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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/516,232	01/14/2020	10531883	Syn2.0/ROAR	6733

27316 7590 12/24/2019

Mayback & Hoffman, P.A.
350 East Las Olas Blvd
Suite 1750
Fort Lauderdale, FL 33301

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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 Data Management (ODM) at (571)-272-4200.

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

Syntheon 2.0, LLC, Miami, FL;
Derek Dee Deville, Coral Gables, FL;
Matthew A. Palmer, Miami, FL;
William T. Bales JR., Miami, FL;
M. Sean McBrayer, Coral Gables, FL;
Eric Petersen, Homestead, FL;
Richard Cartledge, Boca Raton, FL;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	16516232
Filing Date	2019-07-18
First Named Inventor	Derek Dee Deville
Art Unit	3771
Examiner Name	Melanie Ruano Tyson
Attorney Docket Number	Syn2.0/ROAR

	66	20170169374	A1	2017-06-15	HARRIS, et al.	
	67	20170172581	A1	2017-06-22	BOSE, et al.	
	68	20170215902	A1	2017-08-03	LEYNOV, et al.	
	69	20170238950	A1	2017-08-24	YANG, et al.	
	70	20170238951	A1	2017-08-24	YANG, et al.	
	71	20170238953	A1	2017-08-24	YANG, et al.	
	72	20170239440	A1	2017-08-24	YANG, et al.	
	73	20170239441	A1	2017-08-24	YANG, et al.	
	74	20170239447	A1	2017-08-24	YANG, et al.	
Change(s) applied to document, /G.R.P./ 11/26/2019	75	20100217276	A1	08-2010 ~~2017-08-26~~	GARRISON, et al.	
	76	20170252536	A1	2017-09-07	YANG, et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.R.T/

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Fort Lauderdale, FL 33301

EXAMINER	
TYSON, MELANIE RUANO	

ART UNIT	PAPER NUMBER
3771	

MAIL DATE	DELIVERY MODE
11/26/2019	PAPER

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.

PTOL-90A (Rev. 04/07)

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Application No. : 16516232
Applicant : Deville
Filing Date : 07/18/2019
Date Mailed : 11/26/2019

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED.

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Shirley Winslow/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 16516232 **Drawings filed: 07/18/2019**

IDENTIFICATION OF DRAWING DEFICIENCIES

- [ ] There is a hole or the image thereof within the illustration. FIG(s)
- [ ] The illustration is penetrated or traversed by a solid or broken line that is not intended to be part of the drawing, such as a dark line caused by a flaw in the copying process. FIG(s)
- [ ] An ink stamp or the image thereof obscures part of the illustration. FIG(s)
- [ ] The drawing is marred by black smudges, obliterations, or fax/copier marks (for example, speckles or dots in a substantial portion of the drawing). FIG(s)
- [ ] Figure numbers are duplicated or missing. FIG(s)
- [ ] Drawing sheet or figure is missing. FIG(s)
- [ ] Numbers, letters, or reference characters in the drawing have been crossed out or are illegibly handwritten. FIG(s)
- [ ] The character of the lines, numbers, and letters is poor. FIG(s)
- [X] The drawing's background shows that the original drawing was made on graph paper or other paper with a pattern or decoration. FIG(s) 42-46
- [ ] The FIG. number label is placed in a location that causes the drawing to be read upside down. FIG(s)
- [X] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s) 35, 51 & 54
- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
- [ ] This utility application contains a photograph of a view that is capable of being illustrated as a line drawing. FIG(s)
- [ ] A petition under 37 CFR 1.84(a)(2) to accept color drawings has been granted, but the brief description of the drawings in the specification does not contain (or has not been amended to contain) the paragraph required by 37 CFR 1.84(a)(2)(iii).
- [ ] This reissue application contains added and/or amended drawings that are not labeled as “New” or “Amended” or “Canceled” as required by 37 CFR 1.173(b)(3). FIG(s)
- [ ] This Design reissue application contains a drawing that is labeled as “Canceled” but is not surrounded by brackets, or a drawing that is surrounded by brackets but is not labeled as “Canceled.” See 37 CFR 1.173(b)(3). FIG(s)
- [ ] OTHER:
- [ ] COMMENTS:

PATENT

CERTIFICATE OF ELECTRONIC TRANSMISSION

I hereby certify that this correspondence is being electronically transmitted to the U.S. Patent and Trademark Office via EFS-Web on the date indicated below.

Signature: /Chris Mendez/ Date: 12/10/2019

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	16/516,232	Confirmation No.: 6733
Applicant	:	Syntheon 2.0, LLC	
Inventor	:	Derek Dee Deville, et al.	
Filed	:	July 18, 2019	
Title	:	ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER	
TC/A.U.	:	3771	
Examiner	:	Melanie Ruano Tyson	
Docket No.	:	Syn2.0/Roar	
Customer No.	:	27316	

VIA ELECTRONIC FILING
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Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

Dear Commissioner:

Applicant is in receipt of the Notice to File Corrected Application Papers (hereinafter "Notice") issued on November 26, 2019. In response to the Notice, Applicant hereby submits the following items to the U.S. Patent & Trademark Office, which are in compliance with 37 CFR §1.121:

- Replacement Sheets for amended FIGS. 42 through 46; and

- Replacement Sheets for amended FIGS. 35, 49 to 51, and 54.

As required in the Notice, Applicant removed the pattern on FIGS. 42 through 46. Applicant also amended FIGS. 35, 49 to 51, and 54. In particular, the S-curve lines, which were present in FIG. 35 to indicate that the dashed-line conduits have been theoretically cut, have been removed. The labels "FIG. 49", "FIG. 50", and "FIG. 51" have been removed from inside the plot lines to outside. Finally, the three reference arrows in FIG. 54 have been lengthened.

Applicant respectfully submits that no new matter is introduced by virtue of these amendments and that the objections set forth in the Notice have been duly and completely addressed.

Lastly, the U.S. Patent & Trademark Office is hereby given authority to charge Deposit Account No. 04-1061, for any fees due or any deficiencies of payments made for any purpose during the pendency of the present application.

Respectfully submitted,

Date: December 10, 2019 By: _____

Gregory L. Mayback, Esq.
USPTO Reg. No. 40,719
Rebecca A. Tie, Esq.
USPTO Reg. No. 62,095

Attorneys for Applicant

Dickinson Wright PLLC
350 East Las Olas Blvd., Suite 1750
Ft. Lauderdale, FL 33301
Office: 954.991.5420
Fax: 844.670.6009

Penumbra, Inc., Ex. 1029, Page 7 of 728
Penumbra, Inc. v. RapidPulse, Inc.

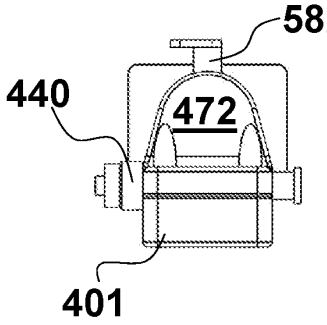


FIG. 37

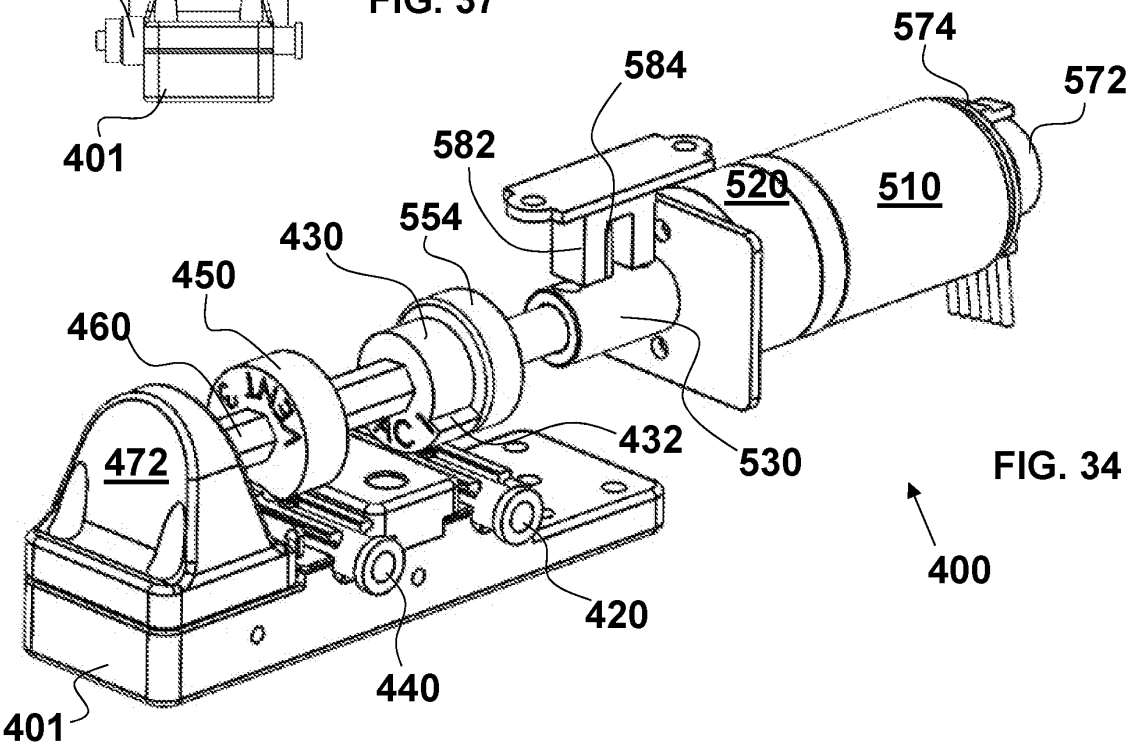


FIG. 34

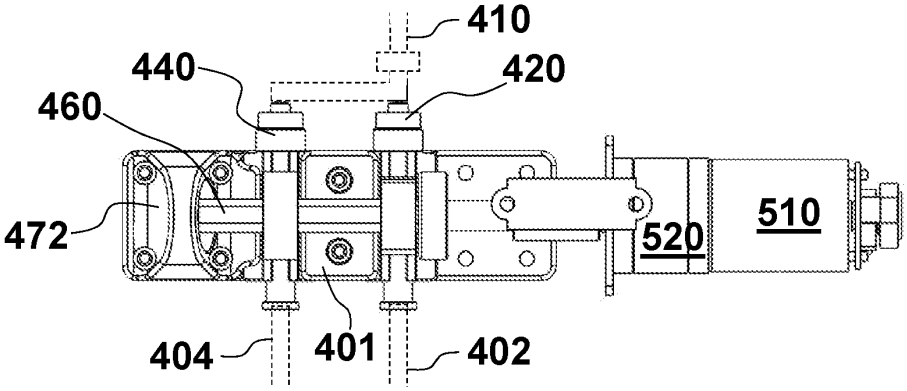


FIG. 35

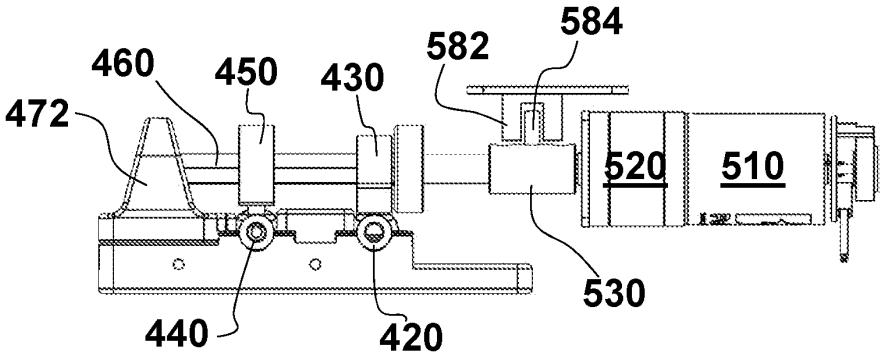


FIG. 36

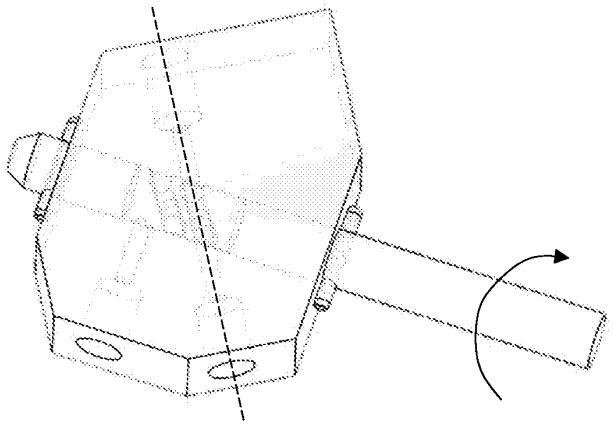


FIG. 42

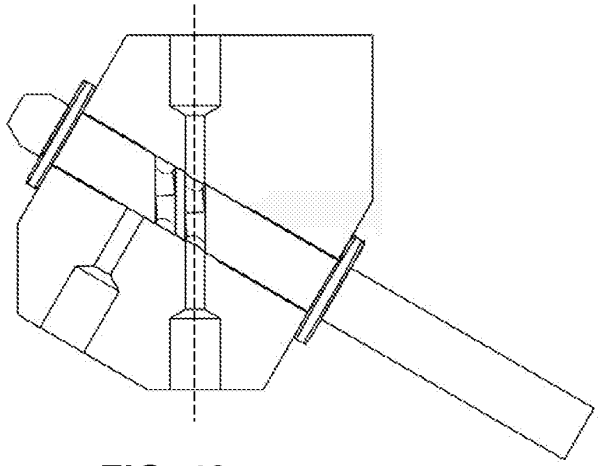


FIG. 43

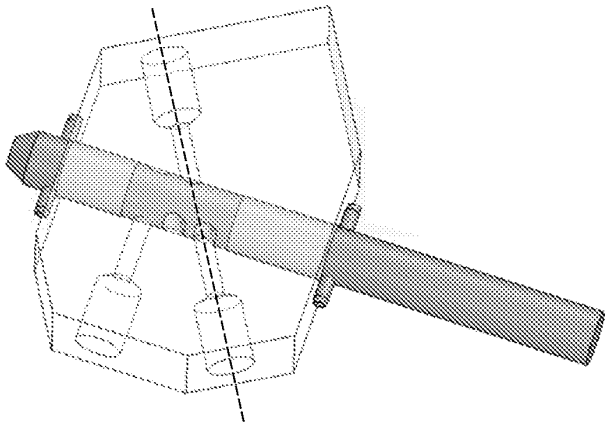


FIG. 44

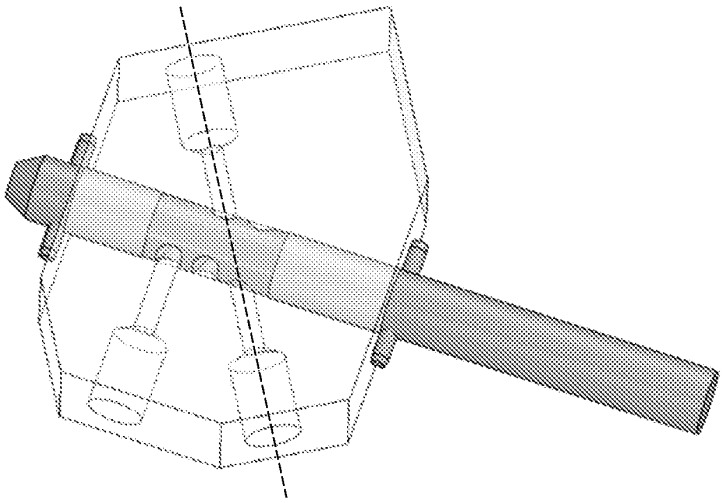


FIG. 45

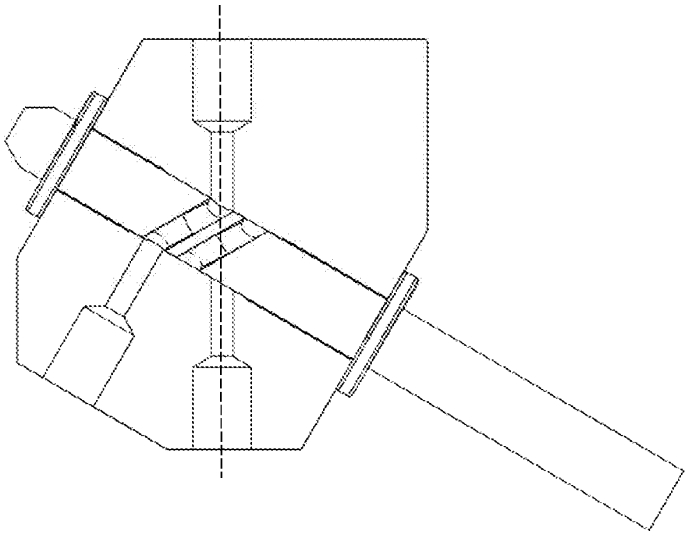


FIG. 46


4
5
8
9
1
3
7
6
1
2
Vac Position (Analog)
Vent Position (Analog)

FIG. 49

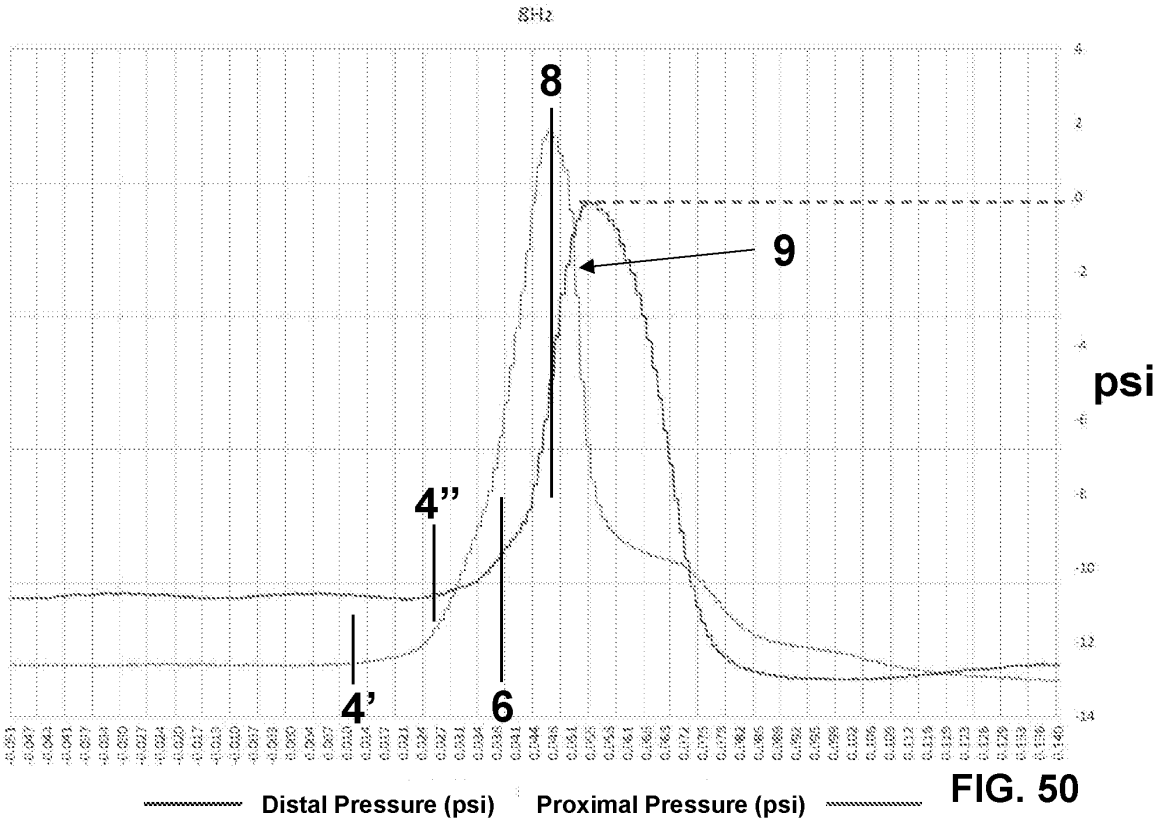

8
9
psi
4”
4’
6
Distal Pressure (psi)
Proximal Pressure (psi)

FIG. 50

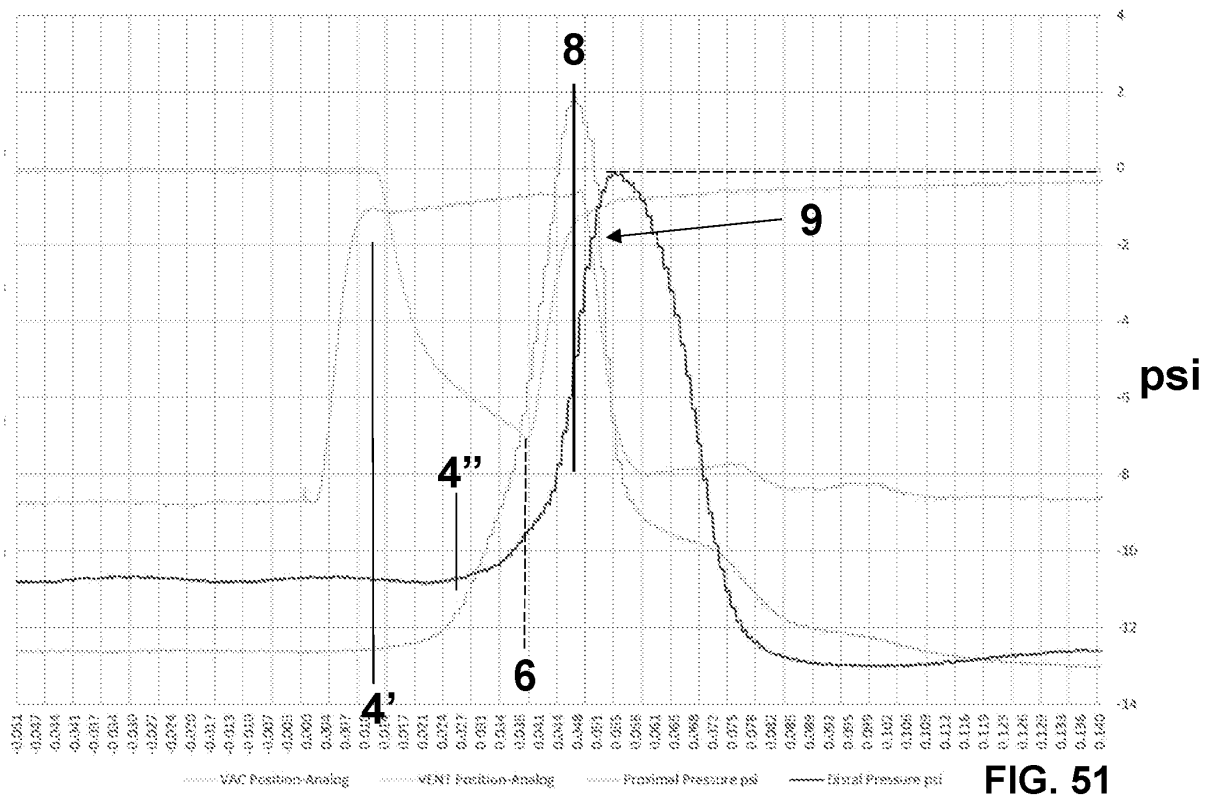

8
9
4”
4’
6
psi
VAC Position-Analog
VENT Position-Analog
Proximal Pressure psi
Distal Pressure psi

FIG. 51

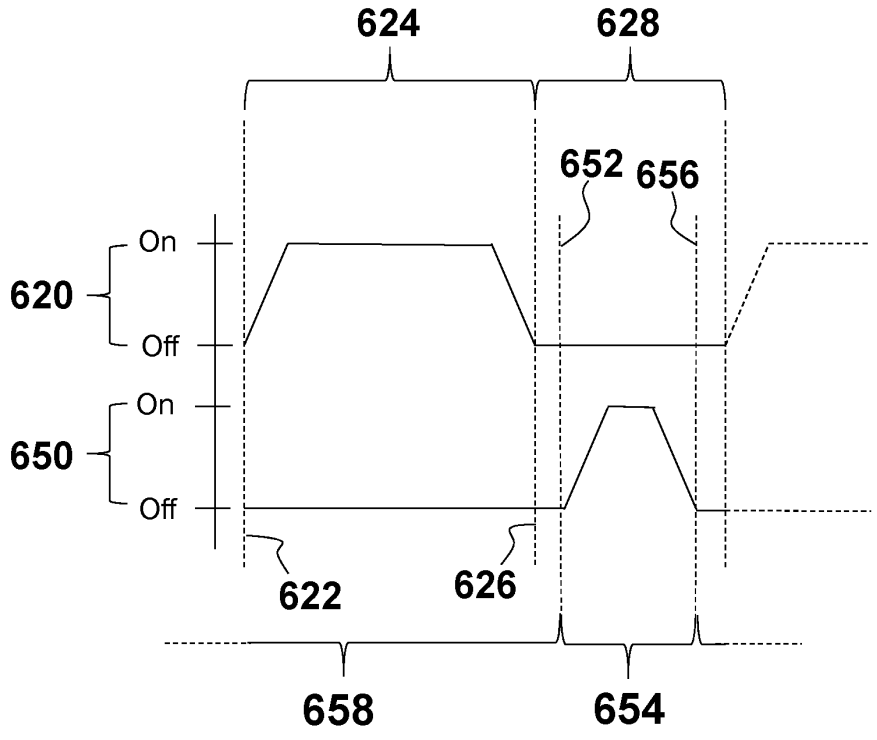

624
628
652
656
On
620
Off
On
650
Off
622
626
658
654

FIG. 52

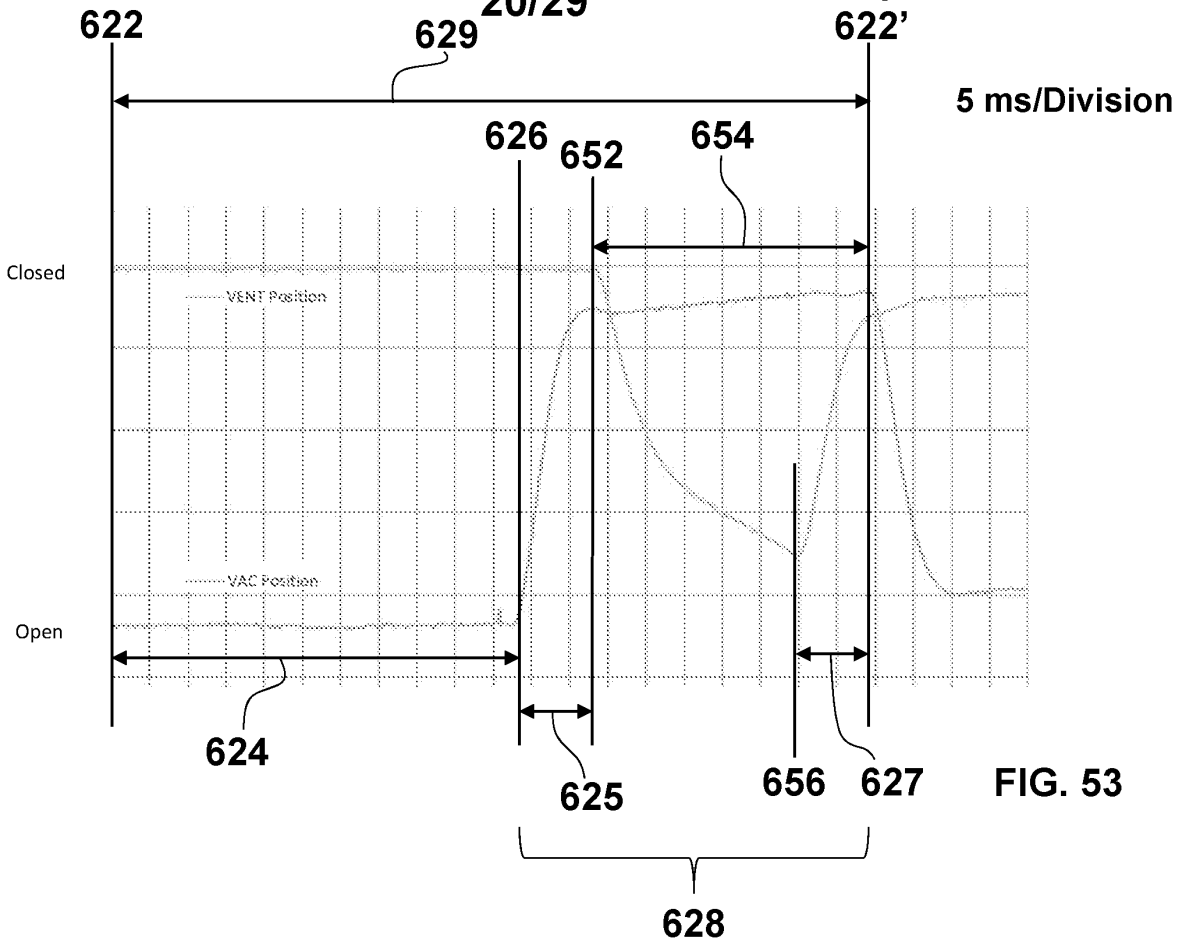

622
629
622'
5 ms/Division
626
652
654
Closed
VENT Position
VAC Position
Open
624
625
656
627
628

FIG. 53

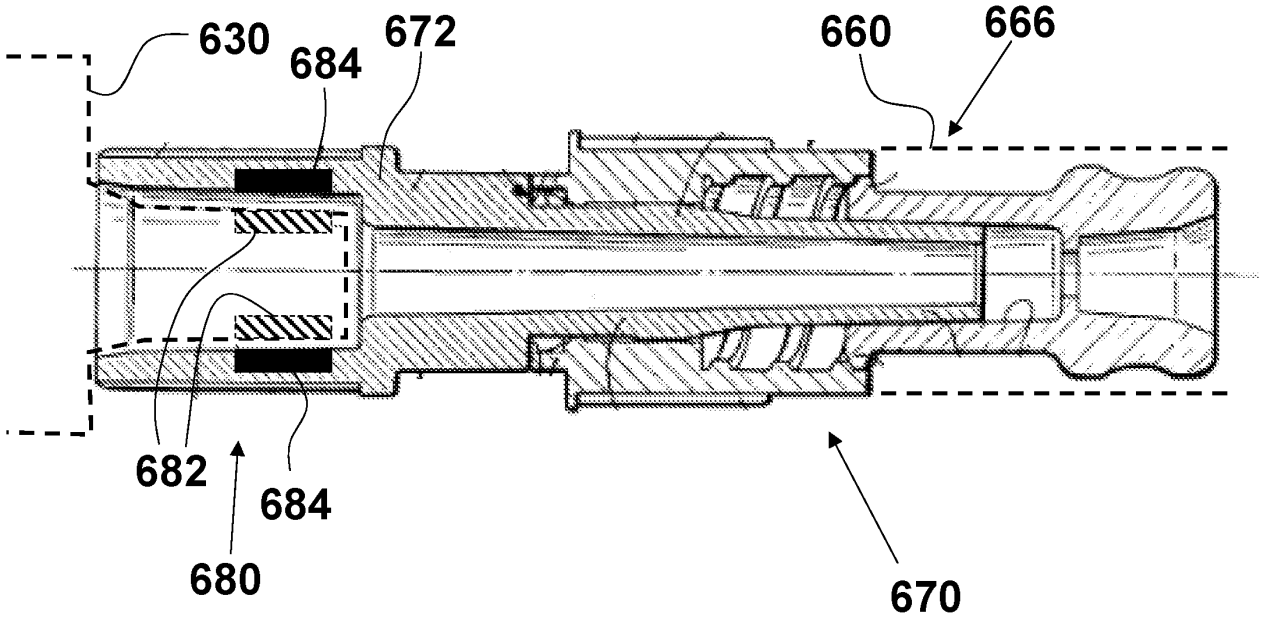

630
684
672
660
666
682
684
680
670

FIG. 54

Electronic Acknowledgement Receipt

EFS ID:	37982338
Application Number:	16516232
International Application Number:	
Confirmation Number:	6733
Title of Invention:	ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER
First Named Inventor/Applicant Name:	Derek Dee Deville
Customer Number:	27316
Filer:	Gregory L. Mayback/Chris Mendez
Filer Authorized By:	Gregory L. Mayback
Attorney Docket Number:	Syn2.0/ROAR
Receipt Date:	10-DEC-2019
Filing Date:	18-JUL-2019
Time Stamp:	12:56:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	2019-12-10_Roar_Notice_Corrected_App_Paper_PTO.PDF	114357 90f41bd1bffcfe84ad7ee18f0d360c7d9907f288	no	3

Warnings:

Information:					
2	Transmittal Letter	2019-12-10_Roar_Response_to_Not_Correct_App.pdf	105135 c1e38699e5e08caf7b7c4e2c0c683b336e5b7319	no	2
Warnings:					
Information:					
3	Drawings-only black and white line drawings	2019-12-10_ROAR_AMD_drawings.pdf	1109262 f3fd9f32b1eeaa4e53efe3b3db53eca156911dee	no	6
Warnings:					
Information:					
		Total Files Size (in bytes):	1328754		

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 a 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.

DocCode – SCORE

SCORE Placeholder Sheet for IFW Content

Application Number: 16516232 Document Date: 12/10/2019

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

Since this was an electronic submission, there is no physical artifact folder, no artifact folder is recorded in PALM, and no paper documents or physical media exist. The TIFF images in the IFW record were created from the original documents that are stored in SCORE.

- Drawing

At the time of document entry (noted above):

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- External customers may access SCORE content via PAIR using the Supplemental Content tab.

Form Revision Date: March 1, 2019

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Fort Lauderdale, FL 33301

EXAMINER	
TYSON, MELANIE RUANO	

ART UNIT	PAPER NUMBER
3771	

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PTOL-90A (Rev. 04/07)

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See attachment(s).

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/Shirley Winslow/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 16516232 **Drawings filed: 07/18/2019**

IDENTIFICATION OF DRAWING DEFICIENCIES

- [ ] There is a hole or the image thereof within the illustration. FIG(s)
- [ ] The illustration is penetrated or traversed by a solid or broken line that is not intended to be part of the drawing, such as a dark line caused by a flaw in the copying process. FIG(s)
- [ ] An ink stamp or the image thereof obscures part of the illustration. FIG(s)
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- [ ] Figure numbers are duplicated or missing. FIG(s)
- [ ] Drawing sheet or figure is missing. FIG(s)
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- [ ] The character of the lines, numbers, and letters is poor. FIG(s)
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- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
- [ ] This utility application contains a photograph of a view that is capable of being illustrated as a line drawing. FIG(s)
- [ ] A petition under 37 CFR 1.84(a)(2) to accept color drawings has been granted, but the brief description of the drawings in the specification does not contain (or has not been amended to contain) the paragraph required by 37 CFR 1.84(a)(2)(iii).
- [ ] This reissue application contains added and/or amended drawings that are not labeled as “New” or “Amended” or “Canceled” as required by 37 CFR 1.173(b)(3). FIG(s)
- [ ] This Design reissue application contains a drawing that is labeled as “Canceled” but is not surrounded by brackets, or a drawing that is surrounded by brackets but is not labeled as “Canceled.” See 37 CFR 1.173(b)(3). FIG(s)
- [ ] OTHER:
- [ ] COMMENTS:

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27316 7590 11/21/2019

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Fort Lauderdale, FL 33301

EXAMINER	
TYSON, MELANIE RUANO	

ART UNIT	PAPER NUMBER
3771	

MAIL DATE	DELIVERY MODE
11/21/2019	PAPER

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.

Supplemental ***Notice of Allowability***	**Application No.** 16/516,232	**Applicant(s)** Deville et al.	
	Examiner MELANIE R TYSON	**Art Unit** 3771	**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 the IDS filed 26 September 2019.
   ☐ 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 1-18 . 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 _____.

/MELANIE R TYSON/
Primary Examiner, Art Unit 3771

SUPPLEMENTAL EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. The amendment addresses a typographical errors in claims 10 and 11. 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.

The application has been amended as follows:

Claim 10 (line 2): "is greater than approximately 15 inHg [[in]] and no greater than approximately 50 ms.

Claim 11 (line 2): "is greater than approximately 20 inHg and no greater than approximately 30 ms[[; and]].

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."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE R TYSON whose telephone number is (571)272-9062. The examiner can normally be reached on M-Th 5:30 AM - 3:30 PM (ET).

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, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MELANIE R TYSON/
Primary Examiner, Art Unit 3771
November 20, 2019

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-15)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16516232
Filing Date	2019-07-18
First Named Inventor	Derek Dee Deville
Art Unit	3771
Examiner Name	Melanie Ruano Tyson
Attorney Docket Number	Syn2.0/ROAR

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EXAMINER SIGNATURE

Examiner Signature	/MELANIE R TYSON/	Date Considered	11/20/2019

*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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	Art Unit	3771
	Examiner Name	Melanie Ruano Tyson
	Attorney Docket Number	Syn2.0/ROAR

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.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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	/Gregory L. Mayback/	Date (YYYY-MM-DD)	2019-09-26
Name/Print	Gregory L. Mayback	Registration Number	40719

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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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.

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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.

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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 inspections 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.

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Penumbra, Inc., Ex. 1029, Page 31 of 728
Penumbra, Inc. v. RapidPulse, Inc.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
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	1	6261283	B1	2001-07-17	MORGAN, et al.	
	2	6423028	B1	2002-07-23	GONON	
	3	8617106	B2	2013-12-31	ZACHARIAS	

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	Application Number	16516232
	Filing Date	2019-07-18
	First Named Inventor	Derek Dee Deville
	Art Unit	3771
	Examiner Name	Melanie Ruano Tyson
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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).

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The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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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	/Gregory L. Mayback/	Date (YYYY-MM-DD)	2019-09-26
Name/Print	Gregory L. Mayback	Registration Number	40719

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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Penumbra, Inc., Ex. 1029, Page 36 of 728
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Doc description: Information Disclosure Statement (IDS) Filed

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Attorney Docket Number	Syn2.0/ROAR

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	53	20160166265	A1	2016-06-21	NITA	
	54	20160220741	A1	2016-08-04	GARRISON, et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.R.T/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	16516232
Filing Date	2019-07-18
First Named Inventor	Derek Dee Deville
Art Unit	3771
Examiner Name	Melanie Ruano Tyson
Attorney Docket Number	Syn2.0/ROAR

	55	20160220807	A1	2016-08-04	BONO, et al.	
	56	20160278895	A1	2016-09-29	CALUORI	
	57	20170027730	A1	2017-02-02	KASSAB, et al.	
	58	20170095259	A1	2017-04-06	TOMPKINS, et al.	
	59	20170105743	A1	2017-04-20	VALE, et al.	
	60	20170120039	A1	2017-05-04	CHILDS, et al.	
	61	20170135700	A1	2017-05-18	ROGOWSKI, et al.	
	62	20170136209	A1	2017-05-18	BURNETT, et al.	
	63	20170143938	A1	2017-05-25	OGLE, et al.	
	64	20170147765	A1	2017-05-25	MEHTA	
	65	20170151032	A1	2017-06-01	LOISEL	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.R.T/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	16516232
Filing Date	2019-07-18
First Named Inventor	Derek Dee Deville
Art Unit	3771
Examiner Name	Melanie Ruano Tyson
Attorney Docket Number	Syn2.0/ROAR

	66	20170169374	A1	2017-06-15	HARRIS, et al.	
	67	20170172581	A1	2017-06-22	BOSE, et al.	
	68	20170215902	A1	2017-08-03	LEYNOV, et al.	
	69	20170238950	A1	2017-08-24	YANG, et al.	
	70	20170238951	A1	2017-08-24	YANG, et al.	
	71	20170238953	A1	2017-08-24	YANG, et al.	
	72	20170239440	A1	2017-08-24	YANG, et al.	
	73	20170239441	A1	2017-08-24	YANG, et al.	
	74	20170239447	A1	2017-08-24	YANG, et al.	
	75	20100217276	A1	2017-08-26	GARRISON, et al.	
	76	20170252536	A1	2017-09-07	YANG, et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.R.T/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	16516232
Filing Date	2019-07-18
First Named Inventor	Derek Dee Deville
Art Unit	3771
Examiner Name	Melanie Ruano Tyson
Attorney Docket Number	Syn2.0/ROAR

	77	20170296195	A1	2017-10-19	PLEIL, et al.	
	78	20170333170	A1	2017-11-23	CALUORI	
	79	20170340797	A1	2017-11-30	RAMAN, et al.	
	80	20170354777	A1	2017-12-14	OFEK, et al.	
	81	20170360450	A1	2017-12-21	TOMPKINS, et al.	
	82	20170367857	A1	2017-12-28	BENNETT, et al.	
	83	20180042623	A1	2018-02-15	BATISTE	
	84	20180064578	A1	2018-03-08	CLAUSON, et al.	
	85	20180132857	A1	2018-05-17	FAGO, et al.	
	86	20180154063	A1	2018-06-07	CRIADO, et al.	
	87	20180193042	A1	2018-07-12	WILSON, et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.R.T/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	16516232
Filing Date	2019-07-18
First Named Inventor	Derek Dee Deville
Art Unit	3771
Examiner Name	Melanie Ruano Tyson
Attorney Docket Number	Syn2.0/ROAR

	88	20180197633	A1	2018-07-12	MEHTA	
	89	20180199944	A1	2018-07-19	HUGHETT, SR., et al.	
	90	20180221029	A1	2018-08-09	MENN	
	91	20180228502	A1	2018-08-16	SHAFFER, et al.	
	92	20180242989	A1	2018-08-30	NITA	
	93	20180263642	A1	2018-09-20	NITA	
	94	20180263646	A1	2018-09-20	LOISEL	
	95	20180271686	A1	2018-09-27	KASSAB, et al.	
	96	20180317922	A1	2018-11-08	WINKLER, et al.	
	97	20180353194	A1	2018-12-13	SHAFFER, et al.	
	98	20190142452	A1	2019-05-16	TROSPER, et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.R.T/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16516232
	Filing Date	2019-07-18
	First Named Inventor	Derek Dee Deville
	Art Unit	3771
	Examiner Name	Melanie Ruano Tyson
	Attorney Docket Number	Syn2.0/ROAR

	99	20190175184	A1	2019-06-12	HUI, et al.	
	100	20190216476	A1	2019-07-18	BARRY, et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	101027004	CN	A	2007-08-29	Penumbra, Inc.		
	2	1799128	EP	B1	2010-03-10	Penumbra, Inc.		
	3	2013184595	WO	A1	2013-12-12	Penumbra, Inc.		
	4	2014151209	WO	A1	2014-09-25	Virginia Commonwealth Univerisity		
	5	2017147493	WO	A1	2017-08-31	Incept, LLC		
	6	2018019829	WO	A1	2018-02-01	Neuravi Limited		
	7	2019115809	WO	A1	2019-06-20	Perfuze Limited		

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16516232
	Filing Date	2019-07-18
	First Named Inventor	Derek Dee Deville
	Art Unit	3771
	Examiner Name	Melanie Ruano Tyson
	Attorney Docket Number	Syn2.0/ROAR

NON-PATENT LITERATURE DOCUMENTS			Remove
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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/MELANIE R TYSON/	Date Considered	11/20/2019

*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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.R.T/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16516232
	Filing Date	2019-07-18
	First Named Inventor	Derek Dee Deville
	Art Unit	3771
	Examiner Name	Melanie Ruano Tyson
	Attorney Docket Number	Syn2.0/ROAR

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.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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	/Gregory L. Mayback/	Date (YYYY-MM-DD)	2019-09-26
Name/Print	Gregory L. Mayback	Registration Number	40719

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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.R.T/

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 the Freedom of Information Act requires disclosure of these record s.

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 inspections 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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.R.T/

Penumbra, Inc., Ex. 1029, Page 56 of 728
Penumbra, Inc. v. RapidPulse, Inc.

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)

27316 7590 09/30/2019
Mayback & Hoffman, P.A.
350 East Las Olas Blvd
Suite 1750
Fort Lauderdale, FL 33301

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.

Chris Mendez	(Typed or printed name)
/Chris Mendez/	(Signature)
11/13/2019	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/516,232	07/18/2019	Derek Dee Deville	Syn2.0/ROAR	6733

TITLE OF INVENTION: ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$500	$0.00	$0.00	$500	12/30/2019

EXAMINER	ART UNIT	CLASS-SUBCLASS
TYSON, MELANIE RUANO	3771	606-127000

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 Gregory L. Mayback
2 Dickinson Wright PLLC
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: SYNTHEON 2.0, LLC

(B) RESIDENCE: (CITY and STATE OR COUNTRY): MIAMI, FL USA

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. 04-1061

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 /Gregory L. Mayback/ Date November 13, 2019

Typed or printed name Gregory L. Mayback Registration No. 40719

Penumbra, Inc., Ex. 1029, Page 57 of 728
Penumbra, Inc. v. RapidPulse, Inc.

Electronic Patent Application Fee Transmittal

Application Number:	16516232
Filing Date:	18-Jul-2019
Title of Invention:	ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER
First Named Inventor/Applicant Name:	Derek Dee Deville
Filer:	Gregory L. Mayback/Chris Mendez
Attorney Docket Number:	Syn2.0/ROAR

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	2501	1	500	500

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**500**

Electronic Acknowledgement Receipt	
EFS ID:	37740087
Application Number:	16516232
International Application Number:	
Confirmation Number:	6733
Title of Invention:	ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER
First Named Inventor/Applicant Name:	Derek Dee Deville
Customer Number:	27316
Filer:	Gregory L. Mayback/Chris Mendez
Filer Authorized By:	Gregory L. Mayback
Attorney Docket Number:	Syn2.0/ROAR
Receipt Date:	13-NOV-2019
Filing Date:	18-JUL-2019
Time Stamp:	14:33:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$500
RAM confirmation Number	E2019ACE33492975
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	2019-11-13_Syn_Roar_Issue_Fee_Transmital_86082-9.pdf	90198 1e4a8b9aef7502a7ea76408d2ecb9dd032925e73	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30809 c7c437c715bca63b6a2fa56cfed14698eaf74797	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	121007		

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 a 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
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Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

27316 7590 09/30/2019

Mayback & Hoffman, P.A.
350 East Las Olas Blvd
Suite 1750
Fort Lauderdale, FL 33301

EXAMINER
TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
3771	

DATE MAILED: 09/30/2019

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/516,232	07/18/2019	Derek Dee Deville	Syn2.0/ROAR	6733

TITLE OF INVENTION: ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$500	$0.00	$0.00	$500	12/30/2019

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 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity 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 and an extra copy of the form should be submitted. 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.

Penumbra, Inc., Ex. 1029, Page 62 of 728
Penumbra, Inc. v. RapidPulse, Inc.

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)

27316 7590 09/30/2019

Mayback & Hoffman, P.A.
350 East Las Olas Blvd
Suite 1750
Fort Lauderdale, FL 33301

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.

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/516,232	07/18/2019	Derek Dee Deville	Syn2.0/ROAR	6733

TITLE OF INVENTION: ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$500	$0.00	$0.00	$500	12/30/2019

EXAMINER	ART UNIT	CLASS-SUBCLASS
TYSON, MELANIE RUANO	3771	606-127000

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_____
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. _____

Penumbra, Inc., Ex. 1029, Page 63 of 728
Penumbra, Inc. v. RapidPulse, Inc.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/516,232	07/18/2019	Derek Dee Deville	Syn2.0/ROAR	6733

27316 7590 09/30/2019

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350 East Las Olas Blvd
Suite 1750
Fort Lauderdale, FL 33301

EXAMINER	
TYSON, MELANIE RUANO	
ART UNIT	PAPER NUMBER
3771	

DATE MAILED: 09/30/2019

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.

PTOL-85 (Rev. 02/11)

Penumbra, Inc., Ex. 1029, Page 64 of 728
Penumbra, Inc. v. RapidPulse, Inc.

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. 16/516,232	Applicant(s) Deville et al.	
	Examiner MELANIE R TYSON	Art Unit 3771	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 the interview conducted 26 September 2019.
   ☐ 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 1-18 . 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. 20190913.
5. ☑ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/MELANIE R TYSON/
Primary Examiner, Art Unit 3771

Penumbra, Inc., Ex. 1029, Page 66 of 728
Penumbra, Inc. v. RapidPulse, Inc.

EXAMINER'S AMENDMENT

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.

Authorization for this examiner's amendment was given in an interview with Gregory Mayback on 26 September 2019.

The application has been amended as follows:

Claims 19 and 20: canceled

EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE

Claims 1-18 are allowed. The following is an examiner's statement of reasons for allowance:

Regarding claims 1-17, the prior art fails to disclose or suggest, in combination with other limitations recited in the claims, a manifold connected to the catheter, to the vacuum valve, and to the vent valve, the manifold fluidically connecting the proximal portion of the liquid column in the lumen to the vacuum source through the vacuum valve and to the vent fluid source through the vent valve, and a controller connected to the vacuum valve and the vent valve and configured to selectively open and close the vacuum valve and the vent valve such that response to opening the vacuum valve, the vacuum source is fluidically connected to the liquid column in the lumen, and responsive to opening the vent valve, the vent fluid source is fluidically connected to the liquid column in the lumen.

Regarding claim 18, the prior art fails to disclose or suggest, in combination with other limitations recited in the claims, a manifold connected to the catheter, to the vacuum valve, and to the vent valve, the manifold fluidically connecting the proximal portion of the liquid column in the lumen to the vacuum source through the vacuum valve and to the vent fluid source through the vent valve, and a controller connected to the vacuum valve and the vent valve and configured to selectively open and close the vacuum valve and the vent valve such that response to opening the vacuum valve, the vacuum source is fluidically connected to the liquid column in the lumen, and responsive to opening the vent valve, the vent fluid source is fluidically connected to the liquid column in the lumen, the controller configured to cyclically open and close the vacuum valve and the vent valve in a repeated cycle comprising a double-closed state in which the vacuum valve is closed and the vent valve is closed to prevent forward flow of the distal portion out from the distal end during each cycle, and a time of the double-closed state is no greater than approximately 30 ms.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Garrison et al. (US Pub. No. 2016/0220741) discloses a clot removal system comprising a catheter (220), a vacuum source (aspiration source that connects to 232; for example, see paragraphs 60-62), a vent liquid source (contrast or saline), and a vacuum and vent control system (for example, see paragraphs 114-118). Garrison fails to disclose the combination of features described in the reasons for allowance above.

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."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE R TYSON whose telephone number is (571)272-9062. The examiner can normally be reached on M-Th 5:30 am - 3:30 pm (IFP).

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, Darwin Erezo can be reached on 571-272-4695. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MELANIE R TYSON/
Primary Examiner, Art Unit 3771
September 26, 2019

Examiner-Initiated Interview Summary	Application No. 16/516,232	Applicant(s) Deville et al.	
	Examiner MELANIE R TYSON	Art Unit 3771	AIA (FITF) Status Yes

All participants (applicant, applicant's representative, PTO personnel):

(1) Melanie Tyson.

(3) Derek Deville.

(2) Gregory Mayback.

(4) _____.

Date of Interview: 26 September 2019.

Type: ☑ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☑ No.
If Yes, brief description: _____.

Issues Discussed ☐ 101 ☑ 112 ☑ 102 ☐ 103 ☐ Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 19-20.

Identification of prior art discussed: Garrison et al.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Discussion was held regarding 112 issues in claims 19 and 20 and paragraphs in Garrison et al. that were pertinent to original claims 19 and 20. Applicant agreed to cancel claims 19 and 20 in order to place the application in immediate condition for allowance..

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.

☐ Attachment

/MELANIE R TYSON/ Primary Examiner, Art Unit 3771	

Notice of References Cited	Application/Control No. 16/516,232	Applicant(s)/Patent Under Reexamination Deville et al.	
	Examiner MELANIE R TYSON	Art Unit 3771	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-20160220741-A1	08-2016	Garrison; Michi E.	A61M1/008	1/1
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/516,232	Deville et al.
	Examiner	**Art Unit**
	MELANIE R TYSON	3771

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61B 17/3207, 22	09/17/2019	MT
A61B2017/00022, 22079, 22082	09/17/2019	MT
A61F 2/013	09/17/2019	MT
A61F 2002/011	09/17/2019	MT
A61M 25/0075	09/17/2019	MT

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**
Text search printout is attached.	09/17/2019	MT
Inventor search performed.	09/17/2019	MT
Forward and backward citation search of relevant prior art.	09/17/2019	MT

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
All	PGPUB text search; see attached interference search printout.	09/26/2019	MT

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Penumbra, Inc. v. RapidPulse, Inc.

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/516,232	Deville et al.
	Examiner	**Art Unit**
	MELANIE R TYSON	3771

CPC							
Symbol						**Type**	**Version**
A61B	/	17	/	22		F	2013-01-01
A61M	/	25	/	0075		I	2013-01-01
A61F	/	2	/	013		I	2013-01-01
A61F	/	2002	/	011		A	2013-01-01
A61B	/	2217	/	007		A	2013-01-01
A61B	/	2017	/	00022		A	2013-01-01
A61B	/	2017	/	22082		A	2013-01-01
A61B	/	2017	/	22079		A	2013-01-01

CPC Combination Sets								
Symbol						**Type**	**Set**	**Ranking**	**Version**
	/		/						

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	18	
/MELANIE R TYSON/ Primary Examiner, Art Unit 3771	26 September 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	47

U.S. Patent and Trademark Office — Part of Paper No.: 20190913

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Penumbra, Inc. v. RapidPulse, Inc.

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/516,232	Deville et al.
	Examiner	**Art Unit**
	MELANIE R TYSON	3771

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61B	/	17	/	22

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
606	127

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

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	18	
/MELANIE R TYSON/ Primary Examiner, Art Unit 3771	26 September 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	47

U.S. Patent and Trademark Office — Part of Paper No.: 20190913

Penumbra, Inc., Ex. 1029, Page 75 of 728
Penumbra, Inc. v. RapidPulse, Inc.

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/516,232	Deville et al.
	Examiner	**Art Unit**
	MELANIE R TYSON	3771

☑ 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	1	10	10												
2	2	11	11												
3	3	12	12												
4	4	13	13												
5	5	14	14												
6	6	15	15												
7	7	16	16												
8	8	17	17												
9	9	18	18												

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	18	
/MELANIE R TYSON/ Primary Examiner, Art Unit 3771	26 September 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	47

U.S. Patent and Trademark Office — Part of Paper No.: 20190913

Penumbra, Inc., Ex. 1029, Page 76 of 728
Penumbra, Inc. v. RapidPulse, Inc.

Bibliographic Data

Application No: 16/516,232

Foreign Priority claimed: ○ Yes ◉ No

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

Verified and Acknowledged: /MELANIE R TYSON/ (Examiner's Signature) | (Initials)

Title: ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
07/18/2019	606	3771	Syn2.0/ROAR
RULE			

APPLICANTS

Syntheon 2.0, LLC, Miami, FL, UNITED STATES

INVENTORS

Derek Dee Deville Coral Gables, FL, UNITED STATES

Matthew A. Palmer Miami, FL, UNITED STATES

William T. Bales JR., Miami, FL, UNITED STATES

M. Sean McBrayer Coral Gables, FL, UNITED STATES

Eric Petersen Homestead, FL, UNITED STATES

Richard Cartledge Boca Raton, FL, UNITED STATES

CONTINUING DATA

This application has PRO of 62750011 10/24/2018

This application has PRO of 62701086 07/20/2018

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

07/31/2019

**** SMALL ENTITY ****

STATE OR COUNTRY

UNITED STATES

ADDRESS

Mayback & Hoffman, P.A.
350 East Las Olas Blvd
Suite 1750
Fort Lauderdale, FL 33301
UNITED STATES

FILING FEE RECEIVED

$3,085

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	29984	A61B17/22,3207.cpc. or A61B2017/00022,22079,22082.CPC. or A61F2/013.CPC. or A61F2002/011.CPC. or A61M25/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/09/17 09:53
S2	90878	catheter with (liquid or fluid)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/09/17 09:55
S3	125020	vent with (liquid or fluid)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/09/17 09:56
S4	568130	(control or controller) with (cycle or cyclically)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/09/17 09:57
S5	1	vacuum and S1 and S2 and S3 and S4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/09/17 09:58
S6	31	S2 same vacuum same S4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/09/17 10:20
S7	0	S1 and S6	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/09/17 10:20
S8	3753	S2 same vacuum	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/09/17 10:21
S9	277	S8 and S4	US-PGPUB; USPAT;	OR	OFF	2019/09/17 10:21

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			USOCR; FPRS; EPO; JPO; DERWENT			
S10	14	S1 and S9	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/09/17 10:21
S11	3609253	vacuum	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/09/17 10:28
S12	0	S1 and (S3 same S4 same S11)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/09/17 10:29
S13	38947	vent adj valve	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/09/17 10:49
S14	26928	vacuum adj valve	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/09/17 10:49
S17	0	S13 and S14 and S1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/09/17 10:50
S18	1621213	valves	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/09/17 10:50
S19	135	S1 and (S11 same S18)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/09/17 10:52

9/17/2019 3:53:20 PM
C:\Users\mtyson1\Documents\EAST\Workspaces\16516232.wsp

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1213	catheter.clm. with liquid.clm.	US-PGPUB	OR	ON	2019/09/26 10:36
L3	217651	valve.clm.	US-PGPUB	OR	ON	2019/09/26 10:37
L4	99813	vacuum.clm.	US-PGPUB	OR	ON	2019/09/26 10:37
L5	34963	vent.clm.	US-PGPUB	OR	ON	2019/09/26 10:37
L6	460988	controller.clm.	US-PGPUB	OR	ON	2019/09/26 10:37
L7	0	1 and 3 and 4 and 5 and 6	US-PGPUB	OR	ON	2019/09/26 10:38

9/ 26/ 2019 10:38:39 AM
C:\ Users\ mtyson1\ Documents\ EAST\ Workspaces\ 16516232.wsp

Penumbra, Inc., Ex. 1029, Page 81 of 728
Penumbra, Inc. v. RapidPulse, Inc.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/516,232	Filing Date 07/18/2019	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) 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 $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $230 =	
☐ 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	09/27/2019	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 $50 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0		x $230 =	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".	/DAWN BREWER/
*** 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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Doc code: IDS
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	16516232
Filing Date	2019-07-18
First Named Inventor	Derek Dee Deville
Art Unit	3771
Examiner Name	Melanie Ruano Tyson
Attorney Docket Number	Syn2.0/ROAR

U.S.PATENTS Remove

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
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	2	4315506		1982-02-16	KAYSER, et al.	
	3	4458877		1984-07-10	HOLMES	
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	8	4911399		1990-03-27	GREEN	

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	Attorney Docket Number	Syn2.0/ROAR

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	21	7178699	B2	2007-02-20	SPRAY, et al.	
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	65	9775621	B2	2017-10-03	TOMPKINS, et al.	
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	68	9901351	B2	2018-02-27	WINKLER, et al.	
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	Attorney Docket Number	Syn2.0/ROAR

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	Application Number	16516232
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	First Named Inventor	Derek Dee Deville
	Art Unit	3771
	Examiner Name	Melanie Ruano Tyson
	Attorney Docket Number	Syn2.0/ROAR

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	Attorney Docket Number	Syn2.0/ROAR

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.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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	/Gregory L. Mayback/	Date (YYYY-MM-DD)	2019-09-26
Name/Print	Gregory L. Mayback	Registration Number	40719

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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Penumbra, Inc. v. RapidPulse, Inc.

[19] 中华人民共和国国家知识产权局

[51] Int. Cl.
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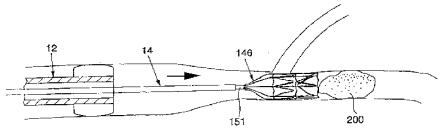
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代理人 丁建春 杨松龄
权利要求书 14 页 说明书 19 页 附图 19 页

[54] 发明名称

用于治疗缺血性中风的系统以及方法

[57] 摘要

一种用于治疗缺血性中风的血栓栓塞去除系统包括导引及阻塞导管、输送及吸取导管、吸取泵、血栓栓塞接收器以及血栓栓塞分离器。



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1. 一种用于从患者的血管去除血栓栓塞材料的系统，所述系统包括：

配设用于输送到血管内的导管，所述导管包括导管腔；

第一延长构件以及位于所述第一延长构件的远端部分的接收器，所述接收器由配置为形成具有中心腔的套筒的多个结构件形成，所述多个结构件包括延伸到所述中心腔内的啮合元件；以及

第二延长构件，其可经所述导管腔延伸并且其上具有分离器元件，所述分离器元件定形为使得所述分离器元件与血管内的血栓栓塞材料主体接触的移动将血栓栓塞材料片从所述主体分离。

2. 根据权利要求 1 所述的系统，其特征在于：进一步包括流体耦接到所述导管腔的吸取源。

3. 根据权利要求 1 所述的系统，其特征在于：所述啮合元件包括延伸到所述接收器的中心腔内的顶点区域。

4. 根据权利要求 3 所述的系统，其特征在于：所述多个结构件包括多个具有纵向定向的顶点的大致 v 形元件，并且其中所述啮合元件包括多个所述 v 形元件。

5. 根据权利要求 1 所述的系统，其特征在于：所述接收器可以从压缩位置径向膨胀到膨胀位置，在所述压缩位置中，所述接收器尺寸限定为在所述导管腔内移动，在所述膨胀位置中所述接收器尺寸限定为在所述血管内的血栓栓塞材料的主体上方推进以便将所述主体接收到所述接收器的中心腔内的，并且其中所述啮合元件定向为啮合所述中心腔内的主体。

6. 根据权利要求 4 所述的系统，其特征在于：所述结构件进一步包括多个隔开的周向环。

7. 根据权利要求 6 所述的系统，其特征在于：所述结构件进一步包括多个在所述周向环之间延伸的纵向支柱。

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8. 根据权利要求 7 所述的系统，其特征在于：各啮合元件定位于所述纵向支柱的相应对之间。

9. 根据权利要求 7 所述的系统，其特征在于：各纵向支柱包括至少一弹簧弯曲。

10. 根据权利要求 6 所述的系统，其特征在于：所述多个周向环包括近端环、远端环以及中间环，并且其中所述 v 形元件包括定位于所述远端环和所述中间环之间的远端 v 形元件列以及定位于所述中间环及所述近端环之间的近端 v 形元件列。

11. 根据权利要求 10 所述的系统，其特征在于：所述啮合元件包括多个处于所述远端列中的 v 形元件。

12. 根据权利要求 2 所述的系统，其特征在于：所述分离器元件包括具有向近端定向的表面的近端部分以及渐缩的远端部分。

13. 根据权利要求 12 所述的系统，其特征在于：所述分离器元件具有从所述向近端定向的部分到所述远端部分延伸的大致锥形轮廓。

14. 根据权利要求 12 所述的系统，其特征在于：所述向近端定向的表面是凹面。

15. 根据权利要求 12 所述的系统，其特征在于：所述向近端定向的表面基本是平面。

16. 根据权利要求 12 所述的系统，其特征在于：所述向近端定向的表面是凸面。

17. 根据权利要求 12 所述的系统，其特征在于：所述延长构件包括挠性远端尖部，并且其中所述分离器元件与所述远端尖部向近端隔开。

18. 根据权利要求 1 所述的系统，其特征在于：进一步包括：

具有配设以接收所述导管的护套管的延长护套；以及

位于所述护套上的阻塞气囊，所述气囊可进行充气以便阻塞血管内的血流。

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19. 根据权利要求 18 所述的系统，其特征在于：进一步包括使用说明，所述说明阐述了使用所述系统的方法，包括一下步骤：

确定血栓栓塞材料的主体的可能性质；

将所述护套定位在要治疗的患者的血管内；

使用所述阻塞气囊阻塞所述血管；

如果确定所述血栓栓塞材料的可能性质是硬的：

将处于压缩位置的所述接收器定位在所述导管内；

经所述护套管腔将所述导管通到所述血管内；

从所述导管延伸所述接收器；

将所述接收器推进到至少部分位于所述血栓栓塞材料的主体上方，使所述主体接收在所述接收器的中心腔内，并且使所述啮合元件啮合所述主体；并且

将所述接收器抽回到所述护套内；

如果确定所述血栓栓塞材料的所述可能性质是软的：

将所述导管经所述护套管腔通到所述血管内并且将所述导管定位在所述血栓栓塞材料的主体附近；

使用所述吸取源，经所述导管腔进行吸取以便将血栓栓塞材料吸入并通过所述导管腔；

在远端方向上从所述导管腔推进所述分离器元件以使所述分离器元件接触所述血栓栓塞材料的主体的一部分；以及

朝所述导管腔抽回所述分离器元件。

20. 一种用于从患者的血管去除血栓栓塞材料的方法，所述方法包括以下步骤：

提供配设用于输送到血管内的导管，所述导管包括导管腔，进一步提供第一延长构件以及位于所述第一延长构件的远端部分上的接收器，所述接收器由配置为形成具有中心腔的套筒的多个结构件形成，所述多个结构件包括延伸到所述中心腔内的啮合元件，并且

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进一步提供可经所述导管腔延伸并且其上具有分离器元件的第二延长构件；

将护套定位在要治疗的患者的血管内，所述护套具有位于其上的阻塞气囊；

使用所述阻塞气囊阻塞所述血管；

确定所述血管内的血栓栓塞材料的可能性质；

如果确定所述血栓栓塞材料的可能性质是硬的：

将处于压缩位置的所述接收器定位所述导管内；

经所述护套将所述导管通到所述血管内；

从所述导管延伸所述接收器；

将所述接收器推进至少部分位于所述血栓栓塞材料的主体上方，使所述主体接收在所述接收器的中心腔内，并且使所述啮合元件啮合所述主体；以及

将所述接收器抽回到所述护套内；

如果确定所述血栓栓塞材料的可能性质是软的：

将所述导管经所述护套管腔通到所述血管内并且将所述导管定位在所述血栓栓塞材料的主体的附近；

使用所述吸取源，经所述导管腔进行吸取以便将血栓栓塞材料吸入并通过所述导管腔；

在远端方向上从所述导管腔推进所述分离器元件以使所述分离器元件接触所述血栓栓塞材料的主体的一部分；以及

朝所述导管腔抽回所述分离器元件。

21. 根据权利要求 20 所述的方法，其特征在于：进一步包括以下步骤，

随着所述接收器至少部分设置在所述血栓栓塞材料主体上方，使用所述吸取源经所述导管腔施加吸力，所述吸力便于由所述接收器保持所述血栓栓塞材料。

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22. 根据权利要求 20 所述的方法，其特征在于：进一步包括以下步骤，

随着所述接收器至少部分设置在所述血栓栓塞材料主体上方，相对所述接收器的近端部分滑动所述导管的远端部分以便使所述接收器在径向向内的方向上对所述血栓栓塞主体施加压力。

23. 根据权利要求 20 所述的方法，其特征在于：朝所述导管腔抽回所述分离器元件的步骤防止进入所述管腔的血栓栓塞材料阻碍其他材料吸取到所述导管腔内。

24. 根据权利要求 20 所述的方法，其特征在于：朝所述导管腔抽回所述分离器元件的步骤将血栓栓塞材料插入所述导管腔。

25. 根据权利要求 20 所述的方法，其特征在于：所述方法进一步包括重复推进以及抽回所述分离器元件的步骤一次或者多次。

26. 根据权利要求 20 所述的方法，其特征在于：推进所述分离器元件的步骤和/或抽回所述分离器元件的步骤打碎聚集在所述导管腔内的血栓栓塞材料。

27. 根据权利要求 20 所述的方法，其特征在于：进一步包括以下步骤，如果在所述确定步骤中确定所述血栓栓塞材料的可能性质是软的：

在朝所述导管腔抽回所述分离器元件的步骤之后，从所述导管取出所述分离器元件；

从所述导管延伸所述接收器；

将所述接收器推进到至少部分位于所述血管内的血栓栓塞材料的剩余主体上方；

使所述剩余主体接收在所述中心腔中并使所述啮合元件啮合所述主体；以及

将所述接收器抽回到所述护套内。

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28. 根据权利要求 20 所述的方法，其特征在于：进一步包括以下步骤，如果在所述确定步骤确定所述血栓栓塞材料的可能性质是硬的：

至少在推进所述接收器的步骤之后，将所述分离器元件引入到所述血管内；

使用所述吸取源经所述导管腔进行吸取以便将血栓栓塞材料吸入并通过所述导管腔；

在远端方向上从所述导管腔推进所述分离器元件以便使所述分离器元件接触血栓栓塞材料的剩余主体的一部分；以及

朝所述导管腔抽回所述分离器元件。

29. 根据权利要求 28 所述的方法，其特征在于：将所述分离器元件引入所述血管的步骤包括经所述接收器延伸所述分离器元件。

30. 根据权利要求 28 所述的方法，其特征在于：将所述分离器元件引入所述血管的步骤在将所述接收器抽回到所述护套内的步骤之后执行。

31. 根据权利要求 20 所述的方法，其特征在于：推进所述分离器元件的步骤和/或抽回所述分离器元件的步骤打碎所述血管内的血栓栓塞材料。

32. 一种用于从患者血管去除血栓栓塞材料的方法，所述方法包括以下步骤：

提供具有管腔的导管，所述管腔包括具有固定内径的远端部，并且进一步提供可经所述管腔延伸并且其上具有分离器元件的延长构件，所述分离器元件的最大直径小于所述管腔远端部的直径；

将所述导管插入血管并将所述导管定位在血栓栓塞材料主体的附近；

经所述管腔进行抽取以便将血栓栓塞材料吸入并通过所述管腔；

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在远端方向上从所述管腔推进所述分离器元件以便使所述分离器元件接触所述血栓栓塞材料主体的一部分；以及

朝所述管腔抽回所述分离器元件。

33. 根据权利要求 32 所述的方法，其特征在于：抽回步骤防止进入所述管腔的血栓栓塞材料阻碍其他材料吸取到所述管腔内。

34. 根据权利要求 32 所述的方法，其特征在于：所述抽回步骤将血栓栓塞材料插入到所述管腔内。

35. 根据权利要求 32 所述的方法，其特征在于：所述方法进一步包括重复所述推进以及抽回步骤一次或多次。

36. 根据权利要求 32 所述的方法，其特征在于：所述推进和/或收回步骤打碎聚集所述管腔内的血栓栓塞材料。

37. 根据权利要求 32 所述的方法，其特征在于：在所述推进和/或抽回步骤过程中，所述延长构件打碎所述血管内的血栓栓塞材料主体。

38. 根据权利要求 32 所述的方法，其特征在于：所述方法进一步包括在所述推进步骤之前阻塞所述血管的步骤。

39. 根据权利要求 38 所述的方法，其特征在于：所述阻塞步骤包括在所述推进步骤之前在所述血管对阻塞气囊进行充气的步骤。

40. 根据权利要求 32 所述的方法，其特征在于：所述提供步骤提供所述分离器元件以便包括具有向近端定向的表面的近端部分以及渐缩的远端部分。

41. 根据权利要求 40 所述的方法，其特征在于：在所述抽回步骤的过程中所述向近端定向的表面在近端方向上携带血栓栓塞材料。

42. 根据权利要求 40 所述的方法，其特征在于：所述向近端定向的表面包括凹面。

43. 根据权利要求 40 所述的方法，其特征在于：所述提供步骤提供所述向近端定向的表面以便包括基本上的平面。

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44. 根据权利要求 40 所述的方法，其特征在于：所述提供步骤提供所述向近端定向的表面以便包括凸面。

45. 根据权利要求 32 所述的方法，其特征在于：所述方法包括提供延长杆以及定位在所述杆的远端部分上的接收元件的步骤，并且其中所述方法包括以下步骤：膨胀所述接收元件，将所述膨胀的接收元件移动成接触血栓栓塞材料，以及将血栓栓塞材料与所述接收元件啮合。

46. 根据权利要求 45 所述的方法，其特征在于：所述啮合步骤包括将所述接收元件至少部分收缩到血栓栓塞材料上。

47. 根据权利要求 45 所述的方法，其特征在于：所述方法包括以下步骤：在推进所述分离器元件步骤之前使所述接收元件通过所述导管腔传送。

48. 根据权利要求 45 所述的方法，其特征在于：所述方法包括以下步骤：在推进所述分离器元件的步骤之后使所述接收元件通过所述导管腔传送。

49. 根据权利要求 32 所述的方法，其特征在于：所述血管是脑动脉。

50. 根据权利要求 32 所述的方法，其特征在于：所述方法包括以下步骤：使导引线通入所述血管内，并且其中在所述插入步骤过程中所述导管在所述导引线上方推进。

51. 根据权利要求 50 所述的方法，其特征在于：所述导引线包括所述延长构件。

52. 一种用于从脑血管去除血栓栓塞材料的系统，所述系统包括：

配设用于插入脑血管的延长导管，所述导管具有经其延伸的管腔，所述管腔包括具有固定内径的远端部；

与所述管腔流体耦接的吸取源；

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可经所述管腔延伸并且其上具有分离器元件的延长构件，所述分离器元件的最大直径小于所述管腔远端部的直径。

53. 根据权利要求 52 所述的系统，其特征在于：所述分离器元件包括具有向近端定向的表面的近端部分以及渐缩的远端部分。

54. 根据权利要求 53 所述的系统，其特征在于：所述分离器元件具有从所述向近端定向的部分到所述远端部分延伸的大致锥形外形。

55. 根据权利要求 53 所述的系统，其特征在于：所述向近端定向的表面为凹面。

56. 根据权利要求 53 所述的系统，其特征在于：所述向近端定向的表面基本为平面。

57. 根据权利要求 53 所述的系统，其特征在于：所述向近端定向的表面为凸面。

58. 根据权利要求 52 所述的系统，其特征在于：所述延长构件包括挠性远端尖部，并且其中所述分离器元件从所述远端尖部向近端间隔。

59. 根据权利要求 52 所述的系统，其特征在于：所述管腔包括内径，并且其中所述分离器元件的最大直径在小于所述管腔远端部的内径 0.003–0.008 英寸的范围内。

60. 根据权利要求 52 所述的系统，其特征在于：进一步包括可在所述脑血管内膨胀以便在所述导管的一定区域内阻塞所述血管的阻塞气囊。

61. 根据权利要求 52 所述的系统，其特征在于：进一步包括位于可经所述管腔延伸的延长杆上的可膨胀接收元件，所述接收元件可在所述血管内推进为与血栓栓塞材料接触并可至少部分收缩以啮合血栓栓塞材料。

62. 根据权利要求 52 所述的系统，进一步包括使用说明，所述说明阐述了使用所述系统的方法，包括以下步骤：

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将所述导管插入血管并将所述导管定位在血栓栓塞材料主体的附近;

使用所述吸取源经所述管腔进行吸取以便将血栓栓塞材料吸入并经过所述管腔;

在远端方向上从所述管腔推进所述分离器元件以便使所述分离器元件接触所述血栓栓塞材料主体的一部分;以及

朝所述管腔抽回所述分离器元件。

63. 根据权利要求 52 所述的系统,其特征在于:所述导管的外径在大约 0.032 英寸到 0.065 英寸的范围内。

64. 一种用于从血管抽出血栓栓塞材料的设备,所述设备包括:

延长构件;以及

位于所述延长构件的远端部分的接收器,所述接收器由配置为形成具有中心腔的套筒的多个结构件形成,所述多个结构件包括啮合元件,所述啮合元件包括延伸到所述中心腔中的顶点区域。

65. 根据权利要求 64 所述的设备,其特征在于:多个所述结构件包括多个具有纵向定向的顶点的大致 v 形元件,其中所述啮合元件为多个所述 v 形元件。

66. 根据权利要求 64 所述的设备,其特征在于:所述接收器可从压缩位置径向膨胀到膨胀位置,在压缩位置中所述接收器尺寸限定为通入血管内,在膨胀位置中在体温下所述接收器尺寸限定为接触所述血管的内表面。

67. 根据权利要求 66 所述的设备,其特征在于:在所述膨胀位置,所述接收器可在所述血管内的血栓栓塞材料主体上方滑动以便将所述主体接收到所述中心腔内,并且其中所述啮合元件定向为啮合所述管腔中的所述主体。

68. 根据权利要求 66 所述的设备,其特征在于:在所述膨胀位置,所述接收器的最大膨胀直径在大约 2-6mm 的范围内。

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69. 根据权利要求 66 所述的设备，其特征在于：在所述膨胀位置，所述接收器的最大膨胀直径在大约 6-9mm 的范围内。

70. 根据权利要求 65 所述的设备，其特征在于：所述结构件进一步包括多个隔开的周向环。

71. 根据权利要求 70 所述的设备，其特征在于：所述周向环中的一个定位在所述接收器的远端部。

72. 根据权利要求 70 所述的设备，其特征在于：所述周向环中的一个定位在所述接收器的近端部。

73. 根据权利要求 70 所述的设备，其特征在于：所述结构件进一步包括在所述周向环之间延伸的多个纵向支柱。

74. 根据权利要求 70 所述的设备，其特征在于：各啮合元件定位在所述纵向支柱的相应一对之间。

75. 根据权利要求 73 所述的设备，其特征在于：各纵向支柱包括至少一个弹簧区域。

76. 根据权利要求 65 所述的设备，其特征在于：所述结构进一步包括：

多个隔开的周向环；

在所述周向环之间延伸的多个纵向支柱；

其中各 v 形元件设置在所述纵向支柱的相邻支柱之间。

77. 根据权利要求 76 所述的设备，其特征在于：所述多个周向环包括近端环、远端环以及中间环，并且其中所述 v 形元件包括定位在所述远端环和所述中间环之间的 v 形元件的远端列，以及定位在所述中间环和所述近端环之间的 v 形元件的近端列。

78. 根据权利要求 77 所述的设备，其特征在于：所述啮合元件包括位于所述远端列中的多个所述 v 形元件。

79. 根据权利要求 77 所述的设备，其特征在于：所述啮合元件包括位于所述近端列的多个所述 v 形元件。

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80. 根据权利要求 66 所述的设备，其特征在于：进一步包括具有导管腔的导管，所述接收器在处于所述压缩位置时可插入所述导管腔，所述接收器配置为使得所述接收器离开所述导管的推进导致所述接收器自膨胀到其膨胀位置。

81. 根据权利要求 80 所述的设备，其特征在于：所述接收器配置为使得所述接收器到所述导管内的抽回导致所述接收器收缩到所述压缩位置。

82. 根据权利要求 81 所述的设备，其特征在于：

所述延长构件包括远端管腔；以及

多个所述结构件包括：

具有连接到所述延长构件的近端部分的多个第一纵向支柱，以及

具有可在所述延长构件的所述远端管腔内滑动的近端部的多个第二纵向支柱。

83. 根据权利要求 82 所述的设备，其特征在于：

多个所述结构件包括多个具有纵向定向的顶点的大致 v 形元件，其中所述啮合元件为多个所述 v 形元件；以及

所述多个第二纵向支柱的至少一部分耦接到所述 v 形元件的顶点。

84. 根据权利要求 83 所述的设备，其特征在于：所述多个第二纵向支柱的至少一个包括耦接到第一大致 v 形构件的顶点区域的远端部分以及耦接到与所述第一大致 v 形构件纵向对齐的第二大致 v 形构件的顶点区域的中间部分。

85. 根据权利要求 64 所述的设备，其特征在于：进一步包括：

具有配设用于接收所述导管的护套管腔的延长护套；以及

位于所述护套上的阻塞气囊，所述气囊可充气为阻塞血管的血液流动。

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86. 一种用于啮合血管内的血栓栓塞主体的方法，所述方法包括以下步骤：

提供由配置为形成具有中心腔的套筒的多个结构件形成的接收器，多个所述结构件包括啮合元件，所述啮合元件包括延伸到所述中心腔内的顶点区域；以及

在血管内的血栓栓塞材料的主体上方推进所述接收器，使得所述主体接收到所述中心腔内，并使所述啮合元件啮合所述管腔内的主体。

87. 根据权利要求 86 所述的方法，其特征在于：进一步包括以下步骤：当所述主体处于所述中心腔内时从所述血管抽回所述接收器。

88. 根据权利要求 86 所述的方法，其特征在于：

所述提供步骤进一步提供导管，所述接收器可在所述导管内滑动，其中所述接收器可从压缩位置径向膨胀到膨胀位置；

所述方法包括以下步骤：

将处于所述压缩位置的所述接收器定位在所述导管内；

将所述导管定位在所述血管内接近所述血栓栓塞材料主体的位置；以及

所述推进步骤包括从所述导管延伸所述接收器。

89. 根据权利要求 88 所述的方法，其特征在于：进一步包括以下步骤：

在所述推进步骤之后，相对所述接收器的近端部分滑动所述导管的远端部分以便使所述接收器在径向向内的方向上向所述血栓栓塞主体施加压力。

90. 根据权利要求 86 所述的方法，其特征在于：进一步包括以下步骤：

将护套定位在所述血管内，所述护套具有位于其上的阻塞气囊；以及

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使用所述阻塞气囊阻塞所述血管。

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用于治疗缺血性中风的系统以及方法

技术领域

本发明大致涉及医学治疗领域，并且更具体涉及一种用于治疗缺血性中风(ischemic stroke)的系统及方法，其包括从患者的脑动脉去除血栓栓塞。

背景技术

中风是死亡以及残废的首要原因，也是不断增长的全球性卫生保健问题。单在美国，每年就有超过 700,000 人经受大中风的痛苦，并且其中超过 150,000 人死亡。更加困扰的是，预期这种已经很麻烦的情况随着“生育高峰”人口到达老龄而变得更糟，特别是那些经受不良饮食、肥胖和/或其他导致中风的起作用因素的人。在中风幸存者中，大约 90%的人在行动、感观、记忆或者思维上受到长期的中度到重度损伤。US 卫生保健系统的总费用为每年超过$500 亿。

中风可以由脑动脉破裂(“出血性中风”）或者由于血栓栓塞产生的脑动脉阻塞（“缺血性中风”）引起。血栓栓塞是经血流行进并沉淀由此阻碍或者阻塞血管的分离血液凝块。在这两种中风之间，缺血性中风包括更大的问题，美国每年超过 600,000 人经受缺血性中风。

缺血性中风治疗可以通过血栓栓塞的药理学消除和/或血栓栓塞的机械消除完成。药理学消除可以通过注射设计为溶解或者防止血栓栓塞进一步生长的溶解血栓剂完成（例如，溶栓酶、尿激酶、组织血浆酶原催化剂（TPA））和/或抗凝血药物（例如，肝磷脂、杀鼠灵(warfarin)）。药理学治疗是非介入性的并且通常对溶解血栓栓塞有效。尽管有这些通常有利的方面，但是使用药理学治疗存在明显的缺陷。一种缺陷是溶解血栓剂和/或抗凝血剂见效以及恢复血流

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所需的时间量相对较大。由于治疗缺血性中风的时间紧迫性，任何附加时间都是潜在地破坏性的。另一明显缺陷是提高了由溶解血栓剂和/或抗凝血剂导致的体内其他位置流血或者出血的可能。

已经尝试使用各种基于导管的经腔血管的介入技术的治疗缺血性中风的血栓栓塞材料的机械消除。一种介入技术包括将线圈(coil)展开到血栓栓塞（例如，通过螺旋作用）以便俘获或者包围血栓栓塞使其能够从患者去除。尽管对缺血性中风的药理治疗进行了改进，但由于血栓栓塞材料滑脱或者被线圈驱散，这种基于线圈的收回系统在克服缺血性中风上仅取得了部分成功（大约 55%）。在后一情况下，血栓栓塞材料的驱散可能在同一动脉或连接动脉内导致另外的中风。

另一种介入技术包括从血栓栓塞向远端（或者下游）展开篮或者网结构，以便俘获或者包围血栓栓塞使其能够从患者去除。同样，尽管克服了药理学治疗的缺陷，但其明显缺陷在于在没有脉管系统的血管造影路标(angiographic roadmap)可视化的情况下从阻塞段向远端操纵篮或网结构的动作增加了损坏血管的风险。此外，不然的话，取出篮或网结构可能使血栓栓塞材料进入连接的动脉。如上文提到的，这将在连接动脉中导致另外的中风。

治疗缺血性中风的再一种介入技术包括将吸管推进到血栓栓塞，以便通过吸取（即，负压力）将其去除。尽管通常是安全的，但是通过吸取去除仅对相对软的血栓栓塞有效。为了加强吸取技术的效果，已经采用旋转刀片切断或者击碎血栓栓塞，随后通过吸管去除。尽管这种旋转刀片零件改进了这种吸取技术的效果，但是增加了由于旋转刀片引起的损坏血管的风险。

上述介入技术，以及现有技术中的其他技术，全都具有一个或多个缺陷并且被认识对于治疗缺血性中风是次最佳的。本发明针对于克服或者至少改进现有技术的缺点。

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附图说明

通过结合所附附图阅读本说明书，本发明的许多优点对于本领域技术人员显而易见，其中相同的附图标记用于相同的元件，并且其中：

图 1 是血栓栓塞去除系统一实施例的部分截面侧视图，包括导引及阻塞导管、输送及吸取导管、吸取泵、血栓栓塞接收器以及血栓栓塞分离器；

图 2 是形成图 1 所示血栓栓塞去除系统的部件的输送及吸取导管的部分截面侧视图，显示了处于未展开状态的血栓栓塞接收器元件；

图 3 是图 1 所示血栓栓塞去除系统的部件的输送及吸取导管的部分截面侧视图，显示了处于展开状态的血栓栓塞接收器元件；

图 4A 是描述装配有多个啮合元件的血栓栓塞接收器的备选实施例的透视图；

图 4B 是沿图 4A 的标记为 4B-4B 的平面的截面视图；

图 4C 是显示图 4A 的血栓栓塞接收器的远端部分的透视图；

图 5 是图 4 的备选血栓栓塞接收器的平面图，尽管接收器优选是管状结构，但图 5 将其显示成打开并展平成片状以便更容易地观察其特征；

图 6 是显示用于将血栓栓塞接收器（例如图 4A 的接收器）挠性耦接到延长构件或输送及吸取导管的挠性区域一实施例的顶部视图；

图 7 是装配有在血栓栓塞接收器展开之后能够选择性展开的多个啮合元件的备选血栓栓塞接收器的透视图；

图 8A 是具有用于促进接收器重新加载到导管内的零件的血栓栓塞接收器的透视图；

图 8B 是与图 5 的视图类似的显示图 8A 的血栓栓塞接收器的平面图；

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图 8C 是图 8A 的血栓栓塞接收器的近端部分以及耦接到血栓栓塞接收器的延长构件的远端部分的透视图，显示了血栓栓塞接收器回缩到输送及吸取导管内；

