端部区域。图21D示出了将凝块拉入导管中的图21C的装置。

[0099] 图22示出了图21D的可扩张的第一端部区域,其在将其向近侧拉出导管之后具有所捕获的凝块。

[0100] 图23A至图23D示出了如本文所描述的机械取栓装置,其捕获血凝块并将其拉入装置中。

[0101] 图23E示出了柔性牵引器管已经从导管去除(例如近侧)之后保持在柔性牵引器管内的凝块。

[0102] 图24是包括柔性牵引器构件的装置的另一个示例,其中,远侧牵引器区域由多个细丝形成,多个细丝布置成非机织或编织材料的条(纵向平行)。这些条(strip)可以是细丝或管等。

[0103] 图25A至图25F示出了柔性牵引器组件的远侧牵引器区域的另一变型,其中,可扩张的第一端部区域(例如,远侧牵引器区域的远侧端部区域)由多个细丝或条形成,类似于在图24中所示的;导管的远侧端部包括通道,如图25A至图24所示;这些条可以装配在这些通道内,如25C至图25D所示。图25E和图25F示出了穿过25C和图25D的截面图。。

[0104] 图26A和图26B示出了具有外套筒(例如,外导管或释放保护器导管或其他外套筒/保护器)的图25A至图25F的装置的变型

[0105] 图27A和图27B示出了穿过26A至图26B的装置的截面图。

[0106] 图28是包括柔性牵引器组件的远侧牵引器区域的装置,该柔性牵引器组件具有多个纵向平行的(非机织/编织的)细丝或条,其中细丝或条的远侧端部通过远侧连接件彼此连接。

[0107] 图29示出了装置中的柔性牵引器组件的远侧牵引器区域,其中纵向平行的(非机织/编织的)细丝或条包括抓取元件。

[0108] 图30A至图30C示出了具有抓取元件的细丝/条的示例。抓取元件(和/或包括它们的细丝)可以用作本文所描述的变型中的任一个的一部分,包括机织或编织的远侧牵引器区域。

[0109] 图31示出了一种变型,其中远侧牵引器区域适于往复运动(例如,推动和拉动)使得可扩张的第一端部区域可被拉入导管中并从导管翻转出。

[0110] 图32示出了如本文所述的装置的另一示例,其中可扩张的第一端部区域的最远侧端部固定到导管的远侧端部的一部分;可扩张的第一端部区域的其余部分具有足够的弹性/柔性以被拉入导管中(用其拉动凝块)。然后柔性牵引器组件可以被收回并且整个装置被拉出。该示例可能包括可选的真空。

[0111] 图33是装置的另一示例,其中柔性牵引器组件的拉动物部分由与远侧牵引器区域相同的材料形成,但可以被层压或以其他方式被增强以具有比远侧牵引器区域更小的柔性/可拉伸性。

[0112] 图34示出了其中远侧牵引器区域适于在被拉入导管中时压缩凝块的另一示例。

[0113] 图35A至图35C示出了如图34所示的装置的操作,其中通过将远侧牵引器区域的可扩张的第一端部区域拉回到压缩凝块(图35A至图35B)的导管中(例如,在牵引器组件的

拉动器区域上拉动) 而将凝块拉入导管; 释放牵引器组件和/或向远侧推动牵引器组件可以进一步破碎凝块并将其从远侧牵引器区域释放, 使得其可以利用手动或动力真空源向近侧抽吸 (图35C)。

[0114] 图36示出了一种使用装置和方法的示例, 其中向近侧拉入柔性牵引器组件可以使装置向远侧行进通过导丝上的主体 (例如血管), 该导丝可以被处理以接合远侧牵引器区域。

[0115] 图37A至图37C示出了一种使用装置和方法, 其中向近侧拉柔性牵引器组件可以使装置向远侧行进。

[0116] 图38A和图38B示出了装置和使用该装置从血管中去除材料的方法的另一变型, 其中该装置是“无限”牵引机构, 其中大量的牵引器材料 (例如, 网状物) 储存在一个外保持区域中, 其被卷起但在扩充使用上不是必须的。

具体实施方式

[0117] 通常, 本文描述了用于从身体机械地去除物体的方法和装置。虽然这些方法和装置可以适用于从身体的各种区域去除各种物体, 但它们可能特别适合于从血管的腔内去除血凝块。因此本文所描述的是机械取栓装置 (例如设备和系统)。

[0118] 本文所描述的装置 (例如, 用于从血管去除凝块的机械取栓装置) 可以是包括具有远侧端部和远侧端部开口的细长导管的组件以及至少部分位于导管内的柔性牵引器组件, 其中, 牵引器组件的远侧端部区域被配置为远侧牵引器区域, 远侧牵引器区域至少部分地在导管内延伸并且在导管的远侧端部上翻折回来。牵引器组件可以包括连接到远侧牵引器区域的近侧推动器区域。柔性牵引器组件包括配置成允许导丝通过的细长腔。柔性牵引器组件还被配置成在近侧端部区域被向近侧拉动时沿着导管腔内的长轴线滑动并且在导管的远侧端部开口上翻转。牵引器组件在本文可被称为柔性牵引器组件、柔性牵引器部分、柔性牵引器管或简单的柔性管, 并且典型地定位在导管内并且可在导管内纵向可滑动, 并且布置成使得远侧端部区域 (“远侧牵引器区域”) 在导管的远侧端部上翻折回来。

[0119] 例如, 图1A示出了可形成本文所描述的装置的一部分的导管的一种变型。在该示例中, 导管100包括远侧端部区域103, 远侧端部区域包括远侧端部105。除了非常远侧尖端 (远侧端部105) 可以实质上比紧邻其的区域较不柔软之外, 远侧端部区域可以具有增加的柔软度 (通过硬度计测量, 例如肖氏硬度计)。因此, 虽然远侧尖端区域 (例如, 最远侧的x线性尺寸, 其中x为10cm、7cm、5cm、4cm、3cm、2cm、1cm、9mm、8mm、7mm、6mm、5mm、4mm、3mm) 具有从近侧端部到远侧端部延伸的增加的柔软度/减小的硬度, 非常远侧端部区域107 (例如, 测量为最远侧的z线性尺寸, 其中z为1cm、9mm、8mm、7mm、6mm、5mm、4mm、3mm、2mm、1mm、0.8mm、0.5mm、0.3mm、0.2mm等, 并且z总是比x小至少三倍) 的硬度大于紧邻其的区域的硬度, 并且可以与远侧尖端区域的最近侧区域一样硬或比其更硬。

[0120] 导管100也可以被称为内导管或牵引器导管。可以使用任何适当类型的导管, 包括适用于神经血管使用的微导管。

[0121] 在一些变型中, 导管的远侧端部105适于使得远侧牵引器区域可以在导管的远侧端部上滑动并翻转而不被捕获 (束缚) 或没有实质摩擦。例如, 在一些变型中, 远侧尖端 (端部) 可以是弯曲的或倒圆的109, 如图1B所示。特别是在外表面上 (例如从外径到内径的过

渡)。在一些变型中,远侧尖端包括一个或多个通道,如图25A至图28所示和所述的,包括围绕面向远侧的边缘的通道,以引导远侧牵引器区域的滑动。

[0122] 图1C示出了柔性牵引器管140的示例。在图1C中,管是柔性的并且细长(具有通常比导管101大的长度),并且包括远侧牵引器区域142,该远侧牵引器区域包括配置成紧邻近侧区域146上折叠的最远侧可扩张的第一端部区域144,其可以是可较少扩张的第二端部区域。通常,可扩张的远侧端部区域被配置成在不受约束时扩张至介于导管的内径的直径的1.3倍至10倍之间的径向直径。图1D示出了处于扩张配置的图1C的可扩张的远侧端部区域。因此可扩张的远侧端部区域可以被偏置以扩张打开。可扩张的远侧端部区域可以形成网状物、机织物或材料片,并且通常适于抓取待去除的物体(例如血凝块)。

[0123] 图1C中一般性示出的柔性牵引器管被示出为图1E中的可扩张的远侧端部区域在其本身上(例如在更近侧的可较少扩张的第二端部区域上)翻折回来。在图1E中,可扩张的远侧端部区域收缩,而在图1F中,可扩张的远侧端部区域扩张。通常,可扩张的远侧端部区域可以与近侧的可较少扩张的第二端部区域区分开,然而在一些变型中,整个柔性牵引器管可以包括在导管内被推动和/或拉动且不包括近侧的可较少扩张的远侧端部区域的可扩张的材料(例如,网状物、机织物等)。

[0124] 图1G和图1H示出了使用诸如由图1A和图1E的部件组装的装置的装置去除凝块。在该示例中,该装置被配置为包括导管101和柔性牵引器管的取栓装置,该柔性牵引器管包括可扩张的远侧端部区域144,该可扩张的远侧端部区域在导管的远侧端部区域上延伸并且在导管的远侧端部上翻折,使得可扩张的远侧端部区域与内近侧的可较少扩张的(在该示例中,可较少扩张的包括不可扩张的)第二远侧端部区域146连续,该第二远侧端部区域在导管内向近侧延伸并形成可使导丝通过的内腔。柔性牵引器管(未示出)的近侧端部可以包括推动器/拉动物构件,该推动器/拉动物构件可以是与远侧端部区域(远侧牵引器区域140)连续的杆或其它构件。在图1G中,装置被示出在凝块155附近的血管160内定位并展开。通过将远侧牵引器区域140取回到导管101中,可以将凝块拉入导管中,如箭头180所示,其示出了柔性牵引器管的内部部分的拉动(例如,使用手柄,未示出),从而导致将可扩张的远侧端部区域拉动到导管远侧端部中并翻转可扩张的远侧端部区域,使得其被拉动到导管中,如箭头182所示。可扩张的远侧端部区域的远侧端部可相对于导管的外壁“松动”,或者其可被去除附接或在一些变型中永久附接。

