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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 17/498,642 | 10/11/2021 | Richard Quick | 111552.8023.US02 | 1040 |

25096 7590 06/25/2024

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

| EXAMINER | |
|---|---|
| NGUYEN, TUAN VAN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3771 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 06/25/2024 | ELECTRONIC |

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

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

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

patentprocurement@perkinscoie.com



*Imperative Care v. Inari Medical*
US Patent 12,016,580
**Imperative Care Ex. 1002**

**INARI_017207**

| APPLICATION NO. | ISSUE DATE | PATENT NO. |
|---|---|---|
| 17/498,642 | 25-Jun-2024 | 12016580 |

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PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

# EGRANT NOTIFICATION

Your electronic patent grant (eGrant) is now available, which can be accessed via Patent Center at https://patentcenter.uspto.gov

The electronic patent grant is the official patent grant under 35 U.S.C. 153. For more information, please visit https://www.uspto.gov/electronicgrants

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|---|---|---|---|---|
| 17/498,642 | 06/25/2024 | 12016580 | 111552.8023.US02 | 1040 |

25096 7590 06/05/2024

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PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

# ISSUE NOTIFICATION

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

The USPTO is implementing electronic patent issuance with a transition period, during which period the USPTO will mail a ceremonial paper copy of the electronic patent grant to the correspondence address of record. Additional copies of the patent (i.e., certified and presentation copies) may be ordered for a fee from the USPTO's Certified Copy Center at https://certifiedcopycenter.uspto.gov/index.html. The Certified Copy Center may be reached at (800)972-6382.

**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 Center (https://patentcenter.uspto.gov).

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

INVENTOR(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional inventors):

Richard Quick, Mission Viejo, CA;
Benjamin Edward Merritt, San Clemente, CA;
John Coleman Thress, Capistrano Beach, CA;
Paul Lubock, Monarch Beach, CA;
Thomas M. Tu, Louisville, KY;

APPLICANT(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional applicants):

Inari Medical, Inc., Irvine, CA;

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.

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | Not Yet Assigned |
| | **Examiner Name** | Not Yet Assigned |
| | **Attorney Docket Number** | 111552-8023.US02 |

| | | | | | |
|---|---|---|---|---|---|
| | 194. | 20150032144 | 01-29-2015 | Holloway | |
| | 195. | 20150059908 | 03-05-2015 | Mollen | |
| | 196. | 20150088190 | 03-26-2015 | Jensen | |
| | 197. | 20150127035 | 05-07-2015 | Trapp et al. | |
| | 198. | 20150133990 | 05-14-2015 | Davidson | |
| | 199. | 20150150672 | ~~05-07-2017~~ | Ma 06/2015 | |
| | 200. | 20150164523 | 06-18-2015 | Brady et al. | |
| | 201. | 20150164666 | 06-18-2015 | Johnson et al. | |
| | 202. | 20150190155 | 07-09-2015 | Ulm III | |
| | 203. | 20150190156 | 07-09-2015 | Ulm III | |
| | 204. | 20150196380 | 07-16-2015 | Berrada et al. | |
| | 205. | 20150196744 | 04-03-2018 | Aboytes | |
| | 206. | 20150209058 | 07-30-2015 | Ferrera et al. | |
| | 207. | 20150209165 | 07-30-2015 | Grandfield et al. | |
| | 208. | 20150238207 | 08-27-2015 | Cox et al. | |
| | 209. | 20150250578 | 09-10-2015 | Cook et al. | |
| | 210. | 20150265299 | 09-24-2015 | Cooper et al. | |
| | 211. | 20150305756 | 10-29-2015 | Rosenbluth | |
| | 212. | 20150305859 | 10-29-2015 | Eller | |
| | 213. | 20150352325 | 12-10-2015 | Quick | |
| | 214. | 20150360001 | 12-17-2015 | Quick | |
| | 215. | 20150374391 | 12-31-2015 | Quick | |
| | 216. | 20160008014 | 08-09-2016 | Rosenbluth | |
| | 217. | 20160022293 | 01-28-2016 | Dubrul et al. | |
| | 218. | 20160058540 | 03-03-2016 | Don Michael | |
| | 219. | 20160074627 | 03-17-2016 | Cottone | |
| | 220. | 20160106448 | 04-21-2016 | Brady et al. | |
| | 221. | 20160106449 | 04-21-2016 | Brady et al. | |
| | 222. | 20160113663 | 04-28-2016 | Brady et al. | |
| | 223. | 20160113664 | 04-28-2016 | Brady et al. | |
| | 224. | 20160113665 | 04-28-2016 | Brady et al. | |
| | 225. | 20160113666 | 04-28-2016 | Quick | |
| | 226. | 20160143721 | 05-26-2016 | Rosenbluth | |

Change(s) applied to document,
/B.P./
11/20/2023



ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.V.N/

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25096 7590 05/01/2024

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| NGUYEN, TUAN VAN | |

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| 05/01/2024 | ELECTRONIC |

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

patentprocurement@perkinscoie.com

| **Supplemental**<br>***Notice of Allowability*** | **Application No.**<br>17/498,642 | **Applicant(s)**<br>Quick et al. | |
|---|---|---|---|
| | **Examiner**<br>TUAN V NGUYEN | **Art Unit**<br>3771 | **AIA (FITF) Status**<br>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 Information Disclosure Statement filed February 14, 2024.
   ☐ 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 21-31 and 41-63 . 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 _____.

/TUAN V NGUYEN/
Primary Examiner, Art Unit 3771

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

**U.S. PATENTS AND PUBLICATIONS**

| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|---|---|---|---|---|---|
| | 1. | 11890180 | 02-06-2024 | Merritt et al. | |
| | 2. | 20140163615 | 06-12-2014 | Gadlage et al. | |
| | 3. | 5323514 | 06-28-1994 | Masuda et al. | |
| | 4. | 5911728 | 06-15-1999 | Sepetka et al. | |
| | 5. | 20200129741 | 04-30-2020 | Kawwas et al. | |
| | 6. | | | | |
| | 7. | | | | |
| | 8. | | | | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initial* | Cite No | Foreign Document Number[3] | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[5] |
|---|---|---|---|---|---|---|
| | | WO2012114633 | 08-30-2012 | TERUMO KABUSHIKI KAISHA | | |

**NON-PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T[5] |
|---|---|---|---|
| | | English translation of Japanese Office Action received for JP Application No. 2022-574456, Applicant: Inari Medical, Inc, Date of Mailing: January 23, 2024, 12 pages. | |

**EXAMINER SIGNATURE**

| Examiner Signature | /TUAN V NGUYEN/ | Date Considered | 04/28/2024 |
|---|---|---|---|

*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. /T.V.N/

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

## CERTIFICATION STATEMENT

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

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

**OR**

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

☐ See attached certification statement.

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

☒ None

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

### COPIES OF REFERENCES

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

## SIGNATURE

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

| | | | |
|---|---|---|---|
| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2024-02-14 |
| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

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



ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.V.N/

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 17/498,642 | 10/11/2021 | Richard Quick | 111552.8023.US02 | 1040 |

25096 7590 03/27/2024

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| EXAMINER | |
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| NGUYEN, TUAN VAN | |

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| 03/27/2024 | ELECTRONIC |

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patentprocurement@perkinscoie.com

| **Supplemental**<br>***Notice of Allowability*** | **Application No.**<br>17/498,642 | **Applicant(s)**<br>Quick et al. | |
|---|---|---|---|
| | **Examiner**<br>TUAN V NGUYEN | **Art Unit**<br>3771 | **AIA (FITF) Status**<br>Yes |

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1. ☑ This communication is responsive to the filling of Information Disclosure Statement on February 26, 2024.
   ☐ 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 21-31 and 41-63 . 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.
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2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
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4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
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7. ☐ Other _____.

/TUAN V NGUYEN/
Primary Examiner, Art Unit 3771

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

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| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

| U.S. PATENTS AND PUBLICATIONS | | | | | |
|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | 1. | 20200129741 | 04-30-2020 | Kawwas et al. | |
| | 2. | 2018014840 | 01-18-2018 | Panian | |
| | 3. | 20240058113 | 02-22-2024 | Strauss et al. | |
| | 4. | | | | |
| | 5. | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Foreign Document Number[3] | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[5] |
| | | | | | | |

| NON-PATENT LITERATURE DOCUMENTS | | | |
|---|---|---|---|
| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T[5] |
| | | Chinese First Office Action received for CN Application No. 201980067623.1, Applicant: Inari Medical, Inc., Date of Mailing: January 31, 2024, 10 pages. | |

| EXAMINER SIGNATURE | | | |
|---|---|---|---|
| Examiner Signature | /TUAN V NGUYEN/ | Date Considered | 03/22/2024 |

*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. /T.V.N/

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

## CERTIFICATION STATEMENT

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

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

**OR**

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

☐ See attached certification statement.

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

☒ None

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

### COPIES OF REFERENCES

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

## SIGNATURE

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

| | | | |
|---|---|---|---|
| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2024-02-26 |
| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

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



ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.V.N/

## PART B – FEE(S) TRANSMITTAL

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

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

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

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence 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. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

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

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

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

**Certificate of Mailing or Transmission**

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

| | |
|---|---|
| JiYoung Anderson | (Typed or printed name) |
| /JiYoung Anderson/ | (Signature) |
| 2024.02.28 | (Date) |

| APPLICATION NO | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO | CONFIRMATION NO |
|---|---|---|---|---|
| 17/498,642 | Oct 11, 2021 | Richard Quick | 111552.8023.US02 | 1040 |

TITLE OF INVENTION: SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

| APPLN. TYPE | ENTITY STATUS | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|---|---|---|---|---|---|---|
| UTILITY | LARGE | 1200 | 0 | 0 | 1200 | 2024-05-28 |

| EXAMINER | ART UNIT | CLASS-SUBCLASS |
|---|---|---|
| Tuan Nguyen | 3771 | 606-200000 |

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/AIA/47 or PTO/SB/47; Rev 03-09 or more recent) attached. Use of a Customer Number is required.

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

1. Perkins Coie LLP
2.
3.

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

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

(A) NAME OF ASSIGNEE: Inari Medical, Inc.

(B) RESIDENCE: (CITY and STATE or COUNTRY): Irvine, CA

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

4a. Fees Submitted: ☑ Issue Fee ☐ Publication Fee (if required)

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

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

☑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 50-0665

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

☐ Applicant certifying micro entity status. See 37 CFR 1.29. 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.

☐ Applicant asserting small entity status. See 37 CFR 1.27. NOTE: If the application was previously under micro entity status, checking this box will be taken as a notification of loss of entitlement to micro entity status.

☐ Applicant changing to regular undiscounted fee status. NOTE: Checking this box will be taken as a notification of loss of entitlement to small or micro entity status, as applicable.

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

Authorized Signature /Matthew S. Williams/ Date 2024-02-28

Typed or printed name Matthew S. Williams Registration No. 77,516

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

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

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

## Privacy Act Statement

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

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

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

UNITED STATES
PATENT AND TRADEMARK OFFICE

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

# ELECTRONIC PAYMENT RECEIPT

| APPLICATION # | RECEIPT DATE / TIME | ATTORNEY DOCKET # |
|---|---|---|
| **17/498,642** | **02/28/2024 06:06:59 PM Z ET** | **111552.8023.US02** |

## Title of Invention

SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

## Application Information

| | | | |
|---|---|---|---|
| APPLICATION TYPE | Utility - Nonprovisional Application under 35 USC 111(a) | PATENT # | - |
| CONFIRMATION # | 1040 | FILED BY | JiYoung Anderson |
| PATENT CENTER # | 64490077 | AUTHORIZED BY | Matthew Williams |
| CUSTOMER # | 25096 | FILING DATE | 10/11/2021 |
| CORRESPONDENCE ADDRESS | - | FIRST NAMED INVENTOR | Richard Quick |

## Payment Information

| PAYMENT METHOD | PAYMENT TRANSACTION ID | PAYMENT AUTHORIZED BY |
|---|---|---|
| **CARD / 5111** | **E20242RI07296240** | **JiYoung Anderson** |

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

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

**New Applications Under 35 U.S.C. 111**

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

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

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

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

**New International Application Filed with the USPTO as a Receiving Office**

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

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
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# ELECTRONIC ACKNOWLEDGEMENT RECEIPT

| APPLICATION # | RECEIPT DATE / TIME | ATTORNEY DOCKET # |
|---|---|---|
| **17/498,642** | **02/28/2024 06:06:59 PM Z ET** | **111552.8023.US02** |

## Title of Invention

SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

## Application Information

| | | | |
|---|---|---|---|
| APPLICATION TYPE | Utility - Nonprovisional Application under 35 USC 111(a) | PATENT # | - |
| CONFIRMATION # | 1040 | FILED BY | JiYoung Anderson |
| PATENT CENTER # | 64490077 | FILING DATE | 10/11/2021 |
| CUSTOMER # | 25096 | FIRST NAMED INVENTOR | Richard Quick |
| CORRESPONDENCE ADDRESS | - | AUTHORIZED BY | Matthew Williams |

## Documents

**TOTAL DOCUMENTS: 2**

| DOCUMENT | PAGES | DESCRIPTION | SIZE (KB) |
|---|---|---|---|
| 2024.2.28 Comments - 111552.8023.US02.pdf | 2 | Miscellaneous Incoming Letter | 90 KB |
| 2024.2.28 Issue Fee Transmittal - 111552.8023.US02.pdf | 2 | Issue Fee Payment (PTO-85B) | 238 KB |

## Digest

| DOCUMENT | MESSAGE DIGEST(SHA-512) |
|---|---|
| 2024.2.28 Comments - 111552.8023.US02.pdf | A7921948275CDE7CE487B23B5B2BF148B2C5562406AD781CD E2CF281AB2CE92004E6DD5BF64CA559AFE24F5D2BA0215FB 39B6653C41FEC743AAAEB1B0BF3012E |

| | |
|---|---|
| 2024.2.28 Issue Fee Transmittal - 111552.8023.US02.pdf | 86B038BDF1E3F2C164DD2CD9BB9E31D6536A5B615C819BAA 68E17C76F832FE1F9D4F344C45A190C52073B2D2DCD9F43F C7841D3DBADDDBE60013E50E32246788 |

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

**New Applications Under 35 U.S.C. 111**

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

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

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**New International Application Filed with the USPTO as a Receiving Office**

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

In re Application of:
Richard Quick et al.

Application No.: 17/498,642 | Confirmation No.: 1040

Filed: October 11, 2021 | Art Unit: 3771

For: SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS | Examiner: Tuan Van Nguyen

**COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE**

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

Dear Commissioner:

In the Notice of Allowability mailed November 8, 2023, the Examiner allowed claims 21–31 and 41–63. The Applicant acknowledges the Examiner's statements of Reasons for Allowance of the above-referenced patent application and agrees that the claimed subject matter is patentable. However, the Applicant takes no position regarding the Reasons for Allowance presented by the Examiner other than the positions Applicant may have previously taken during prosecution. Therefore, the Examiner's Reasons for Allowance should not be attributed to the Applicant as an indication of the basis for the Applicant's belief that the claims are patentable. Furthermore, the Applicant respectfully asserts that there may also be additional reasons for patentability of the claimed subject matter not explicitly stated in this record and the Applicant does not waive its rights to such arguments by not further addressing such reasons herein.