图 9 和图 10 是与输送及吸取导管一同使用的血栓栓塞剥离器或分离器的一实施例的部分截面侧视图；

图 11A 是形成图 9 和图 10 所示的血栓栓塞分离器的部件的分离器元件的放大视图；

图 11B 是血栓栓塞分离器的备选实施例的侧面主视图；

图 11C 是形成图 11B 所示的血栓栓塞分离器的部件的分离器元件的放大视图；

图 11D 是与图 11C 类似的显示血栓栓塞分离器另一个备选实施例的侧面主视图；

图 12 是显示用于动脉系统中的图 1 的血栓栓塞去除系统的患者的部分截面视图；

图 13 是显示用于脑动脉中的图 1 的血栓栓塞去除系统的远端区域的患者的部分截面视图；

图 14 是显示导引线向血栓栓塞推进的部分截面侧视图；

图 15 是显示导引及阻塞导管推进同时气囊处于放气状态的部分截面侧视图；

图 16 是显示气囊阻塞构件充气以便抑制包含血栓栓塞的动脉内的血流的部分截面侧视图；

图 17 是显示根据用于使用图 1 的系统的方法将图 1-图 3 的输送及吸取导管推进到接近血栓栓塞的点的部分截面侧视图；

图 18 是显示图 1-图 3 的血栓栓塞接收器展开的部分截面侧视图；

图 19 是显示图 1-图 3 的输送及吸取导管向远端推进以使图 1-图 3 的血栓栓塞接收器（全部或部分）啮合血栓栓塞的部分截面侧视图；

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图 20 以及图 21 显示了图 1-图 3 的血栓栓塞接收器移动到导引及阻塞导管内以便去除血栓栓塞的部分截面侧视图；

图 22 是显示使用图 1 以及图 9-图 11C 的血栓栓塞分离器来啮合血栓栓塞的远端部的部分截面侧视图；

图 23 是显示使用图 1 以及图 9–图 11C 的血栓栓塞分离器来分裂和/或软化血栓栓塞并且/或者辅助吸取的部分截面侧视图；

图 24 是显示独立使用图 1 以及图 9–图 11C 的血栓栓塞分离器来分裂和/或软化血栓栓塞并且/或者辅助吸取的部分截面视图；

图 25 以及图 26 显示图 4–图 6 的血栓栓塞接收器向远端推进以使其包围血栓栓塞的部分截面视图；以及

图 27 以及图 28 是显示图 4–图 6 血栓栓塞接收器以及输送及吸取导管抽回到导引及阻塞导管内以便去除血栓栓塞的部分截面侧视图。

具体实施方式

下面将描述本发明的示意性实施例。为了清晰起见，在本说明书中不描述实际实现方式的所有特征。当然要知道，在任何这样的实际实施例的开发中，必须作出许多特定应用的决定，以便实现开发者的特定目的，例如依从系统相关以及商业相关的限制，这根据实施方式而彼此不同。此外，要知道开发努力可能是复杂而且耗时的，但是受益于本公开内容的本领域技术人员的非创造性劳动。本申请所公开的血栓栓塞去除系统包含单独或者组合保证专利保护的各种发明性特征以及元件。

系统特征

图 1 显示了血栓栓塞去除系统 10 的示范性实施例。该血栓栓塞去除系统 10 包括导引及阻塞导管 12、输送及吸取导管 14、血栓栓塞剥离器或分离器 16 以及吸取泵 18。如下文更详细描述的，血栓栓

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塞去除系统 10 有利地提供了从患者体内的脑动脉去除血栓栓塞的能力，同时克服了现有技术的缺点及局限。

导引及阻塞导管 12 包括具有在近端部 24 和远端部 26 之间延伸的主管腔 22 的管状导管构件 20。导管构件 20 可由具有适当生物适应性以及强度特征的许多成分构建而成，并且可以依据进入脉管系统之进入点、血栓栓塞的位置、患者解剖结构的差异以及任何减轻情况（extenuating circumstance），将其尺寸限定成许多适当的尺寸以及长度。在示范性实施例中，导管构件 20 可以由带有嵌入式不锈钢编织物的尼龙构成并且尺寸限定为具有从 70cm 到 110cm 的长度以及从 5French（0.065 英寸）到 9French（0.117 英寸）的直径。气囊阻塞构件 28 设置在远端部 26 或者附近。为了对阻塞构件 28 进行选择性充气，提供经设置于管状导管构件 20 的壁内的至少一管腔（未图示）与阻塞构件 28 流体连通的充气端口 30。提供密封件 32 以便使输送及吸取导管 14 以无泄漏、止血方式通过导引及阻塞导管 12 的主管腔 22。

输送及吸取导管 14 包括具有在远端部 38 和近端部 40 之间延伸的主管腔 36 的管状导管元件 34。导管构件 34 可以由具有适当生物适应性和强度特征的许多成分构成并且可以依据进入脉管系统的进入点、血栓栓塞的位置、患者解剖结构的差异以及减轻情况尺寸限定成许多尺寸以及长度。在示范性实施例中，导管构件 34 可以由具有嵌入式不锈钢编织物的 PEBAX 构成并且尺寸限定为具有从 130cm 到 170cm 的长度以及从 2.5French（0.032 英寸）到 5French（0.065 英寸）的直径。

输送及吸取导管 14 还包括耦接到近端部 40 的中枢组件 42，以便将管腔 36 耦接到吸取泵 18。中枢组件 42 还包括密封件 44 以便允许血栓栓塞分离器 16（以及如下文所描述的展开接收器元件 46 的推动装置）以无泄漏、止血方式通过管腔 36。管腔优选包覆有 PTFE 或者本领域公知的各种适当润滑材料的另外一种。

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如参照图 2-图 3 所最佳观察到的，血栓栓塞接收器元件 46 能够在管腔 36（图 2）内保持成收回或未展开状态（图 2）并且能够选择性从远端部 38 推出和/或拔出进入展开状态（图 3）。血栓栓塞接收器 46 可以由具有适当生物适应性以及强度特征的许多成分构成，并且可以依据血栓栓塞的位置、患者解剖结构的差异以及血栓栓塞的尺寸和形状尺寸限定成许多适当的尺寸和形状。如图 3 和图 5 中所最佳观察到的，血栓栓塞接收器 46 由多个支柱构件 47 形成，其在展开后沿血栓栓塞接收器 46 的外围产生大量大致菱形开口 49。根据一个实施例，如图 18-图 23 所示，血栓栓塞接收器 46 的远端区域的结束点（resulting point）装配有钝尖零件 51 以便于血栓栓塞接收器 46 在没有阻碍或者以其他方式粘贴在通到脑动脉的动脉或者分支血管壁的情况下通过脑动脉。

在导管元件 34 内提供推动元件 48 以便用于将接收器元件 46 从管腔 36 内推进或者推动到完全或部分展开的状态。仅作为实例，推动元件 48 包括适当构造（例如，线或者绕线的）的延长构件 50，其具有尺寸限定为接触形成接收器元件 46 的部件（或者耦接于其上的）近端终端 54 的远端邻接件 52。尽管未图示，但要知道推动元件 48 可以包括许多用于推动接收器元件 46 进行展开的适当装置，包括但不局限于具有尺寸限定为接触接收器元件 46 的近端终端 54 的远端部的导管。在一实施例中，这种推进导管可以具有尺寸限定为接收和/或通过血栓栓塞分离器 16 的内设管腔。

图 4A 显示了备选实施例的血栓栓塞接收器 146。血栓栓塞接收器 146 可由具有适当生物适应性以及强度特征的多个成分构成，并且可以依据血栓栓塞的位置、患者解剖结构的差异以及血栓栓塞的尺寸和形状尺寸限定成许多适当的尺寸以及长度。在优选实施例中，血栓栓塞接收器 146 由具有“形状记忆”或者超弹性特性的镍钛诺构成。通过这种方式，血栓栓塞接收器 146 能够在展开之前保持成受限形式或者形状。接收器可以通过将零件激光切割成一定长度的镍

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钛诺管材，并且随后使用本领域普通技术人员公知的方法对材料进行一次或多次化学蚀刻以及形状设定形成。

参照图 4A，接收器 146 安装到延长构件 151 上，延长构件 151 优选配设(proportion)成经输送及吸取导管 14 的管腔 36（图 1）延伸。支柱构件或者“支脚”162 在接收器 146 和延长构件 151 之间延伸并且优选使用粘结、收缩管材或者其他公知方法附着到延长构件 151 上。在优选实施例中，构件 151 是延长的棒、导管、线或者其他延长构件。在本实施例中，配设血栓栓塞接收器 146 使其在输送及吸取导管 14 内（以图 1-图 3 所示的方式类似的方式）限制在压缩位置。作为备选方案，延长构件 151 可以是输送及吸取导管 14，在这种情况下接收器 146 以及输送及吸取导管 14 适于延伸通过导引及阻塞导管 12。

在任一情况下，血栓栓塞接收器 146 可以通过将血栓栓塞接收器 146 简单地推出将其限制在未展开状态的元件（例如，导引及阻塞导管 12 或者输送及吸取导管 14）而自动展开-由于镍钛诺的形状记忆或超弹性特性。一旦展开，血栓栓塞接收器 146 可以用于接收血栓栓塞。优选选定接收器 146 的尺寸以便当其在体温下处于膨胀状态时，接收器的远端部分的外表面接触周围的血管壁。在适于大多数颅内血管的实施例中，接收器可以膨胀到大约 2-6mm 的最大外径，并且更优选为 2-5mm。对于例如普通颈动脉内程序的其他应用，大约 6-9mm 范围内的最大外径是适当的。

在不脱离本发明的范围的情况下，血栓栓塞接收器 146 可以形成为具有各种适当几何外形和特征。根据图 4A 和图 5 所示的一实施例，血栓栓塞接收器 146 由个支柱构件形成，其在展开后沿血栓栓塞接收器 146 的外围产生大量大致矩形的开口 149（图 5 中最佳观察到的）。作为实例，这可以通过提供多个纵向支柱构件或者“立柱”150（大致平行于输送及吸取导管 14 的纵轴）以及多个横向支柱构件 152

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（在相邻立柱之间大致垂直延伸）实现。在优选实施例中，支柱构件共同限定具有如图 4B 所示的中心腔 147 的大致柱状的远端部分。

横向支柱构件 152 可以包括许多弯曲或者波动，例如在横向支柱构件 152 和立柱 150 之间交点附近所示的弯曲 153a 以及图 5 所示的交点中间的弯曲 153b。这些弯曲或波动有助于允许血栓栓塞接收器 146 折叠成压缩或受限状态，这是将血栓栓塞接收器 146 设置在输送及吸取导管 14 或导引及阻塞导管 12 内所需要的。

在优选实施例中，横向支柱构件 152 形成最靠近输送及吸取导管 14 的近端封套 154、定位在血栓栓塞接收器 146 的远端或者开放端的远端封套 156 以及位于近端封套和远端封套之间某点的中间封套 158。各封套（近端封套 154、中间封套 158 以及远端封套 156）为设计成增强血栓栓塞接收器 146 的结构支撑和稳定性以及有助于在展开后将血栓栓塞接收器 146 保持在所需形状的周向环（以便改善到血管壁的附着来优化血栓栓塞的回收）。

由封套 154-158 所提供的结构支撑可以通过在一个或多个大致矩形开口 149 内提供一个或多个稳定支柱构件 160 而加强。根据一实施例，这些稳定支柱构件 160 可以采用从血栓栓塞接收器 146 内的给定大致矩形开口 149 的近端部或者远端部延伸的“V”形式。在优选实施例中，这种“V”形稳定支柱构件 160 提供在血栓栓塞接收器 146 内的大致矩形开口 149 的近端以及远端组内。这样有利地增加血栓栓塞接收器 146 的近端和远端区域的结构稳定性。无论其特定形状，稳定支柱构件 160 优选包括折叠区域或者顶点 169，其允许它们在接收器压缩到收缩位置时在顶点 169（参见图 5 中的箭头 A）折叠。此外，接收器优选构建成允许支柱构件 160 在与形成接收器的其他元件相交的区域折叠，（例如在图 5 的实施例中，支柱构件 160 和立柱 150 之间的相交区域）。

尽管血栓栓塞接收器 146 的结构稳定性是所需目标，但还希望具有特定方面的挠性。根据一实施例，在血栓栓塞接收器 146 和延

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长构件 151 之间的接合点（或者输送及吸取导管 14 的远端部）提供相对挠性。仅作为实例，这通过提供多个在近端封套和延长构件 151 之间延伸的连接器支柱构件或“支脚”162（如图 5 中最佳观察的）以包括靠近延长构件 151 的远端部附近的的挠曲区域 164 实现。挠曲区域164可以形成为任何形状，只要该形状可在不包括沿支柱构件162的长度传递轴向作用力的用户能力的情况下增加支柱构件 162 的挠性。在图 6 所示的备选实施例中，挠曲区域 164a 可以包括位于连接器支柱 162 的近端部的多个蜿蜒的“S”形支柱 166a。根据另一实施例，可以在相邻纵向支柱构件或立柱 150 之间的接合点提供挠曲区域或者弹簧区域 168（图 5）（其可以包括一个或多个“S”形弯曲或者设计为提供挠性同时保持足够的柱强度的形状）。在这两种实例中，这些挠曲区域 164、168 的优点在于它们允许血栓栓塞接收器 146 在不牺牲所需柱强度的情况下更好地跟踪并沿曲折的血管推进。

根据另一实施例，血栓栓塞接收器 146 还可以包括各种零件以加强血栓栓塞接收器 146 和血栓栓塞之间的啮合。仅作为实例，这可以通过在血栓栓塞接收器上提供多个啮合元件 170 实现。如图 4A、图 4B 以及图 5 中最佳观察到的，根据一实施例，啮合元件 170 可以采取耦接在血栓栓塞接收器 146 的远端部或者附近并在相邻立柱 150 之间延伸的“V”形结构。啮合元件优选成角度进入血栓栓塞接收器的管腔 147（参见图 4B 和图 4C）以便允许管腔内俘获的血栓栓塞的啮合。在不脱离本发明的范围的情况下可以采用许多啮合元件 170。在一实施例，可以采用三个（3）分开的啮合元件 170，各啮合元件设置为沿血栓栓塞接收器 146 的外围彼此成一百二十（120）度。在优选实施例中，啮合元件 170 采取图 4A 和图 5 所示的多个稳定支柱构件 160 的形式。

当血栓栓塞接收器 146 展开（如图 4-图 5 所示）时，啮合元件 170 可以自动展开。根据图 7 所示的本发明的另一方面，啮合元件 170a 还可以在血栓栓塞接收器 146a 展开后在任意点选择性展开。根据图

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7 的实施例，通过将一个或多个延长元件 172 通过血栓栓塞接收器 146a 实现啮合元件 170a 的选择性展开以便防止啮合元件 170a 从中间延伸到血栓栓塞接收器 146 的管腔内。当需要展开时，用户仅需要在近端方向上（朝用户）拉动延长元件 172，直到将啮合元件 170a 设定为独立于延长元件 172 的限制。当出现这种情况时，啮合元件 170a 的“形状记忆”或者超弹性属性使得它们呈现自然状态，从中间延伸到血栓栓塞接收器 146a 的管腔内。通过这种方式，啮合元件 170a 将啮合血栓栓塞并因而有助于或者增强血栓栓塞接收器 146a 去除血栓栓塞的能力。

血栓栓塞接收器可以设置有允许医生在接收器已经部分或全部展开在血管内后将接收器缩回到输送及吸取导管内的零件。这可能是必须的，如果医生接收到血管造影或触觉反馈，其指示出分离器是用于去除特定栓塞的优选工具或者不同尺寸的接收器更适于特定过程。

图 8A 显示了与图 4 的接收器 146 类似但包括便于将接收器重新加载到输送及吸取导管 14 内的零件的血栓栓塞接收器 146b 的实施例的一个实例。如图所示，图 8A 的实施例的接收器 146b 包括单个远端封套 152b 以及从封套 152b 向近端延伸的多个纵向支柱构件 150b。

如图 8B 所示，结构支撑构件 160b 配置在与封套 152b 相邻的远端列 171a 以及更近端列 171b 中。与图 4 实施例一样，远端列内的多个结构支撑构件 160b 向内偏置到接收器 146b 的中心腔 147b 内以便作为用于啮合血栓栓塞的啮合构件 170b。

三种类型的稳定支柱构件朝接收器 146b 的近端部延伸。第一种，支柱构件 162b 从远端列 171a 的结构支撑构件 160b 中那些不作为啮合构件的支撑构件的顶点向远端延伸。这些支柱构件 162b 在中间点耦接到近端列 171b 中的纵向对齐的支撑构件 160b 的顶点。第二种，支柱构件 162c 形成纵向支柱构件 150b 的近端外延并且在其近端部

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包括眼孔 163。第三种，支柱构件 162d 从近端列的结构支撑构件 160b 中那些与啮合构件 170b 纵向对齐的支撑构件的顶点延伸。通过将某些或者所有支柱构件构建为包括结合前面的实施例描述的类型的挠曲区域（例如参见图 5 的挠曲区域 168）增加了接收器 146b 的挠性。

参照图 8C，接收器 146b 包括推动器或者延长构件 151b，其在其远端部包括管腔 165。在接收器 146b 的组装过程中，如图所示，支柱构件 162b、162d 的近端部定位在管腔 165 中，并且允许在管腔 165 内自由滑动。使用热收缩管材 167 或者其他适当材料将支柱构件 162c 的近端部结合到延长构件 151b 的外表面。眼孔 163 通过允许结合材料流入眼孔的开口由此使各支柱构件 162c 的更大部分外露于结合材料而便于结合。如果需要，支柱构件 162b 和 162d 可以稍大于接收器的近端部处的支柱构件 162c，以便在组装过程允许容易地对它们进行识别以插入管腔 165。

如果必需将接收器 146b 从完全或部分展开状态收回到输送及吸取导管 14 内，如图 8C 所示，在近端方向上相对导管抽回延长构件 151b。随着接收器 146b 移入导管 14，接收器在结构支撑构件 160b 的顶点开始折叠，由此在近端方向上推动支柱构件 162b、162d。由于特定的结构支撑构件 160b 在其顶点由支柱构件 162b 互连的事实，比利用图 4 的接收器 146 更容易实现折叠。因而，近端列 171b 中的一个构件 160b 的折叠将促进远端列 171a 中相应构件 160b 的折叠。允许支柱构件 162b、162d 在延长构件 151b 的管腔 165 内自由滑动，以使它们在接收器 146b 抽回到导管 14 的过程中不抵抗构件 160b 的折叠。

图 9 中显示了血栓栓塞分离器的第一实施例。第一实施例的血栓栓塞分离器 16 包括具有近端部 58 和远端部 60 的延长元件 56。延长元件 56 可由具有适当生物适应性以及强度特征的许多成分构建而成，并且可以依据进入脉管系统的进入点、血栓栓塞的位置、患者解剖结构的差异以及任何减轻情况尺寸限定成许多适当的尺寸以及

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长度。在示范性实施例中，延长元件 56 可由不锈钢和/或镍钛诺构成并且尺寸限定为具有 150cm 到 200cm 之间的长度以及从 0.010 英寸到 0.021 英寸的直径。润滑表面（例如，PTEE 覆层、亲水性覆层或者其他适当覆层）可以涂覆到延长元件 56 的全部或者部分以便于元件在输送/吸取导管 14 的管腔内和/或脉管系统内的移动。

如果需要，延长元件 56 可以采取在各种脉管应用中使用的类型的导引线形式。因而，延长元件可以任选地包括具有足以在导引线的推进过程中防止对脉管组织的损伤的挠性的线圈式远端部分 57（图 11B）。在示范性实施例中，线圈式远端部分 57 具有在大约 27-33cm 之间的长度。线圈优选定位在线圈式导引线中经常发现的类型的内心轴或者芯（未图示）周围。

分离器 16 的“工作端”包括附着或形成延长元件 56 的远端部 60 的部件的大致钝尖元件 62 以及附着或形成延长元件 56 的部件的分离器元件 64。尖端元件 62 的尺寸优选限定为通过或靠着(against)血栓栓塞以便软化或者击碎血栓栓塞以进行去除。尖端元件 62 的钝属性有利地防止损伤，以便其不会在使用过程中引起脉管系统的内部的损坏。分离器 16 还有助于去除可能由于吸取过程中血栓栓塞材料经其通过而在管腔 36 内形成的阻塞或者流动限制。

在一实施例中，如图 11A 最佳显示的，分离器元件 64 可以采取形状上大致为圆锥形的具有沿延长元件 56 面向近端的开口 66 的篮。分离篮 64 尺寸限定为有助于血栓栓塞击碎过程，以及接收这种血栓栓塞碎片以便有助于它们的去除。在一实施例中，分离篮 64 设置为具有网 68 以及一个或多个支撑构件 70。支撑构件 70 的尺寸限定将网 68 偏置到所示的大致开放位置，并且如果需要则允许网 68 随着分离器 16 通过输送及吸取导管 14、上文所描述的导管型推动器和/或血栓栓塞本身而呈现大致封闭的位置（未图示但是大致相对延长元件 56 平齐）。

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图 11B 以及图 11C 中显示了分离器 16a 的备选实施例，其中相同的附图标记用于识别与图 9、图 10 以及图 11A 所示的零件相似的零件。分离器 16a 主要在分离器元件 64a 的零件与图 9、图 10 以及图 11A 的分离器 16 有区别。参照图 11B，分离器元件 64a 为由聚合物材料形成的圆锥构件，例如聚亚安酯或者 Pebax®聚醚嵌块氨化物。分离器元件 64a 优选是实心构件，表面 65 面向近端方向的，并且元件的锥形定向在远端方向上。表面 65 的轮廓可以多种方式限定。例如，表面 65 可以是如图 11B 所示的略微凹面、如图 11C 所示的基本平面或者如图 11D 所示的略微凸面。

分离器元件 64a 定位在延长元件 56 的线圈式远端部分 57。线圈式部分 57 的一部分内的节距在线圈式远端部分 57 的特定区域内增加。以这种方式开放线圈内的间隔可以便于在成型过程中分离器元件的聚合物材料与线圈材料之间的粘合。分离器元件 64a 和延长元件 56 的远端部 60 之间的间距优选长到允许延长元件的最远端部分具有足以经脉管系统自动移动的挠性，但是短到防止在延长元件 56 的推进过程中最远端部分的折叠。在示范性实施例中，分离器元件 64a 的远端部可以定位成距远端部 60 大约 3-9mm。应该注意到，延长元件 56 的线圈式部分 57 内的心轴或芯（未图示）可以具有选定为增强线圈式部分的挠性的渐缩直径。

在分离器的近端部 58 提供手柄构件 72（图 9）以便向用户提供推进和/或操纵防损伤尖端元件 62 以及分离器 64/64a 的控制点（purchase point）。在一个实施例中，手柄构件 72 可以任何适当方式耦接到延长元件 56，包括但不局限于提供设置在延长元件 56 内以便将这两个元件耦接到一起的大致刚性的外延（未图示）。通过使用许多粘合或熔合技术加强或者增强这种耦接。

在不脱离本发明的范围的情况下，可以以各种不同的配置提供分离器 16。例如，除了上文描述的“自展开”实施例，图 11A 的分离篮 64 可以选择性展开，例如通过为分离篮 64 装配选择性将支撑构

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件 70 从大致相对延长元件 56 平齐放置的初始位置偏置或打开到大致径向膨胀的位置（图 11A 中的箭头所示）的机构。

应该知道，导引及阻塞导管 12、输送及吸取导管 14、血栓栓塞分离器 16 和/或血栓栓塞接收器 46 可以设置许多零件以便于在引入以及使用过程中这些元件的可视化，包括但不局限于具有装配辐射不透明标记以便改善射线照相成像的远端区域。

如前面结合图 1 所讨论的，可以提供本申请描述的各种元件作为用于去除血栓栓塞材料的系统 10 的部件。血栓栓塞去除系统 10 可以包括导引及阻塞导管 12、输送及吸取导管 14、血栓栓塞分离器 16/16a，血栓栓塞接收器（例如接收器 46 或者 146）和吸取泵 18，以及导引线和/或其他适于该程序的工具。在一个实施例，可以提供多个接收器 46/146 允许医生在程序期间顺序收回若干血栓栓塞。为了简单，各分开的接收器可以设置有分开的输送及吸取导管。系统 10 可以附加装配有用于阐述本申请所描述的各种用法的使用说明或其等同物。

系统使用

现在将参照图 12-图 28 描述使用血栓栓塞去除系统 10 的方法。如图 12-图 13 所大致显示的，在第一示范性方法中，血栓栓塞去除系统 10 引入到患者的脉管系统，例如通过 Seldinger 技术。图 14 显示了该过程的第一步，该步骤包括将导引线 104 推进到接近血栓栓塞 100 的点。导引线 104 可以包括许多商业可购得的导引线，其操作是本领域众所周知的。然而，在一种方法中，分离器 16 的延长构件 56（图 11B）作为导引线 104。

图 15 显示了第二步，其包括在导引线 104 上方将导引及阻塞导管 12 推进到接近血栓栓塞的点。图 16 所示的下一步优选包括对气囊阻塞构件 28 进行充气，以便抑制包含血栓栓塞 100 的脑动脉 102 内的血流。如图 17 所示，随后经导引及阻塞导管 12 推进输送及吸

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取导管 14 以使输送及吸取导管 14 的远端部 38 定位在接近血栓栓塞 100 的点。在经导引及阻塞导管 12 延伸的导引线 104 和/或交换长度（exchange-length）的导引线（未图示但本领域众所周知）上方推进输送及吸取导管 14 可以促进这种情况。

如图 18 所示，在该点，血栓栓塞接收器 46 从输送及吸取导管 14 的远端部 38 展开。在一个实施例，气囊阻塞 28 在该点进行充气（与如图 16 所示的在推进输送及吸取导管 14 之前进行充气相反）。随后。向远端推进输送及吸取导管 14-如图 19 所示-使得血栓栓塞接收器 46 啮合和/或（部分或者全部）包围血栓栓塞 100。在该点，如图 20 和图 21 所示，输送及吸取导管 14 可以抽回到导引及阻塞导管 12 内以便从患者 16 去除血栓栓塞 12。

为了加强去除血栓栓塞 100 的能力，或者在血栓栓塞接收器 46 初始不啮合血栓栓塞 100 的情况下，可以激活吸取泵 18 以便在输送及吸取导管 14 内建立负压力。通过这种方式，负压力产生在脑动脉 102 内并施加到血栓栓塞 100。如上文提到的，可以在该过程中采用分离器 16（或者图 11B-图 11D 的分离器 16a）（例如对其进行推进以及缩回到输送及吸取导管 14 的管腔 36 内）以便去除由于血栓栓塞材料经管腔 36 通过而产生的任何阻塞或者流动限制。负压力用于将血栓栓塞 100（部分或全部）吸入血栓栓塞接收器 46 内。随后，可以将输送及吸取导管 14 抽回到导引及阻塞导管 12 内以便从患者去除血栓栓塞 100。

为了进一步加强去除血栓栓塞 100 的能力或者在吸取泵 18 不足以将所有或大部分血栓栓塞 100 吸入接收器 46 的情况下，可以将血栓栓塞分离器 16/16a 推进成与血栓栓塞的一部分接触或者如图 22 所示全部通过血栓栓塞 100，并且用它来偏置或者啮合血栓栓塞 100 的远端部。这将增加与血栓栓塞 100 啮合的表面面积，这样将有利地允许其抽回到导引及阻塞导管 12 内，例如通过将分离器 16/16a 以及输送及吸取导管 14 同时抽回到导引及阻塞导管 12 内。

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如图 23 所示，分离器 16/16a 还可以选择性经血栓栓塞 100 推进以及收回（或保持在接收器 46 外面）。这将用于打碎或者以其他方式软化血栓栓塞 100。推进或者收回分离器 16/16a 还将用于去除在吸取过程中由于血栓栓塞材料通过输送及吸取导管 14 的管腔 36 产生的阻塞或者流动限制。在任一情况下，吸取泵 18 将血栓栓塞碎片 106 或者软化的血栓栓塞 100 吸入或者偏置到血栓栓塞接收器 46 和/或导管 14 内。随后，抽回输送及吸取导管 14 以便将血栓栓塞接收器 46 吸入到导引及阻塞导管 12 内以便从患者去除血栓栓塞 100。

分离器元件 64 经血栓栓塞的选择性推进以及分离器元件收回到输送及吸取导管 14 内，优选结合吸取，还可以用于将小块血栓栓塞材料带入导管 14。例如，分离器元件 64 可以通过血栓栓塞材料，平移某些材料并因而随着其向远端移动而在材料内形成通道。一旦分离器元件进一步定位到血栓栓塞内或者血栓栓塞的远端，某些平移的材料可能流回到该通道内。分离器元件 64 经材料（例如，经重新填充的通道）的后续收回将某些材料吸入到导管 14 内。为了促进该程序，优选提供分离器元件 64 和导管 14 使得导管腔 36 的直径与分离器元件 64 的最大直径之间的公差相当紧密。例如，在示范性实施例，分离器元件 64 的外径与管腔 36 的直径相差大约 0.003-0.008 英寸。

接下来描述一种备选方法，其中优选彼此独立地使用接收器和剥离器，虽然也可以如结合第一示范性方法所描述地组合使用。本方法描述为使用血栓栓塞接收器 146 和分离器 16a 执行，然而应该知道在所描述的方法中可以备选使用这些元件的其他实施例。

根据备选方法。进行关于首先采用接收器 146 还是分离器 16a 的初始确定。这些确定可以随机进行，尽管在优选方法中，医生基于要去除的血栓栓塞材料的可能性质的确定选择适当的工具。具体来说，医生将评定患者以确定材料可能是硬的还是软/凝胶状的。这种评定可以包括评估例如当与血栓栓塞接触时导引线或分离器的尖

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部的响应、血栓栓塞材料位置、患者症状和/或由血栓栓塞引起的中风表明其自身的方式中的一种或多种因素。

如结合第一示范性方法所讨论的，导引及阻塞导管 12 引入到患者的脉管系统，并且对阻塞气囊 28 进行充气以便抑制血管内的血流（例如参见图 14-图 16）。

输送及吸取导管 14 通过导引及阻塞导管 12 并且定位成使其远端部处于接近血栓栓塞 100 的位置。如果医生选择在使用接收器 146 之前使用分离器 16a，或者如果评估结果确定了血栓栓塞材料可能是有些软或者凝胶状的，激活吸取泵 18 以便在输送及吸取导管 14 内建立负压力，并因而将负压力施加到血栓栓塞 100 以便将血栓材料吸入导管 14。

如图 24 所示，分离器 16a 从输送及吸取导管 14 的远端部展开并且移动成与血栓栓塞材料 100 接触。如果需要，可以将分离器推进和收回多次。当如图所示地推进和收回时，分离器可以以一种或多种方式促进将血栓栓塞材料吸取到导管 14 内。首先，与血栓栓塞接触的分离器的移动可以松动、分离或者软化血栓栓塞材料片，以使血栓栓塞片可以吸取到导管内。第二，推进和收回分离器 16a 用于去除由于血栓栓塞材料经管腔 36 通过引起的输送及吸取导管 14 的管腔 36 内的阻塞或者流动限制。此外，在剥离器 16a 的收回过程中，其近端表面 35 将松动的材料推向或者插向和/或推入或者插入导管 14 的远端部以便后续吸取出体外。

如果刚才描述的剥离器 16a 的使用表明血管包括在不进一步介入的情况下不能吸取的血栓栓塞材料硬块，优选将剥离器 16a 从导管 14 抽出并且将血栓栓塞接收器 146 通过输送及吸取导管 14 并在血管内展开。如果系统设置多个尺寸的接收器，医生选择对于正治疗的血管具有适当尺寸的接收器。

参见图 25–图 28，一旦接收器 146 展开，其膨胀成与周围的血管壁接触。随着接收器 146 朝主体血栓栓塞材料 200 推进，接收器 146

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的壁在主体 200 周围滑动以便啮合和/或包围（部分或全部）血栓栓塞。啮合元件 170 啮合血栓栓塞 200，由此将其保持在接收器内。如果需要，可以如图 27 的箭头所指示的，在远端方向上略微推进输送及吸取导管 14，以便彼此朝向地“紧握”支柱构件 162，因而使接收器 146 在径向向内的方向上略微收缩。此外，可以激活吸取泵 18（图 1）以便于将血栓栓塞 200 保持在接收器。输送及吸取导管 14、接收器 146 以及血栓栓塞 100 抽回到导引及阻塞导管 12 并从身体抽回。如果其他血栓栓塞材料剩余在血管中，可以将新的输送及吸取导管 14 通入血管内，并将新的接收器经导管 14 展开以便收回其他血栓栓塞材料主体。

自然地，医生可以选择初始展开接收器，而不是分离器，例如如果初始评定结果确定血栓栓塞材料可能是硬的。随后如前面段落所描述的使用接收器 146 执行该方法。如果后续确定在血管中存在残留血栓栓塞材料（例如，软的或凝胶状材料），优选从身体取出接收器 146，并将分离器 16a 通过输送及吸取导管 14。激活吸取泵 18 并操纵分离器 16a 以便以上述方式促进软材料的吸取。

尽管本发明容易受到各种修改和备选形式的影响，但是已经在附图中以实例形式显示了特定实施例并在本申请中进行了详细描述。然而，应该理解特定实施例的描述并不倾向于将本发明局限于所公开的特殊形式，而恰恰相反，本发明覆盖落入本发明的精神和范围内的所有修改、等同物以及备选方案。

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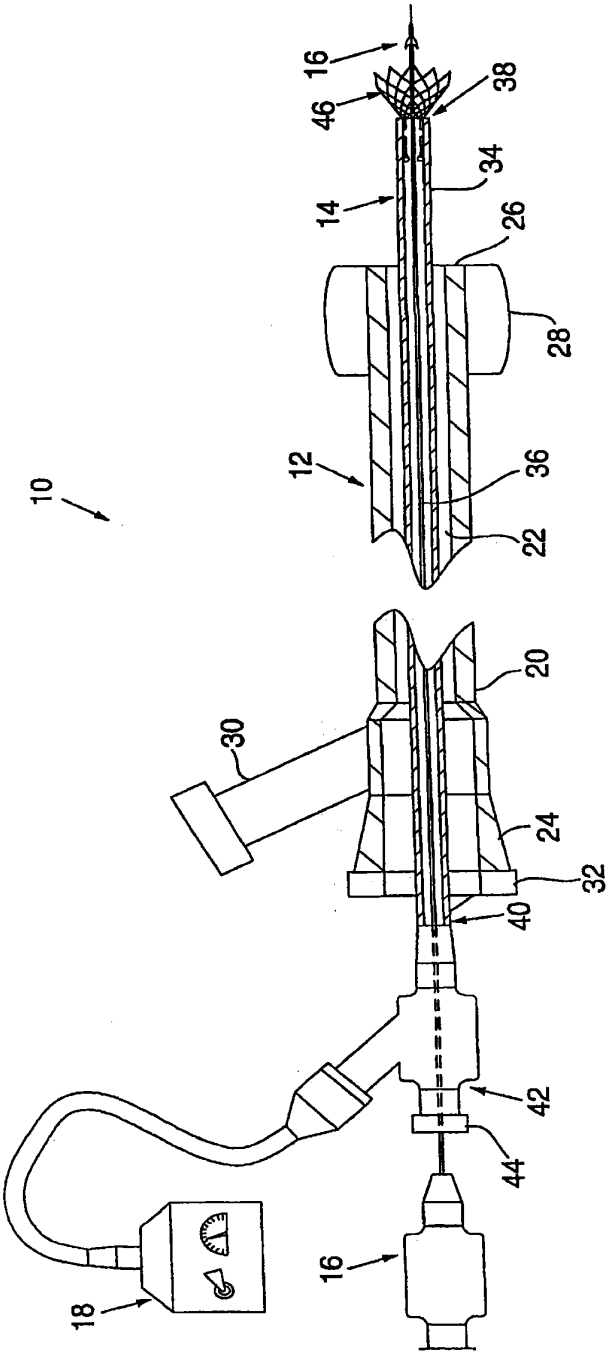


图 1

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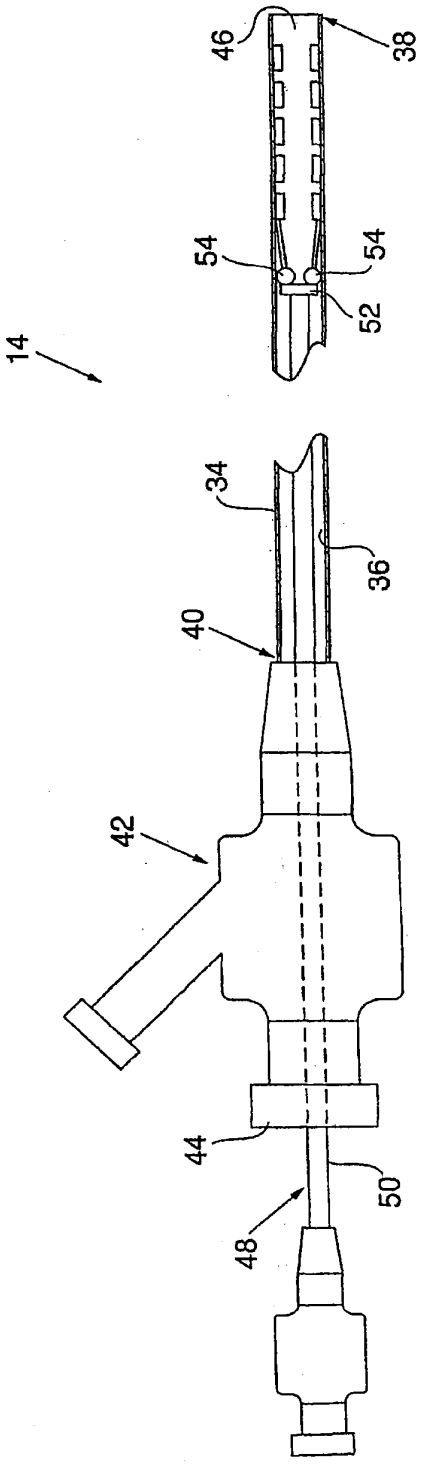


图 2

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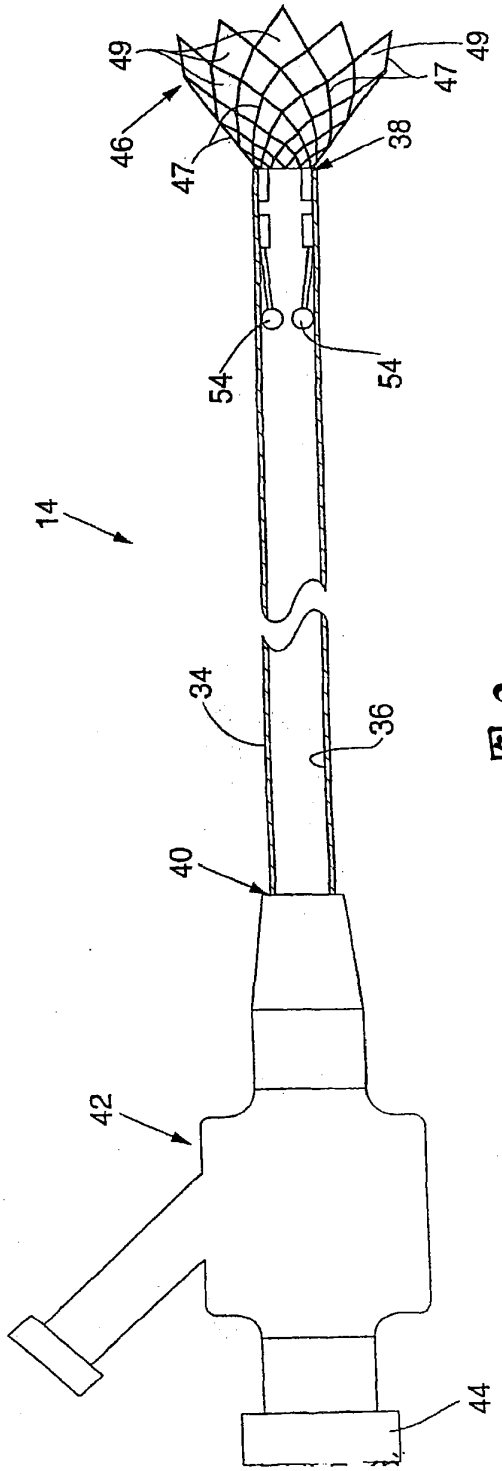


图 3

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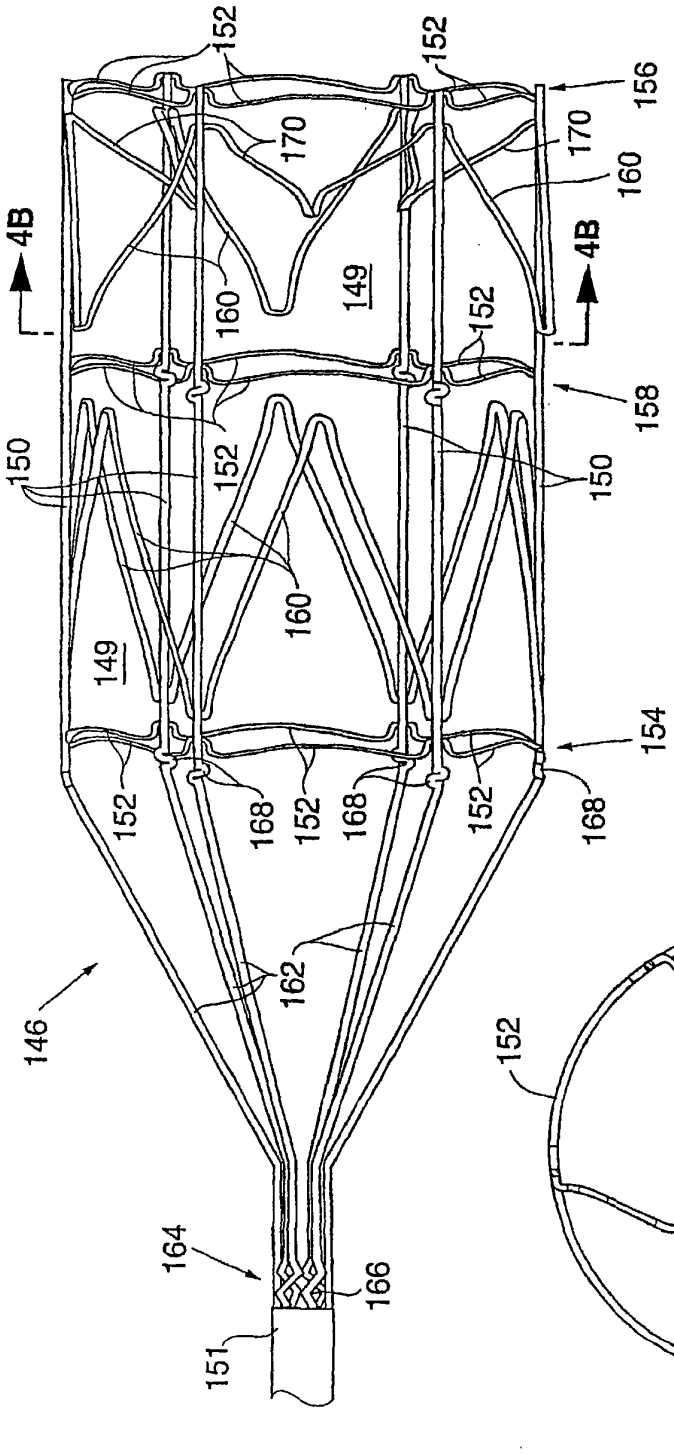


图 4A

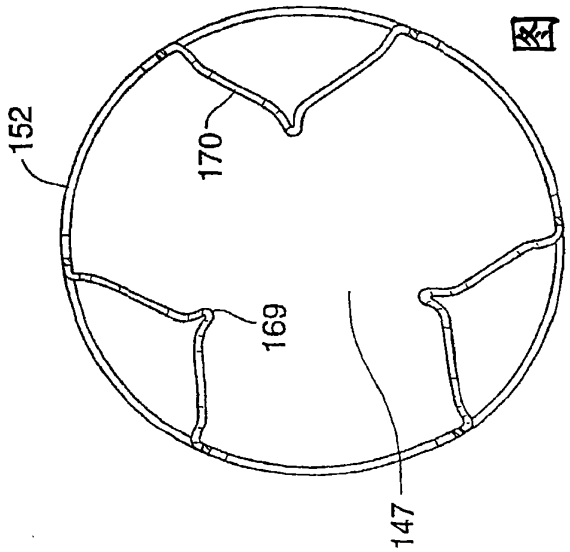


图 4B

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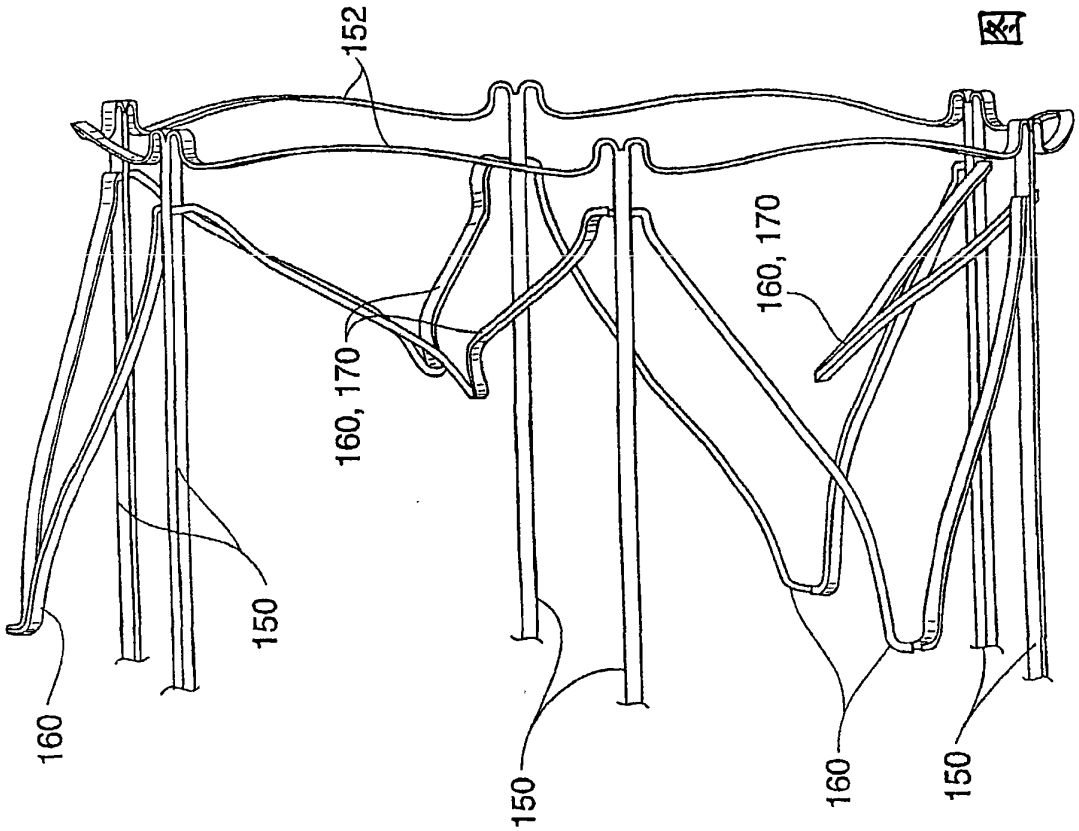


图 4C

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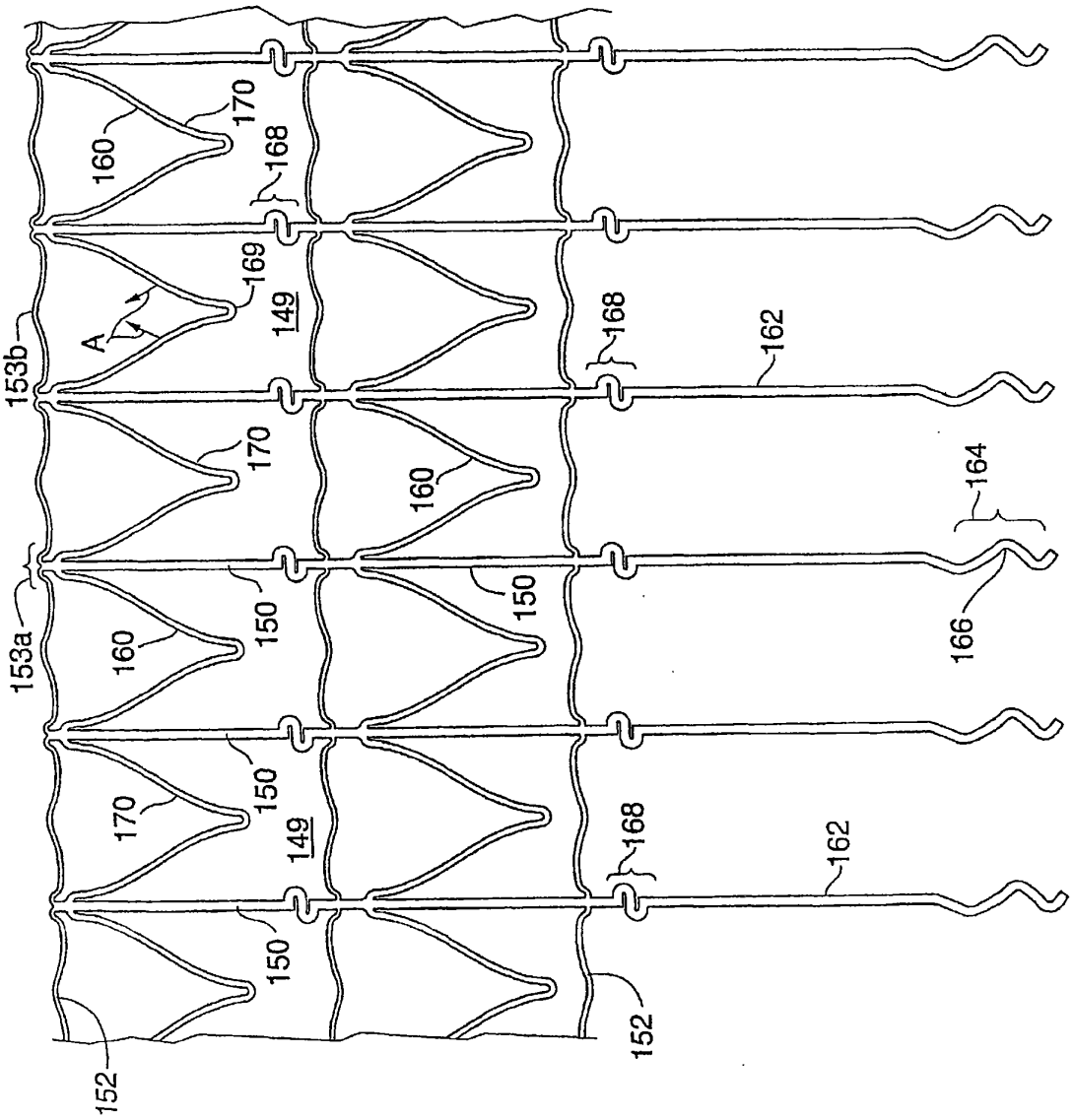


图 5

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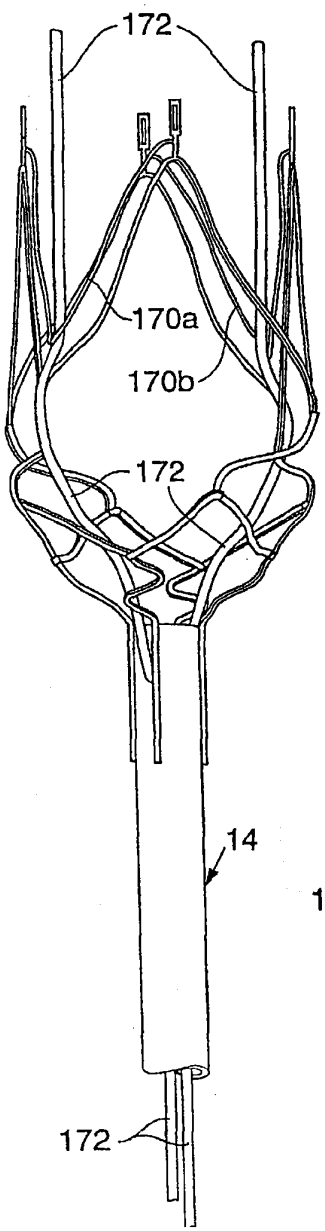


图 7

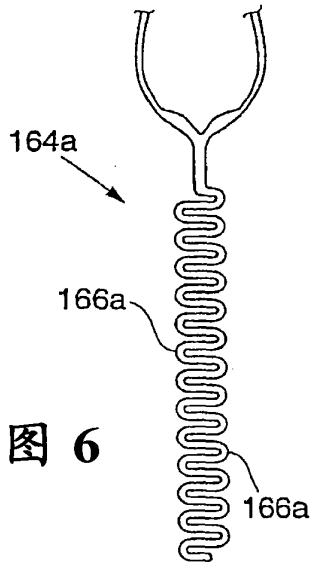


图 6

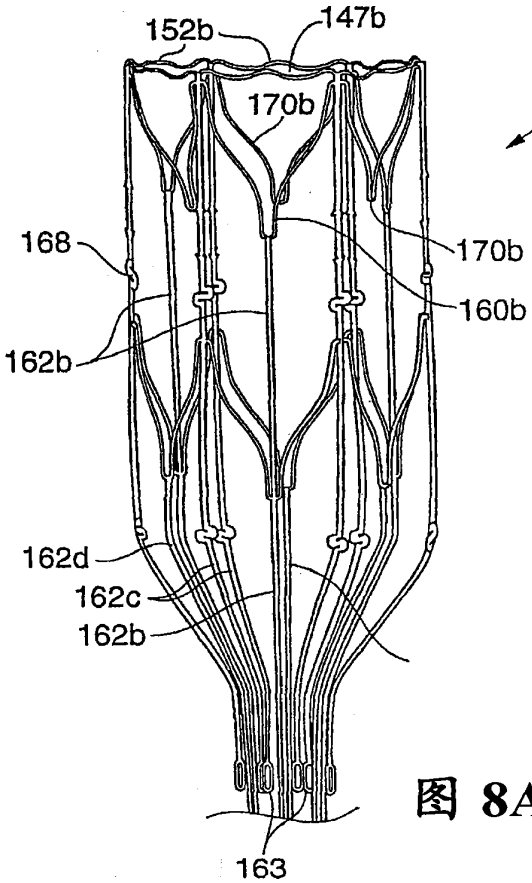


图 8A

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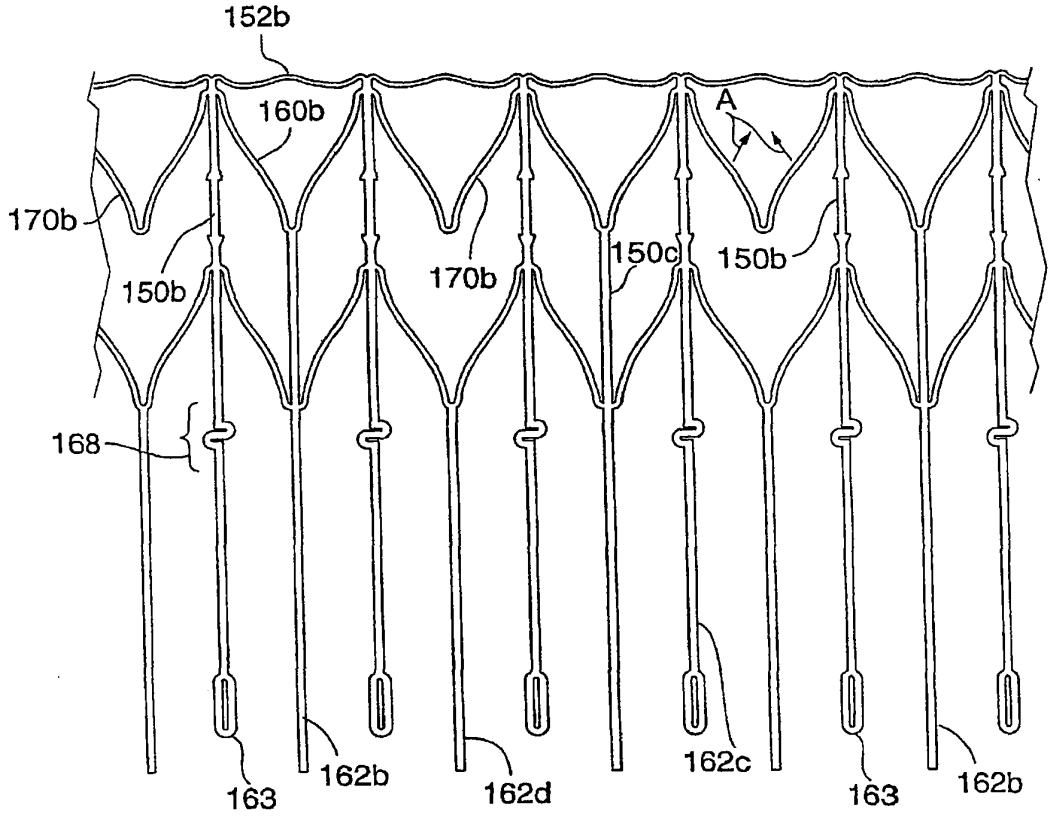


图 8B

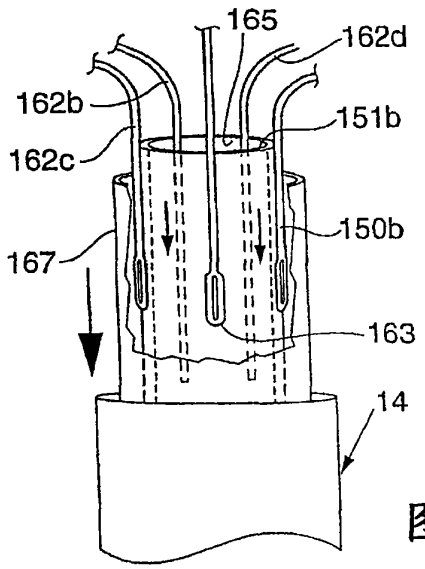


图 8C

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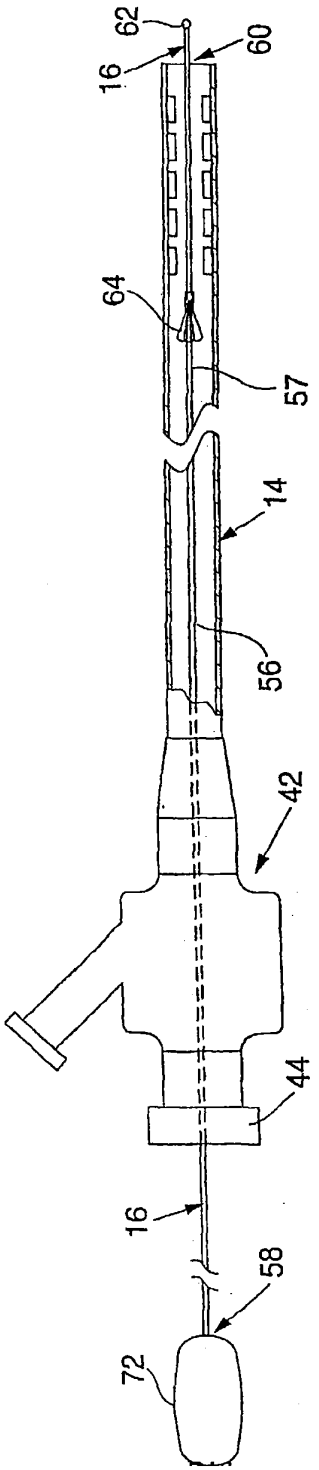


图 9

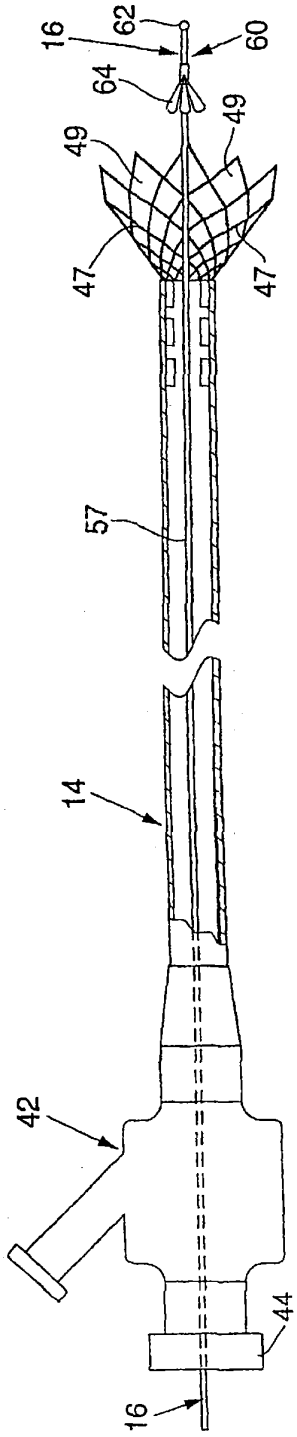


图 10

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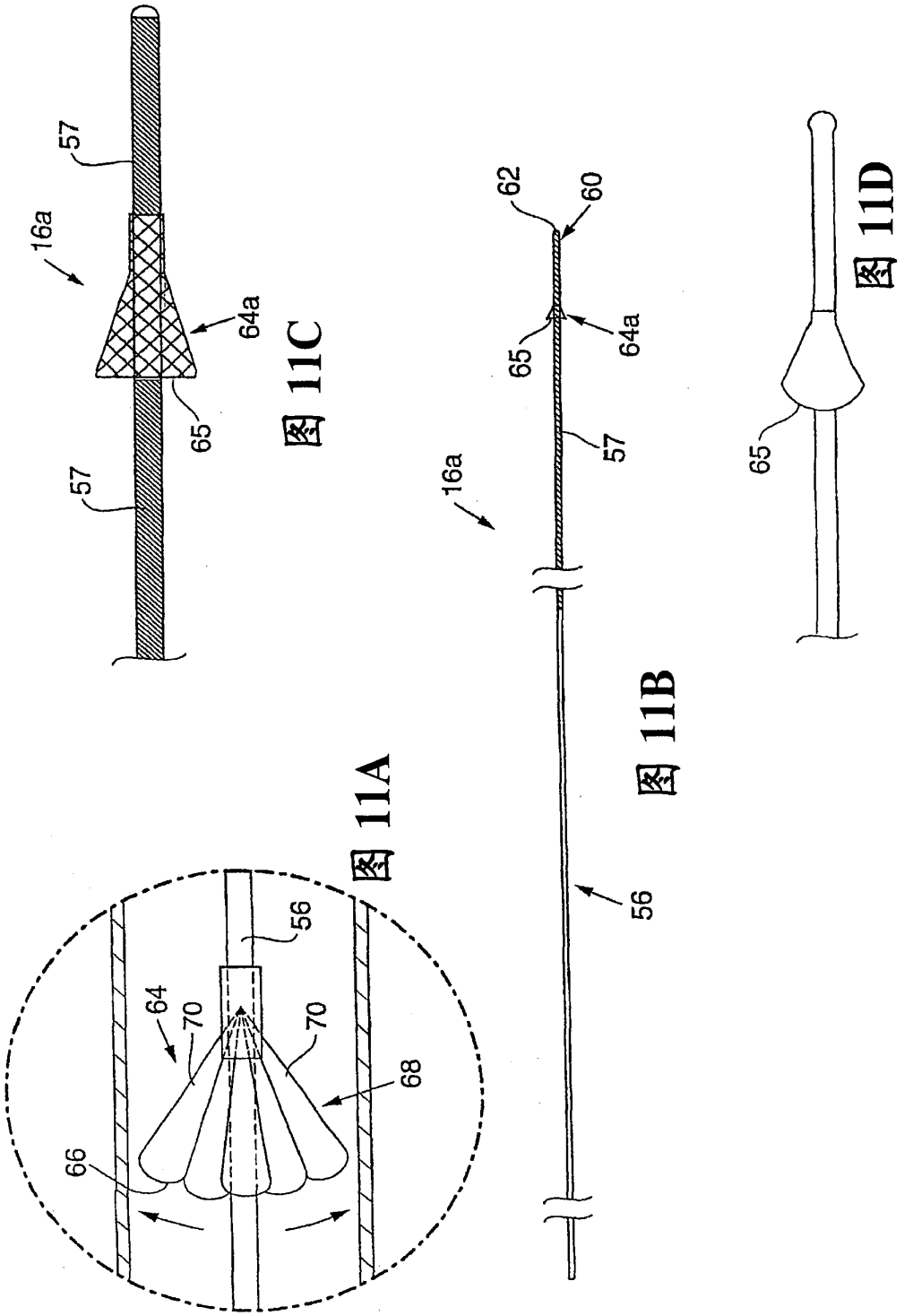


图 11C

图 11B

图 11D

图 11A

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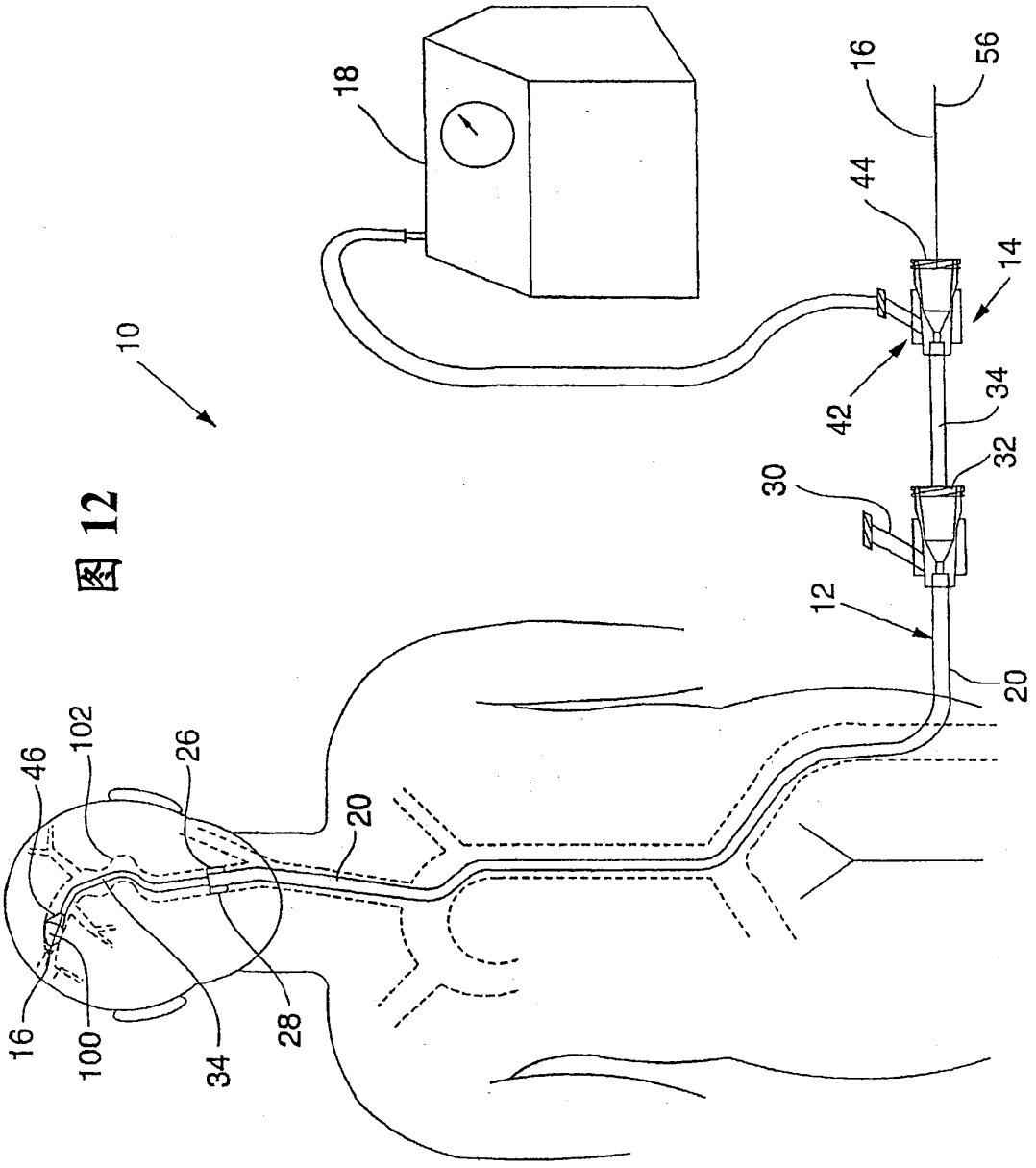


图 12

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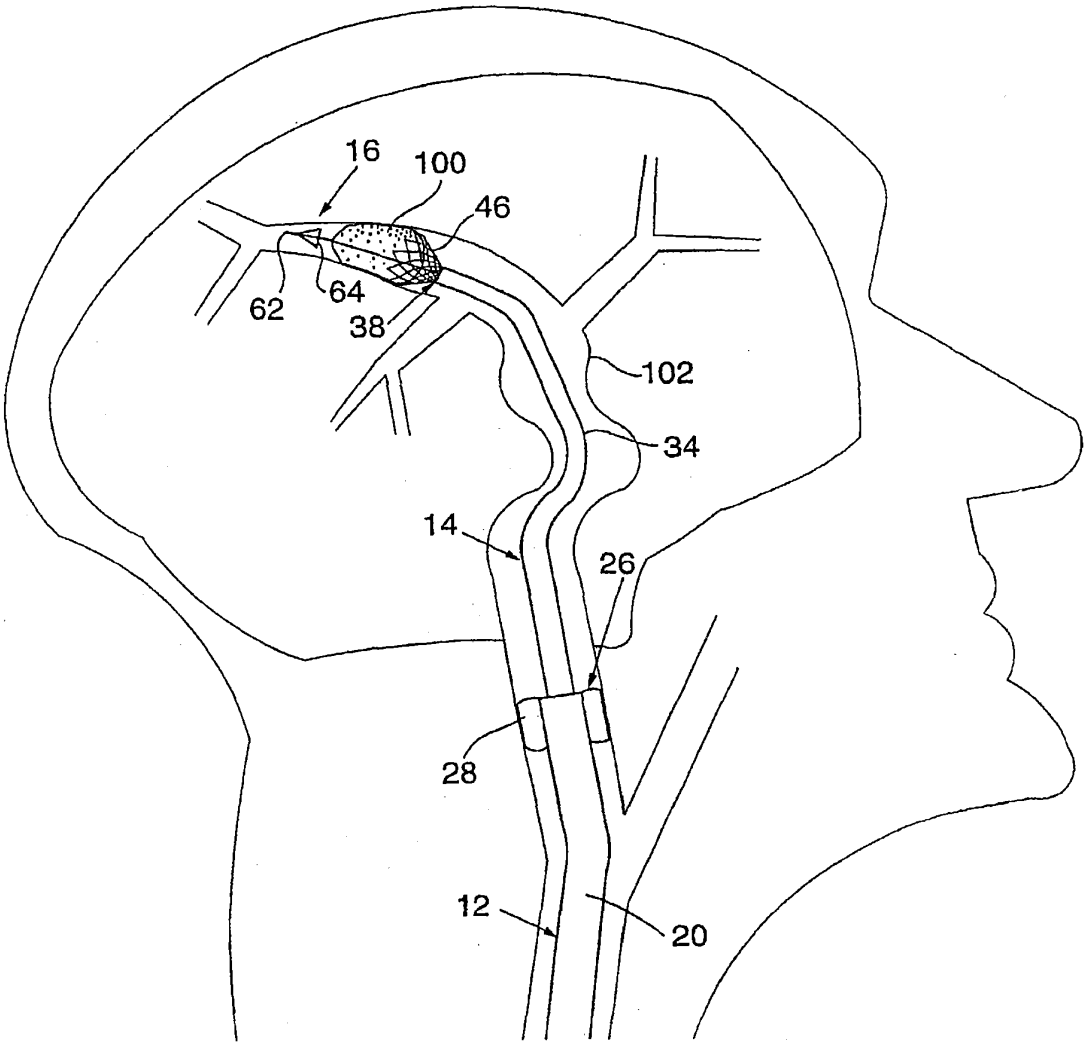


图 13

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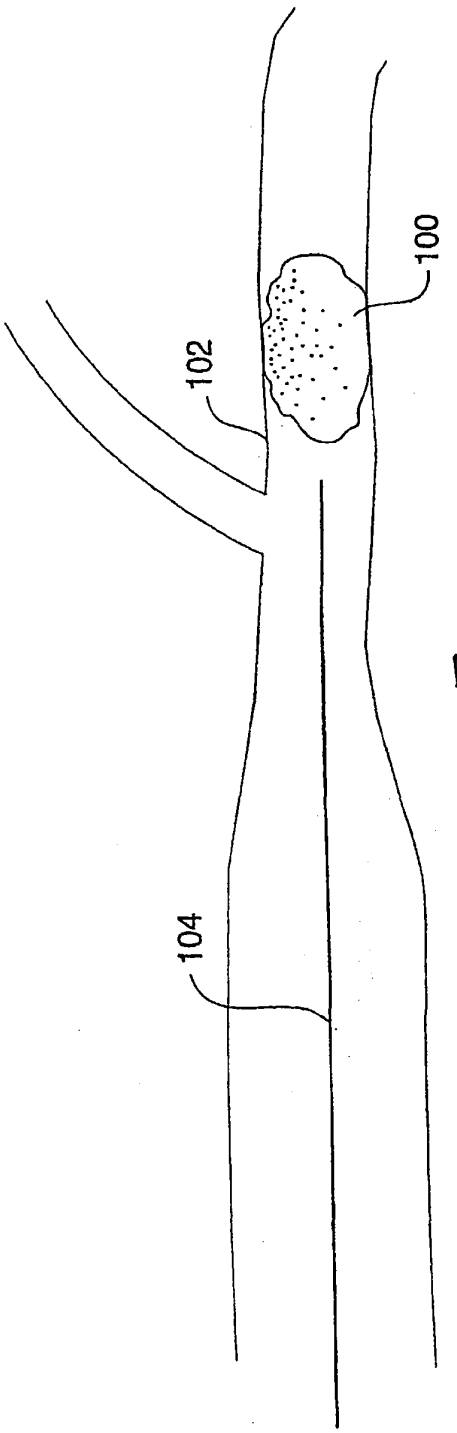


图 14

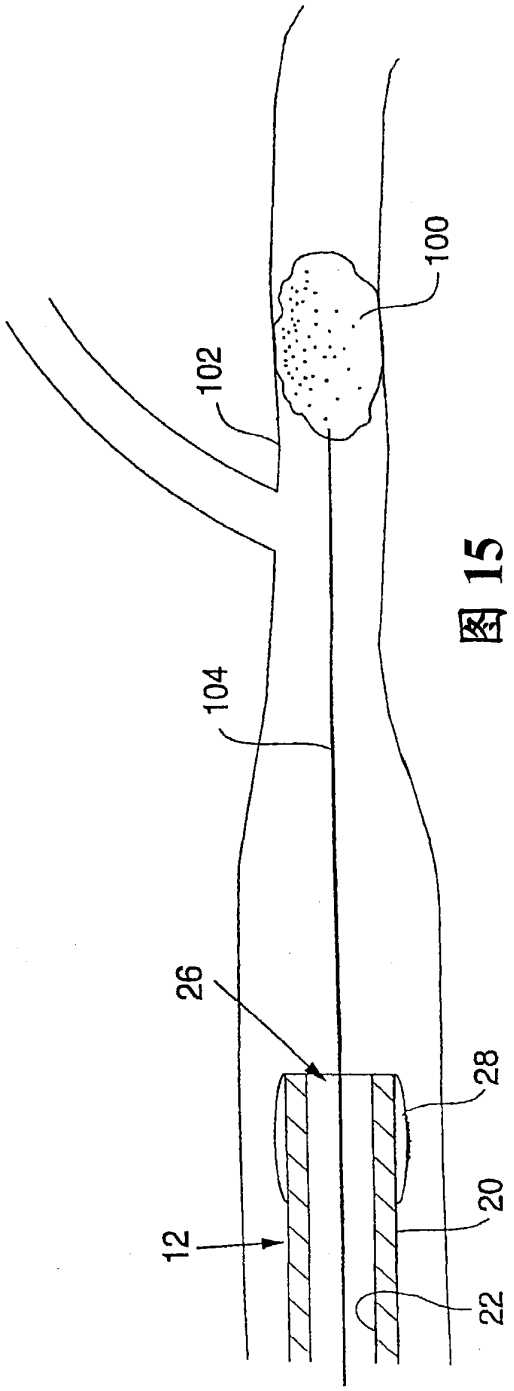


图 15

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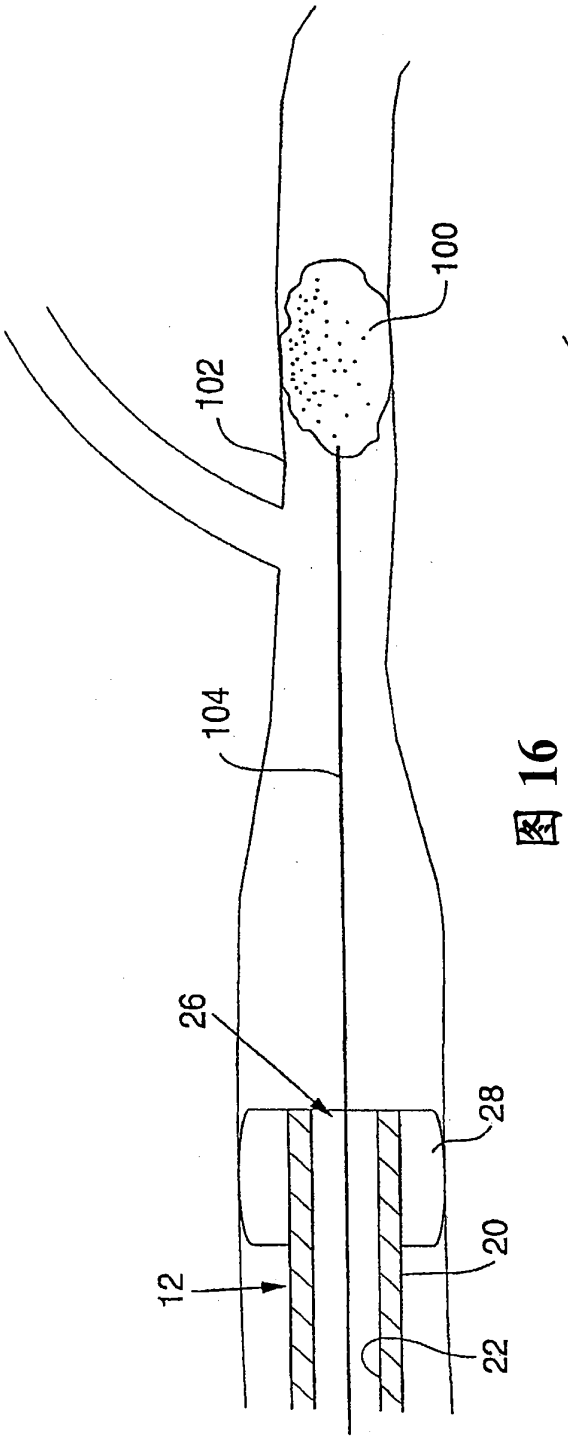


图 16

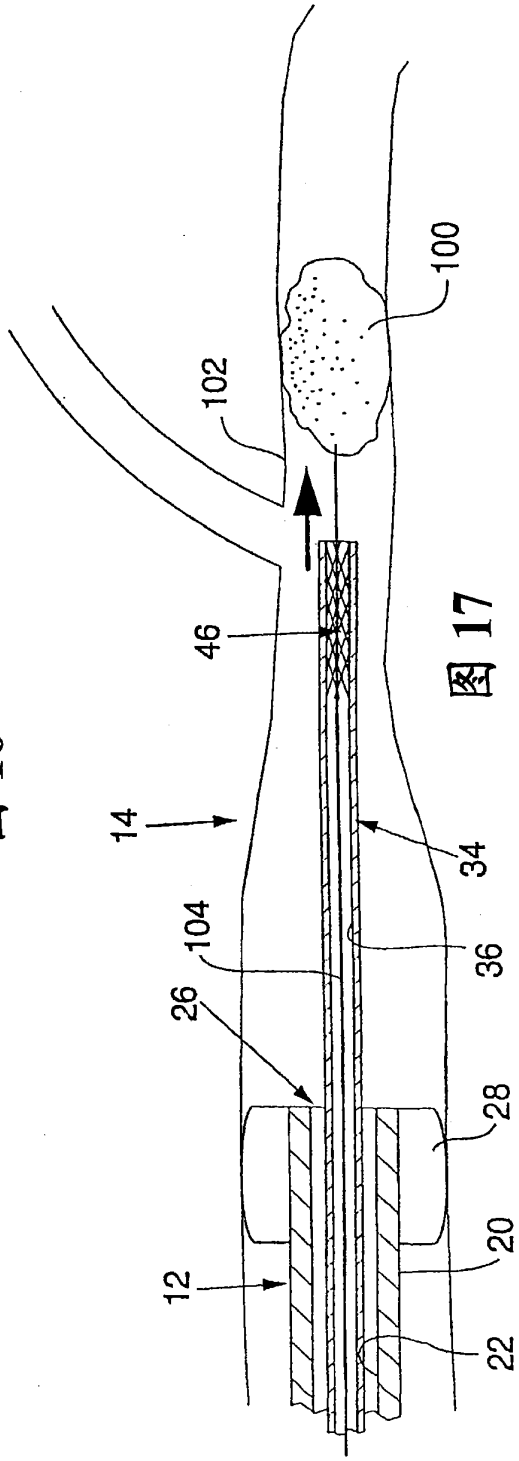


图 17

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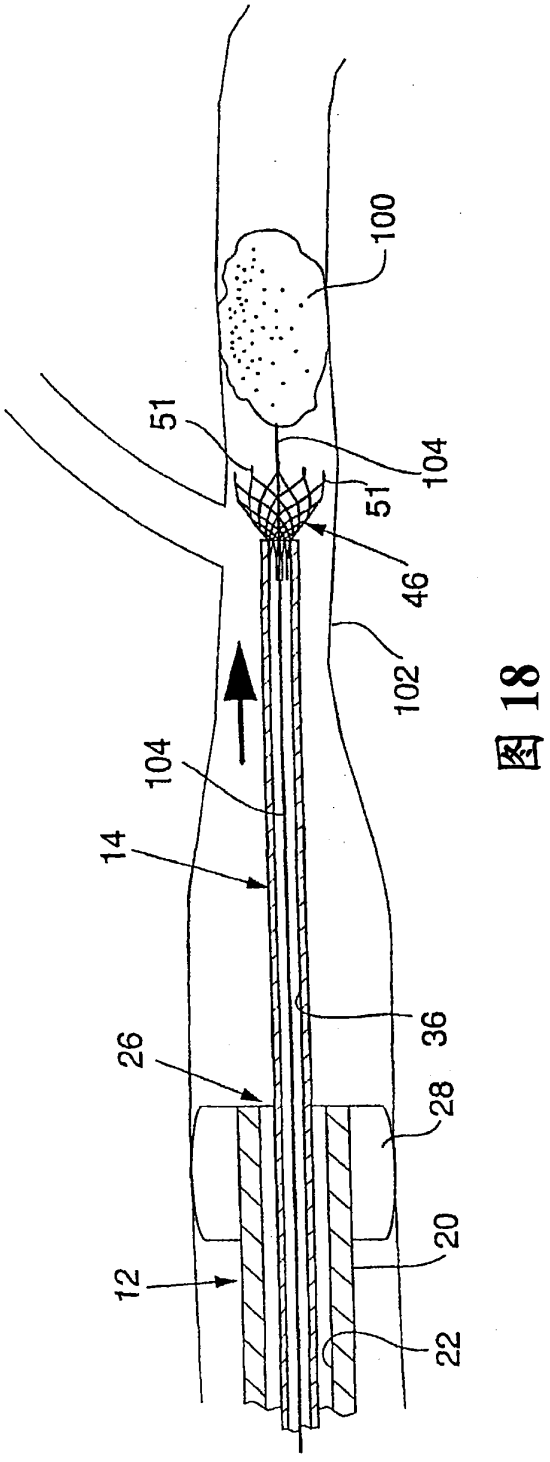


图 18

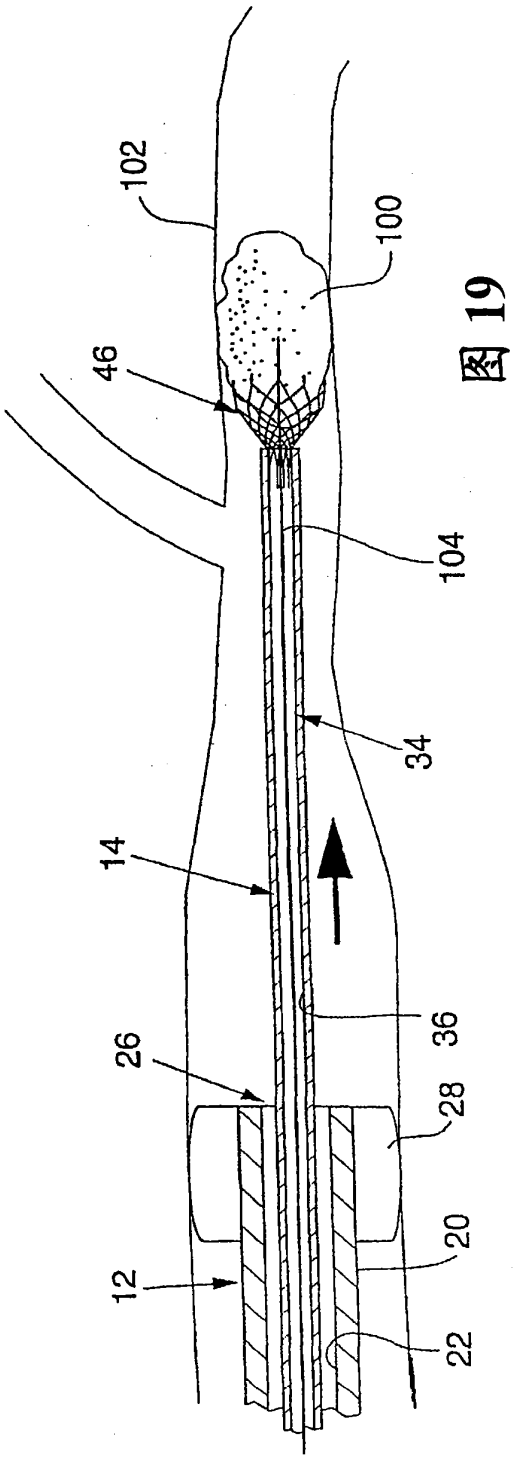


图 19

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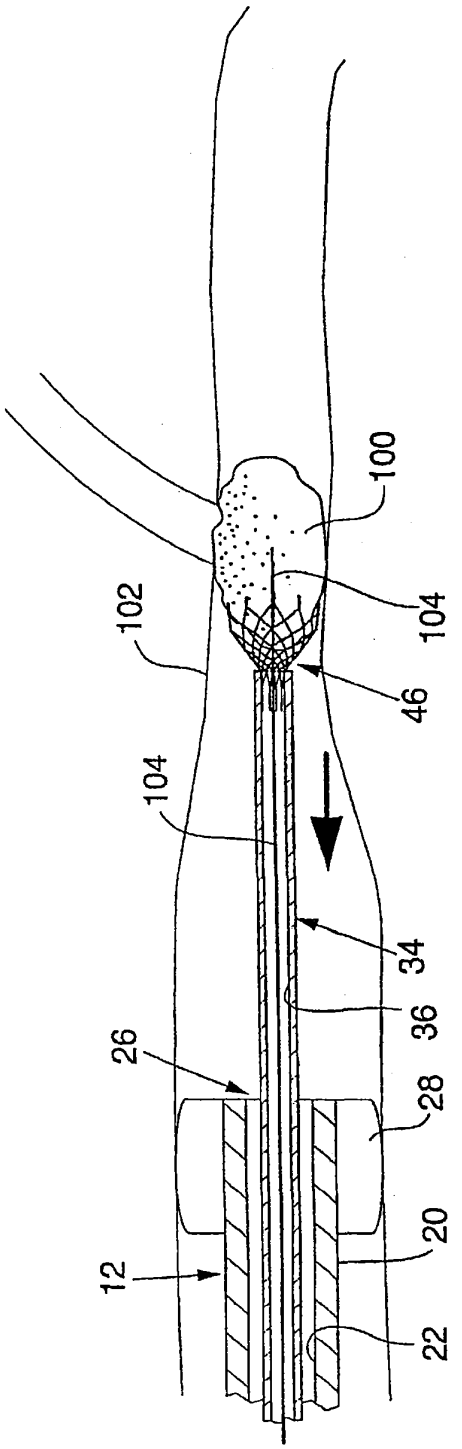