[0125] 通常,定位这些装置并致动它们可能是具有挑战性的,这是因为它们在致动之前和操作期间都必须是高度柔性的。例如,一般来说,柔性牵引器管必须不能增加导管的刚度/柔性,并且特别是导管的远侧端部区域过多,或者对于操纵来说过于困难和/或危险,特别是在神经血管系统的侵蚀血管内。本文所描述的是柔性牵引器管部分,其增加了小于预定百分比(例如,小于10%、12%、15%、18%、20%、25%、30%等)的导管的最后y cm(例如,最远侧的20cm、18cm、15cm、12cm、10cm、9cm、8cm、7cm、6cm、5cm、4cm、3cm、2cm、1cm等)的刚度。例如,本文所描述的是柔性牵引器管部分,其穿过导管并且在导管的远侧端部上翻折回来,但是在没有柔性管延伸穿过其中并且在导管的远侧端部上翻折回来的情况下,将导管的远侧5cm的刚度增加小于导管的远侧5cm的刚度的15%。

[0126] 例如,图2A示出了柔性牵引器管201。在该示例中,柔性牵引器管包括在近侧推动器区域201的远侧的远侧牵引器区域242,该远侧牵引器区域具有可扩张的第一端部区域

244以及可较少扩张的第二端部区域 246。整个柔性牵引器管是中空的并且可以使导丝通过(未示出)。柔性牵引器管的各个区域可以由相同的材料(例如,机织的、编织的等细丝(filament)或多个细丝)制成,或者它们可以由不同的材料制成。

[0127] 图2B示出了具有远侧牵引器区域的柔性牵引器管,或者至少由多个机织纤维形成的可扩张的第一端部区域244'。可替代地,可扩张的第一端部区域可由一个(或多个)针织纤维或机织和针织纤维的组合形成。可扩张的第一端部区域可以通过纤维或机织/针织图案的形状设定特性或通过包含一个或多个偏置构件(例如,环、弹簧、带、细丝等)而被偏置地打开(如图所示),其倾向于至少将可扩张的第一端部区域的远侧端部区域偏置打开。

[0128] 图2C示出了由包括多个开口(例如,孔、穿孔、通道、窗口等)的材料片形成的可扩张的第一端部区域的另一变型。这些开口可以是任何尺寸,包括不均匀尺寸(例如尺寸的范围)或均匀尺寸。穿过片的这些开口的尺寸可取决于所使用的材料,例如聚合物材料(PTFE)、硅树脂材料、聚氨酯、形状记忆合金等。在一些变型中,片的孔隙率大于>60%(大于70%、大于75%、大于80%、大于85%等、在60%至95%之间、在65%至95%之间、在70%至95%之间等)是有益的。

[0129] 在这些变型中的任一个中,远侧牵引器区域被配置成使得其可以在其本身上被翻转(例如,翻折),如图2D所示。在一些变型中,该装置可被执行为使得可扩张的第一端部区域在其本身上和/或在导管的远侧端部区域上翻转,或者其可以被配置成使得其可以在体内(例如在血管内)在导管的远侧端部展开和翻转。通常,在装置可被致动之前,导管可以插入可扩张的第一端部区域与柔性牵引器管上的可扩张的第一端部区域的近侧的区域之间,在一些变型中,其可以是可较少扩张的第二远侧端部区域。该空间289可以通过在可扩张的第一端部区域的远侧端部处或附近的偏置构件而保持打开。如所提到的,该可扩张的第一端部区域开口偏置构件可以是环、带、弹簧、线圈等,并且可以由偏置元件(例如,形状设定材料,诸如形状记忆合金)、橡胶或其他聚合物材料等制成。

[0130] 尽管存在相关的挑战,但是本文所描述的装置的体内展开可以为操作装置的用户提供许多优点。图3A至图3F示出了配置用于体内展开的取栓装置的一个示例。在该示例中,该装置包括导管301,该导管可以使用导丝313定位(如同本文所描述的变型中的任一个)。导丝可以延伸到或进入(或穿过)待去除的物体,其示出为在血管360内的图3A中的凝块355。装置的导管可以与导丝一起插入或在导丝之后插入,并且在有或没有柔性牵引器管在导管的远侧端部处或附近的情况下,可以将导管定位在凝块附近(例如,邻近或紧邻)。在图3A中,在导丝已经定位之后,定位导管,并且如图3B所示,从血管中取出导管。导丝可以是线材,较小的导管或可以定位(例如,操纵)到凝块和/或穿过凝块的装置的组合。在定位导管之后,包括远侧牵引器区域342的内柔性牵引器管340被推动穿过导管至导管的远侧端部区域,如图3C所示。在该示例中,形成远侧牵引器区域的柔性牵引器管的远侧端部包括示出为网状物344的可扩张的第一端部区域,该网状物在近侧端部处(推动器区域305)连接到与柔性牵引器管的其余部分连续的近侧的不可扩张的第二端部区域。可扩张的第一端部区域的机织网状物344在收缩(非扩张)配置中在管状第二端部区域/推动器区域的外侧上预先翻转,并且可以滑动穿过导管的腔,并且(当导丝留在适当的位置或用于调节该位置时)在导丝(未示出)上滑动。如图3D所示,柔性牵引器管的远侧牵引器区域

然后通过延伸(在该示例中,向远侧推动柔性牵引器管和/或向近侧拉动导管)而暴露于导管的外侧,从而允许远侧牵引器区域(示为网状物)344的可扩张的第一端部区域沿着第一端部区域的长度扩张。在图3D中,这显示为可以完全扩张至血管的内膜的支架状结构,在可扩张的第一端部区域与可较少扩张的(在此情况下是不可扩张的)第二端区域346之间形成分离。特别地,第一端部区域的扩张可以大于导管的内腔的直径的1.3倍(例如,大于1.5倍、大于2倍、大于2.2倍、大于2.5倍、大于3倍、大于3.5倍、大于4倍、大于5倍、大于6倍、大于7倍、大于8倍、大于9倍、大于10倍等)。

[0131] 在图3D中,导管在远侧牵引器区域的第一端部区域与第二端部区域之间向远侧滑动。然后通过向近侧拉动柔性牵引器管(例如,近侧牵引器区域)和/或向远侧推进导管中的一者或两者,而可以通过将可扩张的第一端部区域向近侧取回到导管中来移除凝块。在一些变型中,既推进该装置(特别是导管),同时又取回可扩张的第一端部区域并将其翻转到导管中可能是有益的。可以比取回柔性牵引器管更快地推进导管。

[0132] 如图3F所示,凝块355可以被拉入到具有可扩张的第一端部区域的导管中。

[0133] 体内展开方法和装置的另一种变型示于图4A至图4F中。在该示例中,柔性牵引器管的自扩张的第一端部区域被配置成当其被推出导管时在导管的端部上自扩张,使得它将在导管的远侧端部上滑动。如以上对于图3A至图3B所描述,可以使用导丝413等来定位该装置。在图4A中,将导管401定位在邻近待去除的凝块455的导丝413上。在图4B中,导丝可以(可选地)被去除,或者(优选地)保留在位。包括远侧牵引器区域的柔性牵引器管434然后可以在导管内向远侧移动并且以可扩张的第一端部区域444延伸出远侧端部,使得其在远侧端部上翻转466并且在远侧端部区域上向近侧滑动,如图4C所示。该过程可以通过在脉管的腔内向远侧推动装置来辅助,因为第一端部区域444的扩张可以帮助将其抵靠血管的壁固定,如图4D至图4E所示。一旦暴露,通过向近侧拉动柔性牵引器管434和/或向远侧端部推进组件(或至少导管),可扩张的第一端部区域可以取回到装置中,如图4F所示。凝块455然后可以被拉入装置中。

[0134] 图5A至图5E示出了使用机械取栓装置的体内展开和取栓(凝块去除)方法的另一变型。在图5A中,包括导管501和内柔性牵引器管534的装置500(例如,在导丝上,未示出)被推进至凝块555附近。在该示例中(其可以与本文所描述的方法中的任一个相关),该装置与柔性牵引器构件一起定位,该柔性牵引器构件具有未展开的远侧牵引器区域,该远侧牵引器区域已经在远侧定位在装置的远侧端部区域附近。如图5B所示,处于图5A中导管501内的收缩配置的可扩张的第一端部区域544被推出导管的远侧端部并扩张至腔的壁,如图5B和图5C所示。一旦推出并扩张,可向远侧推进导管和导管内的柔性牵引器管的部分,如图5D所示,导致可扩张的第一端部区域544翻转,在导管501的远侧端部区域上翻折。通过图5E,装置已经在凝块555附近展开并且可以如已经描述的那样被致动以去除凝块,但是将远侧牵引器区域的可扩张的第一端部区域拉动到导管中,使得它翻转并将凝块拉入导管中。导管可以可选地同时被推进。注意,上述体内展开的方法也可以用于加载用于插入体内的装置,以便将导管径向地定位在柔性牵引器管的可扩张的第一端部区域与较近侧部分之间。

[0135] 图6A示出了具有柔性牵引器管634的取栓装置的另一变型的示例,该柔性牵引器管634具有形成于编织(例如机织)或针织材料的该示例中的柔性第一(远侧)端部区域

644,其中,柔性第一端部区域(牵引器区域)在导管601的远侧端部上翻转并且附接到柔性牵引器管634的近侧端部区域。如在本文所描述的装置中的任一个中,柔性牵引器管的该近侧端部区域可以是海波管、导管或者在导管内可推动/可拉动并且在其远侧端部附接到柔性牵引器区域(例如,远侧牵引器区域)(包括在一些变型中的可扩张的第一端部区域)的层压机织物/网状物或机织材料。注意,在一些变型中,远侧牵引器区域(第一端部区域)可以是不可扩张的,但是可以只是柔性的。

[0136] 在图6A中,附接到柔性牵引器管的远侧牵引器区域的第一端部区域被外导管或套筒(保护器)677覆盖。在该示例中,该装置还包括在内导管601与保护器导管或套筒677之间的中间导管679。在一些变型中,柔性第一端部区域644可以附接到该中间导管,包括可拆卸地附接使得向近侧拉动柔性牵引器管634将使其脱离并允许网状物(柔性第一端部区域644)在血管中展开。在图6A所示的变型中,柔性第一端部区域644未附接至中间导管679。