Dated: February 28, 2024

Respectfully submitted,

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

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

Attorneys for Applicant

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
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# NOTICE OF ALLOWANCE AND FEE(S) DUE

25096 7590 02/28/2024

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

| EXAMINER | |
|---|---|
| NGUYEN, TUAN VAN | |
| **ART UNIT** | **PAPER NUMBER** |
| 3771 | |

DATE MAILED: 02/28/2024

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 17/498,642 | 10/11/2021 | Richard Quick | 111552.8023.US02 | 1040 |

TITLE OF INVENTION: SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

| APPLN. TYPE | ENTITY STATUS | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|---|---|---|---|---|---|---|
| nonprovisional | UNDISCOUNTED | $1200 | $0.00 | $0.00 | $1200 | 05/28/2024 |

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

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

**HOW TO REPLY TO THIS NOTICE:**

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

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

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

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

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

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

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

## PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

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 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. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

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

25096 7590 02/28/2024
PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

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 the USPTO patent electronic filing system or by facsimile to (571) 273-2885, on the date below.

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

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 17/498,642 | 10/11/2021 | Richard Quick | 111552.8023.US02 | 1040 |

TITLE OF INVENTION: SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

| APPLN. TYPE | ENTITY STATUS | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|---|---|---|---|---|---|---|
| nonprovisional | UNDISCOUNTED | $1200 | $0.00 | $0.00 | $1200 | 05/28/2024 |

| EXAMINER | ART UNIT | CLASS-SUBCLASS |
|---|---|---|
| NGUYEN, TUAN VAN | 3771 | 606-200000 |

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

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

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

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(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)

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

❑ Electronic Payment via the USPTO patent electronic filing system ❑ 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

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.

❑ Applicant asserting small entity status. See 37 CFR 1.27

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.

❑ Applicant changing to regular undiscounted fee status.

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

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

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

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 17/498,642 | 10/11/2021 | Richard Quick | 111552.8023.US02 | 1040 |

25096 7590 02/28/2024

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

| EXAMINER | |
|---|---|
| NGUYEN, TUAN VAN | |
| **ART UNIT** | **PAPER NUMBER** |
| 3771 | |

DATE MAILED: 02/28/2024

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

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

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

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

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

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

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

## Privacy Act Statement

**The Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/ owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).
https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to:

1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;

2) a federal, state, local, or international agency, in response to its request;

3) a contractor of the USPTO having need for the information in order to perform a contract;

4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;

5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;

6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;

7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;

8) 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));

9) the Office of Personnel Management (OPM) for personnel research purposes; and

10)the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

| Notice of Allowability | Application No. 17/498,642 | Applicant(s) Quick et al. | |
|---|---|---|---|
| | Examiner TUAN V NGUYEN | 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 request for Continued Examination filed November 21, 2023.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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

3. ☑ The allowed claim(s) is/are 21-31 and 41-63 . 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 _____.

/TUAN V NGUYEN/
Primary Examiner, Art Unit 3771

***Notice of Pre-AIA or AIA Status***

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

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on November 21, 2023 has been entered.

***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on November 21, 2023, January 17, 2024, January 18, 2024 and February 14, 2024 are being considered by the examiner.

***Allowable Subject Matter***

Claims 21-31 and 41-63 allowed.

Please see Office action dated June 26, 2023 for examiner's statement of reasons for allowance.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached Monday - Friday 8:30 AM - 5:30 PM.

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 published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TUAN V NGUYEN/
Primary Examiner, Art Unit 3771

| Search Notes | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 17/498,642 | Quick et al. |
| | Examiner | Art Unit |
| | TUAN V NGUYEN | 3771 |

| CPC - Searched* | | |
|---|---|---|
| **Symbol** | **Date** | **Examiner** |
| A61M1/60,0001,0003 | 06/17/2023 | TN |
| A61M39/0613 | 06/17/2023 | TN |
| A61B2017/22035,22079,22042,22094,22034 | 06/17/2023 | TN |
| A61B17/221,22031 | 06/17/2023 | TN |
| A61M25/01,0122,0082 | 06/17/2023 | TN |
| A61F2/95 | 06/17/2023 | TN |
| A61M2210/12 | 06/17/2023 | TN |

| 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** |
| Reviewed references cited in parent case | 06/17/2023 | TN |
| Group/subgroups combined with text (see search history printout) | 06/17/2023 | TN |
| Search update (see search history printout) | 11/01/2023 | TN |
| Search update (see search history printout) | 02/16/2024 | TN |

| /TUAN V NGUYEN/<br>Primary Examiner, Art Unit 3771 | |
|---|---|

| Search Notes | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 17/498,642 | Quick et al. |
| | Examiner | Art Unit |
| | TUAN V NGUYEN | 3771 |

| Interference Search | | | |
|---|---|---|---|
| **US Class/CPC Symbol** | **US Subclass/CPC Group** | **Date** | **Examiner** |
| Text search | USPAT; US_PGPUB | 11/01/2023 | TN |
| Text search | USPAT; US_PGPUB | 02/16/2024 | TN |

| | |
|---|---|
| /TUAN V NGUYEN/<br>Primary Examiner, Art Unit 3771 | |

| Issue Classification | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 17/498,642 | Quick et al. |
| | Examiner | Art Unit |
| | TUAN V NGUYEN | 3771 |

| CPC | | | | | | |
|---|---|---|---|---|---|---|
| Symbol | | | | | Type | Version |
| A61B | / | 17 | / | 22031 | F | 2013-01-01 |
| A61M | / | 25 | / | 0082 | I | 2013-01-01 |
| A61B | / | 17 | / | 22 | I | 2013-01-01 |
| A61M | / | 39 | / | 06 | I | 2013-01-01 |
| A61B | / | 17 | / | 221 | I | 2013-01-01 |
| A61B | / | 2017 | / | 22042 | A | 2013-01-01 |
| A61M | / | 2210 | / | 12 | A | 2013-01-01 |
| A61B | / | 2017 | / | 22079 | A | 2013-01-01 |
| A61B | / | 2017 | / | 22094 | A | 2013-01-01 |
| A61B | / | 2017 | / | 22034 | A | 2013-01-01 |
| A61B | / | 2017 | / | 00907 | A | 2013-01-01 |
| A61B | / | 2217 | / | 005 | A | 2013-01-01 |

| CPC Combination Sets | | | | | | | |
|---|---|---|---|---|---|---|---|
| Symbol | | | | | Type | Set | Ranking | Version |
| | / | | / | | | | | |

| NONE | | Total Claims Allowed: | |
|---|---|---|---|
| (Assistant Examiner) | (Date) | 34 | |
| /TUAN V NGUYEN/<br>Primary Examiner, Art Unit 3771 | 16 February 2024 | O.G. Print Claim(s) | O.G. Print Figure |
| (Primary Examiner) | (Date) | 1 | 1 |

U.S. Patent and Trademark Office — Part of Paper No.: 20240216

| Issue Classification | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 17/498,642 | Quick et al. |
| | Examiner | Art Unit |
| | TUAN V NGUYEN | 3771 |

| INTERNATIONAL CLASSIFICATION | | | | |
|---|---|---|---|---|
| CLAIMED | | | | |
| A61B | / | 17 | / | 22 |
| A61M | / | 25 | / | 00 |
| A61M | / | 39 | / | 06 |
| A61B | / | 17 | / | 221 |

| NON-CLAIMED | | | | |
|---|---|---|---|---|
| | / | | / | |

| US ORIGINAL CLASSIFICATION | |
|---|---|
| CLASS | SUBCLASS |
| | |

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

| NONE<br>(Assistant Examiner) | (Date) | Total Claims Allowed:<br>34 | |
|---|---|---|---|
| /TUAN V NGUYEN/<br>Primary Examiner, Art Unit 3771<br>(Primary Examiner) | 16 February 2024<br>(Date) | O.G. Print Claim(s)<br>1 | O.G. Print Figure<br>1 |

U.S. Patent and Trademark Office

Part of Paper No.: 20240216

| Issue Classification | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 17/498,642 | Quick et al. |
| | Examiner | Art Unit |
| | TUAN V NGUYEN | 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 | | 10 | | 19 | 8 | 28 | | 37 | 17 | 46 | 29 | 55 | | |
| | 2 | | 11 | | 20 | 12 | 29 | | 38 | 18 | 47 | 21 | 56 | | |
| | 3 | | 12 | 1 | 21 | 9 | 30 | | 39 | 19 | 48 | 22 | 57 | | |
| | 4 | | 13 | 2 | 22 | 10 | 31 | | 40 | 20 | 49 | 23 | 58 | | |
| | 5 | | 14 | 3 | 23 | | 32 | 11 | 41 | 24 | 50 | 30 | 59 | | |
| | 6 | | 15 | 4 | 24 | | 33 | 13 | 42 | 25 | 51 | 31 | 60 | | |
| | 7 | | 16 | 5 | 25 | | 34 | 14 | 43 | 26 | 52 | 32 | 61 | | |
| | 8 | | 17 | 6 | 26 | | 35 | 15 | 44 | 27 | 53 | 33 | 62 | | |
| | 9 | | 18 | 7 | 27 | | 36 | 16 | 45 | 28 | 54 | 34 | 63 | | |

| NONE<br>(Assistant Examiner) (Date) | Total Claims Allowed:<br>34 | |
|---|---|---|
| /TUAN V NGUYEN/<br>Primary Examiner, Art Unit 3771<br>(Primary Examiner) (Date) | 16 February 2024 | O.G. Print Claim(s)<br>1 | O.G. Print Figure<br>1 |

U.S. Patent and Trademark Office Part of Paper No.: 20240216

## Bibliographic Data

Application No: 17/498,642

Foreign Priority claimed: ○ Yes ◉ No

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

Verified and Acknowledged: /TUAN V NGUYEN/ Examiner's Signature | Initials

Title: SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

| FILING or 371(c) DATE | CLASS | GROUP ART UNIT | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 10/11/2021 | 606 | 3771 | 111552.8023.US02 |
| RULE | | | |

**APPLICANTS**

Inari Medical, Inc., Irvine, CA,

**INVENTORS**

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John Coleman Thress, Capistrano Beach, CA, UNITED STATES

Paul Lubock, Monarch Beach, CA, UNITED STATES

Thomas M. Tu, Louisville, KY, UNITED STATES

**CONTINUING DATA**

This application is a CON of 16258344 01/25/2019 PAT 11154314

16258344 has PRO of 62622691 01/26/2018

**FOREIGN APPLICATIONS**

**IF REQUIRED, FOREIGN LICENSE GRANTED****

10/20/2021

**STATE OR COUNTRY**

UNITED STATES

**ADDRESS**

PERKINS COIE LLP - SEA General

PATENT-SEA

P.O. BOX 1247

SEATTLE, WA 98111-1247

UNITED STATES

**FILING FEE RECEIVED**

$4,300

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

| U.S. PATENTS AND PUBLICATIONS | | | | | |
|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | 1. | 5391152 | 02-21-1995 | Patterson et al. | |
| | 2. | 20210404464 | 12-30-2021 | Patoskie | |
| | 3. | 5971958 | 10-26-1999 | Zhang | |
| | 4. | 3860006 | 01-14-1975 | Patel | |
| | 5. | 20130150793 | 06-13-2013 | Beissel et al. | |
| | 6. | 20230270991 | 08-31-2023 | Merritt et al. | |
| | 7. | 20190015298 | 01-17-2019 | Beatty et al. | |
| | 8. | 20180055999 | 03-01-2018 | Bare et al. | |
| | 9. | 20040019310 | 01-29-2004 | Hogendijk | |
| | 10. | 20080312681 | 12-18-2008 | Ansel et al. | |
| | 11. | 20170143359 | 05-25-2017 | Nguyen et al. | |
| | 12. | 20170143938 | 05-25-2017 | Ogle et al. | |
| | 13. | 20170281204 | 10-05-2017 | Garrison et al. | |
| | 14. | 8021351 | 09-20-2011 | Boldenow et al. | |
| | 15. | 1101890 | 06-30-1914 | TUNSTEAD | |
| | 16. | 10953195 | 03-23-2021 | Jalgaonkar et al. | |
| | 17. | 20210205577 | 07-08-2021 | Jalgaonkar et al. | |
| | 18. | 3416531 | 12-17-1968 | EDWARDS | |
| | 19. | 4981478 | 01-01-1991 | Evard et al. | |
| | 20. | 7815608 | 10-19-2010 | Schafersman et al. | |
| | 21. | 9662129 | 05-30-2017 | Galdonik et al. | |
| | 22. | 8070694 | 12-06-2011 | Galdonik et al. | |
| | 23. | 10058339 | 08-28-2018 | Galdonik et al. | |
| | 24. | 9532792 | 01-03-2017 | Galdonik et al. | |
| | 25. | 20200121334 | 04-23-2020 | Galdonik et al. | |
| | 26. | 11596768 | 03-07-2023 | Stern et al. | |
| | 27. | 10926060 | 02-23-2021 | Stern et al. | |
| | 28. | 11224450 | 01-18-2022 | Chou et al. | |
| | 29. | 11065019 | 07-20-2021 | Chou et al. | |
| | 30. | 11576691 | 02-14-2023 | Chou et al. | |
| | 31. | 2022033888 | 02-03-2022 | Schnall-Levin et al. | |



163916004.1

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.V.N/

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

| U.S. PATENTS AND PUBLICATIONS | | | | | |
|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | 32. | 20220370761 | 11-24-2022 | Chou et al. | |
| | 33. | 20230059721 | 02-23-2023 | Chou et al. | |
| | 34. | 20230122587 | 04-20-2023 | Chou et al. | |
| | 35. | 11305094 | 04-19-2022 | Carrison et al. | |
| | 36. | 10485952 | 11-26-2019 | Carrison et al. | |
| | 37. | 10456555 | 10-29-2019 | Carrison et al. | |
| | 38. | 11383064 | 07-12-2022 | Carrison et al. | |
| | 39. | 11185664 | 11-30-2021 | Carrison et al. | |
| | 40. | 11224721 | 01-18-2022 | Carrison et al. | |
| | 41. | 11395903 | 07-26-2022 | Carrison et al. | |
| | 42. | 20200046940 | 02-13-2020 | Carrison et al. | |
| | 43. | 20210138194 | 05-13-2021 | Carrison et al. | |
| | 44. | 7122034 | 10-17-2006 | Belhe et al. | |
| | 45. | 5639276 | 06-17-1997 | Weinstock et al. | |
| | 46. | 7481805 | 01-27-2009 | Magnusson | |
| | 47. | 9241669 | 01-26-2016 | Pugh et al. | |
| | 48. | 10384034 | 08-20-2019 | Carrison et al. | |
| | 49. | 9265512 | 02-23-2016 | Carrison et al. | |
| | 50. | 20110152889 | 06-23-2011 | Ashland | |
| | 51. | 20230310138 | 10-05-2023 | Merritt et al. | |
| | 52. | 20230310137 | 10-05-2023 | Merritt et al. | |
| | 53. | 20230310751 | 10-05-2023 | Merritt et al. | |
| | 54. | 20030023263 | 01-30-2003 | Krolik et al. | |
| | 55. | 20030135151 | 07-17-2003 | Deng | |
| | 56. | 20200022711 | 01-23-2020 | Look et al. | |
| | 57. | 6017335 | 01-25-2000 | Burnham | |
| | 58. | 20040039351 | 02-26-2004 | Barrett | |
| | 59. | 20140180055 | 06-26-2014 | Glynn et al. | |
| | 60. | 20230329734 | 10-19-2023 | Marchand et al. | |
| | 61. | 5242461 | 09-07-1993 | Kortenbach et al. | |
| | 62. | 11806033 | 11-07-2023 | Marchand et al. | |



ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.V.N/

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

| U.S. PATENTS AND PUBLICATIONS | | | | | |
|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | 63. | 3438607 | 04-15-1969 | Williams et al. | |
| | 64. | 4401107 | 08-30-1983 | Harber et al. | |
| | 65. | 4634421 | 01-06-1987 | Hegemann | |
| | 66. | 5484418 | 01-16-1996 | Quiachon et al. | |
| | 67. | 20080087853 | 04-17-2008 | Kees | |
| | 68. | 10648268 | 05-12-2020 | Jaffrey et al. | |
| | 69. | 20230320834 | 10-12-2023 | Merritt et al. | |
| | 70. | 2784717 | 03-12-1957 | E.O. Thompson | |
| | 71. | 9884387 | 02-06-2018 | Plha | |
| | 72. | 20230338131 | 10-26-2023 | Merritt et al. | |
| | 73. | 20230338130 | 10-26-2023 | Merritt et al. | |
| | 74. | 2010114017 | 05-06-2010 | Lenker et al. | |
| | 75. | 6589264 | 07-08-2003 | Barbut et al. | |
| | 76. | 20230355259 | 11-09-2023 | Marchand et al. | |
| | 77. | 20230355256 | 11-09-2023 | Dinh | |
| | 78. | 20230355938 | 11-09-2023 | Merritt et al. | |
| | 79. | 20230363883 | 11-16-2023 | Merritt et al. | |
| | 80. | 20230363776 | 11-16-2023 | Quick | |
| | 81. | 20170113005 | 04-27-2017 | LINDER et al. | |
| | 82. | 20110309037 | 12-22-2011 | LEE | |
| | 83. | 20080294096 | 11-27-2008 | Uber, III et al. | |
| | 84. | 20130270161 | 10-17-2013 | KUMAR et al. | |
| | 85. | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Foreign Document Number[3] | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[5] |
| | 1. | CN106178227 | 12-07-2016 | Shanghai Microport Medical Group Co., Ltd. | | |
| | 2. | WO2023154612 | 08-17-2023 | Inari Medical, Inc. | | |
| | 3. | WO2018065092 | 04-12-2018 | PRINZESSIN VON ISENBURG, Sarah | | |



ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.V.N/

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

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| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initial* | Cite No | Foreign Document Number[3] | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[5] |
|---|---|---|---|---|---|---|
| | 4. | EP3013404 | 04-15-2020 | NorMedix Inc. | | |
| | 5. | EP3583972 | 12-25-2019 | Covidien LP | | |
| | 6. | EP3589348 | 01-08-2020 | Covidien LP | | |
| | 7. | EP4137070 | 02-22-2023 | ROUTE 92 MEDICAL INC. | | |
| | 8. | EP3620204 | 03-11-2020 | ROUTE 92 MEDICAL INC. | | |
| | 9. | WO2023192925 | 10-05-2023 | Inari Medical, Inc. | | |
| | 10. | WO2019173475 | 09-12-2019 | Innovative Cardiovascular Solutions, LLC | | |
| | 11. | WO2023215779 | 11-09-2023 | Inari Medical, Inc. | | |
| | 12. | | | | | |

**NON-PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T[5] |
|---|---|---|---|
| | | International Search Report and Written Opinion for International App. No. PCT/US23/60927; Date of Filing: January 19, 2023, Applicant: Inari Medical, Inc., Date of Mailing: July 20, 2023, 12 pages. | |
| | | Extended European Search Report issued for EP Application No. 20877370.5, Date of Mailing: October 17, 2023, 11 pages. | |
| | | International Search Report and Written Opinion for International App. No. PCT/US23/65128; Date of Filing: March 30, 2023, Applicant: Inari Medical, Inc., Date of Mailing: November 14, 2023, 14 pages. | |
| | | | |

**EXAMINER SIGNATURE**

| Examiner Signature | /TUAN V NGUYEN/ | Date Considered | 02/16/2024 |
|---|---|---|---|

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

**CERTIFICATION STATEMENT**



ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.V.N/

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

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

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

**OR**

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☐ See attached certification statement.

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

☒ None

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

**COPIES OF REFERENCES**

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

## SIGNATURE

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

| | | | |
|---|---|---|---|
| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2023-11-21 |
| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

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



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Doc code: IDS
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| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

**U.S. PATENTS AND PUBLICATIONS**

| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|---|---|---|---|---|---|
| | 1. | 20090312786 | 12-17-2009 | Trask et al. | |
| | 2. | 20120095448 | 04-19-2012 | KAJII | |
| | 3. | 20160220795 | 08-04-2016 | KORKUCH et al. | |
| | 4. | 20130123705 | 05-16-2013 | Holm et al. | |
| | 5. | | | | |
| | 6. | | | | |
| | 7. | | | | |
| | 8. | | | | |

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| Examiner Initial* | Cite No | Foreign Document Number[3] | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[5] |
|---|---|---|---|---|---|---|
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|---|---|---|---|
| | | International Search Report and Written Opinion for International App. No. PCT/US23/66538; Date of Filing: May 3, 2023, Applicant: Inari Medical, Inc., Date of Mailing: January 4, 2024, 14 pages. | |

**EXAMINER SIGNATURE**

| Examiner Signature | /TUAN V NGUYEN/ | Date Considered | 02/16/2024 |
|---|---|---|---|

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[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. /T.V.N/

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Doc description: Information Disclosure Statement (IDS) Filed

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| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

## CERTIFICATION STATEMENT

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☐ See attached certification statement.

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

☒ None

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## SIGNATURE

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

| | | | |
|---|---|---|---|
| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2024-01-18 |
| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

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



ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.V.N/

## PE2E SEARCH - Search History (Prior Art)

| Ref # | Hits | Search Query | DBs | Default Operator | Plurals | British Equivalents | Time Stamp |
|---|---|---|---|---|---|---|---|
| L211 | 16 | ("11832837"\|"11832838"\|"11833023"\|"11839393"\|"11844921"\|"11849963"\|"20130190701"\|"20170143880"\|"20170172591"\|"20210128182"\|"20210316127"\|"20230389932"\|"20230390045"\|"3785380"\|"6908455"\|"7837630").PN. | (US-PGPUB; USPAT) | OR | ON | ON | 2024/02/16 09:18 AM |
| L212 | 84 | ("10058339"\|"10384034"\|"10456555"\|"10485952"\|"10648268"\|"10926060"\|"10953195"\|"11018090"\|"11065019"\|"11185664"\|"11224450"\|"11224721"\|"11305094"\|"11383064"\|"11395903"\|"11576691"\|"11596768"\|"11806033"\|"20030023263"\|"20030135151"\|"20040019310"\|"20040039351"\|"20080087853"\|"20080294096"\|"20080312681"\|"20100114017"\|"20110152889"\|"20110309037"\|"20130150793"\|"20130270161"\|"20140180055"\|"20170113005"\|"20170143359"\|"20170143938"\|"20170281204"\|"20180055999"\|"20190015298"\|"20200022711"\|"20200046940"\|"20200121334"\|"20210138194"\|"20210205577"\|"20210404464"\|"20220033888"\|"20220370761"\|"20230059721"\|"20230122587"\|"20230270991"\|"20230310137"\|"20230310138"\|"20230310751"\|"20230320834"\|"20230329734"\|"20230338130"\|"20230338131"\|"20230355256"\|"20230355259"\|"20230355938"\|"20230363776"\|"20230363883"\|"2784717"\|"3416531"\|"3438607"\|"3860006"\|"4401107"\|"4634421"\|"4981478"\|"5242461"\|"5 | (US-PGPUB; USPAT) | OR | ON | ON | 2024/02/16 10:55 AM |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | 391152"\|"5484418"\|"5639276"\|"5971958"\|"6017335"\|"6589264"\|"7122034"\|"7481805"\|"7815608"\|"8021351"\|"8070694"\|"9241669"\|"9265512"\|"9532792"\|"9662129"\|"9884387").PN. | | | | | |
| L213 | 4 | ("20090312786"\|"20120095448"\|"20130123705"\|"20160220795").PN. | (US-PGPUB; USPAT) | OR | ON | ON | 2024/02/16 10:56 AM |
| L214 | 5 | ("11890180"\|"20140163615"\|"20200129741"\|"5323514"\|"5911728").PN | (US-PGPUB; USPAT) | OR | ON | ON | 2024/02/16 10:56 AM |
| L215 | 842 | ("1101890" \| "2846179" \| "2955592" \| "3088363" \| "3197173" \| "3416531" \| "3435826" \| "3515137" \| "3675657" \| "3860006" \| "3892161" \| "3923065" \| "4030503" \| "4034642" \| "4222380" \| "4243040" \| "4287808" \| "4324262" \| "4393872" \| "4469100" \| "4523738" \| "4551862" \| "4604094" \| "4611594" \| "4643184" \| "4646736" \| "4650466" \| "4776337" \| "4790812" \| "4863440" \| "4870953" \| "4883458" \| "4886062" \| "4890611" \| "4898575" \| "4946440" \| "4960259" \| "4978341" \| "4981478" \| "5030201" \| "5059178" \| "5100423" \| "5127626" \| "5129910" \| "5135484" \| "5154724" \| "5158533" \| "5158564" \| "5192274" \| "5192286" \| "5192290" \| "5197485" \| "5234403" \| "5244619" \| "5329923" \| "5360417" \| "5364345" \| "5376101" \| "5383887" \| "5389100" \| "5391152" \| "5419774" \| "5421824" \| "5443443" \| "5456667" \| "5476450" \| "5490859" \| "5496365" \| "5527326" \| "5549626" \| "5591137" \| "5639276" \| "5653684" \| "5662703" \| "5746758" \| "5749858" \| "5769816" \| "5782817" \| "5800457" \| "5827229" \| "5846251" \| "5860938" \| "5873866" \| "5873882" | (US-PGPUB; USPAT; USOCR) | OR | ON | ON | 2024/02/16 11:11 AM |

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## PE2E SEARCH - Search History (Interference)

| Ref # | Hits | Search Query | DBs | Default Operator | Plurals | British Equivalents | Time Stamp |
|---|---|---|---|---|---|---|---|
| N77 | 2 | (aspiration SAME system AND vacuum WITH source AND connection WITH tubing AND catheter AND filter WITH chamber SAME tubing SAME housing AND port AND fluid WITH connector AND fluid WITH path AND filter WITH chamber SAME vacuum WITH source AND flow WITH controller AND | (US-PGPUB; USPAT) | OR | ON | ON | 2024/02/16 09:14 AM |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | hemostasis WITH valve SAME second WITH path).clm. | | | | | |
| N78 | 1 | (method SAME clot SAME vessel AND positioning SAME distal SAME elongated WITH shaft SAME clot AND pre NEAR charging SAME vacuum SAME pressure WITH source AND fluidly SAME connecting SAME pressure WITH source SAME shaft AND unsealing SAME attach$5 WITH member SAME shaft AND advancing SAME device SAME through SAME attach$5 WITH member SAME shaft AND engaging SAME device SAME second WITH portion SAME clot).clm. | (US-PGPUB; USPAT) | OR | ON | ON | 2024/02/16 09:14 AM |
| N79 | 0 | (vacuum SAME aspiration AND housing SAME chamber AND cap SAME aspirat$4 AND flow WITH path SAME cap AND catheter SAME flexible SAME port SAME housing AND flow WITH regulator AND first WITH operator SAME actuation WITH mechanism AND second WITH operator AND filter SAME housing SAME flow WITH path).clm. | (US-PGPUB; USPAT) | OR | ON | ON | 2024/02/16 09:14 AM |
| N80 | 2 | (aspiration AND vacuum AND connection SAME tub$4 SAME vacuum AND filter WITH chamber SAME housing AND catheter SAME vacuum SAME flow WITH path AND flow WITH controller SAME filter WITH chamber SAME catheter AND check WITH valve SAME housing SAME second | (US-PGPUB; USPAT) | OR | ON | ON | 2024/02/16 09:15 AM |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | WITH end SAME filter).clm. | | | | | |
| N81 | 1 | (aspiration AND vacuum AND connection SAME tub$4 SAME vacuum AND filter WITH chamber SAME housing AND first WITH end AND second WITH end AND port SAME first WITH end AND fluid WITH connector SAME second WITH end AND filter SAME flow WITH path AND catheter SAME vacuum SAME filter WITH chamber AND flow WITH controller SAME second WITH flow AND check WITH valve SAME connector SAME filter).clm. | (US-PGPUB; USPAT) | OR | ON | ON | 2024/02/16 09:15 AM |
| N82 | 1 | (aspiration AND vacuum AND connection SAME tub$4 SAME vacuum AND filter WITH chamber SAME housing AND first WITH end AND second WITH end AND port SAME first WITH end AND fluid WITH connector SAME second WITH end AND filter SAME flow WITH path AND catheter SAME vacuum SAME filter WITH chamber AND flow WITH controller SAME second WITH flow AND hemostasis WITH valve SAME third WITH flow WITH path AND interventional WITH device).clm. | (US-PGPUB; USPAT) | OR | ON | ON | 2024/02/16 09:15 AM |

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

**U.S. PATENTS AND PUBLICATIONS**

| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|---|---|---|---|---|---|
| | 1. | 3785380 | 01-15-1974 | Brumfield | |
| | 2. | 6908455 | 06-21-2005 | Hajianpour | |
| | 3. | 7837630 | 11-23-2010 | Nieoson et al. | |
| | 4. | 11832837 | 12-05-2023 | Hauser | |
| | 5. | 11832838 | 12-05-2023 | Hauser | |
| | 6. | 11833023 | 12-05-2023 | Hauser | |
| | 7. | 11839393 | 12-12-2023 | Hauser | |
| | 8. | 11844921 | 12-19-2023 | Merritt et al. | |
| | 9. | 11849963 | 12-26-2023 | Quick | |
| | 10. | 20130190701 | 07-25-2013 | Kirn | |
| | 11. | 20170143880 | 05-25-2017 | LUXON et al. | |
| | 12. | 20170172591 | 06-22-2017 | Ulm, III | |
| | 13. | 20210128182 | 05-06-2021 | Teigen et al. | |
| | 14. | 20210316127 | 10-14-2021 | Buck et al. | |
| | 15. | 20230389932 | 12-07-2023 | Ozenne et al. | |
| | 16. | 20230390045 | 12-07-2023 | Merritt et al. | |
| | | | | | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initial* | Cite No | Foreign Document Number[3] | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[5] |
|---|---|---|---|---|---|---|
| | | | | | | |

**NON-PATENT LITERATURE DOCUMENTS**

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|---|---|---|---|
| | | | |



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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

| EXAMINER SIGNATURE | | | |
|---|---|---|---|
| Examiner Signature | /TUAN V NGUYEN/ | Date Considered | 02/16/2024 |

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| | | | |
|---|---|---|---|
| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2024-01-17 |
| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