图 20

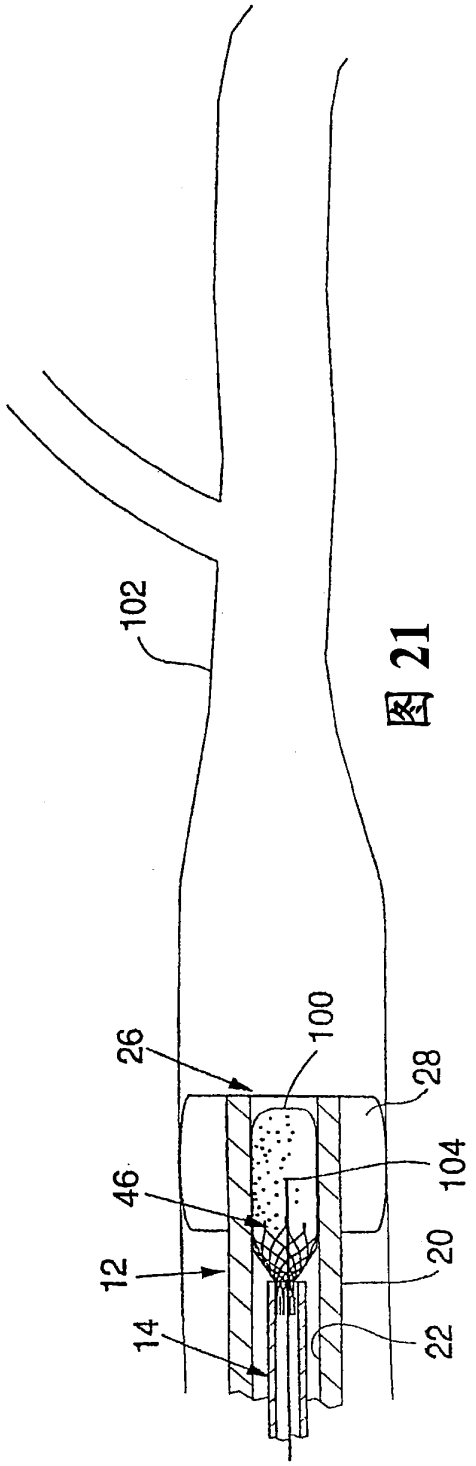


图 21

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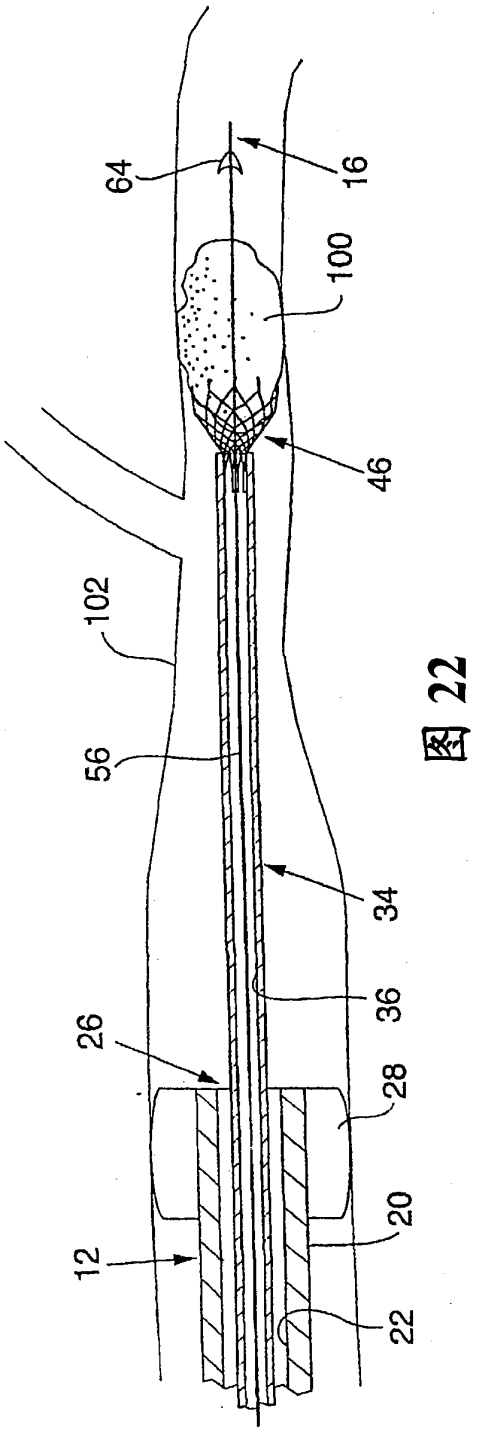


图 22

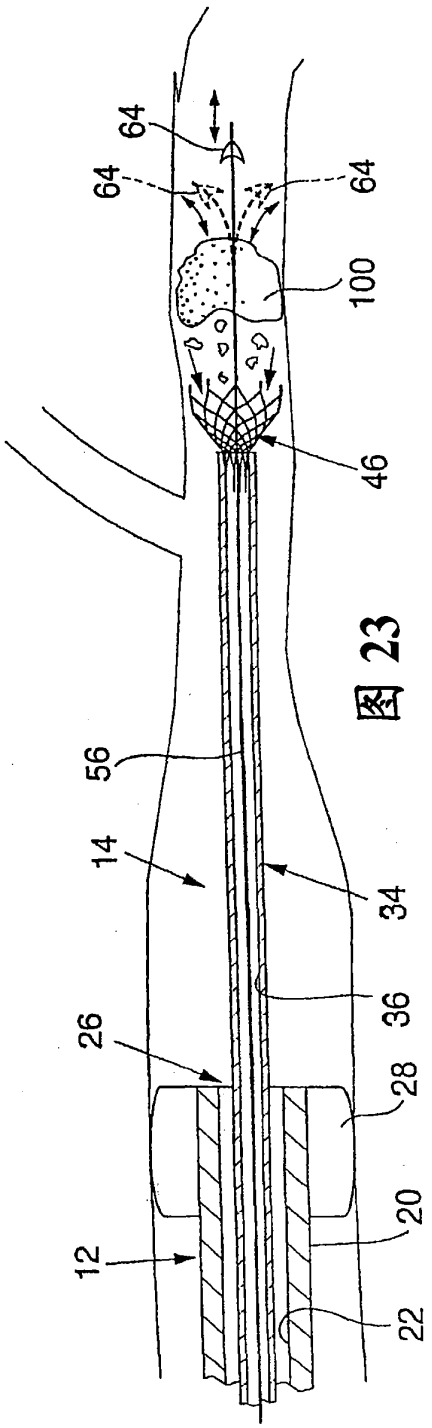


图 23

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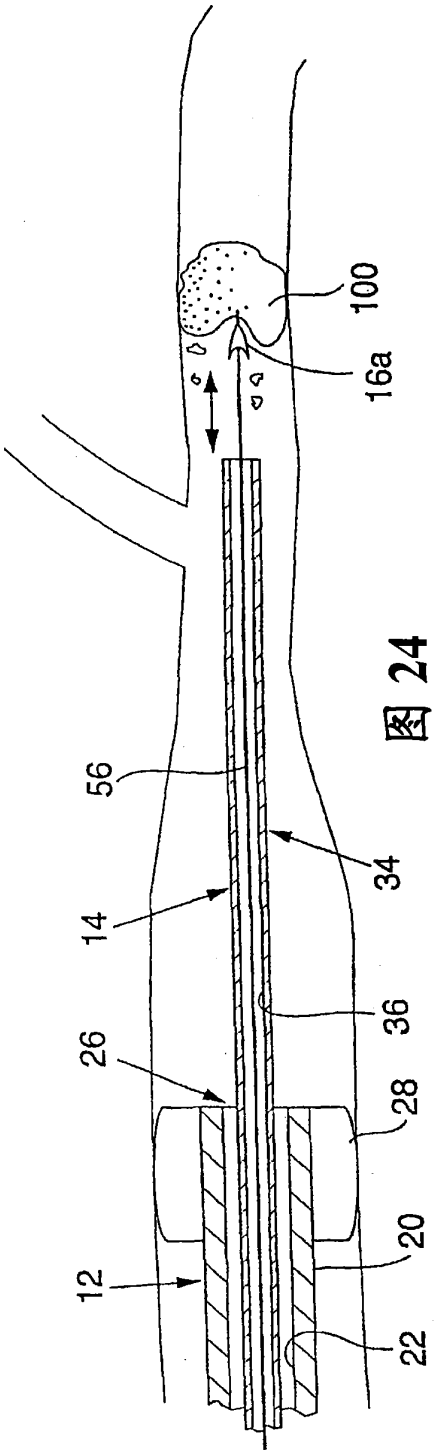


图 24

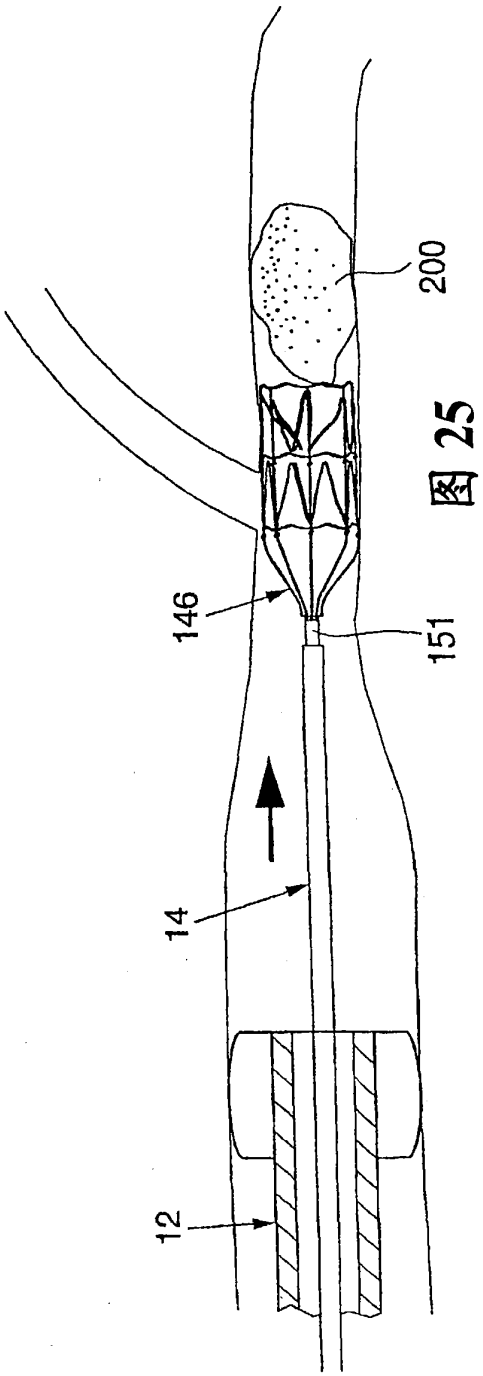


图 25

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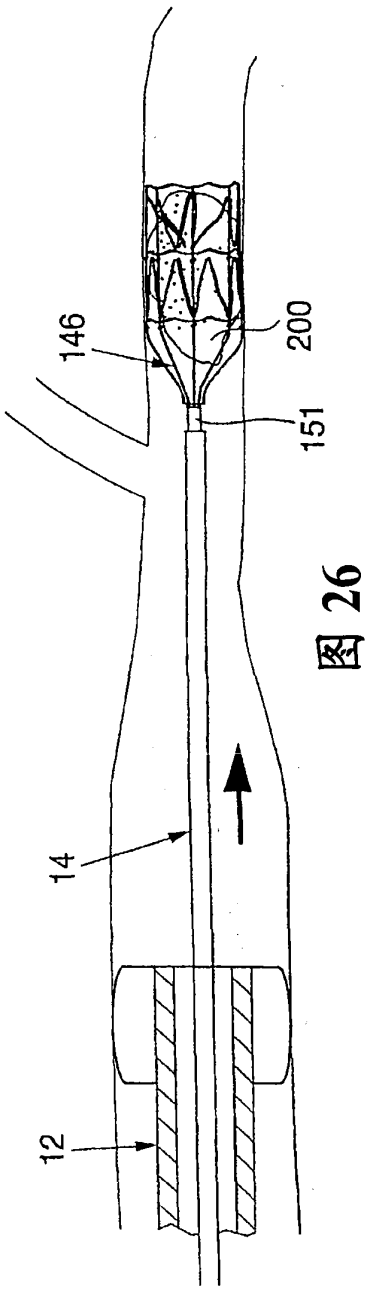


图 26

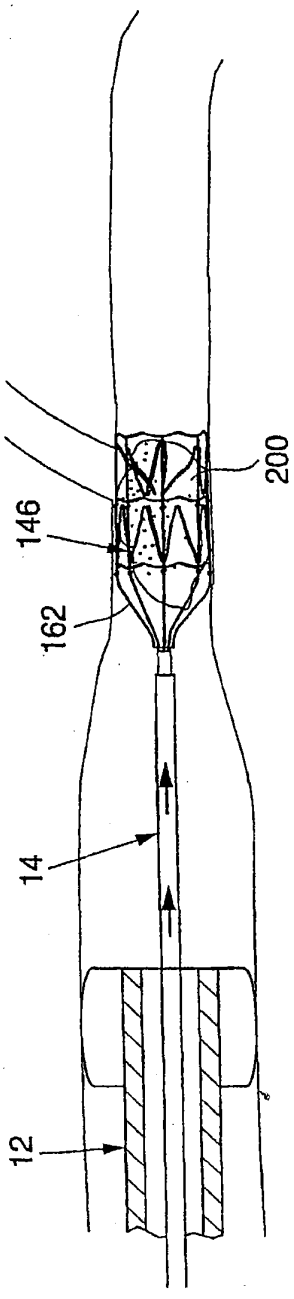


图 27

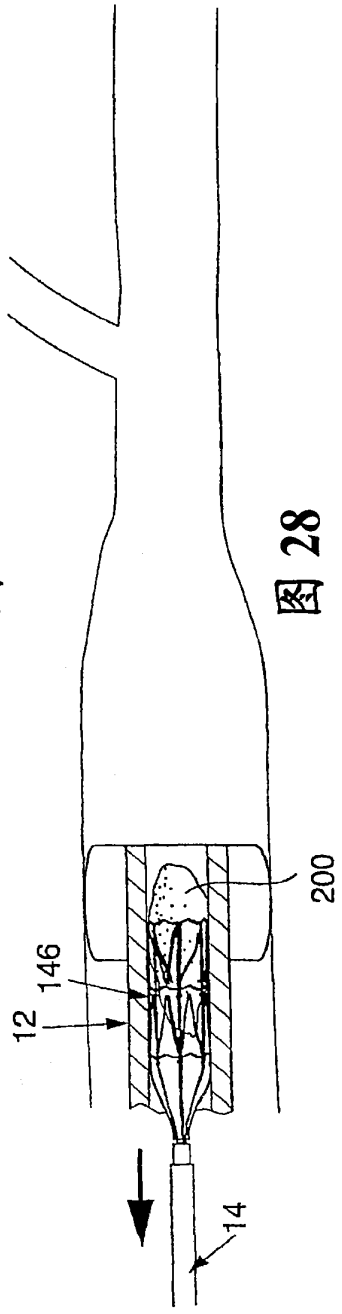


图 28

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(54) **SYSTEM FOR TREATING ISCHEMIC STROKE**

SYSTEM ZUR BEHANDLUNG VON ISCHÄMISCHEM SCHLAGANFALL

SYSTEME POUR TRAITER UN ACCIDENT ISCHEMIQUE CEREBRAL

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US-A1- 2003 163 158
US-B1- 6 517 551

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Description

[0001] The present invention relates to a system for removing thromboembolic material from a cerebral blood vessel, the system comprising a delivery catheter having a lumen including a distal end having a fixed inner diameter, an elongate member extendable through the said lumen and including a distal portion and having a separator element on the distal portion, the separator element being a broadened element and having a maximum diameter portion having a maximum diameter smaller than the said fixed inner diameter, and an aspiration source fluidly coupled to the said lumen.

[0002] Stroke is a leading cause of death and disability and a growing problem to global healthcare. In the US alone, over 700,000 people per year suffer a major stroke and, of these, over 150,000 people die. Even more disturbing, this already troubling situation is expected to worsen as the "baby boomer" population reaches advanced age, particularly given the number of people suffering from poor diet, obesity and/or other contributing factors leading to stroke. Of those who survive a stroke, approximately 90% will have long-term impairment of movement, sensation, memory or reasoning, ranging from mild to severe. The total cost to the US healthcare system is estimated to be over $50 billion per year.

[0003] Strokes may be caused by a rupture of a cerebral artery ("hemorrhagic stroke") or a blockage in a cerebral artery due to a thromboembolism ("ischemic stroke"). A thromboembolism is a detached blood clot that travels through the bloodstream and lodges so as to obstruct or occlude a blood vessel. Between the two types of strokes, ischemic stroke comprises the larger problem, with over 600,000 people in the US suffering from ischemic stroke per year.

[0004] Ischemic stroke treatment may be accomplished via pharmacological elimination of the thromboembolism and/or mechanical elimination of the thromboembolism. Pharmacological elimination may be accomplished via the administration of thombolytics (e.g., streptokinase, urokinase, tissue plasminogen activator (TPA) and/or anticoagulant drugs (e.g., heparin, warfarin) designed to dissolve and prevent further growth of the thromboembolism. Pharmacologic treatment is non-invasive and generally effective in dissolving the thromboembolism. Notwithstanding these generally favourable aspects, significant drawbacks exist with the use of pharmacologic treatment. One such drawback is the relatively long amount of time required for the thrombolytics and/or anticoagulants to take effect and restore blood flow. Given the time-critical nature of treating ischemic stroke, any added time is potentially devastating. Another significant drawback is the heightened potential of bleeding or hemorrhaging elsewhere in the body due to the thombolytics and/or anticoagulants.

[0005] Mechanical elimination of thromboembolic material for the treatment of ischemic stroke has been attempted using a variety of catheter-based transluminal interventional techniques. One such interventional technique involves deploying a coil into a thromboembolism (e.g. via corkscrew action) in an effort two ensnare or envelope the thromboembolism so it can be removed from the patient. Although an improvement over pharmacologic treatments for ischemic stroke, such coil-based retrieval systems have only enjoyed modest success (approximately 55%) in overcoming ischemic stroke due to thromboembolic material slipping past or becoming dislodged by the coil. In the latter case, the dislodgement of thromboembolic material may lead to an additional stroke in the same artery or a connecting artery.

[0006] Another interventional technique involves deploying a basket or net structure distally (or downstream) from the thromboembolism in an effort to ensnare or envelope the thromboembolism so it can be removed from the patient. Again, although overcoming the drawbacks of pharmacologic treatment, this nonetheless suffers a significant drawback in that the act of manipulating the basket or net structure distally from the occluded segment without angiographic roadmap visualization of the vasculature increases the danger of damaging the vessel. In addition, removing the basket or net structure may permit if not cause thromboembolic material to enter into connecting arteries. As noted above, this may lead to an additional stroke in the connecting artery.

[0007] A still further interventional technique for treating ischemic stroke involves advancing a suction catheter to the thromboembolism with the goal of removing it via aspiration (i.e. negative pressure). Although generally safe, removal via aspiration is only effective with relatively soft thrombus-emboli. To augment the effectiveness of aspiration techniques, a rotating blade has been employed to sever or fragment the thromboembolism, which may thereafter be removed via the suction catheter. While this rotating blade feature improves the effectiveness of such an aspiration technique, it nonetheless increases the danger of damaging the vessel due to the rotating blade. Systems with rotatable cutting elements for removing occluding material are also described in US patent application publications US 2002/0147459 and US 2003/0078606. US 2002/0072764 described a system in which the separator element is a coiled element that expands to a maximum diameter greater than that of the microcatheter from which is extended. A mechanical capture element is used to hold thromboembolic material as it is withdrawn from the blood vessel.

[0008] The foregoing interventional techniques, as well as others in the prior art, all suffer one or more drawbacks and are believed to be sub-optimal for treating ischemic stroke. A system of the kind defined hereinbefore at the beginning is described in US 2002/0147459. According to the present invention a system of the kind defined hereinbefore at the beginning is **characterised in that** the distal portion has a distal end and the separator element is in a fixed position on the distal portion and spaced proximally from the distal end, the portion of the elongate member between the separator element

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and the distal end being sufficiently flexible to be movable atraumatically through a cerebral blood vessel without folding; in that the separator element is of substantially solid conical form with a tapered distal portion and a proximal portion with a proximally-facing surface; and in that tolerance between the maximum diameter portion of the separator element and the said fixed inner diameter is tight and the separator element is advanceable from and retractable into the lumen during aspiration using the aspiration source.

[0009] The invention will now be described by way of example with reference to the accompanying drawings, wherein like reference numerals are applied to like elements and wherein:

Figure 1 is a partial sectional side view of one embodiment of a thromboembolic removal system, including a guide and occlusion catheter, a delivery and aspiration catheter, an aspiration pump, a thromboembolic receiver, and a thromboembolic separator;

Figure 2 is a partial sectional side view of a delivery and aspiration catheter forming part of the thromboembolic removal system shown in Figure 1, illustrating a thromboembolic receiver element in an undeployed state;

Figure 3 is a partial sectional side view of a delivery and aspiration catheter forming part of the thromboembolic removal system shown in Figure 1, illustrating the thromboembolic receiver element in a deployed state;

Figure 4A is a perspective view depicting an alternate embodiment of a thromboembolic receiver, equipped with a plurality of engagement elements;

Figure 4B is a cross-section view taken along the plane designated 4B-4B in Figure 4A;

Figure 4C is a perspective view illustrating the distal portion of the thromboembolic receiver of Figure 4A;

Figure 5 is a plan view of the alternate thromboembolic receiver of Figure 4. Although the receiver is preferably a tubular structure, Figure 5 shows it opened and flattened into a sheet so that its features may be more easily viewed;

Figure 6 is a top view illustrating one embodiment of a flex region for use in flexibly coupling the thromboembolic receiver, such as the receiver of FIG. 4A, to an elongate member or a delivery and aspiration catheter;

Figure 7 is a perspective view of an alternate thromboembolic receiver, equipped with a plurality of engagement elements capable of being selectively deployed after the deployment of the thromboembolic receiver;

Figure 8A is perspective view of a thromboembolic receiver having features for facilitating reloading of the receiver into a catheter;

Figure 8B is a plan view similar to the view of Figure 5 showing the thromboembolic receiver of Figure 8A;

Figure 8C is a perspective view of a proximal portion of the thromboembolic receiver of Figure 8A and the distal portion of the elongate member coupled to the thromboembolic receiver, illustrating retraction of the thromboembolic receiver into a delivery and aspiration catheter;

Figures 9 and 10 are partial sectional side views of a thromboembolic disrupter or separator in use with a delivery and aspiration catheter;

Figure 11A is an enlarged view of the separator element forming part of the thromboembolic separator shown in FIGS. 9 and 10;

Figure 11B is a side elevation view of an embodiment of a thromboembolic separator in accordance with the present invention;

Figure 11C is an enlarged view of the separator element forming part of the thromboembolic separator shown in Fig. 11B;

Figure 11D is a side elevation view similar to Fig. 11C showing another alternate embodiment of a thromboembolic separator;

Figure 12 is a partial sectional view of a patient illustrating the thromboembolic removal system of FIG. 1 in use within the arterial system;

Figure 13 is a partial sectional view of a patient illustrating the distal region of the thromboembolic removal system of FIG. 1 in use within a cerebral artery;

Figure 14 is a partial section side view illustrating advancement of a guide wire to a thromboembolism;

Figure 15 is a partial section side view illustrating advancement of the guide and occlusion catheter, with the balloon in a deflated state;

Figure 16 is a partial section side view illustrating inflation of the balloon occlusion member to arrest the blood flow within the artery containing the thromboembolism;

Figure 17 is a partial section side view illustrating the step of advancing the delivery and aspiration catheter of FIGS. 1-3 to a point proximal to the thromboembolism according to a method for using the system of Fig. 1;

Figure 18 is a partial section side view illustrating deployment of the thromboembolic receiver of FIGS. 1-3;

Figure 19 is a partial section side view illustrating advancement of the delivery and aspiration catheter of FIGS. 1-3 distally such that the thromboembolic receiver of FIGS. 1-3 engages (fully or partially) the thromboembolism;

Figures 20 and 21 are partial section side views illustrating movement of the thromboembolic receiver of FIGS. 1-3 into the guide and occlusion catheter so as to remove the thromboembolism;

Figure 22 is a partial section side view illustrating use of the thromboembolic separator of FIGS. 1 and 9-11C to engage the distal end of the thromboembolism;

Figure 23 is a partial section side view illustrating

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use of the thromboembolic separator of FIGS. 1 and 9-11C to fragmentize and/or soften the thromboembolism and/or aid aspiration;

Figure 24 is a partial section view illustrating independent use of the thromboembolic separator of Figs. 1 and 9-11C to fragmentize and/or soften the thromboembolism and/or aid aspiration;

Figures 25 and 26 are partial section side views illustrating advancement of the thromboembolic receiver of FIGS. 4 - 6 distally such that it envelopes the thromboembolism; and

Figures 27 and 28 are a partial section side views illustrating withdrawal of the thromboembolic receiver of FIGS. 4 - 6 and the delivery and aspiration catheter into the guide and occlusion catheter so as to remove the thromboembolism.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0010] Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure. The thromboembolic removal system disclosed herein boasts a variety of inventive features and components that warrant patent protection, both individually and in combination.

System Features

[0011] FIG. 1 illustrates an exemplary embodiment of a thromboembolic removal system 10. The thromboembolic removal system 10 includes a guide and occlusion catheter 12, a delivery and aspiration catheter 14, a thromboembolic disrupter or separator 16, and an aspiration pump 18. As will be described in greater detail below, the thromboembolic removal system 10 advantageously provides the ability to remove a thromboembolism from a cerebral artery within a patient while overcoming the drawbacks and limitations of the prior art.

[0012] The guide and occlusion catheter 12 includes a tubular catheter member 20 having a main lumen 22 extending between a proximal end 24 and a distal end 26. The catheter member 20 may be constructed from any number of compositions having suitable biocompatibility and strength characteristics, and may be dimensioned in any number of suitable sizes and lengths depending upon the entry point into the vasculature, the location of the thromboembolism, variances in patient anatomy, and any extenuating circumstances. In an exemplary embodiment, the catheter member 20 may be constructed from nylon with embedded stainless steel braid and dimensioned having a length ranging from 70 cm to 110 cm and a diameter ranging from 5 French (0.065 inch) to 9 French (0.117 inch). A balloon occlusion member 28 is disposed at or near the distal end 26. To selectively inflate the occlusion member 28, an inflation port 30 is provided in fluid communication with the occlusion member 28 via at least one lumen (not shown) disposed within the wall of the tubular catheter member 20. A seal 32 is provided for passing the delivery and aspiration catheter 14 through the main lumen 22 of the guide and occlusion catheter 12 in leak-free, hemostatic fashion.

[0013] The delivery and aspiration catheter 14 includes a tubular catheter element 34 having a main lumen 36 extending between a distal end 38 and a proximal end 40. The catheter member 34 may be constructed from any number of compositions having suitable biocompatibility and strength characteristics, and may be dimensioned in any number of suitable sizes and lengths depending upon the entry point into the vasculature, the location of the thromboembolism, variances in patient anatomy, and any extenuating circumstances. In an exemplary embodiment, the catheter member 34 may be constructed from pebax with embedded stainless steel braid and dimensioned having a length ranging from 130 cm to 170 cm and a diameter ranging from 2.5 French (0.032 inch) to 5 French (0.065 inch).

[0014] The delivery and aspiration catheter 14 also includes a hub assembly 42 coupled to the proximal end 40 for the purpose of coupling the lumen 36 to the aspiration pump 18. The hub assembly 42 also includes a seal 44 for allowing the passage of the thromboembolic separator 16 (as well as any pushing devices to deploy a receiver element 46, as will be discussed below) through the lumen 36 in leak-free, hemostatic fashion. The lumen is preferably coated with PTFE or another of the various suitable lubricious materials known in the art.

[0015] As best viewed with reference to FIGS. 2-3, the thromboembolic receiver element 46 is capable of being retained in a withdrawn or undeployed state within the lumen 36 (FIG. 2) and selectively pushed out and/or unsheathed from the distal end 38 into a deployed state (FIG. 3). The thromboembolic receiver 46 may be constructed from any number of compositions having suitable biocompatibility and strength characteristics, and may be dimensioned in any number of suitable sizes and lengths depending upon the location of the thromboembolism, variances in patient anatomy, and the size and shape of the thromboembolism. As best viewed in FIGS. 3 and 5, the thromboembolic receiver 46 is formed from a plurality of strut members 47, which upon being deployed, create a multitude of generally diamond-shaped openings 49 along the periphery of the thromboembolic receiver 46. According to one embodiment, as shown in FIGS. 18-23, the resulting points at the distal region of

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the thromboembolic receiver 46 are equipped with blunt tip features 51 to facilitate passage of the thromboembolic receiver 46 through the cerebral artery without snagging or becoming otherwise stuck on the arterial walls or branch vessels leading into the cerebral artery.

[0016] A pusher element 48 may be provided within the catheter element 34 for use in advancing or pushing the receiver element 46 from within the lumen 36 to assume a fully or partially deployed state. By way of example only, the pusher element 48 comprises an elongate member 50 of suitable construction (e.g. wire or wire-wound) having a distal abutment 52 dimensioned to contact proximal terminal(s) 54 forming part of (or coupled to) the receiver element 46. Although not shown, it will be appreciated that the pusher element 48 may comprise any number of suitable devices for pushing the receiver element 46 for deployment, including but not limited to a catheter having a distal end dimensioned to contact the proximal terminal(s) 54 of the receiver element 46. In one embodiment, such a pusher-catheter may have an internally disposed lumen dimensioned to receive and/or pass the thromboembolic separator 16.

[0017] FIG. 4A illustrates a thromboembolic receiver 146 of an alternate embodiment. The thromboembolic receiver 146 may be constructed from any number of compositions having suitable biocompatibility and strength characteristics, and may be dimensioned in any number of suitable sizes and lengths depending upon the location of the thromboembolism, variances in patient anatomy, and the size and shape of the thromboembolism. In a preferred embodiment, the thromboembolic receiver 146 is constructed from Nitinol with "shape memory" or superelastic characteristics. In this fashion, the thromboembolic receiver 146 is capable of being retained in a constrained form or shape prior to deployment. The receiver may be formed by laser cutting features into a length of Nitinol tubing, and then chemically etching and shape-setting the material one or more times using methods known to those skilled in the art.

[0018] Referring to FIG. 4A, receiver 146 is mounted to an elongate member 151 preferably proportioned to extend through lumen 36 (FIG. 1) of the delivery and aspiration catheter 14. Strut members or "legs" 162 extend between receiver 146 and elongate member 151 and are preferably attached to the elongate member 151 using bonding, shrink tubing, or other known methods. In a preferred embodiment, member 151 is an elongate rod, catheter, wire or other elongate member. In this embodiment, the thromboembolic receiver 146 is proportioned so that it may be constrained in a compressed position within the delivery and aspiration catheter 14 (in a manner similar to that shown in FIGS. 1-3). Alternatively, the elongate member 151 may be the delivery and aspiration catheter 14, in which case the receiver 146 and delivery and aspiration catheter 14 are proportioned to extend through the guide and occlusion catheter 12.

[0019] In either event, the thromboembolic receiver 146 may be automatically deployed - due to the shape memory or superelastic characteristics of Nitinol - by simply advancing the thromboembolic receiver 146 out of the element constraining it in the undeployed state (e.g. the guide and occlusion catheter 12 or the delivery and aspiration catheter 14). Once deployed, the thromboembolic receiver 146 may be employed to retrieve a thromboembolism. The dimensions of the receiver 146 are preferably selected such that when it is in an expanded condition at body temperature, the exterior surface of the distal portion of the receiver contacts the surrounding walls of the blood vessel. In one embodiment suitable for most intracranial vessels, the receiver may expand to a maximum outer diameter of approximately 2 - 6 mm, and more preferably 2 - 5 mm. For other applications such as procedures within the common carotid artery, a maximum outer diameter in the range of approximately 6 - 9 mm may be suitable.

[0020] The thromboembolic receiver 146 may be formed having any of a variety of suitable geometries and features without departing from the scope of the present invention. According to one embodiment shown in FIGS. 4A and 5, the thromboembolic receiver 146 is formed from a plurality of strut members, which upon being deployed, create a multitude of generally rectangular openings 149 (best viewed in FIG. 5) along the periphery of the thromboembolic receiver 146. This is accomplished, by way of example, by providing a plurality of longitudinal strut members or "standards" 150 (which are generally parallel to the longitudinal axis of the delivery and aspiration catheter 14), and a plurality of transverse strut members 152 (which extend generally perpendicularly between the adjacent standards). In a preferred embodiment, the strut members collectively define a generally cylindrical distal portion having a central lumen 147 as shown in FIG. 4B.

[0021] The transverse strut members 152 may include any number of curves or undulations, such as curves 153a shown near the points of intersection between the transverse strut members 152 and the standards 150, as well as the curves 153b midway between the points of intersection as shown in FIG. 5. Such curves or undulations help allow the thromboembolic receiver 146 to fold into a compressed or constrained state, which is required in order to dispose the thromboembolic receiver 146 within the delivery and aspiration catheter 14 or within the guide and occlusion catheter 12.

[0022] The transverse strut members 152 form, in a preferred embodiment, a proximal cuff 154 located closest to the delivery and aspiration catheter 14, a distal cuff 156 located at the distal or open end of the thromboembolic receiver 146, and a middle cuff 158 located at some point between the proximal and distal cuffs. Each cuff (proximal 154, middle 158, and distal 156) is a circumferential ring designed to enhance the structural support and stability of the thromboembolic receiver 146, as well as to aid in maintaining the thromboembolic receiver 146 in a desired shape upon deployment (for improved apposition to the vessel wall to optimize thromboembolic

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retrieval).

[0023] The structural support provided by the cuffs 154-158 may be augmented by providing one or more stabilizing strut members 160 within one or more of the generally rectangular openings 149. According to one embodiment, these stabilizing strut members 160 may take the form of a "V" extending from either the proximal end or distal end of a given generally rectangular opening 149 within the thromboembolic receiver 146. In a preferred embodiment, such "V" shaped stabilizing strut members 160 are provided within the proximal and distal set of generally rectangular openings 149 within the thromboembolic receiver 146. This advantageously adds to the structural stability of the proximal and distal regions of the thromboembolic receiver 146. Regardless of their specific shape, the stabilizing strut members 160 preferably include folding regions or apexes 169 that allow them to fold at the apexes 169 (see arrows A in FIG. 5) when the receiver is compressed into the collapsed position. Additionally, the receiver is preferably constructed so as to permit the strut members 160 to fold in the region where they intersect with other elements forming the receiver (e.g. in the FIG. 5 embodiment, the region of intersection between strut members 160 and standards 150).

[0024] While structural stability of the thromboembolic receiver 146 is a desired goal, it is also desired to have certain aspects of flexibility. According to one embodiment, relative flexibility is provided at the junction between the thromboembolic receiver 146 and the elongate member 151 (or the distal end of the delivery and aspiration catheter 14). This is accomplished, by way of example only, by providing the plurality of connector strut members or "legs" 162 extending between the proximal cuff and the elongate member 151 to include (as best viewed in FIG. 5) a flex region 164 near the distal end of the elongate member 151. The flex regions 164 may be formed into any shape that will add flexibility to the strut members 162 without comprising the user's ability to transmit axial forces along the length of the strut members 162. In an alternate embodiment shown in FIG. 6, the flex regions 164a may comprise a plurality of meandering "S" shaped struts 166a at the proximal ends of the connector struts 162. According to another embodiment, a flex region or spring region 168 (FIG. 5) (which may comprise one or more "S" shaped curves or other shapes designed to provide flexibility while maintaining adequate column strength) may be provided at the junction between adjacent longitudinal strut members or standards 150. In both instances, such flex regions 164, 168 are advantageous in that they allow the thromboembolic receiver 146 to better track and follow tortuous vessels without sacrificing needed column strength.

[0025] According to a further embodiment, the thromboembolic receiver 146 may also include a variety of features to augment engagement between the thromboembolic receiver 146 and the thromboembolism. This may be accomplished, by way of example only, by providing a plurality of engagement elements 170 on the thromboembolic receiver. As best viewed in FIGS. 4A, 4B and 5, the engagement elements 170 may, according to one embodiment, take the form of a "V" shaped structure coupled at or near the distal end of the thromboembolic receiver 146 and extending between adjacent standards 150. The engagement elements preferably angle into the lumen 147 of the thromboembolic receiver (see FIGS. 4B and 4C) so as to permit engagement of a thromboembolism captured within the lumen. Any number of engagement elements 170 may be employed without departing from the scope of the present invention. In one embodiment, three (3) separate engagement elements 170 may be employed, each being disposed one hundred and twenty (120) degrees from one another along the periphery of the thromboembolic receiver 146. In a preferred embodiment, the engagement elements 170 take the form of a plurality of the stabilizing strut members 160 as shown in Figs. 4A and 5.

[0026] The engagement elements 170 may be deployed automatically when the thromboembolic receiver 146 is deployed (as shown in FIG. 4-5). In accordance with another aspect of the invention shown in FIG. 7, the engagement elements 170a may also be selectively deployed at any point following the deployment of the thromboembolic receiver 146a. According to the FIG. 7 embodiment, the selective deployment of the engagement elements 170a is accomplished by passing one or more elongate elements 172 through the thromboembolic receiver 146a such that the engagement elements 170a are prevented from extending medially into the lumen of the thromboembolic receiver 146. When deployment is desired, a user need only pull the elongate elements 172 in a proximal direction (towards the user) until the engagement elements 170a are set free from the constraint of the elongate elements 172. When this occurs, the "shape memory" or superelastic nature of the engagement elements 170a will cause them to assume their natural state, extending medially into the lumen of the thromboembolic receiver 146a. In this fashion, the engagement elements 170a will engage the thromboembolism and thus aid or enhance the ability of the thromboembolic receiver 146a to remove a thromboembolism.

[0027] The thromboembolic receiver may be provided with features that allow a surgeon to retract the receiver back into the delivery and aspiration catheter after the receiver has been partially or fully deployed into a blood vessel. This might be necessary if, perhaps, the surgeon receives angiographic or tactile feedback indicating that a separator would be a preferred tool for removal of a particular embolism, or that a receiver of a different size would be more suitable for a particular procedure.

[0028] FIG. 8A illustrates one example of an embodiment of a thromboembolic receiver 146b that is similar to the receiver 146 of FIG. 4, but that includes features that facilitate reloading of the receiver into the delivery and aspiration catheter 14. As shown, receiver 146b of the FIG. 8A embodiment includes a single, distal, cuff 152b and a plurality of longitudinal strut members 150b

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extending proximally from the cuff 152b.

[0029] Structural support members 160b are arranged in a distal row 171a adjacent to the cuff 152b, and a more proximal row 171b as shown in FIG. 8B. As with the FIG. 4 embodiment, a plurality of the structural support members 160b in the distal row are inwardly biased into the central lumen 147b of the receiver 146b so as to function as engagement members 170b for engaging a thromboembolism.

[0030] Three types of stabilizing strut members extend towards the proximal end of the receiver 146b. First, strut members 162b extend distally from the apexes of those of the structural support members 160b in the distal row 171a that do not function as engagement members. These strut members 162b are coupled at an intermediate point to the apexes of longitudinally aligned support members 160b in the proximal row 171b. Second, strut members 162c form the proximal extensions of the longitudinal strut members 150b and include eyelets 163 at their proximal ends. Third, strut members 162d extend from the apexes of those of the structure support members 160b in the proximal row that are longitudinally aligned with the engagement members 170b. Flexibility may be added to the receiver 146b may constructing some or all of the strut members to include flex regions of the type described in connection with earlier embodiments (see, e.g. flex regions 168 of FIG. 5).

[0031] Referring to Fig. 8C, the receiver 146b includes a pusher or elongate member 151b that includes a lumen 165 at its distal end. During assembly of the receiver 146b, the proximal ends of strut members 162b and 162d are positioned within the lumen 165 as shown and are allowed to slide freely within the lumen 165. The proximal ends of strut members 162c are bonded to the exterior surface of the elongate member 151b using heat shrink tubing 167 or other suitable material. The eyelets 163 facilitate bonding by allowing the bonding material to flow into the openings of the eyelets, thereby exposing a larger portion of each strut member 162c to the bonding material. If desired, the strut members 162b and 162d may be somewhat longer than the strut members 162c at the proximal end of the receiver, to allow them to be easily identified for insertion into the lumen 165 during assembly.

[0032] If it should be necessary to withdraw the receiver 146b back into the delivery and aspiration catheter 14 from a fully or partially deployed state, the elongate member 151b is withdrawn in a proximal direction relative to the catheter as shown in FIG. 8C. As the receiver 146b moves into the catheter 14, the receiver begins to fold at the apexes of the structural support members 160b, thereby pushing the strut members 162b and 162d in a proximal direction. Folding is more easily accomplished than with the receiver 146 of FIG. 4 due to the fact that certain of the structural support members 160b are interconnected at their apexes by strut members 162b. Thus, the folding of one member 160b in the proximal row 171b will facilitate the folding of a corresponding member 160b in the distal row 171a. The strut members 162b and 162d are allowed to slide freely within the lumen 165 of the elongate member 151b so that they will not resist folding of the members 160b during withdrawal of the receiver 146b into the catheter 14.

[0033] A thromboembolic separator is shown in FIG. 9. The thromboembolic separator 16 includes an elongated element 56 having a proximal end 58 and a distal end 60. The elongated element 56 may be constructed from any number of compositions having suitable biocompatibility and strength characteristics, and may be dimensioned in any number of suitable sizes and lengths depending upon the entry point into the vasculature, the location of the thromboembolism, variances in patient anatomy, and any extenuating circumstances.

[0034] The elongated element 56 may be constructed from stainless steel and/or Nitinol and dimensioned having a length ranging from 150 cm to 200 cm and a diameter ranging from 0.010 inch to 0.021 inch. A lubricious surface (e.g. a PTFE coating, hydrophilic coating, or other suitable coatings) may be applied to all or a portion of the elongate element 56 to facilitate movement of the element within the lumen of the delivery/aspiration catheter 14 and/or within the vasculature.

[0035] If desired, the elongate element 56 may take the form of a guide wire of the type used in various vascular applications. The elongate element may thus optionally include a coiled distal section 57 (Fig. 11B) having sufficient flexibility to prevent trauma to vascular tissues during advancement of the guidewire. The coiled distal section 57 may have a length in the range of approximately 27 - 33 cm. The coil is preferably positioned around an inner mandrel or core (not shown) of a type commonly found in coiled guidewires.

[0036] The "working end" of the separator 16 includes a generally blunt tip element 62 attached or forming part of the distal end 60 of the elongated element 56, and a separator element 64 attached or forming part of the elongated element 56. The tip element 62 is preferably dimensioned to pass through or against a thromboembolism so as to soften or fragment the thromboembolism for removal. The blunt nature of the tip element 62 is advantageously traumatic such that it will not cause damage to the interior of the vasculature during use. The separator 16 also assists in removing any clogs or flow restrictions that may develop within the lumen 36 due to the passage of thromboembolic material therethrough during aspiration.

[0037] As best shown in FTG. 11A, the separator element 64 takes the form of a basket that is generally conical in shape, with an opening 66 facing proximally along the elongated element 56. The separator basket 64 is dimensioned to assist in the thromboembolic fragmentation process , as well as to receive such thromboembolic fragments to aid in their removal. The separator basket 64 is provided having a web 68 and one or more support members 70. The support members 70 are dimensioned to bias the web 68 into the generally open position shown

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and, if desired, to allow the web 68 to assume a generally closed position (not shown, but generally flush against the elongated element 56) as the separator 16 is passed through delivery and aspiration catheter 14, a catheter-style pusher as described above, and/or the thromboembolism itself.

[0038] A separator 16a in accordance with the invention is shown in Figs. 11B and 11C, in which like reference numerals are used to identify features similar to those shown in Figs. 9, 10 and 11A. Separator 16a differs from separator 16 of Figs. 9, 10 and 11A primarily in the features of separator element 64a. Referring to Fig. 11B, separator element 64a is a conical member formed of a polymeric material such as polyurethane or Pebax® polyether block amides, to name a few. The separator element 64a is preferably a solid member, with a surface 65 facing in the proximal direction, and with the taper of the element oriented in a distal direction. Surface 65 may be contoured in a variety of ways. For example, surface 65 may be slightly concave as shown in Fig. 11B, substantially planar as shown in Fig. 11C, or slightly convex as shown in Fig. 11D.

[0039] The separator element 64a is positioned on the coiled distal section 57 of the elongate element 56. The pitch of a portion of the coiled section 57 may be decreased in certain regions of the coiled distal section 57. Opening the spacing in the coil in this manner can facilitate adhesion between the polymeric material of the separator element and the coil material during the molding process. The spacing between the separator element 64a and the distal end 60 of the elongate element 56 is long enough to allow the distal-most portion of the elongate element sufficient flexibility to move atraumatically through the vasculature, but short enough to prevent folding of the distal-most portion during advancement of the elongate element 56. In an exemplary embodiment, the distal end of separator element 64a may be positioned approximately 3 - 9 mm from the distal end 60. It should be noted that the mandrel or core (not shown) within the coiled section 57 of the elongate element 56 might have a tapered diameter selected to enhance the flexibility of the coiled section.

[0040] A handle member 72 (Fig. 9) is provided at the proximal end 58 of the separator to provide a purchase point for a user to advance and/or manipulate the atraumatic tip element 62 and separator 64/64a . In one embodiment, the handle member 72 may be coupled to the elongated element 56 in any suitable fashion, including but not limited to providing a generally rigid extension (not shown) disposed within the elongated element 56 for the purpose of coupling the two components together. This coupling may be augmented or strengthened through the use of any number of adhesives or fusing techniques.

[0041] The separator 16 may be provided in a variety of different permutations without departing from the scope of the present invention. For example, in addition to the "self deployable" embodiment described above, the separator basket 64 of Fig. 11A may be selectively deployed, such as by equipping the separator basket 64 with a mechanism to selectively bias or open the support members 70 from an initial position lying generally flush against the elongated element 56 to a generally radially expanded position (shown with arrows in FIG. 11A).

[0042] It will be appreciated that the guide and occlusion catheter 12, the delivery and aspiration catheter 14, the thromboembolic separator 16 and/or the thromboembolic receiver 46 may be provided with any number of features to facilitate the visualization of these elements during introduction and usage, including but not limited to having the distal regions equipped with radiopaque markers for improved radiographic imaging.

[0043] As discussed previously in connection with Fig. 1, the various components described herein may be provided as part of a system 10 for removing thromboembolic material. The thromboembolic removal system 10 may include a guide and occlusion catheter 12, a delivery and aspiration catheter 14, a thromboembolic separator 16/16a, a thromboembolic receiver (e.g. receiver 46 or 146), and an aspiration pump 18, as well as guidewires and/or other tools appropriate for the procedure. In one embodiment, multiple receivers 46/146 may be provided, allowing the surgeon to sequentially retrieve several thromboembolisms during the course of a procedure. For simplicity, each separate receiver may be provided with a separate delivery and aspiration catheter. The system 10 may additionally be provided with instructions for use setting forth any of the various methods of use described herein, or equivalents thereof.

System Use

[0044] Methods of using the thromboembolic removal system 10 will now be described with reference to FIGS. 12-28. As shown generally in FIGS. 12-13, in a first exemplary method the thromboembolic removal system 10 is introduced into the patient's vasculature, such as via the Seldinger technique. FIG. 14 illustrates the first step of this process, which involves advancing a guide wire 104 to a point proximal to a thromboembolism 100. The guide wire 104 may comprise any number of commercially available guide wires, the operation of which is well known in the art. However, in one method, the elongate member 56 (FIG. 11B) of the separator 16 functions as the guidewire 104.

[0045] FIG. 15 illustrates a second step, which involves advancing the guide and occlusion catheter 12 over the guide wire 104 to a point proximal to the thromboembolism . The next step, shown in FIG. 16, preferably involves inflating the balloon occlusion member 28 so as to arrest the blood flow within the cerebral artery 102 containing the thromboembolism 100. As shown in FIG. 17, the delivery and aspiration catheter 14 is then advanced through the guide and occlusion catheter 12 such that the distal end 38 of the delivery and aspiration catheter 14 is positioned at a point proximal

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to the thromboembolism 100. This may be facilitated by advancing the delivery and aspiration catheter 14 over the guide wire 104 and/or an exchange-length guide wire (not shown but well known in the art) extending through the guide and occlusion catheter 12.

[0046] At this point, as shown in FIG. 18, the thromboembolic receiver 46 is deployed from the distal end 38 of the delivery and aspiration catheter 14. In one embodiment, the balloon occlusion 28 may be inflated at this point (as opposed to inflating it before the delivery and aspiration catheter 14 is advanced, as shown in FIG. 16). The delivery and aspiration catheter 14 is then advanced distally - as shown in FIG. 19 - such that the thromboembolic receiver 46 engages and/or envelops (partially or fully) the thromboembolism 100. At this point, as shown in FIGS. 20 and 21, the delivery and aspiration catheter 14 may be withdrawn into the guide and occlusion catheter 12 to remove the thromboembolism 12 from the patient 16.

[0047] To augment the ability to remove the thromboembolism 100, or in the instance the thromboembolic receiver 46 does not initially engage the thromboembolism 100, the aspiration pump 18 may be activated to establish negative pressure within the delivery and aspiration catheter 14. In this fashion, negative pressure will be created within the cerebral artery 102 and exerted upon the thromboembolism 100. As noted above, the separator 16 (or the separator 16a of FIGS 11B-D) may be employed during this process (e.g. advancing and retracting it within the lumen 36 of the delivery and aspiration catheter 14) to remove any clogs or flow restrictions due to the passage of thromboembolic material through the lumen 36. The negative pressure will serve to draw the thromboembolism 100 into (partially or fully) the thromboembolic receiver 46. The delivery and aspiration catheter 14 may then be withdrawn into the guide and occlusion catheter 12 to remove the thromboembolism 100 from the patient.

[0048] To further augment the ability to remove the thromboembolism 100, or in the instance the aspiration pump 18 does not adequately draw all or most of the thromboembolism 100 into the receiver 46, the thromboembolic separator 16/16a may be advanced into contact with a portion of the thromboembolism, or completely through the thromboembolism 100 as shown in FIG. 22, and employed to bias or engage the distal end of the thromboembolism 100. This will increase the surface area of engagement with the thromboembolism 100, which will advantageously allow it to be withdrawn into the guide and occlusion catheter 12 such as by withdrawing the separator 16/16a and delivery and aspiration catheter 14 simultaneously into the guide and occlusion catheter 12.

[0049] As shown in FIG. 23, the separator 16/16a may also be selectively advanced and retracted through the thromboembolism 100 (or that remaining outside the receiver 46). This will serve to break up or otherwise soften the thromboembolism 100. Advancing and retracting the separator 16/16a also serves to remove any clogs or flow restrictions within the lumen of the delivery and aspiration catheter 14 during aspiration due to the passage of thromboembolic material through the lumen 36 of the delivery and aspiration catheter 14. In either event, the aspiration pump 18 will draw or bias the thromboembolic fragments 106 or the softened thromboembolism 100 into the thromboembolic receiver 46 and/or into catheter 14. The delivery and aspiration catheter 14 may then be withdrawn such that the thromboembolic receiver 46 is drawn into the guide and occlusion catheter 12 to remove the thromboembolism 100 from the patient.

[0050] Selective advancement of the separator element 64 through the thromboembolism and retraction of the separator element into the delivery and aspiration catheter 14, preferably in combination with aspiration, can additionally be used to carry small "bites" of the thromboembolic material into the catheter 14. For example, the separator element 64 may be passed through the thromboembolic material, displacing some material and thus forming a channel in the material as it moves distally. Once the separator element is positioned further into, or distally of, the thromboembolism, some of the displaced material may flow back into this channel. Subsequent retraction of the separator element 64 through the material (e.g. through the re-filled channel) will then draw some of the material into the catheter 14. To facilitate this procedure, the separator element 64 and the catheter 14 are preferably provided with fairly tight tolerances between the diameter of the catheter lumen 36 and the greatest diameter of the separator element 64. For example, in one exemplary embodiment, the outer diameter of separator element 64 and the diameter of lumen 36 may differ by approximately 0.003 - 0.008 inches.

[0051] An alternative method will next be described in which the receiver and disrupter are preferably used independently of one another, although combined use such as that described in connection with the first exemplary method might also be used. This method will be described as performed using the thromboembolic receiver 146 and the separator 16a, however it should be appreciated that other embodiments of these components may alternatively be used in the disclosed method.

[0052] According to the alternative method, an initial determination is made concerning whether use of receiver 146 or separator 16a will first be employed. This determination may be made at random, although in a preferred method the surgeon selects the appropriate tool based on a determination of the likely nature of the thromboembolic material that is to be removed. In particular, the surgeon will assess the patient to determine whether the material is likely to be hard or soft/gelatinous. This assessment might include an evaluation of one or more factors such as the response of the tip of the guidewire or separator when it is brought in contact with the thromboembolism, the location of the thromboembolic material, patient symptoms, and/or the manner in which the stroke caused by the thromboembolism is manifesting

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itself.

[0053] As discussed in connection with the first exemplary method, the guide and occlusion catheter 12 is introduced into the patient's vasculature, and the occlusion balloon 28 is inflated to arrest the flow of blood within the vessel (see, for example, Figs. 14-16).

[0054] The delivery and aspiration catheter 14 is passed through the guide and occlusion catheter 12 and positioned with its distal end at a location proximal to the thromboembolism 100. If the surgeon elects to use the separator 16a prior to using the receiver 146, or if the assessment results in a determination that the thromboembolic material is likely to be somewhat soft or gelatinous, the aspiration pump 18 is activated to establish negative pressure within the delivery and aspiration catheter 14, and thus to exert negative pressure exerted upon the thromboembolism 100 to draw embolic material into the catheter 14.

[0055] The separator 16a is deployed from the distal end of the delivery and aspiration catheter 14 and moved into contact with the thromboembolic material 100 as shown in Fig. 24. The separator may be advanced and retracted multiple times if desired. When advanced and retracted as shown, the separator can facilitate aspiration of the thromboembolic material into the catheter 14 in one of a variety of ways. First, movement of the separator into contact with the thromboembolism can loosen, separate, or soften pieces of thromboembolic material, such that pieces of the thromboembolism can be aspirated into the catheter. Second, advancing and retracting the separator 16a serves to remove any clogs or flow restrictions within the lumen 36 of the delivery and aspiration catheter 14 that might be caused by the passage of thromboembolic material through the lumen 36. Additionally, during retraction of the disrupter 16a, its proximal surface 35 may push or plunge loosened material towards and/or into the distal end of the catheter 14 for subsequent aspiration out of the body.

[0056] If use of the disrupter 16a as just described reveals that the vessel includes a hard mass of thromboembolic material incapable of aspiration without further intervention, the disrupter 16a is preferably withdrawn from the catheter 14 and a thromboembolic receiver 146 is passed through the delivery and aspiration catheter 14 and deployed within the blood vessel. If the system is provided with multiple sizes of receivers, the surgeon will select a receiver having an appropriate size for the blood vessel being treated.

[0057] Referring to FIGS. 25 - 28, once the receiver 146 is deployed, it expands into contact with the surrounding walls of the vessel. As the receiver 146 is advanced towards the body thromboembolic material 200, the walls of the receiver 146 slip around the body 200 to engage and/or envelop (partially or fully) the thromboembolism. The engaging elements 170 engage the thromboembolism 200, thereby retaining it within the receiver. If desired, the delivery and aspiration catheter 14 may be advanced slightly in a distal direction as indicated by arrows in FIG. 27, so as to "cinch" the strut members 162 towards one another, thus causing the receiver 146 to collapse slightly in a radially inward direction. Additionally, the aspiration pump 18 (FIG. 1) may be activated to facilitate retention of the thromboembolism 200 within the receiver. The delivery and aspiration catheter 14, the receiver 146 and the thromboembolism 100 are withdrawn into the guide and occlusion catheter 12 and are withdrawn from the body. If additional thromboembolic material should remain in the blood vessel, a new delivery and aspiration catheter 14 may be passed into the blood vessel, and a new receiver may be deployed through the catheter 14 for retrieving the additional body of thromboembolic material.

[0058] Naturally, the surgeon may elect to initially deploy the receiver rather than the separator, such as if the initial assessment results in a determination that the thromboembolic material is likely to be hard. The method is then carried out utilizing the receiver 146 as described in the preceding paragraph. If it is later determined that residual thromboembolic material (e.g. soft or gelatinous material) is present in the vessel, the receiver 146 is preferably removed form the body, and the separator 16a is passed through the delivery and aspiration catheter 14. The aspiration pump 18 is activated and the separator 16a is manipulated to facilitate aspiration of the soft material in the manner described above.

[0059] While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof have been shown by way of example in the drawings and are herein described in detail. It should be understood, however, that the description herein of specific embodiments is not intended to limit the invention to the particular forms disclosed, but on the contrary, the invention is to cover all modifications, equivalents, and alternative falling within the scope of the claims.

Claims

1. A system for removing thromboembolic material from a cerebral blood vessel, the system comprising:

   a delivery catheter (14) having a lumen (36) including a distal end having a fixed inner diameter;

   an elongate member (56) extendable through the said lumen (36) and including a distal portion (57) and having a separator element (64a) on the distal portion (57), the separator element (64a) being a broadened element and having a maximum diameter portion having a maximum diameter smaller than the said fixed inner diameter; and

   an aspiration source (18) fluidly coupled to the said lumen (36), wherein

   the distal portion (57) has a distal end (60) and the separator element (64a) is in a fixed position

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on the distal portion (57) and spaced proximally from the distal end (60), the portion of the elongate member (56) between the separator element (64a) and the distal end (60) being sufficiently flexible to be movable atraumatically through a cerebral blood vessel without folding; the separator element (64a) is of substantially solid conical form with a tapered distal portion and a proximal portion with a proximally-facing surface (65); and
tolerance between the maximum diameter portion of the separator element (64a) and the said fixed inner diameter is tight and the separator element (64) is advanceable from and retractable into the lumen (36) during aspiration using the aspiration source (18) .

2. A system according to claim 1, **characterised in that** the maximum diameter of the separator element (64a) is in the range of 0.076 - 0.203 mm (0.003 - 0.008 inches) smaller than the said fixed inner diameter.

3. A system according to claim 1, **characterised in that** the delivery catheter (14) has an outer diameter in the range of approximately 0.813 mm to 1.651 mm (0.032 inch to 0.065 inch).

4. A system according to claim 1, **characterised by** an expandable receiving element (146) on an elongate shaft (151) extendable through the said lumen (36), the receiving element (146) being advanceable within the blood vessel into contact with thromboembolic material, and at least partially collapsible to engage thromboembolic material.

5. A system according to claim 1, **characterised in that** the proximally-facing surface is concave.

6. A system according to claim 1, **characterised in that** the proximally-facing surface is substantially planar.

7. A system according to claim 1, **characterised in that** the proximally-facing surface is convex.

8. A system according to claim 4, **characterised in that** the elongate shaft (151) and the elongate member (56) are extendable through the said lumen (36) independently of one another.

9. A system according to claim 4 or 8, **characterised in that** the receiving element (146) is formed of a plurality of structural members (150,160,162,170) arranged to form a sleeve having a central lumen, a plurality of the structural members comprising engaging elements (170) having apex regions extending into the central lumen, and **in that** a plurality of the structural members (160) comprise a plurality of generally v-shaped elements having longitudinally-oriented apexes, and the engaging elements (170) comprise a plurality of v-shaped elements.

Patentansprüche

1. System zur Entfernung von thromboembolischem Material aus einem cerebralen Blutgefäß, wobei das System Folgendes umfasst:

einen Abgabekatheter (14) mit einem Lumen (36), der ein distales Ende mit einem fixen Innendurchmesser einschließt;
ein längliches Element (56), das durch das Lumen (36) verlängerbar ist und einen distalen Abschnitt (57) einschließt und ein Trennelement (64a) am distalen Abschnitt (57) aufweist, wobei das Trennelement (64a) ein sich verbreiterndes Element darstellt und einen Abschnitt mit einem maximalen Durchmesser aufweist, wobei der maximale Durchmesser kleiner als der fixe Innendurchmesser ist; und
eine Aspirationsquelle (18) in Fließverbindung mit dem Lumen (36) gekoppelt ist, worin:

der distale Abschnitt (57) ein distales Ende (60) aufweist und das Trennelement (64a) sich in einer fixen Position am distalen Abschnitt (57) befindet und mit Abstand proximal vom distalen Ende (60) angeordnet ist, wobei der Abschnitt des länglichen Elements (56) zwischen dem Trennelement (64a) und dem distalen Ende (60) ausreichend flexibel ist, damit es ohne Zusammenfalten atraumatisch durch ein cerebrales Blutgefäß bewegbar ist;
das Trennelement (64a) im Wesentlichen aus einer festen konischen Form mit einem sich verjüngenden distalen Abschnitt und einem proximalen Abschnitt mit einer nach proximal gekehrten Oberfläche (65) besteht; und
die Toleranz zwischen dem Abschnitt mit dem maximalen Durchmesser des Trennelements (64a) und dem fixen Innendurchmesser eng ist und das Trennelement (64) während der Aspiration mithilfe der Aspirationsquelle (18) vorschiebbar aus dem und zurückziehbar in das Lumen (36) ist.

2. System nach Anspruch 1, **dadurch gekennzeichnet, dass** der maximale Durchmesser des Trennelements (64a) im Bereich von 0,076 - 0,203 mm (0,003 Inch - 0,008 Inch) kleiner als der fixe Innendurchmesser ist.

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3. System nach Anspruch 1, **dadurch gekennzeichnet, dass** der Abgabekatheter (14) einen Außendurchmesser im Bereich von ca. 0,813 mm bis 1,651 mm (0,032 Inch bis 0,065 Inch) aufweist.

4. System nach Anspruch 1, **gekennzeichnet durch dass** ein expandierbares Aufnahmeelement (146) an einem länglichen Schaft (151), der **durch** das Lumen (36) verlängerbar ist, wobei das Aufnahmeelement (146) im Blutgefäß vorschiebbar ist, mit dem thromboembolischen Material in Kontakt kommt und mindestens teilweise kollabierbar ist, um das thromboembolische Material einzufangen.

5. System nach Anspruch 1, **dadurch gekennzeichnet, dass** die nach proximal gekehrte Oberfläche konkav ist.

6. System nach Anspruch 1, **dadurch gekennzeichnet, dass** die nach proximal gekehrte Oberfläche im Wesentlichen planar ist.

7. System nach Anspruch 1, **dadurch gekennzeichnet, dass** die nach proximal gekehrte Oberfläche konvex ist.

8. System nach Anspruch 4, **dadurch gekennzeichnet, dass** der längliche Schaft (151) und das längliche Element (56) unabhängig voneinander durch das Lumen (36) verlängerbar sind.

9. System nach Anspruch 4 oder 8, **dadurch gekennzeichnet, dass** das Aufnahmeelement (146) aus einer Vielzahl von Strukturelementen (150, 160, 162, 170) gebildet ist, die zur Bildung einer Hülse mit einem Zentrallumen angeordnet sind, wobei eine Vielzahl der Strukturelemente Einfangelemente (170) mit sich in das Zentrallumen erstreckenden Apex-Regionen umfasst, und dass eine Vielzahl der Strukturelemente (160) eine Vielzahl von im Allgemeinen V-förmigen Elementen mit längs ausgerichteten Apizes aufweist, und die Einfangelemente (170) eine Vielzahl V-förmiger Elemente umfassen.

Revendications

1. Système servant à extraire la substance thromboembolique logée dans un vaisseau sanguin cérébral, ledit système comprenant :

une sonde de déploiement (14) possédant une lumière (36) incluant une extrémité distale à diamètre interne fixe ;
un membre allongé (56) extensible dans ladite lumière (36) incluant une portion distale (57) et portant un élément séparateur (64a) sur la portion distale (57), l'élément séparateur (64a) étant un élément élargi et ayant une portion de diamètre maximum ayant un diamètre maximum inférieur audit diamètre interne fixe ; et
une source d'aspiration (18) fluidement couplée à ladite lumière (36),

dans lequel :

la portion distale (57) a une extrémité distale (60) et l'élément séparateur (64a) est dans une position fixe sur la portion distale (57) et est proximalement espacé de l'extrémité distale (60), la portion du membre allongé (56) entre l'élément séparateur (64a) et l'extrémité distale (60) étant suffisamment flexible pour être atraumatiquement déplacée dans un vaisseau sanguin cérébral sans se plier ;
l'élément séparateur (64a) est d'une forme conique substantiellement solide avec une portion distale effilée et une portion proximale ayant une surface tournée proximalement (65) ; et
la tolérance entre la portion de diamètre maximum de l'élément séparateur (64a) et ledit diamètre interne fixe est serrée et l'élément séparateur (64) peut être poussé de l'intérieur de, et rétracté dans, la lumière (36) durant l'aspiration en utilisant la source d'aspiration (18).

2. Système selon la revendication 1, **caractérisé en ce que** le diamètre maximum de l'élément séparateur (64a) est de quelque 0,076 à 0,203 mm (0,003 à 0,008 pouces) inférieur audit diamètre interne fixe.

3. Système selon la revendication 1, **caractérisé en ce que** la sonde de déploiement (14) a un diamètre externe compris entre approximativement 0,813 mm et 1,651 mm (0,032 pouce et 0,065 pouce).

4. Système selon la revendication 1, **caractérisé par** un élément récepteur expansible (146) sur un axe allongé (151) extensible dans ladite lumière (36), l'élément récepteur (146) pouvant être poussé dans le vaisseau sanguin en contact avec la substance thromboembolique, et être au moins partiellement pliable de manière à saisir la substance thromboembolique.

5. Système selon la revendication 1, **caractérisé en ce que** la surface tournée proximalement est concave.

6. Système selon la revendication 1, **caractérisé en ce que** la surface tournée proximalement est sensiblement plane.

7. Système selon la revendication 1, **caractérisé en ce que** la surface tournée proximalement est convexe.

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8. Système selon la revendication 4, **caractérisé en ce que** l'axe allongé (151) et le membre allongé (56) sont extensibles dans ladite lumière (36) indépendamment l'un de l'autre.

9. Système selon la revendication 4 ou 8, **caractérisé en ce que** l'élément récepteur (146) est formé d'une pluralité de membres structurels (150, 160, 162, 170) disposés de manière à former un manchon ayant une lumière centrale, une pluralité des membres structurels comprenant des éléments enclencheurs (170) munis de régions supérieures s'étendant dans la lumière centrale, et **en ce qu'**une pluralité des membres structurels (160) comprend une pluralité d'éléments généralement en forme de V présentant des sommets orientés longitudinalement, et les éléments enclencheurs (170) comprennent une pluralité d'éléments en forme de V.

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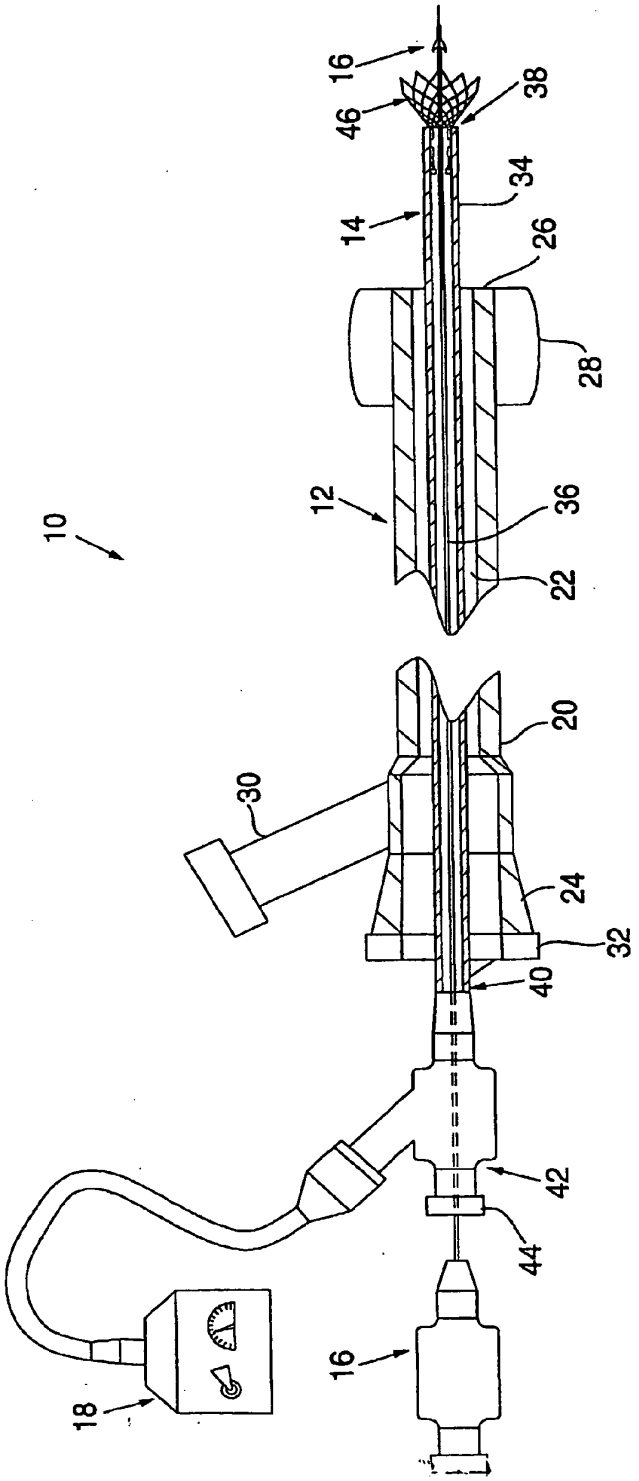


FIG. 1

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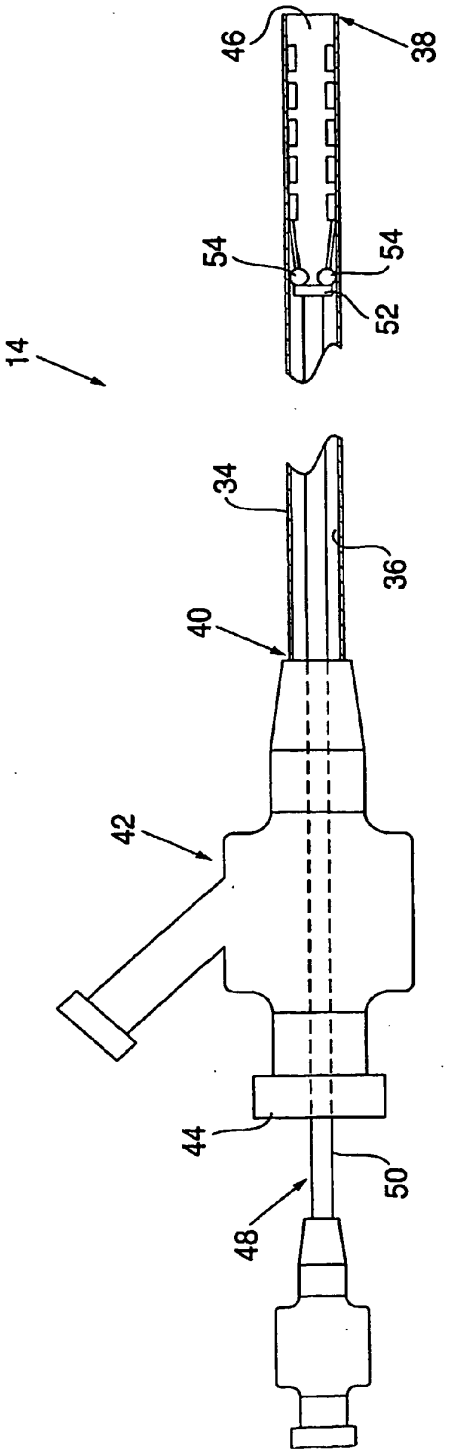


FIG. 2

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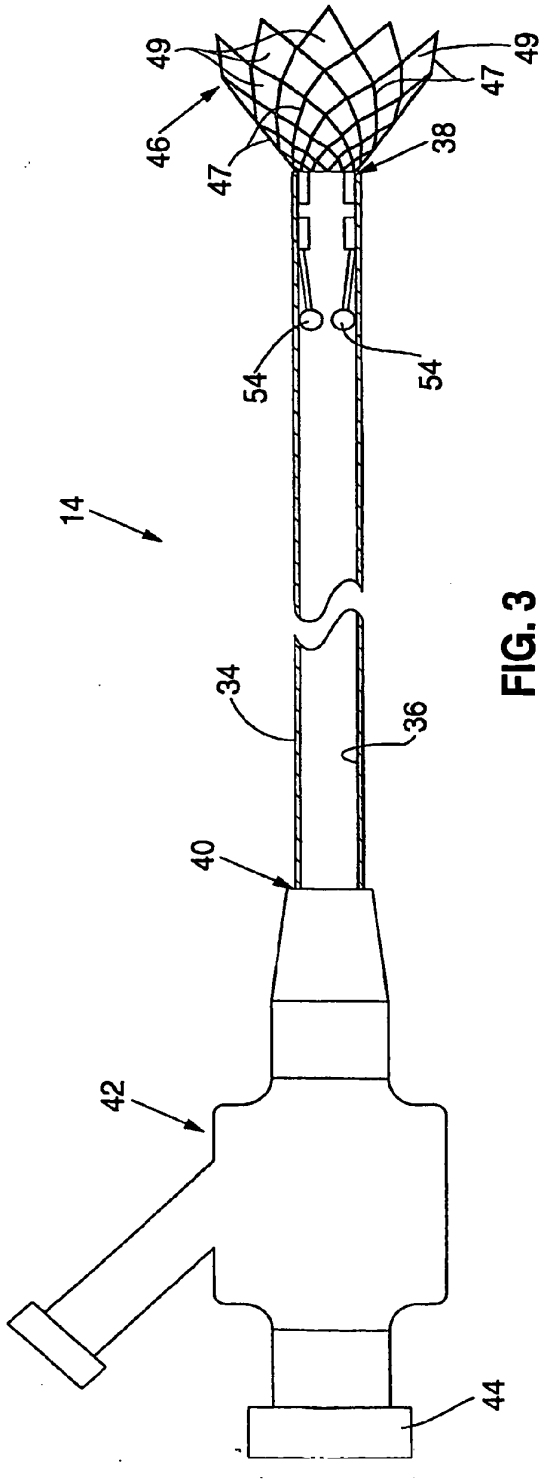


FIG. 3

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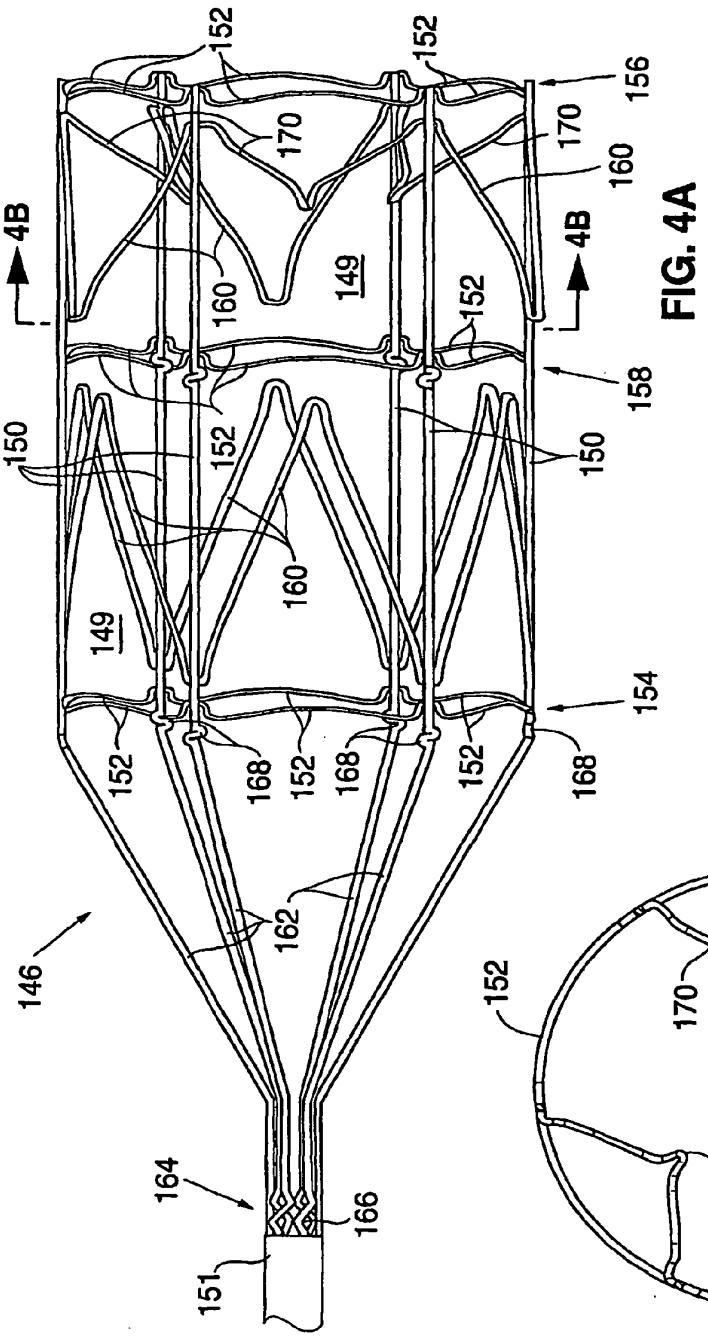


FIG. 4A

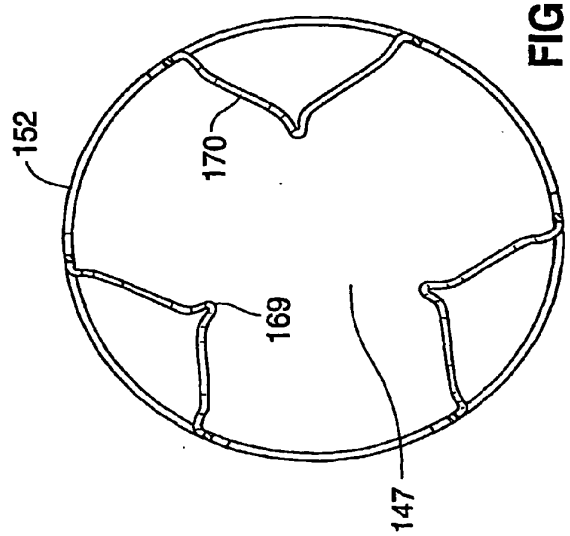


FIG. 4B

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Penumbra, Inc. v. RapidPulse, Inc.