[0137] 本文所描述的装置中的任一个,包括图6A中所示的装置,可以与如图6B所示的导丝633一起使用(并且可以包括导丝)。图7A至7D示出了图6A至图6B中所示的设备的操作以去除凝块755。在该装置中,柔性牵引器管734的近侧端部可以耦接到真空源(未示出),该真空源当向近侧取回牵引器管734以在导管的端部上翻转远侧牵引器区域时可以被致动。在图7A中,装置位于凝块755附近。在图7B中,通过如箭头所示拉动柔性牵引器管734而翻转远侧牵引器区域并将其拉动到导管中。在该示例中,远侧牵引器区域不被扩张,这是因为它仍然被外套筒777覆盖,如图7B和图7C所示。可以通过推动或通过向近侧拉动远侧牵引器端部区域(在该示例中示为网状物744)的动作以使其在导管的远侧端部上翻转中的一者或两者,向远侧朝向凝块或者在凝块上推进该装置。一旦凝块被去除,装置可以被取回并从血管中被拉出,如图7D所示。

[0138] 如上所述,这些变型中的任一个可以包括一个或多个真空源。图8示出了包括真空源的一个示例,其示出了耦接到柔性牵引器管834的腔的近侧端部处的第一可选真空源。例如,与真空和牵引器管834耦接的可以是旋转止血阀(RHV),如图所示。在图8中,在(可选)外导管877和内导管801或(可选)中间导管878之间形成第二(可选)真空连接。可以在该方法的任何适当部分处施加真空,包括在柔性牵引器管834的收回期间去除凝块。

[0139] 如上所述,本文所描述的装置中的任一个可以包括导丝并且可以在手术期间将导丝留在适当的位置。图9A至9D示出了当导丝913留在适当的位置时去除物体(例如凝块)的方法。在该示例中,该装置类似于图6A至图6B中所示的装置,并且可以包括可选的真空源。在图9A中,包括远侧牵引器区域944的柔性第一端部区域944的翻转部分的导管的远侧端部定位成邻近凝块,并且通过向近侧拉动而被致动以将凝块拉入导管中,如图9B所示。在该示例中,凝块已经被导丝913穿透,因此具有翻转的牵引器区域的导管尖端可以通过推动导管927和/或通过向近侧拉动牵引器管919而在导丝上被向前推进。这可以继续直到整个凝块在导管内,如图9C所示。

[0140] 在本文所描述的变型中的任一个中,该装置可以包括一个或多个标记,或者可以被配置成与一种或多种对比剂一起使用以帮助使所描述的方法可视化。进一步地,这些方法中的任一种都可以包括可视化。可视化可以是间接的(例如,使用荧光镜检查或等效技术),或者可以是直接的,例如使用一个光纤用于直接使该装置可视化(例如,通过装置的

腔)。

[0141] 在图9D中,具有捕获物体(例如凝块)的牵引器管可以从装置的近侧去除并且可以检查所去除的材料(例如,通过组织学/细胞学检查)。随后或同时去除导管。如上所述,当去除物体(例如凝块)时,可能期望在柔性牵引器管向近侧拉回(未示出)的同时(向近侧)拉回导丝。在一些变型中,远侧牵引器区域(例如,编织/机织或针织区域)可以抓取导管内的导丝并且还可以帮助在凝块上或朝向凝块向远侧推进该装置,如下面在图36以及图37A至图37C中更详细地描述的。

[0142] 通常,抓取器(远侧牵引器区域)的滚动效果通过导管相对于远侧牵引器区域的运动而被致动。如果远侧牵引器区域向近侧固定并且导管被推进,则远侧牵引器区域可以具有1:1的抓取比。如果远侧牵引器区域被拉动通过导管,则抓取效果可能被放大。例如,当远侧牵引器区域被拉回(通过拉动牵引器管)并且当内导管被向远侧推动1个单元时翻转进入内导管中在导管内的近侧的1个单元,抓取效果大约是2倍。如果当内导管向远侧推进一个单元时,远侧牵引器区域被取回到导管中向近侧两个单元,则抓取效果可以是大约3倍。远侧牵引器区域和导管的同时运动可以通过手柄来协调。

[0143] 通常,本文所描述的装置中的任一个可以包括手柄。手柄可以与柔性牵引器管和/或导管(例如内导管)和/或任何外导管(例如保护器、套筒等)耦接。手柄可被配置成允许柔性牵引器管和/或导管的选择性的分开致动和/或这些部件的协调运动。图10A和图10B示出了可以使用的手柄的示例。在图10A中,手柄包括驱动机构以拉回牵引器管,并且因此在导管的远侧端部上翻转远侧牵引器区域和/或相对于远侧牵引器区域推进导管。在图10A中,手柄包括可旋转手柄1001,该可旋转手柄与导管驱动器1003耦接。手柄连接到导管1005和具有远侧牵引器区域1011的内部柔性牵引器管1009两者。手柄可以被配置成使得导管的推进(向远侧)与牵引器管的拉动(向近侧)的比率可以被选择和/或可以取决于导管驱动螺纹的螺距或其他机械机构。

[0144] 手柄的另一个变型在图10B中示出。在该示例中,手柄可以附接到牵引器管以拉动(或推动)牵引器管1017,并且因此在导管的远侧端部上翻转远侧牵引器区域,并且手柄的另一部分可以耦接到导管以推动/拉动导管1015。

[0145] 图11A示出了手柄机构1107的另一个变型,该手柄机构被配置成通过在附件部位1105处耦接到牵引器管的近侧端部来拉动本文所述的装置中的任一个的抓取器(远侧牵引器区域),和/或通过耦接到导管的近侧端部来推进导管。手柄机构的另一个示例在图11B中示意性地示出,其示出了杠杆机构1109和与可以固定或可调节的内牵引器管耦接的耦接件。

[0146] 在本文所描述的装置中的任一个(例如,机械取栓装置)中,远侧牵引器区域可以被预加载在导管中/上,使得它可以通过向近侧拉动耦接到远侧牵引器区域的牵引器管和/或向远侧推进导管而被致动。在其中远侧牵引器区域包括在导管的远侧端部上翻折的柔性和/或可扩张的第一端部区域(例如,由网状物和/或机织物材料形成)的预加载变型中,装置可以是适于防止第一端部区域在已经被定位在凝块处或凝块附近之前无意地移位和/或扩张。

[0147] 图12A和图12B示出了附接到导管外侧的远侧牵引器区域的可释放附件的示例。通过施加应用于柔性牵引器管的近侧端部的适当量的力(例如拉力)可以释放这些附件中

的任一个。例如,如图12A所示,远侧牵引器区域(示为网状物1204)的外远侧端部被从外导管或管1203延伸的肩部或衬垫覆盖)。类似地,在图12B中,远侧牵引器区域(示为网状物1204)的外远侧端部被单独的带、环或衬垫1209覆盖。通过添加细丝(例如在编织或机织变型中,附加编织细丝)、通过添加涂层、通过热定形至较大直径,和/或通过添加轴向编织间拉线,当张紧(例如在牵引器管上向近侧拉动)时,可以防止远侧牵引器区域收缩或直径减小。

[0148] 本文所描述的变型中的任一个可包括作为柔性牵引器管的一部分的近侧拉杆或拉线。进一步地,牵引器管的近侧端部区域可能比远侧端部(远侧牵引器区域)柔性更小。图13A和图13B示出了柔性牵引器管的示例。在图13A中,管包括近侧锥形区域,其中,远侧牵引器区域1305由向近侧1307渐缩(tapered, 锥化)到拉线的材料(例如,网状物/机织材料)形成,为导丝1309留出空间并允许远侧牵引器区域在导管上翻转。近侧拉线部分可由形成远侧牵引器区域的细丝形成,例如,在其中机织或编织远侧牵引器区域的变型中。这些细丝可以通过例如其他材料(诸如有助于使其更硬或更柔顺的聚合物)来增强。图13B示出了另一个示例,其中,柔性牵引器管的近侧端部由拉线1315形成,该拉线可以是单独的材料或附接到拉线的远侧端部并形成远侧牵引器区域1317的编织线束的延伸部。

[0149] 本文所描述的装置中的任一个可以被处理或适应为减少在导管端部上翻转远侧牵引器区域所需的力。例如,在一些变型中,远侧端部可以被处理为润滑的,或者远侧牵引器区域的全部或一部分可以被处理以提高费力性。例如,在一些变型中,仅远侧牵引器区域的一部分(例如最初在导管的远侧端部上相互作用/翻转的部分)被处理;远侧牵引器区域的其余部分不被处理。图14示出了此类装置的一个示例。在图14中,可扩张和/或柔性第一端部区域(其定位于导管外侧)的最近侧端部1405用润滑涂层处理或由润滑材料形成。第一端部区域的剩余部分(未按比例示出)不是润滑的1403。由于较近侧区域1405暴露于血管和导管的远侧端部,所以它可以更有效地追踪目标或者允许装置追踪目标以及更有效地开始在远侧端部上翻转。该区域可以以任何适当的方式制成润滑的,包括但不限于涂层,诸如疏水/亲水涂层,并且形成或包括更润滑的聚合物材料(例如 PTFE)。

[0150] 通常,本文所描述的远侧牵引器区域中的任一个可以适于包括不同的轮廓,包括预先设定以具有(例如,形状设定)可以更容易地在远侧端部上滑动/移动和/或抓取凝块或其他目标物体以用于去除的轮廓。例如,图15A至图15D示出了具有形成不同远侧牵引器区域的不同远侧端部轮廓的牵引器管。例如,在图15A中,远侧牵引器区域包括由通过多个拉线连接到牵引器管的近侧端部的由编织/网状或机织材料形成的最远侧可扩张和/或柔性第一端部区域1505。这些拉线1517可以由形成编织/网状或机织的远侧端部区域的相同线材或细丝形成。图15B示出了另一种变型,其中,多个离散的编织/网状或机织的远侧端部区域通过拉线1515连接;这些拉线区域1515可以是比编织/网状或机织区域1516更少可扩张的和/或柔性的。在图15C中,远侧端部区域被编织/网状或机织,但预先设定为具有不同的直径。因此这些区域沿其长度可以具有不同的形状;当这些形状被拉入导管中时,这些形状可被热定形以更好地抓取或破碎凝块。图15D示出了编织或支架状第一端部区域1521的示例,其通过形成编织/网状或机织的远侧牵引器的相同细丝或束连接到牵引器管1520的海波管或其他更近侧端部区域1523。