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# ELECTRONIC ACKNOWLEDGEMENT RECEIPT

| APPLICATION # | RECEIPT DATE / TIME | ATTORNEY DOCKET # |
|---|---|---|
| **17/498,642** | **02/26/2024 10:51:39 PM Z ET** | **111552.8023.US02** |

## Title of Invention

SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

## Application Information

| | | | |
|---|---|---|---|
| APPLICATION TYPE | Utility - Nonprovisional Application under 35 USC 111(a) | PATENT # | - |
| CONFIRMATION # | 1040 | FILED BY | JiYoung Anderson |
| PATENT CENTER # | 64455457 | FILING DATE | 10/11/2021 |
| CUSTOMER # | 25096 | FIRST NAMED INVENTOR | Richard Quick |
| CORRESPONDENCE ADDRESS | - | AUTHORIZED BY | Matthew Williams |

## Documents

**TOTAL DOCUMENTS: 2**

| DOCUMENT | PAGES | DESCRIPTION | SIZE (KB) |
|---|---|---|---|
| 2024-2-26 IDS SB08 - 111552-8023.US02.pdf | 2 | Information Disclosure Statement (IDS) Form (SB08) | 122 KB |
| Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems. | | | |
| NPL_CN-Office Action 201980067623.1 mailed Jan. 31 2024 -10 pages.pdf | 10 | Non Patent Literature | 371 KB |

## Digest

| DOCUMENT | MESSAGE DIGEST(SHA-512) |
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| | |
|---|---|
| 2024-2-26 IDS SB08 - 111552-8023.US02.pdf | 9BCDC95C1D5B45938F40D496421B1EB8E1BFB86C097DEAD1A08FDC5ACE9D8BC5D80561961529E13EBCB5A3338D3DDCBC7995FCB7960B3ECC9E119B1C0A4E7C27 |
| NPL_CN-Office Action 201980067623.1 mailed Jan. 31 2024 -10 pages.pdf | 67A4EFF504AA331CEC2C9D259CD544739D92C7C66DC4824A0FC1237FB36FC905AA26A95EF95F26FED5E827B5C61B45BBD219D6ACB245089061913101DC669601 |

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**New Applications Under 35 U.S.C. 111**

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

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

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

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**U.S. PATENTS AND PUBLICATIONS**

| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|---|---|---|---|---|---|
| | 1. | 20200129741 | 04-30-2020 | Kawwas et al. | |
| | 2. | 2018014840 | 01-18-2018 | Panian | |
| | 3. | 20240058113 | 02-22-2024 | Strauss et al. | |
| | 4. | | | | |
| | 5. | | | | |

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|---|---|---|---|
| | | Chinese First Office Action received for CN Application No. 201980067623.1, Applicant: Inari Medical, Inc., Date of Mailing: January 31, 2024, 10 pages. | |

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| Examiner Signature | | Date Considered | |
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| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

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(19) 世界知的所有権機関
国際事務局

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2012 年 8 月 30 日(30.08.2012)

WIPO | PCT

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WO 2012/114633 A1

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*A61M 39/00* (2006.01) *A61M 25/02* (2006.01)

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(26) 国際公開の言語: 日本語

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特願 2011-039159 2011 年 2 月 25 日(25.02.2011) JP

(71) 出願人 (米国を除く全ての指定国について): テルモ株式会社 (TERUMO KABUSHIKI KAISHA) [JP/JP]; 〒1510072 東京都渋谷区幡ヶ谷２丁目４４番１号 Tokyo (JP).

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(74) 代理人: 千葉剛宏, 外 (CHIBA Yoshihiro et al.); 〒1510053 東京都渋谷区代々木２丁目１番１号 新宿マインズタワー １６階 Tokyo (JP).

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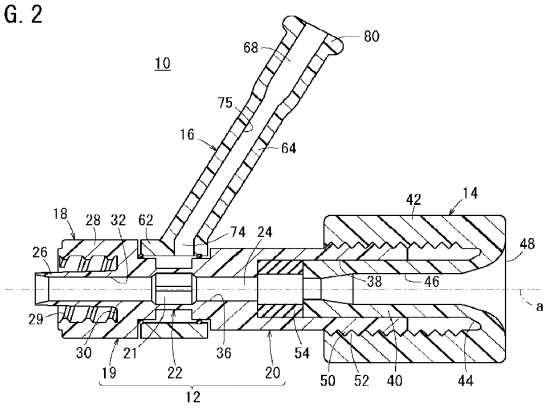
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添付公開書類:
— 国際調査報告 (条約第 21 条(3))

(54) **Title**: MEDICAL CONNECTOR

(54) 発明の名称 : 医療用コネクタ

FIG. 2




(57) **Abstract**: The medical connector (10) is provided with a connector body (12) and a branch (16) that branches off of the connector body (12). A communicating channel (21) that connects the inside and the outside of the connector body (12) is formed in the trunk of the connector body (12). The branch (16) comprises: a rotating tubular part (62) that is rotatably connected to the connector body (12) to be liquid-tight at a position that overlies the communicating channel (21); and a branch lumen (68), which forms a flow channel from the inner circumferential surface of the rotating tubular part (62) to a side port (80) and communicates with the lumen (24) of the connector body (12).

(57) 要約:

[続葉有]

WO 2012/114633 A1

医療用コネクタ（１０）は、コネクタ本体（１２）と、コネクタ本体（１２）から分岐した分岐部（１６）とを備える。コネクタ本体（１２）の胴体部には、コネクタ本体（１２）の内外を連通する連通路（２１）が形成されている。分岐部（１６）は、連通路（２１）を覆う位置でコネクタ本体（１２）に対して回転可能に液密に接続した回転管状部（６２）と、回転管状部（６２）の内周面からサイドポート（８０）に至る流路を形成し且つコネクタ本体（１２）のルーメン（２４）と連通する分岐ルーメン（６８）とを有する。

# 明　細　書

## 発明の名称 ： 医療用コネクタ

## 技術分野

[0001] 本発明は、チューブ状の医療機器の基端部に接続して使用する医療用コネクタに関する。

## 背景技術

[0002] 動脈硬化等により狭窄した血管（脈管）の治療のために、先端部に拡張体を有するカテーテルを狭窄部に挿入し、拡張体を膨張させることにより狭窄部を拡張し、末梢側の血流を改善する経皮的動脈形成術（ＰＴＣＡ）が行われている。この手技においては、拡張体付カテーテル（バルーンカテーテル）を血管内に挿入するに先立ち、拡張体付カテーテルを狭窄部位へ導くためのガイディングカテーテルを血管内に留置しておき、このガイディングカテーテルの基端部に予め接続しておいた医療用コネクタであるＹコネクタより拡張体付カテーテルを挿入することが一般的である。

[0003] 従来のＹコネクタは、拡張体付カテーテルを挿通可能なルーメンが設けられたコネクタ本体と、当該コネクタ本体の側面から分岐するとともに先端にサイドポートが設けられた分岐部とを有している。分岐部は、コネクタ本体の胴体部に一体的に設けられている。コネクタ本体の一端には、ガイドカテーテルの基端部に接続可能に構成された接続部が、コネクタ本体の軸線を中心に回転自在に設けられている。コネクタ本体の他端には、コネクタ本体に対して軸線を中心に回転可能なキャップ部が設けられている。当該キャップ部とコネクタ本体間には、当該キャップ部と前記コネクタ本体との間での押圧により内径が変化することで前記ルーメンの開閉を行う弾性体で構成された弁体が収容されている（例えば特許第４４７２３１０号公報を参照）。

## 発明の概要

[0004] 上記のように構成されたＹ字型コネクタの使用に際し、例えば造影剤等の液体をＹコネクタに接続したガイディングカテーテルに供給するために、サ

イドポートには液体注入具が接続される。この場合、サイドポートと液体注入具とを接続しやすくするために、サイドポートの向きを調整しようとすると、Ｙコネクタのコネクタ本体と治療用カテーテルなどのデバイスを固定するＹコネクタ内部の弁体（止血弁）とが相対回転不可能に固定され、且つ、コネクタ本体と分岐部とが相対回転不可能に固定されているため、Ｙコネクタの回転に伴って弁体に固定された治療用カテーテルなどのデバイスも回転する。治療用カテーテルなどのデバイスが回転すると、その先端部の向きが変わるため、迅速な手技の遂行に影響が出ることが懸念される。

[0005] 本発明はこのような課題を考慮してなされたものであり、コネクタ本体に挿入された治療用カテーテルなどのデバイスを回転させることなく、サイドポートの向きを任意の向きに調整することができる医療用コネクタを提供することを目的とする。

[0006] 上記の目的を達成するため、本発明は、チューブ状の医療機器の基端部に接続される医療用コネクタであって、軸線方向に延在するルーメンが形成されるとともに、前記医療機器の基端部に接続可能に構成された接続部を一端に有するコネクタ本体と、前記コネクタ本体から分岐して設けられるとともに他のデバイスと接続可能なサイドポートを有する分岐部と、を備え、前記コネクタ本体の胴体部には、前記コネクタ本体の内外を連通する連通路が形成され、前記分岐部は、前記連通部を覆う位置で前記コネクタ本体に対して回転可能に液密に接続した回転管状部と、前記回転管状部の内周面から前記サイドポートに至る流路を形成し且つ前記ルーメンと連通する分岐ルーメンとを有することを特徴とする。

[0007] 本発明の構成によれば、本体を回転させることなくサイドポートの向きを独立して変更することができるため、サイドポートに液体注入具を接続する際に、サイドポートを任意の向きに調整し、前記液体注入具の接続を容易に行うことができる。また、サイドポートの向きを変更しても、本体に挿入された治療用カテーテルなどのデバイス（例えば、バルーンカテーテル）は回転しないため、手技を円滑に遂行することができる。

[0008] 上記の医療用コネクタにおいて、前記連通路は、前記コネクタ本体の周方向に複数設けられるとよい。

[0009] 上記の構成によれば、コネクタ本体内のルーメンと、分岐部内の分岐ルーメンとを連通する流路の断面積を大きく確保でき、分岐部からコネクタ本体への流体の移動をスムーズに行うことができる。

[0010] 上記の医療用コネクタにおいて、前記回転管状部と前記コネクタ本体との間に、前記回転管状部の内周面に沿って環状に連通した空間が形成されるとよい。

[0011] 上記の構成によれば、回転環状部とコネクタ本体との周方向の位置関係に関わらず、ルーメンと分岐ルーメンとが常に前記空間及び連通部を介して確実に連通するので、サイドポートの向きが限定されず、液体注入具の接続をより簡易且つ迅速に遂行することができる。

[0012] 上記の医療用コネクタにおいて、前記コネクタ本体は、前記接続部を含む第１要素と、前記コネクタ本体の基端部を含む第２要素と、前記第１要素と前記第２要素とを回転不可能に連結するとともに前記連通部が形成された連結部とを備えるとよい。

[0013] 上記の構成によれば、従来の医療用コネクタと異なり、接続部が回転構造を有しないので、その分、コネクタ本体の全長を短くすることができ、よって、医療用コネクタに挿通して使用する医療用デバイス（例えば、治療カテーテル）の有効長を長くとることができる。

[0014] 上記の医療用コネクタにおいて、前記第１要素の前記第２要素側の端部には縮径して軸線方向に突出した第１縮径部が設けられ、前記第２要素の前記第１要素側の端部には縮径して軸線方向に突出した第２縮径部が設けられ、前記回転管状部の内周面と前記第１縮径部の外周面との間が第１シール部材を介して液密にシールされ、前記回転管状部の内周面と前記第２縮径部の外周面との間が第２シール部材を介して液密にシールされ、前記回転管状部は、前記第１縮径部による段差の側面と、前記第２縮径部による段差の側面との間で、前記コネクタ本体に対して軸線方向に位置決めされるとよい。

[0015] 上記の構成によれば、相互に相対回転可能な回転管状部とコネクタ本体との間を確実に液密に保持できるとともに、コネクタ本体に対する回転管状部の軸線方向の位置を好適に位置決めすることができる。

[0016] 本発明の医療用コネクタによれば、コネクタ本体に接続された医療機器を回転させることなく、サイドポートの向きを任意の向きに調整することができ、よって、手技を円滑に遂行することができる。

## 図面の簡単な説明

[0017] [図1]本発明の一実施形態に係る医療用コネクタの斜視図である。

[図2]図１に示した医療用コネクタの軸線方向に沿った縦断面図である。

[図3]図１に示した医療用コネクタの使用状態を示す縦断面図である。

[図4]図１に示した医療用コネクタの部分拡大断面図である。

[図5]図５Ａは、図４のＶＡ－ＶＡ線に沿った横断面図であり、図５Ｂは、第１変形例に係る連結部及びその周辺部位を示す横断面図であり、図５Ｃは、第２変形例に係る連結部及びその周辺部位を示す横断面図である。

[図6]図６Ａは、第１変形例に係る分岐部の回転管状部及びその周辺部位を示す縦断面図であり、図６Ｂは、第２変形例に係る分岐部の回転管状部及びその周辺部位を示す縦断面図である。

[図7]図７Ａは、第１変形例に係るシール構造及びその周辺部位を示す縦断面図であり、図７Ｂは、第２変形例に係るシール構造及びその周辺部位を示す縦断面図であり、図７Ｃは、第３変形例に係るシール構造及びその周辺部位を示す縦断面図である。

## 発明を実施するための形態

[0018] 以下、本発明に係る医療用コネクタについて好適な実施の形態を挙げ、添付の図面を参照しながら説明する。

[0019] 図１は、本発明の一実施形態に係る医療用コネクタ１０の斜視図であり、図２は、医療用コネクタ１０の軸線ａ方向に沿った縦断面図であり、図３は、カテーテル８２のハブ８４に接続した状態の医療用コネクタ１０を示す縦断面図である。

[0020] この医療用コネクタ１０は、チューブ状の医療機器の基端部（ハブ）に接続して使用されるものである。医療用コネクタ１０が接続されるチューブ状の医療機器は、例えば、ガイディングカテーテル、治療用カテーテル（例えば、バルーンカテーテル、血栓吸引カテーテル）等のカテーテル８２（図３参照）である。

[0021] 医療用コネクタ１０は、コネクタ本体１２と、当該コネクタ本体１２の基端部に設けられたキャップ部１４と、コネクタ本体１２から分岐する分岐部１６と備え、全体としてＹ字形状をなすＹコネクタとして構成されている。以下、医療用コネクタ１０の各構成要素の構成について説明する。なお、説明の都合上、コネクタ本体１２に関し、図２、図３、図４中の左側を「先端」、右側を「基端（後端）」という。

[0022] まず、コネクタ本体１２の構成を説明する。コネクタ本体１２は、カテーテル８２の基端部を構成するハブ８４に接続可能に構成された接続部１８を含む第１要素１９と、コネクタ本体１２の基端部を含む第２要素２０と、第１要素１９と第２要素２０とを回転不可能に連結するとともに連通路２１が形成された連結部２２と、第１要素１９、第２要素２０及び連結部２２を軸線ａ方向に貫通したルーメン２４とを有する。