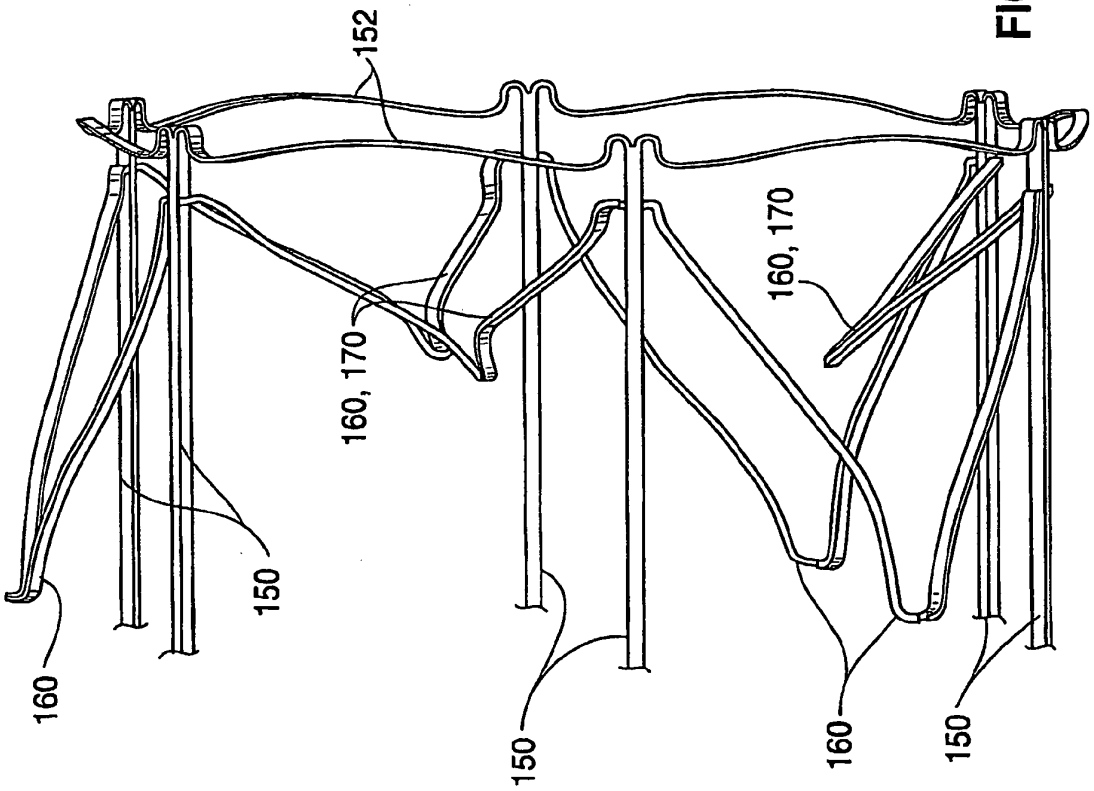


FIG. 4C

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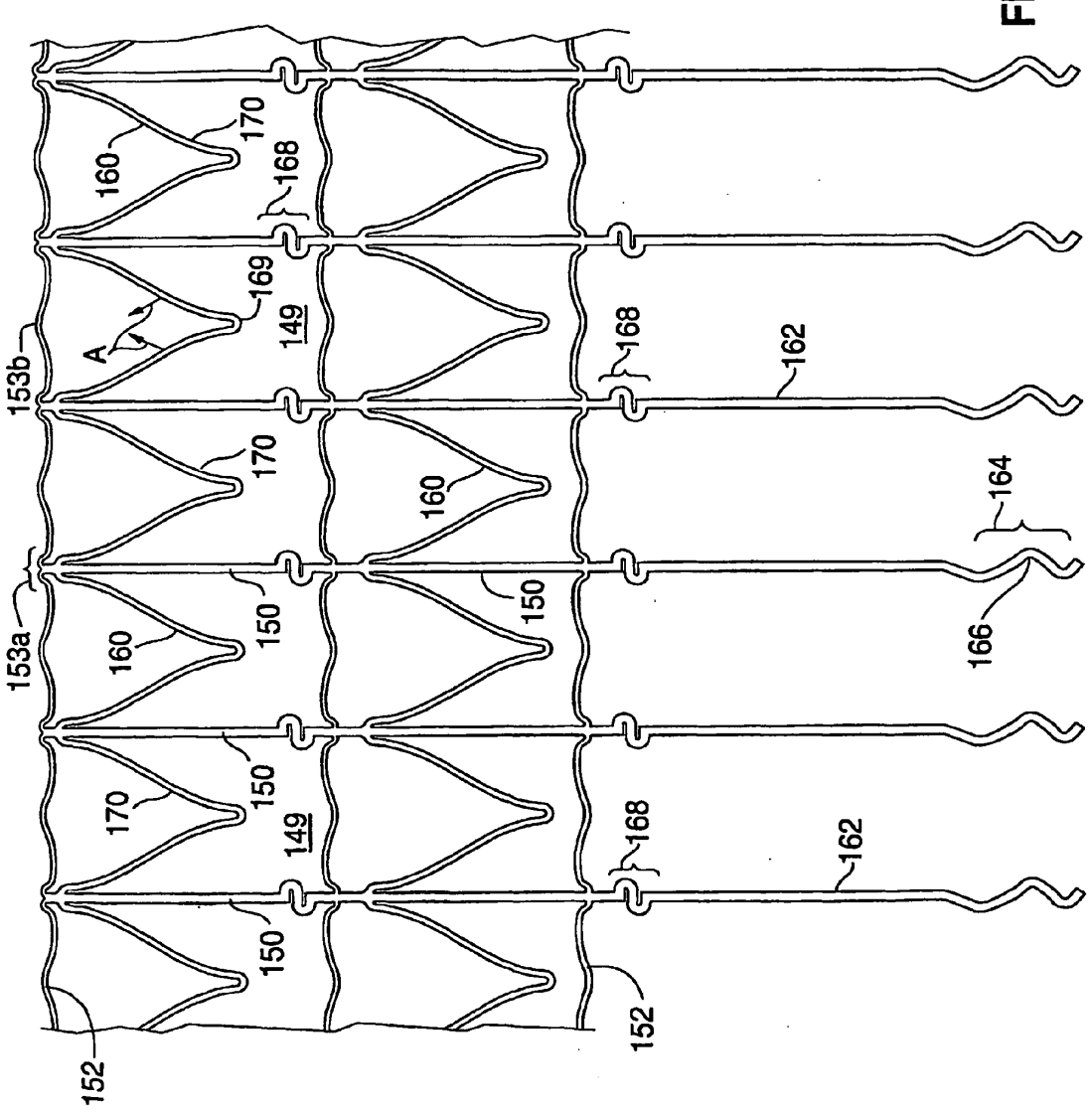


FIG. 5

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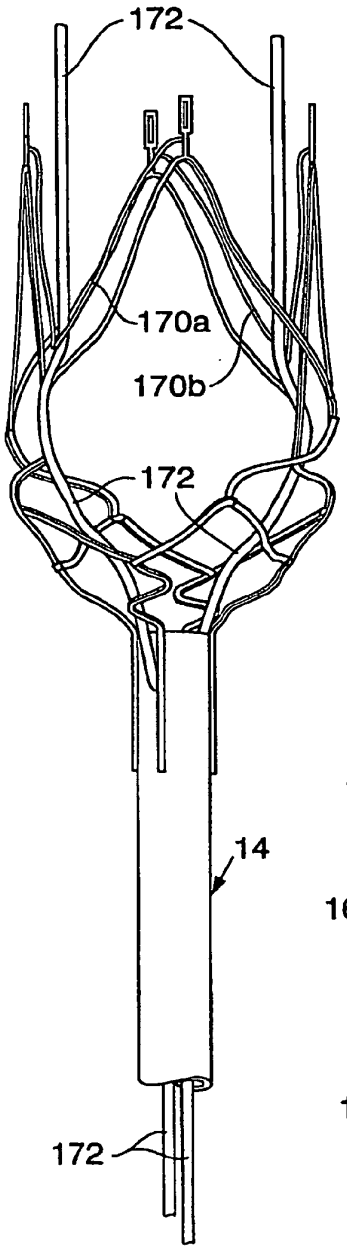


FIG. 7

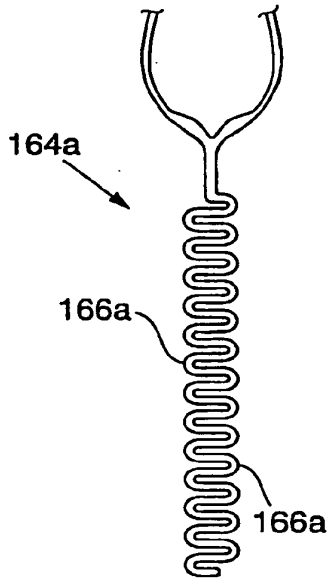


FIG. 6

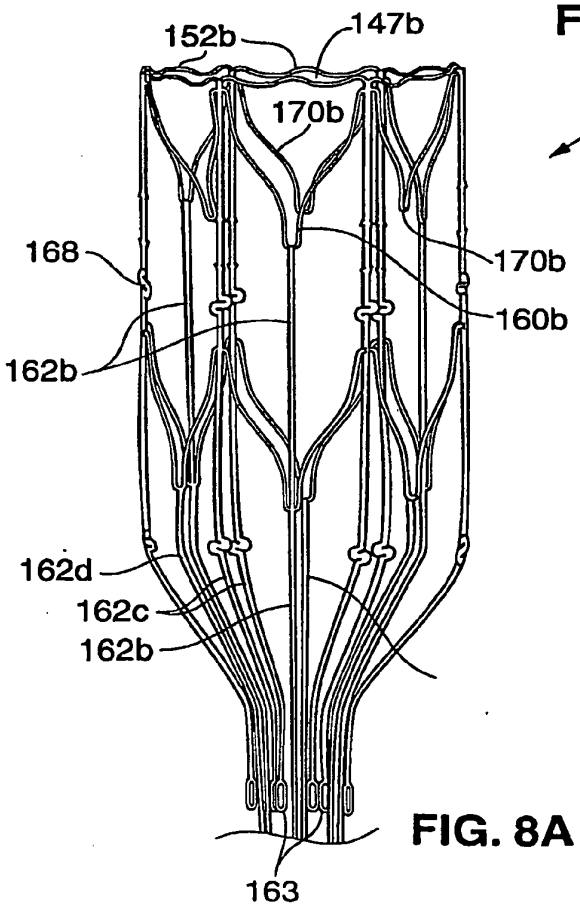


FIG. 8A

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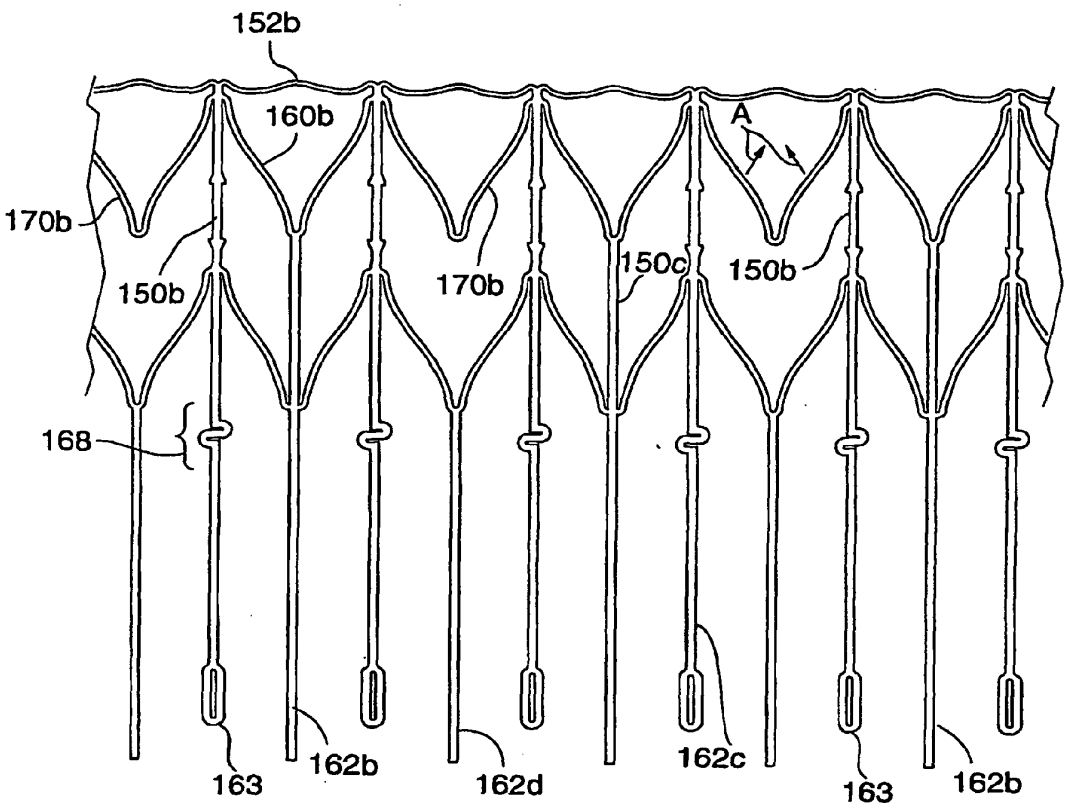


FIG. 8B

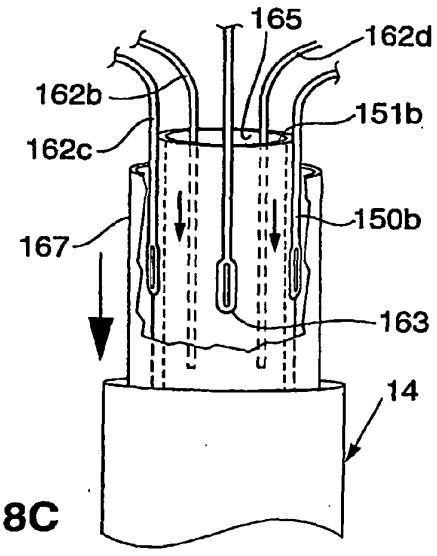


FIG. 8C

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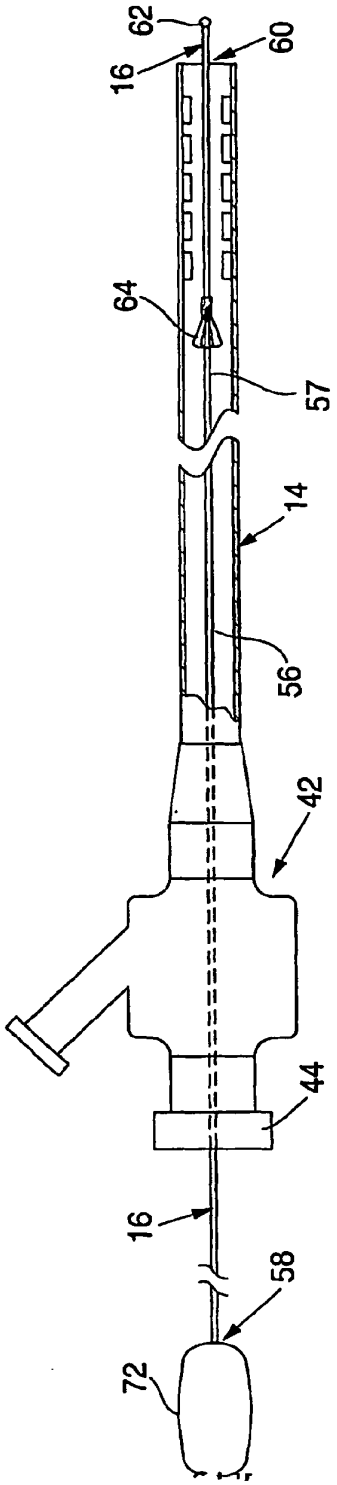


FIG. 9

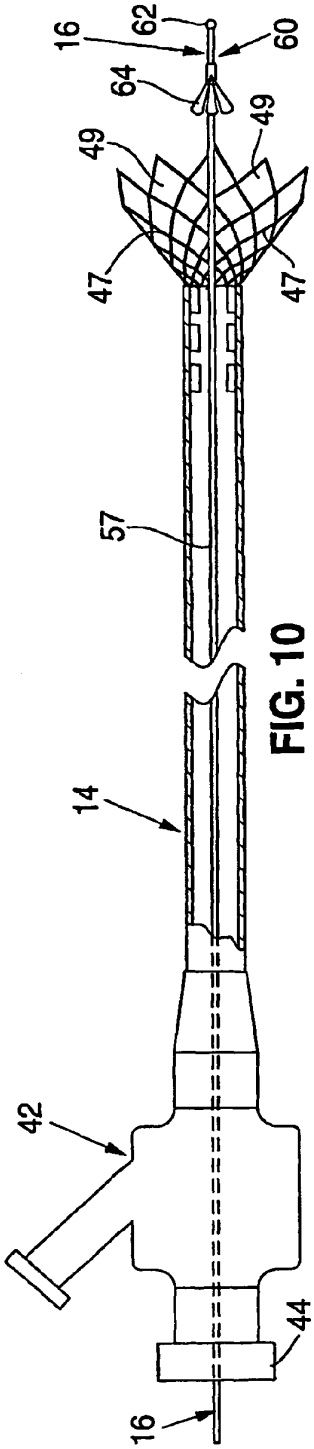


FIG. 10

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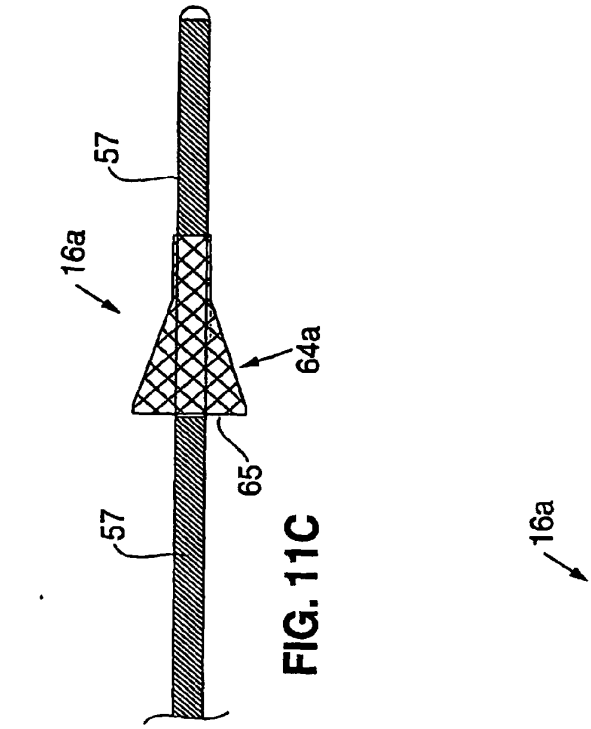


FIG. 11C

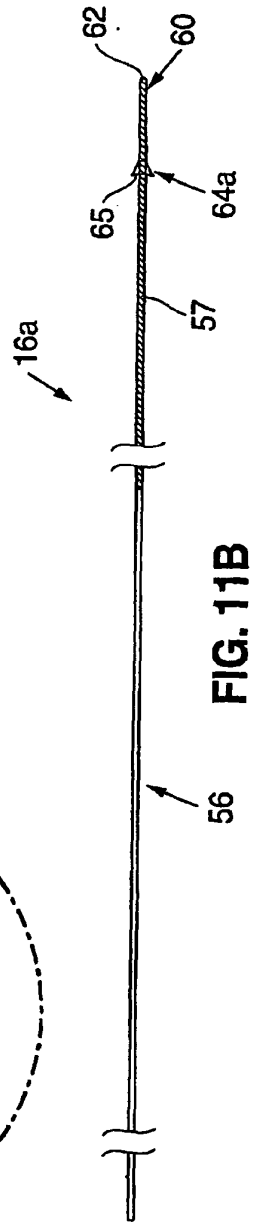


FIG. 11B

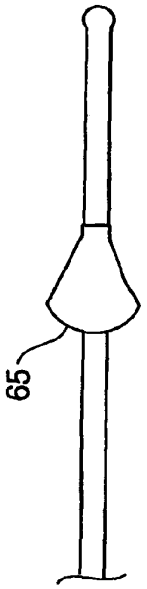


FIG. 11D

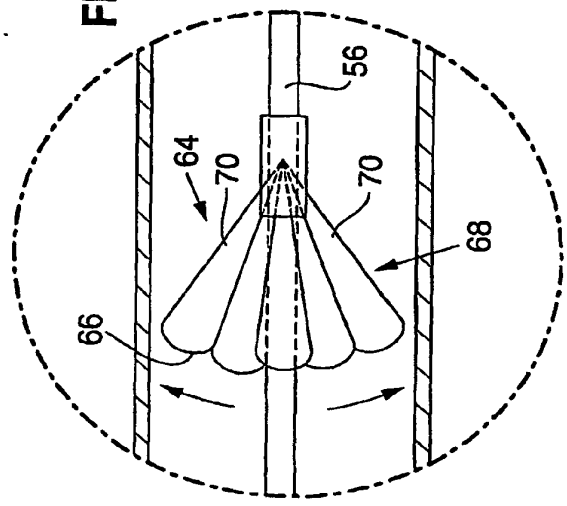


FIG. 11A

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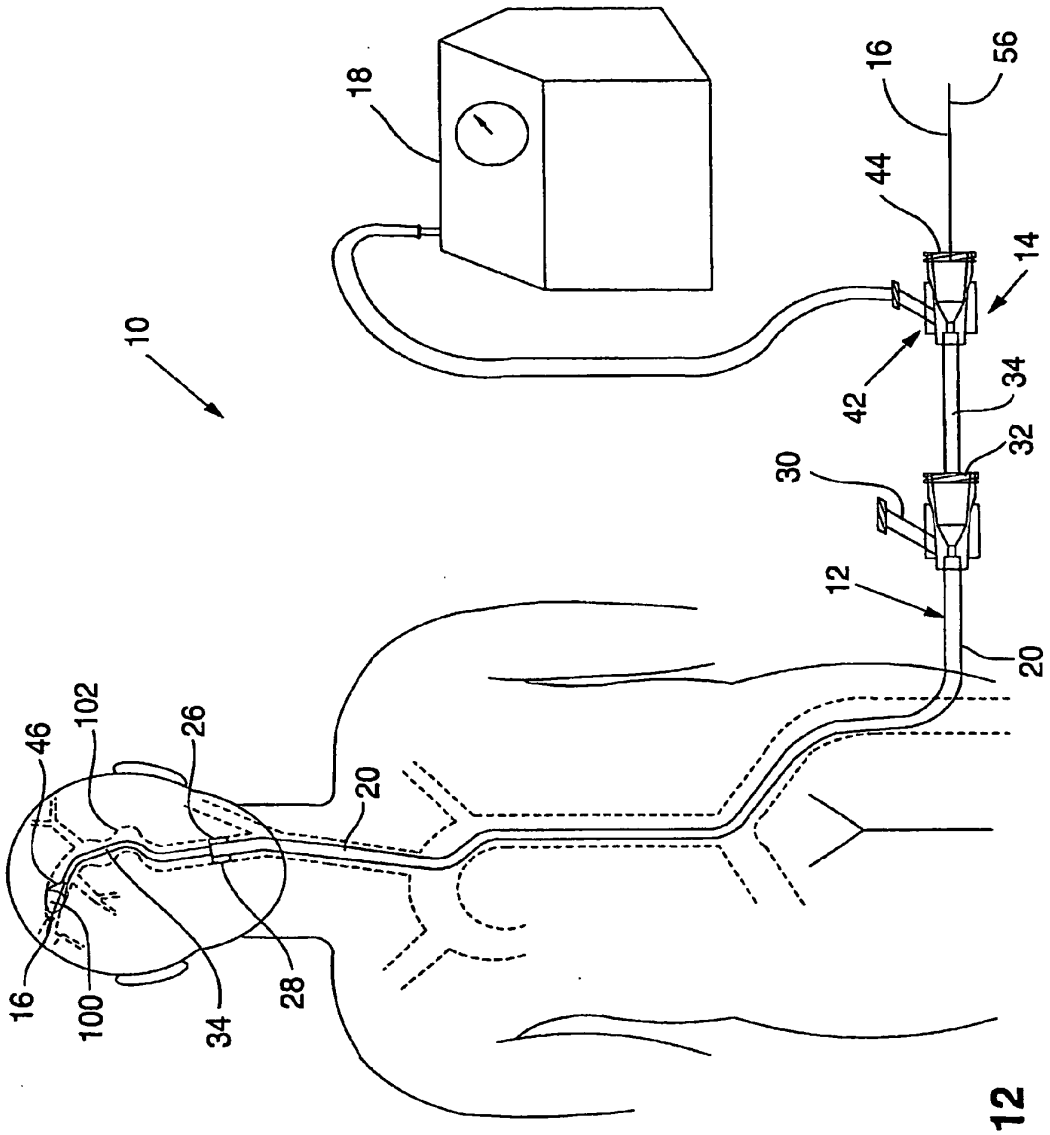


FIG. 12

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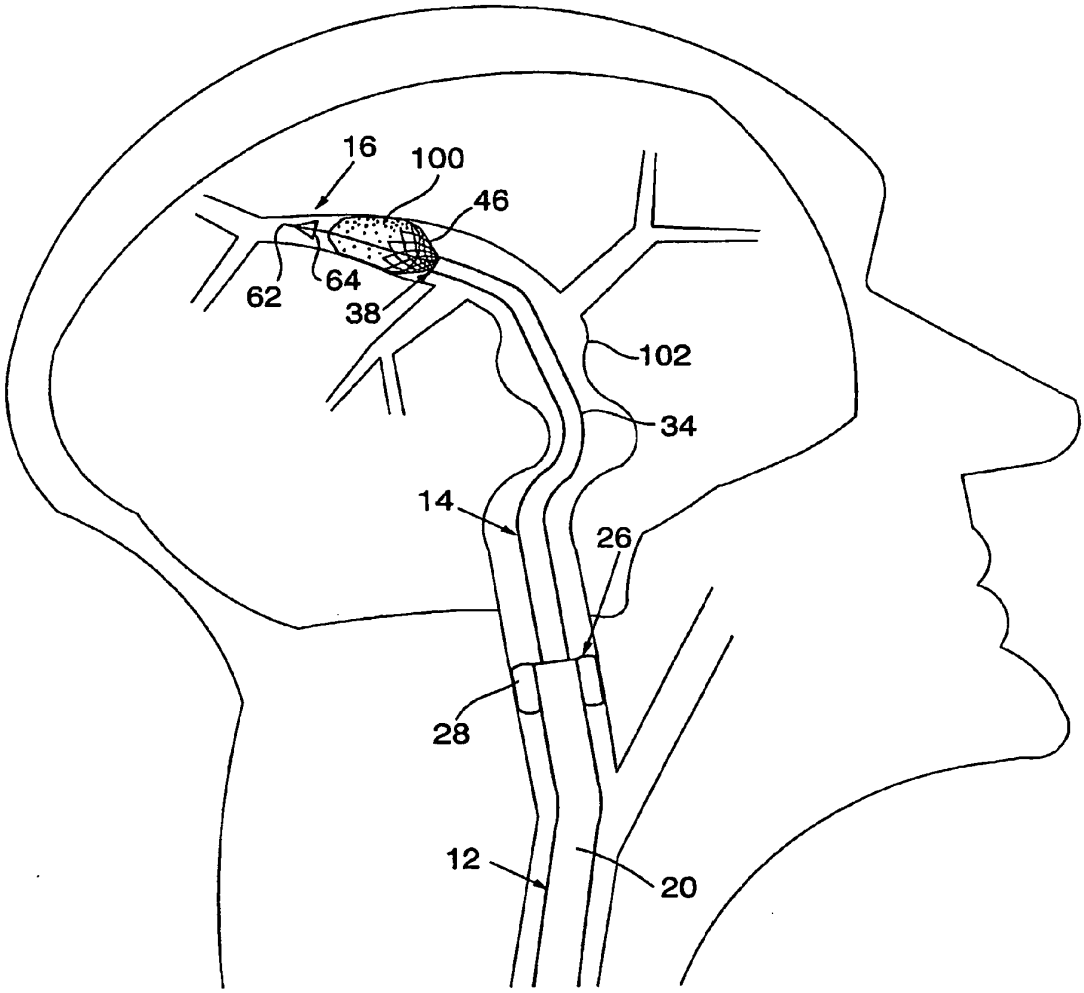


FIG. 13

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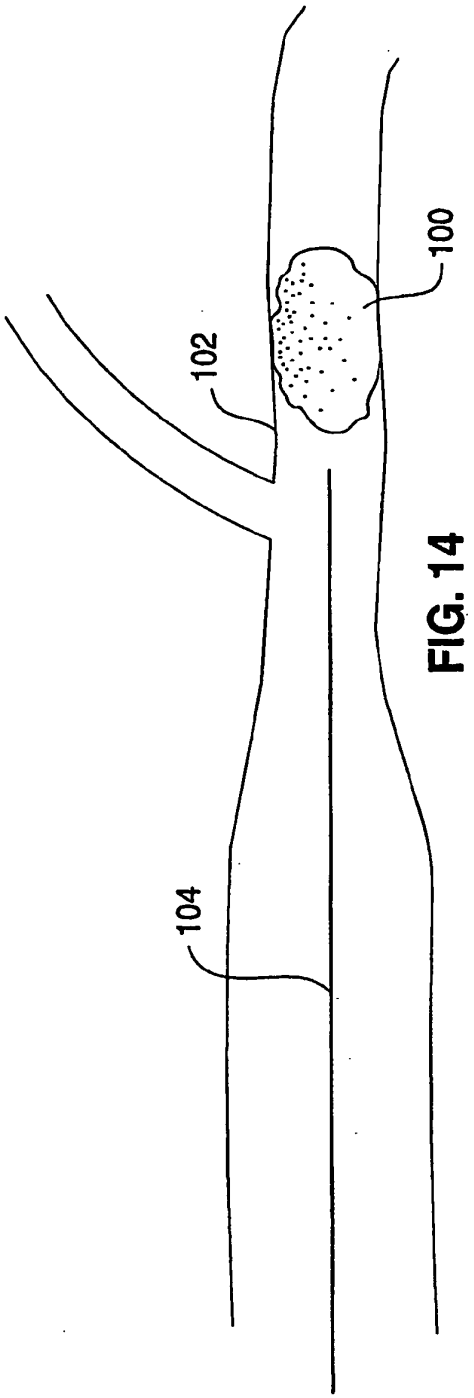


FIG. 14

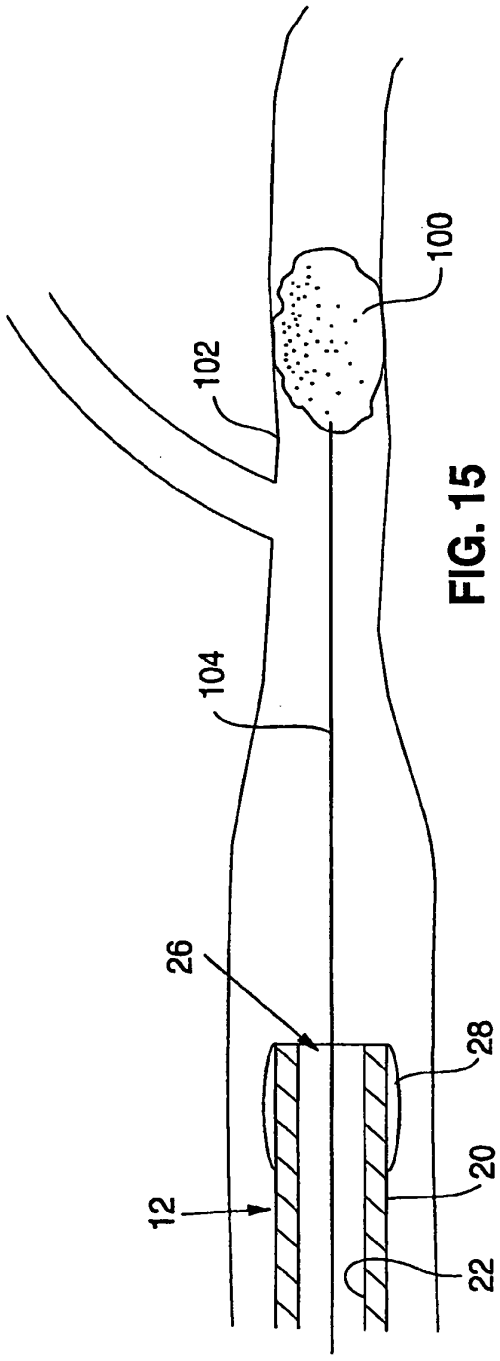


FIG. 15

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Penumbra, Inc. v. RapidPulse, Inc.

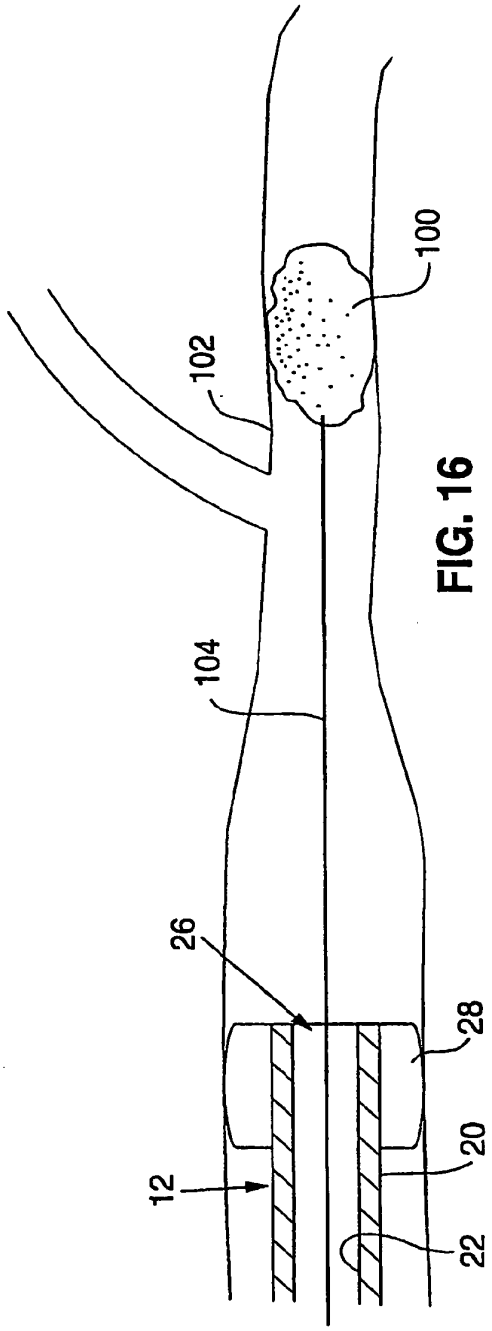


FIG. 16

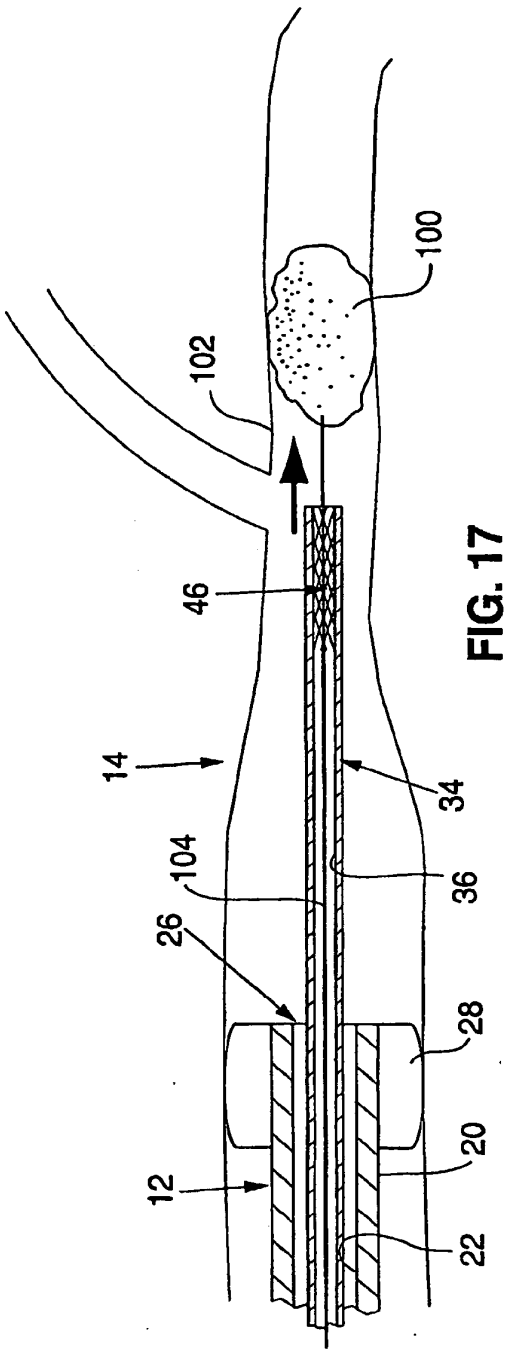


FIG. 17

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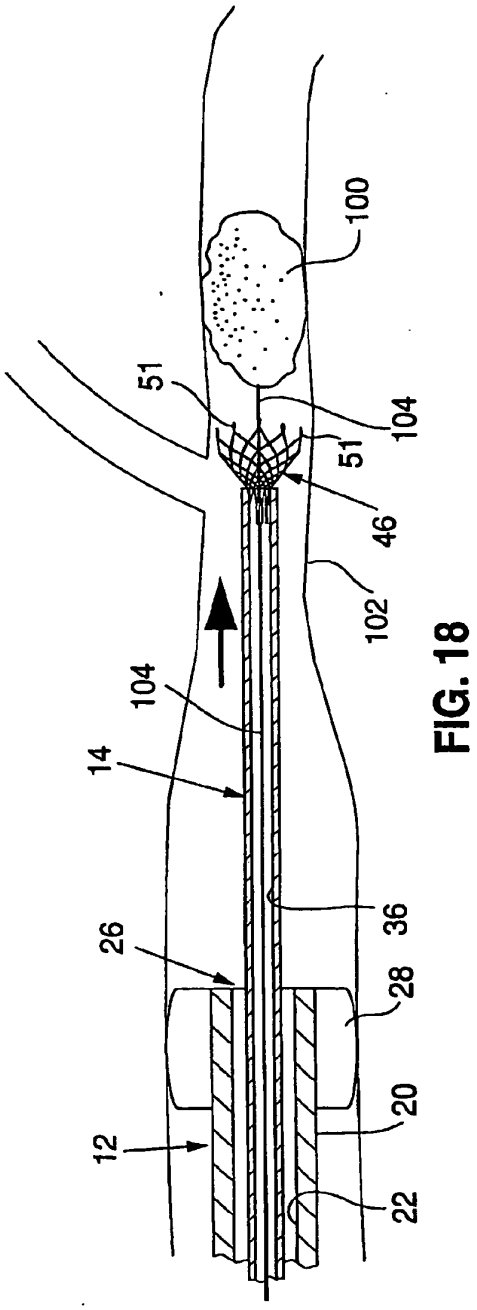


FIG. 18

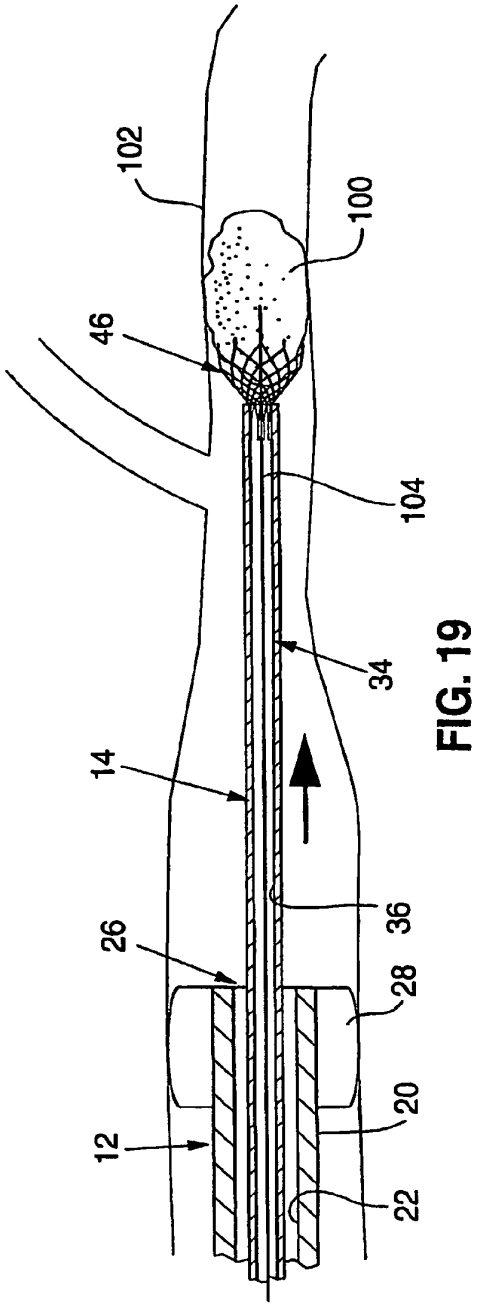


FIG. 19

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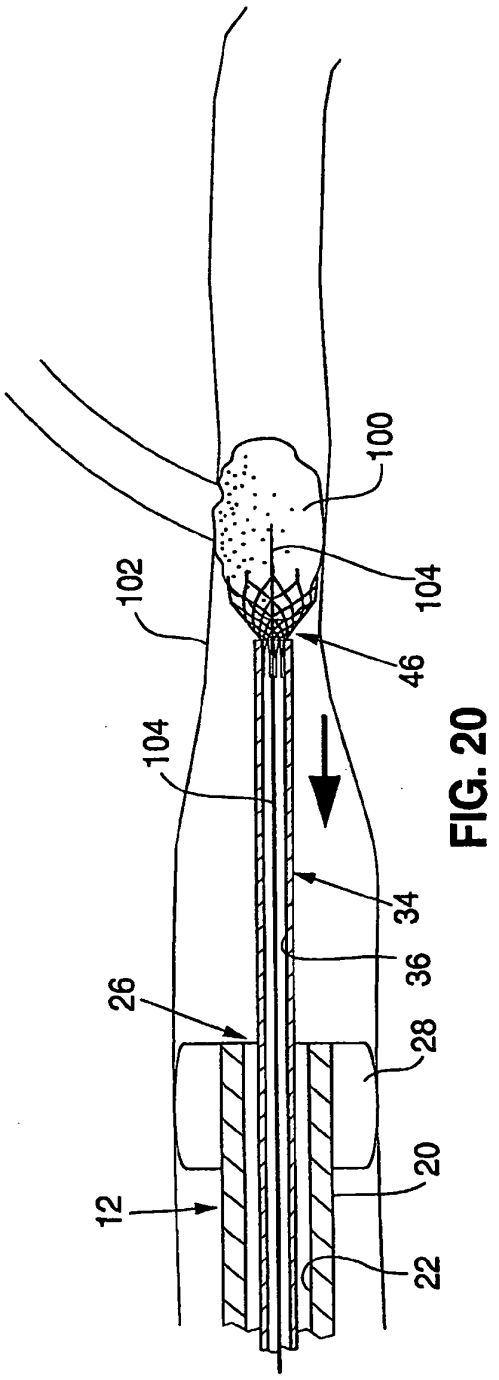


FIG. 20

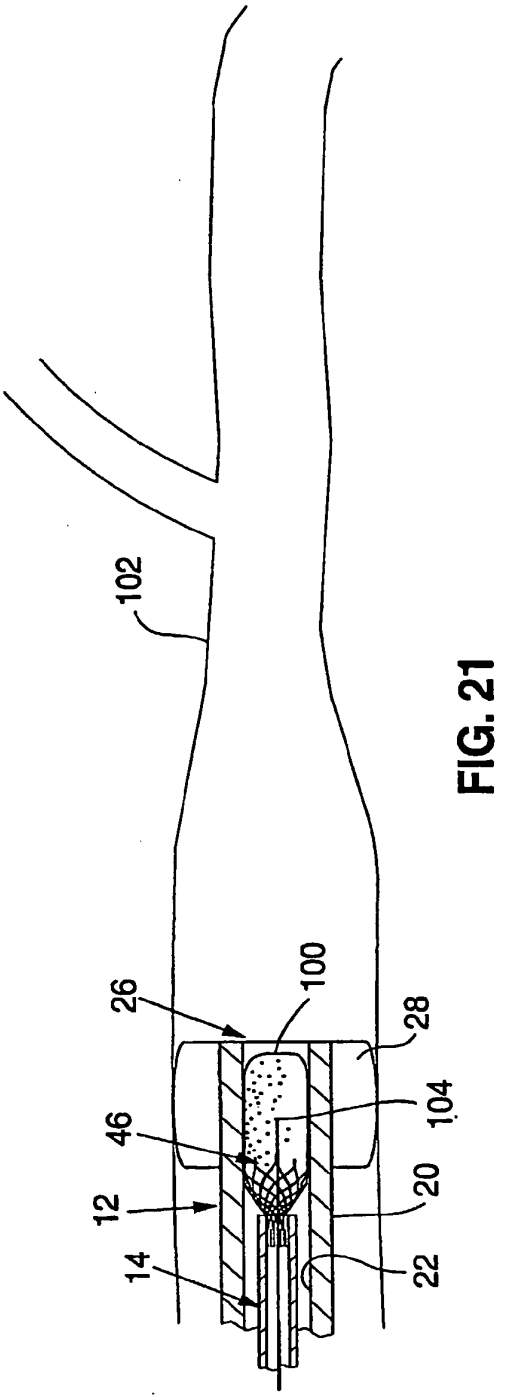


FIG. 21

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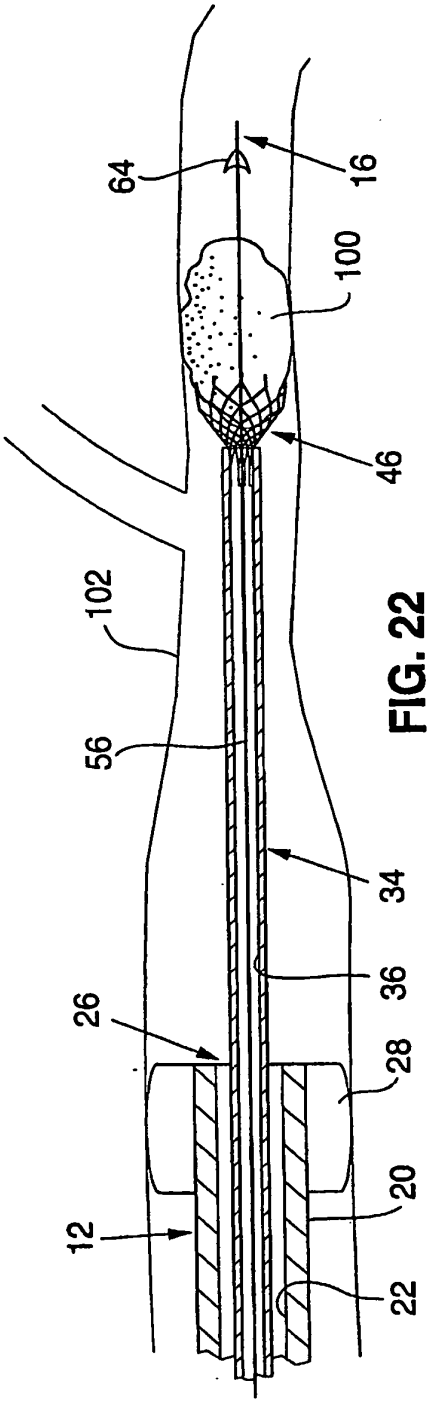


FIG. 22

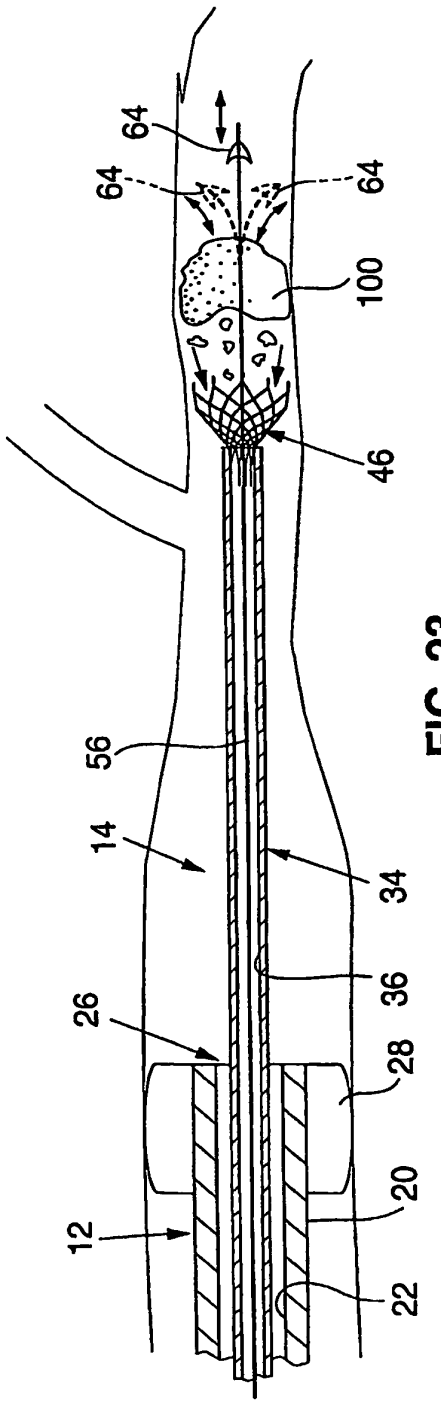


FIG. 23

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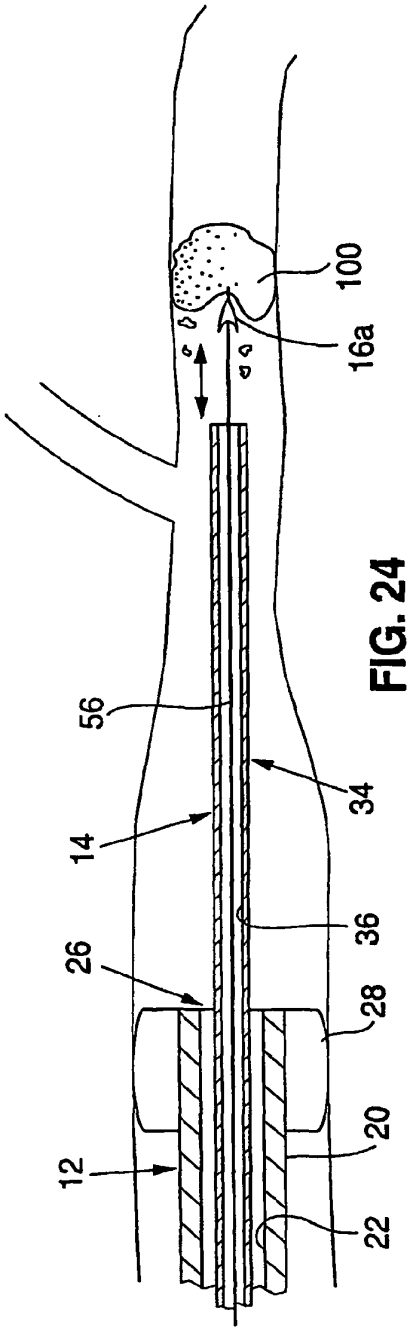


FIG. 24

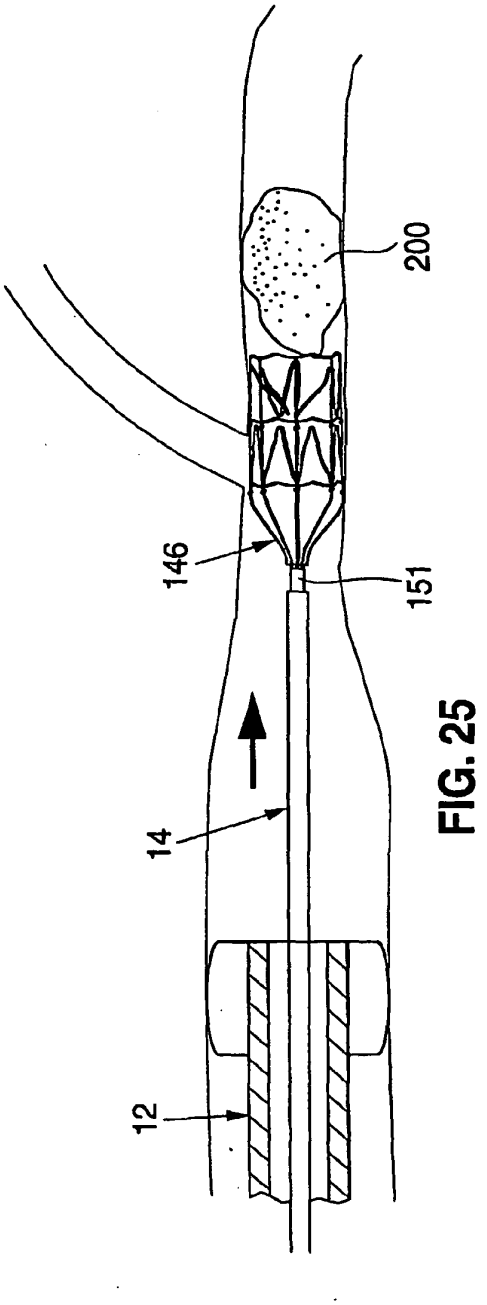


FIG. 25

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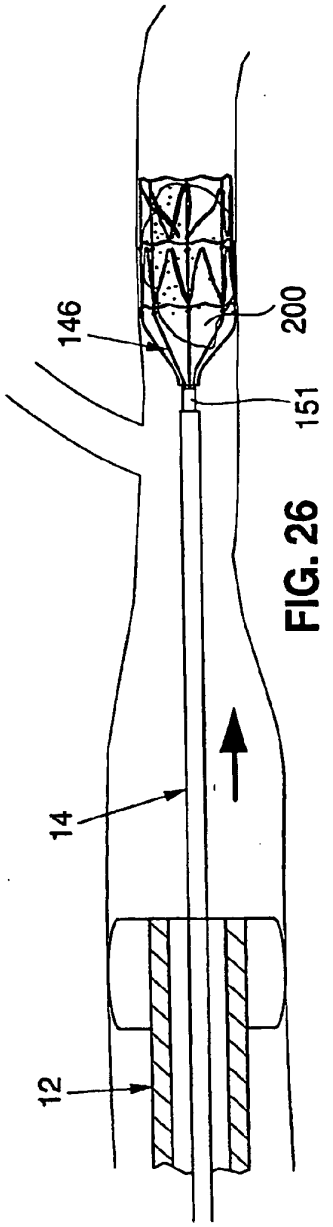


FIG. 26

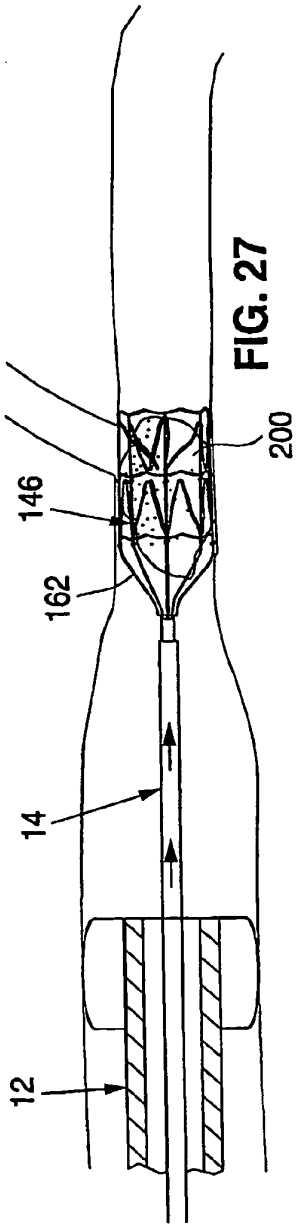


FIG. 27

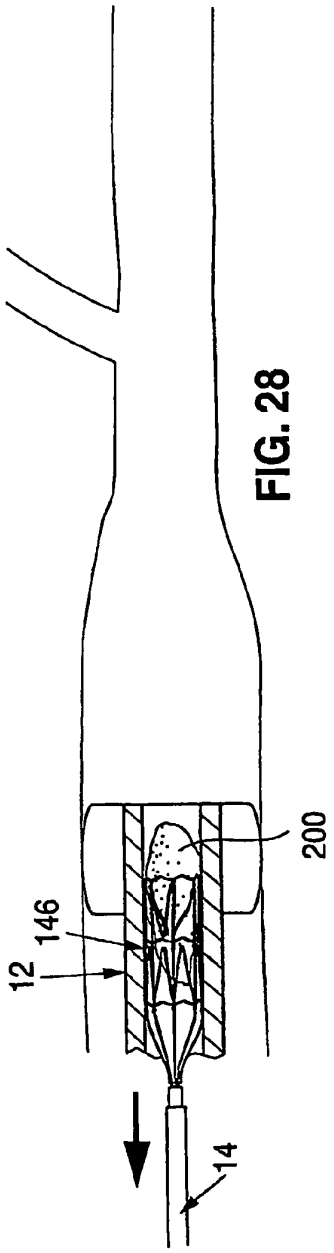


FIG. 28

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REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 20020147459 A **[0007] [0008]**
- US 20030078606 A **[0007]**
- US 20020072764 A **[0007]**

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(74) Agents: **HESLIN, James, M.** et al.; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304-1050 (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, 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, 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, PA, 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.

(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, 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**: ANEURYSM OCCLUSION SYSTEM AND METHOD

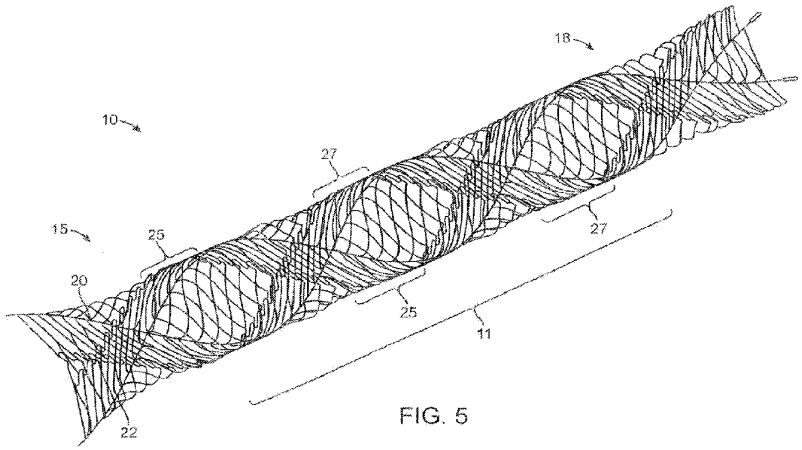


FIG. 5

(57) **Abstract**: An aneurysm occlusion system includes a device positionable within a cerebral blood vessel covering a neck of an aneurysm on the blood vessel. The device includes an expandable tubular element having a lumen surrounded by a sidewall including a plurality of gaps. When expanded, the tubular element includes longitudinal standards arrayed helically in a proximal to distal direction. The standards support struts and the gaps are defined between adjacent struts and are sufficiently large to permit delivery of embolic coils or other embolic materials therethrough.

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ANEURYSM OCCLUSION SYSTEM AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

[001] This application claims priority to U.S. Provisional Application No. 61/655,116 (Attorney Docket No. 41507-714.101), filed June 4, 2012; and is a continuation-in-part of U.S Patent Application Serial No. 13/312,816 (Attorney Docket No. 41507-713.201), filed December 6, 2011; and is also a continuation-in-part of U.S. Patent Application Serial No. 11/784,236 (Attorney Docket No. 41507-705.201), filed April 6, 2007, which claims priority to U.S. Provisional Application Serial No. 60/790,160 (Attorney Docket No. 41507-705.101), filed April 7, 2006, the disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[002] 1. Field of the Invention. The present invention relates generally to the fields of systems and methods for treatment of aneurysm, including implanting one or more intravascular devices for occlusion of the aneurysm.

[003] An aneurysm is an abnormal ballooning of a region of a blood vessel wall due to weakening of the wall tissue. While aneurysms can occur in any artery of the body, a large percentage of aneurysm are found in the cerebral blood vessels. If left untreated, such aneurysms can rupture, leading to life threatening hemorrhaging in the brain which can result in death or severe deficit.

[004] Aneurysms that do not rupture can form blood clots which can break away from the aneurysm potentially causing a stroke. In some patients, aneurysm can put pressure on nerves or brain tissue, causing pain, abnormal sensations, and/or seizures.

[005] One current practice for treatment of an aneurysm includes surgical placement of an aneurysm clip across the aneurysm to prevent blood flow into the aneurysm. Naturally, this procedure requires highly invasive brain surgery and thus carries many risks.

[006] In a less invasive catheter-based technique for aneurysm treatment, filler material is carried through the vasculature to the site of the aneurysm and used to pack the aneurysm. Materials used for this purpose include platinum coils and cellulose acetate polymer to fill the aneurysm sac. While these techniques have had some success, questions remain concerning their long-term effectiveness, ease of use, as well as their potential for rupturing the aneurysm or triggering clot formation. In addition, there is some risk of post procedure migration of embolic material from the aneurysm into the parent blood vessel.

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[007] According to another prior art aneurysm treatment, a mesh or braided stent-like device is positioned within a blood vessel such that it bridges the aneurysm, blocking flow of blood into the aneurysm. A problem encountered with devices of this type is that the sidewalls of the devices not only occlude blood flow into the aneurysm, but they will also block flow between the blood vessel and any side branch vessels that the stent happens to cover. See FIG. 1A, which shows a blood vessel V, aneurysm A, and side branch vessel B. In some prior art modifications to the stent-type devices, the devices include sidewalls that are not occlusive around the full circumference of the device. In implanting these devices, the physician must make certain that the occlusive portion of the device's circumference covers the aneurysm and not any of the side branch vessels.

[008] Returning to the aneurysm coil embolization solution mentioned above, a typical procedure is illustrated in FIGS. 2A-2D. A typical occlusion coil is a wire coil having an elongate primary shape with windings coiled around a longitudinal axis. It is constrained in an elongate configuration or primary shape within the catheter for delivery through the interior of the catheter. The catheter is introduced into the femoral artery and navigated through the vascular system under fluoroscopic visualization. The catheter distal end is positioned at the site of an aneurysm within the vasculature of the brain. (See FIG. 2A, illustrating catheter distal end D as it is being positioned at the site of aneurysm A.)

[009] With proper positioning of catheter distal end D confirmed, the coil is passed from the catheter into the aneurysm. The coil reverts to a three dimensional configuration after release from the distal end of the catheter into the interior of the aneurysm. Once released from the catheter, the coil assumes a secondary shape selected to optimize filling of the aneurysm cavity, and the catheter may be withdrawn from the vessel. (See FIGS. 2B-2C, illustrating the release of coil C into aneurysm A.) Multiple coils may be introduced into a single aneurysm cavity for optimal filling of the cavity. The deployed coils serve to block blood flow into the aneurysm and reinforce the aneurysm against rupture. The implants are intended to embolize the blood inside the aneurysm in order to diminish additional blood flow into the aneurysm. Eventually the embolization completely closes the aneurysm to further flow of blood into the aneurysm. For a more detailed description of embolic coils and related methods, see commonly owned U.S. Patent Application No. 12/498,752 and No. 12/695,035.

[010] In some cases, there is a significant risk of migration of the coils or other implants out of the aneurysm and into the parent vessel after delivery and deployment (or release or

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detachment) of the coils. This is especially a risk in the case of a "wide neck" aneurysm. (See FIG. 2D). Migration of a coil or coils into the circulatory system is undesirable and can lead to occlusion of the parent vessel, other vessels, as well as lead to other unintended effects.

[011] In such cases, it may be desirable to "bridge" the neck of the aneurysm with a device prior to the delivery of embolic implants. Such a bridge device may be a generally tubular structure that is positionable via catheter within the parent vessel, covering the neck of the aneurysm. Positioning of such a device is typically performed with the assistance of a guidewire and fluoroscopic visualization. The generally tubular aneurysm bridge is deployed across the neck of the aneurysm and allowed to expand into contact with the vessel walls. Embolic coils are then delivered into the aneurysm through voids in the "walls" of the tubular bridge.

[012] Shortcomings of prior art attempts to bridge the neck of an aneurysm prior to embolic coil delivery include difficulties with tracking and deployment of the device, problems resheathing and repositioning the device, entanglement between the coil delivery catheter and the bridge device, and problems with portions of the device "bulging" into the aneurysm. Therefore, there remains a need for smooth, kink-free tracking, deployment, repositioning, and reliable, uniform deployment. There also remains a need for a sufficiently flexible device having adequate column strength.

BRIEF DESCRIPTION OF THE DRAWINGS

[013] Fig. 1 schematically illustrates an aneurysm in a blood vessel and the corresponding blood flow.

[014] Fig. 2A-2D illustrate some of the steps of a method of implanting one or more embolic coils into an aneurysm in a blood vessel.

[015] Figs. 3A-3E illustrate some of the steps of a method of implanting a device to bridge the neck of an aneurysm and then implanting one or more embolic coils into the aneurysm.

[016] Fig. 4A-4G illustrate some of the steps of an alternative method of implanting a device to bridge the neck of an aneurysm and then implanting one or more embolic coils into the aneurysm.

[017] Fig. 5 is a perspective view of a finished device according to the invention, in a deployed configuration that results when the device is not placed in a vessel prior to deployment, hereinafter referred to as a "deployed in air".

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[018] Fig. 6 illustrates a side view of a device according to the invention deployed within a curved, transparent model vessel.

[019] Fig. 7 illustrates a truncated side elevational view of a device according to the invention in a deployed in air configuration.

[020] Figs. 7A-7C are cross-sectional end views of the embodiment of Fig. 7 taken along section lines A, B, and C.

[021] Fig. 8 is a perspective proximal end view of a finished device according to the invention in a deployed in air configuration.

[022] Fig. 9 is a plan view of a cut pattern for manufacture of a device according to the invention. Although devices according to the invention are preferably cut from tubular structures, twisted and shape set, Fig. 8 illustrates the cut tube as though it were longitudinally cut and flattened into a sheet before twisting, so that the pattern features may be more easily viewed.

[023] Fig. 10 is a plan view of a cut pattern of an alternative embodiment according to the invention. Although the bridge devices are preferably tubular structures, cut from a tube, twisted and shape set, Fig. 9 illustrates the device as though it were longitudinally cut and flattened into a sheet before it is twisted, so that its features may be more easily viewed.

[024] Fig. 11 is a truncated plan view of an embodiment according to the invention. Although the bridge devices are preferably tubular structures, Fig. 11 illustrates the device as though, after shape setting to include a right hand twist, it were longitudinally cut and unrolled so that its features are more easily viewed.

[025] Figs. 11A-11B are enlarged views of Details A and B of Fig. 10.

[026] Fig. 12 is a side elevation, partial cross sectional view of the distal end of a pusher catheter according to the invention, shown within a vessel and with the proximal end an aneurysm bridge device according to the invention mounted thereon.

[027] Fig. 13 is a perspective view of a pusher tip according to the invention.

[028] Fig. 14 is a perspective view of an alternative embodiment of the pusher tip of Fig. 11.

DETAILED DESCRIPTION OF THE DRAWINGS

[029] Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous

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implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be routine undertaking for those of ordinary skill in the art having the benefit of this disclosure. The aneurysm occlusion system disclosed herein boasts a variety of inventive features and components that warrant patent protection, both individually and in combination.

[030] In FIG. 3A, a system for bridging the neck of an aneurysm before delivering embolics to the aneurysm is illustrated during a step of a method according to the invention. (An alternative exemplary method is discussed below in relation to a description of FIGS. 4A-4G.) FIG. 3A illustrates a system after the step of positioning the system in a vessel V having aneurysm A. The aneurysm bridge device and accompanying delivery system include aneurysm bridge device 1, sheath 2 and pusher 5. A guide wire (not pictured) may also be utilized in the step of positioning the system in a vessel. Aneurysm bridge device is a generally tubular device capable of being retained in a reduced profile delivery configuration. The aneurysm bridge device 1 is proportioned to be implanted within the cerebral vasculature including, but not limited to, the Internal Carotid Artery, External Carotid Artery, Vertebral Artery, Basilar Artery, Middle Cerebral Artery, Anterior Cerebral Artery, and the Posterior Cerebral Artery.

[031] Generally speaking, aneurysm bridge device 1 is a tubular device having central lumen 6. It is retained in a reduced profile delivery configuration by sheath 2, and it is capable of expanding into contact with the vessel walls when released or deployed to a larger diameter configuration. Preferred devices 1 are expandable to an outer diameter in the range of 2.0mm-6.0mm. The user may be provided with a set of multiple aneurysm bridge devices of different diameters and different lengths so that the device with the most appropriate dimensions may be chosen for the procedure.

[032] Suitable materials for device 1 include shape memory materials including superelastic Nitinol or shape memory polymers, or other materials such as stainless steel, composite materials, or combinations of metals and polymeric materials. In a preferred embodiment, the aneurysm bridge device 1 may be formed by laser cutting features into a length of superelastic Nitinol tubing, then chemically processing and shape-setting the material one or more time using methods known to those skilled in the art. The device may

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then be chilled to below its shape memory transition temperature and loaded onto pusher 5 and retained by sheath 2.

[033] In the example of a method according to the invention illustrated beginning in FIG. 3A, proximal end 3 of aneurysm bridge device 1 is disposed upon the distal end 4 of pusher 5 while being retained by sheath 2. Sheath 2 is an elongate tubular catheter preferably formed of a polymeric material such as Pebax nylon, urethane, PTFE, Polyimide, metals such as Stainless Steel, Platinum, etc., or other suitable material. A central lumen extends the length of sheath 2. The sheath is proportioned for passage through cerebral vasculature, and may have an outer diameter in the range of 1mm-3mm.

[034] Pusher 5 is an elongate tubular member having optional lumen 7. The pusher may be formed of suitable polymers, metals, and/or composite materials. Distal end or tip 4 of pusher 5, which is described in greater detail below in a description of FIGS 11-14, includes apertures 8. When loaded onto distal tip 4, device 1 is threaded over pusher 5, and positioned so that bumps 9 of its proximal end 3 are aligned with, or inserted into, apertures 8. Bumps 9 may alternatively be projections, tabs, posts, clips, or any structures, preferably male, that are suitable for engaging apertures 8. Similarly, apertures 8 may alternatively be pockets, holes, hollows, grooves, or any structures, preferably female, for receiving bumps 9. Sheath 2 retains bumps 9 in engagement with apertures 8 as it retains aneurysm bridge device 1 in a reduced profile configuration. Device 1 remains in the reduced profile configuration during tracking of the device under fluoroscopic visualization to a treatment site within the vasculature of a subject.

[035] After positioning aneurysm bridge 1 across the opening of aneurysm A, the device is then deployed and either temporarily or permanently implanted in the vessel. As illustrated beginning with FIGS. 3B, in order to deploy aneurysm bridge 1, sheath 2 is withdrawn proximally to permit the device 1 to expand to its unconstrained configuration into contact with the inner walls of the parent vessel V. When sheath 2 is completely withdrawn from the length of bridge device 1, device 1 expands to a deployed diameter, as illustrated in FIG. 3C. Also, when sheath 2 is withdrawn from along the length of device 1, bumps 9 are no longer retained in apertures 8. Pusher 5 may then be withdrawn from the vessel V. Alternatively, pusher 5 may be left positioned in vessel V, and central lumen 7 may be utilized as a conduit or passage in a subsequent step. Further, if the user wishes to reposition device 1, sheath 2 can be advanced distally in order to resheath device 1. The steps of positioning and deploying device 1 described above can then be repeated.

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[036] Voids in the walls of the tubular device 1 permit the catheter-based delivery of embolic coils through the walls and into the aneurysm. (Alternatively, embolic coils may be implanted according to a method in which the coils are not delivered through the voids in the wall of device 1, as described in greater detail below.) As illustrated in FIG. 3D, delivery catheter D may be positioned within vessel V (and/or alternatively within pusher lumen 7). Embolics including one or more embolic coils may then be delivered to the aneurysm, in much the same manner as described above in relation to FIGS. 2A-2C, except that they are delivered through the voids in the "walls" of the bridge 1. The position of the device 1 across the neck of the aneurysm prevents the unintended escape of embolic materials out of the aneurysm and into the parent vessel following the conclusion of the procedure (See FIG. 3E). The device remains in place in the parent vessel across the aneurysm neck during the delivery of coils, thereafter, and if desired, permanently.

[037] Turning now to an alternative method according to the invention, FIGS. 4A-4G illustrate exemplary steps according to the alternative method. In the steps illustrated in FIGS. 4A-4G, the aneurysm bridge 1 described above in relation to FIGS 3A-3E is again utilized, but according to a somewhat different method than that described in the foregoing paragraphs. FIG. 4A illustrates an early step according to the invention following the introduction of delivery catheter D into a vessel V having aneurysm A. One or more embolic coils, in the elongate configuration, is constrained by and carried within delivery catheter D. The distal end of delivery catheter D is positioned proximate aneurysm A.

[038] Following positioning of delivery catheter D proximate aneurysm A, the aneurysm bridge device 1 and accompanying delivery system are introduced into the vessel V and positioned proximate aneurysm A, generally as illustrated in FIG. 4B. In addition to aneurysm bridge device 1, the delivery system includes sheath 2 that was illustrated and discussed above. Sheath 2 retains aneurysm bridge device 1 in a reduced profiled configuration. Device 1 is capable of expanding into contact with the vessel walls, or released or deployed to a larger diameter configuration, when sheath 2 is withdrawn.

[039] There are many similarities between the delivery system illustrated in FIG. 3B and FIG. 4B. However, the system illustrated in FIG. 4B includes alternative pusher 14. Pusher 14 may be formed of suitable polymers, metals, and/or composite materials. Pusher 14 may include any of the materials and dimensions of pusher 5 described above, but pusher 14 does not include a central lumen. A guide wire (not pictured) may also be utilized in the step of positioning the system in a vessel.

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[040] Prior to introduction into vessel V, the proximal end 3 of aneurysm bridge device 1 is disposed upon the distal end of pusher 14. Exemplary distal tips of pusher 14 are described in greater detail below in a description of FIGS 11-14. Distal tip 4 again includes apertures 8. When loaded onto distal tip 4, device 1 is threaded over pusher 14, and positioned so that bumps 9 of its proximal end 3 are aligned with, or inserted into, apertures 8. Bumps 9 may alternatively be projections, tabs, posts, clips, or any structures, preferably male, that are suitable for engaging apertures 8. Similarly, apertures 8 may alternatively be pockets, holes, hollows, grooves, or any structures, preferably female, for receiving bumps 9. Sheath 2 retains bumps 9 in engagement with apertures 8 as it retains aneurysm bridge device 1 in a reduced profile configuration. Device 1 remains in the reduced profile configuration during tracking of the device under fluoroscopic visualization to a treatment site within the vasculature of a subject.

[041] After positioning aneurysm bridge 1 across the opening of aneurysm A, and proximate the distal end of delivery catheter D, the device is then deployed. As illustrated beginning with FIGS. 4C, in order to deploy aneurysm bridge 1, sheath 2 is withdrawn proximally to permit the device 1 to expand to its unconstrained configuration into contact with the inner walls of the parent vessel V. When sheath 2 is completely withdrawn from the length of bridge device 1, device 1 expands to a deployed diameter, as illustrated in FIG. 4D. If the user wishes to reposition device 1, sheath 2 can be advanced distally in order to resheath device 1. The steps of positioning and deploying device 1 described above can then be repeated. Pusher 5 may then be either withdrawn from the vessel V or may be left positioned in vessel V. As illustrated in FIGS. 4C and 4D, delivery catheter D remains in place proximate the aneurysm during the steps of the method described herein.

[042] As illustrated in FIG. 4E-4F, one or more embolic coils (or other embolic material) may then be delivered to the aneurysm, in much the same manner as described above, except that they are delivered directly into the aneurysm, instead of through the voids in the "walls" of the bridge 1. The position of the device 1 across the neck of the aneurysm prevents the unintended escape of embolic materials out of the aneurysm and into the parent vessel following the conclusion of the procedure (See FIG. 4G). The device remains in place in the parent vessel across the aneurysm neck during the delivery of coils, thereafter, and if desired, permanently.

[043] Details of an aneurysm bridge device according to the invention are illustrated in FIG. 5. Aneurysm bridge 10 is illustrated in a deployed "in air" configuration. Aneurysm

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bridge 10 is a more or less tubular device capable of being retained in a constrained form or shape prior to deployment, and then expanded (or permitted to expand) into contact with the walls of a vessel when deployed. Consequently, it may be positioned and delivered using a variety of methods similar to those summarized above in conjunction with the description of Figs. 3A-4G. As described in detail below, aneurysm bridge 10 has many advantages over prior art devices for improved delivery, deployment, retraction, repositioning, and redeployment .

[044] Aneurysm bridge 10 may be constructed from any number of compositions having suitable biocompatibility and strength characteristics. In the embodiment illustrated in Fig. 5, aneurysm bridge 10 is constructed from Nitinol® with "shape memory" or superelastic characteristics to optimize self expansion of the device upon deployment. Aneurysm bridge 10 is constructed by cutting features into a Nitinol tube. For example, a tube of 3.5mm outer diameter and .005 inch thickness may be cut in a predetermined pattern of bands, struts, and/or connectors. Examples of suitable patterns are illustrated below in FIGS. 9 and 10, though variations on the patterns are within the scope of the invention. After the features are cut into the tube, the tube is twisted and shape set. It has been found that a helical arrangement resulting from the twist helps the deployed device conform to the vessel walls, and it also improves the ability of the device to resist kinking.

[045] An aneurysm bridge according to the invention may be dimensioned in any number of suitable sizes and lengths, depending upon the location of the aneurysm, variances in patient anatomy, and the size and shape of the aneurysm. Aneurysm bridge 10 of FIG. 5 in its expanded configuration is approximately 2.0-6.0 mm at its maximum outer diameter, and between 10-45 mm in length. Aneurysm bridge 10 can be described while viewing FIG. 5 from left to right, with its proximal end 15 on the left side of the figure, its distal end 18 on the right, and a central region 11 disposed therebetween. As described in greater detail below in conjunction with a description of FIGS. 7-7C, generally tubular aneurysm bridge 10 has a generally ovular shaped cross section at its proximal end 15 and its distal end 18 when it is deployed in air. It is however generally circular in cross section throughout most of its central region 11. When bridge 10 is deployed in a vessel, it generally takes the shape and cross section of the vessel.

[046] In FIG. 5, two standards 20 and 22 can be seen extending in a helical fashion from proximal end 15 to distal end 18, more or less the entire length of tubular element 10, though alternative embodiments may have a greater number of standards. The helical array of

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aneurysm bridge 10 may be imparted to a cut tube by grasping standards 20 and 22 and applying a circumferential twist. (The extent of circumferential twist can be characterized in terms of the resulting angle of standards 20 and 22 to the longitudinal axis of device 10, and is illustrated in FIG. 7 below). Standards 20 and 22 have a width in the range of 0.0020-0.0050 inch, preferably between 0.0030-0.0045 inch, and impart axial and columnar strength upon aneurysm bridge 10. The standards may also be used to provide axial force to the device if it is necessary to reposition the device after partial deployment within the vessel as discussed above. Standards 20 and 22 may further be equipped with features to facilitate loading of the finished device 10 into a sheath.

[047] Standard 22 defines a portion of first helical spine 25. First helical spine 25 extends in a helical fashion along the length of aneurysm bridge 10 from proximal end 15 to distal end 18 as a result of the circumferential twist applied to standards 20 and 22. Similarly, standard 22 defines a portion of second helical spine 27. Second helical spine 27 extends in a helical fashion from proximal end 15 to distal end 18 of aneurysm bridge 10. First helical spine 25 and second helical spine 27 impart columnar strength and uniform, reduced size gap spacing along the length of the device 10. The specific features that define first helical spine 25 and second helical spine 27 will be described in detail in relation to FIGS. 8 and 9, in which the features are more easily viewed.

[048] Among the advantages of the invention herein are its superior, kink-resistant, reversible trackability and reversible deployability within tortuous vasculature. In order to illustrate the superior tracking and reliable deployment of the system, device 10 is shown deployed within a transparent vessel model 30 in FIG. 6. Transparent model vessel 30 has a curved configuration and model aneurysm 34 located on the "outer" side of curve 36. Device 10 was tracked through curve 36 and across the neck of aneurysm 34. Aneurysm bridge 10 was permitted to expand radially outwardly to closely meet the walls of the vessel model. And despite the curved configuration of the vessel model, aneurysm bridge device readily deploys to contact the walls of the lumen. Moreover, when deployed in a curved vessel, the features of device 10, (which are described more specifically below in conjunction with a discussion of FIG. 9) are disposed in a uniform, orderly configuration. No portion of aneurysm bridge device 10 bulges or protrudes into aneurysm 34. Consequently, aneurysm bridge device 10 can be repositioned and redeployed readily if needed, or withdrawn completely from the vessel. And aneurysm bridge device 10 provides orderly gaps between

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struts or bands through which occlusion coils (not pictured) may be both delivered to aneurysm 34 and prevented from escape therefrom.

[049] FIG. 7 illustrates other aspects of aneurysm bridge 10 from a truncated side elevational view. Firstly, the twist angle mentioned above in relation to FIG. 5 is more easily viewed in FIG. 7. Twist angle α is illustrated as the angle between standard 20 and longitudinal axis *x* of device 10. Twist angle α is between 15° and 40°, and preferably between 20° and 35°, in either a clockwise or a counterclockwise direction. A particular twist angle may be imparted on device 10 after pattern features illustrated in FIGS. 9 and 10 below are cut into a Nitinol tube.

[050] FIGS. 7A-7C illustrate cross sectional shapes of device 10 (when it is deployed in air), along lines A, B and C of FIG. 7 above. Fig 7A illustrates the cross section of proximal end 15 at Detail A. At proximal end 15 of aneurysm bridge 10, standard 20 is generally opposite standard 22. Fig. 7B illustrates the cross section of central region 11 at Detail B. And Fig. 7C illustrates the cross section of aneurysm bridge 10 at detail C. At distal end 18, standards 20 and 22 intersect one another along a wall of aneurysm bridge 10. Apexes 24 are disposed opposite one another, at the narrowest portions of the oval. Central lumen 28, which extends the length of tubular element 10, is consequently ovular in cross section at the proximal and distal ends of aneurysm bridge 10, and circular in cross section in the central region of the device.

[051] FIG. 8 illustrates aneurysm bridge 10 from a perspective view of proximal end 15, revealing central lumen 28. (For clarity, the portion of bridge 10 on the "back side" of lumen 28 is illustrated merely by dotted helical lines.) Distal end 18 is essentially facing away from the viewer in FIG. 8. Bridge 10 is again shown deployed in air, and proximal end 15 has a generally ovular cross section. At proximal end 15, the proximal-most ends of standards 20 and 22 lie essentially opposite one another, along the narrowest portions of the oval.

[052] FIG. 9 illustrates an example of a cut pattern used to make a device according to the invention. Although an aneurysm bridge according to the invention is a generally tubular device shape set into a twisted configuration, FIG. 9 illustrates the device as though, before being shape set into a twist, it has been cut along its length and laid flat so that its features may be more easily viewed. Cut pattern 50 has a proximal end 52 and a distal end 53. Cut pattern 50 also has standards 55 and 57. Standard 55 and standard 57 have a similar set of features arrayed in a repeating pattern. For ease of reference, these features will be described especially in relation to standard 55, though standard 57 is also oriented to bands, struts or

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connectors having generally the same features. Extending laterally or diagonally from standard 55 is a plurality of bands 60. Bands 60 have strut widths in the range of 0.00050-0.00150 inch, and preferably between 0.00060-0.00120 inch. Bands 60 in turn extend to define S-connectors 65. Standard 55, bands 60 and S-connectors 65 define a first spine 68. Second spine 69 is defined by the corresponding features in conjunction with standard 57. In the cut pattern 50, spines 68 and 69 are generally straight. In a finished device, however, a circumferential twist will be shape set into the device, placing spines 68 and 69 in a helical configuration.

[053] Connected to the other ends of S-connectors 65 are bands referred to as V-struts 70. Each V-strut 70 includes a short leg 71, a long leg 72, and an apex 73 therebetween. Apexes 73 are disposed pointing toward distal end 53. Though other geometries are possible within the scope of the invention, the resulting lattice of first spine 68, V-struts 70, second spine 69 and V-struts 74 will define the skeletal "walls" of the generally tubular aneurysm bridge and the shape and size of voids within the walls.

[054] The function of S-connectors 65 can be described as limiting the expansion between bands 60. The expansion limiting function can most easily be viewed in FIG. 6. Aneurysm bridge 10, deployed in curved model vessel 30, has bands 12 and S-connectors 13. The tighter spacing between bands 12 is illustrated in comparison to the wider spacing of V-struts 19. S-connectors 13 tighten the gaps in the walls of the device, effectively reducing the size of gaps 26 by roughly half, thereby providing a barrier to coils that may be implanted into aneurysm 34. S-connectors 13 also prevent bands 12 and V-struts 19 from "poking" or protruding into aneurysm 34, an important advantage if the device must be repositioned, especially when the aneurysm is disposed in a curved vessel, as in the example of FIG. 6. The closely spaced and generally uniform array imparted by S-connectors 13 is imparted along the length of first helical spine 25 (and second helical spine 27, which is not visible in FIG. 5), and consequently along the length of aneurysm bridge 10.

[055] The function of V-struts 19 can be characterized as maximizing the flexibility of the device 10. The flexibility imparted by V-struts 19 is very important for accommodating the flexure of the device both prior to deployment and over the life of the device. Prior to deployment of the device, most of the stress imparted on the device occurs during crimping down and loading the device into a sheath, and then tracking the crimped device through tortuous vasculature while crimped down and sheathed. Following deployment of the device within the vessel, most of the stress imparted on the device is a result of the ongoing, long

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term expansion and contraction due to pulsation of the vessel. In both configurations, the majority of the stress on the device is absorbed by the V-struts 19. It is desirable for the device to be able to flex at the "V"; otherwise the stress may break the device, or deform the device beyond its ability to recover, or otherwise cause the device to fail.

[056] The specific structures of bands 12, S-connectors 13 and V-struts 19 of FIGS. 5-8 are similar to the corresponding features of FIGS. 9 and 10, but can be most easily viewed in FIG. 10. FIG. 10 illustrates an alternative embodiment according to the invention. Similar to FIG. 9, it illustrates a cut pattern of a generally tubular device as though it were cut along the length of the tube before the tube has been shape set, and laid flat so that the features of the pattern may be more easily viewed. Cut pattern 90 has proximal end 92, distal end 93, and standards 95 and 97. Cut pattern 90 has a lesser number of bands 100 than does cut pattern 50 described above. Cut pattern 90 has a correspondingly fewer number of S-connectors 105 and V-struts 110. Cut pattern 90 accordingly will form a shorter length device than cut pattern 50.

[057] An important similarity between the embodiment of FIG. 10 and other embodiments is that S-connectors 105 perform the same gap-limiting function without sacrificing needed flexibility. In order to perform this function, S-connectors 105 are disposed between bands 100 and V-struts 110, and specifically very near apexes 112 of V-struts 110. V-struts 110 consequently have a short leg 114 and a long leg 116. S-connectors 110 thereby maintain close spacing between bands 100, while permitting flexure of apexes 112. Because most of the stress during flexure of the device made from cut pattern 90 is absorbed by apexes 112, it is important that the S-connector not completely prevent flexure of apexes 112. The positioning of S-connectors illustrated in FIG. 9 help define first spine 94 and second spine 96, yet permit flexure of V-struts 110. Apexes 112 additionally point in the direction of distal end 93, facilitating resheathing of the device if needed.

[058] FIG. 11 illustrates a truncated view of a cut pattern to which a right hand twist has been applied. Cut pattern 130 is illustrated as though a twisted tubular aneurysm bridge according to the invention were cut along its axis and unrolled to better display its features. More easily viewed in FIG. 11A, Detail A, taken from a distal portion of cut pattern 130 of Fig. 11, reveals the structure of bands 150, S-connectors 155, and V-struts 160. Also visible in Fig. 11A is marker 165, which is disposed on the distal end of standard 170. The distal extension 175 of standard 170 is between 0.0200-0.110 inch, and preferably between 0.0300 and 0.1050 inch in length.

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[059] FIG. 11B is an enlarged view of Detail B, taken from a proximal region of Fig. 11, to better illustrate some of its features. Again S-connectors 155 are visible, as are V-struts 160, and standard 170. Affixed near the proximal end of standard 170 is bump 180 (shown from a top view of bump 180). As mentioned above, bump 180 is useful in loading a finished device on the distal end of a pusher prior to retaining the device with a sheath (see FIGS. 3A-3C).

[060] See also FIG. 12, showing an enlarged schematic illustration of a device 200 according to the invention mounted on a pusher and retained by a sheath. Proximal end 201 of aneurysm bridge 200 is shown mounted on the distal end of a pusher 202. Bumps 205 are seen in engagement with apertures 210. Sheath 215 retains aneurysm bridge 200 in its reduced profile delivery configuration, and consequently keeps bumps 205 in engagement with apertures 210 until either proximal withdrawal of sheath 215, or until pusher 202 pushes the device out of the end of sheath 215.

[061] FIG. 13 is a perspective view of a pusher tip 300 that is not affixed to the distal end of a pusher. Pusher tip 300 has a central lumen 305, and three apertures 310. A greater or lesser number of apertures are within the scope of the invention. Similar to the apertures described in relation to FIGS. 10-11 above, apertures 310 permit the engagement of bumps on the proximal end of an aneurysm bridge device. Legs 315 and eyelets 317 permit the attachment of pusher tip 300 onto the distal end of a pusher.

[062] FIG. 13is a perspective view of an alternative embodiment of a pusher tip according to the invention. Pusher tip 400 has central lumen 405 and two apertures 410 which can accommodate bumps on the proximal end of an aneurysm bridge device, to enhance retention of the device on the distal end of a pusher until deployment of the device at a desired time. Legs 415 and eyelets 417 enhance attachment of pusher tip 400 on the distal end of a pusher.

[063] It should be recognized that a number of variations of the above-identified embodiments will be obvious to one of ordinary skill in the art in view of the foregoing description. Accordingly, the invention is not to be limited to those specific embodiments and methods of the present invention illustrated and described herein. Rather, the scope of the invention is to be defined by the claims and their equivalents.

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WHAT IS CLAIMED IS:

1. An intravascular device comprising:

a tubular element that is radially expandable from a compressed position to an expanded position, said tubular element comprising a wall, a proximal end, a distal end and a central portion therebetween;

the tubular element further comprising at least two elongate standards extending in a helical fashion along the wall from the proximal end to the distal end when the tubular element is in the expanded position; and

the tubular element further comprising a first plurality of bands including at least one end connected to a first elongate standard, wherein the first elongate standard and the first plurality of bands together define a first helical spine, and a second plurality of bands including at least one end connected to a second elongate standard, wherein the second elongate standard and the second plurality of bands together define a second helical spine.

2. The intravascular device according to claim 1 wherein at the proximal end, a first standard is disposed along a first side of the wall, and a second standard is disposed along an opposing side of the wall, and near the distal end, the first standard crisscrosses the second standard.

3. The intravascular device according to claim 1 wherein said tubular element comprises a generally oval cross section near said proximal end and said distal end, and a generally circular cross section near said central portion.

4. The intravascular device according to claim 1 wherein said bands comprise a V-shape.

5. The intravascular device according to claim 4 wherein said V-shaped bands further comprise S-shaped connecting members.

6. The intravascular device according to claim 5 wherein said V-shaped bands comprise apexes and said S-shaped connecting members are disposed near said apexes, but not upon said apexes.

7. The intravascular device according to claim 1 wherein said tubular element is cut from a length of tubing comprising shape memory material according to a pattern, and wherein in said pattern, the elongate standards extend parallel to one another from the proximal end to the distal end.

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Penumbra, Inc. v. RapidPulse, Inc.

8. The intravascular device according to claim 1 wherein said tubular element has a longitudinal axis and at the least two elongate standards are oriented in opposite directions at angles of between 15° and 45° to said longitudinal axis when said tubular element is in said expanded position.

9. The intravascular device according to claim 1 wherein in addition to said first and second helical spines, said wall is defined by said bands.

10. The intravascular device according to claim 1 wherein said device comprises only two elongate standards.

11. A system for treatment of intracranial aneurysm comprising:

a device for bridging the neck of an aneurysm of a cerebral vessel, said device comprising a tubular element including a plurality of standards, a plurality of bands connected to the standards, a longitudinal axis, a reduced-profile delivery configuration and a deployed configuration, wherein said standards are oriented at an angle to said longitudinal axis when said tubular element is in said deployed configuration so that the standards and the bands together define a plurality of helical spines;

an introducer for introducing said tubular element into a vessel; and

a delivery device for delivering embolic material into the aneurysm.

12. The system according to claim 11 wherein said angle is between 15° and 45°.

13. The system of claim 11 wherein the bands further comprise one or more S-shaped connectors.

14. The system of claim 11 wherein said standards comprise a width of between .0020 inch and .0050 inch.

15. The system of claim 11 wherein said tubular element comprises shape memory material and reversibly converts between said delivery configuration and said deployed configuration.