[0151] 本文所描述的装置中的任一个还可以或可替代地包括附接到导管的外表面上的

多个可释放附件,从而将远侧牵引器区域(并且特别是远侧端部部分)固定到外表面。在图16中,示出了形成可释放附件的三个环1603、16.3'、1603",其将远侧牵引器区域1644的远侧端部固定到导管1601的外侧。在该示例中,聚合物涂层/膜与编织物附接或成一体,形成远侧牵引器区域以帮助防止其过早地滑出或滑离导管(例如,直到由使用者拉动)。该装置可以包括沿着导管的长度径向定位的多个附件,如图所示,以帮助其保持固定到导管输送系统的外径。在一些变型中,这些可释放附件是弹性构件(例如聚氨酯环),但可以是脆的,并且允许破坏以释放远侧牵引器区域。

[0152] 图17示出了另一种变型,其中,可释放附件定位成使得远侧牵引器区域的一部分被弹簧加载(偏置)以驱动它在导管远侧端部上滚动并进入导管腔中。在图17中,远侧牵引器区域1704的远侧端部可被固定(固定、附接或松动但受约束),并且在导管的远侧端部附近的较近侧端部区域可被可释放地固定到导管1707。例如,聚合物涂层或膜可以附接到远侧牵引器区域(在图17中示出为编织物1744)并且被耦接以使远侧牵引器区域1705的在远侧端部1704与可释放附接部位1707之间的一部分保持张紧(例如,压缩)。然后释放可释放附件1707可以施加驱动围绕导管远侧端部的远侧牵引器区域的力,以帮助将凝块拉入装置中,并减小翻转远侧牵引器区域所需的力。

[0153] 如上所述,形成远侧牵引器区域(并且特别是最远侧柔性和/或可扩张的第一端部区域)的材料可以由任何适当的材料形成。例如,该材料可以包括织物、机织物、针织物、编织物、缝合物、管和/或平片。该材料可以具有任何合适的厚度,例如在0.0005"至0.015"的壁厚之间,并且可以具有从低至高孔隙率的任何合适间隔/尺寸(孔隙率)的孔。远侧牵引器区域的全部或部分可以是不透射线的或无线电透明的。在机织、针织、编织或缝制的变型中,材料可以由多丝或单丝形成。不同尺寸的细丝可以混合在一起(例如,大和/或小)以通过增加或减少织物表面纹理来改变抓取效果。在一些变型中,材料(包括形成材料的细丝)可以是基于聚合物的(例如PET、尼龙、聚丙烯、PTFE、ePTFE)、弹性和非弹性的(例如PU、硅酮、橡胶、莱卡)、金属细丝(例如镍钛、包括DFT的拉伸充填的镍钛,即带Pt内芯的镍钛、钢、不锈钢、钴铬合金等)以及金属和聚合物细丝的混合物。织物的端部可以是激光切割/焊接或自由切割。在一些变型中,远侧牵引器区域的全部或部分包括膜或片。该膜可以在0.0005"至0.008"厚度之间。该膜可以通过管挤出或片形成并且卷成管。在一些变型中,膜是纱线增强的。膜可以是开槽的(例如,可以包括被切割的孔和/或狭缝以改进抓持或滑入导管)。在一些变型中,膜具有纹理化表面(例如,翻转时暴露的纹理化内表面)。膜可形成具有沿长度具有脊和/或环(径向环)和/或线和/或具有锯齿形图案的管。纹理化内表面可以包括大丝和小丝的混合物,和/或可以由更多孔的较密度的织物形成。

[0154] 在一些变型中,抓取器元件的可视性是期望的,但并非始终需要。例如,如上所述,标记可以位于设备上。在一些变型中,可能期望看到结构的整个结构或近侧端部和远侧端部。例如,材料可以是镍钛诺或在铂材料(DFT)上拉制的镍钛诺以增强可视性。

[0155] 变型中的任一个可以包括位于编织结构中的任一个的内侧的旋转螺旋钻元件以协助将凝块拉回到鞘。如上所述,这些装置中的任一个都可以包括真空源。向系统添加真空可能有助于远侧牵引器区域将凝块/栓塞拉入导管中的能力。所施加的真空可以是稳定的/恒定的、倾斜的或脉动的。

[0156] 在一些变型中,使用它们的装置和方法可以包括阻流近侧球囊(例如,定位在凝

块附近),其可以在手术期间减少凝块上的压力。

[0157] 本文所描述的装置和方法可以用于捕获活检样品(例如,来自乳房或任何其他器官)。例如,当执行腹腔镜手术时,可以使用这些装置去除较大的组织段(例如,癌症、胆囊等)。

[0158] 当形成远侧牵引器区域的材料是机织/编织材料时,所得到的网状结构可具有范围从1cm到100cm长以围绕导管的外径(OD)的编织物长度,优选地长度为在约3cm至30cm之间。

[0159] 在这些变型中的任一种中,牵引器管和/或导管(包括远侧牵引器区域)可以被构造使得可以拉动远侧牵引器区域,使得远侧牵引器区域以最小的力在导管远侧端部的外径周围被拉入(翻转),使得导管尖端不会在血管中弯曲或显著变形(例如,蛇形扭动),其中,拉力小于约:50克、100克、300克、500克、800克、1000克、2千克、3千克、5千克、8千克、10千克、15千克、20千克等。

[0160] 在其中抓取器(远侧牵引器区域)至少在远侧端部(例如,可扩张的和/或柔性第一端部区域)上构造为机织(例如编织)结构的变型中,形成机织结构的细丝的示例可以包括:镍钛、镍钛-PT DFT线材(Pt内部的镍钛管)、PET、PP、尼龙、Algiloy、SS、混合材料。当使用时,镍钛可能被蚀刻以使其非常平滑。细丝端部的数量可以是约:16、24、36、48、77、96、144或这些整数之间的任何数量。任何编织结构都可以使用。例如,示例性编织结构可以包括1×1(1×1)、1×2、2×2等。在一些变型中,形成机织和/或针织材料的细丝包括单丝,例如所具有的外径(O.D.)尺寸约为:0.0005”、0.00075”、0.001”、0.0015”、0.002”、0.003”或在本文列出的整数之间的尺寸或直径尺寸的组合。如上所述,这些装置可以适用于使用的神经脉管系统,例如假设2mm至3mm脉管内径(ID)。例如,如本文所描述的适于神经脉管应用的装置可以包括韧炼至3mm至7mm OD的0.001”至0.002”聚合物编织物的36个至72个端部。在一些变型中,远侧牵引器区域包括24个编织线材,其具有以45度角度编织的在2mm心轴上韧炼的0.0005”至0.0015”或0.002”的扁平镍钛线材。可替代地,在一个变型中,远侧牵引器区域包括编织材料,该编织材料由以45度角度编织的在2mm心轴上韧炼的0.002”厚度的镍钛线材的24个线材形成。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括以45度角度编织的在2mm心轴上韧炼的0.002”DFT镍钛线材的24个线材。在一个示例中,远侧牵引器区域包括机织材料,该机织材料包括与在2mm心轴上的0.002”镍钛线材的8个附加端部混合的0.003”线材的8个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括在2mm心轴上韧炼的0.002”铂铱线材的16个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括具有0.002”直径的外径的PP单丝的24个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括0.003”PP单丝的12个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括0.003”PP单丝的16个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括1x1、90度编织角度、8mm心轴的0.001”PET或PP的72个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括1x1、75度编织角度、6mm心轴的0.001”PET或PP的36个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括1x1、90度编织角度、8mm心轴的0.002”PET或PP的48个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括1x1、70度编织角度、6mm心轴的0.002”PET或PP的48个端部。

[0161] 在其中远侧牵引器区域包括网状物的变型中,管状网状物可由针织或替代结构形成,该针织或替代结构被构造使得当网状牵引器被轴向拉动并且围绕导管尖端的外侧并进入导管ID中时,径向压缩(管状网状物内径ID的变化)经受直径减小5%至20%。这种5%至20%网状物直径的减小可以有助于在将网状物拉动到导管中时抓取凝块或异物,而不会产生很大的径向压缩力使得在拉动时管状网状物结合在导管尖端上并且不容易围绕导管尖端滚动。相反,当向近侧拉入时,机织的网状物可在导管内收缩20%至60%之间,这可提供其他所去除材料的凝块的大量压缩。

[0162] 在其中该装置被配置用于外围血管(例如,具有4mm至8mm血管ID)的变型中,远侧牵引器区域可以被配置用于该应用。例如,远侧牵引器区域可以包括具有形成在4mm心轴上并被韧炼的0.009"PP单丝的24个端部的编织材料。远侧牵引器区域可以包括具有4mm心轴韧炼的0.008"PP单丝的编织材料。远侧牵引器区域可以包括具有4mm心轴韧炼的0.006"PP单丝的72个端部的编织材料。远侧牵引器区域可以包括具有4mm心轴韧炼的36个端部的编织材料。远侧牵引器区域可以包括具有心轴韧炼的0.004"DFT镍钛的48个端部的编织材料。

[0163] 在其中装置被配置为活检装置(例如,具有4mm至12mm样本大小)的变型中,该装置可以是机织材料,其包括在10mm心轴上形成的PP 0.007"单丝的72个端部。在一些变型中,装置(例如,远侧牵引器区域)可以包括在1mm心轴上形成的0.004"镍钛的48个端部。在一些变型中,装置(例如,远侧牵引器区域)可以包括在12mm心轴上的PP 0.008"单丝的48个端部。

[0164] 在本文所描述的变型中的任一个中,所述装置可以被配置成具有相对低的摩擦。特别地,远侧牵引器区域可以具有低摩擦力以允许在收回凝块时更容易和/或可靠地拉动穿过导管。如上所述,这些变型中的任一个可以包括润滑材料和/或涂层,包括在抓取器(远侧牵引器区域)上使用或涂覆一种或多种以下材料:PET、PP、PTFE、ePTFE。当形成装置的材料是小直径细丝金属结构时,细丝的直径可以在0.0005"至0.003"之间。材料可以是镍钛、不锈钢、MP35n、Ti、铂、铂铱、钴铬合金等。