[0023] 第１要素１９は、コネクタ本体１２の先端部を構成する部分であり、先端管部２６と、当該先端管部２６を同心状に囲むとともに内周部に雌ネジ部２９が形成された筒状部２８とを有し、先端管部２６と筒状部２８とにより先端側に開放する環状凹溝３０が形成されている。第１要素１９の中心には、ルーメン２４の一部を構成する内腔３２が軸線ａ方向に貫通形成されている。第１要素１９の基端部（第２要素２０側の端部）には、縮径して軸線ａ方向に突出した第１縮径部３４（図４参照）が設けられている。

[0024] 先端管部２６は、筒状部２８よりも先端側に突出し、外径が先端側に向かって徐々に縮径する先細り形状のルアーテーパとして構成されており、図３に示すように、カテーテル８２のハブ８４に挿入されたとき、先端管部２６の外周面とハブ８４の内周面とが液密に嵌合するようになっている。筒状部

２８は、その内周部に設けられた雌ネジ部２９を介して、ハブ８４の基端に設けられた雄ネジ部８５に螺合可能である。

[0025] 第２要素２０には、ルーメン２４の一部を構成する内腔３６が軸線ａ方向に設けられるとともに、当該内腔３６よりも基端側に、内腔３６よりも拡径した拡径部３８が形成されている。第２要素２０の先端部（第１要素１９側の端部）には、縮径して軸線ａ方向に突出した第２縮径部３９（図４参照）が設けられている。

[0026] キャップ部１４は、コネクタ本体１２の基端部（第２要素２０の基端部）に、第２要素２０に対して軸線ａを中心に回転可能に設けられている。キャップ部１４は、内筒部４０と、当該内筒部４０を同心状に囲む円筒形状の回転操作部４２とを有し、内筒部４０と回転操作部４２とにより、先端側に開放した環状凹溝４４が形成されている。

[0027] 内筒部４０には、ルーメン２４の一部を構成する内腔４６が軸線ａ方向に貫通形成されている。当該内腔４６は、キャップ部１４の基端側にて、コネクタ本体１２に接続されるカテーテル８２とは別のカテーテル（例えば、治療用カテーテル８６）の挿入口となるポート４８として開口している。

[0028] 回転操作部４２は、使用者（術者）が指でつまんで回転させる部分であり、図１に示すように、回転操作部４２の外周面には、半径方向外方に隆起し且つ軸線ａ方向に沿って延在する滑り止め用のリブ５１が周方向に間隔を置いて形成されている。

[0029] 図２に示すように、回転操作部４２の内周部には、第２要素２０の基端外周面に設けられた雄ネジ部５０に螺合する雌ネジ部５２が形成されている。よって、回転操作部４２を回転させると、雌ネジ部５２と雄ネジ部５０との螺合によって、回転操作部４２がコネクタ本体１２に対して軸線ａ方向に移動する。

[0030] 第２要素２０と内筒部４０との間には、弾性部材により構成された中空円筒形状の弁体５４が配設されている。より具体的には、弁体５４は、第２要素２０の拡径部３８に配置されるとともに、内腔３６と拡径部３８とによる

段差と、内筒部４０の先端面との間に挟持されている。

[0031] 弁体５４を構成する弾性部材の構成材料としては、特に限定されないが、例えば、シリコーンゴム、フッ素ゴム、イソプレン、天然ゴム等の各種ゴム類、ポリウレタン、ポリアミドエラストマー、ポリブタジエン、軟質塩化ビニル等の各種樹脂またはこれらのうち２以上を組み合わせたもの等が挙げられる。

[0032] 回転操作部４２を操作して回転させると、回転操作部４２は回転しながら先端側に移動する。すると、弁体５４は、先端方向に移動する内筒部４０により軸線ａ方向に押圧されて弾性変形し、この結果、弁体５４の内径が縮小する（図３参照）。回転操作部４２を逆方向に回転させると、内筒部４０が後退して内筒部４０による弁体５４に対する押圧が解除されることで、弁体５４の形状が弾性力で復元し、再び図２に示す状態に戻る。

[0033] 図４は、コネクタ本体１２における連結部２２及びその周辺部位の一部省略拡大縦断面図であり、図５Ａは、図４のＶＡ－ＶＡ線に沿った横断面図である。連結部２２は、コネクタ本体１２において、第１要素１９と第２要素２０との間を構成する部分であり、コネクタ本体１２の胴体部の内外を連通する連通路２１が設けられている。

[0034] 図４及び図５に示すように、本実施形態に係る医療用コネクタ１０において、連結部２２は、軸線ａ方向に沿って延在するとともに周方向に間隔をおいて配置された複数のロッド状の連結体５６を有し、隣接する連結体５６間に形成された隙間によって、上述した連通路２１が構成されている。図示した構成例では、複数の連結体５６は、軸線ａ回りの周方向に等間隔に配置されている。

[0035] 連通路２１とルーメン２４の境界部分（接続部１８の内周基端及び第２要素２０の内周先端が連通路２１に面した部分）の端部は面取りされている。このように構成されることで、治療用カテーテルの先端が連通路２１とルーメン２４の境界部分の角ばった端部に引っ掛かることを防止でき、治療用カテーテルをスムーズにルーメン２４に挿入又は抜去することができる。

[0036] 図５Ａに示した連結部２２では、ロッド状の連結体５６を有しているが、図５Ｂに示す第１変形例に係る連結部２２ａのように、軸線ａ方向に沿って延在する板状の連結体５８を周方向に間隔をおいて有してもよい。あるいは、図５Ｃに示す第２変形例に係る連結部２２ｂのように、複数の孔部６０を有する筒状体（図示例では円筒体）で構成してもよい。連結部２２ｂの場合、複数の孔部６０は、周方向及び軸線ａ方向に千鳥状又はマトリックス状などに配置にしてもよい。

[0037] 次に、分岐部１６の構成を説明する。図２に示すように、分岐部１６は、連通路２１を覆う位置でコネクタ本体１２に対して回転可能に液密に接続した回転管状部６２と、回転管状部６２から延出する分岐管状部６４と、当該分岐管状部６４の自由端に設けられ、他のデバイスと接続可能なサイドポート８０と、回転管状部６２の内周面からサイドポート８０に至る流路を形成し且つコネクタ本体１２のルーメン２４と連通する分岐ルーメン６８とを有する。

[0038] 図４及び図５Ａに示すように、回転管状部６２は、中空円筒形をなしている。上述した連結部２２は、回転管状部６２の内周面から離間しており、これにより、回転管状部６２と連結部２２との間には、回転管状部６２の内周面に沿って環状に、すなわち軸線ａ回りに３６０°の範囲で連通した空間６６が形成されている。このため、ルーメン２４と分岐ルーメン６８は、空間６６及び連通路２１を介して連通している。

[0039] 回転管状部６２の内周面と第１縮径部３４の外周面との間には、例えばＯリングで構成されたリング状の第１シール部材７０が配置され、回転管状部６２の内周面と第２縮径部３９の外周面との間には、例えばＯリングで構成されたリング状の第２シール部材７２が配置されている。第１シール部材７０及び第２シール部材７２により、コネクタ本体１２と回転管状部６２との間が液密にシールされている。

[0040] 第１シール部材７０は、回転管状部６２における分岐ルーメン６８の一部を構成する孔７４よりも先端側の内周面に設けられた第１環状溝部７６に配

置されている。第２シール部材７２は、回転管状部６２における孔７４より基端側の内周面に設けられた第２環状溝部７８に配置されている。

[0041] 図示した構成例において、第１環状溝部７６は、回転管状部６２の先端面及び内周面に開放する溝形状であり、第２環状溝部７８は、回転管状部６２の内周面にのみ開放する溝形状である。なお、第１環状溝部７６は、第２環状溝部７８と同様に、回転管状部６２の内周面にのみ開放する溝形状としてもよい。第２環状溝部７８は、回転管状部６２の基端面及び内周面に開放する溝形状としてもよい。

[0042] 回転管状部６２は、第１縮径部３４による段差の側面３５と、第２縮径部３９による段差の側面３７との間で、コネクタ本体１２に対して軸線ａ方向に位置決めされている。換言すれば、コネクタ本体１２には、第１縮径部３４と第２縮径部３９によって周方向に３６０°の範囲で延在する凹部が形成され、回転管状部６２は、当該凹部に収容（装着）されている。

[0043] 分岐管状部６４には、その軸線方向に沿って、分岐ルーメン６８の一部を構成する内腔７５が形成されている。当該内腔７５は、分岐管状部６４の自由端（図２、図３、図５で上端）に設けられたサイドポート８０にて開口している。サイドポート８０は、造影剤を注入するための図示しない液体注入具を接続するための接続口として機能する。

[0044] 上述したコネクタ本体１２、分岐部１６及びキャップ部１４の構成材料としては、特に限定されないが、例えば、ポリカーボネート、ポリアミド、ポリサルホン、ポリアリレート、メタクリレートーブチレンースチレン共重合体等の熱可塑性樹脂が好適に使用できる。

[0045] 本実施形態に係る医療用コネクタ１０は、基本的には以上のように構成されるものであり、以下、その作用及び効果について説明する。以下では、医療用コネクタ１０の使用方法について、経皮的動脈形成術（ＰＴＣＡ）を行う際に用いるガイディングカテーテルのハブに接続する場合を例として説明する。

[0046] ＰＴＣＡを行うに際し、医療用コネクタ１０は、図３に示すように、カテ

ーテル８２のハブ８４に接続して使用され、この場合、上述したように、コネクタ本体１２とハブ８４とは、ネジ嵌合によって一体的に固定される。ここで、カテーテル８２は、ＰＴＣＡに用いるガイディングカテーテルとして構成されているものとする。

[0047] まず、セルジンガー法により図示しないカテーテルイントロデューサー（以下、「イントロデューサー」という）を動脈（血管）に穿刺する。次に、ポート４８を通して、医療用コネクタ１０及びカテーテル８２に図示しないガイドワイヤーを挿入し、前記ガイドワイヤーを挿入した状態のカテーテル８２を前記イントロデューサーに挿入する。

[0048] そして、カテーテル８２の先端に対して前記ガイドワイヤーを先行させた状態で、カテーテル８２の先端を、前記イントロデューサーを介して動脈内へ挿入し、大動脈を経由して、カテーテル８２の先端部を冠動脈口（右冠動脈口又は左冠動脈口）に係合させ、カテーテル８２の先端部の位置を固定する。

[0049] なお、イントロデューサーの代わりにガイディングシースを使用したセルジンガー法においても、本発明の医療用コネクタを同様の方法で使用することができる。

[0050] カテーテル８２の先端部を冠動脈口に係合させたら、カテーテル８２及び医療用コネクタ１０から前記ガイドワイヤーを抜去するとともに、造影剤を注入するための液体注入具を、分岐部１６のサイドポート８０に接続する。この場合、分岐部１６はコネクタ本体１２の軸線ａを中心として回転自在であるため、術者は、分岐部１６を任意の向きに調整したうえで、前記液体注入具をサイドポート８０に接続することができる。

[0051] 次に、前記液体注入具を操作し、造影剤を医療用コネクタ１０の分岐部１６に供給する。この場合、分岐ルーメン６８とルーメンとは、連結部２２に形成された連通路２１を介して連通しているので、前記液体注入具から分岐部１６に導入された造影剤は、医療用コネクタ１０の連通路２１及びルーメン２４を介してカテーテル８２内に導入され、さらに、カテーテル８２内の

ルーメンを通ってその先端開口から目的部位である冠動脈内に噴出される。これによりカテーテル８２の先端部の冠動脈口への挿入位置の確認、冠動脈の造影が可能となる。

[0052] 造影剤の注入が完了したら、次に、コネクタ本体１２内のルーメン２４及びカテーテル８２内のルーメンを経由して、ＰＴＣＡバルーンカテーテル等の治療用カテーテルを冠動脈内に挿入し、治療用カテーテルにより所定の処置（例えば、狭窄部の拡張）を行う。

[0053] 本実施形態に係る医療用コネクタ１０によれば、コネクタ本体１２を回転させることなくサイドポート８０の向きを独立して変更することができるため、サイドポート８０に前記液体注入具を接続する際に、サイドポート８０を任意の向きに調整し、前記液体注入具の接続を容易に行うことができる。

[0054] また、サイドポート８０の向きを変更しても、コネクタ本体１２に挿入された治療用カテーテルは回転しないため、治療用カテーテルの先端の処置のための向きや位置が変わることを防止できる。すなわち、サイドポート８０の向きを変更しても、カテーテル８２の先端部の向きを保持すると共にコネクタ本体１２に挿入された治療用カテーテルの血管内での先端の向きや位置を維持できるため、手技を円滑に遂行することができる。

[0055] 本実施形態に係る医療用コネクタ１０において、連通路２１は、コネクタ本体１２の周方向に複数設けられるので、コネクタ本体１２内のルーメン２４と、分岐部１６内の分岐ルーメン６８とを連通する流路の断面積を大きく確保でき、分岐部１６からコネクタ本体１２への流体の移動をスムーズに行うことができる。

[0056] 本実施形態に係る医療用コネクタ１０では、回転管状部６２と連通路２１との間に、回転管状部６２の内周面に沿って環状に連通する空間６６が形成されているので、回転管状部６２と連通路２１との周方向の位置関係に関わらず、ルーメン２４と分岐ルーメン６８とが常に空間６６及び連通路２１を介して確実に連通する。よって、サイドポート８０の向きが限定されず、上述した液体注入具の接続をより簡易且つ迅速に遂行することができる。

[0057] 本実施形態に係る医療用コネクタ１０において、コネクタ本体１２は、第１要素１９と第２要素２０とが連結部２２によって互いに相対回転不可能に連結された構成であり、従来の医療用コネクタ１０と異なり、接続部１８が回転構造を有しないため、その分、コネクタ本体１２の全長を短くすることができる。よって、医療用コネクタ１０に挿通して使用する医療用デバイス（例えば、治療カテーテル）の有効長を長くとることができる。

[0058] 本実施形態に係る医療用コネクタ１０では、回転管状部６２は、第１縮径部３４による段差の側面３５と、第２縮径部３９による段差の側面３７との間で、コネクタ本体１２に対して軸線ａ方向に位置決めされるので、相互に相対回転可能な回転管状部６２とコネクタ本体１２との間を確実に液密に保持できるとともに、コネクタ本体１２に対する回転管状部６２の軸線ａ方向の位置を好適に位置決めすることができる。

[0059] 上述した分岐部１６に代えて、図６Ａに示す第１変形例に係る分岐部１６ａを採用してもよい。第１変形例に係る分岐部１６ａは、回転管状部６２の内周部に流体ガイド部８１が設けられている点で、上述した分岐部１６と異なる。この流体ガイド部８１は、連結部２２に向かって突出し、分岐ルーメン６８のうち回転管状部６２の内周部で開口する孔７４よりも第１要素１９側に位置し、且つ内周面８１ａが第２要素２０側から第１要素１９側に向かって連結部２２側に寄るように形成されている。

[0060] 図６Ａに示す流体ガイド部８１は、具体的には、回転管状部６２の内周部において周方向に延在したリング状であり、第２要素２０側から第１要素１９側に向かって内周面８１ａが縮径している。軸線ａ方向に関して、流体ガイド部８１の基端の位置は、孔７４の第１要素１９側の内壁面と同じか近傍位置であるのがよい。