16. The system of claim 11 wherein said system further comprises a sheath, whereby said tubular element is retained in said low profile delivery configuration, and wherein withdrawal of said sheath permits said tubular element to convert to its deployed configuration.

17. The system of claim 16 wherein said tubular element can be returned to its delivery configuration within said sheath.

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Penumbra, Inc. v. RapidPulse, Inc.

18. The system of claim 11 wherein said system further comprises a sheath, and said tubular element can be withdrawn into said sheath via said introducer.

19. The system of claim 11, the introducer further comprising a tip comprising a central lumen, one or more legs, and at least one aperture.

20. The system according to claim 19 wherein said first and second standards further comprises at least one bump configured to engage the at least one aperture.

21. A method of manufacture of an intravascular device, said method comprising the steps of:

providing a tube comprising one or more shape memory materials, a longitudinal axis, a proximal end and a distal end;

cutting the tube according to a predetermined pattern, wherein the predetermined pattern defines at least two parallel elongate standards;

applying a circumferential twist to the cut tube to orient the elongate elements at an angle to said longitudinal axis; and

applying a shape memory set to the twisted cut tube.

22. The method according to claim 21 wherein said shape memory material is nitinol.

23. The method according to claim 21 wherein said predetermined pattern defines only two parallel elongate standards.

24. The method according to claim 21 wherein said predetermined pattern further defines a plurality of V-shaped bands having at least one end connected to an elongate standard.

25. The method according to claim 24 wherein said V-shaped bands comprise apexes and S-shaped connectors, wherein said S-connectors are disposed near, but not upon, said apexes.

26. The method according to claim 21 wherein the step of applying a circumferential twist to the cut tube is performed so that at least one of the elongate standards crisscrosses a second elongate standard at the distal end.

27. The method according to claim 21 wherein said angle is between 15° and 45°.

28. A method of treating an aneurysm located in a blood vessel of a subject, the method comprising the steps of:

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Penumbra, Inc. v. RapidPulse, Inc.

introducing an elongate tubular delivery device into the blood vessel and proximate the aneurysm, the delivery device suitable for delivery of embolic material;

introducing a tubular element for bridging the neck of the aneurysm, the tubular element being radially expandable from a compressed position to an expanded position, having a proximal end, a distal end, and a longitudinal axis, and at least two elongate standards and a plurality of bands attached thereto, the elongate standards arranged helically about the longitudinal axis from the proximal end to the distal end when the tubular element is in the expanded position, the elongate standards and bands together forming a first helical spine and a second helical spine;

bridging a neck of the aneurysm with the tubular element;

permitting the expandable tubular element to expand;

delivering one or more embolic materials to the aneurysm; and

withdrawing the tubular delivery device.

Penumbra, Inc., Ex. 1029, Page 207 of 728
Penumbra, Inc. v. RapidPulse, Inc.

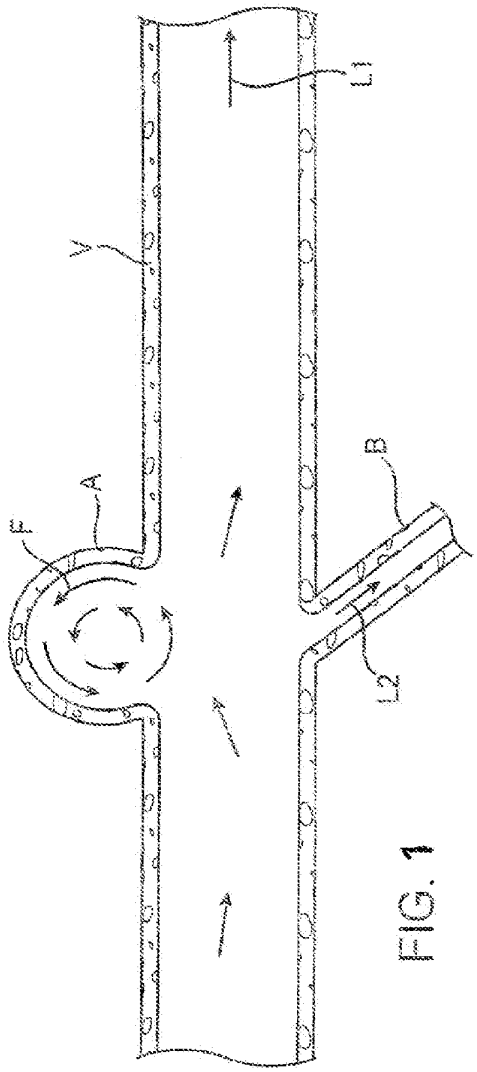


FIG. 1

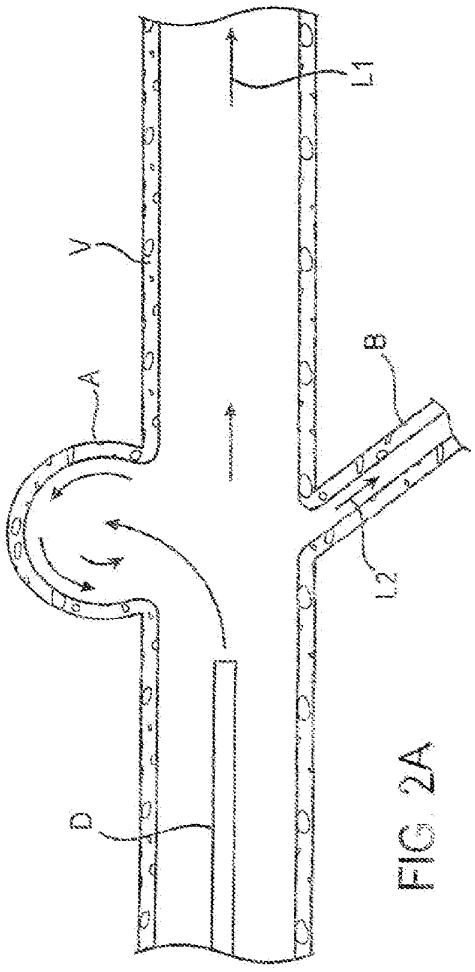


FIG. 2A

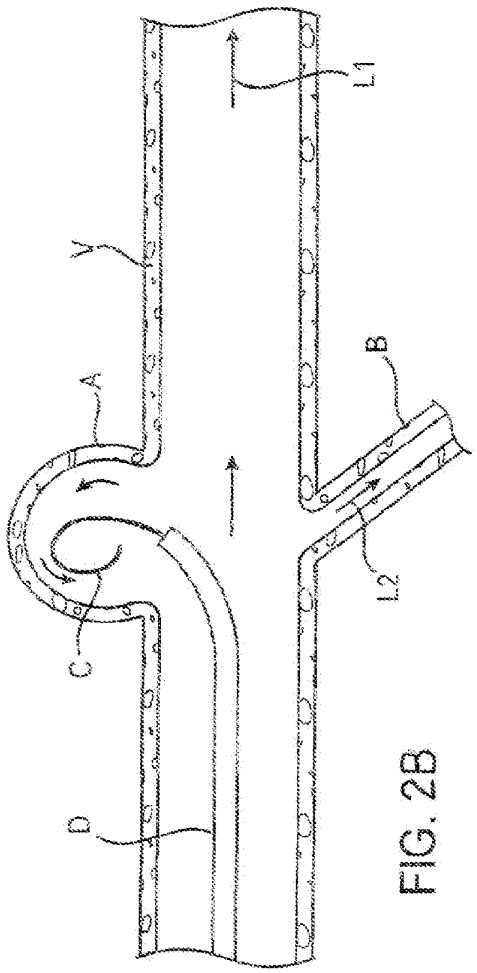


FIG. 2B

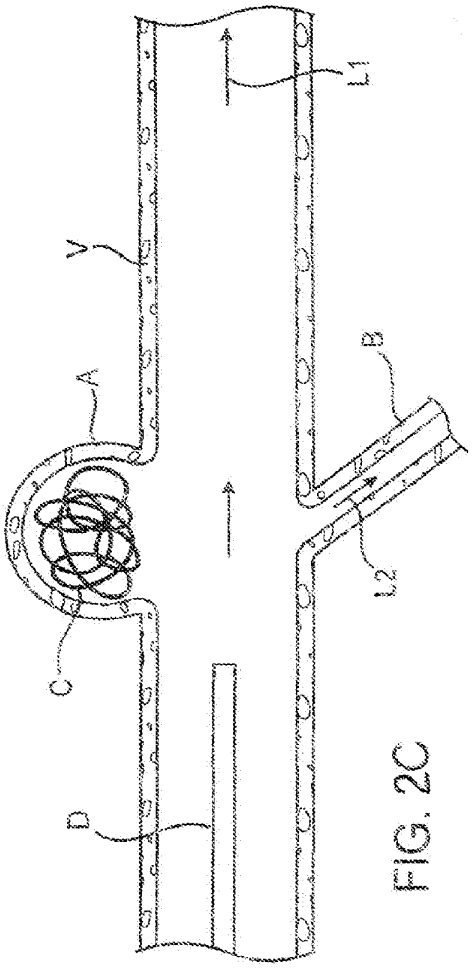


FIG. 2C

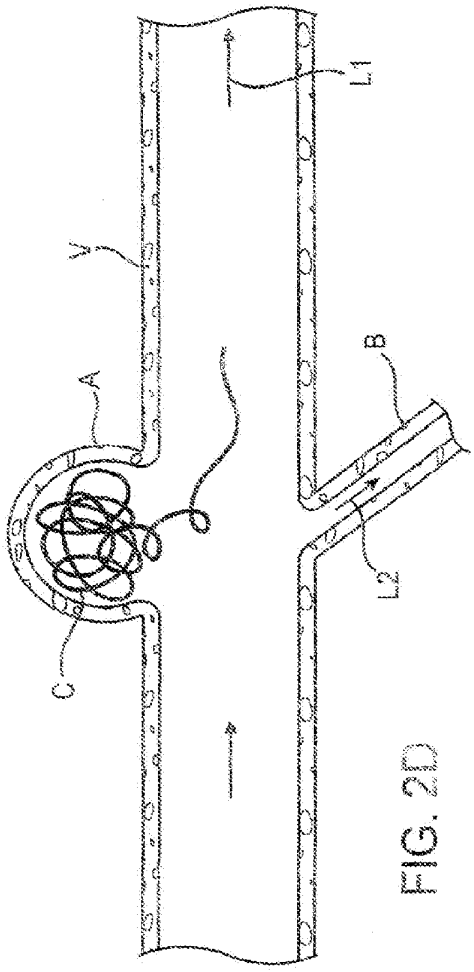


FIG. 2D

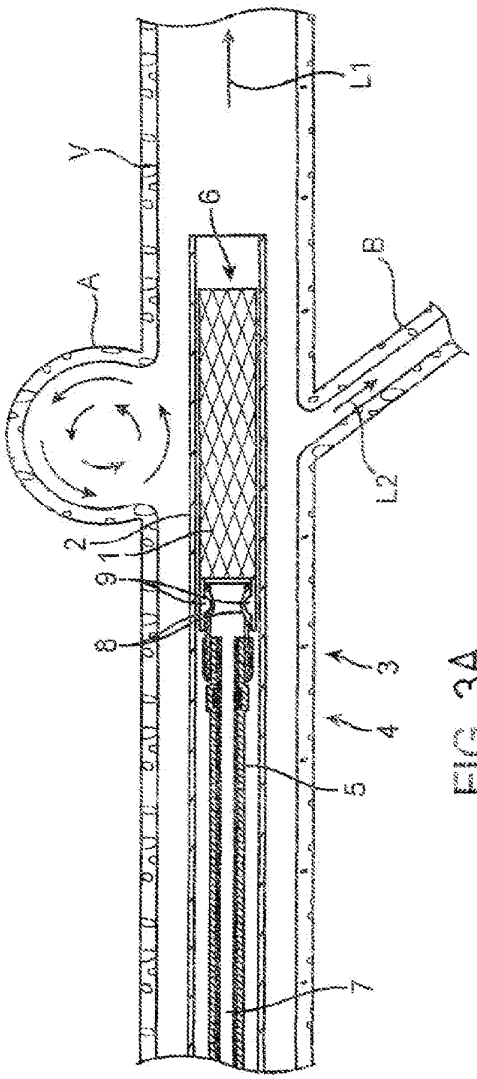


FIG. 3A

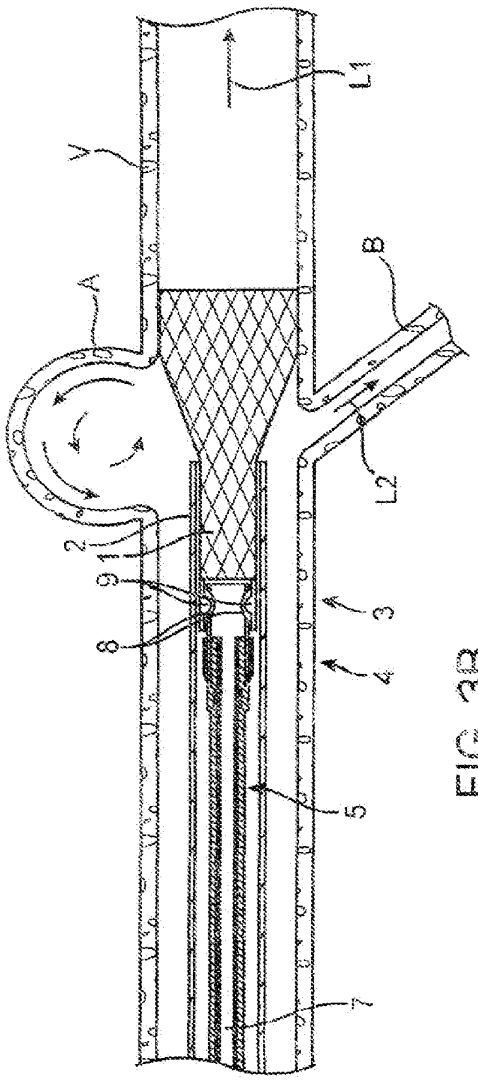


FIG. 3B

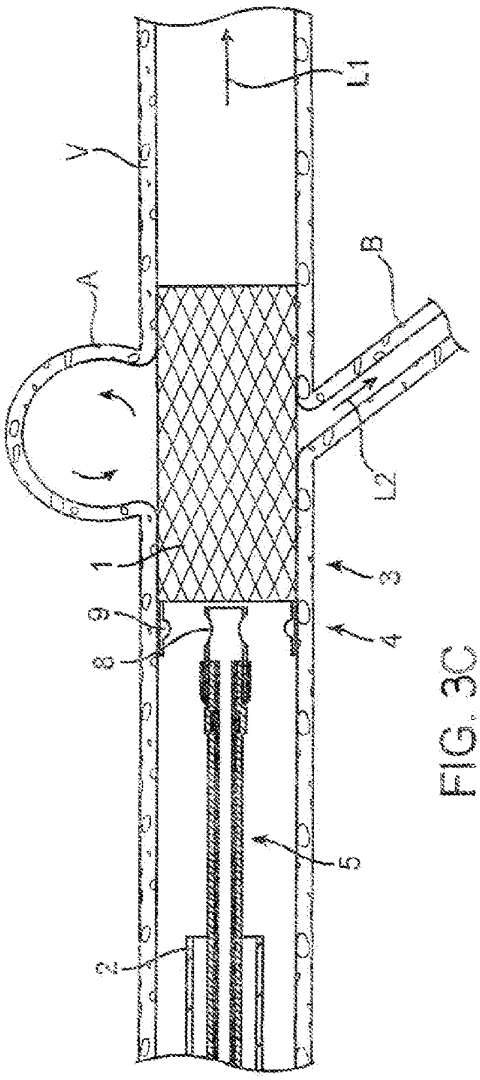


FIG. 3C

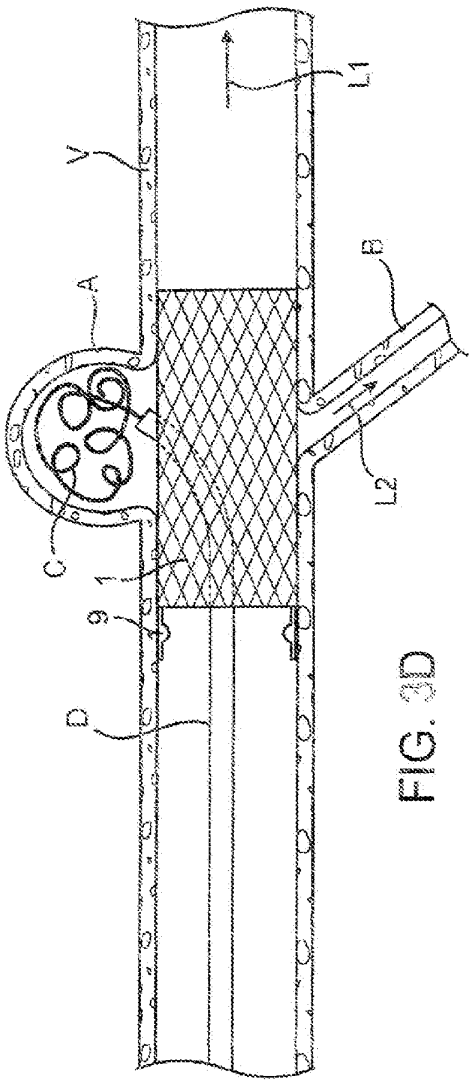


FIG. 3D

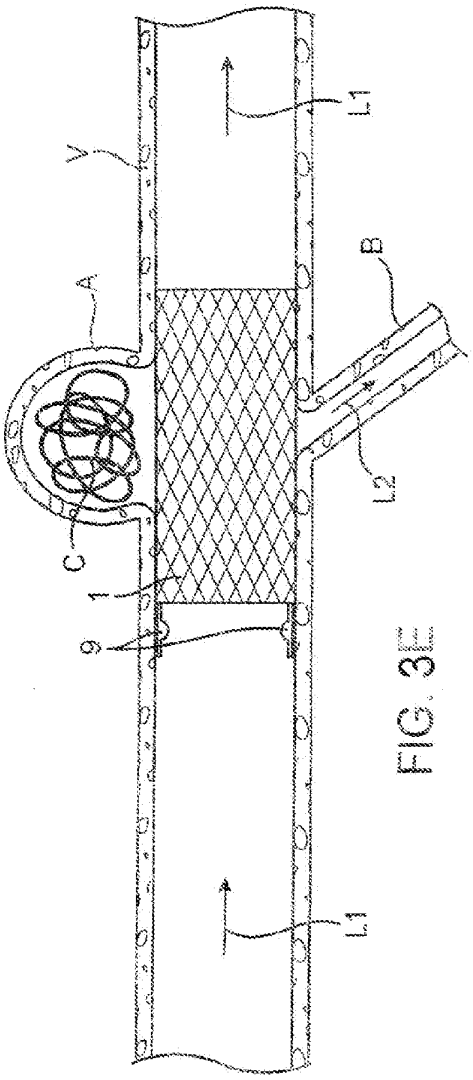


FIG. 3E

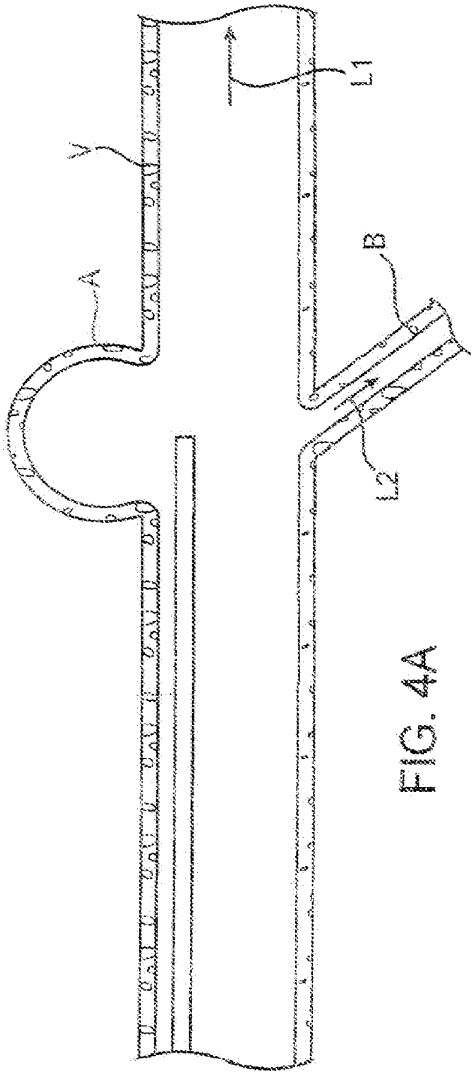


FIG. 4A

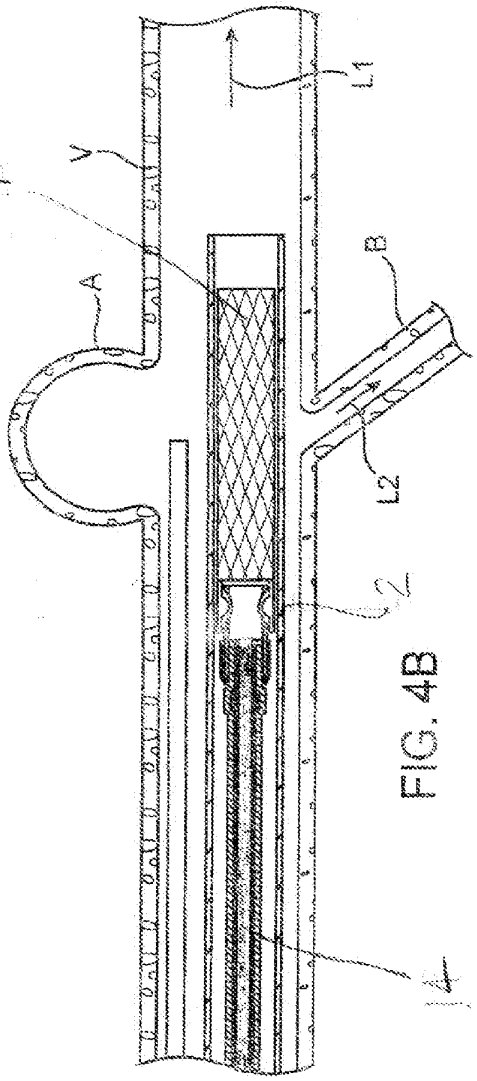


FIG. 4B

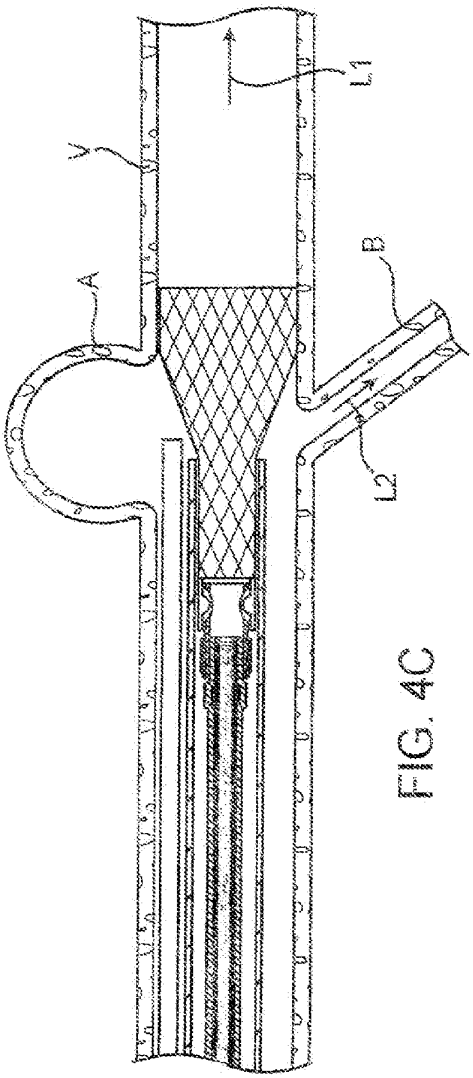


FIG. 4C

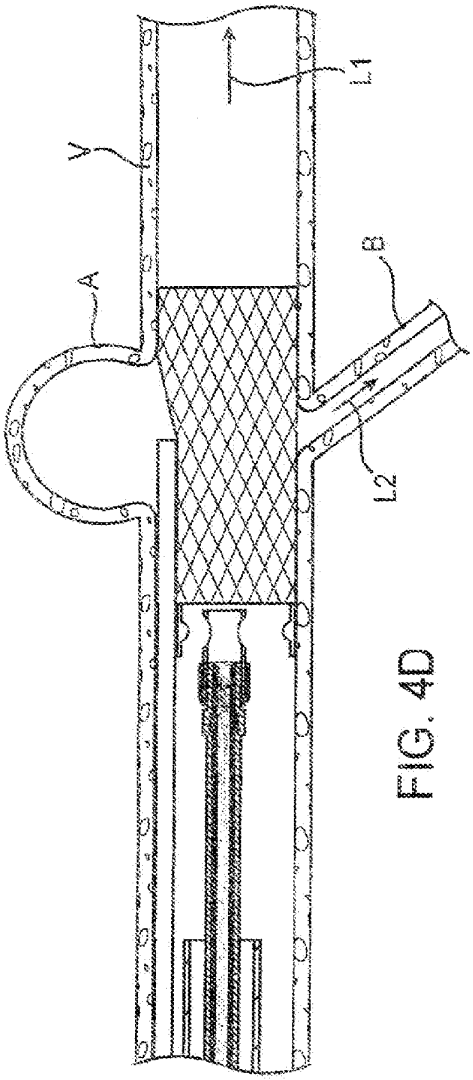


FIG. 4D

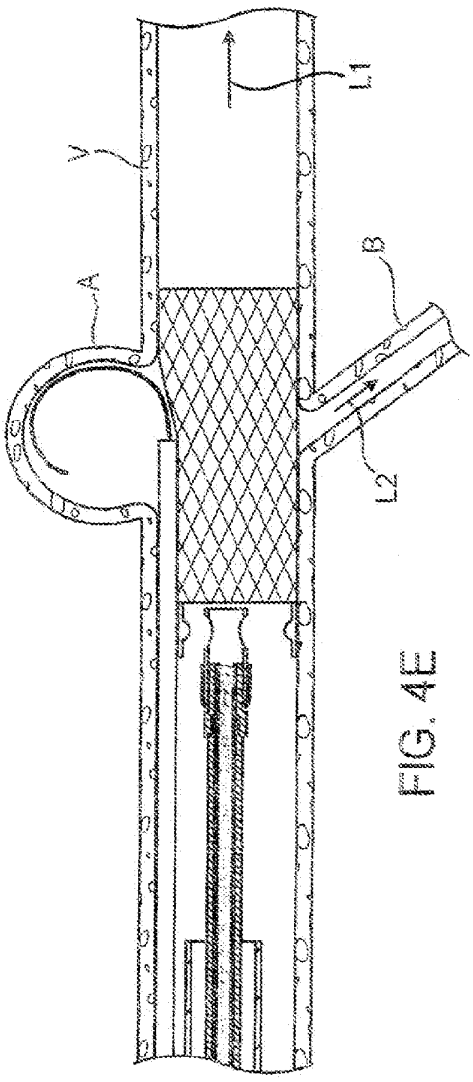


FIG. 4E

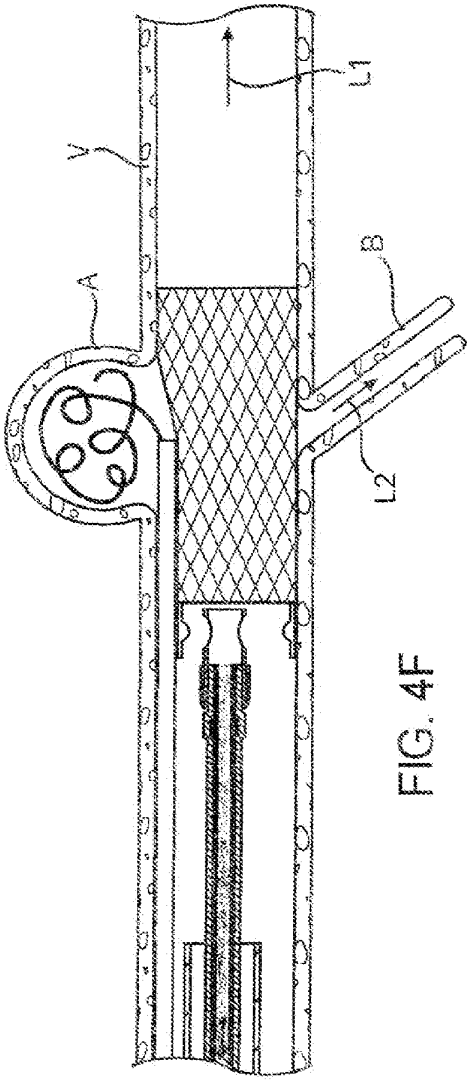


FIG. 4F

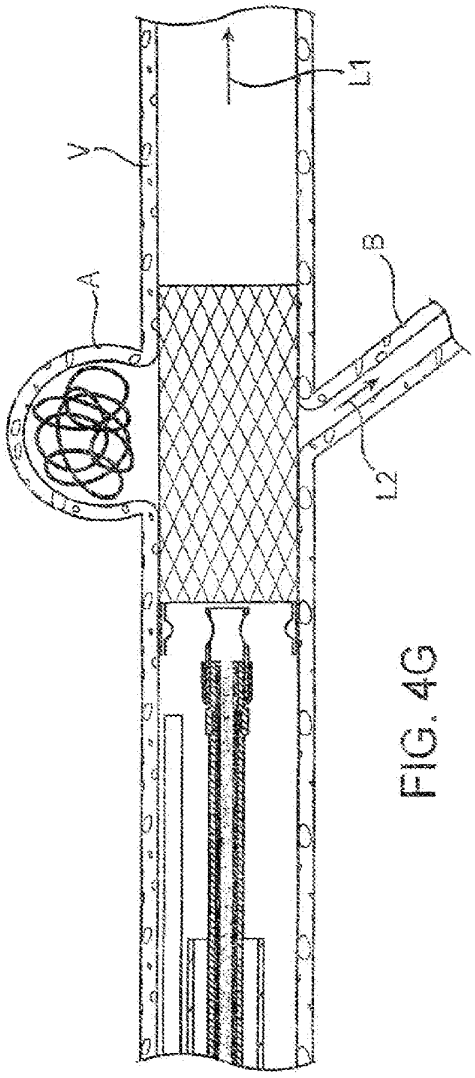


FIG. 4G

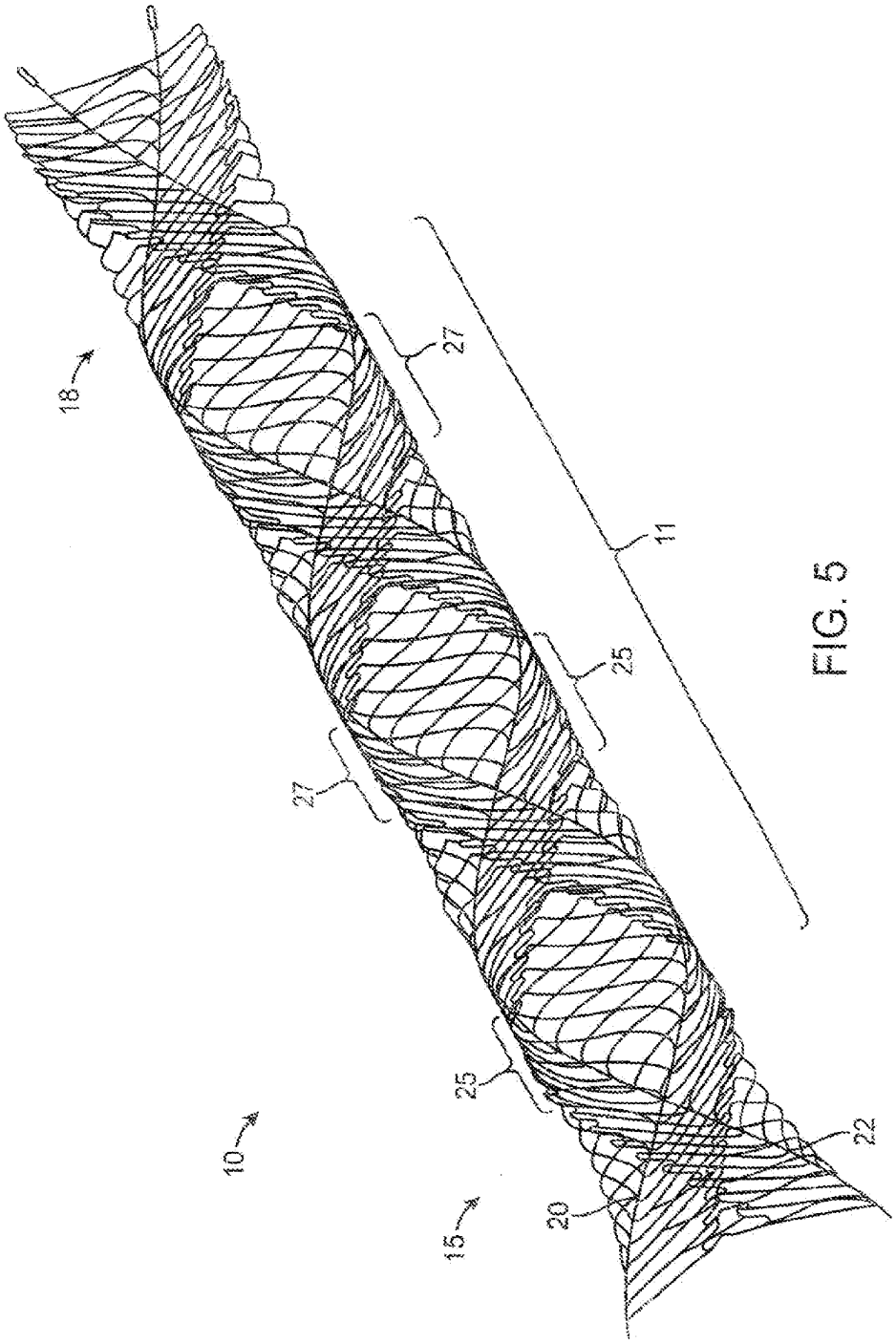


FIG. 5

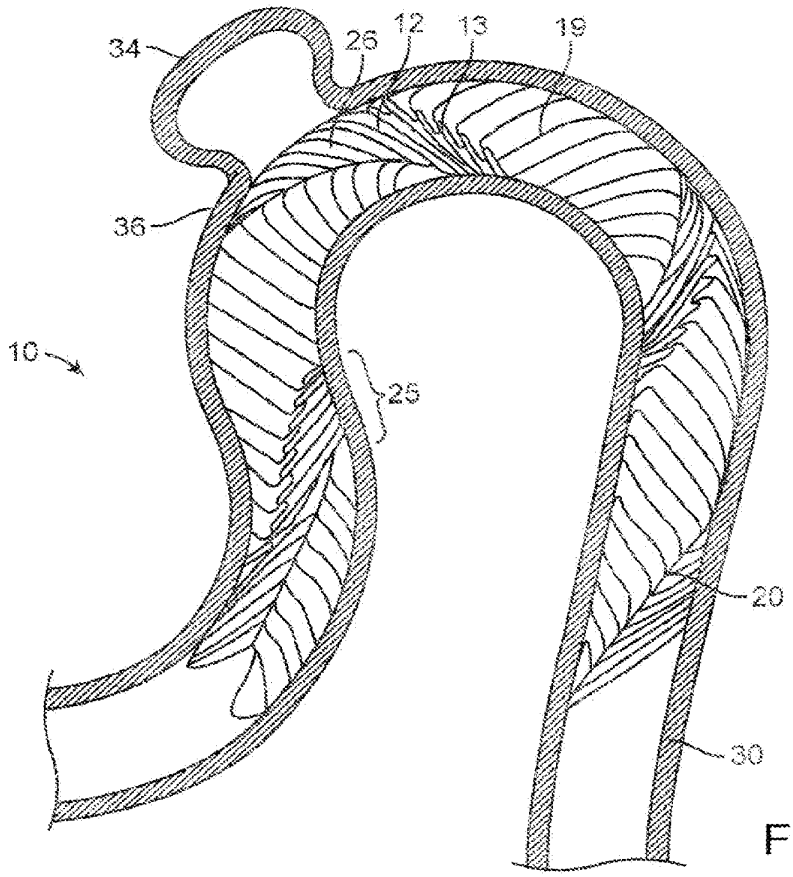


FIG. 6

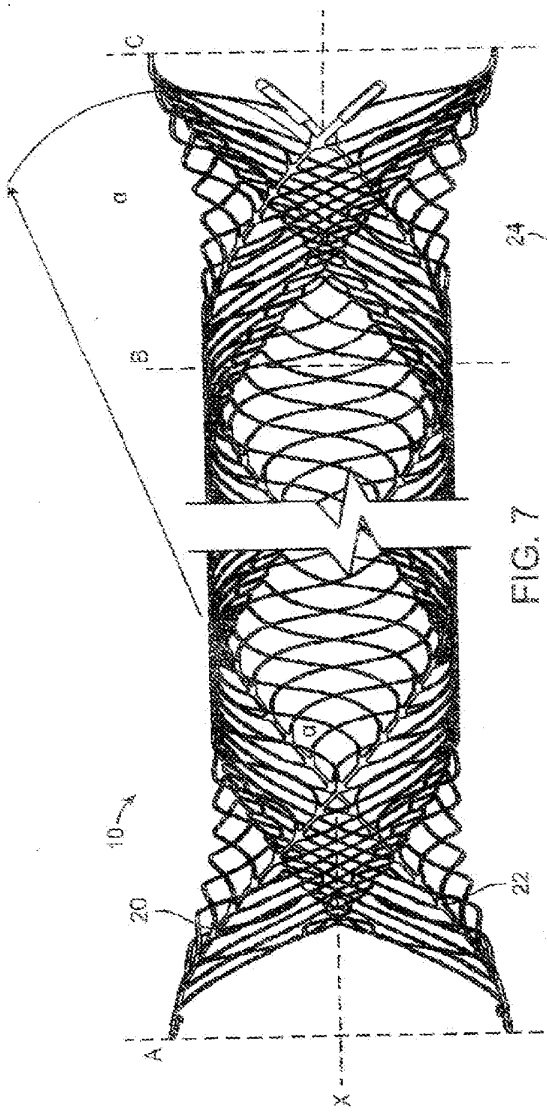


FIG. 7

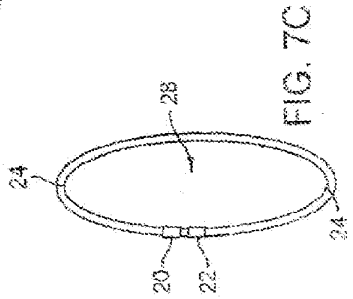


FIG. 7C

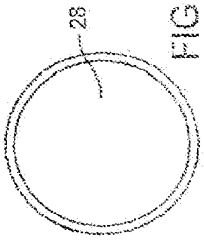


FIG. 7B

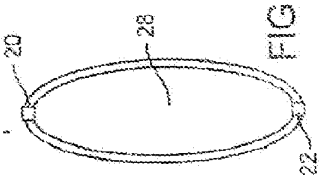


FIG. 7A

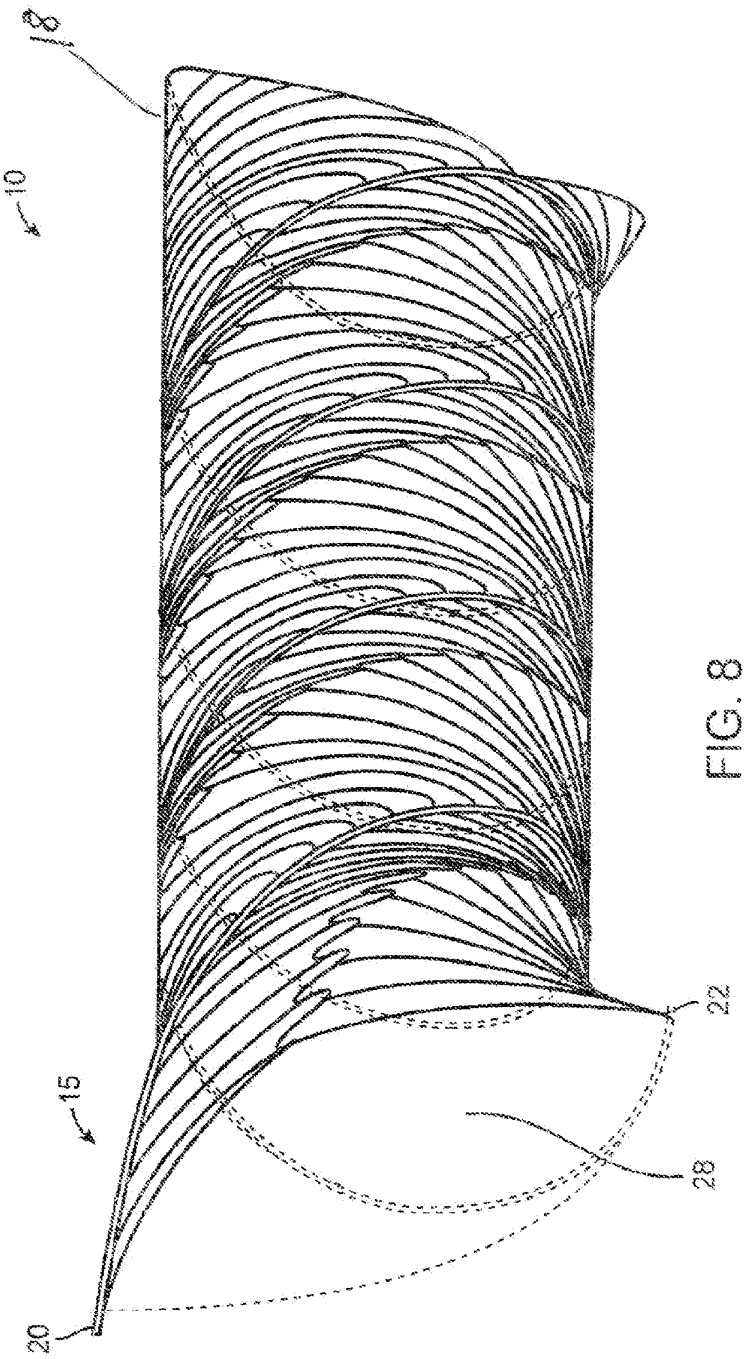


FIG. 8

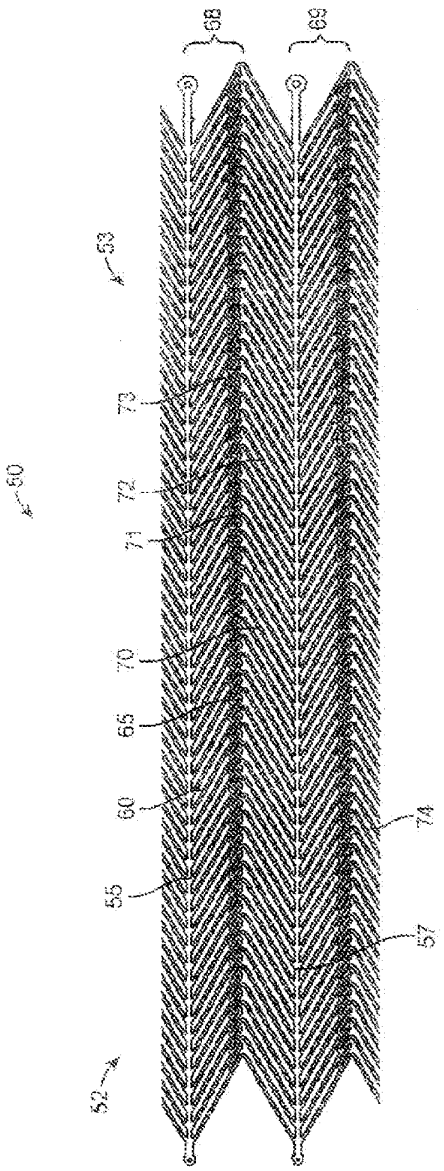


FIG. 9

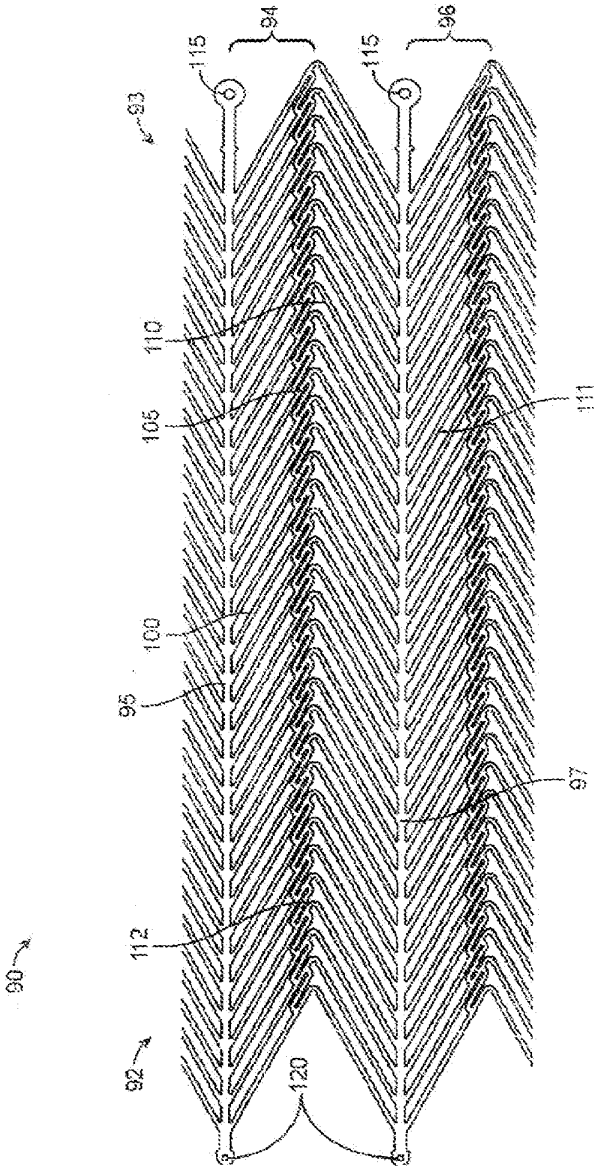


FIG. 10

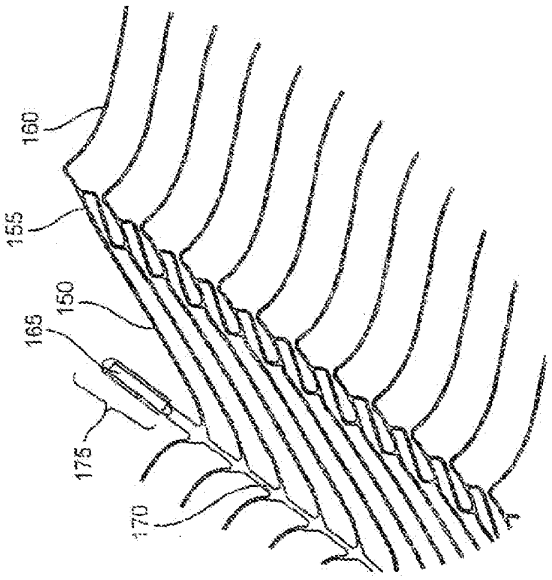


FIG. 11A

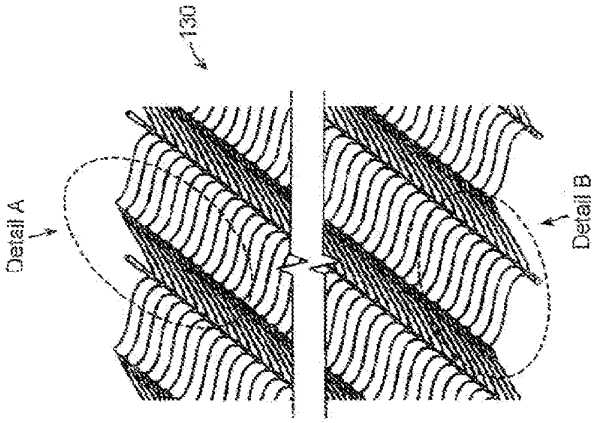


FIG. 11

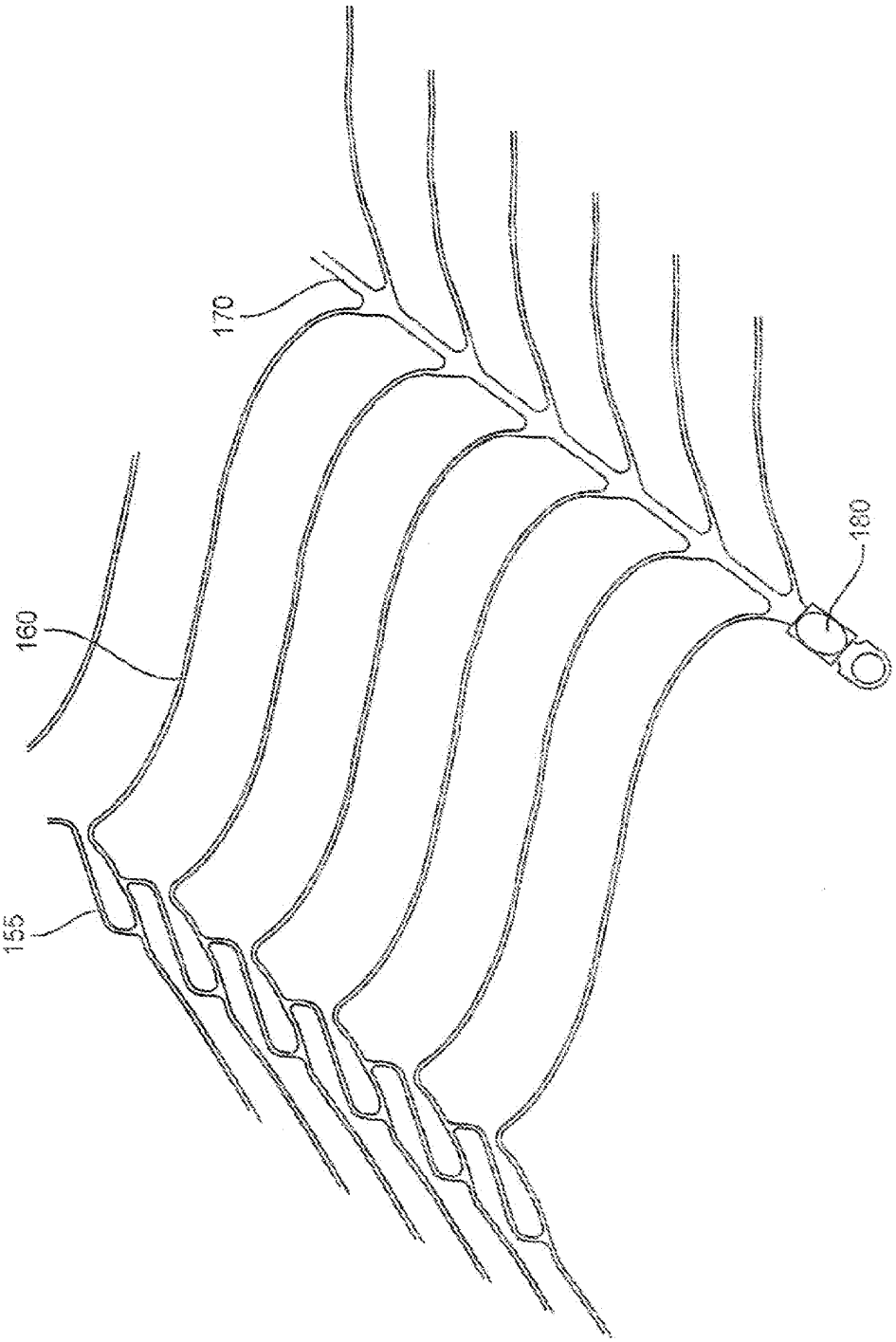


FIG. 11B

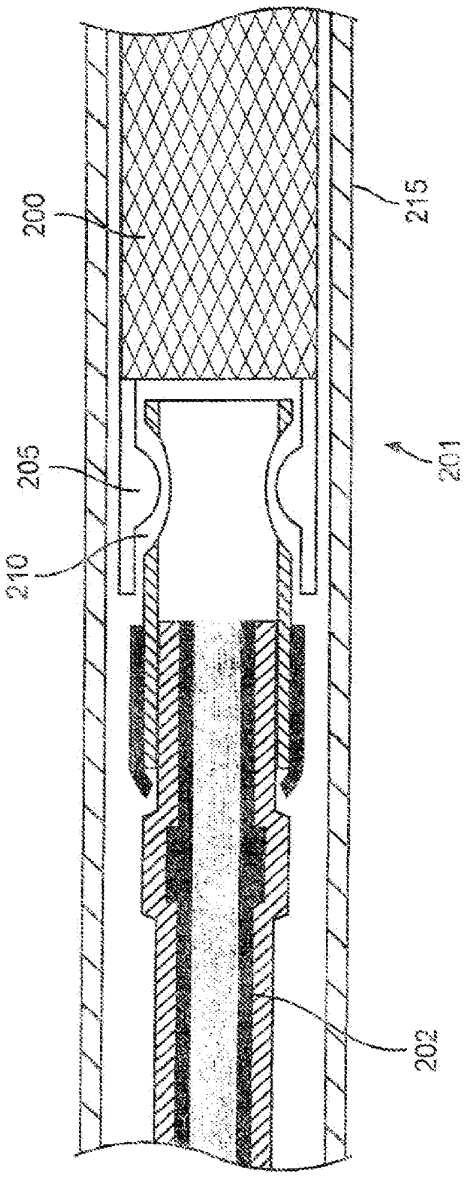


FIG. 12

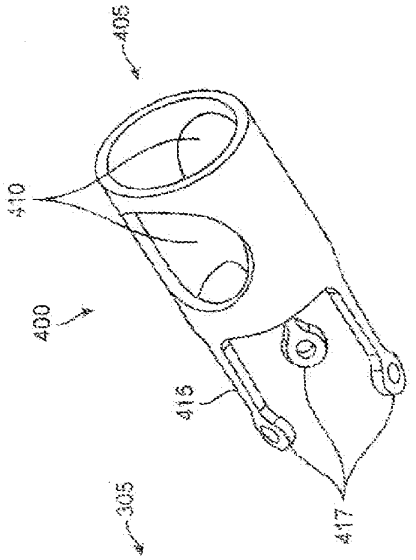


FIG. 14

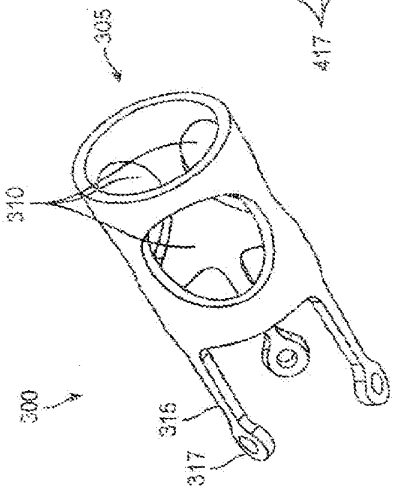


FIG. 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/043931

A. CLASSIFICATION OF SUBJECT MATTER

A61F 2/06(2006.01)i, A61F 2/02(2006.01)i, A61F 2/07(2013.01)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)
A61F 2/06; A61M 25/00; A61F 2/02; A61F 2/07

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & keywords: tubular, aneurysm, helical, standard, band, coil

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007-0239261 A1 (BOSE et al.) 11 October 2007 See abstract, claims 1, 3, 10, 12, 24, pages 2-6, and figures 3, 7, 8.	1-10,21-27
Y		11-20
Y	US 6663607 B2 (SLAIKEU et al.) 16 December 2003 See abstract, claim 14, column 11 and figure 5.	11-20
A	WO 02-09617 A1 (BIONX IMPLANTS, INC.) 7 February 2002 See abstract, page 17 and figure 4.	1-27
A	US 2004-0193246 A1 (FERRERA) 30 September 2004 See abstract, claims 1, 25, page 8 and figure 6.	1-27
A	US 2009-0036976 A1 (BEACH et al.) 5 February 2009 See abstract, claim 1 and figure 1.	1-27

☐ 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 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	Date of mailing of the international search report
13 September 2013 (13.09.2013)	**13 September 2013 (13.09.2013)**

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea
Facsimile No. +82-42-472-7140

Authorized officer
KIM Seung Beom
Telephone No. +82-42-481-3371

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/043931

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.: 28
because they relate to subject matter not required to be searched by this Authority, namely:
Claim 28 pertains to a method for treatment of the human body by surgery and thus relates to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.

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 addtional 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.

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.

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Penumbra, Inc. v. RapidPulse, Inc.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/043931

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2007-0239261 A1	11/10/2007	CN 101415380 A	22/04/2009
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		WO 2009-017827 A1	05/02/2009

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Penumbra, Inc. v. RapidPulse, Inc.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
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(54) **Title**: ENHANCED FLEXIBILITY NEUROVASCULAR CATHETER

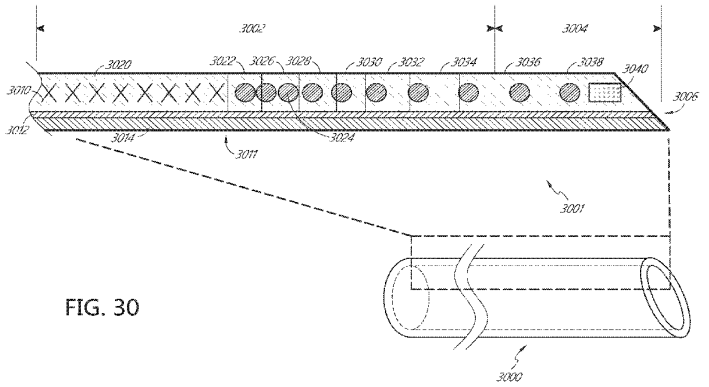


FIG. 30

(57) **Abstract**: A catheter is provided, such as for distal neurovascular access or aspiration. The catheter includes an elongate flexible body, having a proximal end, a distal end and a side wall defining a central lumen. A distal zone of the side wall includes a tubular inner liner, a tie layer separated from the lumen by the inner liner, a helical coil surrounding the tie layer, adjacent windings of the coil spaced progressively further apart in the distal direction. An outer jacket surrounds the helical coil. The outer jacket is formed from a plurality of tubular segments positioned end to end, coaxially about the coil. The flexural load profile of the catheter as a function of catheter length is configured to provide enhanced distal flexibility while maintaining high backup support.

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ENHANCED FLEXIBILITY NEUROVASCULAR CATHETER

Cross-reference to Related Applications

This application claims the benefit of U.S. Provisional Application No. 62/299,418, filed February 24, 2016, and U.S. Provisional Application No. 62/443,595, filed January 6, 2017, the entirety of these applications are hereby incorporated by reference herein.

BACKGROUND OF THE INVENTION

Stroke is the third most common cause of death in the United States and the most disabling neurologic disorder. Approximately 700,000 patients suffer from stroke annually. Stroke is a syndrome characterized by the acute onset of a neurological deficit that persists for at least 24 hours, reflecting focal involvement of the central nervous system, and is the result of a disturbance of the cerebral circulation. Its incidence increases with age. Risk factors for stroke include systolic or diastolic hypertension, hypercholesterolemia, cigarette smoking, heavy alcohol consumption, and oral contraceptive use.

Hemorrhagic stroke accounts for 20% of the annual stroke population. Hemorrhagic stroke often occurs due to rupture of an aneurysm or arteriovenous malformation bleeding into the brain tissue, resulting in cerebral infarction. The remaining 80% of the stroke population are ischemic strokes and are caused by occluded vessels that deprive the brain of oxygen-carrying blood. Ischemic strokes are often caused by emboli or pieces of thrombotic tissue that have dislodged from other body sites or from the cerebral vessels themselves to occlude in the narrow cerebral arteries more distally. When a patient presents with neurological symptoms and signs which resolve completely within 1 hour, the term transient ischemic attack (TIA) is used. Etiologically, TIA and stroke share the same pathophysiologic mechanisms and thus represent a continuum based on persistence of symptoms and extent of ischemic insult.

Emboli occasionally form around the valves of the heart or in the left atrial appendage during periods of irregular heart rhythm and then are dislodged and follow the blood flow into the distal regions of the body. Those emboli can pass to the brain and cause an embolic stroke. As will be discussed below, many such occlusions occur in the middle cerebral artery (MCA), although such is not the only site where emboli come to rest.

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When a patient presents with neurological deficit, a diagnostic hypothesis for the cause of stroke can be generated based on the patient's history, a review of stroke risk factors, and a neurologic examination. If an ischemic event is suspected, a clinician can tentatively assess whether the patient has a cardiogenic source of emboli, large artery extracranial or intracranial disease, small artery intraparenchymal disease, or a hematologic or other systemic disorder. A head CT scan is often performed to determine whether the patient has suffered an ischemic or hemorrhagic insult. Blood would be present on the CT scan in subarachnoid hemorrhage, intraparenchymal hematoma, or intraventricular hemorrhage.

Traditionally, emergent management of acute ischemic stroke consisted mainly of general supportive care, e.g. hydration, monitoring neurological status, blood pressure control, and/or anti-platelet or anti-coagulation therapy. In 1996, the Food and Drug Administration approved the use of Genentech Inc.'s thrombolytic drug, tissue plasminogen activator (t-PA) or Activase®, for treating acute stroke. A randomized, double-blind trial, the National Institute of Neurological Disorders and t-PA Stroke Study, revealed a statistically significant improvement in stoke scale scores at 24 hours in the group of patients receiving intravenous t-PA within 3 hours of the onset of an ischemic stroke. Since the approval of t-PA, an emergency room physician could, for the first time, offer a stroke patient an effective treatment besides supportive care.

However, treatment with systemic t-PA is associated with increased risk of intracerebral hemorrhage and other hemorrhagic complications. Patients treated with t-PA were more likely to sustain a symptomatic intracerebral hemorrhage during the first 36 hours of treatment. The frequency of symptomatic hemorrhage increases when t-PA is administered beyond 3 hours from the onset of a stroke. Besides the time constraint in using t-PA in acute ischemic stroke, other contraindications include the following: if the patient has had a previous stroke or serious head trauma in the preceding 3 months, if the patient has a systolic blood pressure above 185 mm Hg or diastolic blood pressure above 110 mmHg, if the patient requires aggressive treatment to reduce the blood pressure to the specified limits, if the patient is taking anticoagulants or has a propensity to hemorrhage, and/or if the patient has had a recent invasive surgical procedure. Therefore, only a small percentage of selected stroke patients are qualified to receive t-PA.

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Obstructive emboli have also been mechanically removed from various sites in the vasculature for years. Mechanical therapies have involved capturing and removing the clot, dissolving the clot, disrupting and suctioning the clot, and/or creating a flow channel through the clot. One of the first mechanical devices developed for stroke treatment is the MERCI Retriever System (Concentric Medical, Redwood City, Calif.). A balloon-tipped guide catheter is used to access the internal carotid artery (ICA) from the femoral artery. A microcatheter is placed through the guide catheter and used to deliver the coil-tipped retriever across the clot and is then pulled back to deploy the retriever around the clot. The microcatheter and retriever are then pulled back, with the goal of pulling the clot, into the balloon guide catheter while the balloon is inflated and a syringe is connected to the balloon guide catheter to aspirate the guide catheter during clot retrieval. This device has had initially positive results as compared to thrombolytic therapy alone.

Other thrombectomy devices utilize expandable cages, baskets, or snares to capture and retrieve clot. Temporary stents, sometimes referred to as stentrievers or revascularization devices, are utilized to remove or retrieve clot as well as restore flow to the vessel. A series of devices using active laser or ultrasound energy to break up the clot have also been utilized. Other active energy devices have been used in conjunction with intra-arterial thrombolytic infusion to accelerate the dissolution of the thrombus. Many of these devices are used in conjunction with aspiration to aid in the removal of the clot and reduce the risk of emboli. Suctioning of the clot has also been used with single-lumen catheters and syringes or aspiration pumps, with or without adjunct disruption of the clot. Devices which apply powered fluid vortices in combination with suction have been utilized to improve the efficacy of this method of thrombectomy. Finally, balloons or stents have been used to create a patent lumen through the clot when clot removal or dissolution was not possible.

Notwithstanding the foregoing, there remains a need for new devices and methods for treating vasculature occlusions in the body, including acute ischemic stroke and occlusive cerebrovascular disease.

SUMMARY OF THE INVENTION

There is provided in according with one aspect, a telescoping catheter, comprising: an elongate, flexible tubular body, comprising a proximal section having at least one lumen and

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a distal section axially movably positioned within the lumen; and a control for advancing the distal section from a first, proximally retracted position within the proximal section to a second, extended position, extending distally beyond the proximal section; and an active tip on the distal end of the distal section, comprising a distal opening that is movable between a smaller and a larger configuration.

In one aspect of present disclosure, the control comprises a pull wire extending through the proximal section. In another aspect of present disclosure, the distal section is distally advanceable to extend beyond the proximal section for a distance of at least about 10 cm. In yet another aspect of present disclosure, the distal section is distally advanceable to extend beyond the proximal section for a distance of at least about 25 cm.

In one aspect of present disclosure, the distal opening is movable in response to movement of a control wire. In another aspect of present disclosure, the distal opening is movable between a smaller and a larger configuration in response to application of vacuum to the lumen. In yet another aspect of present disclosure, the size of the distal opening is changed by lateral movement of a side wall on the distal section. In yet another aspect of present disclosure, the distal opening comprises at least one movable jaw. In another aspect of present disclosure, the distal end of the distal section comprises a duck bill valve configuration.

In one aspect of present disclosure, the telescoping catheter may further comprise a controller for applying intermittent vacuum to the lumen. The controller may be configured to apply pulses of vacuum to the lumen spaced apart by spaces of neutral pressure. The controller may be configured to alternate between applying pulses of higher negative pressure and lower negative pressure. The distal tip of the catheter may axially reciprocate in response to application of pulses of vacuum to the lumen.

In accordance with one aspect, there is provided a system for aspirating a vascular occlusion from a remote site, comprising: an elongate, flexible tubular body, comprising at least one central lumen extending along its longitudinal length; an agitator extendable through the central lumen of the tubular body to position a distal end of the agitator near a distal end of the tubular body; a driver connectable to a proximal end of the agitator and

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configured to actuate the agitator; and a vacuum port near the proximal end of the tubular body and in fluid communication with the central lumen of the tubular body.

In one aspect of present disclosure, the agitator comprises an elongate tube. The agitator may comprise a wire extending through the elongate tube and having at least one bend near its distal end. In another aspect of present disclosure, the agitator comprises a proximal end, a distal end, and a loop at the distal end. In yet another aspect of present disclosure, the driver is configured to rotate the agitator cyclically in alternating directions.

In one aspect of present disclosure, the agitator comprises: at least one lumen along its longitudinal length, an influent port near its proximal end configured to allow fluid communication between the lumen of the agitator and a source of media, and at least one effluent port configured to allow fluid communication between the lumen of the agitator and the central lumen of the tubular body. The system for aspirating a vascular occlusion may further comprise a control, for expressing media from the effluent port of the agitator into the central lumen of the tubular body. The distal portion of the tubular body may be configured to vibrate in a transverse direction in response to the injection of media.

In one aspect of present disclosure, the system for aspirating a vascular occlusion further comprises a controller for applying a pulsatile vacuum cycle to the central lumen. In another aspect of present disclosure, the system for aspirating a vascular occlusion further comprises a rotating hemostasis valve coupled to the proximal end of the tubular body, the rotating hemostasis valve comprising: at least one main lumen along its longitudinal length, through which the proximal portion of the agitator is configured to pass, and an aspiration lumen bifurcating from the main lumen and provided with a vacuum port. In yet another aspect of present disclosure, the system further comprises a proximal drive assembly coupled to the proximal end of the tubular body, the proximal drive assembly comprising: at least one main lumen along its longitudinal length for receiving the agitator; a media injection port, into which media is injected, in fluid communication with the central lumen of the tubular body, and a proximal drive connection at the proximal end, which operably connects between the agitator and the driver.

In accordance with one aspect, there is provided an enhanced flexibility neurovascular catheter, comprising: an elongate flexible body, having a proximal end, a distal end and a

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side wall defining a central lumen, a distal zone of the side wall comprising: a tubular inner liner; a soft tie layer separated from the lumen by the inner liner; a helical coil surrounding the tie layer, adjacent windings of the coil spaced progressively further apart in the distal direction; and an outer jacket surrounding the helical coil, the outer jacket formed from a plurality of tubular segments positioned coaxially about the coil; wherein a proximal one of the tubular segments has a durometer of at least about 60D and a distal one of the tubular segments has a durometer of no more than about 35D. In one aspect of present disclosure, the tubular liner is formed by dip coating a removable mandrel. In another aspect of present disclosure, the tubular liner comprises PTFE.

In yet another aspect of present disclosure, the tie layer comprises polyurethane. The tie layer may have a wall thickness of no more than about 0.005 inches and may extend along at least the most distal 20 cm of the flexible body. In one aspect of present disclosure, the coil comprises a shape memory material. The coil may comprise Nitinol, and the Nitinol may comprise an Austenite state at body temperature.

In one aspect of present disclosure, the outer jacket is formed from at least five discrete tubular segments. The outer jacket may be formed from at least nine discrete tubular segments. The difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments may be at least about 20D. The difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments may be at least about 30D.

In another aspect of present disclosure, the enhanced flexibility neurovascular catheter, further comprises a tension support for increasing the tension resistance in the distal zone. The tension support may comprise a filament and may comprise an axially extending filament. The axially extending filament may be carried between the inner liner and the helical coil. The axially extending filament may increase the tensile strength to at least about 5 pounds.

In accordance with one aspect, there is provided an enhanced flexibility neurovascular catheter, comprising: an elongate flexible body, having a proximal end, a distal end and a side wall defining a central lumen, a distal zone of the side wall comprising: an outer jacket surrounding a helical coil, the outer jacket formed from a plurality of tubular segments

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positioned coaxially about the coil; wherein a proximal one of the tubular segments has a durometer of at least about 60D and a distal one of the tubular segments has a durometer of no more than about 35D; and an axially extending filament within the side wall, extending at least about the most distal 10 cm of the length of the catheter. The filament may extend at least about the most distal 15 cm of the length of the catheter. The filament may extend at least about the most distal 20 cm of the length of the catheter. The filament may comprise multiple fibers and may extend axially in between the coil and the inner liner.

In one aspect of present disclosure, the side wall further comprises: a tubular inner liner; a soft tie layer separated from the lumen by the inner liner; wherein the helical coil surrounds the tie layer, and adjacent windings of the coil are spaced progressively further apart in the distal direction. The tubular liner may be formed by dip coating a removable mandrel and may comprise PTFE. The tie layer may comprise polyurethane and may have a wall thickness of no more than about 0.005 inches. The tie layer may extend along at least the most distal 20 cm of the flexible body. The coil may comprise a shape memory material and may comprise Nitinol. The Nitinol may comprise an Austenite state at body temperature.

In one aspect of present disclosure, the outer jacket may be formed from at least five discrete tubular segments. In another aspect of present disclosure, the outer jacket may be formed from at least nine discrete tubular segments. The difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments may be at least about 20D. The difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments may be at least about 30D. In another aspect of present disclosure, the catheter can withstand at least about 3.5 pounds tension before failure. In yet another aspect, the catheter can withstand at least about 5 pounds tension before failure.

In accordance with one aspect, there is provided a method of making a high flexibility distal zone on a neurovascular catheter, comprising the steps of: dip coating a removable mandrel to form a tubular inner layer on the mandrel; coating the tubular inner layer with a soft tie layer; applying a helical coil to the outside of the tie layer; positioning a plurality of tubular segments on the helical coil; the plurality of segments having durometers that decrease in a distal direction; heating the tubular segments to form the high flexibility distal zone on the neurovascular catheter; and removing the mandrel. In one aspect of present

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disclosure, removing the mandrel step includes axially elongating the mandrel. In another aspect of present disclosure, the method of making a high flexibility distal zone on a neurovascular catheter comprises positioning at least seven segments on the helical coil. In yet another aspect of present disclosure, the method of making a high flexibility distal zone on a neurovascular catheter comprises positioning at least nine segments on the helical coil.

In one aspect of present disclosure, the difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments is at least about 20D. The difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments may be at least about 30D. The tubular inner layer may comprise PTFE. In another aspect of present disclosure, the tie layer comprises polyurethane. The tie layer may have a wall thickness of no more than about 0.005 inches. The tie layer may extend along at least the most distal 20 cm of the flexible body.

In one aspect of present disclosure, the coil comprises a shape memory material. The coil may comprise Nitinol. The Nitinol may comprise an Austenite state at body temperature. In another aspect of present disclosure, the method of making a high flexibility distal zone on a neurovascular catheter further comprises the step of positioning at least one tensile strength enhancing filament in between the coil and the tie layer prior to heat shrinking the tubular segments. The filament may extend along at least about the most distal 15 cm of the length of the catheter. The filament may extend along at least about the most distal 20 cm of the length of the catheter. The filament may comprise multiple fibers. In yet another aspect of present disclosure, the method of making a high flexibility distal zone on a neurovascular catheter further comprises the step of positioning at least one tensile strength enhancing filament over the tie layer before the applying a helical coil step.

In accordance with one aspect, there is provided a neurovascular catheter, comprising: an elongate flexible tubular body, having a proximal end, a distal end and a side wall defining a central lumen, a distal zone of the tubular body comprising: a tubular inner liner; a tie layer separated from the lumen by the inner liner; a helical coil surrounding the tie layer, adjacent windings of the coil spaced progressively further apart in the distal direction; an outer jacket surrounding the helical coil, and an opening at the distal end which is enlargeable from a first inside diameter for transluminal navigation to a second, larger inside diameter to facilitate

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aspiration of thrombus into the lumen. In one aspect of present disclosure, the distal opening is enlargeable in response to exposure to blood. In another aspect of present disclosure, the distal opening is enlargeable in response to exposure to body temperature. In yet another aspect of present disclosure, the distal opening is enlargeable in response to removal of a constraint. The constraint may comprise a polymer having a structural integrity that decreases in the intravascular environment.

In one aspect of present disclosure, the catheter body adjacent the distal opening comprises a radially outwardly biased embedded support. The catheter body adjacent the distal opening may comprise an embedded Nitinol frame. The support may comprise a wire mesh. The support may comprise a stent. In another aspect of present disclosure, the catheter body adjacent the distal opening comprises a hydrophilic blend. In yet another aspect of present disclosure, the tubular liner is formed by dip coating a removable mandrel. The tubular liner may comprise PTFE.

In one aspect of present disclosure, the tie layer comprises polyurethane. The tie layer may have a wall thickness of no more than about 0.005 inches. The tie layer may extend along at least the most distal 20 cm of the flexible body. In another aspect of present disclosure, the coil comprises a shape memory material. The coil may comprise Nitinol. The Nitinol may comprise an Austenite state at body temperature. In one aspect of present disclosure, the outer jacket is formed from at least five discrete tubular segments. The outer jacket may be formed from at least nine discrete tubular segments. The difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments may be at least about 20D. The difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments may be at least about 30D.

In accordance with one aspect, there is provided a neurovascular catheter extension segment, comprising:an elongate flexible control wire, having a proximal end and a distal end; a tubular extension segment having a side wall defining a central lumen carried by the distal end of the control wire, the side wall comprising: a tubular inner liner; a tie layer separated from the lumen by the inner liner; a helical coil surrounding the tie layer; and an outer jacket surrounding the helical coil. In one aspect of present disclosure, the outer jacket is formed from a plurality of tubular segments positioned coaxially about the coil. A

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proximal one of the tubular segments may have a durometer of at least about 60D, and a distal one of the tubular segments may have a durometer of no more than about 35D.

In another aspect of present disclosure, the tubular liner is formed by dip coating a removable mandrel. The tubular liner may comprise PTFE. In yet another aspect of present disclosure, the tie layer comprises polyurethane. The tie layer may have a wall thickness of no more than about 0.005 inches. The tie layer may extend along at least the most distal 20 cm of the tubular extension segment. In one aspect of present disclosure, the coil comprises a shape memory material. The coil may comprise Nitinol. The Nitinol may comprise an Austenite state at body temperature.

In one aspect of present disclosure, the outer jacket is formed from at least five discrete tubular segments. The outer jacket may be formed from at least nine discrete tubular segments. The difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments may be at least about 20D. The difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments may be at least about 30D. In another aspect of present disclosure, the control wire comprises a central lumen. The control wire central lumen may be in communication with the central lumen of the tubular extension segment. In yet another aspect of present disclosure, the inside diameter of the neurovascular catheter extension segment is at least 2X the inside diameter of the control wire central lumen. The inside diameter of the neurovascular catheter extension segment may be at least 3X the inside diameter of the control wire central lumen.

In accordance with another aspect, there is provided a neurovascular catheter extension segment system, comprising the neurovascular catheter extension segment described above and an agitator configured to extend through the control wire central lumen and into the central lumen of the tubular extension segment.

Any feature, structure, or step disclosed herein can be replaced with or combined with any other feature, structure, or step disclosed herein, or omitted. Further, for purposes of summarizing the disclosure, certain aspects, advantages, and features of the embodiments have been described herein. It is to be understood that not necessarily any or all such advantages are achieved in accordance with any particular embodiment disclosed herein. No individual aspects of this disclosure are essential or indispensable. Further features and

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advantages of the embodiments will become apparent to those of skill in the art in view of the Detailed Description which follows when considered together with the attached drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevational schematic view of an intracranial aspiration catheter in accordance with the present invention, with a distal segment in a proximally retracted configuration.

FIG. 2 is a side elevational view as in FIG. 1, with the distal segment in a distally extended configuration.

FIGS. 3A–3B are cross-sectional elevational views of a distal end of catheter 10, with the distal section 34 fully extended.

FIGS. 4A–4C schematically illustrate different cutting tip configurations.

FIGS. 4D–4E and 4J–4K schematically illustrate a distal dynamic funnel tip configuration.

FIGS. 4F–4G illustrate a dynamic flared tip having a first restraint system.

FIGS. 4H–4I illustrate a dynamic flared tip having an alternative restraint system.

FIG. 5 depicts cerebral arterial vasculature including the Circle of Willis, and an access catheter positioned at an occlusion in the left carotid siphon artery.

FIGS. 6 through 9 show a sequence of steps involved in positioning of the catheter and aspirating obstructive material from the middle cerebral artery.

FIG. 10 illustrates removal of the catheter following aspiration of obstructive material.

FIGS. 11A–11F depict a sequence of steps to access a neurovascular occlusion for aspiration.

FIGS. 12A–12F depict an alternative sequence of steps in accordance with an aspect of the present invention involved in accessing a neurovascular occlusion for aspiration.

FIG. 13 illustrates an aspiration system configured to apply pulsatile negative pressure through the aspiration catheter.

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FIG. 14 illustrates an alternative aspiration system configured to apply pulsatile negative pressure through the aspiration catheter.

FIG. 15 illustrates a further alternative aspiration system configured to apply mechanical vibration through the aspiration catheter.

FIGS. 16 and 17 illustrate a further alternative aspiration system configured to apply mechanical vibration through the aspiration catheter.

FIG. 18 illustrates a further alternative aspiration system having an agitator configured to apply mechanical vibration at a vibration zone on the aspiration catheter.

FIG. 19 depicts a simplified agitator such as a hypo tube supported wire placed in a catheter to create a vibration zone.

FIGS. 20A–20C depict agitators with various distal tip configurations.

FIGS. 20D–20E depict an agitator positioned within a swellable polymer distal funnel tip.

FIGS. 21A–21B illustrate a moving or wiggling distal tip of a catheter in response to activating the agitator.

FIGS. 22A–22B illustrate media injection from a moving or wiggling distal tip of an agitator.

FIGS. 23A–23B illustrate media injection from a distal tip of an agitator to assist aspiration.

FIG. 24 depicts a proximal aspiration port carried by a catheter.

FIGS. 25A-25C depict a pulsed aspiration cycle according to an embodiment.

FIG. 26 depicts a perspective view of a rotating hemostasis valve and a proximal drive assembly.

FIG. 27A illustrates a longitudinal cross-sectional elevational view taken along the line 27A-27A in FIG. 26.

FIG. 27B illustrates an enlarged longitudinal cross-sectional elevational view of the proximal drive assembly 2602 from FIG. 27A.

FIG. 28 depicts a cross-sectional perspective view of the proximal portion of FIG. 26.

FIG. 29 depicts a perspective view of an agitator driver, a proximal drive assembly, and a rotating hemostasis valve.

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FIG. 30 illustrates a cross-sectional elevational view of a catheter wall according to an embodiment.

FIG. 31A illustrates a cross-sectional elevational view of a catheter wall according to another embodiment, showing one or more axially extending filaments.

FIG. 31B describes a side elevational view of the catheter of FIG. 31A

FIG. 31C illustrates a cross-sectional view taken along the line C-C of FIG. 31B, showing one or more axially extending filaments.

FIG. 32A depicts a side elevational view of a catheter according to one embodiment.

FIG. 32B describes a cross-sectional elevational view taken along the line A-A of FIG. 32A.

FIG. 32C illustrates a cross-sectional view taken along the line B-B of FIG. 32A.

FIG. 33A depicts a side elevational view of a catheter according to another embodiment.

FIG. 33B describes a cross-sectional elevational view taken along the line A-A of FIG. 33A, showing one or more axially extending filaments.

FIG. 33C illustrates a cross-sectional view taken along the line B-B of FIG. 33A, showing one or more axially extending filaments.

FIG. 34A illustrates a side elevational view of a progressively enhanced flexibility catheter according to an embodiment.

FIG. 34B is a proximal end view of the enhanced flexibility catheter of FIG. 34A.

FIG. 35 illustrates back-up support of the catheter in accordance with the present invention.

FIG. 36 depicts a graph of modulus or durometer of the catheter along the length of the catheter, from the proximal end to the distal end.

FIG. 37 depicts a graph of flexure test profiles of catheters in accordance with the present invention compared with conventional catheters.

FIG. 38 is a side elevational schematic view of a transformable catheter in accordance with the present invention.

FIG. 39 is a cross-sectional view taken along the lines 18-18 of FIG. 38, showing heating elements within the catheter sidewall.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. 1, there is disclosed a catheter 10 in accordance with one aspect of the present invention. Although primarily described in the context of an axially extendable distal segment aspiration catheter with a single central lumen, catheters of the present invention can readily be modified to incorporate additional structures, such as permanent or removable column strength enhancing mandrels, two or more lumen such as to permit drug, contrast or irrigant infusion or to supply inflation media to an inflatable balloon carried by the catheter, or combinations of these features, as will be readily apparent to one of skill in the art in view of the disclosure herein. In addition, the present invention will be described primarily in the context of removing obstructive material from remote vasculature in the brain, but has applicability as an access catheter for delivery and removal of any of a variety of diagnostics or therapeutic devices with or without aspiration.

The catheters disclosed herein may readily be adapted for use throughout the body wherever it may be desirable to distally advance a low profile distal catheter segment from a larger diameter proximal segment. For example, axially extendable catheter shafts in accordance with the present invention may be dimensioned for use throughout the coronary and peripheral vasculature, the gastrointestinal tract, the urethra, ureters, Fallopian tubes and other lumens and potential lumens, as well. The telescoping structure of the present invention may also be used to provide minimally invasive percutaneous tissue access, such as for diagnostic or therapeutic access to a solid tissue target (e.g., breast or liver or brain biopsy or tissue excision), delivery of laparoscopic tools or access to bones such as the spine for delivery of screws, bone cement or other tools or implants.

The catheter 10 generally comprises an elongate tubular body 16 extending between a proximal end 12 and a distal functional end 14. The length of the tubular body 16 depends upon the desired application. For example, lengths in the area of from about 120 cm to about 140 cm or more are typical for use in femoral access percutaneous transluminal coronary applications. Intracranial or other applications may call for a different catheter shaft length depending upon the vascular access site, as will be understood in the art.

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In the illustrated embodiment, the tubular body 16 is divided into at least a fixed proximal section 33 and an axially extendable and retractable distal section 34 separated at a transition 32.

Referring to FIG. 3A and 3B, there is illustrated a cross-sectional view of the distal segment 34 shown extended distally from the proximal segment 33 in accordance with the present invention. Distal segment 34 extends between a proximal end 36 and a distal end 38 and defines at least one elongate central lumen 40 extending axially therethrough. Distal end 38 may be provided with one or more movable side walls or jaws 39, which move laterally in the direction of an opposing side wall or jaw 41 under the influence of aspiration, to enable the distal end 38 to bite or break thrombus or other material into smaller particles, to facilitate aspiration through lumen 40. Both walls 39 and 41 may be movable towards and away from each other to break up thrombus as is discussed further below. For certain applications, the proximal section 33 may also or alternatively be provided with one or two opposing jaws, also responsive to vacuum or mechanical actuation to break up thrombus.

The inner diameter of the distal section 34 may be between about 0.030 inches and about 0.112 inches, between about 0.040 inches and about 0.102 inches, between about 0.045 inches and about 0.097 inches, between about 0.050 inches and about 0.092 inches, between about 0.055 inches and about 0.087 inches, between about 0.060 inches and about 0.082 inches, between about 0.062 inches and about 0.080 inches, between about 0.064 inches and about 0.078 inches, between about 0.066 inches and about 0.076 inches, between about 0.068 inches and about 0.074 inches, or between about 0.070 inches and about 0.072 inches.

The inner diameter and the outer diameter of the distal section 34 may be constant or substantially constant along its longitudinal length. Alternatively, the distal section 34 may be tapered near its distal end. The distal section 34 may be tapered at less than or equal to about 5cm, about 10cm, about 15cm, about 20cm, about 23cm, about 25cm, about 30cm, about 31cm, about 35cm, about 40cm, about 45cm, about 50cm, about 60cm, or about 70cm from its distal end.

The inner diameter of the distal section 34 may be tapered or decreased near the distal end by less than or equal to about 95%, about 90%, about 85%, about 80%, about 75%, about 70%, about 65%, about 60%, about 55%, about 50%, about 45%, about 40%, about 35%,

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about 30%, about 25%, about 20%, about 10%, or about 5%. The inner diameter of the distal section 34 may be tapered or decreased near the distal end by greater than or equal to about 95%, about 90%, about 85%, about 80%, about 75%, about 70%, about 65%, about 60%, about 55%, about 50%, about 45%, about 40%, about 35%, about 30%, about 25%, about 20%, about 10%, or about 5%. The tapered inner diameter of the distal section 34 may be by less than or equal to about 0.11 inches, about 0.1 inches, about 0.090 inches, about 0.080 inches, about 0.070 inches, about 0.065 inches, about 0.060 inches, about 0.055 inches, about 0.050 inches, about 0.045 inches, about 0.040 inches, about 0.035 inches, about 0.030 inches, about 0.025 inches, about 0.020 inches, about 0.015 inches, or about 0.010 inches.