[0165] 在远侧牵引器区域是网状物(例如,机织和/或针织材料)的变型中,远侧牵引器区域相对于导管直径的直径可以取决于机织/针织结构。例如,当编织时,比率可以在2至1之间或更大;当经编时,比率在1.5至1之间或更大。当形成为激光管时,比例在1.1至1之间或更大。类似地,对于编织管或带结构,导管内部的编织角度应该在导管内侧在编织角度的0度至45度之间,并且在导管外侧在编织角度的约20度至90度之间。在远侧牵引器区域包括针织编织(例如,经编)管的变型中,该装置可以包括每英寸12个至16个端部。对于具有0.0035" ID导管的装置:可以使用20至40D PET复丝的12个至16个端部,或者可以使用0.0007"至0.003" PET或聚丙烯(Polypro)或PTFE单丝的12个至16个端部,或者可以使用0.0007"至0.002"镍钛、不锈钢、MP35n等的12个至16个端部。

[0166] 如上所述,在一些变型中,远侧牵引器区域由ePTFE形成为片(例如,形成为管或带)。这种材料可以是薄壁的(例如厚度在0.0005"至0.003"之间),被认为是具有壁厚的(在0.0005"至0.002"之间),并且可以在导管尖端上折叠/起作用。该材料可能包括0.001"至0.004",带有支架状的激光图案。

[0167] 包括不同形状的远侧牵引器区域的装置的设计的其他示例可以是导管ID的功

能。例如,在一些变型中,装置可以选择导管ID、细丝的数量、细丝的直径/长度、弯曲/滚动刚度的刚度、泊松比、抓取器的内表面的摩擦(和/或纹理)等。较小直径的导管比较大直径的导管可能需要更少的网状物细丝或者更小的ePTFE管IDS。例如,在编织远侧牵引器区域的一些变型中,该装置可以包括具有远侧牵引器区域的0.072" ID导管,该远侧牵引器区域具有以90度编织角度编织在6mm心轴上的0.0008"至0.002" 镍钛线材的24个至72个端部。在一些变型中,远侧牵引器区域由以90度编织角度编织在6mm心轴上的0.0008"至0.002PP单丝的24个至72个端部形成。在一些变型中,远侧牵引器区域由针织编织物(假定0.072" 导管)形成,并且可以包括在3mm心轴上韧炼的16个端部或40D PET 复丝自由经编针织物。在一些变型中,远侧牵引器区域由在3mm心轴上韧炼的经编针织的0.002" PP单丝的16个端部形成。在具有由ePTFE管形成的远侧牵引器区域(同样,假设0.072" 导管)的变型中,远侧牵引器区域可以是0.002"厚的3mm的管。可替代地,远侧牵引器区域可以是0.002"厚的3mm的管激光器,其被开槽以收缩和抓取凝块。

[0168] 如所提及的,在一些变型中,该装置被配置成在远侧牵引器区域中包括抓持内网状表面。例如,该装置可以包括具有较大直径编织细丝和/或混合直径细丝的激光开槽ePTFE管。在一些变型中,抓持内网状表面可以用作为经编针织成型管的针织编织物形成。此类结构可以具有自然的宏观结构以允许网状物滚动和抓持凝块,因为细丝不会平行于导管进入导管ID,而是它们相对于导管长轴线是垂直或环状的。对于其中远侧牵引器区域由ePTFE激光开槽材料(材料片)形成的示例,该结构可以包括切割成允许泊松比影响管直径同时产生抓持纹理以抓取凝块的狭缝。

[0169] 通常,通过使用自扩张的和/或较硬的远侧牵引器区域(例如,远侧牵引器区域的自扩张的和/或柔性第一端部区域),可以增强远侧牵引器区域在抓取凝块中的有效性)。当远侧牵引器区域的第一端部区域由编织物形成时,较硬的细丝(例如,由较大直径的细丝、较硬的材料、较大数量的纤维等形成)可导致远侧牵引器的更扩张的第一端部区域,如图18A至图18C所示。在图18A中,较柔软的远侧牵引器区域不会扩张超出导管的OD相当大的距离。图18B示出了远侧牵引器区域的略微更硬/更可扩张的第一端部区域。图18C示出了最可扩张的远侧牵引器区域1801,其可以最佳地扩张至血管1803的内膜。

[0170] 如图18A至图18C所示,可扩张的牵引器区域的唇缘的嘴部可相对于导管OD的长轴线形成切向角度或滚动角度(ϕ)。该角度可以在大约5°至60°的范围内(例如,10°至60°、10°至50°、10°至45°、10°至40°等,并且优选地至少为10度)。本发明人惊奇地发现,在一些变型中,当牵引器区域被收回到导管中时与管具有至少约10度(例如10°至60°、10°至50°、10°至45°、10°至40°)的滚动角度可防止导管尖端上的束缚或堵塞。网状管可以被修改(例如,在远侧尖端或端部区域处),包括通过修改远侧尖端的刚度和/或形状,以确保滚动角度大于10度。可替代地或与保持最小滚动角度的组合,可能期望在导管最远侧尖端处保持管材料ID与导管的OD之间的物理空间或间隙(参见例如图18A至图18C)。间隙可能需要大于0.1mm、0.2mm、0.3mm、0.4mm、0.5mm、0.7mm、0.8mm或1.0mm,以确保当管收回时,管围绕导管的远侧端部滚动。

[0171] 在这些变型中的任一个中,如上所述,远侧牵引器区域可以是润滑的(例如,亲水涂层、硅树脂涂层、薄氨基甲酸酯或其他薄弹性体涂层)。可以包括一个或多个聚合物编织物端部以增强润滑性(例如,聚丙烯、尼龙等)。进一步地,编织角可保持较小(例如,小于70

度、50度、45度 等)以允许更好的拉动。当远侧牵引器区域在导管的尖端周围/上方滚动时,可以测量该角度。增加机织物的端部的数量也可以防止第一端部区域在导管内的锁定,使得编织元件之间的间隙/空间更小并且当远侧牵引器区域在导管的端部上滚动时不太可能阻碍导管尖端。当形成为编织元件时,这些装置中的任一个还可以包括轴向元件,该轴向元件在拉动时不太可能收缩或直径减小,并且因此当在尖端上滚动时不太可能挂在导管开口上。当使用镍钛(例如 $>0.0001''$ 直径)时使用稍大的编织细丝也是有利的;直径越大,编织物可变形以锁定到导管尖端的可能性就越小。如上所述,在一些变型中,远侧牵引器区域可被热定形以在向远侧推进时在导管的远侧端部上自动滚动。

[0172] 图19A和图19B示出了用于形成远侧牵引器区域的翻折回来配置的替代方法。在图19A中,管状远侧牵引器区域1903可以耦接到拉动器/推动器1901,然后如上所述在导管尖端上翻转。在图19B中,管状编织物1905穿过编织物向远侧附接到线材/拉动器1901并被拉动以在导管的远侧端部上使其翻转。

[0173] 通常,远侧牵引器区域的第一端部区域可具有任何适当的形状(参见图15A至图15D)。图20A和图20B示出了可以形成远侧牵引器区域的渐缩机织物的示例。在图20A中,编织物具有锥形侧面轮廓,其可以附接到拉动器(柔性牵引器管的近侧端部)并且翻转。本文所述的编织物中的任何一种可以包括标记线材(例如,DFT、金、铂、铂铱等)以帮助可视化(例如,荧光镜)。在图20B中,网状物比图20A中更突然地渐缩。

[0174] 如上所述,通常,本文所描述的导管中的任一个可适用于这些装置。例如,合适的导管可以是高度柔性的,并具有良好的柱刚度(例如,当向远侧推进时其长度不会缩短)。导管可以具有高角度编织物加强元件。例如,导管可以具有穿过近侧端部至远侧端部的高角度编织物(70度至85度,小线材镍钛、不锈钢、钴铬、MP35N、扁平或圆形线材),以及针对导管的远侧1cm至5cm的较小编织角度。这将允许当施加轴向压缩时和/或在内扩张力(例如血块)下导管的内径扩张。

[0175] 通常,这些导管中的任一个都可以包括改变的刚度/顺应性。例如,近侧三分之一($1/3$)可能较硬;中间部分可能不太硬,而远侧20%($1/5$)可能是最不硬的。进一步地,导管的远侧尖端可以具有如图1A和图1B中所描述的适当的半径(曲线)。通常,半径应该是平滑且圆形的,而不是方形的。另外,导管的远侧尖端可以由足够硬的材料(约72D或更硬)制成,以允许编织物滚动而不抓取尖端。例如,导管尖端可以具有硬质金属结构以减少摩擦(例如,不锈钢、Pt等)。当拉动远侧牵引器区域时导管尖端压缩/弯曲越少越好。在一些变型中,导管包括附加加强件,诸如编织增强件而不是线圈加强件,以防止导管最后5cm至10cm的编织物屈曲。因此,如本文所描述的,在一些变型中,导管的尖端可由润滑和/或硬质材料制成,以当编织物围绕导管尖端被拉动或被推动时帮助减少编织物与导管尖端的摩擦。润滑材料可以包括诸如PTFE、FEP和/或亲水涂层的粉状聚合物。如尼龙之类的硬质材料或不锈钢之类的金属材料、铂和PT铱合金可用于该尖端,并且向近侧熔合/附接到较柔软材料。如果硬质尖端被放置在导管尖端的远侧端部上,则其长度可能是短的(例如 $<5\text{mm}$ 并且优选地 $<3\text{mm}$),因此它不会不利地影响导管追踪。

[0176] 图21A至图21D示出了用于去除凝块的装置的示例。在该示例中,远侧牵引器区域由拉下到 $0.071''$ 的导管上的10mm(扩张)直径的大约72个端部的细旦尼尔PET网状物形成,如图21A和图21B所示。图21A示出了在耦接到导管之前的可扩张的第一端部区域的示例。

图21B示出了通过拉动柔性(牵引器)管的近侧端部将血管(玻璃管)内的可扩张的第一端部区域拉入导管中。图21C示出了装置的远侧端部区域,其包括在导管的远侧端部区域上翻折的可扩张的第一端部区域。图21D示出了将凝块拉入导管中的图21C的装置。