[0061] 図６Ａに示した構成によれば、分岐部１６のルーメンからコネクタ本体１２へ液体（造影剤等）を移動させる際に、流体ガイド部８１に沿って流体をスムーズに移動させることができる。すなわち、流体ガイド部８１を設けることにより、流体ガイド部８１がない構成（図４参照）と比較して、回転管

状部６２と連結部２２との間の空間６６の先端側で流れの滞留が生じにくくなるので、分岐ルーメン６８からコネクタ本体１２への液体の移動を促進することができる。

[0062] 上述した分岐部１６に代えて、図６Ｂに示す第２変形例に係る分岐部１６ｂを採用してもよい。第２変形例に係る分岐部１６は、分岐ルーメン６８の一部を構成する孔７４の形状において、上述した分岐部１６と異なる。具体的には、孔７４の、第１要素１９側の内壁面７４ａは、第２要素２０側から第１要素１９側に向かって連結部２２側に寄るように形成されている。内壁面７４ａは、軸線ａに対してテーパ状に傾斜しており、その最先端位置は、第１縮径部３４の端面３４ａ（第２縮径部３９に対向する面）の近傍に位置している。

[0063] 図６Ｂに示した構成によれば、分岐ルーメン６８からコネクタ本体１２へ液体（造影剤等）を移動させる際に、テーパ状の内壁面７４ａにより液体をスムーズに移動させることができる。すなわち、分岐ルーメン６８においてコネクタ本体１２側の開口部を構成する孔７４にテーパ状の内壁面７４ａを設けることにより、当該内壁面７４ａがない構成（図４参照）と比較して、回転管状部６２と連結部２２との間の空間６６の先端側で流れの滞留が生じにくくなるので、分岐ルーメン６８からコネクタ本体１２への液体の移動を促進することができる。

[0064] 図４に示したコネクタ本体１２と回転管状部６２との間のシール構造に代えて、図７Ａ～図７Ｃに示すシール構造を採用してもよい。図７Ａに示すシール構造は、図４と同様に第１シール部材７０と第２シール部材７２とを備えるものであるが、図４のシール構造と異なり、第２要素２０の第２縮径部３９の外周部に第２環状溝部８６が設けられている。図７Ａに示すシール構造における第１シール部材７０及び第２シール部材７２の機能及び作用は、図４に示したシール構造における第１シール部材７０及び第２シール部材７２の機能及び作用と同様である。

[0065] 図７Ｂに示すシール構造は、コネクタ本体１２と回転管状部６２との間に

設けられた第１シール部８８及び第２シール部９０を有する。第１シール部８８は、分岐ルーメン６８のうち回転管状部６２の内周部で開口する孔７４よりも先端側の位置に設けられている。具体的には、第１シール部８８は、回転管状部６２の内周面と先端面との角部に設けられた環状溝部９２に装着された弾性体からなるリング状のシール部材９４である。このシール部材９４は、図４に示した第１シール部材７０と同様に構成されている。シール部材９４は、第１縮径部３４の外周面と環状溝部９２とにより軸線ａ方向の両側から挟まれるとともに、第１縮径部３４による段差の側面３５と環状溝部９２とにより半径方向に挟まれ、弾性圧縮状態で保持されている。

[0066] 第２シール部９０は、孔７４よりも基端側の位置に設けられており、コネクタ本体１２において周方向及び半径方向に延在する第１摺動面９６と、回転管状部６２において周方向及び半径方向に延在する第２摺動面９７との密着により構成されている。第２摺動面９７は、シール部材９４の弾性力（弾発力）により第１摺動面９６に押圧されている。これにより、第１摺動面９６と第２摺動面９７は、液密に密着している。図７Ｂの構成例において、第１摺動面９６は、第２縮径部３９の外周部から半径方向外方に膨出し且つ周方向に延在する環状突起９８の先端面により形成され、第２摺動面９７は、回転管状部６２の基端側に設けられた環状の段差１００の側面１００ａにより形成されている。

[0067] 図７Ｂのシール構造によれば、回転管状部６２とコネクタ本体１２との間に配置されるシール部材９４が１つだけであるため、図４の構成と比較して部品点数を低減でき、構成を簡素化できる。また、シール部材９４の弾性力により、第１摺動面９６と第２摺動面９７とがよく密着するので、シール部材９４が設けられていない第２シール部９０においても、良好なシール効果が発揮される。

[0068] なお、第１シール部８８と第２シール部９０の配置を入れ替えた構成を採用してもよい。すなわち、回転管状部６２の先端側に第２シール部９０を前後に反転させた構成を設け、回転管状部６２の基端側に第１シール部８８を

前後に反転させた構成を設けてもよい。

[0069] 図７Ｃに示すシール構造は、コネクタ本体１２と回転管状部６２との間に設けられたシール部材９４（以下、「第１シール部材９４」という）及び第２シール部材１０２を有する。第１シール部材９４及びその配置構造は、図７Ｂに示したシール部材９４及びその配置構造と同じである。第２シール部材１０２は、孔７４よりも軸線ａ方向の基端側の位置に、コネクタ本体１２と回転管状部６２とにより軸線ａ方向の両側から挟まれて弾性圧縮状態で保持されている。具体的には、第２縮径部３９の外周部から半径方向外方に膨出し且つ周方向に延在する環状突起１０４の先端面に、周方向に延在する環状のシール装着溝１０５が形成され、当該シール装着溝１０５に第２シール部材１０２が装着されている。第２シール部材１０２は、回転管状部６２の基端側に設けられた環状の段差１００の側面１００ａと、シール装着溝１０５との間に挟まれている。第１シール部材９４の弾性力により、当該側面１００ａと第２シール部材１０２とが液密に密着するとともに、第２シール部材１０２とシール装着溝１０５とが液密に密着している。また、第２シール部材１０２の弾性力により、第１縮径部３４による段差の側面３５と第１シール部材９４とが液密に密着するとともに、第１シール部材９４と環状溝部９２とが液密に密着している。

[0070] 図７Ｃのシール構造によれば、第１シール部材９４の弾性力により、第２シール部材１０２の密着性を高めることができ、第２シール部材１０２の弾性力により、第１シール部材９４の密着性を高めることができるので、これらの相乗効果によって一層良好なシール効果が発揮され、優れた液漏れ防止効果が得られる。

[0071] なお、第１シール部材９４の配置構造と第２シール部材１０２の配置構造とを入れ替えた構成を採用してもよい。すなわち、回転管状部６２の先端側に第２シール部材１０２の配置構造を前後に反転させた構成を設け、回転管状部６２の基端側に第１シール部材９４の配置構造を前後に反転させた構成を設けてもよい。

[0072] 上記において、本発明について好適な実施の形態を挙げて説明したが、本発明は前記実施の形態に限定されるものではなく、本発明の要旨を逸脱しない範囲において、種々の改変が可能なことは言うまでもない。

# 請求の範囲

［請求項1］ チューブ状の医療機器の基端部に接続される医療用コネクタ（１０）であって、

軸線方向に延在するルーメン（２４）が形成されるとともに、前記医療機器の基端部に接続可能に構成された接続部（１８）を一端に有するコネクタ本体（１２）と、

前記コネクタ本体（１２）から分岐して設けられるとともに他のデバイスと接続可能なサイドポート（８０）を有する分岐部（１６、１６ａ、１６ｂ）と、を備え、

前記コネクタ本体（１２）の胴体部には、前記コネクタ本体（１２）の内外を連通する連通路（２１）が形成され、

前記分岐部（１６、１６ａ、１６ｂ）は、前記連通路（２１）を覆う位置で前記コネクタ本体（１２）に対して回転可能に液密に接続した回転管状部（６２）と、前記回転管状部（６２）の内周面から前記サイドポート（８０）に至る流路を形成し且つ前記ルーメン（２４）と連通する分岐ルーメン（６８）とを有する、

ことを特徴とする医療用コネクタ（１０）。

［請求項2］ 請求項１記載の医療用コネクタ（１０）において、

前記連通路（２１）は、前記コネクタ本体（１２）の周方向に複数設けられる、

ことを特徴とする医療用コネクタ（１０）。

［請求項3］ 請求項１記載の医療用コネクタ（１０）において、

前記回転管状部（６２）と前記コネクタ本体（１２）との間に、前記回転管状部（６２）の内周面に沿って環状に連通した空間（６６）が形成される、

ことを特徴とする医療用コネクタ（１０）。

［請求項4］ 請求項１記載の医療用コネクタ（１０）において、

前記コネクタ本体（１２）は、前記接続部（１８）を含む第１要素

（１９）と、前記コネクタ本体（１２）の基端部を含む第２要素（２０）と、前記第１要素（１９）と前記第２要素（２０）とを回転不可能に連結するとともに前記連通路（２１）が形成された連結部（２２、２２ａ、２２ｂ）とを備える、

ことを特徴とする医療用コネクタ（１０）。

［請求項5］ 請求項４項記載の医療用コネクタ（１０）において、

前記第１要素（１９）の前記第２要素（２０）側の端部には縮径して軸線方向に突出した第１縮径部（３４）が設けられ、

前記第２要素（２０）の前記第１要素（１９）側の端部には縮径して軸線方向に突出した第２縮径部（３９）が設けられ、

前記回転管状部（６２）の内周面と前記第１縮径部（３４）の外周面との間が第１シール部材（７０）を介して液密にシールされ、

前記回転管状部（６２）の内周面と前記第２縮径部（３９）の外周面との間が第２シール部材（７２）を介して液密にシールされ、

前記回転管状部（６２）は、前記第１縮径部（３４）による段差の側面（３５）と、前記第２縮径部（３９）による段差の側面（３７）との間で、前記コネクタ本体（１２）に対して軸線方向に位置決めされる、

ことを特徴とする医療用コネクタ（１０）。

[図1]

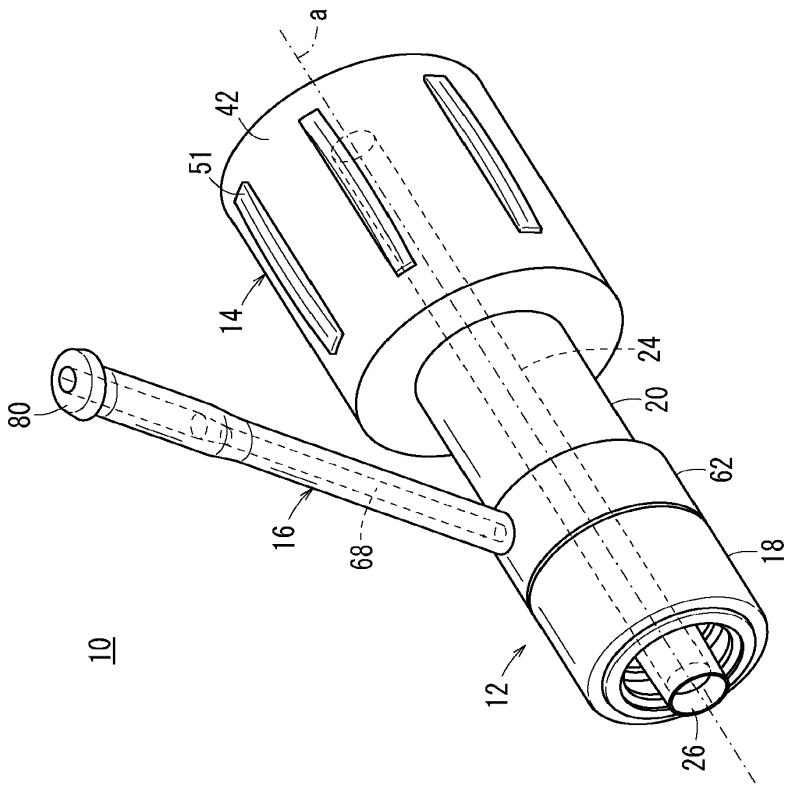



FIG. 1

[図2]

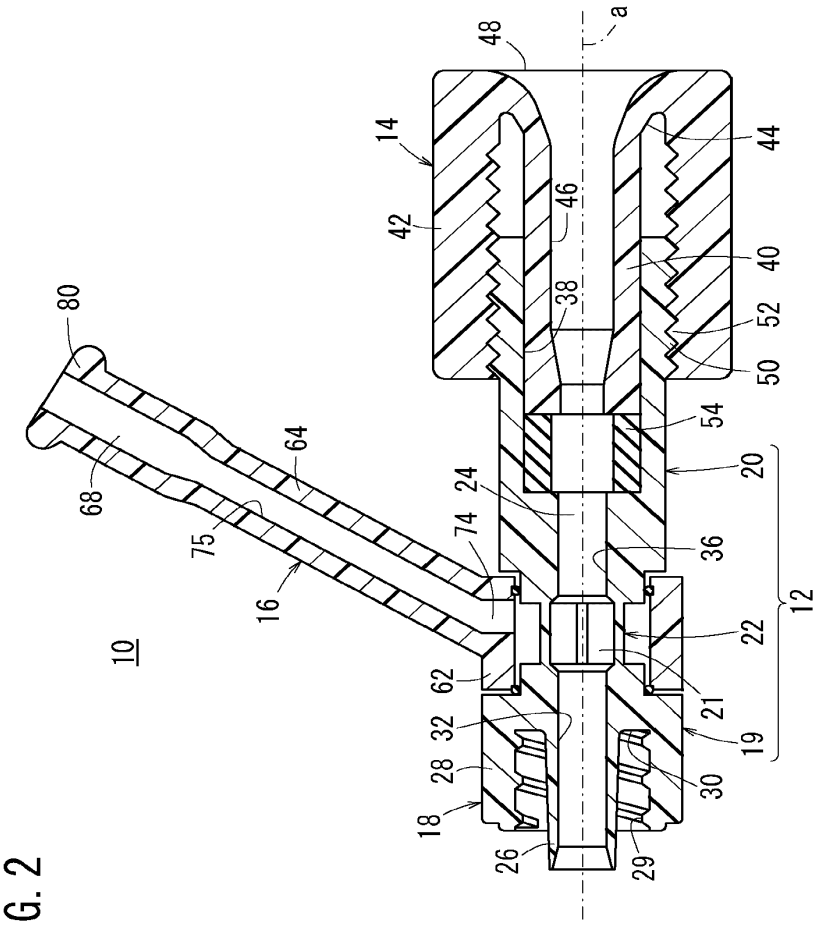

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FIG. 2

[図3]