The length of the distal section 34 may be between about 13cm and about 53cm, between about 18cm and about 48cm, between about 23cm and about 43cm, or between about 28cm and about 38cm. The length of the distal section 34 may be less than or equal to about 20cm, about 25cm, about 30cm, about 33cm, about 35cm, about 40cm, about 41cm, about 45cm, about 50cm, about 55cm, about 60cm, about 70cm, or about 80cm. The length of the distal section 34 may depend on the degree of tapering of the internal diameter of the distal section 34.

The proximal end 36 of distal section 34 is provided with a proximally extending pull wire 42. Pull wire 42 extends proximally throughout the length of the tubular body 16, to control 24 which may be carried by manifold 18. Axial movement of control 24 produces a corresponding axial movement of distal section 34 with respect to proximal section 33 as has been discussed. Alternatively, the proximal end of pull wire 42 may exit through a port on manifold 18, such that it may be manually grasped and pulled or pushed by the clinician to extend or retract the distal section 34. The length of the pull wire 42 may be between about 700mm and about 1556mm, between about 800mm and about 1456mm, between about 850mm and about 1406mm, between about 900mm and about 1356mm, between about 950mm and about 1306mm, between about 1000mm and about 1256mm, between about 1020mm and about 1236mm, between about 1040mm and about 1216mm, between about 1060mm and about 1196mm, between about 1080mm and about 1176mm, between about 1100mm and about 1156mm, between about 1110mm and about 1146mm, or between about 1120mm and about 1136mm.

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Upon distal advance of pull wire 42 to its limit of travel, an overlap 44 remains between the proximal end 36 of distal section 34 and the proximal section 33. This overlap 44 is configured to provide a seal to enable efficient transmission of vacuum from proximal section 33 to distal section 34. Overlap 44 may be provided with any of a variety of additional features to facilitate a seal, such as a gasket, coating or tightly toleranced sliding fit. Preferably the clearance between the OD of the distal section 34 and ID of the proximal section 33, at least in the vicinity of transition 32, will be no more than about 0.005 inches and preferably no more than about 0.003 inches to provide an effective seal in a blood environment.

Following positioning of the distal end of proximal section 33 within the vasculature, such as within the cervical carotid artery, the control 24 is manipulated to distally advance distal section 34 deeper into the vasculature. For this purpose, the pull wire 42 will be provided with sufficient column strength to enable distal advance of the distal tip 38 as will be discussed below.

The pull wire 42 and distal section 34 may be integrated into a catheter as illustrated in Figures 1 and 2. Alternatively, distal section 34 and pull wire 42 may be configured as a stand-alone catheter extension device as is discussed in greater detail below. The catheter extension device may be introduced into the proximal end of proximal section 33 after placement of proximal section 33 and advanced distally there through as illustrated in Figure 3 A, to telescopically extend the reach of the aspiration system.

Referring to FIG. 3B, the pull wire 42 may comprise a tubular wall having an axially extending central lumen 45. The central lumen 45 permits introduction of media such as lubricants, drugs, contrast agents or others into the distal section 34. In addition, the central lumen 45 extending through pull wire 42 permits introduction of an agitator as is discussed in greater detail below.

Referring to FIGS. 4A through 4C, the distal tip 38 may be provided any of a variety of structures which produce an active movement such as a biting action in response to the application of an activation force such as a vacuum in lumen 40. Alternatively, an axially movable control wire may be connected with respect to a side wall of the distal tip 38, to enable cutting action under positive mechanical force. FIG. 4A illustrates a distal tip 38 in an

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open configuration, while FIG. 4B illustrates distal tip 38 with opposing side walls 39 and 41 drawn together by the negative pressure in aspiration lumen 40. This may be accomplished by providing a tapered thickness in side walls 39 and 41, or a groove or living hinge which facilitates lateral movement of at least one of side wall 39 or 41.

Alternatively, referring to FIG. 4C, a pivot point or hinge 43 may be provided to enable lateral movement of side wall 39 to operate as a jaw. Two opposing side walls may be moveable medially and laterally with bilateral symmetry like a duck bill valve. Three or more jaws may be provided, such as three triangular jaws separated at about 120° spacing which under an aspiration pulse close to form a pyramid closed tip.

In some implementations of the present invention, the distal tip 14 is preferably provided with the capability to dilate beyond the nominal diameter of distal section 34. This provides a conical funnel like tip with an enlarged distal opening, to facilitate introduction of thrombotic material into the lumen 40. See FIGS. 4D-4K. The diameter at the distal opening of the fully opened funnel exceeds the diameter of a cylindrical extension of the adjacent tubular body by at least about 10%, preferably at least about 25% or 45% or more. This may be accomplished by providing the distal end 14 with an expandable material, or a plurality of laterally movable jaws or petals such as at least about three or five or six or more petals that are advanceable radially inwardly into a coaptive orientation, and radially outwardly to provide a flared inside diameter of aspiration lumen 40 which increases in the distal direction.

The flexible petals may be retained in a radially inwardly inclined configuration such as by application of negative pressure via lumen 40 during transluminal navigation of the distal section 34. Upon removal of the negative pressure, the panels may incline radially outwardly in response to a preset bias. Application of pulsatile vacuum may thereafter cause the panels to close radially inwardly to perform the biting function described previously.

The distal funnel opening may be actuated in a variety of other ways as will be apparent to those of skill in the art, such as by providing a pull wire or axially slideable outer or inner sleeve to open and close the funnel in response to mechanical movement of the wire or sleeve. Alternatively the funnel opening may be controlled by rotation of a control wire or

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tubular sleeve relative to the distal section 34, to activate an iris or spiral mechanism such as a helical ribbon or wire carried by the distal tip.

The normal state of the distal funnel may be a cylindrical configuration, and a mechanical, thermal or electrical actuator may be utilized to enlarge the distal funnel opening. Alternatively, the normal state of the funnel may be conical, and a mechanical, thermal or electrical actuator may be utilized to reduce the diameter such as for transluminal navigation. The petals or other wall of the funnel or elements disposed within the wall of the funnel may comprise a shape memory material such as a shape memory polymer or metal alloy such as nitinol, which may be laser cut from tube stock or woven into a fine mesh. The geometry of the funnel may be transformed by application of heat, such as body heat, or heat from a heat source carried by the catheter such as an electrical resistance wire within the wall or adjacent the catheter tip. Heat may alternatively be applied from a heat source introduced by way of central lumen 40, such as a heated fluid, or a removable heater such as an elongate flexible body carrying a resistance coil. Transformation of the funnel from one configuration to the other may alternatively be accomplished by reducing the temperature of the funnel below body temperature such as by introducing a cooled fluid into thermal communication with the funnel tip or providing the catheter or a removable cooling catheter with a Joule – Thomson expansion chamber located near the distal end.

In an alternate configuration, the sidewall of the funnel is provided with an inflatable balloon in the form of a ring or hoop, in communication with an inflation lumen extending throughout the length of the catheter. Introduction of inflation media inflates the annular balloon, transforming the configuration of the funnel tip from a reduced diameter to an enlarged diameter.

In an alternate configuration, the distal tip is biased into the funnel configuration, and restrained into a cylindrical configuration such as for transluminal navigation. When the funnel tip is desired to be enlarged, the restraint can be removed. The restraint may comprise an outer tubular covering membrane or loop configured to be removed by pulling a pull wire in a proximal direction. Alternatively, the restraint may be a bioabsorbable material, which dissolves following a preset amount of time that exceeds the anticipated time from vascular access to reach the final intravascular position.

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Referring to FIGS. 4J– 4K, the distal flared tip may comprise embedded elastic elements (e.g., a coil, struts or cage) such as spring steel, Nitinol or others known in the art that bias the tip into the flared configuration. The elastic elements such as in the form of a Nitinol cage may alternatively reside on the ID of the catheter. The polymer tip restrains the elastic elements to provide a cylindrical exterior configuration for transluminal navigation as seen in FIG. 4J. Softening the polymer (e.g., a hydrophilic blend) such as by body heat or moisture allows the elastic elements to transform the tip into the funnel configuration as seen in FIG. 4K. Alternatively, a conical NiTi cage at the tip is coated with a double hydrophilic non-cross linked glue. As the catheter advances the glue dissolves and gradually flares the tip into a funnel. The polymer tip may be formed without embedded elastic components and instead comprise a coextrusion with multiple layers, varying thickness in multiple layers, blending hydrophilic components at different ratios to control flaring. Multiple axially extending pull wires may be embedded through extruded lumen extending axially throughout the catheter wall. The wires are pushed or pulled to open/close the catheter distal end to flare or collapse. Funnel-shaped, underexpanded NiTi stent can be deployed at the tip area straddling between high and low durometer regions but greater length into high durometer region. Once ready to engage a clot, the stent can be pushed distally further into the low durometer tip. After complete clot retrieval the stent is pulled back into high durometer region, collapsing the funnel. This is an example of an active on-demand funneling tip.

Referring to FIG. 4F, there is illustrated a cross-sectional view of a distal end of a tubular catheter body such as distal section 34. The tubular body is provided with a distal tip 38 in the form of a self expandable (e.g., NiTinol) mesh 50, constrained by an outer tubular restraint 52. Restraint 52 may comprise a proximately retractable tubular body extending proximally to a control on the proximal manifold; a peel away sheath carried by an elongate proximally retractable pull wire, or other mechanism disclosed elsewhere herein. As shown in FIG 4G, proximal retraction of tubular restraint 52 with respect to tubular body 34, or distal advance of tubular body 34 with respect to restraint 52 exposes and releases the mesh 50 to self expand to a funnel shape to facilitate capture and removal of intravascular debris.

Referring to FIGS. 4H and 4I, the self expandable conical mesh 50 is restrained by interweaving an internal restraint wire 54. Restraint wire 54 may be a procedure guide wire,

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or a dedicated restraint wire. Proximal retraction of the restraint wire 54 releases the mesh 50, to self expanded to a final, funnel configuration. Release of the mesh 50 may be accomplished in a variety of alternative ways, such as bio absorbable materials, and electrolytic detachment.

The proximal end 12 of catheter 10 is additionally provided with a manifold 18 having one or more access ports as is known in the art. Generally, manifold 18 is provided with a proximal port such as a guidewire port 20 in an over-the-wire construction, and at least one side port such as aspiration port 22. Alternatively, the aspiration port 22 may be omitted if the procedure involves removal of the guidewire proximally from the guidewire port 20 following placement of the aspiration catheter, and aspiration through the guidewire port. Additional access ports and lumen may be provided as needed, depending upon the functional capabilities of the catheter. Manifold 18 may be injection molded from any of a variety of medical grade plastics, or formed in accordance with other techniques known in the art.

Manifold 18 may additionally be provided with a control 24, for controlling the axial position of the distal segment 34 of the catheter. Control 24 may take any of a variety of forms depending upon the mechanical structure and desired axial range of travel of the distal segment 34. In the illustrated embodiment, control 24 comprises a slider switch which is mechanically axially movably linked to the distal segment such that proximal retraction of the slider switch 24 produces a proximal movement of the distal segment 34. This retracts the distal segment 34 into the proximal section 33 as illustrated in FIG. 1. Distal axial advancement of the slider switch 24 produces a distal axial advance of the distal segment 34, as illustrated in FIGS. 2 and 3.

Any of a variety of controls may be utilized, including switches, buttons, levers, rotatable knobs, pull/push wires, and others which will be apparent to those of skill in the art in view of the disclosure herein. The control will generally be linked to the distal segment by a control wire 42.

Alternatively, the proximal section 33 and distal section 34 maybe provided as separate devices, in which construction the proximal control may be omitted. The distal end of proximal section 33 may be provided with one or more jaws as has been discussed

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previously herein, for morcellating or otherwise breaking thrombus or other obstruction into pieces or otherwise facilitating aspiration. The proximal section 33 may additionally be mechanically coupled to or adapted for coupling to a source of vibrational or rotational movement, such as to provide the intermittent or pulsatile movement discussed elsewhere herein to facilitate navigation into the vasculature.

Using axial reciprocation, and/or rotation, and/or biting action of the distal jaws, the clinician may be able to reach the obstruction using proximal section 33. See, for example, FIG. 5 in which proximal section 33 is able to reach an obstruction in the left carotid siphon. If, however, the proximal section 33 is not able to advance sufficiently close to the obstruction, a separate telescoping distal section 34 may be introduced into the proximal section 33 and advanced therethrough and beyond, as illustrated in FIGS. 2 and 6-10, to reach the obstruction.

The cerebral circulation is regulated in such a way that a constant total cerebral blood flow (CBF) is generally maintained under varying conditions. For example, a reduction in flow to one part of the brain, such as in acute ischemic stroke, may be compensated by an increase in flow to another part, so that CBF to any one region of the brain remains unchanged. More importantly, when one part of the brain becomes ischemic due to a vascular occlusion, the brain compensates by increasing blood flow to the ischemic area through its collateral circulation.

FIG. 5 depicts cerebral arterial vasculature including the Circle of Willis. Aorta 100 gives rise to right brachiocephalic artery 82, left common carotid artery (CCA) 80, and left subclavian artery 84. The brachiocephalic artery 82 further branches into right common carotid artery 85 and right subclavian artery 83. The left CCA gives rise to left internal carotid artery (ICA) 90 which becomes left middle cerebral artery (MCA) 97 and left anterior cerebral artery (ACA) 99. Anteriorly, the Circle of Willis is formed by the internal carotid arteries, the anterior cerebral arteries, and anterior communicating artery 91 which connects the two ACAs. The right and left ICA also send right posterior communicating artery 72 and left posterior communicating artery 95 to connect, respectively, with right posterior cerebral artery (PCA) 74 and left PCA 94. The two posterior communicating arteries and PCAs, and

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the origin of the posterior cerebral artery from basilar artery 92 complete the circle posteriorly.

When an occlusion occurs acutely, for example, in left carotid siphon 70, as depicted in FIG. 5, blood flow in the right cerebral arteries, left external carotid artery 78, right vertebral artery 76 and left vertebral artery 77 increases, resulting in directional change of flow through the Circle of Willis to compensate for the sudden decrease of blood flow in the left carotid siphon. Specifically, blood flow reverses in right posterior communicating artery 72, right PCA 74, left posterior communicating artery 95. Anterior communicating artery 91 opens, reversing flow in left ACA 99, and flow increases in the left external carotid artery, reversing flow along left ophthalmic artery 75, all of which contribute to flow in left ICA 90 distal the occlusion to provide perfusion to the ischemic area distal to the occlusion.

As illustrated in FIG. 5, the proximal segment of catheter 10 is transluminally navigated along or over the guidewire, to the proximal side of the occlusion. Transluminal navigation may be accomplished with the distal section 34 of the catheter in the first, proximally retracted configuration. This enables distal advance of the proximal section 33 until further progress is inhibited by small and/or tortuous vasculature. Alternatively, the distal section 34 is a separate device, and is not inserted into the proximal section 33 until it is determined that the proximal section 33 cannot safely reach the occlusion. In the example illustrated in FIG. 5, the occlusion may be safely reached by the proximal section 33, without the need to insert or distally extend a distal section 34.

The distal end of the proximal section 33 of aspiration catheter 10 is inserted typically through an incision on a peripheral artery over a guidewire and advanced as far as deemed safe into a more distal carotid or intracranial artery, such as the cervical carotid, terminal ICA, carotid siphon, MCA, or ACA. The occlusion site can be localized with cerebral angiogram or IVUS. In emergency situations, the catheter can be inserted directly into the symptomatic carotid artery after localization of the occlusion with the assistance of IVUS or standard carotid doppler and TCD.

If it does not appear that sufficient distal navigation of the proximal section 33 to reach the occlusion can be safely accomplished, the distal section 34 is inserted into the

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proximal port 20 and/or distally extended beyond proximal section 33 until distal tip 38 is positioned in the vicinity of the proximal edge of the obstruction.

Referring to FIG. 6, an obstruction 70 is lodged in the middle cerebral artery 97. Proximal section 33 is positioned in the ICA and not able to navigate beyond a certain point such as at the branch 96 to the MCA artery 97. The proximal section 33 may be provided with a distal section 34 carried there in. Alternatively, a separate distal section 34 may be introduced into the proximal end of proximal section 33 once the determination has been made that the obstruction 70 cannot be reached directly by proximal section 33 alone. As seen in FIGS. 7 and 8, the distal section 34 may thereafter be transluminally navigated through the distal tortuous vasculature between proximal section 33 and the obstruction 70.

Referring to FIG. 9, the obstruction 70 may thereafter be drawn into distal section 34 upon application of constant or pulsatile negative pressure with or without the use of jaws or other activation on the distal end of distal section 34 as discussed elsewhere herein. Once the obstruction 70 has either been drawn into distal section 34, or drawn sufficiently into distal section 34 that it may be proximately withdrawn from the body, proximal section 33 and distal section 34 are thereafter proximally withdrawn.

Aspiration may be applied via lumen 40, either in a constant mode, or in a pulsatile mode. Preferably, pulsatile application of vacuum will cause the distal tip 38 to open and close like a jaw, which facilitates reshaping the thrombus or biting or nibbling the thrombus material into strands or pieces to facilitate proximal withdrawal under negative pressure through lumen 40. Application of aspiration may be accompanied by distal advance of the distal tip 38 into the thrombotic material.

Pulsatile application of a vacuum may oscillate between positive vacuum and zero vacuum, or between a first lower negative pressure and a second higher negative pressure. Alternatively, a slight positive pressure may be alternated with a negative pressure, with the application of negative pressure dominating to provide a net aspiration through the lumen 40. Pulse cycling is discussed in greater detail in connection with FIG. 25.

The proximal manifold and/or a proximal control unit (not illustrated) connected to the manifold may enable the clinician to adjust any of a variety of pulse parameters including

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pulse rate, pulse duration, timing between pulses as well as the intensity of the pulsatile vacuum.

The distal section may thereafter be proximally retracted into proximal section 33 and the catheter proximally retracted from the patient. Alternatively, proximal retraction of the catheter 10 may be accomplished with the distal section 34 in the distally extended position. A vasodilator, e.g., nifedipine or nitroprusside, may be injected through a second lumen to inhibit vascular spasm induced as a result of instrumentation.

Pressure may be monitored by a manometer carried by the catheter or a wire positioned in a lumen of the catheter. A pressure control and display may be included in the proximal control unit or proximal end of the catheter, allowing suction within the vessel to be regulated.

Focal hypothermia, which has been shown to be neuroprotective, can be administered by perfusing hypothermic oxygenated blood or fluid. Moderate hypothermia, at approximately 32 to 34°C, can be introduced during the fluid infusion. Perfusion through a port on manifold 18 can be achieved by withdrawing venous blood from a peripheral vein and processing through a pump oxygenator, or by withdrawing oxygenated blood from a peripheral artery, such as a femoral artery, and pumping it back into the carotid artery.

If continuous and/or intermittent suction fails to dislodge the occlusion, a thrombolytic agent, e.g., t-PA, can be infused through central lumen 40 or a second lumen to lyse any thrombotic material with greater local efficacy and fewer systemic complications. Administration of thrombolytic agent, however, may not be recommended for devices which are inserted directly into the carotid artery due to increased risk of hemorrhage.

The intensity of intermittent or pulsatile vacuum applied to lumen 40 may be adjusted to cause the distal tip 38 of the catheter 10 to experience an axial reciprocation or water hammer effect, which can further facilitate both translumenal navigation as well as dislodging or breaking up the obstruction. Water hammer, or more generally fluid hammer, is a pressure surge or wave caused when a fluid in motion is forced to stop or change direction suddenly, creating a momentum change. A water hammer commonly occurs when a valve closes suddenly at the end of a pipeline system, and a pressure wave propagates in the pipe. A pressure surge or wave is generated inside the lumen 40 of the aspiration catheter 10

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when a solenoid or valve closes and stops the fluid flow suddenly, or other pulse generator is activated. As the pressure wave propagates in the catheter 10, it causes the catheter 10 to axially vibrate. Since vibration can reduce surface friction between the outer diameter of the catheter 10 and the inner diameter of the vessel wall, it enables catheter to track through tortuous anatomies as well as assist capturing thrombus.

Referring to FIGS. 11A-11F, the cerebral circulation 1100 is simplified for the ease of demonstrating procedural steps. A thrombotic occlusion 1102 is in the right middle cerebral artery (RMCA) 1104. The RMCA 1104 branches from the right internal carotid artery (RICA) 1106. The RICA 1106 branches from the right common carotid artery (RCCA) (not shown). The RICA 1106 comprises cerebral 1108 (most distal from the aorta 100), cavernous 1110, and petrous 1112 (most proximal from the aorta 100) segments. The RCCA branches from the brachiocephalic artery. The brachiocephalic artery branches from the arch 1114 of the aorta 100.

The procedural steps for aspirating a thrombotic occlusion are described as follows. Referring to FIG. 11A, an introducer sheath 1120 is introduced at the femoral artery 1118. The outer diameter of the introducer sheath 1120 may be equal to or less than about 12F, 11F, 10F, 9F, 8F, 7F, or 6F. Then, a guide sheath 1122 is inserted through the introducer sheath 1120. The outer diameter of the guide sheath 1122 may be equal to or less than about 9F, 8F, 7F, 6F, 5F, 4F, or 3F, and the inner diameter of the introducer sheath 1120 may be greater than the outer diameter of the guide sheath 1122.

Referring to FIG. 11B, an insert catheter 1124 is inserted through the guide sheath 1122. The outer diameter of the insert catheter 1124 may be equal to or less than about 9F, 8F, 7F, 6F, 5F, 4F, or 3F, and the inner diameter of the guide sheath 1122 may be greater than the outer diameter of the insert catheter 1124. In some cases, a first guidewire 1126 may be introduced through the insert catheter 1124 (not shown in FIG. 11B). Then, the guide sheath 1122, the insert catheter 1124, and optionally the first guidewire 1126 are tracked up to the aortic arch 1114. The insert catheter 1124 is used to engage the origin of a vessel. In FIG. 11B, the insert catheter 1124 engages the origin 1116 of the brachiocephalic artery 82. An angiographic run is performed by injecting contrast media through the insert catheter 1124.

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In the cases where the first guidewire 1126 is used before the angiographic run, the first guidewire 1126 is removed prior to injecting the contrast media.

Referring to FIG. 11C, the first guidewire 1126 is inserted through the lumen of the insert catheter 1124. Then, the first guidewire 1126, the insert catheter 1124, and the guide sheath 1122 are advanced together to the ICA 1106. Referring to FIG. 11D, due to the stiffness of a typical guide sheath 1122 currently available in the market (e.g., Neuron MAX System produced by Penumbra Inc.), the most distal vessel that the guide sheath 1122 could navigate to is the petrous segment 1112 of the ICA 1106. Once the first guidewire 1126, the insert catheter 1124, and the guide sheath 1122 are advanced to the ICA 1106, both the first guidewire 1126 and the insert catheter 1124 are removed.

Referring to FIG. 11E, a second guidewire 1132 loaded inside the central lumen of a reperfusion catheter 1130 (e.g., 3Max), which is loaded inside the central lumen of an aspiration catheter 1128 (e.g., ACE 68), are introduced through the guide sheath 1122. The diameter of the second guidewire 1132 may be equal to or less than about 0.03″, about 0.025″, about 0.02″, about 0.016″, about 0.014″, about 0.01″, or about 0.005″. The inner diameter of the reperfusion catheter 1130 may be greater than the outer diameter of the second guidewire 1132. The inner diameter of the aspiration catheter 1128 may be greater than the outer diameter of the reperfusion catheter 1130. The inner diameter of the guide sheath 1122 may be greater than the outer diameter of the aspiration catheter 1128. Then, the second guidewire 1132 is advanced distally and positioned at the proximal end of the clot 1102 in the MCA 1104.

Referring to FIG. 11F, the aspiration catheter 1128 is tracked over the reperfusion catheter 1130 and the second guidewire 1132 to the proximal end of the clot 1102 in the MCA 1104. Both the second guidewire 1132 and the reperfusion catheter 1130 are removed. A vacuum pressure is then applied at the proximal end of the aspiration catheter 1128 to aspirate the clot 1102 through the central lumen of the aspiration catheter 1128.

A preferable, simplified method for aspirating a thrombotic occlusion in accordance with the present invention is described in connection with FIGS. 12A—12F. The alternative steps for aspirating a thrombotic occlusion make use of a transitional guidewire and a transitional guide sheath. The transitional guidewire has a soft and trackable distal segment

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with a smaller diameter so that the transitional guidewire may be advanced deeper than the guidewire 1126 described in FIG. 11C. In addition, the transitional guide sheath has a soft and trackable distal segment such that the transitional guide sheath may be advanced deeper than the guide sheath 1122 described in FIG. 11D. Using a transitional guidewire and a transitional guide sheath that can be advanced to an area near the clot eliminates the need to use a second guidewire or a reperfusion catheter to reach the clot.

Referring to FIG. 12A, an introducer sheath 1220 is introduced at the femoral artery 1218. The outer diameter of the introducer sheath 1220 may be equal to or less than about 12F, 11F, 10F, 9F, 8F, 7F, or 6F. Then, a transitional guide sheath 1222 such as the combination access and aspiration catheter discussed in greater detail below is inserted through the introducer sheath 1120 at the femoral artery 1218. The outer diameter of the guide sheath 1222 may be equal to or less than about 9F, 8F, 7F, 6F, 5F, 4F, or 3F. Referring to FIG. 12B, an insert catheter 1224 is inserted through the transitional guide sheath 1222. The outer diameter of the insert catheter 1224 may be less than about 9F, 8F, 7F, 6F, 5F, 4F, or 3F, and the inner diameter of the transitional guide sheath 1222 may be greater than the outer diameter of the insert catheter 1224. In some cases, a first guidewire may be introduced through the insert catheter 1224 (not shown in FIG. 12B). The diameter of the proximal section of the first guidewire may be equal to or less than about 0.079″, about 0.066″, about 0.053″, about 0.038″, about 0.035″, about 0.030″, or about 0.013″.

The transitional guide sheath 1222, the insert catheter 1224, and optionally the first guidewire are tracked up to the aortic arch 1214. See FIG. 12B. The insert catheter 1224 may be used to select the origin of a vessel. In FIG. 12B, the insert catheter 1224 engages the origin 1216 of the brachiocephalic artery 82. An angiographic run may be performed by injecting contrast media through the insert catheter 1224. In the cases where the first guidewire is used before the angiographic run, the first guidewire is preferably removed prior to injecting the contrast media.

Referring to FIG. 12C, the transitional guidewire 1226 is inserted through the lumen of the insert catheter 1224 or guide sheath 1222. The diameter of at least a portion of the transitional guidewire 1226 (e.g., proximal diameter) is substantially similar to that of the first guidewire 1126. The diameter of at least a portion of the transitional guidewire 1226

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(e.g., distal diameter) may be smaller than that of the first guidewire 1126 and may have a diameter along a proximal segment of at least about 0.030" and in one implementation about 0.038". A transition begins within the range of from about 15 cm – 30 cm from the distal end, and typically no more than about 20 cm or 25 cm from the distal end, distally of which the diameter tapers down to no more than about 0.018" and in one implementation about 0.016". Referring to FIG. 12D, if utilized, the insert catheter 1224 may be removed because it is too stiff to be advanced to the MCA 1204. In certain implementations of the invention, the transitional guidewire 1226 provides sufficient back up support that the combination access and aspiration catheter 1224 may be advanced directly over the transitional guidewire without any intervening devices. Then, the transitional guidewire 1226 is advanced to the MCA 1204. The transitional guidewire 1226 has a distal segment that has a smaller diameter than that of the first guidewire 1126 described in FIG. 11C. The distal segment of the transitional guidewire 1226 comprises a soft and atraumatic tip and can be tracked to the remote neurovasculature such as the MCA 1204, which is distal to the petrous segment 1212 of the ICA 1206.

Referring to FIG. 12E, the transitional guide sheath 1222 is advanced to or beyond the cavernous segment 1210 or the cerebral 1208 segment of the ICA 1206. Unlike the guide sheath 1122 described in FIG. 11D, the transitional guide sheath 1222 may be advanced to the cavernous segment 1210 or the cerebral 1208 segment of the ICA 1206 beyond the petrous segment 1212 because the transitional guide sheath 1222 has a soft yet trackable distal segment described in further detail below, for example in connection with Figure 30. The larger proximal diameter and stiffer body of the transitional guidewire 1226 may provide better support for the transitional guide sheath 1222 to track through the vasculature.

Referring to FIG. 12F, after the transitional guide sheath 1222 is advanced to the cerebral segment 1208 of the ICA 1206, the transitional guidewire 1226 is removed. Then, a vacuum pressure is applied at the proximal end of the transitional guide sheath 1222 to aspirate the clot 1202 through the central lumen of the transitional guide sheath 1222. The inner diameter of the transitional guide sheath 1222 may be equal to about or greater than about 0.100″, about 0.088″, about 0.080″, about 0.070″, or about 0.060″. The inner diameter of the transitional guide sheath 1222 is larger than the aspiration catheter 1128 described in

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FIG. 11E, which translates to more effective aspiration. The cross-sectional area of the central lumen of the transitional guide sheath 1222 may be almost twice as large as that of the largest aspiration catheter 1128 currently available.

If the guide sheath 1222 is not able to track deep enough into the distal vasculature to reach the clot or other desired target site, a telescopic extension segment as discussed elsewhere herein may be introduced into the proximal end of sheath 1222 and advanced distally to extend beyond the distal end of the sheath 1222 and thereby extend the reach of the aspiration system. In one implementation of the invention, the extension segment has an ID of about 0.070".

If thrombotic material is not able to be drawn into the sheath 1222 or extension segment under constant vacuum, pulsatile vacuum may be applied as discussed below. If pulsatile vacuum does not satisfactorily capture the clot, an agitator may be advanced through the sheath 1222 and extension segment to facilitate drawing the clot into the central lumen. Additional details of the agitator and its use are disclosed below.

A pulsatile vacuum pressure aspirator may be used in order to improve effectiveness of aspiration for vascular thrombectomy and to improve catheter trackability through tortuous vasculatures. FIG. 13 shows an embodiment of a pulsatile vacuum pressure aspirator 300 that applies intermittent or pulsatile vacuum to lumen 40. In the illustrated embodiment, the pulsatile vacuum pressure aspirator 300 is in fluid connection with the proximal end 12 of the catheter 10 and comprises vacuum generator 302, vacuum chamber 310, collection canister 312, solenoid valve 314, frequency modulator 316, valve controller 318, and remote controller 320.

Vacuum generator 302 comprises a vacuum pump 304, a vacuum gauge 306, and a pressure adjustment control 308. The vacuum pump 304 generates vacuum. The vacuum gauge 306 is in fluid connection with the vacuum pump 304 and indicates the vacuum pressure generated by the pump 304. The pressure adjustment control 308 allows the user to set to a specific vacuum pressure. Any of a variety of controls may be utilized, including switches, buttons, levers, rotatable knobs, and others which will be apparent to those of skill in the art in view of the disclosure herein.

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Vacuum chamber 310 is in fluid connection with the vacuum generator 302 and acts as a pressure reservoir and/or damper. Collection canister 312 is in fluid connection with the vacuum chamber 310 and collects debris. The collection canister 312 may be a removable vial that collects debris or tissues, which may be used for pathologic diagnosis. Vacuum chamber 310 and collection canister 312 may be separate components that are in fluid connection with each other or a merged component. In the illustrated embodiment, the vacuum chamber 310 and the collection canister 312 is a merged component and is in fluid connection with the vacuum generator 302.

Solenoid valve 314 is located in the fluid connection path between a luer or other connector configured to releasably connect to an access port of the catheter 10 and the vacuum chamber 310 / collection canister 312. The solenoid valve 314 controls the fluid flow from the catheter 10 to the vacuum chamber 310 / collection canister 312.

Pulsatile vacuum pressure aspirator 300 may comprise frequency modulator 316 for control of the solenoid valve 314. The frequency modulator 316 generates different electrical wave frequencies and forms, which are translated into the movement of the solenoid valve 314 by the valve controller 318. The wave forms generated from the frequency modulator 316 comprise sinusoidal, square, and sawtooth waves. The wave forms generated from the frequency modulator 316 typically have frequencies less than about 500 Hz, in some modes of operation less than about 20 Hz or less than about 5 Hz. The wave forms have duty cycles ranging from 0%, in which the solenoid valve 314 is fully shut, to 100%, in which the solenoid valve 314 is fully open.

Valve controller 318 modulates the solenoid valve 314 on and off. The valve controller 318 may be electrically or mechanically connected to the solenoid valve 314. Any of a variety of controls may be utilized, including electrical controllers, switches, buttons, levers, rotatable knobs, and others which will be apparent to those of skill in the art in view of the disclosure herein. The valve controller 318 may be mechanically controlled by users or may be electrically controlled by the frequency modulator 316. The frequency modulator 316 and the valve controller 318 may be separate components that are electrically or mechanically connected or a merged component.

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Remote control 320 enables physicians to control the frequency modulator 316 and/or the valve controller 318 for various purposes, such as turning the valve on/off, selecting different wave frequencies, and selecting different wave forms, while manipulating the catheter 10 at the patient side. Remote control 320 may be in wired or wireless communication with aspirator 300.

By tuning frequency, duty cycle, and wave form, one skilled in the art may match or approximate the resonating frequency to the natural frequency of the catheter. This may further enhance the efficacy of aspiration. The natural frequency of the catheter is typically less than about 260 Hz.

In another embodiment, shown in FIG. 14, the solenoid valve 414 is positioned in and fluidly connects between the air/fluid reservoir 422 at the atmospheric pressure and the aspiration line 424 connecting the catheter 10 to the vacuum chamber 410 / collection canister 412. Unlike the first embodiment in FIG. 13, this system modulates pressure in the catheter 10 by allowing pressure to vary from vacuum to atmospheric pressure. When the solenoid valve 414 is open to the air/fluid reservoir 422 at the atmospheric pressure, the vacuum pressure in the aspiration line 424 decreases to the atmospheric pressure. When the solenoid valve 414 is closed, it increases the vacuum pressure in the aspiration line 424.

In yet another embodiment, shown in FIG. 15, an electro-magnetic actuated diaphragm 522 is attached to the aspiration line 524 connecting the catheter 10 to the vacuum chamber 510 / collection canister 512. The electromagnetic actuated diaphragm 522, which is similar to that of a speaker driver, generates acoustic pressure waves in the catheter 10. The diaphragm 522 typically has a structure similar to a speaker driver and comprises frame 526, cone 528, dust cap 530, surround 532, spider or damper 534, voice coil 536 and magnet 538. Strength of the acoustic pressure waves may be modulated by the strength of the magnet 538. The frequency modulator 516 connected to the remote control 520 is electrically connected to the diaphragm 522 and generates different electrical wave frequencies and forms, which are translated by the diaphragm 522 into acoustic pressure waves in the aspiration line 524 and the catheter 10.

Tortuous vasculature is a common reason for failure to treat vasculature occlusions in the body due to inability to track the catheter to the location of the disease. Navigating

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catheters through tortuous anatomy such as neurovasculature can be a challenge. The catheter has to be very soft as not to damage the vessel wall. At the same time, it also has to be able to negotiate multiple tight turns without kinking. In addition, it has to have sufficient column strength to transmit force axially for advancing through the vasculature. All these performance characteristics are competing design requirements. It is difficult to optimize one performance characteristic without sacrificing the others.

Reducing friction between the inner diameter of the vessel and the outer diameter of the catheter can minimize axial force required to advance catheter through tortuous vasculature. Therefore, the column strength of the catheter may be traded off for optimizing other performance requirements of the catheter. An example of a method to reduce friction between the inner diameter of the blood vessel and the outer diameter of the catheter is to apply a thin layer of coating, usually hydrophilic in nature, to the outer diameter of the catheter to reduce its surface friction coefficient while in vivo.

In addition or as an alternative to the water hammer construction discussed above, axial mechanical vibration or shock waves may be propagated to or generated at the distal end of the catheter using a variety of vibration generators, such as spark gap generators, piezoelectric pulse generators, electric solenoids, rotational shaft (wire) having one or more bends or carrying an eccentric weight, or any of a variety of other impulse generating sources well understood for example in the lithotripsy arts. Mechanical shock wave or pulse generators may be built into the proximal manifold 18, and or mechanically coupled to the manifold or proximal catheter shaft as desired. Preferably, controls are provided on the manifold or on a proximal control coupled to the manifold, to enable the clinician to vary the intensity and time parameters of the mechanical pulses. Shock waves may be propagated along the proximal section 33 to assist in translumenal advance, and/or distal section 34 by way of pull wire 42, depending upon the desired clinical performance.

In an embodiment shown in FIGS. 16 and 17, the distal end 608 of a vibrating device 600 is placed in fluid connection with the proximal end 12 of the catheter 10 (not illustrated) and generates transverse and/or longitudinal vibration in the catheter 10. By inducing transverse vibration in the catheter 10, it reduces effective contact surface area between the vessel and the catheter 10, which in turn reduces surface friction force between the inner

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diameter of the vessel and the outer diameter of the catheter. In addition, by inducing longitudinal vibration in the catheter 10, the vibrating device 600 breaks static friction between the inner diameter of the vessel and the outer diameter of the catheter 10, which reduces overall surface friction. By reducing the friction between the inner diameter of the vessel and the outer diameter of the catheter 10, the vibrating device 600 improves catheter trackability through tortuous vasculatures.

In the illustrated embodiment, the proximal end 602 of the vibrating device 600 may be connected to a vacuum pressure source such as a vacuum generator. The proximal connector 604 is attached to the housing 606. In at least one embodiment, the proximal connector 604 may be a luer connector. The distal end 608 of the vibrating device 600 is connected to the catheter 10. The distal connector 610 is held in place by a flexible seal 612 that is attached to the housing 606. In at least one embodiment, the distal connector 610 may be a luer connector. The flexible seal 612 allows the distal connector 610 to move longitudinally as well as transversely. The flexible tubing links the proximal connector 604 and the distal connector 610, creating an aspiration channel 614 for the fluid to travel through.

The vibrating device has a controller 616 to turn on/off the vibrating action as well as to vary its frequency. In this embodiment, the controller 616 is drawn as a sliding switch. Any of a variety of controls may be utilized, including electrical controllers, switches, buttons, levers, rotatable knobs, and others which will be apparent to those of skill in the art in view of the disclosure herein.

A vibration generator such as a motor 618 has an eccentrically mounted inertial weight on its shaft generating vibration. Any of a variety of motors may be used, including an electric motor, an electro-magnetic actuator, and a piezoelectric transducer. The frequency of the vibration is related to the RPM of the motor 618. A driving circuit 620 is connected to the motor 618 and the controller 616 and drives the motor 618 at different RPMs based on the manipulation of the controller 616. In the illustrated embodiment, the circuit 620 drives the motor 618 at different RPMs based on the position of the sliding switch. A battery 622 is connected to and powers the driving circuit 620 and the motor 618.

The motor 618 may be mounted perpendicularly to the length of the aspiration channel 614 to create longitudinal vibration. Also, a mechanical cam may be attached to the

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motor 618 to create larger magnitude longitudinal reciprocating motion. The frequency range generated by the electric motor is typically less than about 85 Hz. To achieve sonic frequencies in the range from about 85 Hz to about 260 Hz, one might replace the electric motor with an electro-magnetic actuator. To achieve ultrasonic frequencies in the range of about 20 Hz to about 1.6MHz, one might employ a piezoelectric transducer.

In yet another embodiment, shown in FIG. 18, an agitator such as stylet 702 is permanently or removably inserted into a lumen 40 of the catheter 10 and rotated to generate vibration in the catheter 10 and thus improve catheter trackability through tortuous vasculatures. The stylet 702, whose outer diameter is within the range of from about 0.005 inches (about 0.127mm) to about 0.035 inches (about 0.889mm), may have at least one bend or at least one weight. The peak to peak transverse distance between the bends will be less than the inner diameter of the catheter 10 when positioned within the catheter. The bends or weights of the stylet 702 may be positioned at different locations along the entire length of the catheter 10 or contained within a vibration zone within the distal most 50% or 30% or 10% of the length of the catheter depending upon desired performance, with the purpose to create the most desirable vibration when tracking the catheter 10 through the distal vasculature.

Alternatively, the stylet 702 may have an asymmetric weight such as a bead at a distal vibration zone or at its distal end. The stylet 702 may comprise a monofilament or braided or woven filaments or wires.

In another alternative, the stylet 702 may have a heater (e.g., an electric coil) at its distal end that facilitates the dissolution of the thrombus or changes the size of the thrombus that is aspirated into the catheter.

The proximal end of the stylet is attached to a motor driver 704 capable of generating rotational and or axially reciprocating motion at various frequencies to form a motor driver-stylet assembly 700. The assembly 700 has a controller 706 to turn on/off the rotating action as well as to vary its frequency. In this embodiment, the controller 706 is drawn as an on/off button. Any of a variety of controls may be utilized, including electrical controllers, switches, buttons, levers, rotatable knobs, and others which will be apparent to those of skill in the art

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in view of the disclosure herein. The proximal luer 708 or other connector of the catheter 10 reversibly attaches the catheter 10 to the motor driver 804.

Once the catheter 10 has reached its intended location, the entire motor driver-stylet assembly 700 may be detached and removed from the catheter 10 leaving a central aspiration lumen.

In patients with vertebral artery occlusions, treatment with angioplasty can result in complications due to embolization of the occlusive lesion downstream to the basilar artery. Emboli small enough to pass through the vertebral arteries into the larger basilar artery are usually arrested at the top of the basilar artery, where it bifurcates into the posterior cerebral arteries. The resulting reduction in blood flow to the ascending reticular formation of the midbrain and thalamus produces immediate loss of consciousness. The devices described herein can be used to remove thromboembolic material from the vertebral artery or more distally such as in M1, M2, or M3 arteries.

Agitators for providing vibratory assistance for navigation and/or assisting in the capture and aspiration of debris are described further in connection with FIGS. 19-24. Referring to FIG. 19, an agitator 1900 may comprise an elongate, flexible body such as a wire or hypo tube having a proximal, control end and a distal, active zone or end. The hypo tube agitator has an inside lumen extending longitudinally that allows infusion of media. Referring to FIG. 19, an agitator 1900 comprises a wire or hypo tube 1904, introduced into the proximal end of a catheter 1902 and advanced to the distal end 1907 of the catheter 1902. The distal tip 1905 of the agitator 1900 may be placed at, beyond, or inside the distal end of the catheter 1902. The agitator 1900 can be either preloaded into the catheter 1902 and inserted into the patient's body together with the catheter 1902 or added after the catheter 1902 has been placed. When loaded inside the catheter 1902, the agitator 1900 may extend substantially longitudinally along the length of the catheter 1902. The agitator 1900 may further comprise a controller at the proximal end to axially adjust the distal tip position. The controller of the agitator 1900 may be used to axially adjust the position of the distal tip 1905 when the agitator 1900 is introduced into a variable length catheter such as that discussed in connection with FIG. 3.

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In one implementation of the invention, the agitator and drive system are configured as a stand-alone device. Once the distal section 34 (Figure 3B) has been positioned within a few (e.g., no more than about 3 or 2) centimeters of the obstruction, the distal end of agitator 1900 maybe introduced into the proximal end of central lumen 45 of pull wire 42. Agitator 1900 may thereafter be distally advanced so that a distal segment of agitator 1900 extends beyond the distal end of pull wire 42, and into the distal section 34. The portion of the agitator 1900 contained within lumen 45 of pull wire 42 is restrained from any significant lateral motion. However, the distal portion of agitator 1900 which extends beyond the distal end of pull wire 42 is relatively laterally unconstrained and is able to agitate thrombus to facilitate drawing the thrombus into and through the distal section 34. Once the thrombus has been drawn proximally under vacuum and with activation of the agitator as needed, to reach the step up in ID at the proximal end of distal section 34, the risk of clogging is greatly reduced.

The agitator 1900 may be rotated manually or via a motor 1906 driven from the catheter 1902's proximal end to rotate or translate the distal end of the agitator 1900. The driver 1906 may be connected to the proximal end of the agitator 1900 either permanently or removably. The driver 1906 may be a manual driver that is manually controlled such as a guidewire torquer. The driver 1906 may be a motorized driver. The motorized driver may be manually controlled with respect to one or more factors such as rotational direction (CCW/CW), speed, duration, etc. The motorized driver may be automatically controlled with respect to one or more factors such as direction (CCW/CW), speed, duration, etc. In one mode, the rotational direction of the agitator is periodically reversed.

The automatically controlled driver may comprise an actuator, and actuating the actuator may execute a pre-programmed series of steps. The actuator may be a button, a dial, a knob, a switch, a lever, a valve, a slide, a keypad, or any combinations thereof. The driver 1906 may also be under synchronized control, in which the driver 1906 drives the agitator 1900 in synchronization with aspiration and media injection. The agitator 1900 may be configured to promote motion at the distal end to help engage and move the clot.

Media may be infused into/around the clot area to help liberate the clot from the vasculature.

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The agitator 1900 comprises a distal end 1912, a proximal end 1914 and a distal tip 1905. The proximal end 1914 of the agitator 1900 has a cross-section and/or wall thickness that is large enough to transmit the torque required to rotate the distal end 1912 of the agitator 1900 when placed in the catheter 1902, within the curved vasculature. The outer diameter of the agitator 1900 may be from about 0.25 mm to about 0.65 mm, from about 0.3 mm to about 0.6 mm, from about 0.35 mm to about 0.55 mm, from about 0.4 mm to about 0.5 mm, from about 0.42 mm to about 0.48 mm, or from about 0.44 mm to about 0.46 mm. In case of the hypo tube 1904, the wall thickness of the hypo tube 1904 may be from about 0.01 mm to about 0.29 mm, from about 0.05 mm to about 0.25 mm, from about 0.1 mm to about 0.2 mm, from about 0.12 mm to about 0.18 mm, from about 0.13 mm to about 0.17 mm, or from about 0.14 mm to about 0.16 mm.

The agitator 1900 may additionally be provided with a guide tube 1910, such as a hypo tube, to allow the agitator to spin, or axially or rotationally reciprocate, while constraining a proximal drive segment of the agitator 1900 against lateral motion. A distal end 1911 of guide tube 1910 may be positioned within about 25 cm or within about 20 cm or 15 cm or less of the distal end of the agitator 1900, depending upon desired performance. The distal section of the agitator 1900, extending beyond distal end 1911 of guide tube 1910, is laterally unconstrained within the ID of distal segment 34 and available to agitate and facilitate aspiration of material into and through the central lumen.

The diameter of the agitator 1900 may be constant along its longitudinal length. The diameter of the agitator 1900 may increase or decrease along its longitudinal length to coincide with features of the catheter 1902. In one implementation, the diameter of the agitator 1900 decreases in the distal direction along its longitudinal length by at least one step or tapered zone to provide increasing flexibility.

The distal end 1912 of the agitator 1900 may be straight. Alternatively, the distal end 1912 of the agitator 1900 may be curved or formed into different shapes to interact with the clot. FIG. 19 illustrates a bend 1917 spaced apart from the distal tip 1905 by a motion segment 1909 having a length of from about 1 mm to about 15 mm. FIGS. 20A-20C depict more complex exemplary shapes of the motion segment 1909 of the agitator 1900. FIGS. 20D-20E depict an agitator positioned within a swellable polymer distal funnel tip.

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The agitator 1900 may be comprise a single, uniform material or multiple materials. The materials of the agitator 1900 may be processed (e.g., heat treatment/annealing) to give varying properties for the local performance requirements. The agitator 1900 may be structured to provide flexibility while exhibiting high torque transmission. The agitator 1900 may made of Nitinol, 304 Stainless Steel, 316 LVM Stainless Steel, PTFE, Parylene, or any combinations thereof. At least a portion of the surface of the agitator 1900 may be coated. The entire length of the agitator 1900 may be coated. The coating on the agitator 1900 may provide lubrication between the ID wall of the catheter 1902 and the agitator 1900. In a case that an intermediate hypotube is placed between the wall of the catheter 1902 and the agitator 1900, e.g., constraining tube 1910 or tubular pull wire 42, the coating on the agitator 1900 may provide lubrication between the intermediate hypotube and the proximal drive portion of the agitator 1900. The coating materials of the wire or hypo tube 1904 include PTFE, Parylene, Teflon, or any combinations thereof.

Any of the ID or OD of any of the catheter shafts or other catheter components disclosed herein may be provided with a lubricious coating or may be made from a lubricious material. For example, a hydrophilic polymer such as Polyacrylamide, PEO, thermoplastic starch, PVP, copolymers of hydrophilic polymer can be extruded with hydrophobic polymers such as PEO soft segmented polyurethane blended with Tecoflex. The lubricious coating or the lubricious material may include surface modifying additive (SMA) during melt processing. The lubricious coating or the lubricious material contributes to at least ease of navigation, lower ID skin friction, or better clot removal. In some embodiments, post processing wire ebeam, Gamma, UV, etc. additionally may be desirable to expose to moisture, temperature, etc. Catheters may be made from PEO impregnated polyurethanes such as Hydrothane, Tecophilic polyurethane for both OD and ID lubricity and inherent thromboresistant property without requiring a secondary coating process.

Referring to FIG. 20A, the distal end 2012 of the agitator 1900 may comprise a coil 2020 to grip a corked clot and wiggle the distal end 2010 of the catheter 2002 and the clot during rotation 2006. The coil 2020 may be a tight, offset coil, and may comprise at least one and optionally two or three or more complete revolutions.

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Referring to FIG. 20B, the distal end 2012 of the agitator 1900 may comprise a hook 2022 to grip and emulsify a clot. The hook 2022 may be concave proximally, or may extend transversely to the axis of the agitator body, extending in a circumferential orientation. Referring to FIG. 20C, the distal end 2012 of the agitator 1900 may comprise a loose coil or spring 2024. The loose coil or spring 2024 may expand (lengthen) and contract (shorten) with a change in direction of rotation.

Referring to FIGS. 20D–20E, the distal end 2012 of the agitator 2000 may comprise a coil 2026 to grip a corked clot and wiggle the distal end 2010 of the catheter 2002 and the clot during rotation. In addition, the distal end 2010 of the catheter 2002 may include a polymer sidewall that reforms by hydration. The coil 2026 maintains a guide wire lumen during placement of the catheter. The polymer enables the distal end 2010 of the catheter 2002 to expand to a funnel shape after absorption of serum from blood. See FIG. 20E.

Referring to FIGS. 21A–21B, the distal tip 2110 of the catheter 2102 may move or wiggle by interacting with the agitator 1900. When the distal end of the agitator 1900 rotates (e.g., via a driver 2106), the motion segment 1909 and distal tip 1905 of the agitator interact with the side wall of the catheter 2102 which wiggles as shown by broken lines 2112. The length of the motion segment, stiffness of the agitator 1900 and rotational velocity determines the interaction with the wall of the catheter 2102 and the amount of wiggle transmitted to the catheter 2101 with rotation of the agitator 1900.

Alternatively, the distal tip 2110 of the catheter 2102 may move or wiggle by pulsed media jets existing one or more holes near the distal end of the hypo tube 2124. The hypo tube 2124 has an inside lumen extending along the longitudinal length of the hypo tube 2124. One or more side holes 2128 may be placed near the distal end of the hypo tube 2124 and allow fluid communication between the lumen of the hypo tube 2124 and the outside of the hypo tube 2124 (i.e., the lumen of the catheter 2102). Media (e.g. saline) may be introduced under pressure into the proximal end of the hypo tube 2124, through the lumen of the hypo tube 2124, and then through the one or more holes of the hypo tube 2124. When media is injected into the hypo tube 2124 in a pulsed manner, pulsed media jets eject from the holes of the hypo tube 2124 and transmit forces on the wall of the catheter 2102, resulting in a wiggle

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motion of the catheter 2102. The hypo tube 2124 may additionally rotate (e.g., via a driver 2106) to facilitate a wiggle motion of the catheter 2102.

Referring to FIGS. 22A–22B, the hypo tube 2204 may have one or more holes 2210 and is bent near its distal portion to provide a motion segment 1909. Media (e.g. saline, a drug, a lubricant such as polyethylene glycol) is injected from the proximal end 2200, through the inside lumen, and out of the holes 2210 of the hypo tube 2204 (direction of media ejection shown as 2208). Vacuum is applied to the central lumen at the proximal end 2200 of the catheter 2202 such that media ejecting from the holes 2210 of the hypo tube 2204 is drawn proximally along the central lumen of the catheter 2202 toward its proximal end 2200.

As the hypo tube 2204 rotates, the hypo tube 2204 ejects media and simultaneously makes the distal tip of the catheter 2202 wriggle. When the distal tip of the catheter 2202 wriggles by the rotation of the hypo tube 2204, the wriggle of the catheter 2202 may push the clot 2214 from side to side, and the hypo tube 2204 simultaneously ejects media at the interface between the clot 2214 and the catheter 2202, providing a lubricious avenue for the clot 2214 to release and flow into the catheter 2202.

With or without injection of media, rotation of the motion segment 1909 helps to break up or reshape the thrombus and facilitate entry into the aspiration lumen. In certain situations, the clot can be aspirated completely within the central lumen. In other situations, the clot may only be able to be partially drawn into the central lumen, such as illustrated in FIG. 22B. In this situation, rotation of the agitator may be stopped with application of vacuum remaining on to retain the clot on the distal end of the catheter. The catheter may then be proximally withdrawn, pulling the clot along with it, into the access sheath and out of the proximal vascular access point.

Referring to FIGS. 23A–23B, the hypo tube 2304 may have one or more holes along its surface more proximal from the distal end to facilitate the movement or flow of the clot 2314 inside the catheter 2302 toward its proximal end 2300. Vacuum 2316 is applied at the proximal end 2300 of the catheter 2302 to move the removed clot 2314 from the distal end to the proximal end 2300 of the catheter 2302. As shown in FIG. 23A, the holes may provide a thin film 2312 around the inside of the wall of the catheter 2302 to facilitate the flow of media and/or the clot 2314 and minimize any clogging of the clot 2314. As shown in FIG.

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23B, the hypo tube 2304 may have one or more holes to provide media jets ejecting radially from the hypo tube 2304 to grab, pull, and/or emulsify the clot 2314 as the clot 2314 passes by the one or more holes on the surface of the hypo tube 2304.

Referring to FIG. 24, a vacuum port 2416 may be provided near the proximal end 2400 of the catheter 2402 such as on the manifold for releasable connection to a vacuum source to aspirate the clot from the vasculature. This allows the vacuum port 2416 to be distinct from the proximal port 2417 for receiving the agitator 1900. This can minimize the risk that the movement or control of the wire or hypo tube 2404 at its proximal end may be adversely affected by vacuum, aspirated clot, and/or media. The vacuum port may be connected to the catheter 2400 via a rotating hemostasis valve, discussed below.

Referring to FIGS. 25A–25C, experiments showed that an interrupted vacuum can help aspirating a corked clot stuck at the distal end 2512 of the catheter 2510 by loosening the clot and reshaping it to fit into the catheter 2510 after each vacuum and release cycle. Merely stopping the vacuum is not sufficient to loosen the clot. Completely releasing (venting to atmospheric pressure) the vacuum and allowing the clot to relax before reapplying a vacuum is found to aspirate the corked clot most efficiently. The period of each vacuum and release cycle may be equal to or greater than about 0.1, 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 seconds.

FIGS. 25A-25C show a logical progression of the vacuum and release cycle as applied to the catheter 2510. A release line 2518 and a vacuum line 2520 are connected to or near the proximal end of the catheter 2510. The release line 2518 is in communication with atmospheric pressure on its proximal end and has a release valve 2514 configured to open or close the fluid communication between the catheter 2510 and the vacuum. The vacuum line 2520 is connected to vacuum on its proximal end and has a vacuum valve 2516 configured to open or close the fluid communication between the catheter 2510 and the vacuum.

In the first step as shown in FIG. 25A, the release valve 2514 is closed, and the vacuum valve 2516 is open such that the vacuum is applied to the catheter 2510 to aspirate the clot. Then, as shown in FIG. 25B, the release valve 2514 is opened while the vacuum valve 2516 stays open. Because the release line 2518 and the vacuum line 2520 are in fluid communication, either directly or via at least a portion of the catheter 2510, the vacuum is applied mainly through the release line 2518, dropping vacuum applied to the catheter.

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Finally, as shown in FIG. 25C, the vacuum valve 2516 is shut off, allowing the vacuum to be completely released and the clot to relax. Then, another cycle from FIG. 25A to FIG. 25C begins by closing the release valve 2514 and opening the vacuum valve 2516.

Referring to FIG. 26, there is illustrated a proximal drive assembly and/or the rotating hemostasis valve to provide the interface for driving the agitator 1900, providing the port for injecting media, and the aspiration port. Referring to FIGS. 26, 27A, 27B, and 28, the proximal drive assembly 2602 and the rotating hemostasis valve 2620 may be releasably or permanently coupled to the proximal end of the agitator 1900. The proximal portion of the agitator 1900 passes proximally through a lumen of the rotating hemostasis valve 2620 and then that of the proximal drive assembly 2602. The proximal end of the agitator 1900 may terminate inside the lumen of the proximal drive assembly 2602. The distal portion of the proximal drive assembly 2602 is inserted into the proximal end of the rotating hemostasis valve 2620. In another embodiment, the proximal drive assembly 2602 may be integrated into the rotating hemostasis valve 2620.

The rotating hemostasis valve (RHV) 2620 comprises a distal connector 2630 at its distal end, which is configured to couple the rotating hemostasis valve to the proximal end of the catheter (not shown). The distal connector 2630 may be a luer connector. The rotating hemostasis valve 2620 comprises a central lumen along its longitudinal length, through which a proximal section of agitator 1900 passes. The rotating hemostasis valve 2620 further comprises an aspiration port 2622, which bifurcates from the central lumen of the rotating hemostasis valve 2620 and provides the aspiration flow path. The rotating hemostasis valve 2620 comprises a RHV seal 2626 and a proximal rotating collar 2628 at its proximal end. The proximal rotating collar 2628 controls the opening and closing of the RHV seal 2626. The user (e.g., physician) can either open or close the RHV seal 2626 by rotating the proximal rotating collar 2628. The RHV seal 2626, when closed, does not allow fluid communication between the inside lumen distal of the RHV seal 262 and the inside lumen proximal of the RHV seal 262. At the same time, the RHV seal 262 does not hamper the longitudinal movement of the distal portion of the proximal drive assembly 2602 inside the rotating hemostasis valve 2629.

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Experiments showed that as the wire or hypo tube 1900 is rotated back and forth (i.e., oscillating), the distal end of the agitator 1900 changes its position relative to the catheter. The distal end of the agitator 1900 was shown to foreshorten/lengthen as the wire or hypo tube 2624 wound/unwound within the catheter due to the rotation of the agitator 1900 or the increase/decrease in media injection pressure. The proximal rotating collar 2628 and the RHV seal 2626 permit the user (e.g., physician) to account for this variance in length and advance/withdraw the agitator 1900 relative to the catheter and fix it in place by simply moving the proximal drive assembly 2602 in/out of the rotating hemostasis valve 2629. If the agitator 1900 is preloaded into the catheter, the distance may be initially set at a nominal position. In another embodiment, the proximal rotating collar 2628 of the rotating hemostasis valve 2620 may be part of the proximal drive assembly 2602.

The proximal drive assembly 2602 comprises a proximal drive connector 2604, to which the driver is connected, and a media injection port 2610, into which media is injected. The proximal drive assembly also comprises a bearing 2606, which allows free rotation of the proximal drive connector 2604 with respect to the proximal drive assembly 2602. The proximal drive connection 2604 may be coupled to the proximal end of the agitator 1900 such that the rotation of the proximal drive connector 2604 is translated to the rotation of the wire or hypo tube 1900. The proximal drive assembly further comprises a drive tube seal 2608, which prevents fluid communication between the inside lumen (of the proximal drive assembly 2602) distal of the drive tube seal 2608 and the inside lumen proximal of the drive tube seal 2608.

Referring to FIG. 29, the driver 2950 is removably connected to the proximal end of the proximal drive assembly 2902 via the proximal drive connection 2604. The driver 2950 is configured to drive the agitator 1900. The driver 2950 is a motorized driver that is automatically controlled with respect to one or more factors such as direction (CCW/CW), speed, duration, etc. The driver 2950 comprises a control 2954 such as a button, which executes a pre-programmed series of steps when pushed. The driver 2954 may be under synchronized control, in which the driver 2954 drives the agitator 1900 in synchronization with aspiration and media injection, when the back of the driver 2950 is plugged into the synchronization port 2952.

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The system for retrieving clots comprises the aspiration catheter; the agitator 1900 longitudinally extendable inside the lumen of the aspiration catheter; and the driver connectable to the proximal end of the agitator 1900 (e.g., via the rotating hemostasis valve or the proximal drive assembly) with or without a synchronization port. The system may allow impulse aspiration and/or impulse injection of media. The media may comprise water, saline solution, or media with an effective amount of drug (e.g., drug therapy such as heparin, plavix, tPA). The components may be manipulated individually or in a synchronized manner using predetermined operating parameters (e.g., for synchronized aspiration, injection, and rotation).

The method of retrieving a clot may comprise providing the aspiration catheter, the agitator longitudinally extending or positionable inside the lumen of the aspiration catheter; and the driver coupled to the proximal end of the agitator; placing the catheter adjacent to the clot; attempting to aspirate clot; if not successful, advancing an agitator distally through the catheter; activating the driver to rotate the agitator and loosen the clot; optionally injecting media through the agitator to lubricate the clot and/or create a media jet from the distal end of the agitator, configured to help aspirate the clot; transporting the clot proximally inside the lumen of the catheter by applying the vacuum at the proximal end of the catheter; and optionally pulsing the vacuum. As pieces of the clot separate, transport may be assisted by the rotating agitator and/or injection media.

In order to detach a more stubborn clot, aspiration, media injection, and/or rotation of the wire or hypo tube may be timed. Building up a surplus of media around the clot will form a plug. When aspiration is activated and/or pulsed, the vacuum can draw the "plug" proximally inside the lumen of the wire or hypo tube like a syringe plunger. A higher local vacuum around the clot is maintained, and more momentum is added to the "plug" as more media is added. Timing the rotation of the wire or hypo tube with aspiration and media injection may help wiggle or fatigue the clot and detach it out of the vasculature.

Any of the catheter shaft or sections of the catheter shaft or telescoping extensions in accordance with the present invention may comprise a multi-layer construct having a high degree of flexibility and sufficient push ability to reach deep into the cerebral vasculature,

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such as at least as deep as the petrous, cavernous, or cerebral segment of the internal carotid artery (ICA).

In one example, referring to FIG. 30, the catheter 3000 may have an effective length from the manifold to distal tip from about 70cm to about 150cm, from about 80cm to about 140cm, from about 90cm to about 130cm, from about 100cm to about 120cm, or from about 105cm to about 115cm. The outer diameter of the catheter 3000 may be from about 0.07 inches to about 0.15 inches, from about 0.08 inches to about 0.14 inches, from about 0.09 inches to about 0.13 inches, from about 0.1 inches to about 0.12 inches, or from about 0.105 inches to about 0.115 inches, and may be lower in a distal segment than in a proximal segment. The inner diameter 3108 of the catheter 3000 in a single central lumen embodiment may be greater than or equal to about 0.11 inches, greater than or equal to about 0.1 inches, greater than or equal to about 0.09 inches, greater than or equal to about 0.088 inches, greater than or equal to about 0.08 inches, greater than or equal to about 0.07 inches, greater than or equal to about 0.06 inches, or greater than or equal to about 0.05 inches. The inner diameter 3108 of the catheter 3000 in a single central lumen embodiment may be less than or equal to about 0.11 inches, less than or equal to about 0.1 inches, less than or equal to about 0.09 inches, less than or equal to about 0.088 inches, less than or equal to about 0.08 inches, less than or equal to about 0.07 inches, less than or equal to about 0.06 inches, or less than or equal to about 0.05 inches. Referring to FIG. 30, an inner liner 3014 may be formed by dip coating a mandrel (not shown) to provide a thin walled tubular inside layer of the catheter body 3000. The dip coating may be produced by coating a wire such as a silver coated copper wire in PTFE. The mandrel may thereafter be axially elongated to reduce diameter, and removed to leave the tubular inner liner. The outside surface of the tubular inner liner 3014 may thereafter be coated with a soft tie layer 3012 such as polyurethane (e.g., Tecoflex™), to produce a layer having a thickness of no more than about 0.005 inches, and in some implementations approximately 0.001 inches. The tie layer 3012 will generally extend along at least about the most distal 10 cm or 20 cm of the catheter shaft 3000 generally less than about 50 cm and may in one implementation extend approximately the distal 30 cm of the catheter shaft 3000, 3100.

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A braid such as a 75 ppi stainless steel braid 3010 may thereafter be wrapped around the inner liner 3014 through a proximal zone up to a distal transition 3011. From the distal transition 3011 to the distal end of the catheter 3000, a coil 3024 comprising a shape memory material such as a Nitinol alloy may thereafter be wrapped around the inner liner 3014. In one implementation, the Nitinol coil has a transition temperature below body temperature so that the Nitinol reside in the austinsite (springy) state at body temperature. Adjacent loops or filars of the coil may be closely tightly wound in a proximal zone with a distal section having looser spacing between adjacent loops. In an embodiment having a coil section 3024 with an axial length of between about 20% and 30% of the overall catheter length, (e.g., 28 cm coil length in a 110 cm catheter shaft 3000), at least the distal 1 or 2 or 3 or 4 cm of the coil will have a spacing that is at least about 130%, and in some implementations at least about 150% or more than the spacing in the proximal coil section. In a 110 cm catheter shaft 3000 having a Nitinol coil the spacing in the proximal coil may be about 0.004 inches and in the distal section may be at least about 0.006 inches or 0.007 inches or more.

The distal end of the coil 3024 is spaced proximally from the distal end of the inner liner 3014 to provide room for an annular radiopaque marker 3040. In one embodiment, the distal end of the catheter 3000 is provided with a beveled distal surface 3006 residing on a plane having an angle of at least about 10° or 20° and in one embodiment about 30° with respect to a longitudinal axis of the catheter 3000. The radiopaque marker 3040 may reside in a plane that is transverse to the longitudinal axis. Alternatively, at least the distally facing edge of the annular radiopaque marker 3040 may be an ellipse, residing on a plane which is inclined with respect to the longitudinal axis to complement the bevel angle of the distal surface 3006.

After applying the proximal braid 3010, the distal coil 3024 and the RO marker 3040 an outer Jacket 3020 maybe applied such as a shrink wrap tube to enclose the catheter body 3000. The outer shrink-wrapped sleeve 3020 may comprise any of a variety of materials, such as polyethylene, polyurethane, PEBAX, nylon or others known in the art. Sufficient heat is applied to cause the polymer to flow into and embed the proximal braid and distal coil.

In one implementation, the outer shrink wrap jacket 3020 is formed by sequentially advancing a plurality of short tubular segments 3022, 3026, 3028, 3030, 3032, 3034, 3036,

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3038 concentrically over the catheter shaft subassembly, and applying heat to shrink the sections on to the catheter 3000 and provide a smooth continuous outer tubular body. The foregoing construction may extend a long at least the most distal 10 cm, and preferably at least about the most distal 20 or 25 cm of the catheter body 3000.

The durometer of the outer wall segments may decrease in a distal direction. For example, proximal segments such as 3022 and 3026, may have a durometer of at least about 60 or 70D, with gradual decrease in durometer of successive segments in a distal direction to a durometer of no more than about 35D or 25D or lower. A 25 cm section may have at least about 3 or 5 or 7 or more segments and the catheter 3000 overall may have at least about 6 or 8 or 10 or more distinct flexibility zones. The distal 1 or 2 or 4 or more segments 3036, 3038, may have a smaller OD following shrinking than the more proximal segments 3022-3034 to produce a step down in OD for the finished catheter body 3000. The length of the lower OD section 3004 may be within the range of from about 3 cm to about 15 cm and in some embodiments is within the range of from about 5 cm to about 10 cm such as about 7 or 8 cm, and may be accomplished by providing the distal segments 3036, 3038 with a lower wall thickness.

Referring to FIGS. 31A-31C, the catheter may further comprise a tension support for increasing the tension resistance in the distal zone. The tension support may comprise a filament and, more specifically, may comprise one or more axially extending filaments 3042. The one or more axially extending filaments 3042 may be axially placed inside the catheter wall near the distal end of the catheter. The one or more axially extending filaments 3042 serve as a tension support and resist elongation of the catheter wall under tension (e.g., when the catheter is being proximally retracted through tortuous vasculature). At least one of the one or more axially extending filaments 3042 may proximally extend along the length of the catheter wall from near the distal end of the catheter to less than about 5cm from the distal end of the catheter, less than about 10cm from the distal end of the catheter, less than about 15cm from the distal end of the catheter, less than about 20cm from the distal end of the catheter, less than about 25cm from the distal end of the catheter, less than about 30cm from the distal end of the catheter, less than about 35cm from the distal end of the catheter, less than about 40cm from the distal end of the catheter, or less than about 50cm from the distal

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end of the catheter. The one or more axially extending filaments 3042 may have a length greater than or equal to about 50cm, greater than or equal to about 40cm, greater than or equal to about 35cm, greater than or equal to about 30cm, greater than or equal to about 25cm, greater than or equal to about 20cm, greater than or equal to about 15cm, greater than or equal to about 10cm, or greater than or equal to about 5cm. At least one of the one or more axially extending filaments 3042 may have a length less than or equal to about 50cm, less than or equal to about 40cm, less than or equal to about 35cm, less than or equal to about 30cm, less than or equal to about 25cm, less than or equal to about 20cm, less than or equal to about 15cm, less than or equal to about 10cm, or less than or equal to about 5cm. At least one of the one or more axially extending filaments 3042 may extend at least about the most distal 50 cm of the length of the catheter, at least about the most distal 40 cm of the length of the catheter, at least about the most distal 35 cm of the length of the catheter, at least about the most distal 30 cm of the length of the catheter, at least about the most distal 25 cm of the length of the catheter, at least about the most distal 20 cm of the length of the catheter, at least about the most distal 15 cm of the length of the catheter, at least about the most distal 10 cm of the length of the catheter, or at least about the most distal 5 cm of the length of the catheter.

The one or more axially extending filaments 3042 may be placed near or radially outside the tie layer 3012 or the inner liner 3014. The one or more axially extending filaments 3042 may be placed near or radially inside the braid 3010 and/or the coil 3024. The one or more axially extending filaments 3042 may be carried between the inner liner 3014 and the helical coil 3024.

When more than one axially extending filaments 3042 are placed in the catheter wall, the axially extending filaments 3042 may be placed in a radially symmetrical manner. For example, the angle between the two axially extending filaments 3042 with respect to the radial center of the catheter may be about 180 degree. Alternatively, depending on desired clinical performances (e.g., flexibility, trackability), the axially extending filaments 3042 may be placed in a radially asymmetrical manner. The angle between any two axially extending filaments 3042 with respect to the radial center of the catheter may be less than about 180 degree, less than or equal to about 165 degree, less than or equal to about 150 degree, less

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than or equal to about 135 degree, less than or equal to about 120 degree, less than or equal to about 105 degree, less than or equal to about 90 degree, less than or equal to about 75 degree, less than or equal to about 60 degree, less than or equal to about 45 degree, less than or equal to about 30 degree, less than or equal to about 15 degree, less than or equal to about 10 degree, or less than or equal to about 5 degree.

The one or more axially extending filaments 3042 may be made of materials such as Kevlar, Polyester, Meta-Para-Aramide, or any combinations thereof. At least one of the one or more axially extending filaments 3042 may comprise a single fiber or a multi-fiber bundle, and the fiber or bundle may have a round or rectangular cross section. The terms fiber or filament do not convey composition, and they may comprise any of a variety of high tensile strength polymers, metals or alloys depending upon design considerations such as the desired tensile failure limit and wall thickness. The cross-sectional dimension of the one or more axially extending filaments 3042, as measured in the radial direction, may be no more than about 1%, 2%, 3%, 4%, 5%, 6%, 7%, 8%, 9%, 10%, 11%, 12%, 13%, 14%, 15%, 20%, 25%, or 30% of that of the catheter 3000. The cross-sectional dimension of the one or more axially extending filaments 3042, as measured in the radial direction, may be no more than about 0.001 inches, about 0.002 inches, about 0.003 inches, about 0.004 inches, about 0.005 inches, about 0.006 inches, about 0.007 inches, about 0.008 inches, about 0.009 inches, about 0.010 inches, about 0.015 inches, about 0.020 inches, about 0.025 inches, or about 0.030 inches.

The one or more axially extending filaments 3042 may increase the tensile strength of the distal zone of the catheter to at least about 1 pound, at least about 2 pounds, at least about 3 pounds, at least about 4 pounds, at least about 5 pounds, at least about 6 pounds, at least about 7 pounds, at least about 8 pounds, or at least about 10 pounds or more.

Referring to FIGS. 32A-32C, depending on whether the catheter 3000 is able to navigate sufficiently distally to reach the target site, an intraluminal catheter 3200 such as a telescopic extension segment having a proximally extending control wire as has been described elsewhere herein (e.g., distal segment 34 in FIGS. 3A and 3B) may be inserted through the catheter 3000 from the proximal end of the catheter 3000. The intraluminal catheter 3200 is inserted such that the distal end of the intraluminal catheter 3200 reaches further distally beyond the distal end of the catheter 3000. The outer diameter of the

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intraluminal catheter 3200 is smaller than the inner diameter of the catheter 3000. This way, the intraluminal catheter 3200 can slide inside the lumen of the catheter 3000.

The intraluminal catheter 3200 incorporates characteristics of the side wall construction of the catheter 3000 described herein. The axial length of the tubular extension segment may be less than about 50 % and typically less than about 25% of the length of the catheter 3000. The axial length of the tubular extension segment will generally be at least about 10 cm or 15 cm or 20 cm or 25 cm or more but generally no more than about 70 cm or 50 cm or 30 cm.

Referring to FIGS. 33A-33C, the intraluminal catheter 3200 may have one or more axially extending filaments 3242. The one or more axially extending filaments 3242 incorporate characteristics of the one or more axially extending filaments 3042 of the catheter 3000, except the cross-sectional dimension as measured in the radial direction of the one or more axially extending filaments 3242 of the intraluminal catheter 3200 may be less than the corresponding dimension of the filament 3042 in the catheter 3000.

Referring to FIGS. 34A–34B, there is illustrated one example of an outer jacket segment stacking pattern for a progressive flexibility catheter of the type discussed in connection with FIG. 30. A distal segment 3038 may have a length within the range of about 1 – 3 cm , and a durometer of less than about 35D or 30D. An adjacent proximal segment 3036 may have a length within the range of about 4 – 6 cm, and a durometer of less than about 35D or 30D. An adjacent proximal segment 3034 may have a length within the range of about 4 – 6 cm, and a durometer of about 35D or less. An adjacent proximal segment 3032 may have a length within the range of about 1 – 3 cm, and a durometer within the range of from about 35D to about 45D (e.g., 40D). An adjacent proximal segment 3030 may have a length within the range of about 1 – 3 cm, and a durometer within the range of from about 50D to about 60D (e.g., about 55D). An adjacent proximal segment 3028 may have a length within the range of about 1 – 3 cm, and a durometer within the range of from about 35D to about 50D to about 60D (e.g., about 55D). An adjacent proximal segment 3026 may have a length within the range of about 1 – 3 cm, and a durometer of at least about 60D and typically less than about 75D. More proximal segments may have a durometer of at least about 65D or 70D. The distal most two or three segments may comprise a material such as Tecothane, and

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more proximal segments may comprise PEBAX or other catheter jacket materials known in the art. At least three or five or seven or nine or more discrete segments may be utilized, having a change in durometer between highest and lowest along the length of the catheter shaft of at least about 10D, preferably at least about 20D and in some implementations at least about 30D or 40D or more.

Performance metrics of a catheter include back-up support, trackability, pushability, and kink resistance. Back-up support means ability of the catheter to remain in position within anatomy and provide a stable platform through which endoluminal devices may advance. Referring to FIG. 35, when the devices are pushed through the catheter 3202, if there is not enough back-up support in the catheter 3202, the distal portion 3204 of the catheter 3202 may prolapse, pull out, or back out of a vessel 3206 that branches out of a main blood vessel (e.g., brachiocephalic artery 82, common carotid artery 80, or subclavian artery 84). Back-up support for the catheter 3202 may be improved by providing a proximal region with high durometer or modulus and a distal region with low durometer or modulus. Durometer or modulus of the proximal region of the catheter 3202 may be improved by braid reinforcement. The region of the catheter at which durometer or modulus is strengthened may be placed near branching points at which the aortic arch 1114, 1214 branches into brachiocephalic artery 82, common carotid artery 80, or subclavian artery 84 or near other anatomical structures (i.e., branching points) at which a main vessel branches into one or more smaller vessels, providing an opportunity for a catheter with poor back-up support to prolapse. For example, the region of the catheter at which durometer or modulus is strengthened may be placed within about 0.5cm, about 1cm, about 2cm, about 3cm, about 4cm, about 5cm, or about 6cm from a branching point at which a main vessel branches into one or more smaller vessels.

Trackability means ability of the catheter to track further distally than other catheters (e.g., to M1). For example, a catheter that can reach a cerebral segment of the internal carotid artery (ICA) has better trackability than a catheter that can reach a cavernous or petrous segment of the ICA. Trackability of the catheter may be improved by using a catheter wall with low durometer or modulus or by adding a coating (e.g., a hydrophilic coating) on at least a portion of the catheter wall. In one embodiment, the hydrophilic coating may be placed

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along the distal most region of the catheter. The hydrophilic coating on the catheter may extend to about 1cm, about 5cm, about 10cm, about 15cm, or about 20cm from the distal end of the catheter. The region with lower durometer or modulus may locate at the distal most region of the catheter. The region with lower durometer or modulus may extend to about 1cm, about 5cm, about 10cm, about 15cm, or about 20cm from the distal end of the catheter.

Pushability means rigidity of the catheter sufficient to push through anatomy without "buckling". Pushability of the catheter may be improved by increasing its durometer or modulus. Pushability of the catheter may also be improved by providing a proximal region with high durometer or modulus and a distal region with low durometer or modulus. A transition region of the catheter in which durometer or modulus changes along its longitudinal length (e.g., decreasing durometer or modulus from the proximal end to the distal end) may begin at about 50%, 60%, 70%, 75%, 80%, or more of the length of the catheter from its proximal end.

Kink resistance means resistance of the catheter to kinking. In addition, if the catheter does kink, kink resistance of the catheter helps it return to its original shape. Kink resistance is important in the distal segment of the catheter, which is more prone to kinking than the proximal segment. Kink resistance of the catheter may be improved by adding one or more NiTi coils (or a coil at least portion of which is Nitinol) to the catheter wall.

FIG. 36 describes a graph of durometer or modulus of a catheter in accordance with the present invention along the length of the catheter, from the proximal end (x = 0) to the distal end (x = 1). The catheter according to an embodiment may have a decreasing durometer or modulus (E) approaching its distal end. The proximal end of the catheter has higher durometer or modulus than that of the distal end of the catheter. High durometer or modulus near the proximal end provides superior back-up support of the catheter. Durometer or modulus of the catheter is substantially constant along its length near the proximal end 3302 of the catheter. Then, durometer or modulus of the catheter decreases near the distal end 3304 of the catheter. Durometer or modulus of the catheter may begin to decrease (i.e., transition region) at about 50%, 70%, 75%, 80%, or 90% of the length of the catheter from its proximal end. The catheter may have successively decreasing durometer or modulus near its distal end by using materials with less durometer or modulus or having a thinner catheter wall

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near the distal end. Decreased durometer or modulus near the distal end provides superior trackability of the catheter.

FIG. 37 describes flexibility test profiles of catheters in accordance with the present invention compared with conventional catheters. Flexibility of a catheter was measured by the three point flexural test with a span of one inch and a displacement of 2mm. In other words, FIG. 37 describes a force (i.e., flexural load) necessary to vertically displace an one-inch-long catheter segment by 2 mm with respect to distance from strain relief (i.e., proximal end of the catheter) to the point of force application. All catheters tested in FIG 37 show modulus or flexibility profiles similar to one shown in FIG. 36. Modulus of the catheters stays substantially constant along its length near the proximal end and then gradually decreases near the distal end.

Catheters according to the present invention have a flexural load that is substantially constant along the longitudinal length near the proximal end and a rapidly decreasing flexural load near the distal end. In a catheter having a length of about 125 cm, the catheters may have a flexural load greater than or equal to about 1.0 lbF, about 1.5 lbF, about 2.0 lbF, about 2.5 lbF, about 3.0 lbF, or about 3.5 lbF at about 85 cm from the proximal end. The catheters may have a flexural load less than or equal to about 2.5 lbF, about 2.0 lbF, about 1.5 lbF, about 1.0 lbF, or about 0.5 lbF at about 95 cm from the proximal end. The catheters may have a flexural load less than or equal to about 1.5 lbF, about 1.0 lbF, about 0.75 lbF, about 0.5 lbF, about 0.25 lbF, or about 0.1 lbF at about 105 cm from the proximal end. The catheters may have a flexural load less than or equal to about 1.0 lbF, about 0.75 lbF, about 0.5 lbF, about 0.4 lbF, about 0.3 lbF, about 0.2 lbF, or about 0.1 lbF at about 115 cm from the proximal end. For catheters having different lengths, the foregoing dimensions can be scaled from the distal end of the catheter as a percentage of catheter length.

In certain implementations constructed in accordance with FIG. 30, the flexural load is less than about 3.0 or 3.25 lbF at 65 cm from the proximal end and greater than about 2.25 or 2.5 lbF on average from 65 cm to 85 cm from the proximal end. Flexural load drops to no more than about 1.0 and preferably no more than about 0.5 lbF at about 95 cm from the proximal end. This provides enhanced backup support in the aorta while maintaining enhanced trackability into the distal vasculature.

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In other embodiments, the catheters may have a flexural load greater than or equal to about 1.0 lbF, about 1.5 lbF, about 2.0 lbF, about 2.5 lbF, about 3.0 lbF, or about 3.5 lbF at about 60 cm from the proximal end. The catheters may have a flexural load less than or equal to about 2.0 lbF, about 1.5 lbF, about 1.0 lbF, or about 0.5 lbF at about 70 cm from the proximal end. The catheters may have a flexural load less than or equal to about 1.0 lbF, about 0.75 lbF, about 0.5 lbF, about 0.4 lbF, about 0.3 lbF, about 0.2 lbF, or about 0.1 lbF at about 80 cm from the proximal end. The catheters may have a flexural load less than or equal to about 1.0 lbF, about 0.75 lbF, about 0.5 lbF, about 0.4 lbF, about 0.3 lbF, about 0.2 lbF, or about 0.1 lbF at about 90 cm from the proximal end.

The catheters may have a transition region, in which its flexural load changes by greater than or equal to about 1.0 lbF, about 1.5 lbF, about 2.0 lbF, about 2.5 lbF, about 3.0 lbF, or about 3.5 lbF. The longitudinal length of the transition region may be less than or equal to about 20cm, about 15cm, about 10cm, about 5 cm, about 3cm, or about 1cm.

Compared to Neuron Max (Penumbra, Inc.) 3402, catheters according to the present invention (e.g., 3404, 3406, 3408, 3410) have comparable modulus near its proximal end. This way, the catheters according to the present invention provide back-up support comparable to that of Neuron Max. In addition, the catheters have modulus that falls more rapidly near the transition region (between the proximal end and the distal end) than that of Neuron Max.

Compared to Ace 68 catheter (Penumbra) 3412, Ace 64 catheter (Penumbra) 3414, Benchmark 71 catheter (Penumbra) 3416, and Sofia Plus (MicroVention) 3418, the catheters according to the present inventions have greater modulus near its proximal end and comparable modulus near its distal end. This way, the catheters according to the present invention provide superior back-up support with comparable trackability compared to conventional catheters. The catheters according to the present invention may achieve this modulus profile even when their inner diameters (and thus lumen volumes) are greater than or equal to those of Ace 68, Ace 64, Benchmark 71, and Sofia Plus, which range from 0.064 inch to 0.071 inch.

Referring to FIG. 38, there is illustrated a transformable access sheath 200. The access sheath 200 comprises an elongate flexible tubular body 202 extending between a proximal

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end 204 and a distal end 206. A proximal access port 208 is in communication with a distal port 210 on the distal end 206 by way of a central lumen 212. See FIG. 39.

At least one transition zone 214 is provided on the tubular body 202. Transition zone 214 is controllably transformable between a relatively stiff configuration and a relatively flexible configuration. The access sheath 200 may be distally advanced through tortuous anatomy with at least one transition zone 214 in a relatively stiff configuration as desired such as to provide column strength or to facilitate the introduction of instruments therethrough. The transition zone 214 may be controllably transformed to a relatively flexible configuration as desired, such as to navigate tight bends in the vasculature.

In the illustrated embodiment, three transition zones 214 are shown. However, one or two or three or four or more transition zones may be utilized, depending upon the desired clinical performance. The transition zone 214 may be from about 1 cm to about 20 or 30 cm or more in length. In certain embodiments, the transition zones will be within the range of from about 2 cm to about 10 cm in length. The length and location of the transition zones may depend upon the target anatomy for the access catheter, and can be located accordingly.

Referring to FIG. 39, there is illustrated a cross-sectional view taken along the lines 18-18 of FIG. 38, through a transition zone 214. The tubular body 202 comprises a sidewall 216 having at least one heating element 218 carried by or embedded within the sidewall 216. In the illustrated embodiment, the heater 218 may be an electrically conductive filament, such as a filar on an electrically conductive helical coil or braid. The electrically conductive filament may be placed within or laminated within an inner layer and an outer layer of the sidewall 216. In at least one embodiment, an inner layer of the sidewall 216 may comprise polytetrafluorothylene (PTFE) for lubricity. In at least one embodiment, an outer layer of the sidewall 216 may comprise biocompatible material preferably with a glass transition temperature from about 40 °C to about 80 °C.

Alternatively, an electrically conductive polymer may be utilized to form the sidewall 216. Electrically conductive coatings may alternatively be printed, laminated, embedded or otherwise applied to the outside, the inside, or laminated within an inner layer and an outer layer of the sidewall 216. In at least one embodiment, the resistance of the heater 218 may be calibrated to a specific heating temperature, such as 40 – 80°C, for a predetermined voltage

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level of the power source. This may eliminate the need for a thermocouple and prevent potential overheating.

One or more electrical conductors may extend between the transition zone 214 and a proximal activation port 215, adapted for coupling to a source of electricity from an external controller. In a mono polar construction, a single conductor for each transition zone 214 may extend proximally to the activation port 215. A second conductor may lead to or comprise an electrically conductive surface on the tubular body 202, for conducting electricity through the body of the patient to an external electrode as is understood in the art. Alternatively, in a bipolar embodiment, each transition zone 214 may be provided with at least two electrical conductors extending proximally to the activation port 215.