[0177] 另一个示例检查了由具有72个端部和0.001”直径细丝的6mm编织物形成的远侧牵引器区域,该细丝滚动进入0.071”ID导管并且在0.071”ID导管上翻折。成功去除20cm长的“中等硬度”5mm凝块。图22示出了在将其向近侧拉出导管之后具有所捕获的凝块的图21D的可扩张的第一端部区域。

[0178] 图23A至图23D示出了如本文所述的机械取栓装置,其捕获血凝块并将其拉入装置中。图23E示出了在柔性牵引器管已经从导管去除(例如向近侧)之后保持在柔性牵引器管内的凝块。

[0179] 在本文所描述的一些变型中,远侧牵引器区域不是由机织或针织材料形成,而是由纵向布置(例如,平行或近似平行布置)的条或束构成。例如,图24是包括柔性牵引器构件的装置的另一个示例,其中,远侧牵引器区域由多个细丝形成,该多个细丝布置位未机织或编织的材料条(纵向平行)。这些条可以是细丝或管等。

[0180] 图25A至图25F示出了柔性牵引器组件的远侧牵引器区域的另一变型,其中,可扩张的第一端部区域(例如,远侧牵引器区域的远侧端部区域)由多个细丝或条形成,类似于图24中所示的;如图25A至图24所示,导管的远侧端部包括通道;这些条可以装配在这些通道内,如图25C至图25D所示。图25E和图25F示出了穿过图25C和图25D的截面图。图25A、图25C和图25E示出了侧视图并且图25B、图25D和图25F示出了轴向视图。在该示例中,导管尖端包括细丝/条2503在其中行进的通道2502。形成远侧牵引器区域的条附接到柔性牵引器管2505的更近侧的拉动器区域,如图25E所示。

[0181] 图26A和图26B示出了具有外套筒(例如,外导管或释放保护器导管或其他外套筒/保护器)的图25A至图25F的装置的变型

[0182] 图27A至图27B示出了穿过图26A至图26B的装置的截面图。

[0183] 图28是包括柔性牵引器组件的远侧牵引器区域的装置,柔性牵引器组件具有多个纵向平行的(非机织/编织)细丝或条,其中,细丝或条的远侧端部通过远侧连接件彼此连接。

[0184] 图29示出了装置中的柔性牵引器组件的远侧牵引器区域,其中,纵向平行的(非机织/编织)细丝或条包括抓取元件。

[0185] 图30A至图30C示出了具有抓取元件的细丝/条的示例。抓取元件(和/或包括它们的细丝)可以用作本文所描述的变型中的任一个的一部分,包括机织或编织的远侧牵引器区域。带有抓取元件的对于细丝/条的其他选择可以包括编织条、网状物/机织条和微线圈。

[0186] 在本文所描述的这些配置中的任一种中,该装置可以适于允许远侧牵引器区域的往复运动,从导管的远侧端部的外侧至内侧并回到外侧而循环。例如,图31示出了其中远侧牵引器区域适于往复运动(例如,推动和拉动)使得可扩张的第一端部区域可被拉入导管中并且从导管翻转出的变型。在该示例中,牵引器管(拉动器)3105附接到远侧牵引器区域3144,该远侧牵引器区域可以附接(并且在一些变型中不附接)到内导管3101上的第二导管3109。中间导管3109可以耦接到拉动器3105,并且两者一起往复运动,使得编织物

在导管3101的内侧来回往复运动。这可以帮助 破碎凝块,这可能特别是在与抽吸一起使用时。

[0187] 图32示出了如本文所述的装置的另一示例,其中,远侧牵引器区域 的柔性第一端部区域的最远侧端部3205不可释放地固定到导管3201的外 侧的远侧端部;可扩张的第一端部区域3209的其余部分具有足够的弹性/ 柔性以被拉入导管中(用其拉动凝块3255)。然后柔性牵引器组件可以被 收回并且整个装置被取回。该示例可能包括可选的真空3260。

[0188] 图33是装置的另一个示例,其中,柔性牵引器组件的拉动器部分3305 由与远侧牵引器区域3344相同的材料形成,但可以层压或以其他方式加 强以具有比远侧牵引器区域更小的柔性/可拉伸性。

[0189] 图34示出了另一个示例,其中,远侧牵引器区域3444适于当拉入导 管3401中时压缩凝块3455。图35A至图35C示出了如图34所示的装置 的操作,其中,凝块3455通过将远侧牵引器区域的可扩张的第一端部区 域取回到压缩凝块的导管中(例如在牵引器组件的牵引器区域3505上拉 动)而被拉入导管中(图35A至图35B);释放牵引器组件和/或向远侧推动牵引器组件可以进一步破碎凝块并且将其从远侧牵引器区域释放,使得 它可以向近侧分段(图35C)。

[0190] 图36示出了一种装置和使用方法的示例,其中,向近侧拉柔性牵引 器组件可以向远侧推进装置穿过导丝上的主体(例如血管),该导丝可以 被处理以接合远侧牵引器区域。在该示例中,该装置可以被配置成拉动具 有形成远侧牵引器区域3644的网状物的内牵引器管(导管3605),该远侧 牵引器区域附接到其远侧端部并且在导管3601的远侧端部上翻转。拉动 柔性牵引器管3605使编织物在导管3601的开口上滚动。形成远侧牵引器 区域(例如,远侧牵引器区域的第一端部区域)的网状物/编织物被构造成 当拉伸负载施加到该结构上并且锁定/抓取内线材(导丝3677)时在直径 上收缩。该内导丝可能具有抓取线材的粘性、粗糙或多变的表面辅助网状 物/编织物。当网状物/编织物抓取在导丝上时,牵引器管由于反作用力而 将在脉管中被向前驱动。可替代地,用户将能够在拉回牵引管的同时能够 容易地将外导管3601向前推进穿过血管。

[0191] 图37A至图37C示出了另一种装置和使用方法,其中,向近侧拉柔 性牵引器组件可以向远侧推进该装置。在图37A中,远侧牵引器区域3744 附接至中间导管3703(可包括可选的外导管3705),并且远侧牵引器区域3744的相对端部结合至在该导管的内径内的内导管 3701的远侧端部。在 图37B中,向远侧推进内导管,从而使远侧牵引器区域在侧向和前方扩张。如图37C所示,然后可以向远侧推动外导管和内导管,以使装置向远侧移 动。

[0192] 在一些变型中,远侧柔性牵引器区域可以被保持预先加载在导管的外 侧,例如以卷或束的形式被保持预先加载在导管的远侧端部区域上,使得 其可以被逐渐拉出外存储区域并且在导管的远侧端部上滚动和翻转。一个 此类变型的示例示出在图38A和图38B中,该示例性装置可用于从血管 内去除材料,如图38B所示,并且可以称为“无限(infinite)”牵引器机 构,因为大量(例如,大于50cm、大于60cm、大于70cm、大于80cm、 大于90cm、大于100cm、大于150cm、200cm、大于300cm、大于400 cm、大于500cm等)的牵引器材料(例如,网状物)可存储在外保持区 域中,其被卷起但在扩大使用上不是必要的。

[0193] 在图38A中,该装置可以包括导管(内导管)3811并且远侧牵引器 区域3806由在导管的远侧端部附近的壳体区域3813中卷起的网状物3803 形成。通过在导管内向近侧拉动

远侧牵引器区域,凝块3805可被拉入导管中。由于大量远侧牵引器区域可能存储在近侧并且向近侧被取回,因此 这种变化对于非常长的手术或者需要去除大量材料的情况可能是有用的。

[0194] 这种变型可以允许使用者展开较长长度的网状物,这对于更刚度的工具(诸如在手术期间的刚度海波管)可能是有利的,例如,在吸脂手术中 去除脂肪、去除脑内出血或更大的外周血管凝块中的凝块。

[0195] 如上所述,在本文所描述的变型中的任一个中,远侧牵引器构件可以是机织(例如针织)或编织的网状材料。网状物可以是针织材料,包括例如纬编针织物、圆形针织物、经编针织物和/或编织针织物。

[0196] 当特征或元件在本文中被称为“在”另一特征或元件“上”时,其可以直接在另一特征或元件上,或者也可以存在中间特征和/或元件。相反,当特征或元件被称为“直接在”另一特征或元件“上”时,不存在中间特征或元件。还将理解,当特征或元件被称为“连接”、“附接”或“耦接”到另一特征或元件时,其可直接连接、附接或耦接到另一特征或元件,或者可能存在中间特征或元件。相反,当特征或元件被称为“直接连接”、“直接附接”或“直接耦接”到另一特征或元件时,不存在中间特征或元件。虽然相对于一个实施例进行了描述或示出,但是所描述或示出的特征和元件可以应用于其他实施例。本领域的技术人员还将认识到,对“邻近”另一个特征设置的结构或特征的提及可以具有与邻近特征重叠或位于其下面的部分。

[0197] 本文所使用的术语仅用于描述特定实施例的目的,而不意图限制本发明。例如,如本文所使用的,除非上下文另外明确指出,否则单数形式“一”,“一个”和“该”也旨在包括复数形式。将进一步理解,当在本说明书中使用术语“包括”和/或“包含”指定所述特征、步骤、操作、元件和/或部件的存在,但不排除一个或多个其他特征、步骤、操作、元件、部件和/或其组合的存在或添加。如本文所使用的,术语“和/或”包括相关所列项目中的一个或多个的任何和所有组合,并且可以缩写为“/”。

[0198] 为便于描述,本文可以使用诸如“在...之下”、“在...下方”、“下”、“在...上”、“上”等的空间相对术语以描述一个元件或特征与另一个元件或特征的关系,如图所示。将理解,空间相对术语旨在包括除了附图中所描绘的方位之外的装置在使用或操作中的不同方位。例如,如果附图中的设备是翻转的,则被描述为在其他元件或特征“之下”或“下方”的元件将被定向为“在”其他元件或特征“上”。因此,示例性术语“在...下面”可以包括上方和下方两种方向。设备可以以其他方式定向(旋转90度或以其他方位)并且相应地解释在本文所使用的空间相对描述符。类似地,除非另外特别指出,否则术语“向上”、“向下”、“竖直”、“水平”等仅用于解释的目的。