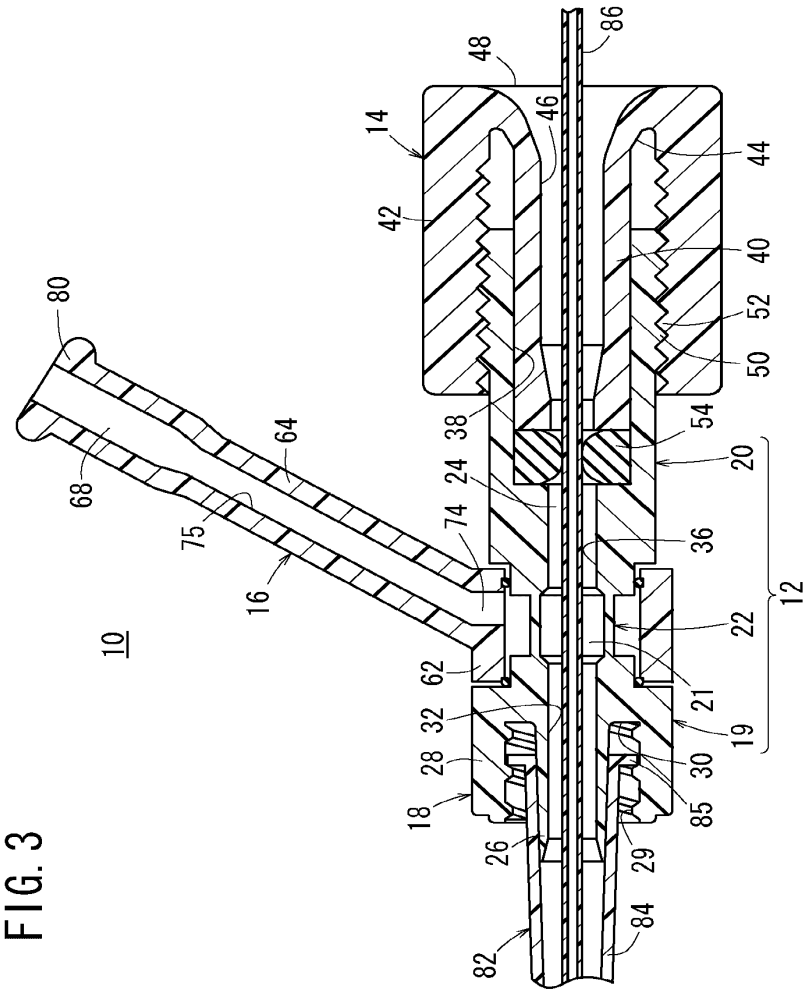
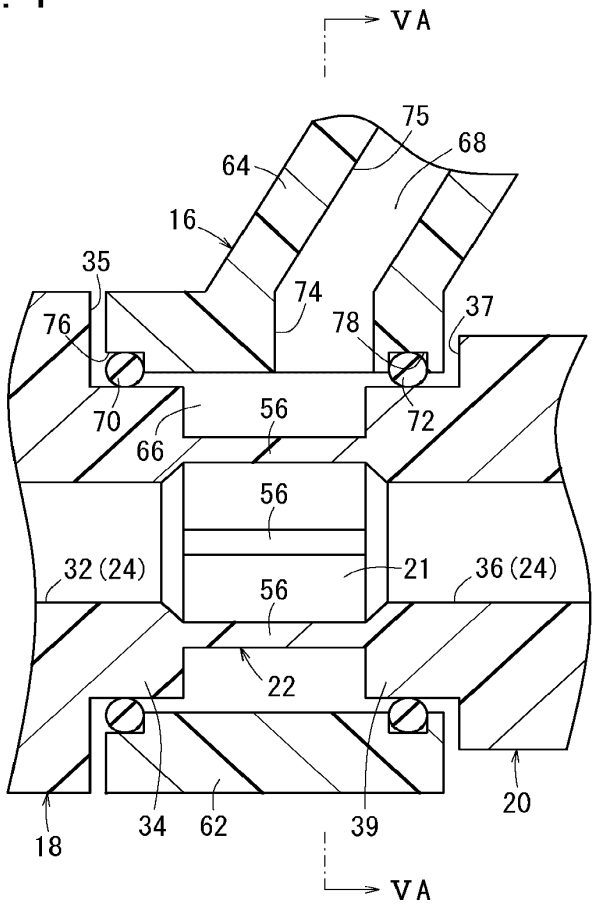

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FIG. 3

[図4]

FIG. 4


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[図5]

FIG. 5A

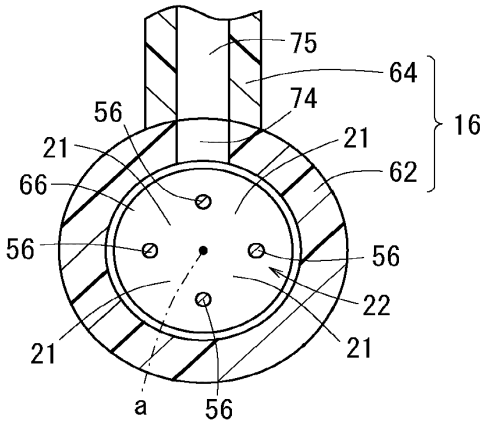



FIG. 5B

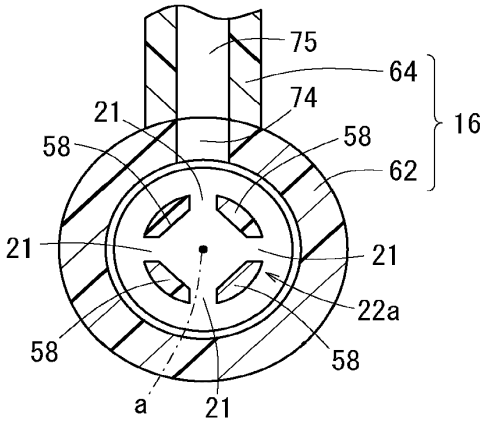
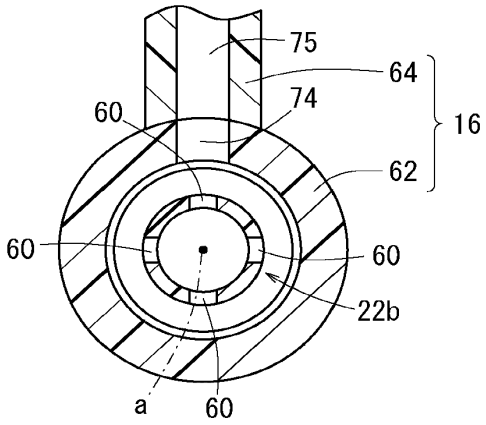



FIG. 5C



[図6]

FIG. 6B

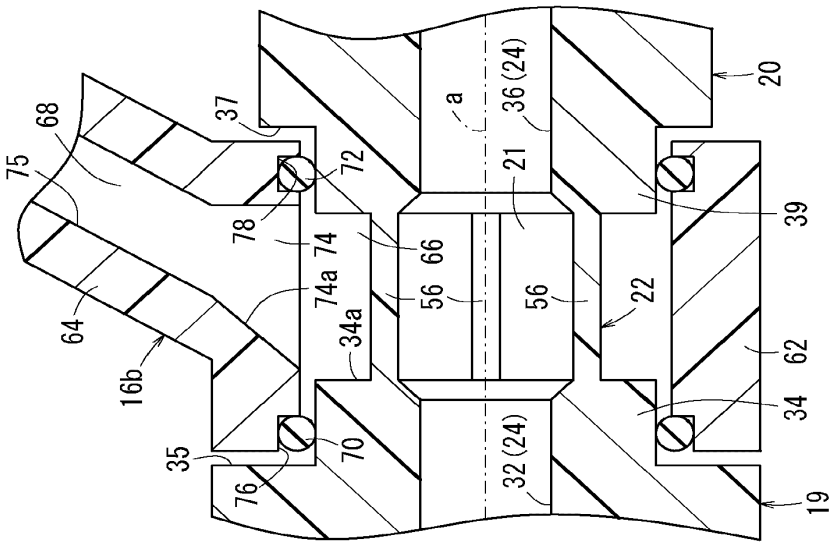
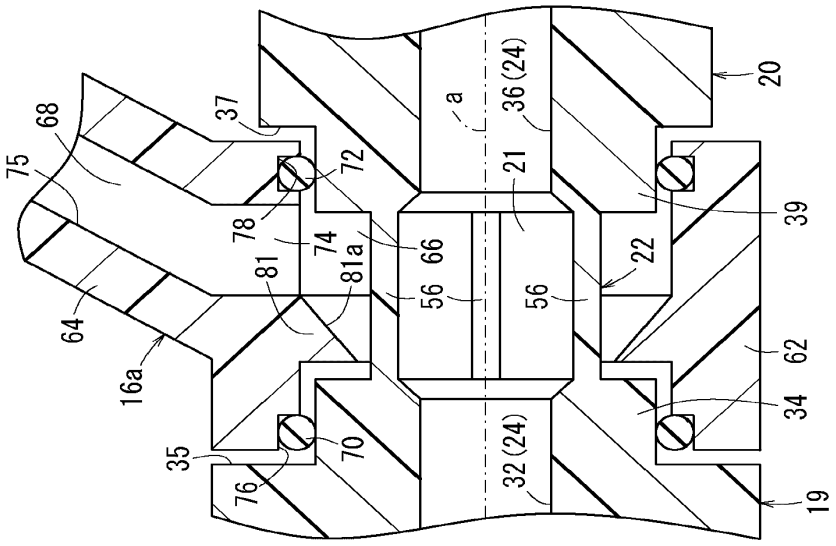



FIG. 6A



[図7]

FIG. 7C

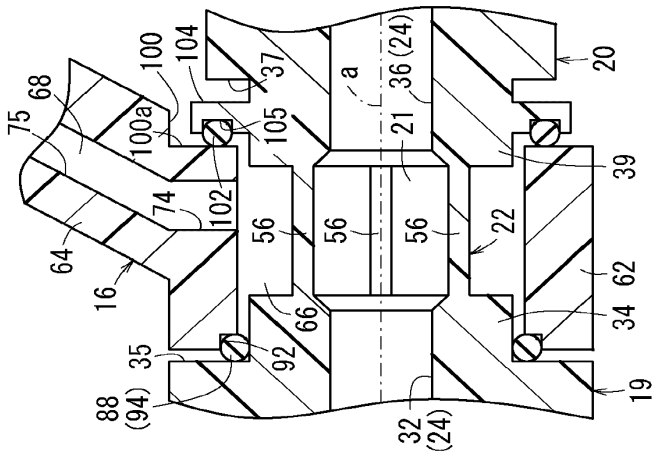



FIG. 7B

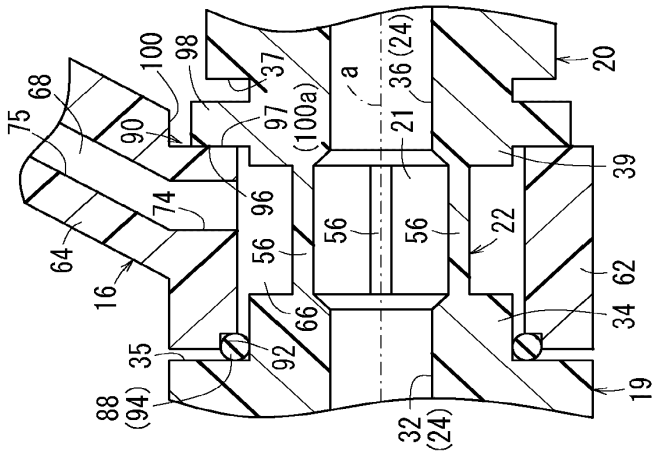
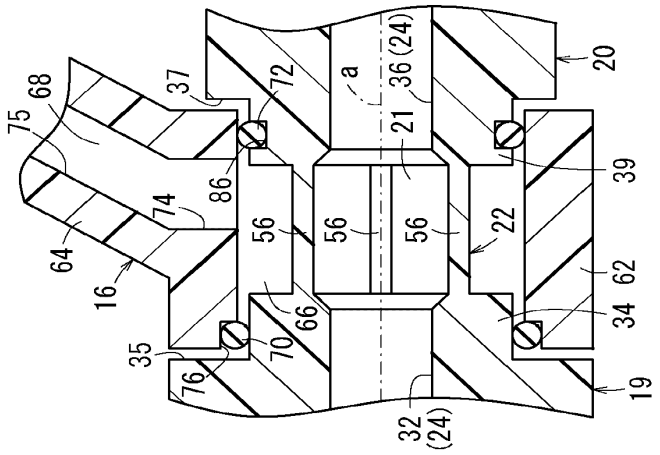



FIG. 7A



**INTERNATIONAL SEARCH REPORT**

International application No.
PCT/JP2011/079651

A. CLASSIFICATION OF SUBJECT MATTER
*A61M39/00*(2006.01)i, *A61M25/02*(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M39/00, A61M25/02

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

| | | | |
|---|---|---|---|
| Jitsuyo Shinan Koho | 1922-1996 | Jitsuyo Shinan Toroku Koho | 1996-2012 |
| Kokai Jitsuyo Shinan Koho | 1971-2012 | Toroku Jitsuyo Shinan Koho | 1994-2012 |

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | JP 7-114813 B2 (Cardiopulmonics, Inc.), 13 December 1995 (13.12.1995), claim 1; column 14, line 9 to column 15, line 49; fig. 1 to 7 & US 5125915 A & WO 1991/012840 A1 | 1-5 |
| A | JP 2003-62089 A (Sumitomo Bakelite Co., Ltd.), 04 March 2003 (04.03.2003), claims 1 to 3; fig. 1 to 7 (Family: none) | 1-5 |
| A | US 6579261 B1 (ADAM SPENCE CORP.), 17 June 2003 (17.06.2003), fig. 1a, 1b; column 1, line 45 to column 2, line 4 (Family: none) | 1-5 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier 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
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"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 22 March, 2012 (22.03.12) | 03 April, 2012 (03.04.12) |
| Name and mailing address of the ISA/ Japanese Patent Office<br>Facsimile No. | Authorized officer<br>Telephone No. |

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

国際調査報告

国際出願番号　ＰＣＴ／ＪＰ２０１１／０７９６５１

Ａ．　発明の属する分野の分類（国際特許分類（ＩＰＣ））

Int.Cl.　A61M39/00(2006.01)i, A61M25/02(2006.01)i

Ｂ．　調査を行った分野

調査を行った最小限資料（国際特許分類（ＩＰＣ））

Int.Cl.　A61M39/00, A61M25/02

最小限資料以外の資料で調査を行った分野に含まれるもの

| | |
|---|---|
| 日本国実用新案公報 | １９２２－１９９６年 |
| 日本国公開実用新案公報 | １９７１－２０１２年 |
| 日本国実用新案登録公報 | １９９６－２０１２年 |
| 日本国登録実用新案公報 | １９９４－２０１２年 |

国際調査で使用した電子データベース（データベースの名称、調査に使用した用語）

Ｃ．　関連すると認められる文献

| 引用文献のカテゴリー＊ | 引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示 | 関連する請求項の番号 |
|---|---|---|
| A | JP 7-114813 B2 (カーディオパルモニックス・インコーポレーテッド) 1995.12.13, 【請求項１】, 第１４欄第９行－第１５欄第４９行, 第１－７図 & US 5125915 A & WO 1991/012840 A1 | １－５ |
| A | JP 2003-62089 A (住友ベークライト株式会社) 2003.03.04, 【請求項１】－【請求項３】, 【図１】－【図７】（ファミリーなし） | １－５ |