At least the transition zone comprises a biocompatible material that is relatively firm at body temperature (e.g., 37°C) but transitions to a relatively soft, flexible material upon application of heat. Typical suitable materials have a relatively low melting point so as to be softenable at temperatures not so high as to damage living vessels. In any event the material will have a softening point or a glass transition temperature above body temperature, with a melting point significantly above body temperature and above the temperature reached by activating the heating element 218. In one embodiment, the biocompatible material preferably has a glass transition temperature from about 40°C to about 80°C. Suitable materials may include polymers with a polymer chain orientation that causes the polymer to break when heated.

Examples of suitable biostable materials are polymers, typically thermoplastic polymers such as polyolefins and polyurethanes and most other biocompatible polymers. Typical suitable bioabsorbable materials include polyglycolide (PGA), poly(L-lactide) (PLLA), poly(.epsilon.-caprolactone) (PCL), and blends or combinations thereof. Polyglycolide for example has a glass transition temperature between 35-40°C, such having a considerably higher melting point.

Typical operating (softening) temperatures in this regard are on the order of between about 40 and 80°C, often between about 40°C and 60°C to cause a softening transition of the transition zone 214, and allow a transition back to a firm state upon removal of power and reversion of the transition zone 214 back to body temperature. A temperature higher than

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about 80°C may be acceptable for a short period of time, depending upon the total energy delivered. Any temperature to which the heater 218 is elevated is limited by what the body of the patient can handle without causing damage to the vessel wall or causing thrombus to form. For this reason, it may be desirable to remain within the lower end of the temperature ranges illustrated above if the eligible polymers exhibit suitable flexibility at the softening point temperature and suitable firmness at the lower body temperature.

Upon being heated, the biocompatible energy-activated transition zone 214 softens so that it may be navigated through a tight bend for example. The material is to be softened enough by the energy application so that it increases in flexibility, but retains the structural integrity necessary for navigation and retains its shape so that upon interruption of the heat source it will harden back to its original configuration. To maintain the integrity of the tubular body, side wall 216 may be provided with flexible reinforcing structures such as a helically wrapped wire, ribbon or polymeric strand such as polyimide, or other braid or weave as is understood in the neurovascular catheter arts. A resistance coil or other resistance filaments may also provide the mechanical reinforcing function while the transition zone is in the softened state.

Heating may alternatively be provided by positioning a heat source such as a resistance heat element carried by a heater catheter within the central lumen 212. Once the catheter has reached its final position in the vasculature, the heater catheter may be proximally withdrawn from the central lumen 212, which is now available for aspiration or to receive a distal section 34 therethrough. In either heater configuration, a power source may be provided within or electrically coupled to a proximal manifold on the aspiration catheter or heater catheter.

Access for the catheter of the present invention can be achieved using conventional techniques through an incision on a peripheral artery, such as right femoral artery, left femoral artery, right radial artery, left radial artery, right brachial artery, left brachial artery, right axillary artery, left axillary artery, right subclavian artery, or left subclavian artery. An incision can also be made on right carotid artery or left carotid artery in emergency situations.

Avoiding a tight fit between the guidewire 40 and inside diameter of guidewire lumen 28 enhances the slidability of the catheter over the guidewire. In ultra small diameter catheter

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designs, it may be desirable to coat the outside surface of the guidewire 40 and/or the inside surface of the wall defining lumen 38 with a lubricous coating to minimize friction as the catheter 10 is axially moved with respect to the guidewire 40. A variety of coatings may be utilized, such as Paralene, Teflon, silicone, polyimide-polytetrafluoroethylene composite materials or others known in the art and suitable depending upon the material of the guidewire or inner tubular wall 38.

Aspiration catheters of the present invention which are adapted for intracranial applications generally have a total length in the range of from 60 cm to 250 cm, usually from about 135 cm to about 175 cm. The length of the proximal segment 33 will typically be from 20 cm to 220 cm, more typically from 100 cm to about 120 cm. The length of the distal segment 34 will typically be in the range from 10 cm to about 60 cm, usually from about 25 cm to about 40 cm.

The catheters of the present invention may be composed of any of a variety of biologically compatible polymeric resins having suitable characteristics when formed into the tubular catheter body segments. Exemplary materials include polyvinyl chloride, polyethers, polyamides, polyethylenes, polyurethanes, copolymers thereof, and the like. In one embodiment, both the proximal body segment 33 and distal body segment 34 will comprise a polyvinyl chloride (PVC), with the proximal body segment being formed from a relatively rigid PVC and the distal body segment being formed from a relatively flexible, supple PVC. Optionally, the proximal body segment may be reinforced with a metal or polymeric braid or other conventional reinforcing layer.

The proximal body segment will exhibit sufficient column strength to permit axial positioning of the catheter through a guide catheter with at least a portion of the proximal body segment 33 extending beyond the guide catheter and into the patient's vasculature. The proximal body segment may have a shore hardness in the range from 50 D to 100 D, often being about 70 D to 80 D. Usually, the proximal shaft will have a flexural modulus from 20,000 psi to 1,000,000 psi, preferably from 100,000 psi to 600,000 psi. The distal body segment 34 will be sufficiently flexible and supple so that it may navigate the patient's more narrow distal vasculature. In highly flexible embodiments, the shore hardness of the distal

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body segment 34 may be in the range of from about 20 A to about 100 A, and the flexural modulus for the distal segment 34 may be from about 50 psi to about 15,000 psi.

The catheter body may further comprise other components, such as radiopaque fillers; colorants; reinforcing materials; reinforcement layers, such as braids or helical reinforcement elements; or the like. In particular, the proximal body segment may be reinforced in order to enhance its column strength and torqueability (torque transmission) while preferably limiting its wall thickness and outside diameter.

Usually, radiopaque markers will be provided at least at the distal end 14 and the transition region 32 at the distal end of proximal segment 33. One radiopaque marker comprises a metal band which is fully recessed within or carried on the outside of the distal end of the proximal body segment 33. Suitable marker bands can be produced from a variety of materials, including platinum, gold, and tungsten/rhenium alloy. Preferably, the radiopaque marker band will be recessed in an annular channel to produce a smooth exterior surface.

The proximal section 33 of tubular body 16 may be produced in accordance with any of a variety of known techniques for manufacturing interventional catheter bodies, such as by extrusion of appropriate biocompatible polymeric materials. Alternatively, at least a proximal portion or all of the length of tubular body 16 may comprise a polymeric or metal spring coil, solid walled hypodermic needle tubing, or braided reinforced wall, as is known in the microcatheter arts.

In a catheter intended for neurovascular applications, the proximal section 33 of body 16 will typically have an outside diameter within the range of from about 0.117 inches to about 0.078 inches. In one implementation, proximal section 33 has an OD of about 0.104 inches and an ID of about 0.088 inches. The distal section 34 has an OD of about 0.085 inches and an ID of about 0.070 inches.

Diameters outside of the preferred ranges may also be used, provided that the functional consequences of the diameter are acceptable for the intended purpose of the catheter. For example, the lower limit of the diameter for any portion of tubular body 16 in a given application will be a function of the number of fluid or other functional lumen

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contained in the catheter, together with the acceptable minimum aspiration flow rate and collapse resistance.

Tubular body 16 must have sufficient structural integrity (e.g., column strength or "pushability") to permit the catheter to be advanced to distal locations without buckling or undesirable bending of the tubular body. The ability of the body 16 to transmit torque may also be desirable, such as to avoid kinking upon rotation, to assist in steering. The tubular body 16, and particularly the distal section 34, may be provided with any of a variety of torque and/or column strength enhancing structures. For example, axially extending stiffening wires, spiral wrapped support layers, braided or woven reinforcement filaments may be built into or layered on the tubular body 16. See, for example, U.S. Pat. No. 5,891,114 to Chien, et al., the disclosure of which is incorporated in its entirety herein by reference.

In many applications, the proximal section 33 will not be required to traverse particularly low profile or tortuous arteries. For example, the proximal section 33 will be mostly or entirely within the relatively large diameter guide catheter. The transition 32 can be located on the catheter shaft 16 to correspond approximately with or beyond the distal end of the guide catheter.

For certain applications, such as intracranial catheterizations, the distal section 34 is preferably at least about 5 cm or 10 cm long and small enough in diameter to pass through vessels as low as 3 mm or 2 mm or lower. The distal section may have a length of at least about 20 cm or 30 cm or 40 cm or more, depending upon the intended target vessel or treatment site.

The distal section, whether carried within the proximal section as an integrated device, or is a separate device to be inserted into the proximal section during a procedure, is substantially shorter than the proximal section. When the distal end of the distal section and the distal end of the proximal section are axially aligned, the proximal end of the distal section is spaced distally apart from the proximal end of the proximal section. The control element such as a control wire or tube spans the distance between the proximal end of the distal section and the proximal manifold or proximal control.

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In the foregoing configuration, the proximal end of the distal section will generally be spaced apart distally from the proximal end of the proximal section by at least about 25%, and in some embodiments at least about 50% or 70% or more of the length of the proximal section.

Although the present invention has been described in terms of certain preferred embodiments, it may be incorporated into other embodiments by persons of skill in the art in view of the disclosure herein. The scope of the invention is therefore not intended to be limited by the specific embodiments disclosed herein, but is intended to be defined by the full scope of the following claims.

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WHAT IS CLAIMED IS:

1. An enhanced flexibility neurovascular catheter, comprising:

an elongate flexible body, having a proximal end, a distal end and a side wall defining a central lumen, a distal zone of the side wall comprising:

a tubular inner liner;

a tie layer separated from the lumen by the inner liner;

a helical coil surrounding the tie layer, adjacent windings of the coil spaced progressively further apart in the distal direction; and

an outer jacket surrounding the helical coil, the outer jacket formed from a plurality of tubular segments positioned coaxially about the coil; wherein

a proximal one of the tubular segments has a durometer of at least about 60D and a distal one of the tubular segments has a durometer of no more than about 35D.

2. An enhanced flexibility neurovascular catheter as in Claim 1, wherein the tubular liner is formed by dip coating a removable mandrel.

3. An enhanced flexibility neurovascular catheter as in Claim 1, wherein the tubular liner comprises PTFE.

4. An enhanced flexibility neurovascular catheter as in Claim 1, wherein the tie layer comprises polyurethane.

5. An enhanced flexibility neurovascular catheter as in Claim 4, wherein the tie layer has a wall thickness of no more than about 0.005 inches.

6. An enhanced flexibility neurovascular catheter as in Claim 4, wherein the tie layer extends along at least the most distal 20 cm of the flexible body.

7. An enhanced flexibility neurovascular catheter as in Claim 1, wherein the coil comprises a shape memory material.

8. An enhanced flexibility neurovascular catheter as in Claim 7, wherein the coil comprises Nitinol.

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9. An enhanced flexibility neurovascular catheter as in Claim 8, wherein the Nitinol comprises an Austenite state at body temperature.

10. An enhanced flexibility neurovascular catheter as in Claim 1, wherein the outer jacket is formed from at least five discrete tubular segments.

11. An enhanced flexibility neurovascular catheter as in Claim 1, wherein the outer jacket is formed from at least nine discrete tubular segments.

12. An enhanced flexibility neurovascular catheter as in Claim 11, wherein the difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments is at least about 20D.

13. An enhanced flexibility neurovascular catheter as in Claim 11, wherein the difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments is at least about 30D.

14. An enhanced flexibility neurovascular catheter as in Claim 1, further comprising a tension support for increasing the tension resistance in the distal zone.

15. An enhanced flexibility neurovascular catheter as in Claim 14, wherein the tension support comprises a filament.

16. An enhanced flexibility neurovascular catheter as in Claim 15, wherein the tension support comprises an axially extending filament.

17. An enhanced flexibility neurovascular catheter as in Claim 16, wherein the axially extending filament is carried between the inner liner and the helical coil.

18. An enhanced flexibility neurovascular catheter as in Claim 16, wherein the axially extending filament increases the tensile strength to at least about 5 pounds.

19. A telescoping catheter, comprising:

an elongate, flexible tubular body, comprising a proximal section having at least one lumen and a distal section axially movably positioned within the lumen; and

a control for advancing the distal section from a first, proximally retracted position within the proximal section to a second, extended position, extending distally beyond the proximal section; and

an active tip on the distal end of the distal section, comprising a distal opening that is movable between a smaller and a larger configuration.

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20. A telescoping catheter as in Claim 19, wherein the control comprises a pull wire extending through the proximal section.

21. A telescoping catheter as in Claim 19, wherein the distal section is distally advanceable to extend beyond the proximal section for a distance of at least about 10 cm.

22. A telescoping catheter as in Claim 19, wherein the distal section is distally advanceable to extend beyond the proximal section for a distance of at least about 25 cm.

23. A telescoping catheter as in Claim 19, wherein the distal opening is movable in response to movement of a control wire.

24. A telescoping catheter as in Claim 19, wherein the distal opening is movable between a smaller and a larger configuration in response to application of vacuum to the lumen.

25. A telescoping catheter as in Claim 19, wherein the size of the distal opening is changed by lateral movement of a side wall on the distal section.

26. A telescoping catheter as in Claim 19, wherein the distal opening comprises at least one movable jaw.

27. A telescoping catheter as in Claim 19, wherein the distal end of the distal section comprises a duck bill valve configuration.

28. A telescoping catheter as in Claim 19, further comprising a controller for applying intermittent vacuum to the lumen.

29. A telescoping catheter as in Claim 28, wherein the controller is configured to apply pulses of vacuum to the lumen spaced apart by spaces of neutral pressure.

30. A telescoping catheter as in Claim 28, wherein the controller is configured to alternate between applying pulses of higher negative pressure and lower negative pressure.

31. A telescoping catheter as in Claim 28, wherein the distal tip of the catheter axially reciprocates in response to application of pulses of vacuum to the lumen.

32. A system for aspirating a vascular occlusion from a remote site, comprising:

an elongate, flexible tubular body, comprising at least one central lumen extending along its longitudinal length;

an agitator extendable through the central lumen of the tubular body to position a distal end of the agitator near a distal end of the tubular body;

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a driver connectable to a proximal end of the agitator and configured to actuate the agitator; and

a vacuum port near the proximal end of the tubular body and in fluid communication with the central lumen of the tubular body.

33. A system as in Claim 32, wherein the agitator comprises an elongate tube.

34. A system as in Claim 33, wherein the agitator comprises a wire extending through the elongate tube and having at least one bend near its distal end.

35. A system as in Claim 32, wherein the agitator comprises a proximal end, a distal end, and a loop at the distal end.

36. A system as in Claim 32, wherein the driver is configured to rotate the agitator cyclically in alternating directions.

37. A system as in Claim 32, wherein the agitator comprises:

at least one lumen along its longitudinal length,

an influent port near its proximal end configured to allow fluid communication between the lumen of the agitator and a source of media, and

at least one effluent port configured to allow fluid communication between the lumen of the agitator and the central lumen of the tubular body.

38. A system as in Claim 37, further comprising a control, for expressing media from the effluent port into the central lumen of the tubular body.

39. A system as in Claim 37, wherein the distal portion of the tubular body is configured to vibrate in a transverse direction in response to the injection of media.

40. A system as in Claim 32, further comprising a controller for applying a pulsatile vacuum cycle to the central lumen.

41. A system as in Claim 32, further comprising a rotating hemostasis valve coupled to the proximal end of the tubular body, the rotating hemostasis valve comprising:

at least one main lumen along its longitudinal length, through which the proximal portion of the agitator is configured to pass, and

an aspiration lumen bifurcating from the main lumen and provided with a vacuum port.

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42. A system as in Claim 32, further comprising a proximal drive assembly coupled to the proximal end of the tubular body, the proximal drive assembly comprising:

at least one main lumen along its longitudinal length for receiving the agitator;

a media injection port, into which media is injected, in fluid communication with the central lumen of the tubular body, and

a proximal drive connection at the proximal end, which operably connects between the agitator and the driver.

43. An enhanced flexibility neurovascular catheter, comprising:

an elongate flexible body, having a proximal end, a distal end and a side wall defining a central lumen, a distal zone of the side wall comprising:

an outer jacket surrounding a helical coil, the outer jacket formed from a plurality of tubular segments positioned coaxially about the coil; wherein

a proximal one of the tubular segments has a durometer of at least about 60D and a distal one of the tubular segments has a durometer of no more than about 35D; and

an axially extending filament within the side wall, extending at least about the most distal 10 cm of the length of the catheter.

44. An enhanced flexibility neurovascular catheter as in Claim 43, wherein the filament extends at least about the most distal 15 cm of the length of the catheter.

45. An enhanced flexibility neurovascular catheter as in Claim 43, wherein the filament extends at least about the most distal 20 cm of the length of the catheter.

46. An enhanced flexibility neurovascular catheter as in Claim 44, wherein the filament comprises multiple fibers.

47. An enhanced flexibility neurovascular catheter as in Claim 44, wherein the filament extends axially in between the coil and the inner liner.

48. An enhanced flexibility neurovascular catheter as in Claim 44, wherein the side wall further comprises:

a tubular inner liner;

a soft tie layer separated from the lumen by the inner liner;

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wherein the helical coil surrounds the tie layer, and adjacent windings of the coil are spaced progressively further apart in the distal direction.

49. An enhanced flexibility neurovascular catheter as in Claim 48, wherein the tubular liner is formed by dip coating a removable mandrel.

50. An enhanced flexibility neurovascular catheter as in Claim 48, wherein the tubular liner comprises PTFE.

51. An enhanced flexibility neurovascular catheter as in Claim 48, wherein the tie layer comprises polyurethane.

52. An enhanced flexibility neurovascular catheter as in Claim 51, wherein the tie layer has a wall thickness of no more than about 0.005 inches.

53. An enhanced flexibility neurovascular catheter as in Claim 51, wherein the tie layer extends along at least the most distal 20 cm of the flexible body.

54. An enhanced flexibility neurovascular catheter as in Claim 48, wherein the coil comprises a shape memory material.

55. An enhanced flexibility neurovascular catheter as in Claim 54, wherein the coil comprises Nitinol.

56. An enhanced flexibility neurovascular catheter as in Claim 55, wherein the Nitinol comprises an Austenite state at body temperature.

57. An enhanced flexibility neurovascular catheter as in Claim 48, wherein the outer jacket is formed from at least five discrete tubular segments.

58. An enhanced flexibility neurovascular catheter as in Claim 48, wherein the outer jacket is formed from at least nine discrete tubular segments.

59. An enhanced flexibility neurovascular catheter as in Claim 58, wherein the difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments is at least about 20D.

60. An enhanced flexibility neurovascular catheter as in Claim 58, wherein the difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments is at least about 30D.

61. An enhanced flexibility neurovascular catheter as in Claim 43, wherein the catheter can withstand at least about 3.5 pounds tension before failure.

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62. An enhanced flexibility neurovascular catheter as in Claim 43, wherein the catheter can withstand at least about 5 pounds tension before failure.

63. An enhanced flexibility neurovascular catheter as in Claim 43, wherein the catheter can withstand at least about 7 pounds tension before failure.

64. A method of making a high flexibility distal zone on a neurovascular catheter, comprising the steps of:

dip coating a removable mandrel to form a tubular inner layer on the mandrel;

coating the tubular inner layer with a soft tie layer;

applying a helical coil to the outside of the tie layer;

positioning a plurality of tubular segments on the helical coil; the plurality of segments having durometers that decrease in a distal direction;

heating the tubular segments to form the high flexibility distal zone on the neurovascular catheter; and

removing the mandrel.

65. A method as in Claim 64, wherein removing the mandrel step includes axially elongating the mandrel.

66. A method as in Claim 64, comprising positioning at least seven segments on the helical coil.

67. A method as in Claim 64, comprising positioning at least nine segments on the helical coil.

68. A method as in Claim 67, wherein the difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments is at least about 20D.

69. A method as in Claim 68, wherein the difference is at least about 30D.

70. A method as in Claim 64, wherein the tubular inner layer comprises PTFE.

71. A method as in Claim 64, wherein the tie layer comprises polyurethane.

72. A method as in Claim 71, wherein the tie layer has a wall thickness of no more than about 0.005 inches.

73. A method as in Claim 71, wherein the tie layer extends along at least the most distal 20 cm of the flexible body.

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74. A method as in Claim 64, wherein the coil comprises a shape memory material.

75. A method as in Claim 74, wherein the coil comprises Nitinol.

76. A method as in Claim 75, wherein the Nitinol comprises an Austenite state at body temperature.

77. A method as in Claim 64, further comprising the step of positioning at least one tensile strength enhancing filament in between the coil and the tie layer prior to heat shrinking the tubular segments.

78. A method as in Claim 77, wherein the filament extends along at least about the most distal 15 cm of the length of the catheter.

79. A method as in Claim 77, wherein the filament extends along at least about the most distal 20 cm of the length of the catheter.

80. A method as in Claim 77, wherein the filament comprises multiple fibers

81. A method as in Claim 64, further comprising the step of positioning at least one tensile strength enhancing filament over the tie layer before the applying a helical coil step.

82. A neurovascular catheter, comprising:

an elongate flexible tubular body, having a proximal end, a distal end and a side wall defining a central lumen, a distal zone of the tubular body comprising:

a tubular inner liner;

a tie layer separated from the lumen by the inner liner;

a helical coil surrounding the tie layer, adjacent windings of the coil spaced progressively further apart in the distal direction;

an outer jacket surrounding the helical coil, and

an opening at the distal end which is enlargeable from a first inside diameter for transluminal navigation to a second, larger inside diameter to facilitate aspiration of thrombus into the lumen.

83. A neurovascular catheter as in Claim 82, wherein the distal opening is enlargeable in response to exposure to blood.

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84. A neurovascular catheter as in Claim 82, wherein the distal opening is enlargeable in response to exposure to body temperature.

85. A neurovascular catheter as in Claim 82, wherein the distal opening is enlargeable in response to removal of a constraint.

86. A neurovascular catheter as in Claim 85, wherein the constraint comprises a polymer having a structural integrity that decreases in the intravascular environment.

87. A neurovascular catheter as in Claim 82, wherein the catheter body adjacent the distal opening comprises a radially outwardly biased embedded support.

88. A neurovascular catheter as in Claim 87, wherein the catheter body adjacent the distal opening comprises an embedded Nitinol frame.

89. A neurovascular catheter as in Claim 82, wherein the catheter body adjacent the distal opening comprises a hydrophilic blend.

90. A neurovascular catheter as in Claim 82, wherein the tubular liner is formed by dip coating a removable mandrel.

91. A neurovascular catheter as in Claim 82, wherein the tubular liner comprises PTFE.

92. A neurovascular catheter as in Claim 82, wherein the tie layer comprises polyurethane.

93. A neurovascular catheter as in Claim 92, wherein the tie layer has a wall thickness of no more than about 0.005 inches.

94. A neurovascular catheter as in Claim 92, wherein the tie layer extends along at least the most distal 20 cm of the flexible body.

95. A neurovascular catheter as in Claim 82, wherein the coil comprises a shape memory material.

96. A neurovascular catheter as in Claim 95, wherein the coil comprises Nitinol.

97. A neurovascular catheter as in Claim 96, wherein the Nitinol comprises an Austenite state at body temperature.

98. A neurovascular catheter as in Claim 82, wherein the outer jacket is formed from at least five discrete tubular segments.

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99. A neurovascular catheter as in Claim 82, wherein the outer jacket is formed from at least nine discrete tubular segments.

100. A neurovascular catheter as in Claim 98, wherein the difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments is at least about 20D.

101. A neurovascular catheter as in Claim 98, wherein the difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments is at least about 30D.

102. A neurovascular catheter as in Claim 87, wherein the support comprises a wire mesh.

103. A neurovascular catheter as in Claim 87, wherein the support comprises a stent.

104. A neurovascular catheter extension segment, comprising:

an elongate flexible control wire, having a proximal end and a distal end;

a tubular extension segment having a side wall defining a central lumen carried by the distal end of the control wire, the side wall comprising:

a tubular inner liner;

a tie layer separated from the lumen by the inner liner;

a helical coil surrounding the tie layer; and

an outer jacket surrounding the helical coil.

105. A neurovascular catheter extension segment as in Claim 104, wherein the outer jacket is formed from a plurality of tubular segments positioned coaxially about the coil.

106. A neurovascular catheter extension segment as in Claim 105, wherein a proximal one of the tubular segments has a durometer of at least about 60D and a distal one of the tubular segments has a durometer of no more than about 35D.

107. A neurovascular catheter extension segment as in Claim 104, wherein the tubular liner is formed by dip coating a removable mandrel.

108. A neurovascular catheter extension segment as in Claim 104, wherein the tubular liner comprises PTFE.

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Penumbra, Inc. v. RapidPulse, Inc.

109. A neurovascular catheter extension segment as in Claim 104, wherein the tie layer comprises polyurethane.

110. A neurovascular catheter extension segment as in Claim 109, wherein the tie layer has a wall thickness of no more than about 0.005 inches.

111. A neurovascular catheter extension segment as in Claim 109, wherein the tie layer extends along at least the most distal 20 cm of the tubular extension segment.

112. A neurovascular catheter extension segment as in Claim 104, wherein the coil comprises a shape memory material.

113. A neurovascular catheter extension segment as in Claim 112, wherein the coil comprises Nitinol.

114. A neurovascular catheter extension segment as in Claim 113, wherein the Nitinol comprises an Austenite state at body temperature.

115. A neurovascular catheter extension segment as in Claim 105, wherein the outer jacket is formed from at least five discrete tubular segments.

116. A neurovascular catheter extension segment as in Claim 115, wherein the outer jacket is formed from at least nine discrete tubular segments.

117. A neurovascular catheter extension segment as in Claim 116, wherein the difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments is at least about 20D.

118. A neurovascular catheter extension segment as in Claim 117, wherein the difference is at least about 30D.

119. A neurovascular catheter extension segment as in Claim 104, wherein the control wire comprises a central lumen.

120. A neurovascular catheter extension segment as in Claim 119, wherein the control wire central lumen is in communication with the central lumen of the tubular extension segment.

121. A neurovascular catheter extension segment system, comprising a neurovascular catheter extension segment as in Claim 119, and an agitator configured to extend through the control wire central lumen and into the central lumen of the tubular extension segment.

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Penumbra, Inc. v. RapidPulse, Inc.

122. A neurovascular catheter extension segment as in Claim 119, wherein the inside diameter of the neurovascular catheter extension segment is at least 2X the inside diameter of the control wire central lumen.

123. A neurovascular catheter extension segment as in Claim 122, wherein the inside diameter of the neurovascular catheter extension segment is at least 3X the inside diameter of the control wire central lumen.

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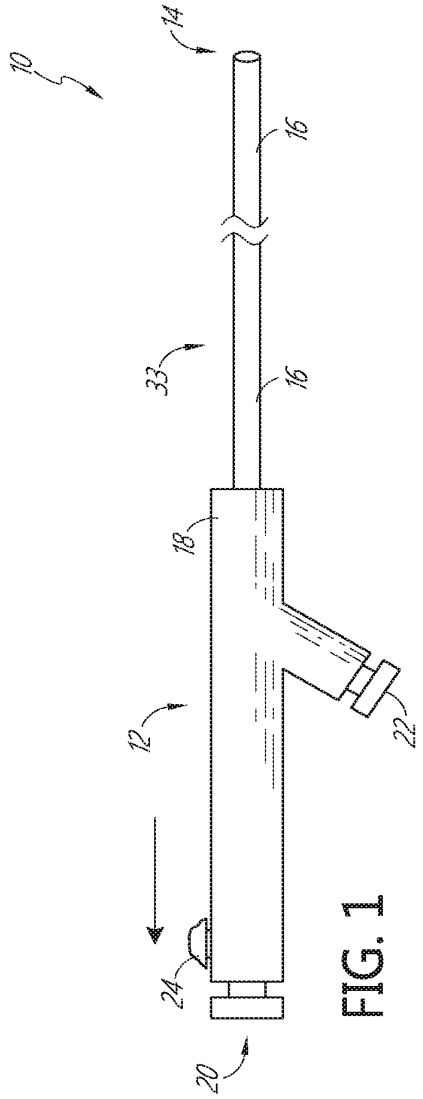


FIG. 1

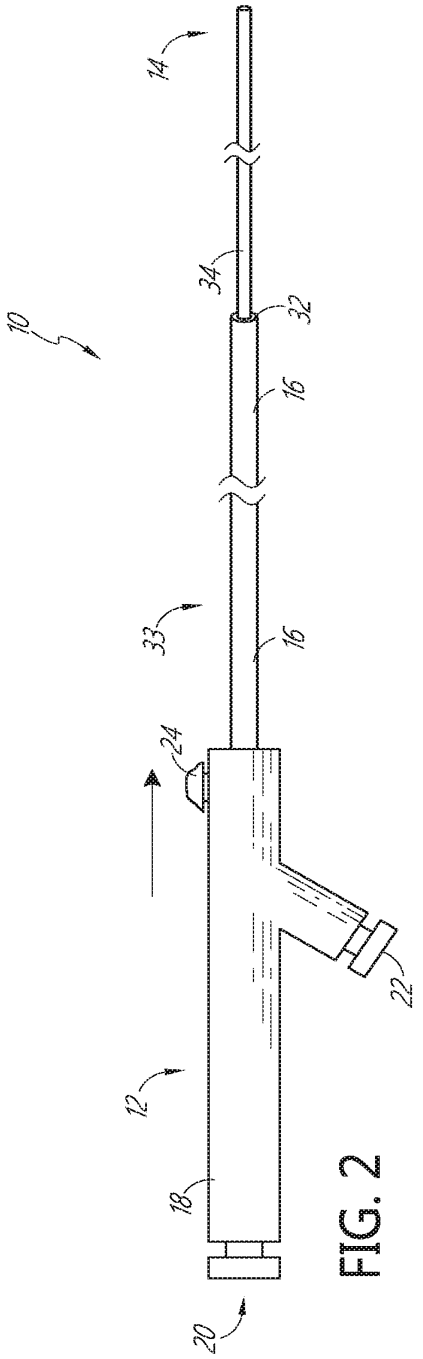


FIG. 2

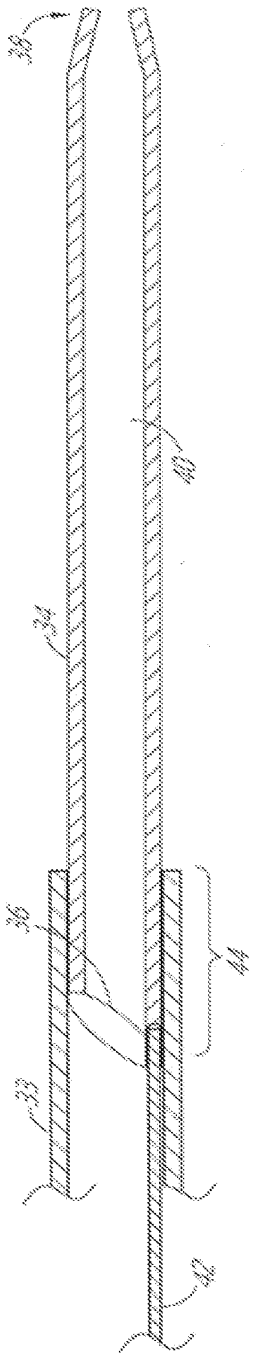


FIG. 3A

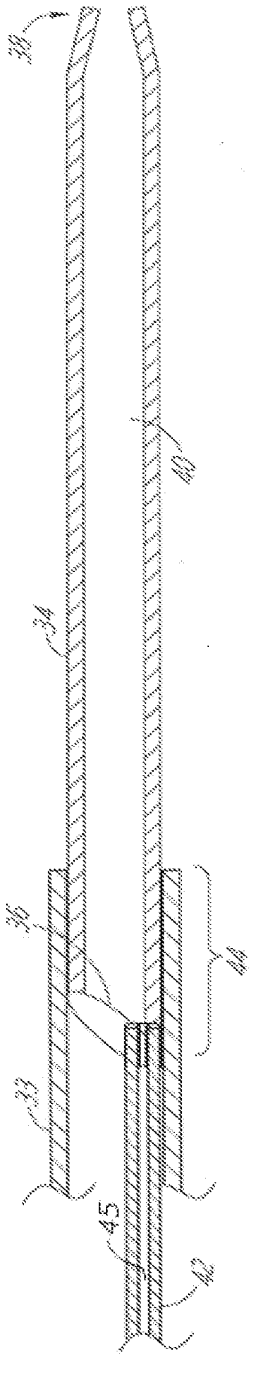


FIG. 3B

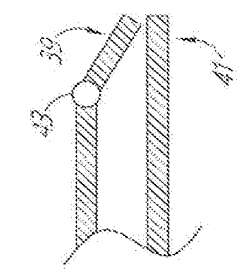


FIG. 4C

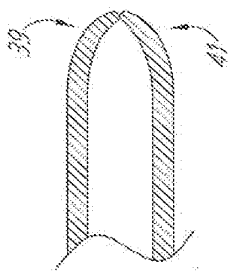


FIG. 4B

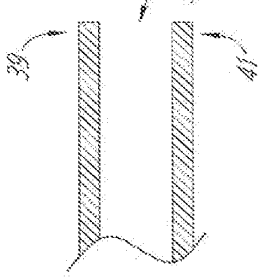


FIG. 4A

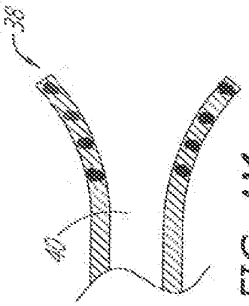


FIG. 4K

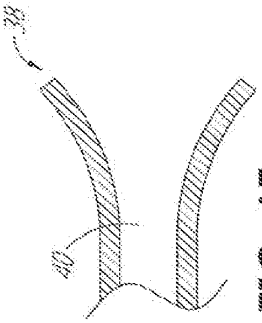


FIG. 4E

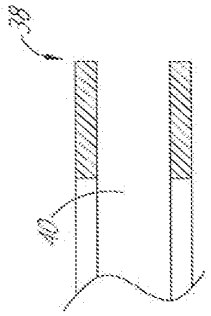


FIG. 4D

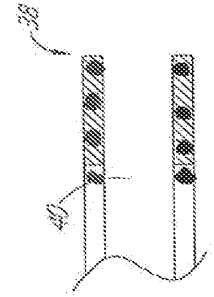


FIG. 4J

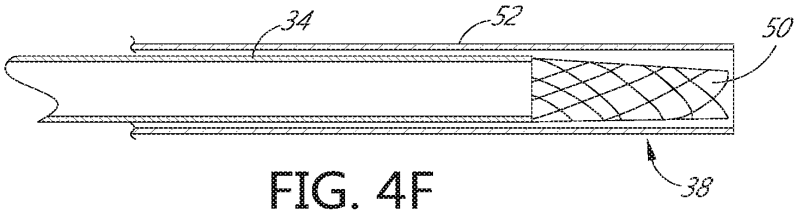


FIG. 4F

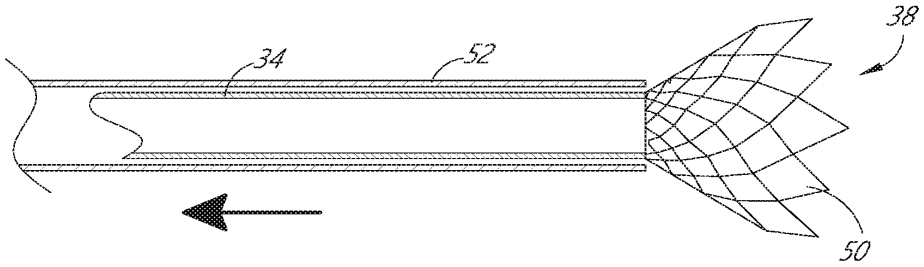


FIG. 4G

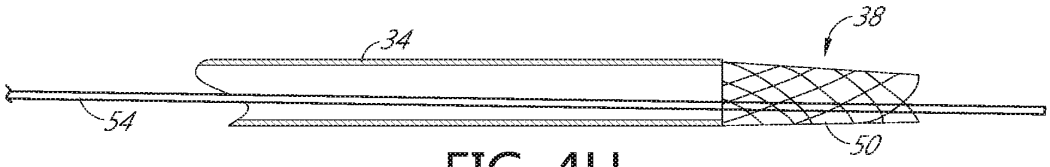


FIG. 4H

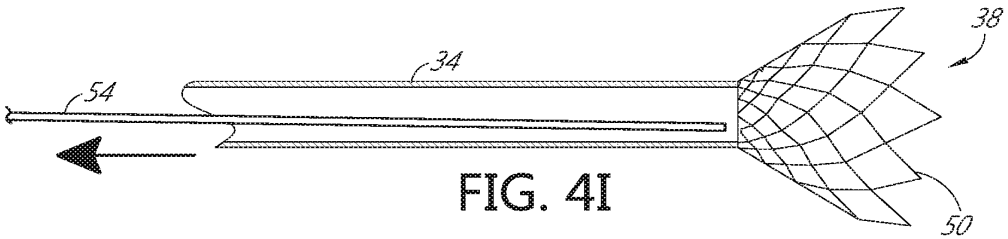
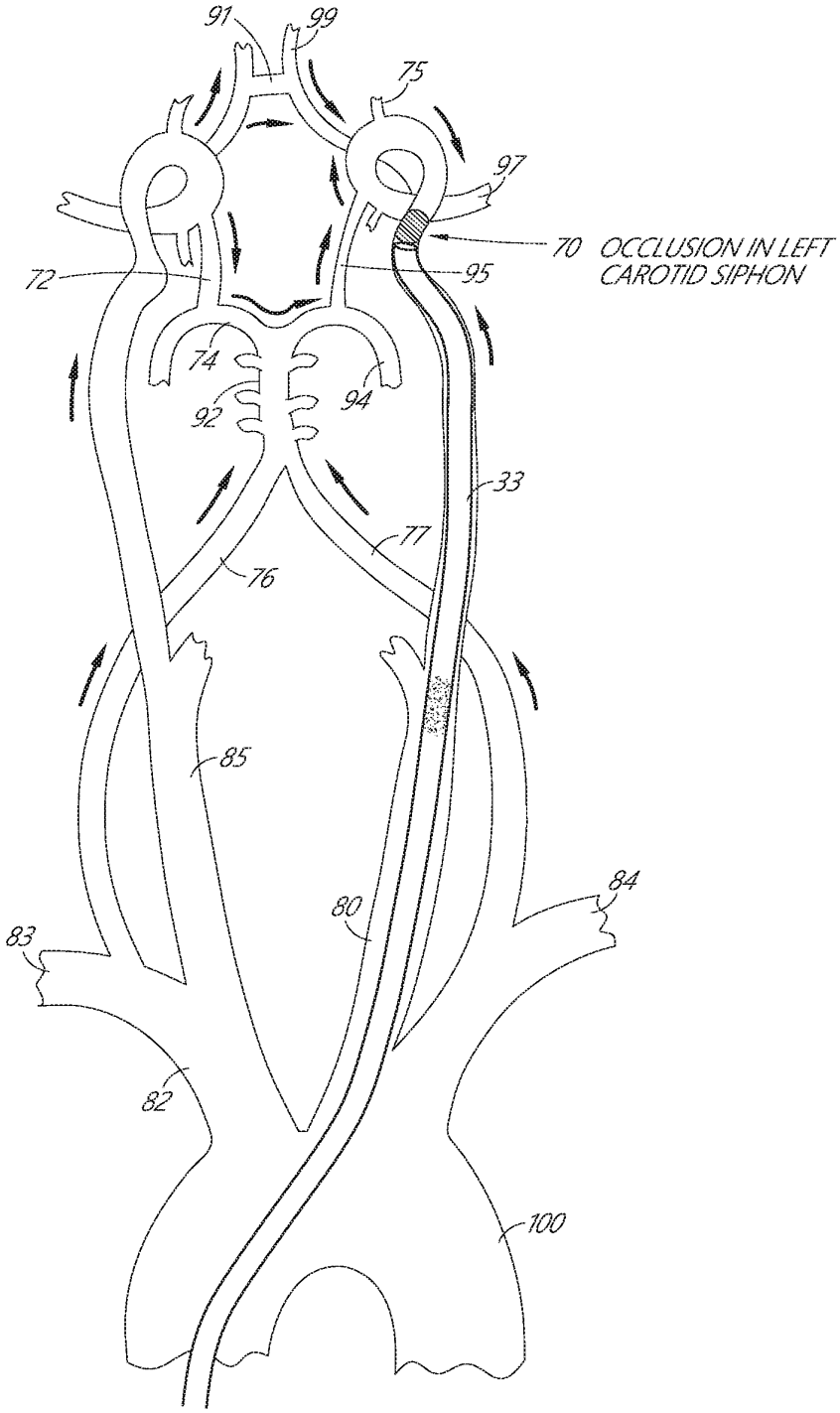


FIG. 4I

FIG. 5


91
99
75
97
70
OCCLUSION IN LEFT CAROTID SIPHON
72
95
74
92
94
33
77
76
85
84
80
83
82
100

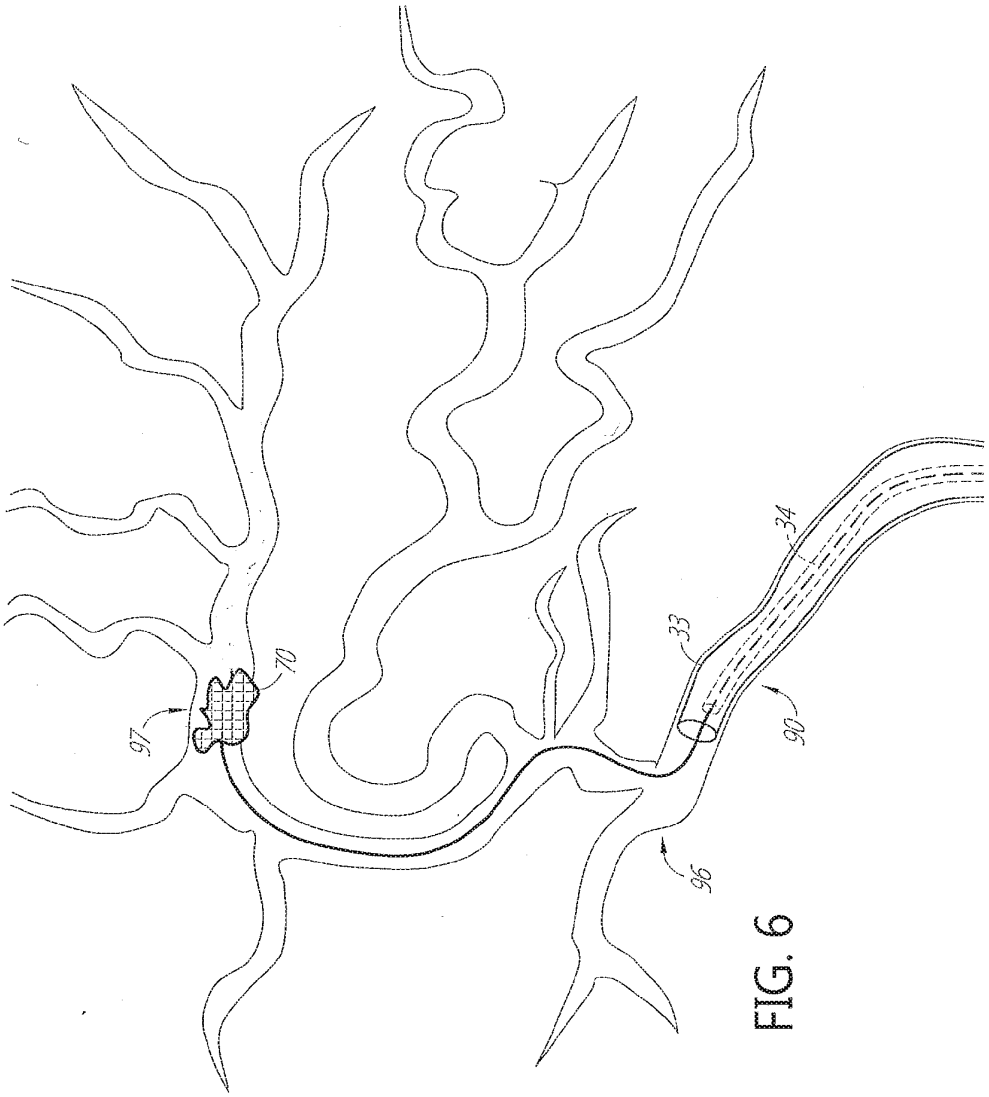


FIG. 6

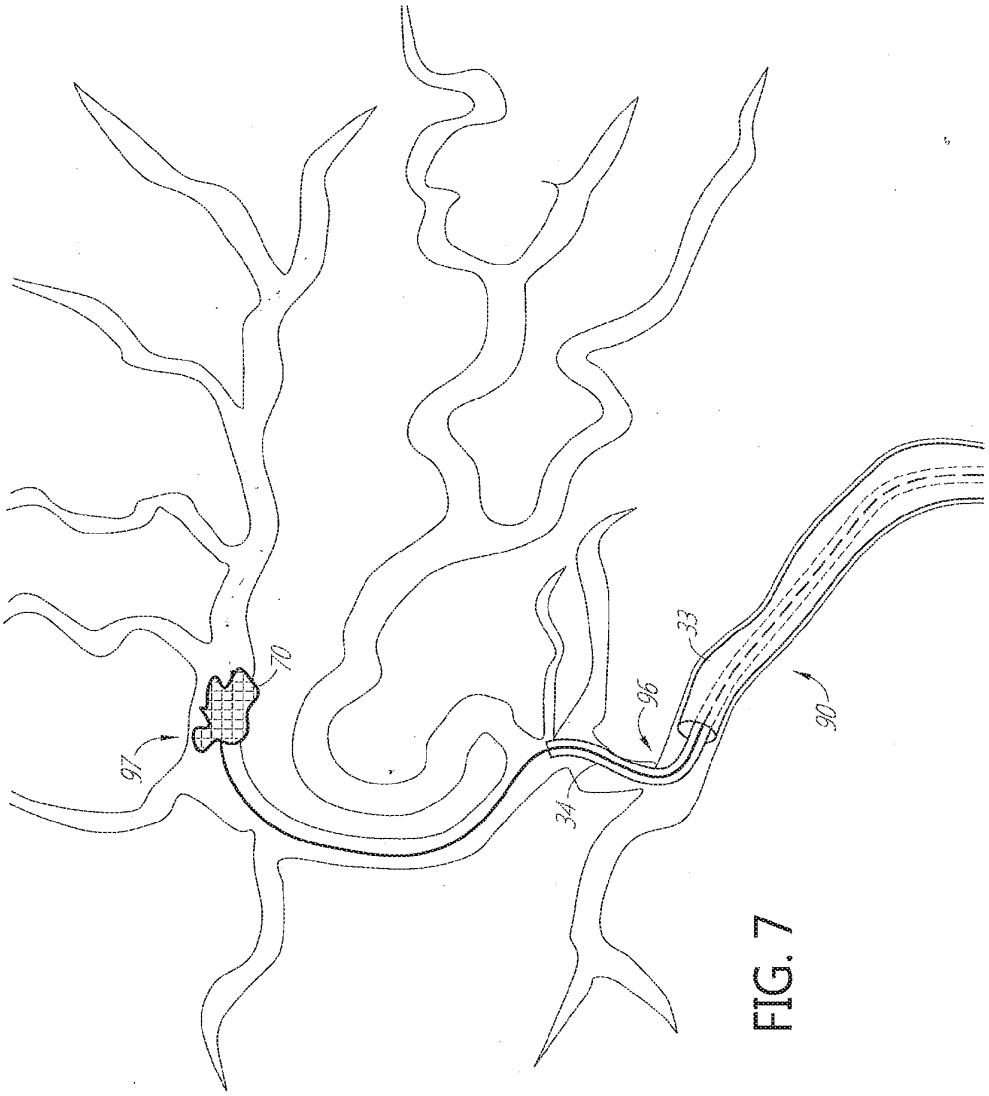


FIG. 7

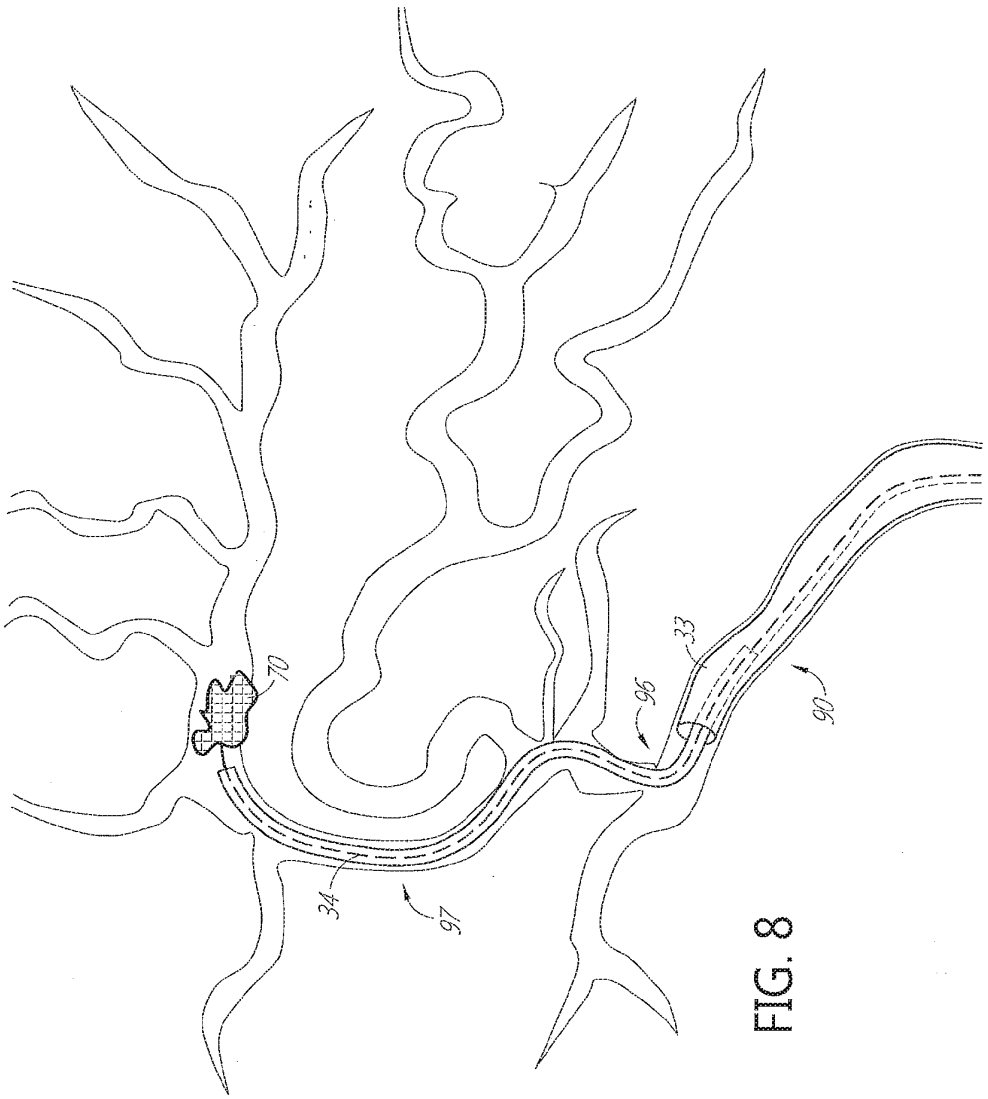


FIG. 8

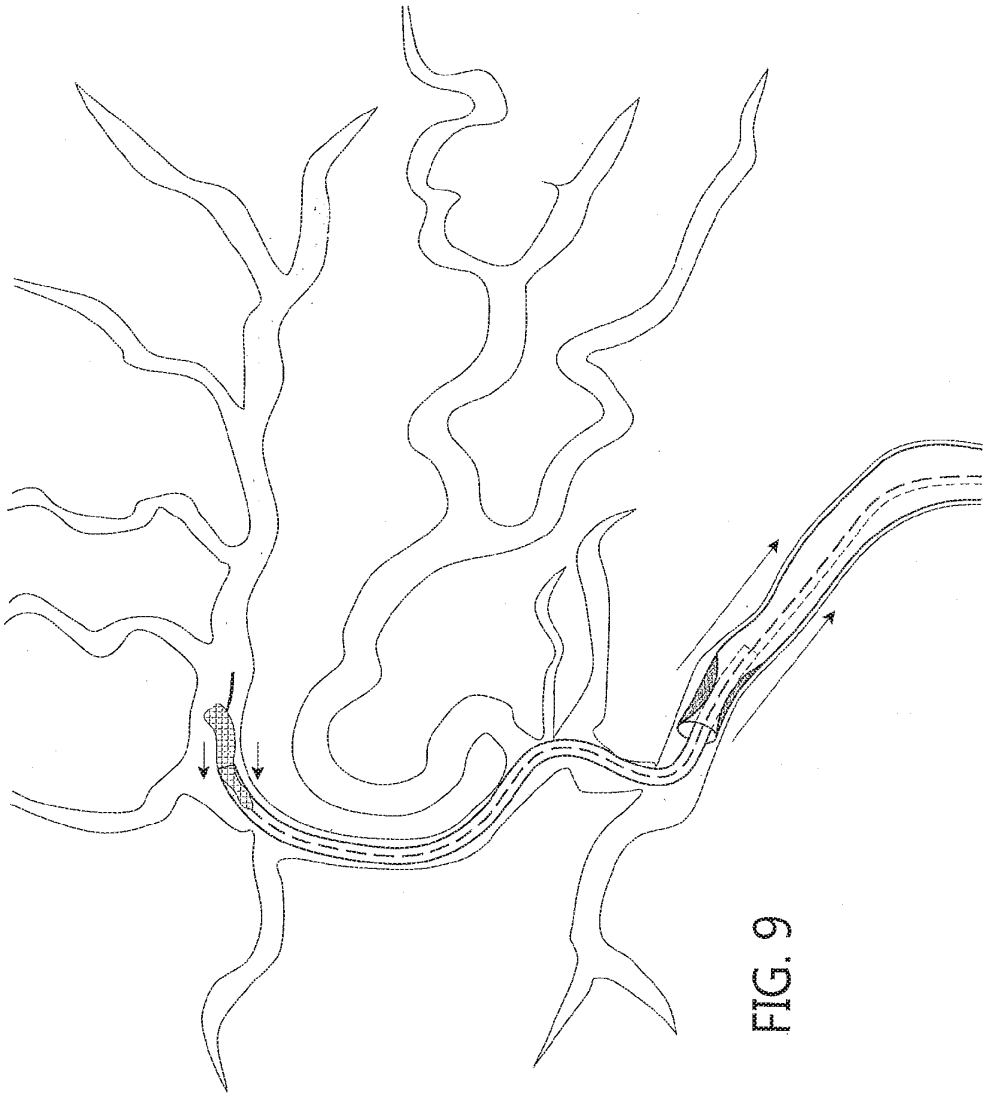


FIG. 9

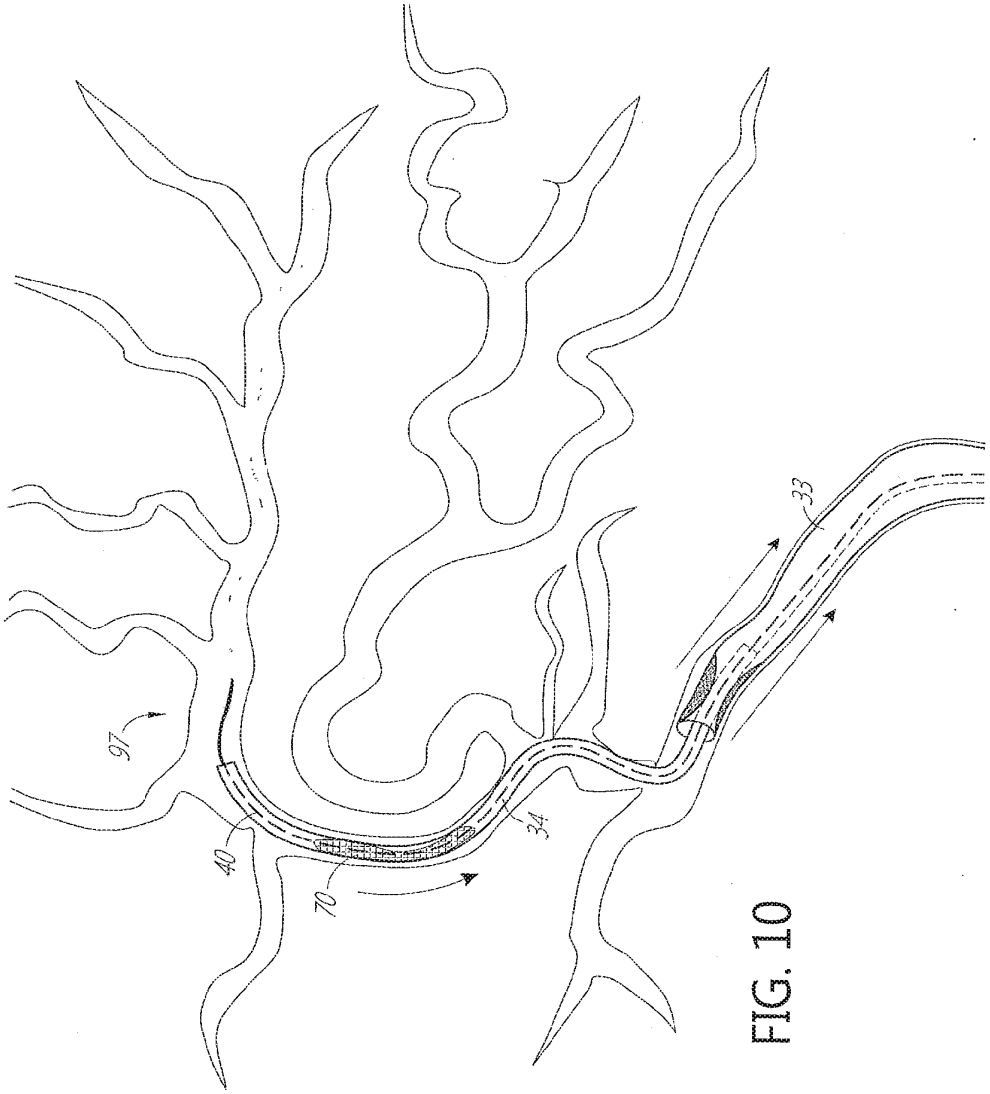


FIG. 10

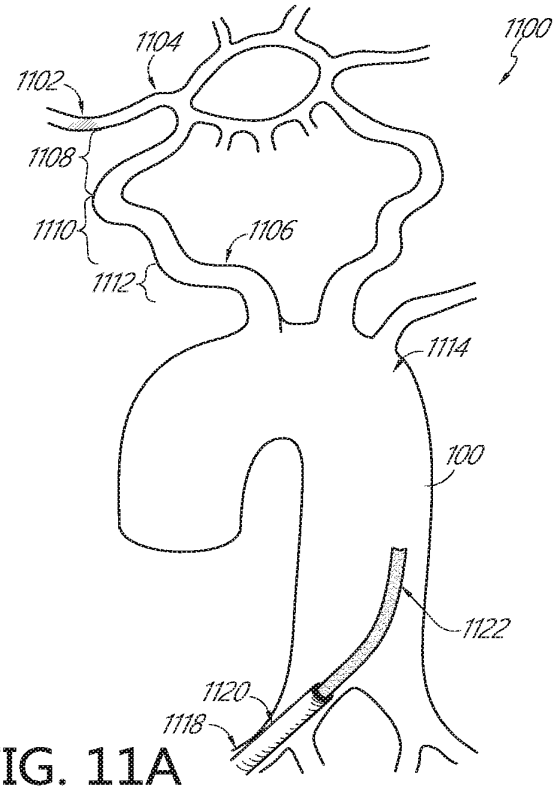


FIG. 11A

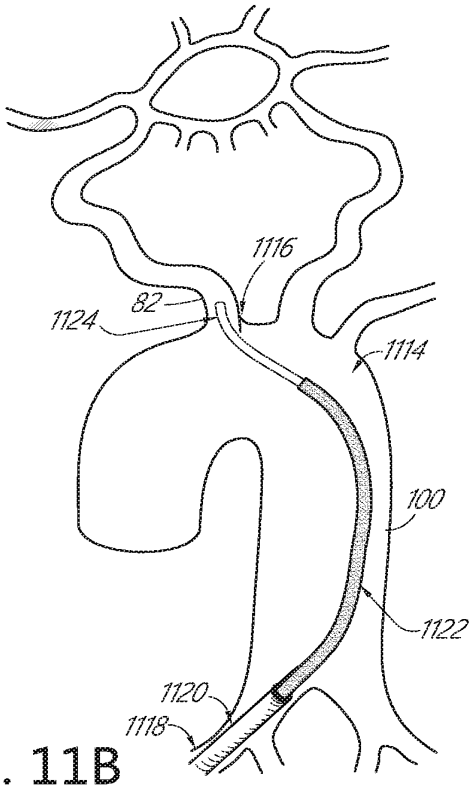


FIG. 11B

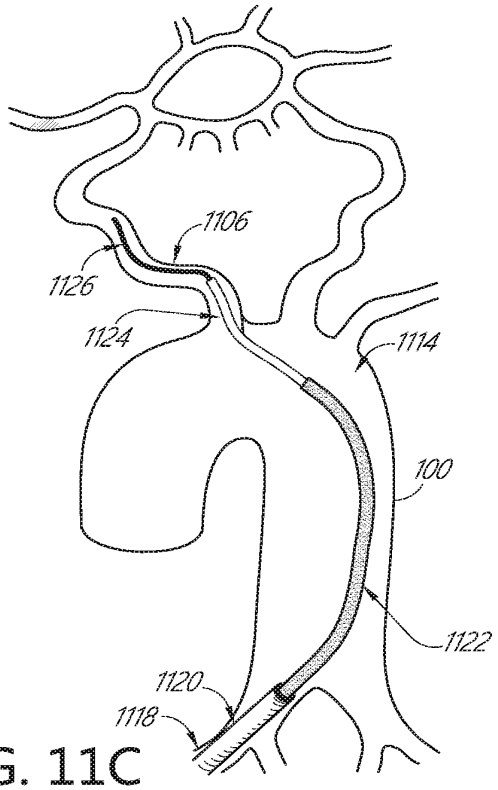


FIG. 11C

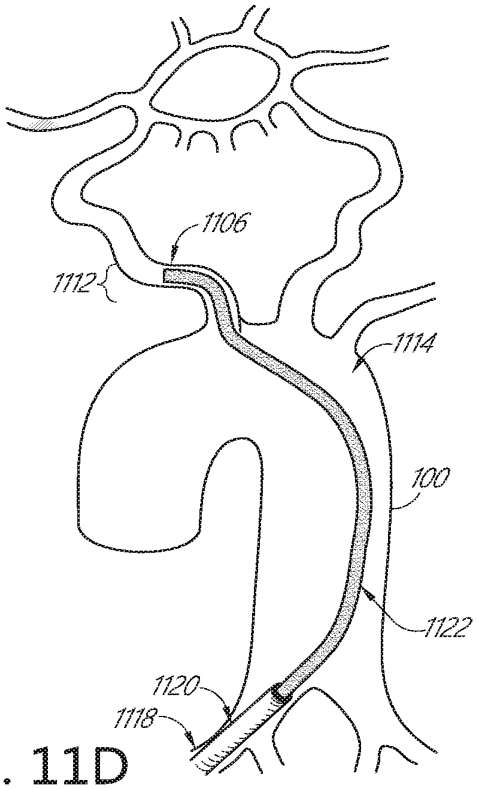


FIG. 11D

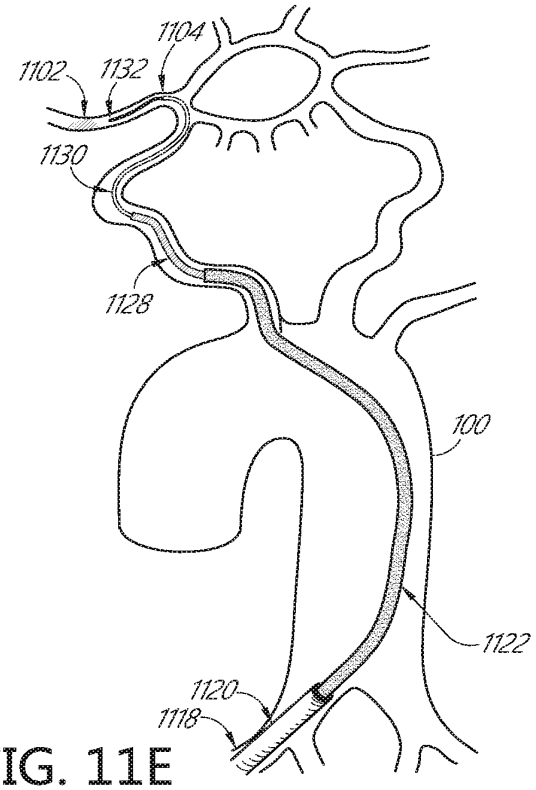


FIG. 11E

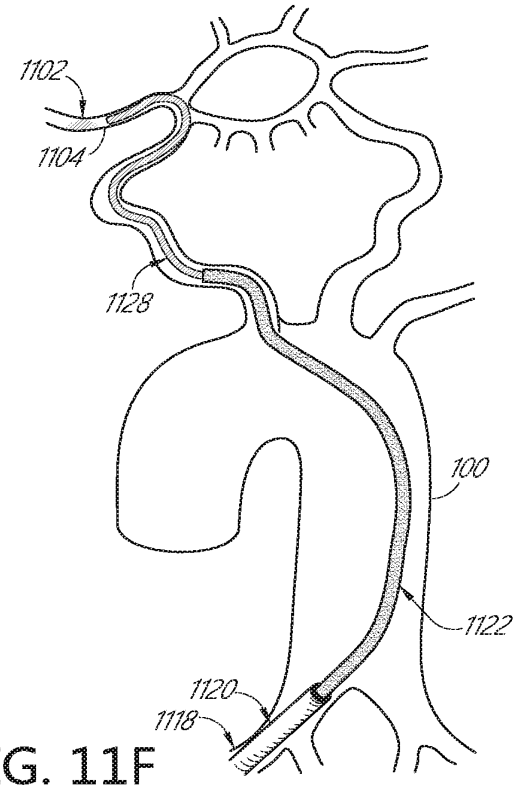


FIG. 11F

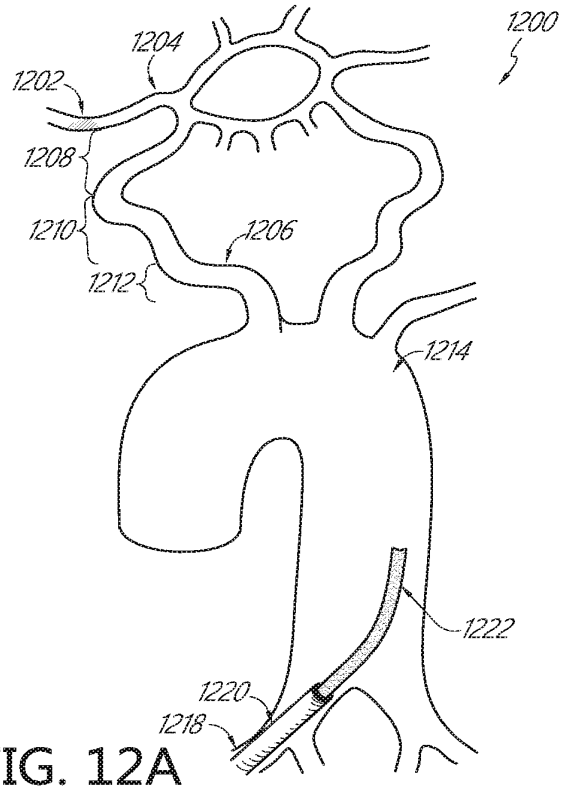


FIG. 12A

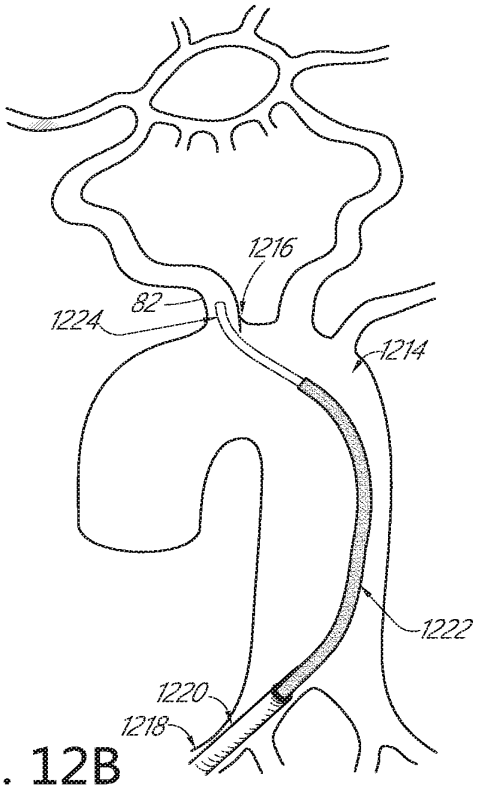


FIG. 12B

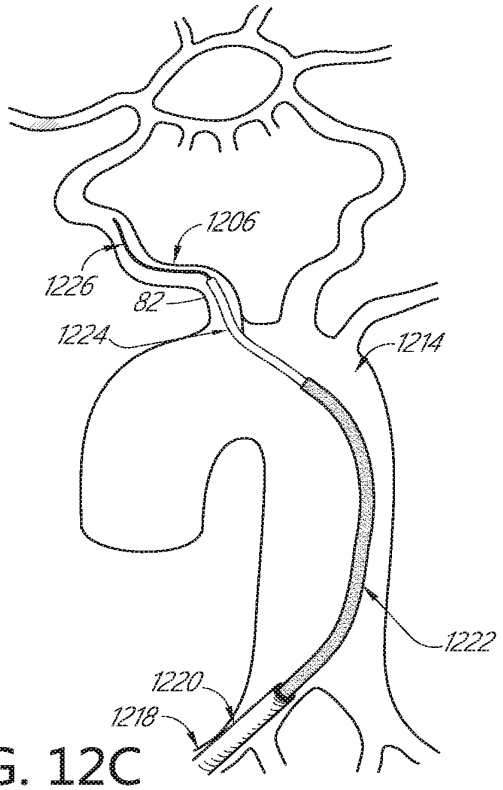


FIG. 12C

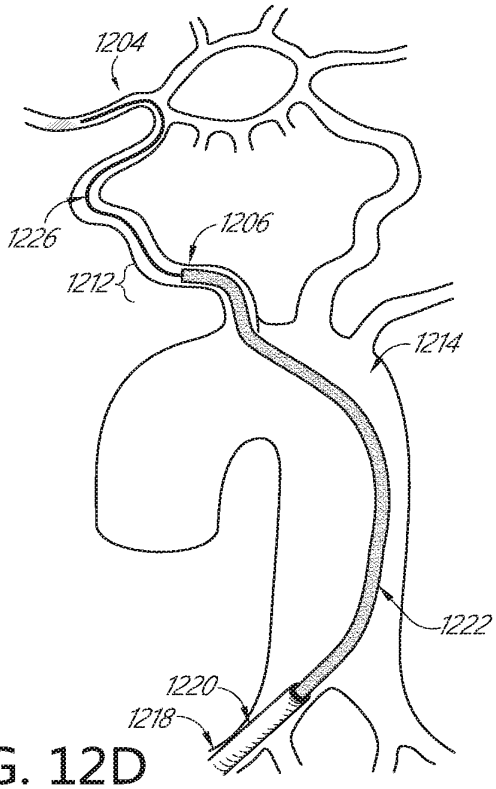


FIG. 12D

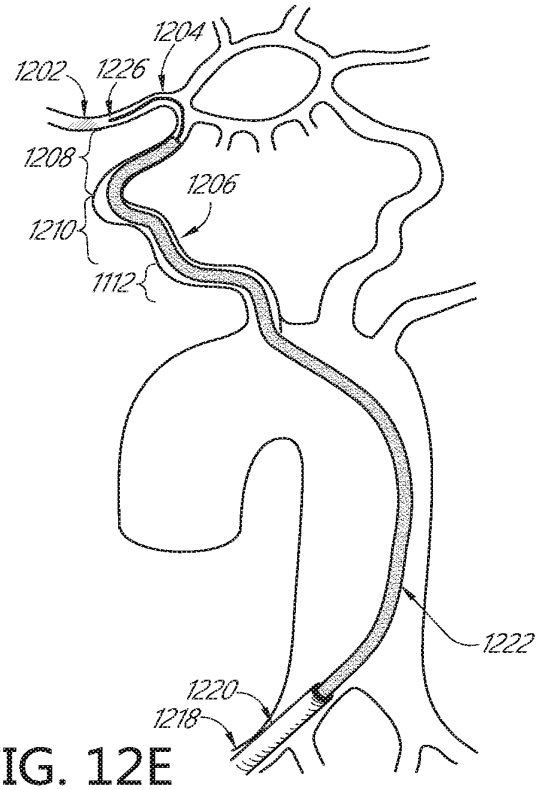


FIG. 12E

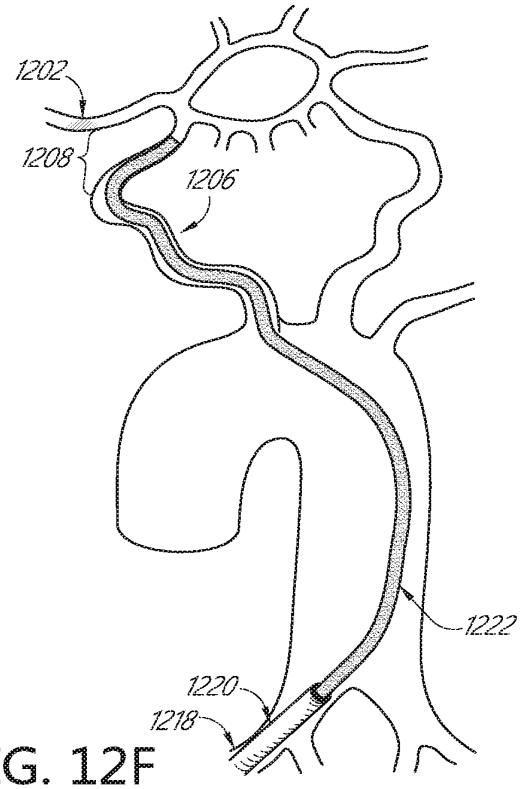


FIG. 12F

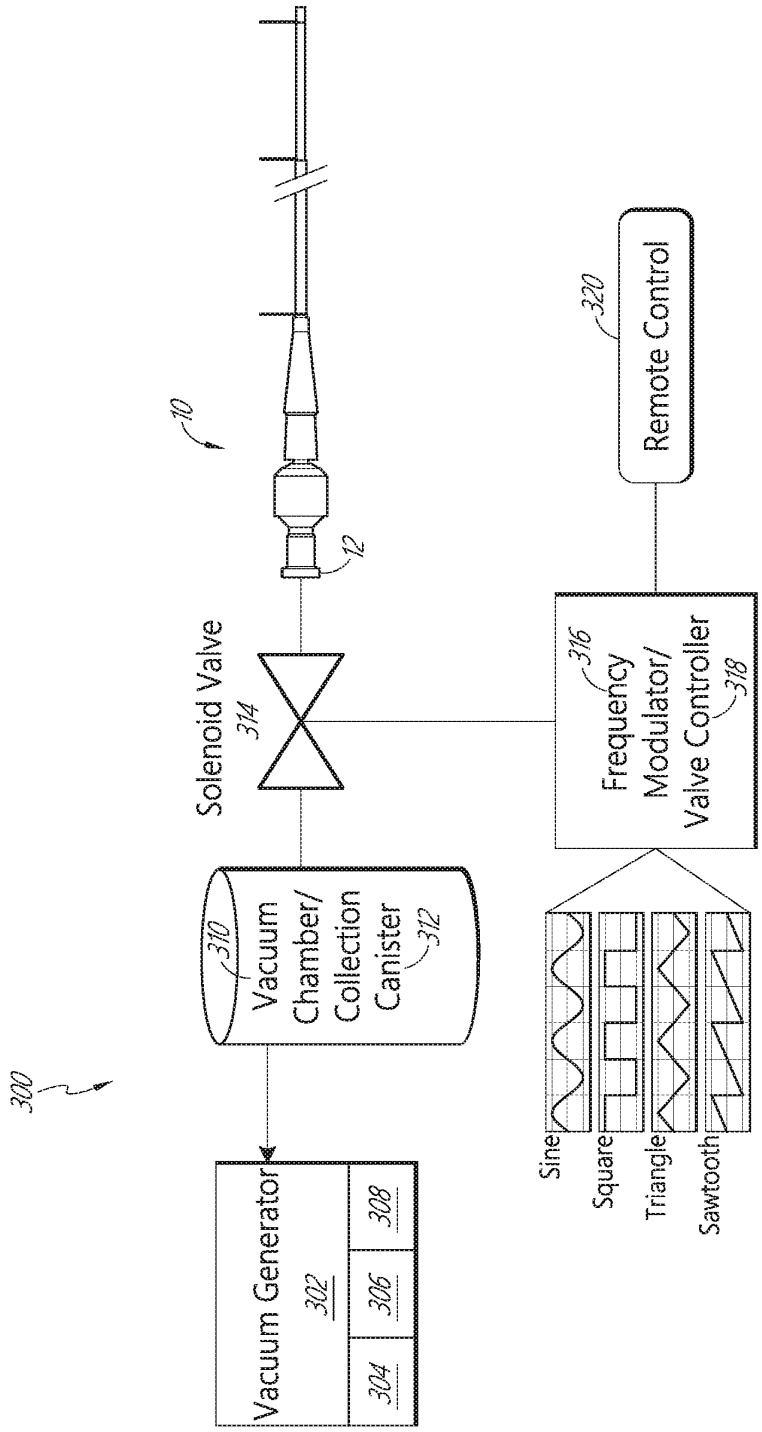

300
10
12
Solenoid Valve
314
Vacuum Chamber/ Collection Canister
310
312
Vacuum Generator
302
304
306
308
Remote Control
320
Frequency Modulator/ Valve Controller
316
318
Sine
Square
Triangle
Sawtooth

FIG. 13

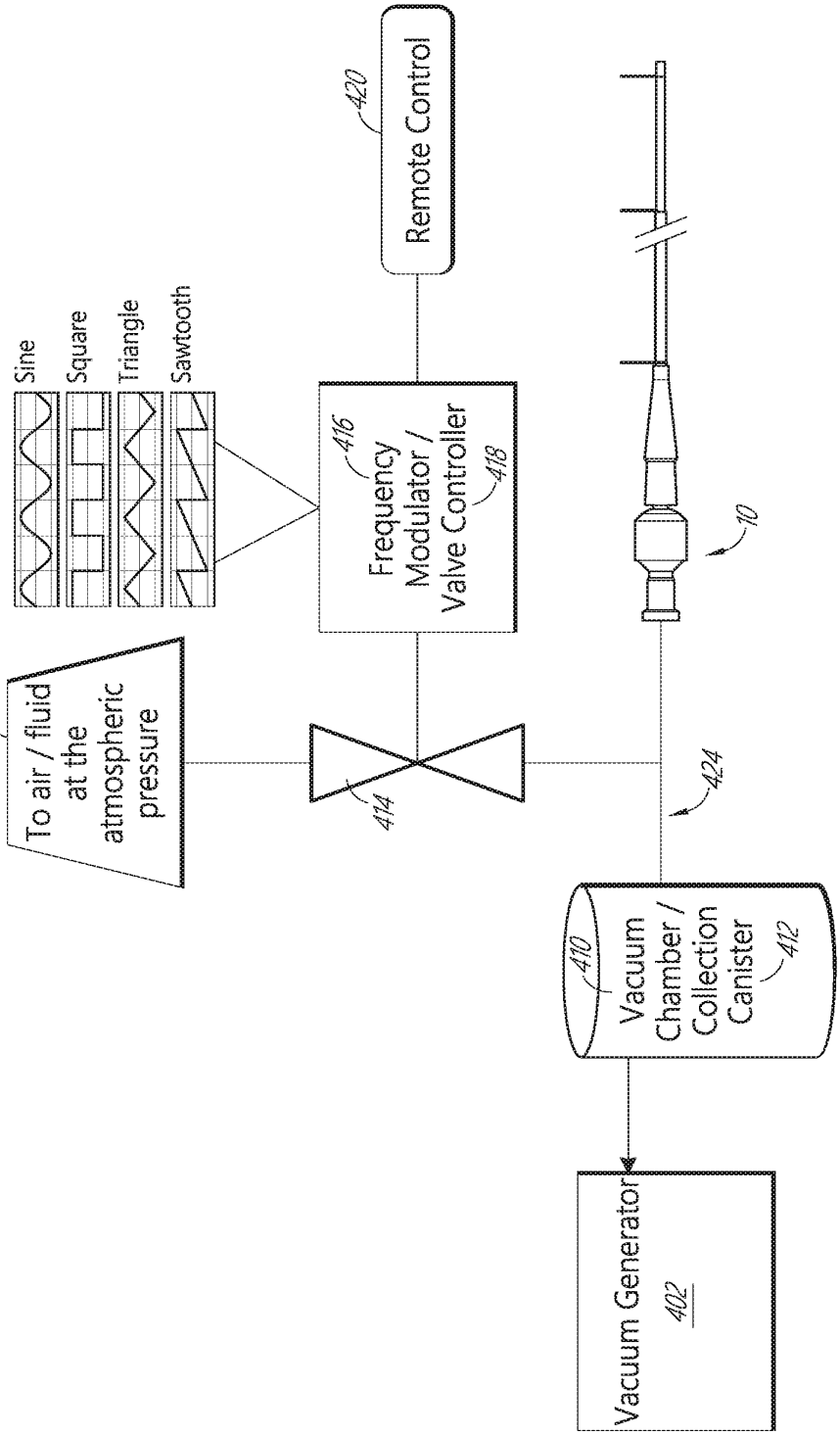

Vacuum Generator
402
Vacuum Chamber / Collection Canister
410
412
To air / fluid at the atmospheric pressure
422
414
424
Frequency Modulator / Valve Controller
416
418
Sine
Square
Triangle
Sawtooth
Remote Control
420
10

FIG. 14

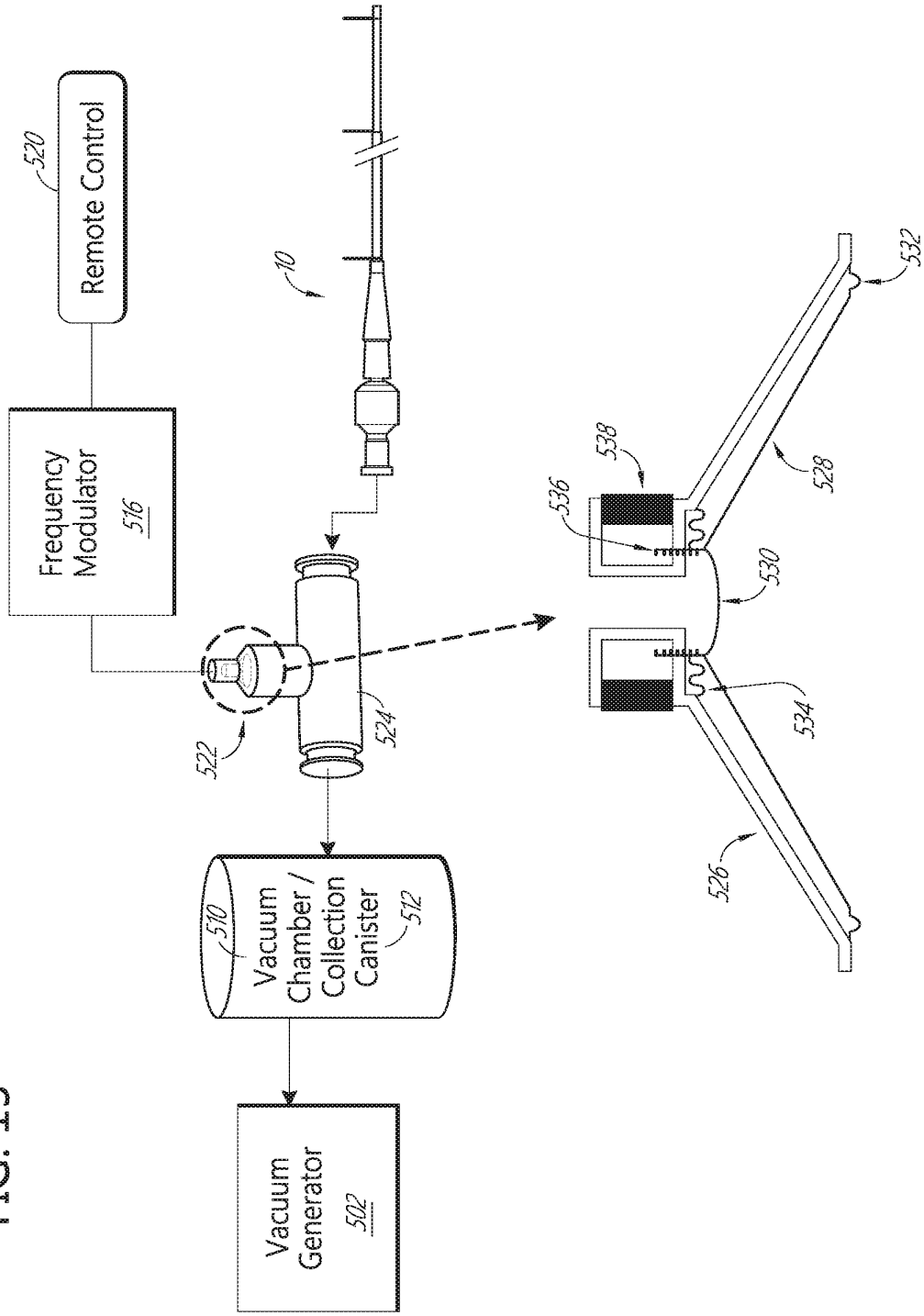

Remote Control
520
Frequency Modulator
516
10
522
524
Vacuum Chamber / Collection Canister
510
512
Vacuum Generator
502
526
528
530
532
534
536
538