[0199] 虽然术语“第一”和“第二”在本文中可以用于描述各种特征/元件(包括步骤),但除非上下文另有指示,否则这些特征/元件不应受这些术语限制。这些术语可以用于区分一个特征/元件与另一个特征/元件。因此,下面论述的第一特征/元件可以被称为第二特征/元件,并且类似地,在不脱离本发明的教导的情况下,下面所论述的第二特征/元件可以被称为第一特征/元件。

[0200] 在整个说明书和所附的权利要求书中,除非上下文另有要求,否则词语“包含”以及诸如“包含了”和“其包含”的变型意味着各种部件可以在方法和物品中共同采用(例如,

包括设备和方法的组合物和装置)。例如,术语“其包含”将被理解为暗示包含任何陈述的元件或步骤,但不排除任何其他元件或步骤。

[0201] 如在本说明书和权利要求书中所使用的,包括在示例中所使用的并且除非另有明确说明,即使术语没有明确出现,所有的数字也可以读作像“约”或“大约”这样的词语开头。当描述幅度和/或位置以指示所描述的值和/或位置在值和/或位置的合理预期范围内时,可以使用短语“约”或“大约”。例如,数值可以具有所述值(或值的范围)的 $\pm 0.1\%$ 的值、所述值(或值的范围)的 $\pm 1\%$ 的值、所述值(或值的范围)的 $\pm 2\%$ 的值、所述值(或值的范围)的 $\pm 5\%$ 的值、所述值(或值的范围)的 $\pm 10\%$ 的值等。本文给出的任何数值也应被理解为包括约或大约该值,除非上下文另有指示。例如,如果公开了值“10”,则“约10”也被公开。本文列举的任何数值范围旨在包括其中所包含的所有子范围。还应理解,当公开值时,“小于或等于”该值、“大于或等于该值”以及值之间的可能范围也被公开,如本领域技术人员所适当理解的。例如,如果公开了值“X”,则还公开了“小于或等于X”以及“大于或等于X”(例如,其中X是数值)。还应该理解,在整个申请中,数据以多种不同的格式提供,并且该数据表示端点和起点以及数据点的任何组合的范围。例如,如果公开了特定的数据点“10”和特定的数据点“15”,则可以理解,大于、大于或等于、小于、小于或等于并且等于10和15被认为是公开的以及在10和15之间。还应该理解,还公开了两个特定单元之间的每个单元。例如,如果公开了10和15,则还公开了11、12、13和14。

[0202] 尽管以上描述了各种说明性实施例,但是在不脱离如权利要求所描述的本发明的范围的情况下可以对各种实施例进行多种改变中的任何一种。例如,其中执行各种所描述的方法步骤的顺序通常可以在替代实施例中改变,并且在其他替代实施例中,可以完全跳过一个或多个方法步骤。各种设备和系统实施例的可选特征可以包括在一些实施例中而不包括在其他实施例中。因此,前面的描述主要是为了示例性的目的而提供的,并且不应该被解释为限制如在权利要求中所阐述的本发明的范围。

[0203] 本文包括的示例和说明通过说明而非限制的方式示出了其中可以实践主题的特定实施例。如上所述,其他实施例可以被利用并从中导出,使得可以在不脱离本公开的范围的情况下进行结构和逻辑替换和改变。本发明主题的此类实施例在本文中单独地或共同地由术语“发明”引用,仅仅是为了方便,并且无意将本申请的范围自愿地限制到任何单个发明或发明构思,如果事实上公开了不止一个的话。因此,尽管本文已经说明和描述了具体实施例,但是为了实现相同目的而计算出的任何布置都可以替代所示的具体实施例。本公开旨在覆盖各种实施例的任何和所有修改或变型。上述实施例的组合以及本文中未具体描述的其它实施例对于本领域技术人员在查看以上描述时将是显而易见的。