FIG. 15

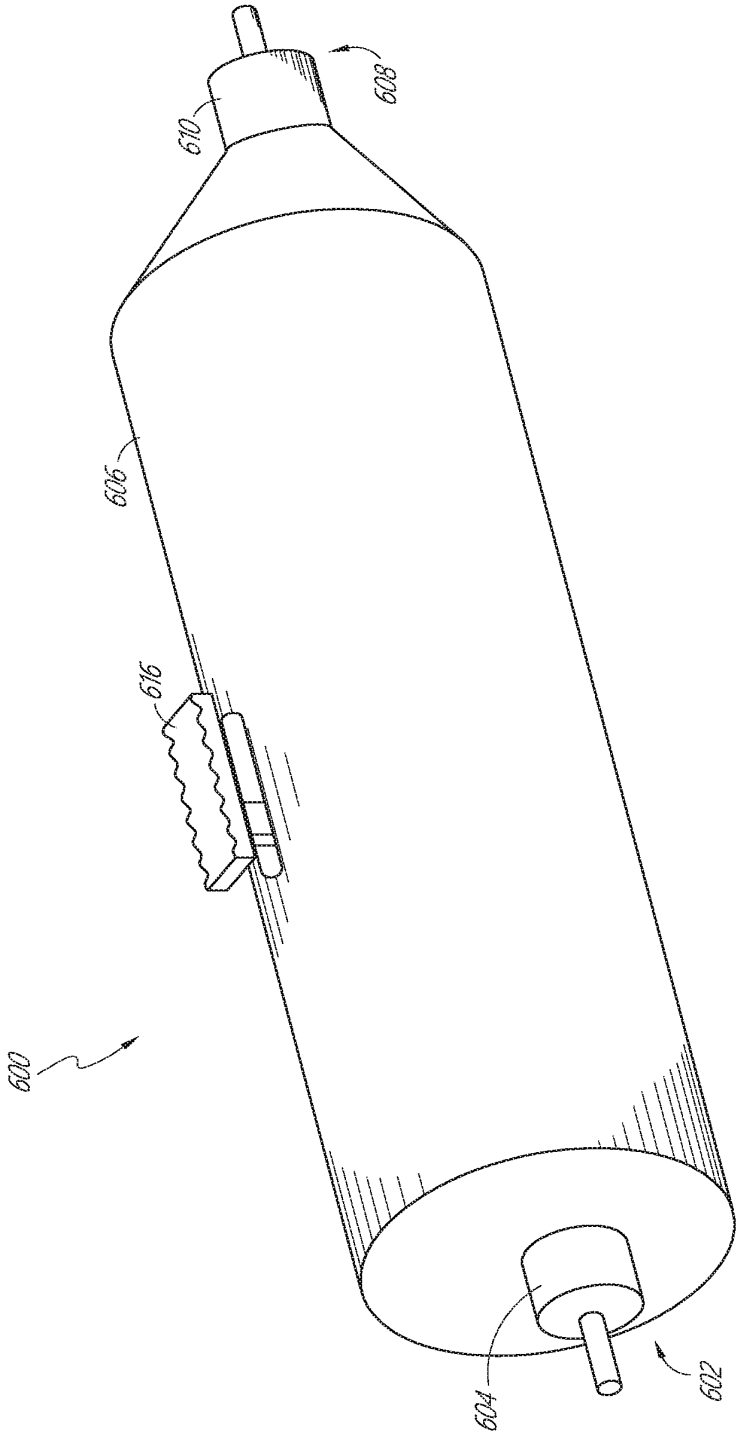


FIG. 16

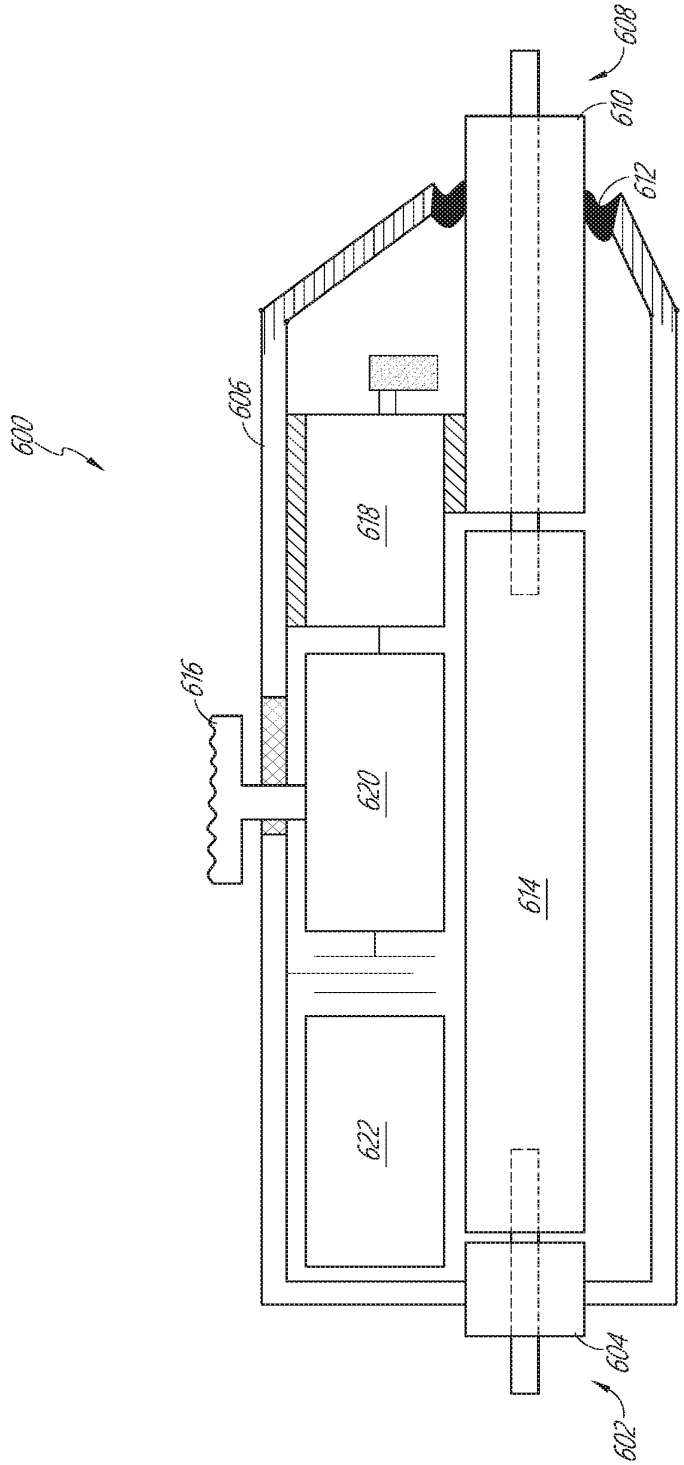


FIG. 17

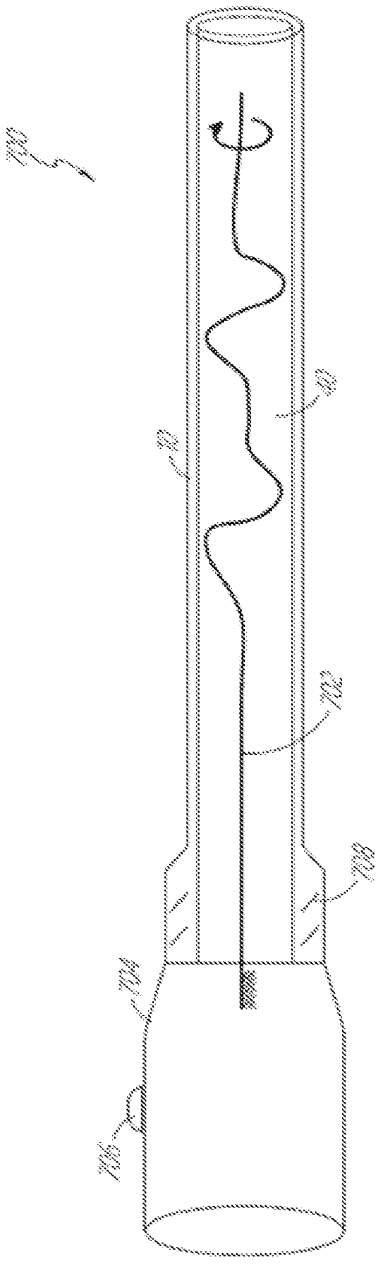

700
710
702
708
704
706

FIG. 18

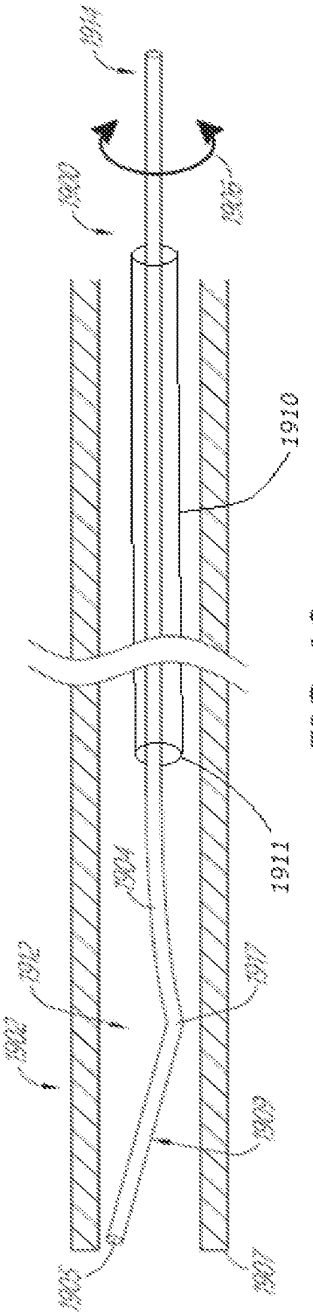

1914
1900
1910
1911
1904
1902
1907
1909
1905

FIG. 19

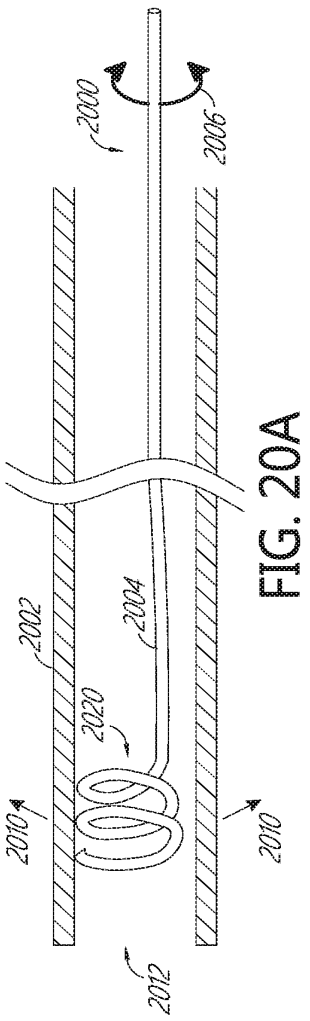


FIG. 20A

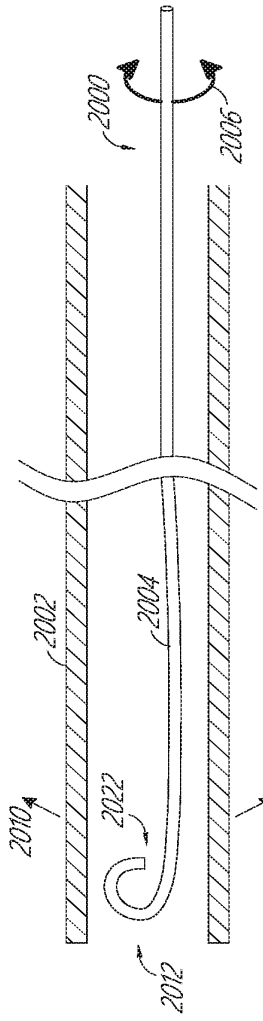


FIG. 20B

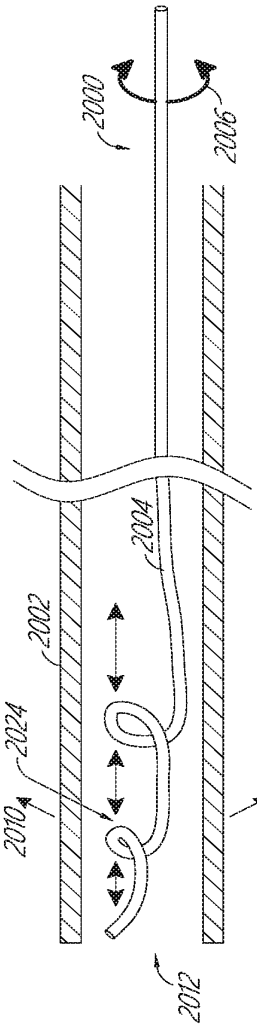


FIG. 20C

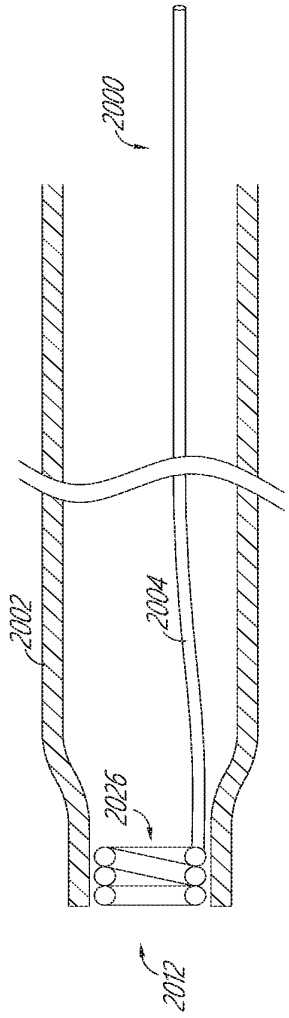


FIG. 20D

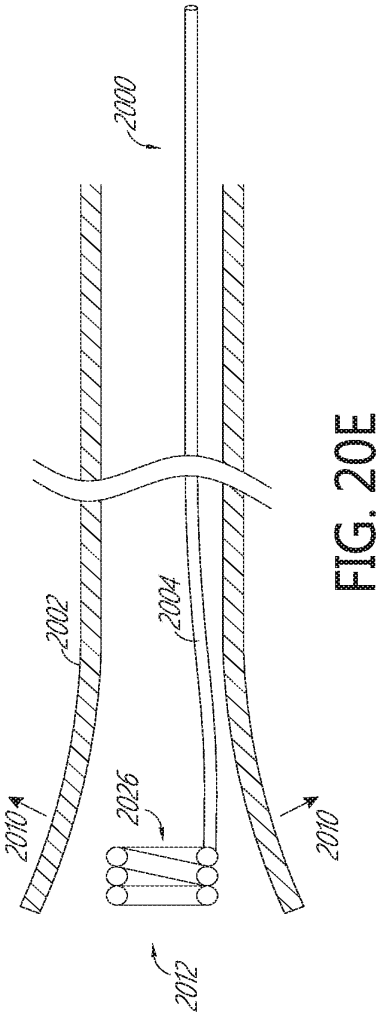


FIG. 20E

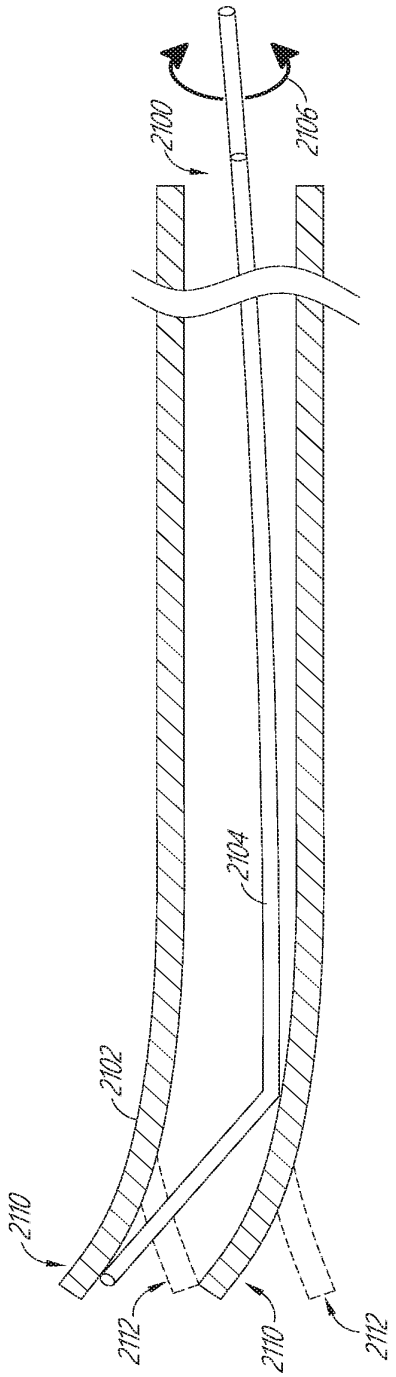


FIG. 21A

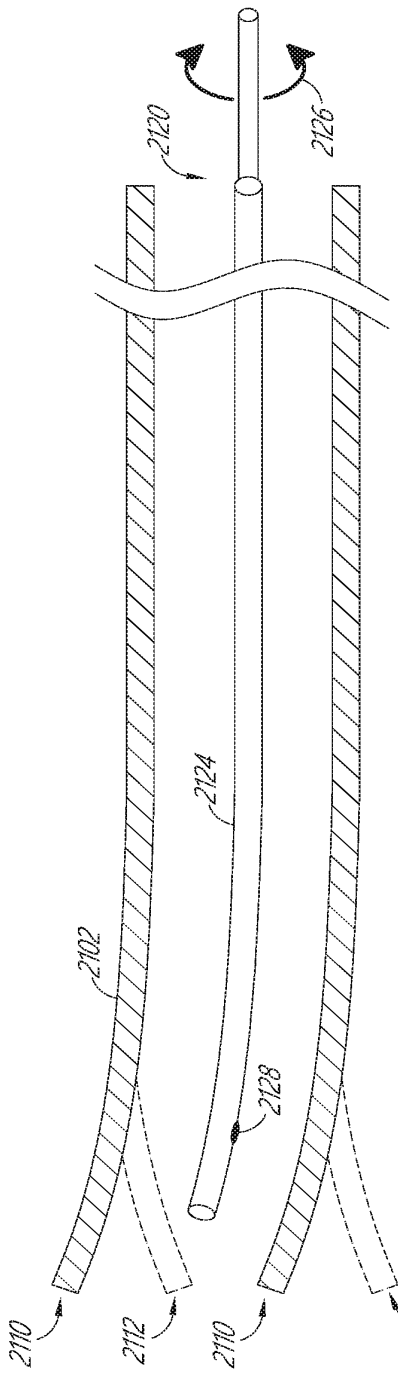


FIG. 21B

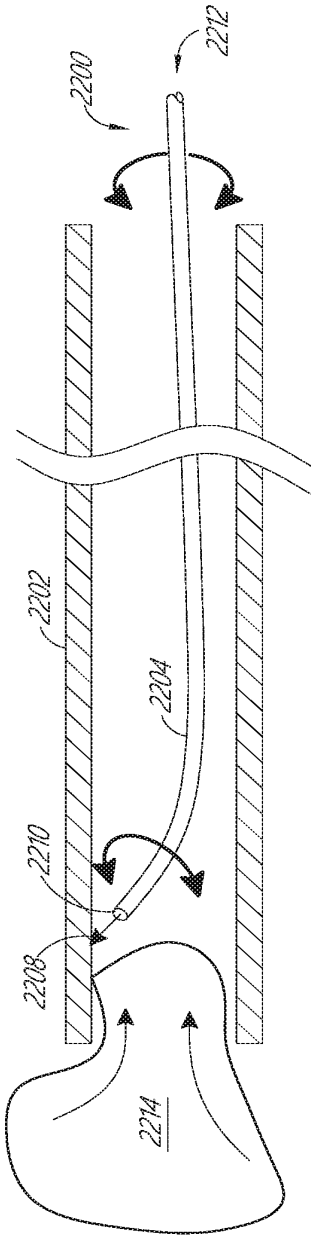


FIG. 22A

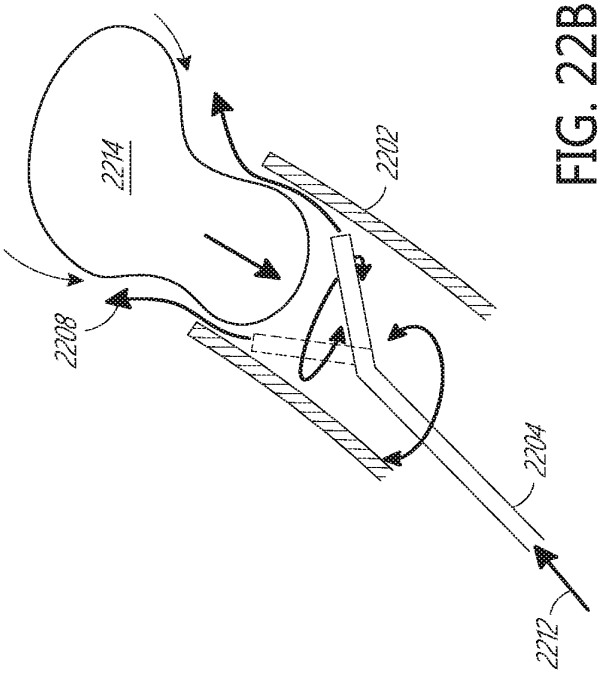


FIG. 22B

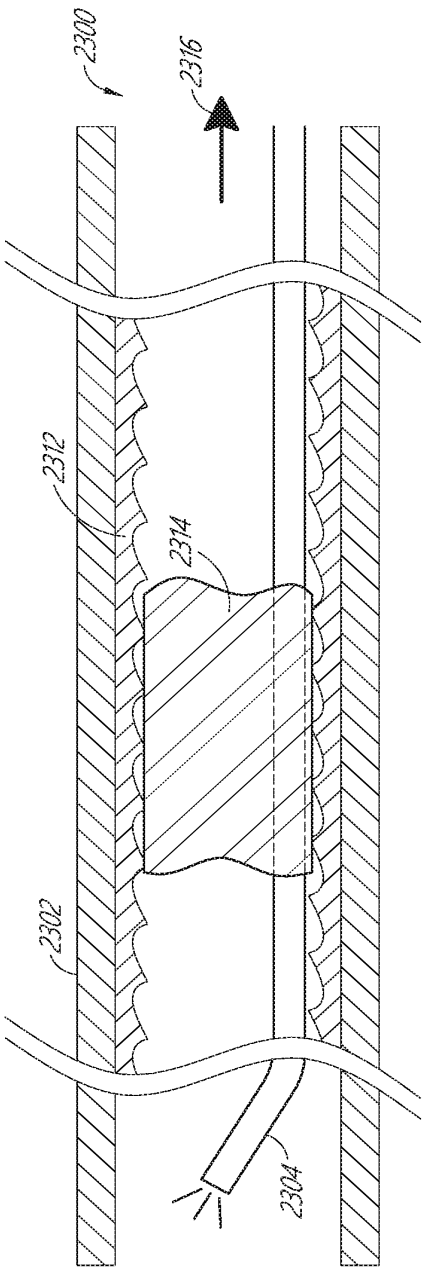


FIG. 23A

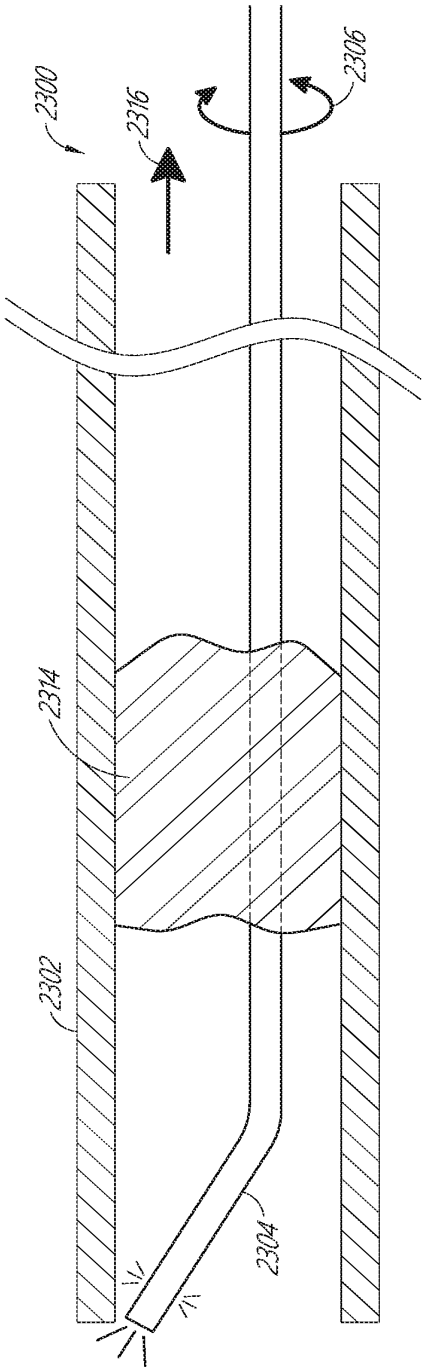


FIG. 23B

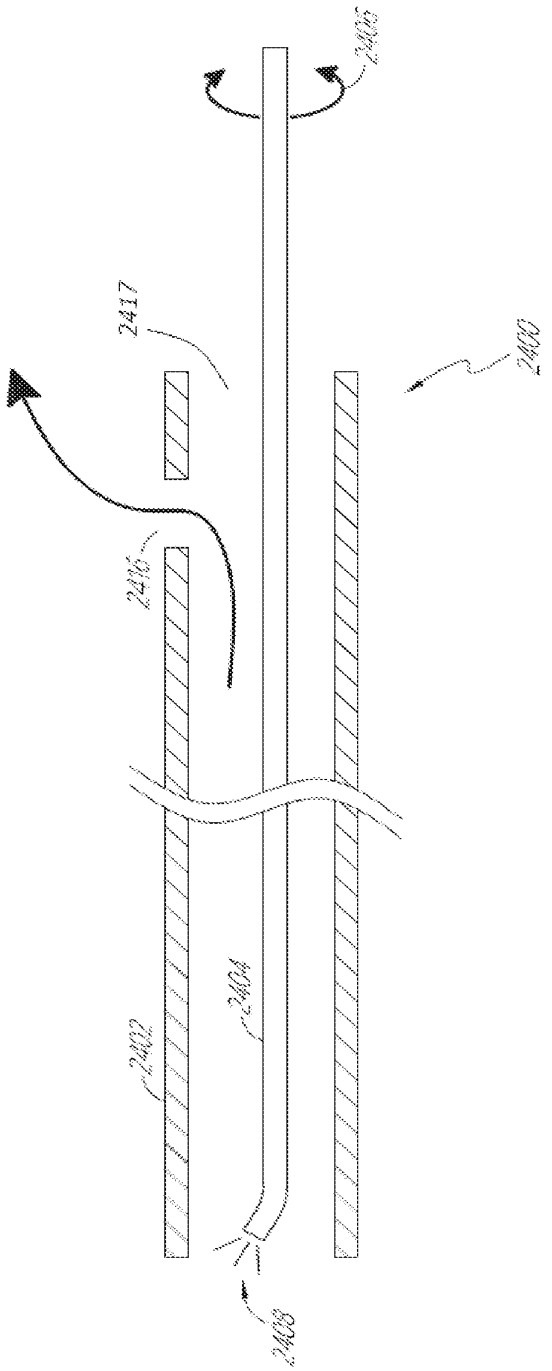


FIG. 24

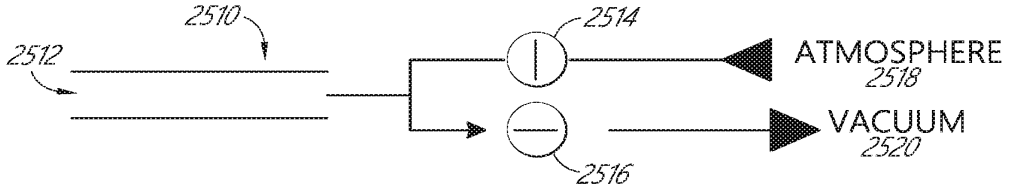


FIG. 25A

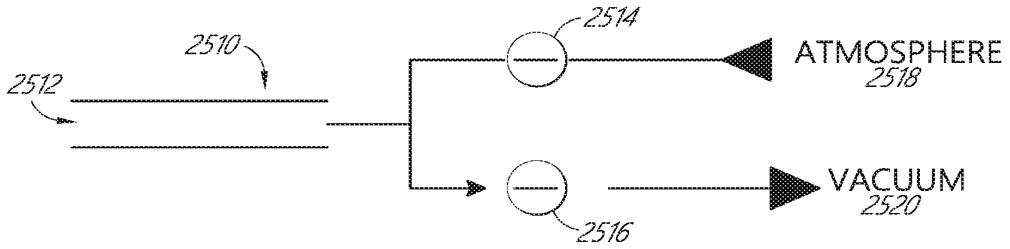


FIG. 25B

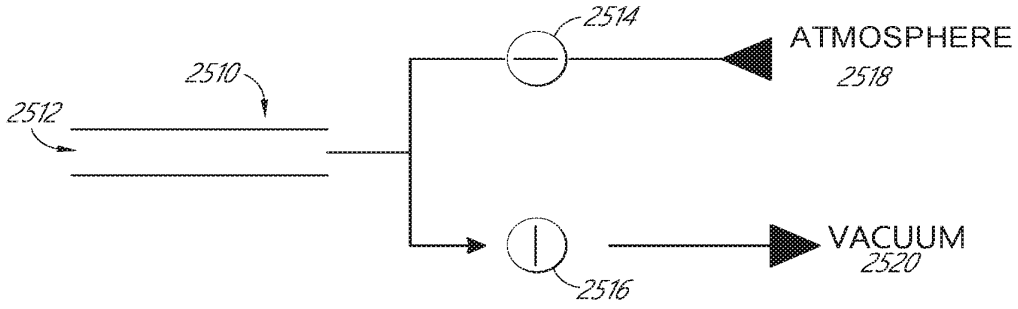


FIG. 25C

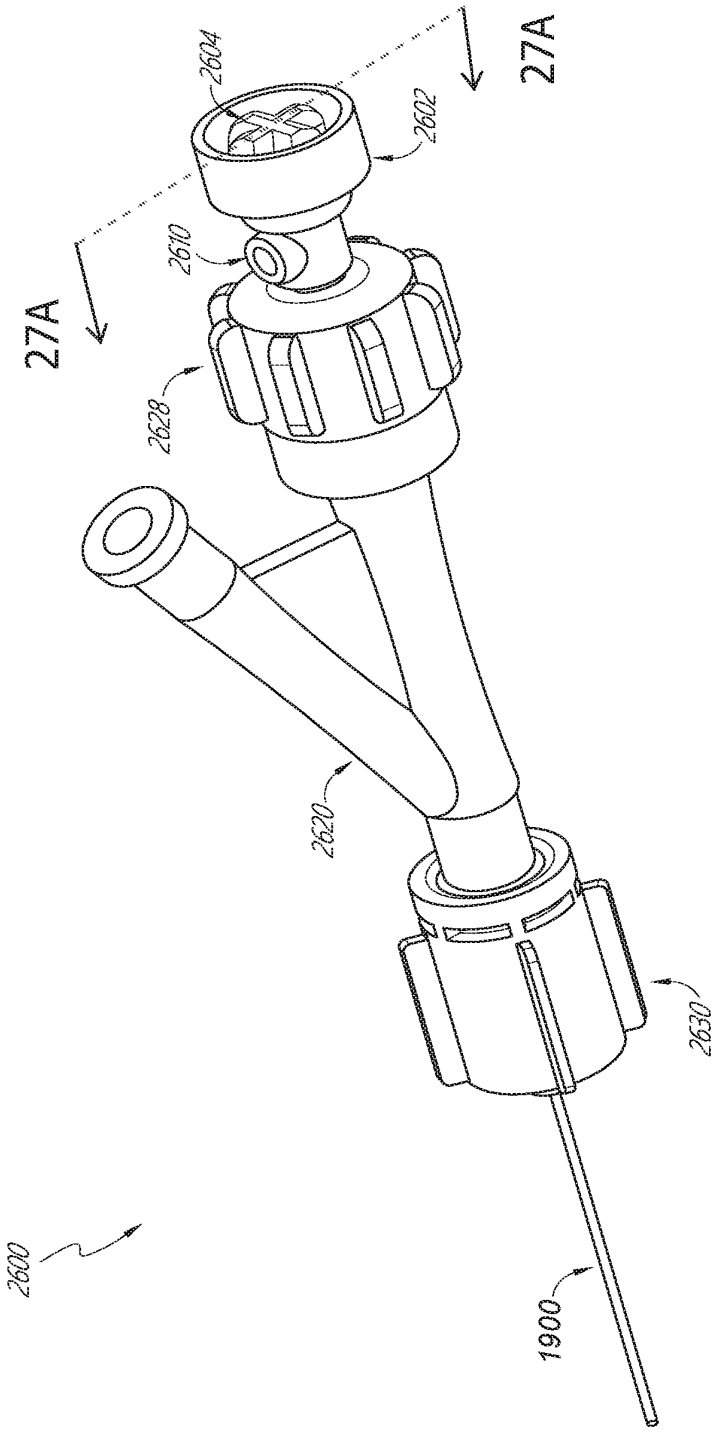


FIG. 26

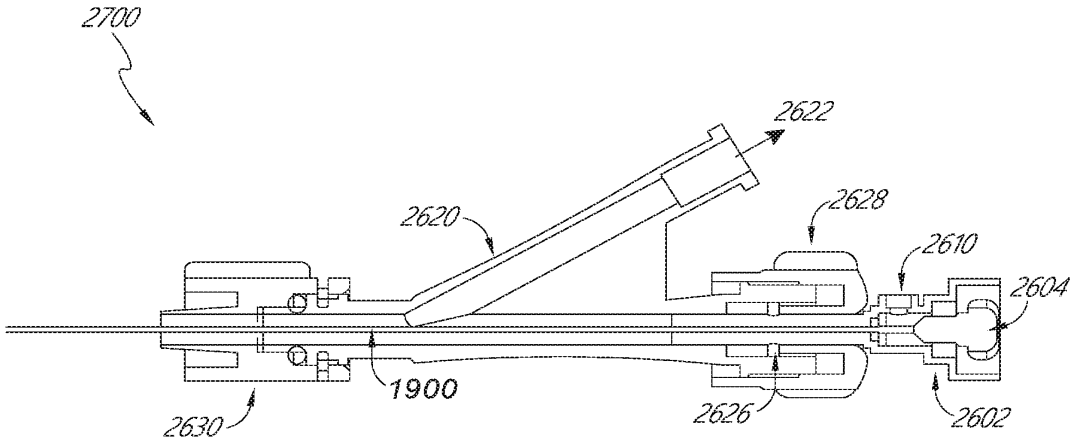


FIG. 27A

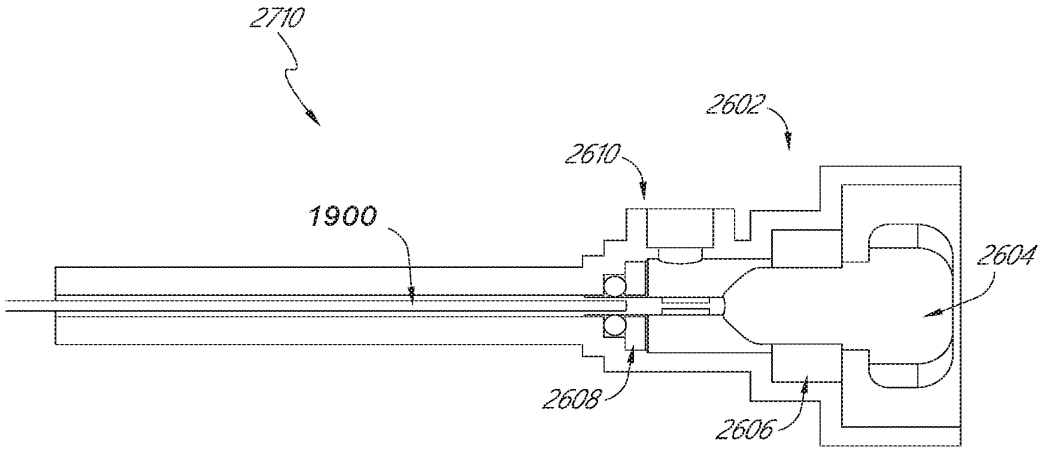


FIG. 27B

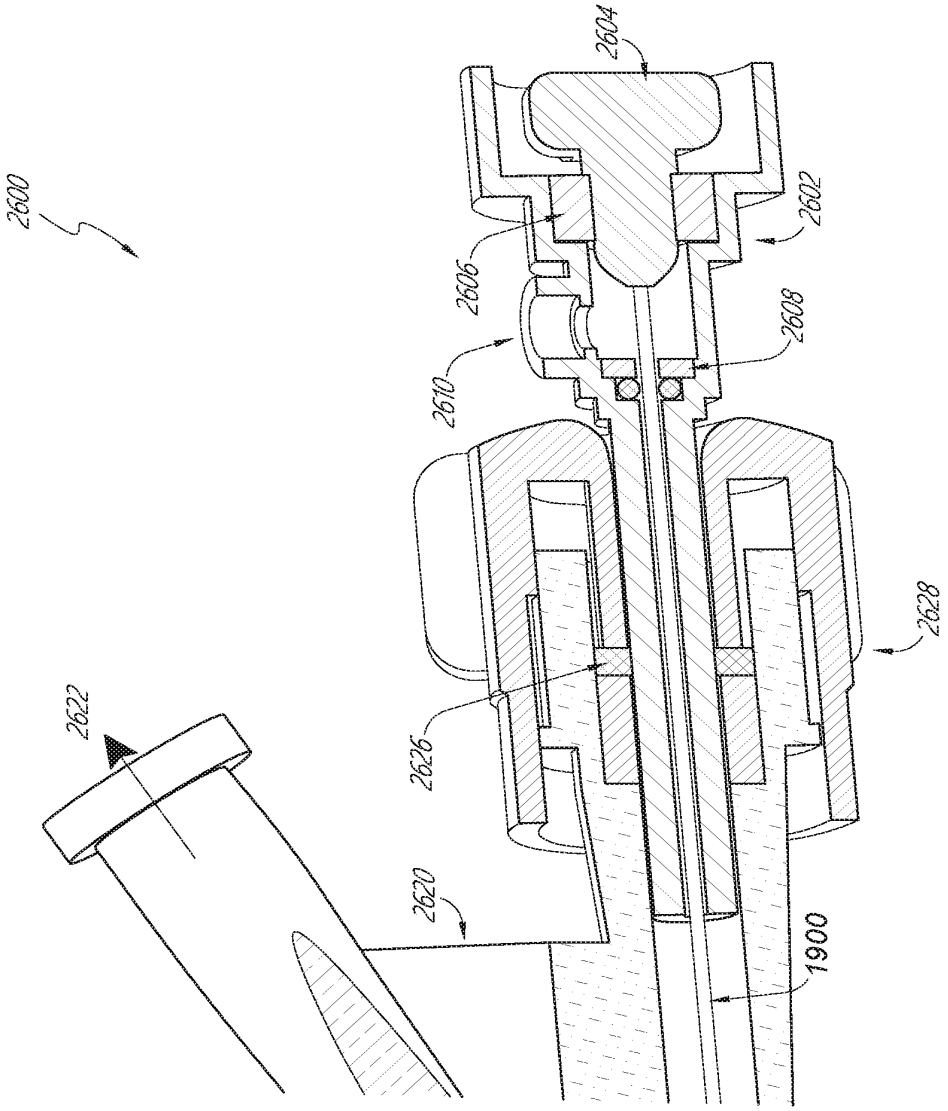


FIG. 28

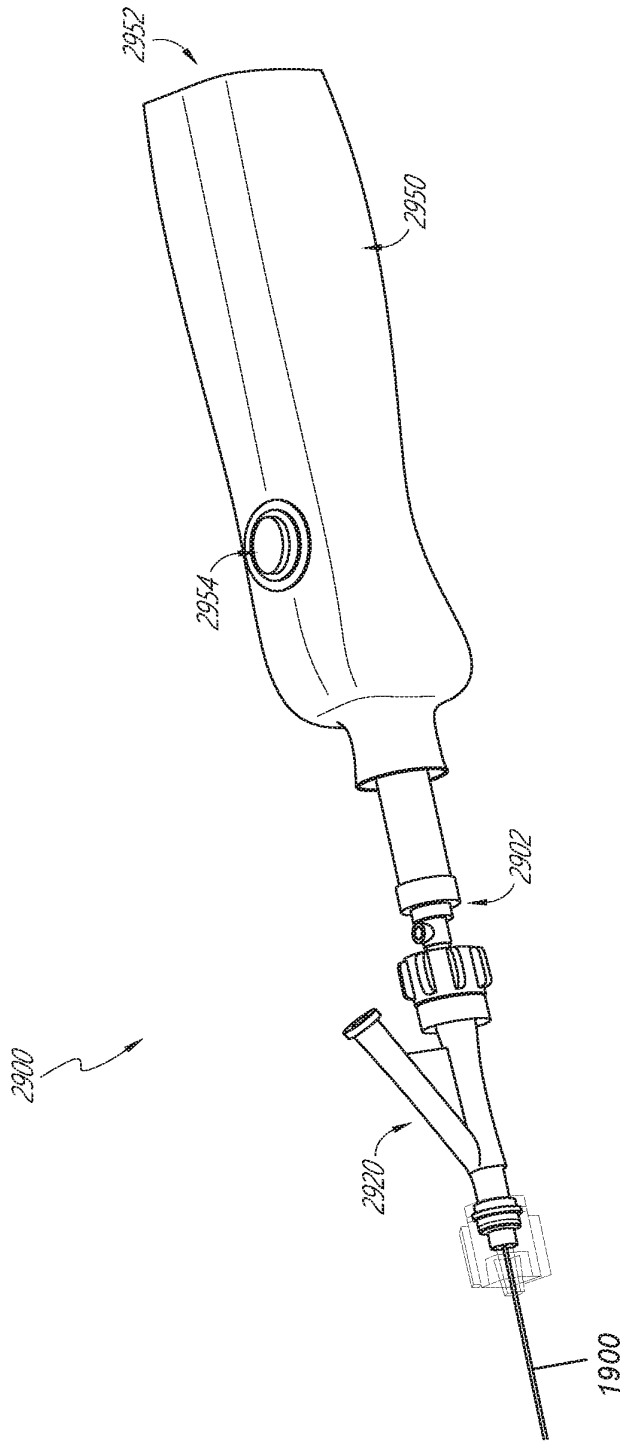


FIG. 29

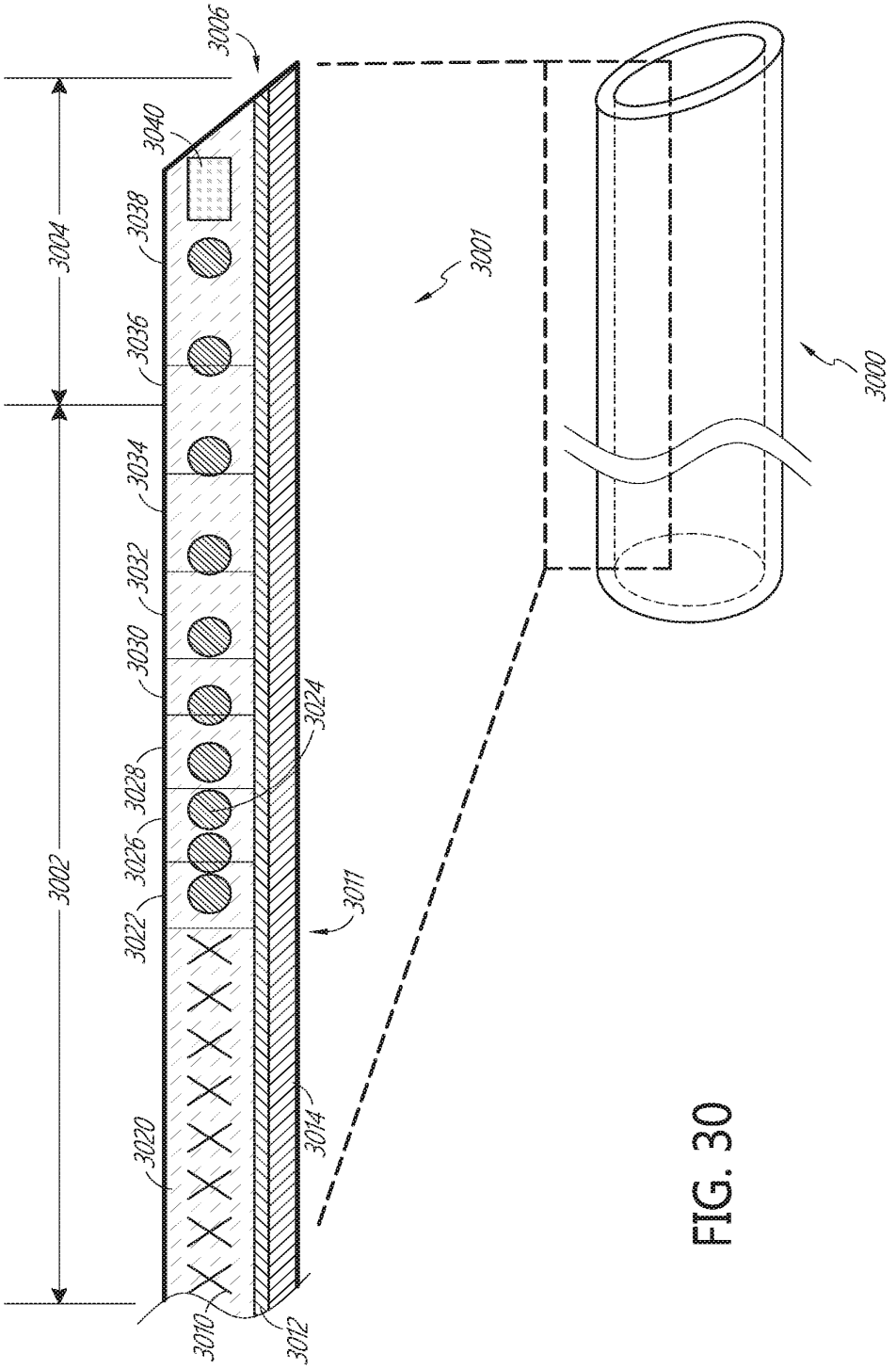

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FIG. 30

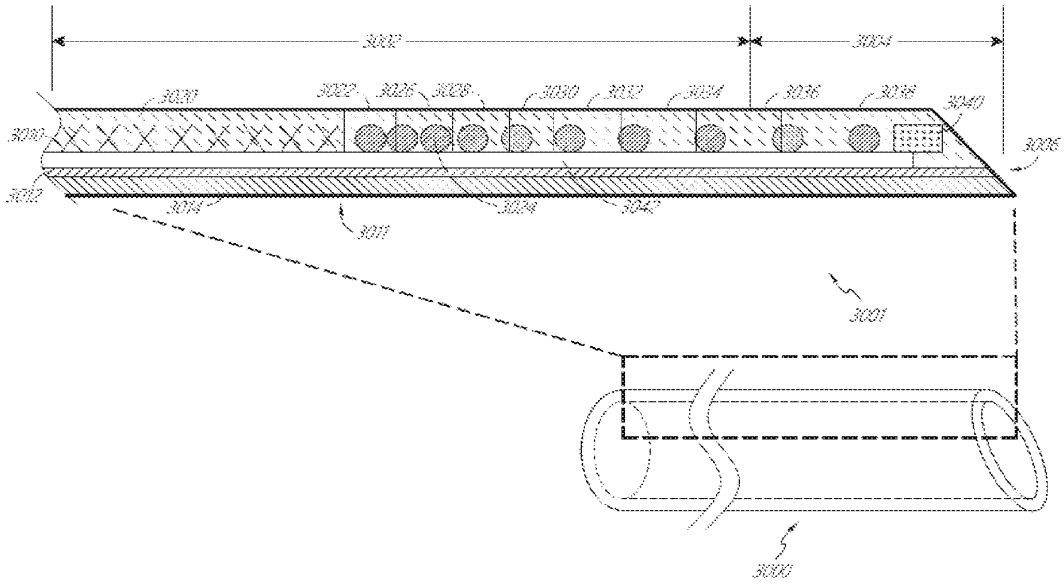


FIG. 31A

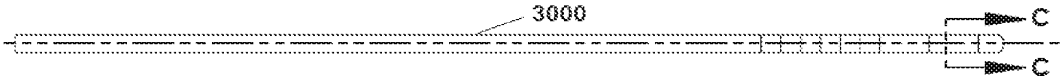


FIG. 31B

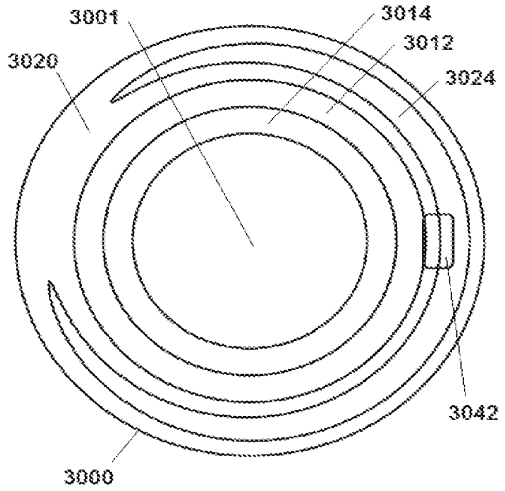


FIG. 31C

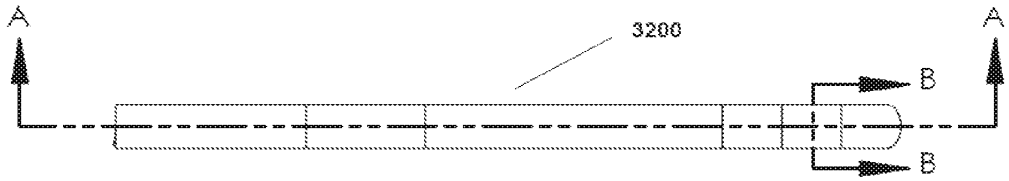


FIG. 32A

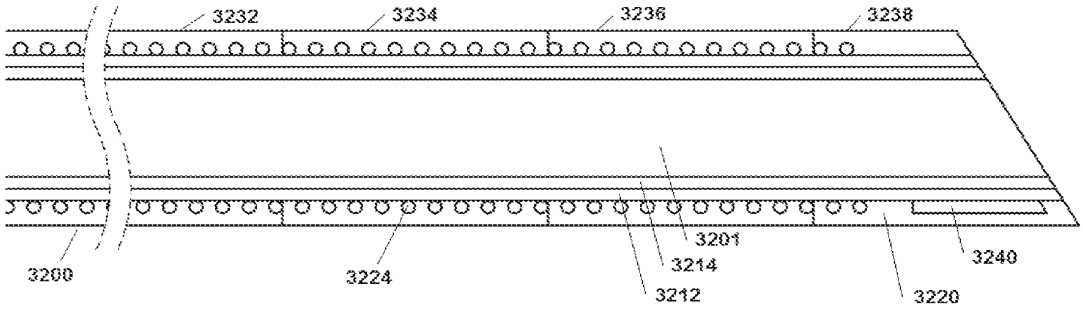


FIG. 32B

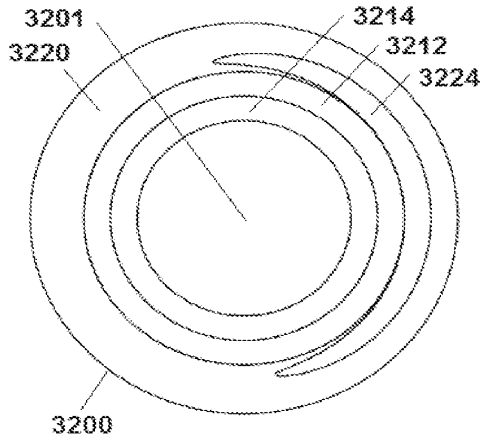


FIG. 32C

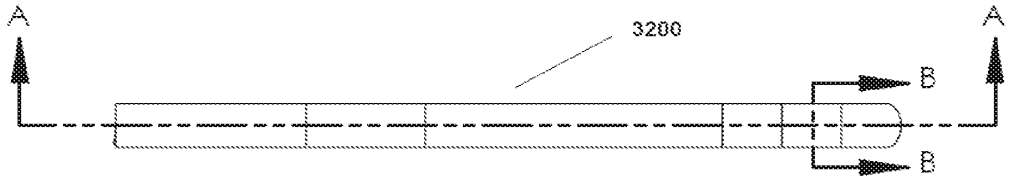


FIG. 33A

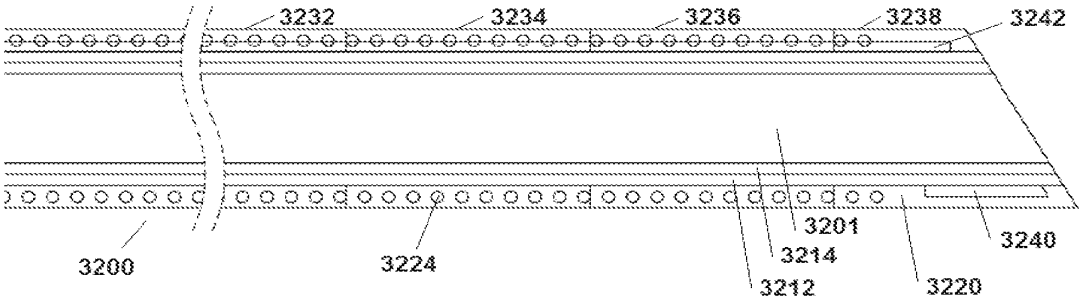


FIG. 33B

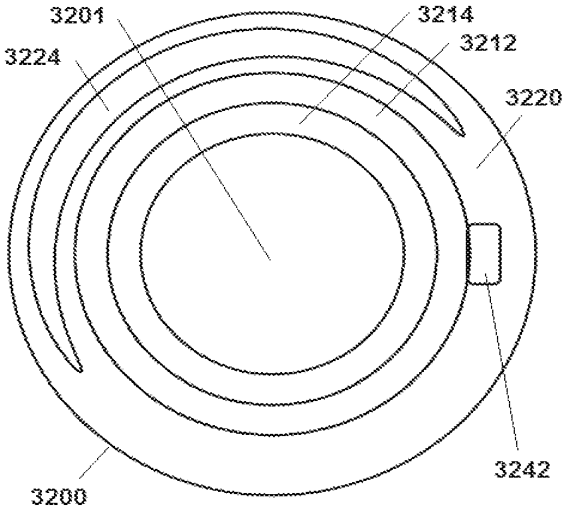


FIG. 33C

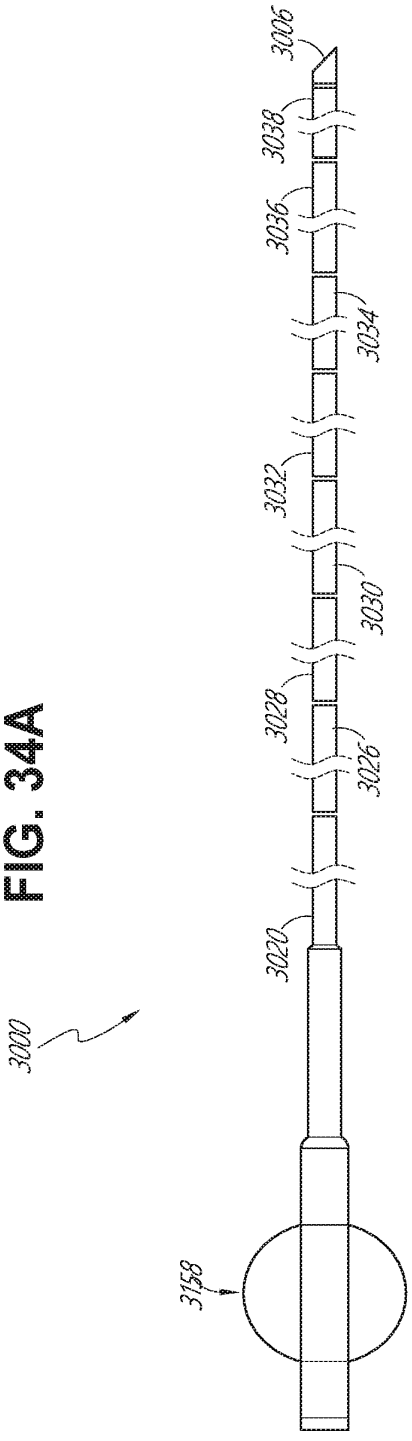


FIG. 34A

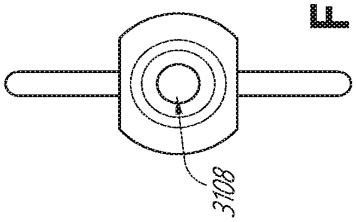


FIG. 34B

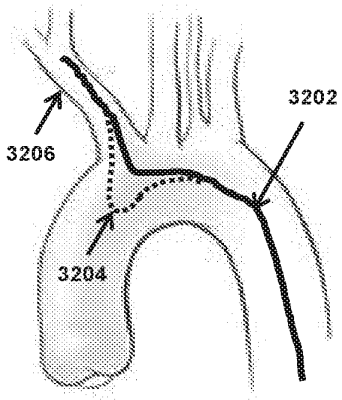

3206
3202
3204

FIG. 35

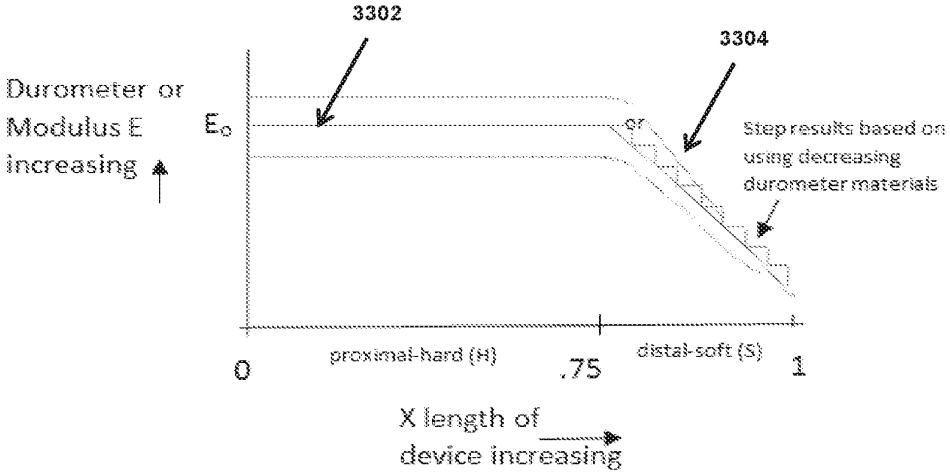

3302
3304
Durometer or
Modulus E
increasing
E_o
or
Step results based on
using decreasing
durometer materials
0
proximal-hard (H)
.75
distal-soft (S)
1
X length of
device increasing

FIG. 36

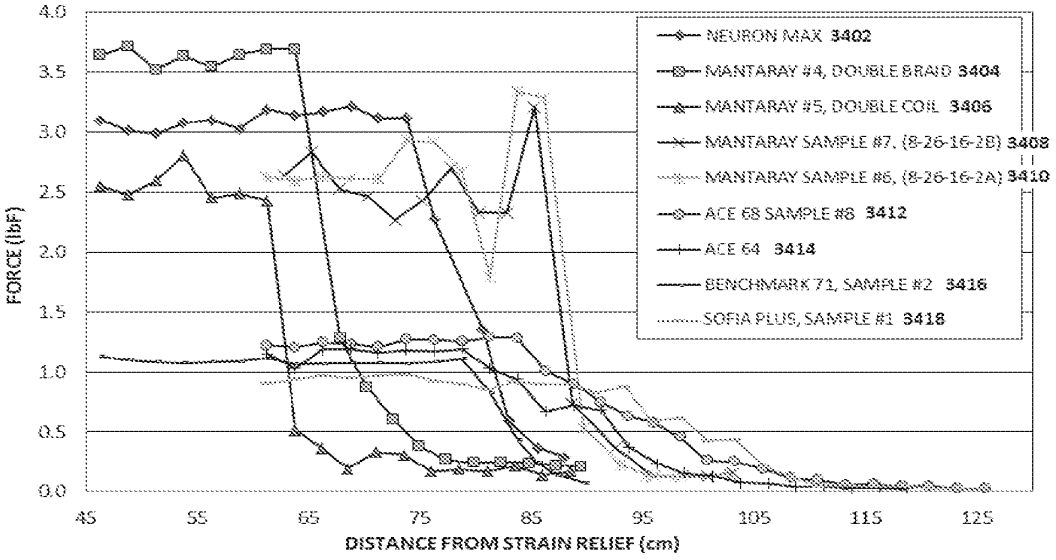

4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
FORCE (lbF)
45
55
65
75
85
95
105
115
125
DISTANCE FROM STRAIN RELIEF (cm)
NEURON MAX 3402
MANTARAY #4, DOUBLE BRAID 3404
MANTARAY #5, DOUBLE COIL 3406
MANTARAY SAMPLE #7, (8-26-16-2B) 3408
MANTARAY SAMPLE #6, (8-26-16-2A) 3410
ACE 68 SAMPLE #8 3412
ACE 64 3414
BENCHMARK 71, SAMPLE #2 3416
SOFIA PLUS, SAMPLE #1 3418

FIG. 37

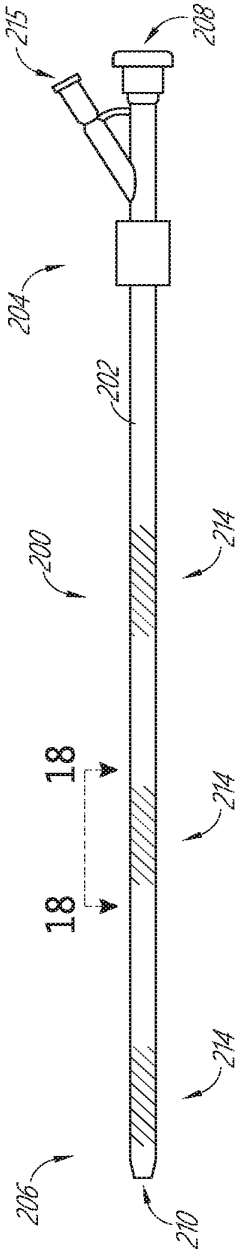


FIG. 38

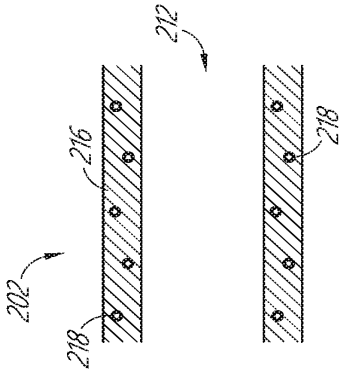


FIG. 39

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/019453

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/00; A61M 25/00; A61M 25/01; A61M 29/00 (2017.01)

CPC - A61M 25/0053; A61M 25/0012; A61M 25/0045; A61M 25/005; A61M 25/0051; A61M 25/0054; A61M 25/0662; A61M 25/09; A61M 25/104 (2017.02)

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
USPC - 604/525; 604/264; 604/523; 604/524; 604/526; 604/527 (keyword delimited)

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 2013/0046285 A1 (GRIFFIN et al) 21 February 2013 (21.02.2013) entire document	1, 3-13
A	US 2004/0153049 A1 (HEWITT et al) 05 August 2004 (05.08.2004) entire document	1-18, 64-81
A	US 2007/0016132 A1 (OEPEN et al) 18 January 2007 (18.01.2007) entire document	1-18, 64-81
A	US 2010/0049168 A1 (PARKER et al) 25 February 2010 (25.02.2010) entire document	1-18, 64-81

☐ 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	Date of mailing of the international search report
17 May 2017	09 JUN 2017
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/019453

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 extra sheet(s).

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.:
1-18, 64-81

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.

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Penumbra, Inc. v. RapidPulse, Inc.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/019453

Continued from Box No. III Observations where unity of invention is lacking

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 need to be paid.

Group I, claims 1-18, 64-81 are drawn to a flexible catheter with variably flexible tubular segments.
Group II, claims 19-31, 82-103 are drawn to a catheter with an expanding distal opening.
Group III, claims 32-42 are drawn to a catheter having an agitator, driver and vacuum port.
Group IV, claims 43-63, 104-123 are drawn to a neurovascular catheter with a control filament.

The inventions listed in Groups I, II, III, and IV 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 special technical features of Group I, dip coating a removable mandrel to form a tubular inner layer on the mandrel; coating the tubular inner layer with a soft tie layer; applying a helical coil to the outside of the tie layer; positioning a plurality of tubular segments on the helical coil; the plurality of segments having durometers that decrease in a distal direction; heating the tubular segments to form the high flexibility distal zone on the neurovascular catheter; and removing the mandrel, are not present in Groups II, III, or IV; the special technical features of Group II, a control for advancing the distal section from a first, proximally retracted position within the proximal section to a second, extended position, extending distally beyond the proximal section; and an active tip on the distal end of the distal section, comprising a distal opening that is movable between a smaller and a larger configuration, an opening at the distal end which is enlargeable from a first inside diameter for transluminal navigation to a second, larger inside diameter to facilitate aspiration of thrombus into the lumen, are not present in Groups I, III, and IV; the special technical features of Group III, an agitator extendable through the central lumen of the tubular body to position a distal end of the agitator near a distal end of the tubular body; a driver connectable to a proximal end of the agitator and configured to actuate the agitator; and a vacuum port near the proximal end of the tubular body and in fluid communication with the central lumen of the tubular body, are not present in Groups I, II, or IV; and the special technical features of Group IV, an axially extending filament within the side wall, extending at least about the most distal 10 cm of the length of the catheter, an elongate flexible control wire, having a proximal end and a distal end; a tubular extension segment having a side wall defining a central lumen carried by the distal end of the control wire, are not present in Groups I, II, or III.

Groups I, II, III, and IV share the technical features of a medical system comprising an elongate, flexible tubular body, comprising at least one central lumen extending along its longitudinal length. However, these shared technical features do not represent a contribution over the prior art. Specifically, US 2002/0139785 A1 to Peacock, III et al. teaches of a medical system (Abstract) comprising an elongate, flexible tubular body (Fig. 1, catheter 10 is a flexible tubular body, para. [0010]), comprising at least one central lumen extending along its longitudinal length (Fig. 1, inner lumen 14 extends along the catheter 10, para. [0023]).

Groups I and II share the technical features of a medical system comprising an elongate flexible tubular body, having a proximal end, a distal end and a side wall defining a central lumen, a distal zone of the tubular body comprising: a tubular inner liner; a tie layer separated from the lumen by the inner liner; a helical coil surrounding the tie layer; an outer jacket surrounding the helical coil. However, these shared technical features do not represent a contribution over the prior art. Specifically, US 2002/0139785 A1 to Peacock, III et al. teaches of a medical system (Abstract) comprising an elongate flexible tubular body (Fig. 1, catheter 10 is a flexible tubular body, para. [0010]), having a proximal end, a distal end and a side wall defining a central lumen (Fig. 1, inner lumen 14 extends along the catheter 10, para. [0023]), a distal zone of the tubular body comprising: a tubular inner liner (Fig. 1, inner lining 13, para. [0023]); a tie layer separated from the lumen by the inner liner (Fig. 1, adhesive 18 is separate from lumen 14 by lining 13, para. [0023]); a helical coil surrounding the tie layer (Fig. 1, coil 15 includes spaces 16, wherein the adhesive 18 is within the spaces 16, the coil thereby surrounds the adhesive layer 18, para. [0023]); an outer jacket surrounding the helical coil (Fig. 1, outer jacket 17 surrounding the coil 15, para. [0023]).

Groups I and IV share the technical features of a medical system comprising a tubular extension segment having a side wall defining a central lumen carried by the distal end of the control wire, the side wall comprising: a tubular inner liner; a tie layer separated from the lumen by the inner liner; a helical coil surrounding the tie layer; and an outer jacket surrounding the helical coil. However, these shared technical features do not represent a contribution over the prior art. Specifically, US 2002/0139785 A1 to Peacock, III et al. teaches of a medical system (Abstract) comprising an elongate flexible tubular body (Fig. 1, catheter 10 is a flexible tubular body, para. [0010]), having a proximal end, a distal end and a side wall defining a central lumen (Fig. 1, inner lumen 14 extends along the catheter 10, para. [0023]), a distal zone of the tubular body comprising: a tubular inner liner (Fig. 1, inner lining 13, para. [0023]); a tie layer separated from the lumen by the inner liner (Fig. 1, adhesive 18 is separate from lumen 14 by lining 13, para. [0023]); a helical coil surrounding the tie layer (Fig. 1, coil 15 includes spaces 16, wherein the adhesive 18 is within the spaces 16, the coil thereby surrounds the adhesive layer 18, para. [0023]); an outer jacket surrounding the helical coil (Fig. 1, outer jacket 17 surrounding the coil 15, para. [0023]).

Groups II and III share the technical features of a medical system comprising an elongate, flexible tubular body, comprising a proximal section having at least one lumen, the lumen configured to facilitate aspiration of thrombus into the lumen. However, these shared technical features do not represent a contribution over the prior art. Specifically, US 2007/0106211 A1 to Provost-Time et al. teaches of a medical system (Abstract) comprising an elongate, flexible tubular body (Fig. 1, catheter 10 is a flexible tubular body, para. [0027] & [0015]), comprising a proximal section having at least one lumen (Fig. 1, aspiration lumen 12, para. [0027]), the lumen configured to facilitate aspiration of thrombus into the lumen (Fig. 1, wherein the aspiration lumen 12 is configured to aspirate a thrombus therethrough, para. [0027] & [0015]).

Since none of the special technical features of the Group I, II, III, and IV inventions are found in more than one of the inventions, unity is lacking.

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Penumbra, Inc. v. RapidPulse, Inc.

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International Bureau

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01 February 2018 (01.02.2018)

W!P O | PCT

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(30) Priority Data:
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62/474,383 21 March 2017 (21.03.2017) US

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(54) Title: A CLOT RETRIEVAL SYSTEM FOR REMOVING OCCLUSIVE CLOT FROM A BLOOD VESSEL

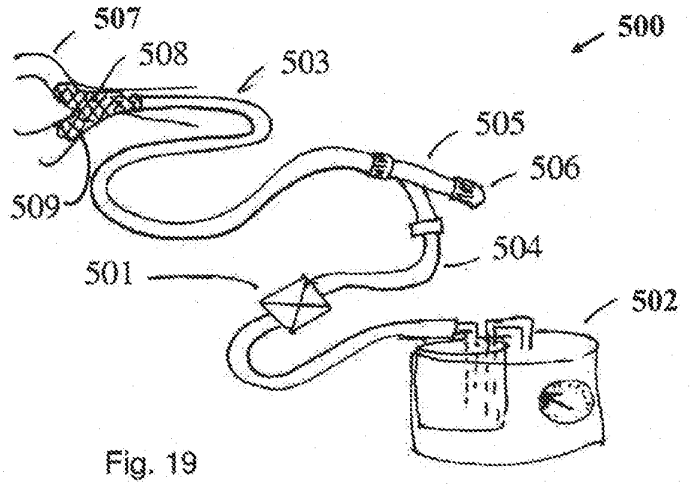


Fig. 19

(57) Abstract: A system for removing occlusive clot from a blood vessel comprises a catheter and an apparatus for generating a pulsatile vacuum force to pulse the pressure gradient at a distal end of the catheter. The pulse generator may be integral with or separate from the vacuum pump. The pulse generator may be applied to a flexible tubing between the vacuum pump and the proximal end of the catheter.

[Continued on next page]

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"A clot retrieval system for removing occlusive clot from a blood vessel"

Field of the Invention

This invention relates to devices intended for removing acute blockages from blood vessels. 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 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 suffering from pulmonary embolism (PE) and from other peripheral arterial and venous vessels in which clot is causing an occlusion.

Background

Despite a wealth of information in the literature on the clotting cascade and on the biochemistry and etiology of thrombus in humans, remarkably little information is available on the physical and mechanical properties of this material. These properties are very pertinent to the interaction between thrombus and clot retrieval catheters and devices and the surrounding vasculature during mechanical thrombectomy of vessels occluded by thrombus material. Through extensive experimentation and research into thrombus material the inventors have discovered aspects of the properties and behaviour of certain clot/thrombus types that help to explain why these clot types can be particularly challenging to retrieve. Some of these findings are described in our WO2012/120490A, the entire contents of which are herein incorporated by reference.

Clot properties

Clot is essentially a living polymer, comprising a matrix of intertwined and cross linked fibrin strands within which are situated red and white blood cells, platelets and numerous other proteins and components. The inventors have discovered that the mechanical properties of a clot are strongly influenced by the relative percentages of fibrin and red blood cells, and that clots with a high (and highly organised) fibrin content and low red blood cell content tend to be much firmer

and more cohesive than clots of a higher red cell content. Such clots have also been found to have a higher coefficient of friction, or in other words to be "stickier". These firm and sticky clots can be very challenging to remove from a vessel.

Clots with a low fibrin content and high red cell content have been found to be less cohesive and more friable and to have a lower coefficient of friction than the more organised fibrin rich clots previously described. These properties mean that such clots may be easier to dislodge from the site of occlusion, but may tend to fragment during the retrieval process, with the consequent risk of loss of clot fragments into distal or new vascular territories.

Furthermore, the inventors have discovered that the fibrin matrix of the clot can result in the clot material exhibiting viscoelastic behaviour in certain circumstances. A series of experiments were carried out in which a range of clots of varying fibrin content were tested. The clot samples were held in a receptacle and an indentor was placed on the surface of the clot and subject to a fixed indenting force. The depth of penetration of the indentor into the clot was measured as a function of time for each clot type. Clots with a high fibrin content and low red blood cell content were found to exhibit the greatest viscoelastic effect, with the indentor effectively "creeping" into the clot over a period of several minutes, whereas with low fibrin content clots the indentor tended to almost fully penetrate the clots in a matter of seconds, greater levels of organisation (and clot maturity) of the fibrin structure resulted in firmer clots which were penetrated to a much lesser extent by the indentor.

This behaviour combined with the higher frictional properties of fibrin rich clots tend to make these clot types particularly challenging to retrieve by mechanical thrombectomy. Conventional stent-retrievers may find it difficult to penetrate and grip these firm clots, and the high level of friction they maintain with the vessel wall can result in a tendency for the clot to roll and compress.

Attempts to aspirate such clots into a catheter can also be very challenging as the clot must be deformed in order to fit into the catheter lumen, and the energy required to deform such clots is not easily attained by aspiration. The high frictional coefficient of these clot types adds further to the challenge of aspirating them into the distal mouth of a catheter. Even maintaining a suction grip on such clots so that they can be retracted to the safety of a more proximal guide or sheath is very difficult, as these firm clots do not tend to deform and reshape easily and thus do

not readily conform to the shape of the catheter tip in order to effect a seal and consequent suction grip.

Statements of the Invention

This invention solves the challenge of aspirating fibrin rich clot material into a catheter by addressing the key challenges of 1) the friction between the clot and the catheter and 2) the energy/work required to deform these firm clots as they are aspirated into the catheter tip.

Conventional clot aspiration involves inserting a catheter (sometimes referred to as an intermediate catheter or aspiration catheter or distal access catheter) into the patient's vasculature and advancing the catheter up to the occlusive clot. A syringe or vacuum pump is then attached to the proximal end of the catheter and a vacuum applied to attempt to suck the clot into the catheter tip and out through the catheter. The level of the vacuum applied can be controlled to a very limited extent by the force applied to the syringe or by the pump setting, and typically a fairly constant pressure drop of 500mmHg to 760mmHg (or "full" vacuum) is applied. The difference in pressure between the blood vessel in which the clot is situated and the interior of the catheter creates a pressure gradient (which may exceed 760mmHg as the patient's blood pressure is higher than atmospheric pressure) which urges the clot into the catheter mouth.

The diameter of the clot however is greater than the diameter of the catheter therefore for a clot to be aspirated into a catheter the clot must deform and elongate to fit into the catheter tip. The energy to deform the clot to fit into the catheter is effectively an extrusion energy as the catheter tip acts as a form of extrusion die for the clot. This extrusion energy is related to the fibrin content of the clot with higher fibrin clots requiring increased extrusion energy to aspirate the clot into the catheter. Current techniques to aspirate the clot involve applying a steady state vacuum to the tip of the catheter; however in many cases this does not provide sufficient energy to aspirate the clot fully into the catheter. Subsequent retrieval of the catheter either does not dislodge the clot or dislodges the partially retrieved clot and creates the risk of losing the partially exposed clot into a side branch or new vessel creating an ENT (Embolization in New Territory).

This invention improves the ability of a catheter to aspirate a clot fully, including clots which have higher fibrin content. As stated above, vacuum is applied to the catheter tip to create a pressure differential between the catheter and the blood vessel with the aim of aspirating or

sucking the clot into the catheter and out of the vasculature. When the apparatus detailed in this invention is operating, the steady state vacuum normally applied at the tip of the catheter is modified to a pulsatile or wave configuration so that in one design configuration, the pressure differential between the catheter tip and the blood vessel plotted against time resembles a sine wave. The application of the aspiration force to the clot in a wave or pulsatile configuration applies an 'impact load' to the clot which can deform the clot and overcome the resistance or extrusion energy required to get the clot into the catheter more quickly and effectively than applying a continuous or steady aspiration force.

In addition, when clot occludes the distal tip of an aspiration catheter, part of the clot is inside the tip of the catheter. Testing has shown that compression and manipulation of thrombus increases the friction of the clot. Therefore compression of the clot at the tip of the catheter further increases the static friction between the clot and the inside surface of the catheter tip. The static friction between the clot and the catheter needs to be overcome to allow the clot to be aspirated fully into the catheter. The application of a pulsatile force to the clot can cause the clot to vibrate or move slightly proximally and distally, so that the interaction between the clot and the internal surface of the catheter changes from static friction to a dynamic friction interaction. Dynamic friction of clot has been shown in our testing to be lower than static friction therefore the total force to remove the clot is reduced when using the apparatus detailed in this invention.

The fibrin matrix of a thrombus is porous and red blood cells can migrate and flow within the matrix depending on pressure differentials and fibrin density. Applying a pulsatile energy or vacuum at the catheter tip can promote this movement of clot elements, allowing the red blood cells to be aspirated out of the fibrin matrix. The thrombus is then easier to aspirate as the red blood cell content of the clot decreases facilitating deformation of the fibrin matrix with reduced energy.

This invention is suitable for the aspiration of clots with varying fibrin content from 0% to 100%, and is particularly suited to the aspiration of clot or thrombus which has fibrin content greater than 30%. The invention relates to the removal of a blood clot from the human vascular system. In particular it more specifically relates to the removal of a blood clot from the neurovasculature including the anterior and posterior circulation. Techniques and means of removing blood clots, or clotted blood particles in the form of emboli are already well known and established in use. When the presence of a clot is identified in the body it may be treated by

best medical treatment (BMT) in the form of medication or by surgical intervention. Surgical intervention can involve the use of mechanical means to dislodge and remove the clot. Blood clots may also be identified and referred to as emboli. Surgical intervention may be in the form of minimally invasive endovascular intervention where by the clot or embolism is accessed within the blood vessel by the distal end of a catheter that has been introduced within the arterial system at a remote location such as the Common Iliac artery. This is well known and relevant to the background of this invention.

Referring to an endovascular intervention described herein one of the means used to effect the removal of a clot through surgical endovascular intervention, is to use what is commonly referred to as 'aspiration' of the clot mass through a catheter. Aspiration is a technique whereby negative pressure or suction can be applied to the clot mass within the blood vessel through the distal end of a catheter, the catheter being connected at the proximal end to a vacuum source.

It is well known that there are clots which cannot be moved or removed even with the maximum intensity of vacuum or aspiration being applied to them. The present invention relates to but is not limited to this situation and to the removal of these types of arduous blood clots. This invention presents and describes a method of removing blood clots by applying a pulsatile energy comprising of a sequence of alternating forces through the distal tip of a catheter which is adjacent to or abutting the blood clot wherein this sequence of pulsatile forces applied to the clot and having the effect of deforming the clot in addition to aspirating the clot back through the catheter. The pulsatile force may also be described as being in the form of a sequence of pulses applied to the clot over a period of time, commonly referred do as frequency. Each pulse comprises of a sequential positive and negative volumetric displacement of fluid at the catheter distal tip. This cyclical positive and forward projecting pressure followed by negative pressure can be described mathematically in general but not limited to a sinusoidal function.

It is known that the aspiration function applies a negative force in the form of negative pressure of approximately 500 - 760 millimetres of mercury (mm Hg) at the tip of the catheter creating a flow from the distal to the proximal end of the catheter and recovering the content of this flow in a container which is part of the circuit and located close to the vacuum source. This pulsatile sequence of positive and negative pressures are applied through the catheter in conjunction with the aspirated negative pressure. The source of the pulsatile force is separate and independent of the source of the aspirated suction.

Waveforms which represent the sequence of pulsatile positive and negative pressures constitute inventive steps.

It is well known that there are clots which cannot be moved or removed by the level of aspiration being applied to them. The present invention relates to the removal of these types of clots. The invention describes in method of applying pulsatile force through a catheter at the distal tip to the clot which has the effect of aspirating the clot in one or more pieces and retrieving it into the catheter. The pulsatile force is in the form of a sequence of pulses applied to the clot over a period of time. Each pulse comprises of a sequential positive and negative volumetric displacement of fluid at the catheter distal tip or varying negative volumetric displacements.

This period cycle of varying negative pressure can be described mathematically in general but not limited to a sinusoidal function. The pulsatile sequence of pressures are applied in conjunction with the application of a steady state negative pressure / suction force. It has also been observed as a further inventive step that the blood clot can be recovered by applying the pulse without any aspiration.

With regard to the sinusoidal profile of the pressure emitted at the tip of the catheter then the pressure profile may vary about a pure sine wave in the following ways. A sine wave can be described for this purpose as having four components to it which are equal in frequency and amplitude but may be positive or negative. If the first part of the wave is an increasing pressure induced by the forward motion of a piston then the second part will be a negative pressure caused by a reverse motion of the piston. The piston is driven by a shaft or connecting rod that is rotated in a cycle along the length of the shaft and thus directing the piston in a forward and reverse motion. In terms of the since wave describing this motion the first part of the curve indicating the increasing pressure is referred to as the rise time. The next part of the curve which represents a reverse motion of the piston and results in negative pressure at the catheter tip, this is referred to as the fall time or the decay time. The curve has one positive peak and one negative peak in each cycle. In a sequence of cycles constituting a sequence of pulses, the time from peak to peak is the same in a sine wave. The peak of a sine wave can be said to have no duration as the intensity or amplitude of the wave is changing continuously even as it transitions from positive to negative.

The present invention describes wave profiles applied at the catheter tip which can be at variance to a pure sine wave in the following manner. One is that the rise time may not be equal to the decay time. The rise time may be longer or shorter duration that the fall time duration. Secondly the peak of the wave may have a duration or a dwell time. The purpose of the dwell time is to allow fluid or blood some time to fill into the space in the piston chamber or time to pass through the orifice at the end of the chamber.

The nature of the pulse applied to dislodge and retrieve the blood clot can be defined by the following variables or control aspects:

- Reciprocation
- Frequency
- Amplitude
- Rise time
- Dwell time
- Decay / Fall time

While the application of the reciprocal motion of both positive and negative displacement in sequence is not well known, there are a number of methods available that are well known for reciprocal motion as described.

One is a purely mechanical cyclical drive system whereby the moving piston within the chamber is connected to crank shaft or the outer radius of a disk which is rotated so as to drive the piston to and fro. This to and fro distance is known as the stroke length. It is well known to use this method in positive displacement pumps but not positive and negative displacement in sequence.

Another well known method of generating reciprocal motion is by electromechanical means using electromagnetic induction whereby a magnetic field is induced in a coil of wire or alternately in two coils of wire for more control over different forces in each direction to create the forces necessary to move the piston to and fro in the chamber

The source of the power can be an alternating current and voltage or a direct current whereby the positive and negative cycles are achieved by switching mode control circuit.

As mentioned heretofore the cyclical motion which results in a symmetrical sinusoidal wave form of positive and negative pressure is the simplest. It may be desirable to alter the shape of the wave form so that the negative pressure is greater than the positive pressure or so that the rate of increase in pressure is greater of less than the rate of decline in pressure. It is recognised herein that there may be an advantage in having no or less positive pressure than negative pressure so that vibration of the clot mass is reduced. It is recognised and presented as an inventive step that the introduction of dwell time on the peak and the trough of the wave form allows time for the fluid displacement to take place on both the positive and negative parts of each cycle. This is more relevant and important as the frequency of the cycles increases.

According to the invention there is provided a system for removing occlusive clot from a blood vessel comprising a vacuum source and collection chamber, a catheter to communicate the negative pressure to the location of the clot, and an apparatus to modify a steady state vacuum provided by a vacuum source to a series of pulses or a waveform configuration. In one iteration this apparatus contains a mechanical drive system whereby a moving piston within a fluid chamber is connected to crank shaft or the outer radius of a disk which is rotated so as to drive the piston to and fro creating a positive and negative fluid displacement in sequence. This variable fluid displacement is combined with the steady state vacuum or negative displacement provided by the vacuum pump to produce a waveform pressure differential between the catheter and the blood pressure at the tip of the catheter adjacent to the clot in the vasculature.

In one iteration the reciprocal motion to create the positive and negative fluid displacement is generated by electromechanical means using electromagnetic induction whereby a magnetic field is induced in a coil of wire or alternately in two coils of wire for more control over different forces in each direction to create the forces necessary to move a piston to and fro in the fluid chamber.

In another iteration the fluid displacement is generated by moving the piston using other electromechanical means such as the piezoelectric effect.

In another iteration the fluid displacement is generated using other mechanical means such as a pneumatic drive.

In one configuration of the invention, the apparatus to create the pulsatile or waveform pressure differential is separate to the vacuum pump and chamber and is connected through tubing and connectors. In another iteration the apparatus of the invention and the vacuum pump are integrated in a single unit.

In one embodiment of the invention the piston to generate the pressure differential at the catheter tip is located within the catheter body which acts as the fluid chamber. The piston is moved proximally and distally in the catheter through a linear connection to a drive system located at the proximal end of the catheter. Alternatively the piston is moved in the catheter through electronic means positioned within the catheter.

In one configuration of the invention, the apparatus to create the fluid displacement to produce a waveform pressure differential contains a single piston in a fluid chamber which is moved forward and back using a mechanical or electromechanical drive. In a different configuration of the apparatus multiple fluid chambers with pistons are connected to facilitate complex waveforms. The displacement output of the apparatus can then be a summation of the displacements of each piston which can be programmed to operate independently.

In one iteration of the device the piston used to create the fluid displacement is similar to a syringe with a moving seal between the piston and the fluid chamber. In another iteration other known hydraulic cylinder configurations are used to produce different waveform configurations.

In another iteration of the invention the tip of the catheter is vibrated by electromechanical means to reduce the friction between the catheter and the clot and help overcome the extrusion or deformation energy required to aspirate the clot. The catheter tip vibration can be combined with a large aspiration lumen with a cross sectional area greater or equivalent to a 0.030" diameter lumen and in the preferred embodiment has a cross sectional area greater or equivalent to a 0.040" diameter lumen. The catheter with the vibrating tip may be used with a steady state aspiration vacuum or with the waveform pressure differential as described elsewhere in the patent. The frequency of the tip vibration may range from 5 Hz to ultrasonic frequencies of greater than 20,000 Hz.