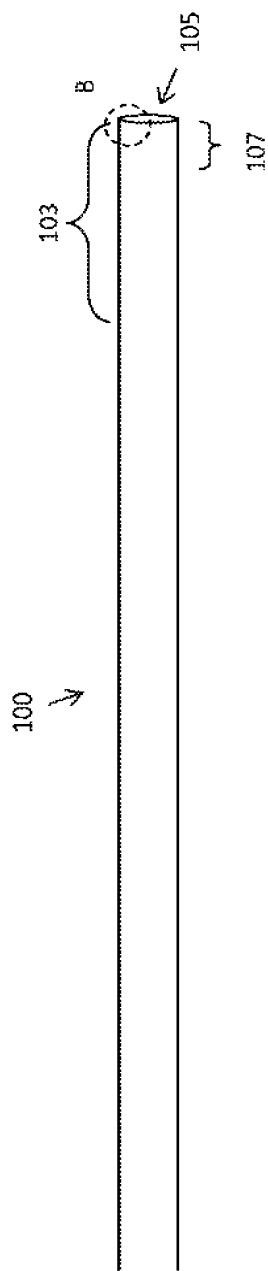


图1A

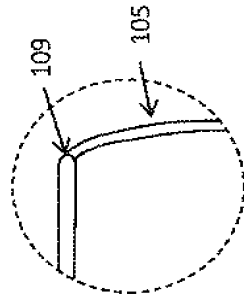


图1B

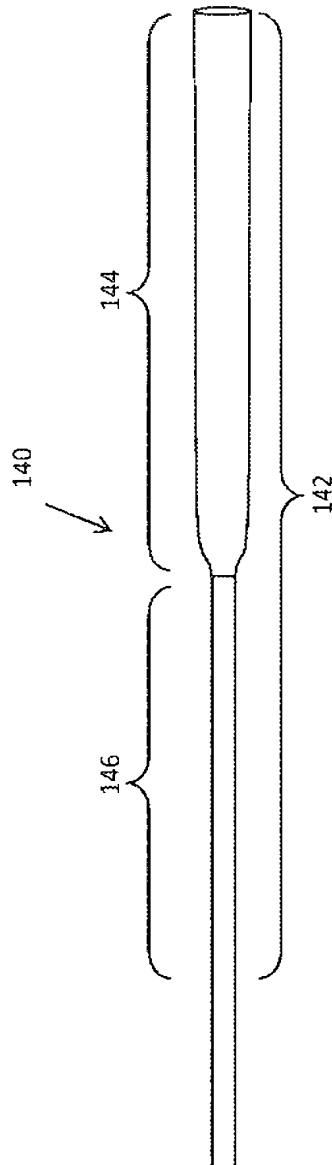


图1C

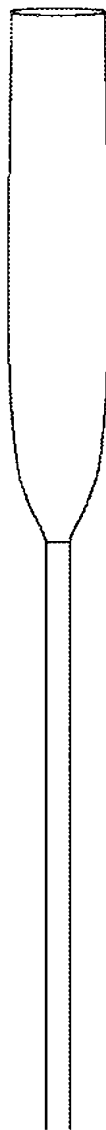


图1D

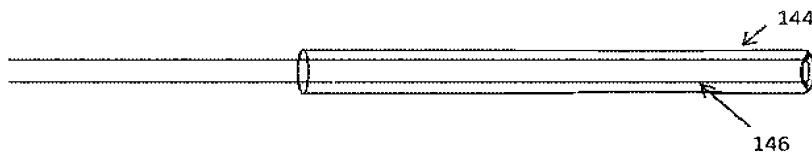


图1E

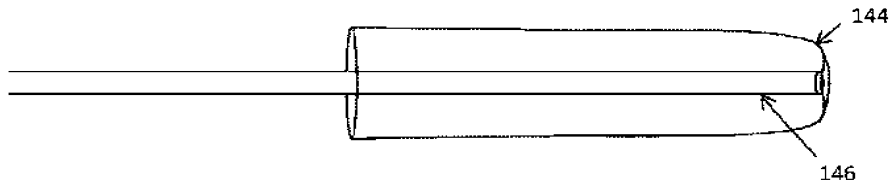


图1F

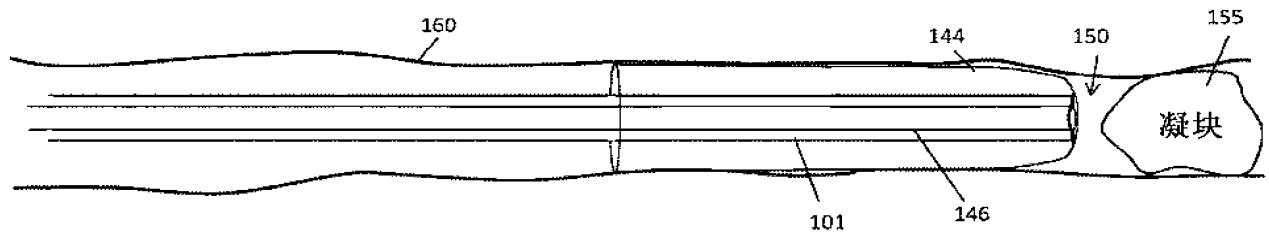


图1G

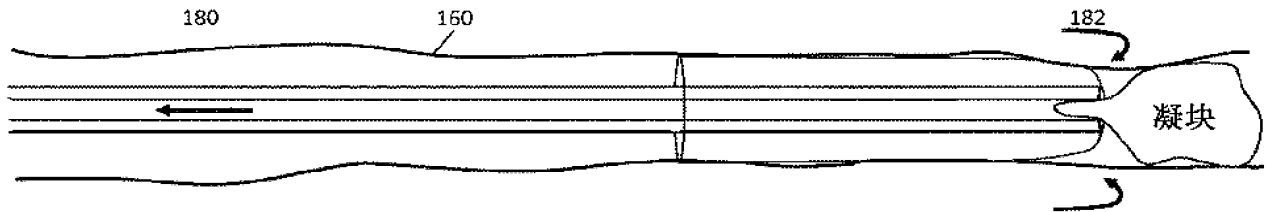


图1H

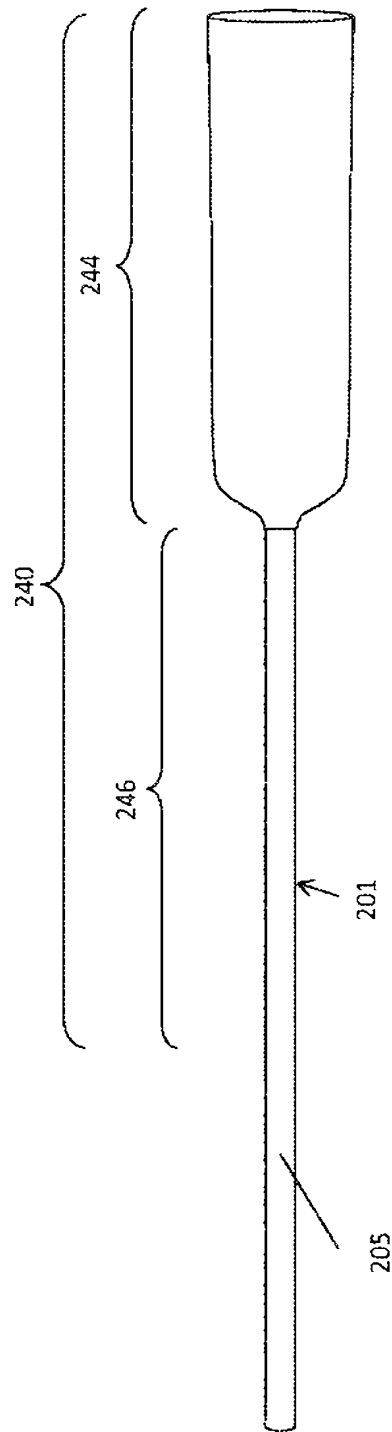


图2A

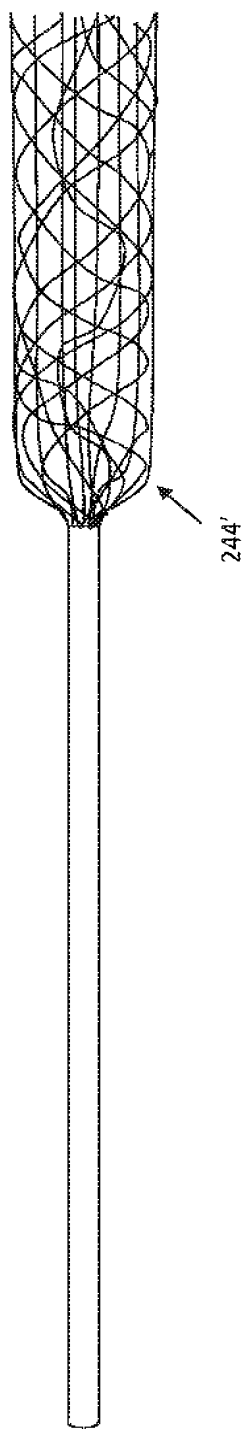


图2B

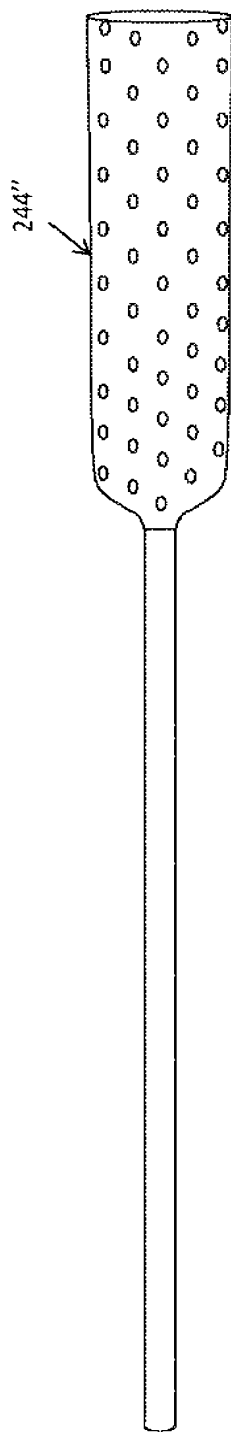


图2C

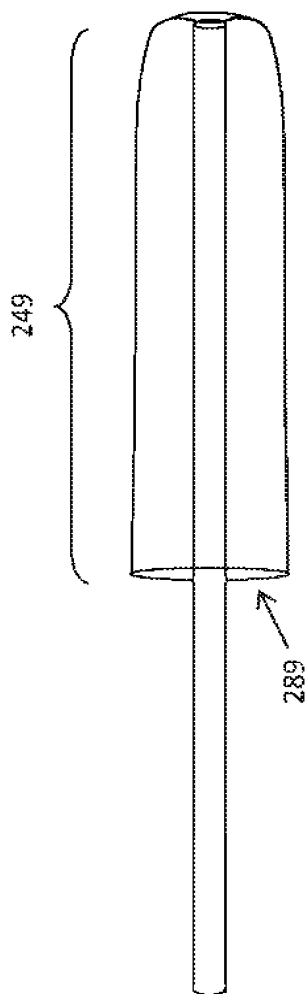


图2D

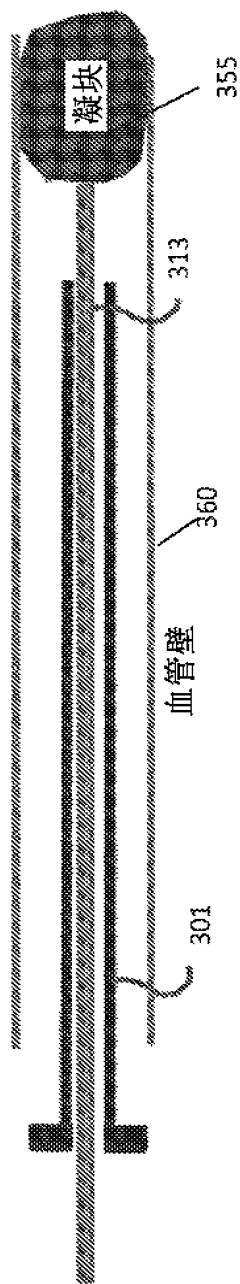


图3A

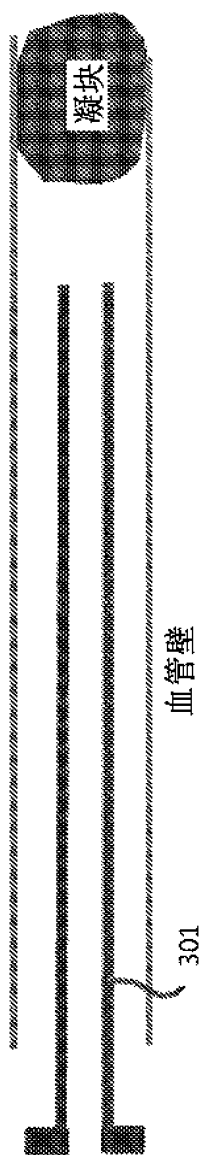


图3B

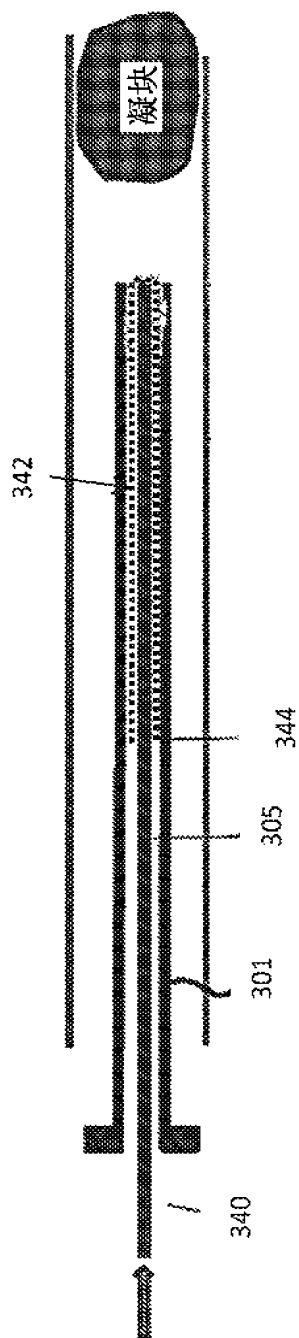


图3C

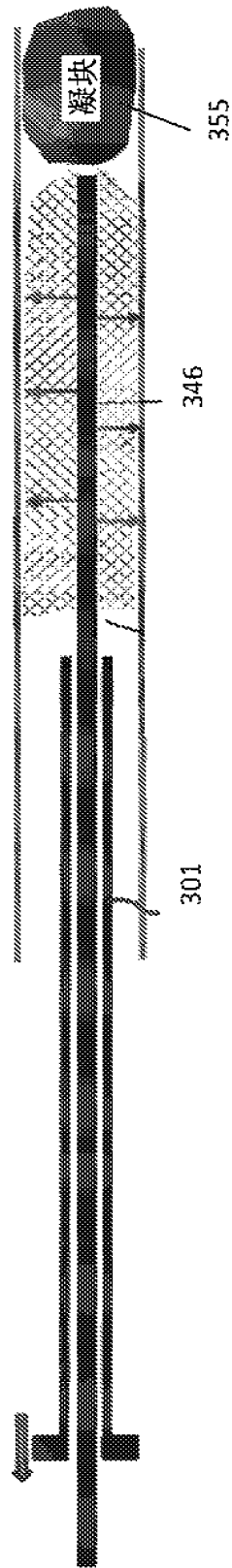


图3D

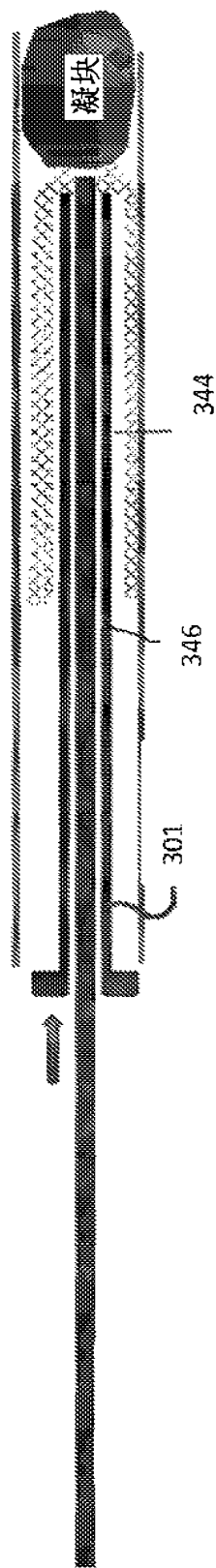


图3E