☑　Ｃ欄の続きにも文献が列挙されている。　　☐　パテントファミリーに関する別紙を参照。

＊　引用文献のカテゴリー
「Ａ」特に関連のある文献ではなく、一般的技術水準を示すもの
「Ｅ」国際出願日前の出願または特許であるが、国際出願日以後に公表されたもの
「Ｌ」優先権主張に疑義を提起する文献又は他の文献の発行日若しくは他の特別な理由を確立するために引用する文献（理由を付す）
「Ｏ」口頭による開示、使用、展示等に言及する文献
「Ｐ」国際出願日前で、かつ優先権の主張の基礎となる出願の日の後に公表された文献
「Ｔ」国際出願日又は優先日後に公表された文献であって出願と矛盾するものではなく、発明の原理又は理論の理解のために引用するもの
「Ｘ」特に関連のある文献であって、当該文献のみで発明の新規性又は進歩性がないと考えられるもの
「Ｙ」特に関連のある文献であって、当該文献と他の１以上の文献との、当業者にとって自明である組合せによって進歩性がないと考えられるもの
「＆」同一パテントファミリー文献

| | |
|---|---|
| 国際調査を完了した日<br>２２．０３．２０１２ | 国際調査報告の発送日<br>０３．０４．２０１２ |
| 国際調査機関の名称及びあて先<br>日本国特許庁（ＩＳＡ／ＪＰ）<br>郵便番号１００－８９１５<br>東京都千代田区霞が関三丁目４番３号 | 特許庁審査官（権限のある職員）　３Ｅ　９３３４<br>鈴木　洋昭<br>電話番号　０３－３５８１－１１０１　内線　３３４４ |

様式ＰＣＴ／ＩＳＡ／２１０（第２ページ）（２００９年７月）

Ｃ（続き）．　関連すると認められる文献

| 引用文献のカテゴリー＊ | 引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示 | 関連する請求項の番号 |
|---|---|---|
| Ａ | US 6579261 B1（ＡＤＡＭ　ＳＰＥＮＣＥ　ＣＯＲＰＯＲＡＴＩＯＮ）2003.06.17, ＦＩＧ．１ａ，ＦＩＧ．１ｂ，第１欄第４５行－第２欄第４行（ファミリーなし） | １－５ |

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

**U.S. PATENTS AND PUBLICATIONS**

| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|---|---|---|---|---|---|
| | 1. | 11890180 | 02-06-2024 | Merritt et al. | |
| | 2. | 20140163615 | 06-12-2014 | Gadlage et al. | |
| | 3. | 5323514 | 06-28-1994 | Masuda et al. | |
| | 4. | 5911728 | 06-15-1999 | Sepetka et al. | |
| | 5. | 20200129741 | 04-30-2020 | Kawwas et al. | |
| | 6. | | | | |
| | 7. | | | | |
| | 8. | | | | |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initial* | Cite No | Foreign Document Number[3] | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[5] |
|---|---|---|---|---|---|---|
| | | WO2012114633 | 08-30-2012 | TERUMO KABUSHIKI KAISHA | | |

**NON-PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T[5] |
|---|---|---|---|
| | | English translation of Japanese Office Action received for JP Application No. 2022-574456, Applicant: Inari Medical, Inc, Date of Mailing: January 23, 2024, 12 pages. | |

**EXAMINER SIGNATURE**

| Examiner Signature | | Date Considered | |
|---|---|---|---|

*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.

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|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

## CERTIFICATION STATEMENT

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

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

**OR**

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

☐ See attached certification statement.

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

☒ None

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

### COPIES OF REFERENCES

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

## SIGNATURE

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

| | | | |
|---|---|---|---|
| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2024-02-14 |
| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

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

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# ELECTRONIC ACKNOWLEDGEMENT RECEIPT

| APPLICATION # | RECEIPT DATE / TIME | ATTORNEY DOCKET # |
|---|---|---|
| **17/498,642** | **02/14/2024 04:54:14 PM Z ET** | **111552.8023.US02** |

## Title of Invention

SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

## Application Information

| | | | |
|---|---|---|---|
| APPLICATION TYPE | Utility - Nonprovisional Application under 35 USC 111(a) | PATENT # | - |
| CONFIRMATION # | 1040 | FILED BY | JiYoung Anderson |
| PATENT CENTER # | 64325187 | FILING DATE | 10/11/2021 |
| CUSTOMER # | 25096 | FIRST NAMED INVENTOR | Richard Quick |
| CORRESPONDENCE ADDRESS | - | AUTHORIZED BY | Matthew Williams |

## Documents

**TOTAL DOCUMENTS: 3**

| DOCUMENT | PAGES | DESCRIPTION | SIZE (KB) |
|---|---|---|---|
| 2024-2-14 IDS SB08 - 111552-8023.US02.pdf | 2 | Information Disclosure Statement (IDS) Form (SB08) | 122 KB |
| Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems. | | | |
| NPL_EN Translation of JP Official Action JP 2022-574456 mailed Jan 23 2023 12 pages.pdf | 12 | Non Patent Literature | 91 KB |
| FOR_WO2012114633.pdf | 30 | Foreign Reference | 1051 KB |

## Digest

| DOCUMENT | MESSAGE DIGEST(SHA-512) |
|---|---|
| 2024-2-14 IDS SB08 - 111552-8023.US02.pdf | 7DBDEA2F0DECD97BEC5CE132F070918541BA8D0A498C1BFCCD6F9AC2EC503049A1A4E55B0A208DFAE8918ACA9A936223D3725901AE307EEBE07CD244CB217B0C |
| NPL_EN Translation of JP Official Action JP 2022-574456 mailed Jan 23 2023 12 pages.pdf | 8FE5FDE20C13A1EAB315826C2B2E39B7E0E6CE2AEF62BDE20DFD8B716DA495C3D7BAC423879A9611348E4CB1C4613B7EE01F8D54BE1580CE6E5F9E3C436302C9 |
| FOR_WO2012114633.pdf | 686B21251DE173EEDE1A69F56BB0D3888962CBEF494AD6AE574FAFDA438BFCDCABAA90DE7E1EC169DB112EDF154EFF47F1D1D803B115ADD1652AAB0A55BCF2EF |

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**New Applications Under 35 U.S.C. 111**

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

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

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

**New International Application Filed with the USPTO as a Receiving Office**

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

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

**U.S. PATENTS AND PUBLICATIONS**

| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|---|---|---|---|---|---|
| | 1. | 20090312786 | 12-17-2009 | Trask et al. | |
| | 2. | 20120095448 | 04-19-2012 | KAJII | |
| | 3. | 20160220795 | 08-04-2016 | KORKUCH et al. | |
| | 4. | 20130123705 | 05-16-2013 | Holm et al. | |
| | 5. | | | | |
| | 6. | | | | |
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| Examiner Initial* | Cite No | Foreign Document Number[3] | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[5] |
|---|---|---|---|---|---|---|
| | | | | | | |

**NON-PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T[5] |
|---|---|---|---|
| | | International Search Report and Written Opinion for International App. No. PCT/US23/66538; Date of Filing: May 3, 2023, Applicant: Inari Medical, Inc., Date of Mailing: January 4, 2024, 14 pages. | |

| EXAMINER SIGNATURE | | | |
|---|---|---|---|
| Examiner Signature | | Date Considered | |

*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.

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

## CERTIFICATION STATEMENT

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

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

**OR**

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

☐ See attached certification statement.

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

☒ None

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

### COPIES OF REFERENCES

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

## SIGNATURE

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

| | | | |
|---|---|---|---|
| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2024-01-18 |
| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

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

UNITED STATES
PATENT AND TRADEMARK OFFICE

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

# ELECTRONIC ACKNOWLEDGEMENT RECEIPT

| APPLICATION # | RECEIPT DATE / TIME | ATTORNEY DOCKET # |
|---|---|---|
| **17/498,642** | **01/18/2024 12:18:27 PM Z ET** | **111552-8023.US02** |

## Title of Invention

SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

## Application Information

| | | | |
|---|---|---|---|
| APPLICATION TYPE | Utility - Nonprovisional Application under 35 USC 111(a) | PATENT # | - |
| CONFIRMATION # | 1040 | FILED BY | JiYoung Anderson |
| PATENT CENTER # | 63997213 | FILING DATE | 10/11/2021 |
| CUSTOMER # | 25096 | FIRST NAMED INVENTOR | Richard Quick |
| CORRESPONDENCE ADDRESS | - | AUTHORIZED BY | Matthew Williams |

## Documents

**TOTAL DOCUMENTS: 2**

| DOCUMENT | PAGES | DESCRIPTION | SIZE (KB) |
|---|---|---|---|
| 2024-1-18 IDS SB08 - 111552-8023US2.pdf | 2 | Information Disclosure Statement (IDS) Form (SB08) | 123 KB |
| Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems. | | | |
| NPL_ISR-PCTUS23_66538 Jan 4 2024 - 14 pages.pdf | 14 | Non Patent Literature | 1697 KB |

## Digest

| DOCUMENT | MESSAGE DIGEST(SHA-512) |
|---|---|

| | |
|---|---|
| 2024-1-18 IDS SB08 - 111552-8023US2.pdf | B2452DD1FC29C146CF8E74225A6D6883A6FC88BCBBCA1C56E9C091524C5B3258FBD42D4FBE1BC2A9DF09EC3AAF9885D1C2517D7A4BE2181F474A364118C4B26F |
| NPL_ISR-PCTUS23_66538 Jan 4 2024 - 14 pages.pdf | 413F5954C40B9EAE1F11B8341F4D3C84EC7CC651BC247C016C6A36ADF29A2609FFB59D69495EB01A386C6B24513BC57266FEA4116D96CD8322285885O8B55111 |

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

**New Applications Under 35 U.S.C. 111**

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

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

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

**New International Application Filed with the USPTO as a Receiving Office**

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

# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: BENJAMIN D. CASHDOLLAR
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

RECEIVED
PATENT DOCKETING

JAN 11 2024

PERKINS COIE LLP

# PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

| | |
|---|---|
| Applicant's or agent's file reference<br>111552-8042WO00 | Date of mailing (day/month/year) JAN 04 2024<br>FOR FURTHER ACTION See paragraphs 1 and 4 below |
| International application No.<br>PCT/US 23/66538 | International filing date (day/month/year) 03 May 2023 (03.05.2023) |

Applicant INARI MEDICAL, INC.

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

**Filing of amendments and statement under Article 19:**
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

**When?** The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

**How?** Directly to the International Bureau preferably through ePCT, or on paper to:
The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland

**For more detailed instructions,** see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

The applicant may **submit comments on an informal basis on the written opinion of the International Searching Authority** to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

Shortly after the expiration of **18 months from the priority date, the international application will be published** by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Within **22 months from the priority date, the applicant may request that a supplementary international search be carried out** by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

| | |
|---|---|
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US<br>Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | Authorized officer<br>Kari Rodriquez<br>Telephone No. PCT Helpdesk: 571-272-4300 |

Form PCT/ISA/220 (revised January 2020)

PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| Applicant's or agent's file reference | FOR FURTHER ACTION |
|---|---|
| 111552-8042WO00 | see Form PCT/ISA/220 as well as, where applicable, item 5 below. |

| International application No. | International filing date *(day/month/year)* | (Earliest) Priority Date *(day/month/year)* |
|---|---|---|
| PCT/US 23/66538 | 03 May 2023 (03.05.2023) | 04 May 2022 (04.05.2022) |

Applicant
INARI MEDICAL, INC.

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the language, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☒ **Unity of invention is lacking** (see Box No. III).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the drawings to be published with the abstract is Figure No. 2A

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 23/66538

**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 -*-

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.:
1-8

**Remark on Protest**

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 23/66538

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61M 29/00 (2023.01)
ADD. A61M 25/00 (2023.01)

CPC - INV. A61M 29/00, A61M 25/0662
ADD. A61M 2025/0687, A61M 2025/0681, A61B 2017/347

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 2009/0312786 A1 (Trask et al.) 17 December 2009 (17.12.2009), entire document, especially Fig 1, para [0009], para [0028]-[0034], para [0038] | 1-5 |
| X | US 2016/0220741 A1 (Route 92 Medical, Inc.) 4 August 2016 (04.08.2016), entire document, especially Fig 1, Fig 12A, para [0017]-[0018], para [0044], para [0091]-[0095] | 1, 6-8 |
| A | US 2012/0095448 A1 (Kajii) 19 April 2012 (19.04.2012), entire document | 1-8 |
| A | US 2016/0220795 A1 (Teleflex Medical Incorporated) 4 August 2016 (04.08.2016), entire document | 1-8 |
| A | US 2013/0123705 A1 (W. L. Gore & Associates, Inc.) 16 May 2013 (16.05.2013), entire document | 1-8 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 07 September 2023 (07.09.2023) | JAN 04 2024 |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | Authorized officer<br>Kari Rodriquez<br>Telephone No. PCT Helpdesk: 571-272-4300 |

INARI_017311

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 23/66538

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-8 directed to a dilator comprising a coupling component, a tip, and body regions between the coupling component and tip having different flexibilities.

Group II: Claims 9-19 and 25-33 directed to a vascular access system comprising a valve, a catheter and a dilator.

Group III: Claims 20-24 directed to a method of treating clot material using a vascular access system.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical features of a dilator comprising a tip; a coupling component; a first body region between the tip and the coupling component with a first flexibility profile; a second body region between the first body region and the tip with a second flexibility profile greater than the first flexibility profile, not required by the claims of Groups II or III.

The invention of Group II includes the special technical features of a catheter defining a lumen and coupled to the valve; wherein the dilator is configured to be positioned within the lumen through the valve, not required by the claims of Group I or III.

The invention of Group III includes the special technical features of positioning a dilator within a vascular access system such that a valve of the vascular access system releasably engages a notch of the dilator to inhibit further movement of the dilator relative to the vascular access system; activating a button of the valve to release the notch from the valve to allow further movement of the dilator relative to the vascular access system; and moving the dilator relative to the vascular access system and/or the vascular access system relative to the dilator, not required by the claims of Group I or II.

COMMON TECHNICAL FEATURES

Groups I-III share the common technical features of a dilator for use in a vascular access system. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2013/0123705 A1 to W.L. Gore & Associates, Inc. (hereinafter 'Gore').

Gore discloses a dilator for use in a vascular access system (introducer assembly for a vascular treatment site including a dilator, para [0020]).

Groups II-III further share the common technical features of a vascular access system comprising a valve, wherein the valve is configured to releasably engage a notch of the dilator to inhibit movement of the dilator relative to the vascular access system when the dilator is inserted through the valve and into the vascular access system. However, this shared technical feature does not represent a contribution over prior art as being anticipated by

Gore discloses a vascular access system (see introducer sheath 10, Fig 2; introducer sheath 10, para [0014]) comprising a valve (see valve 400, Fig 2; valve 400, para [0014]), wherein the valve is configured to releasably engage a notch of the dilator (see a locking knob 500 on the valve 400 to releasably engage a notch surface 104 of dilator 100, Fig 2-3; dilator tool 100, para [0014]; 100 includes hub 102 with annular bearing surface 104, para [0015]; lock knob 500 includes a radially extending rib 520 to engage 104 to axially constrain 500 and 102 relative to each other, para [0016]; locking mechanism 300 such as knob 500 to allow selective locking of the tool 100 to the valve 400, para [0014]-[0016]) to inhibit movement of the dilator relative to the vascular access system when the dilator is inserted through the valve and into the vascular access system (the mechanism is actuable between locked and unlocked positions to releasably axially lock 100 to the valve 400 of sheath 100, para [0016]).

Groups I-II further share the common technical features of a dilator for use in a vascular access system having a first body region with a first flexibility profile, a second body region with a second different flexibility profile, wherein the first body region and the second body region have a same diameter. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2009/0312766 A1 to Trask et al. (hereinafter 'Trask').

Trask discloses a dilator for use in a vascular access system (see dilator 30 for use in a vascular access sheath assembly 10, Fig 1; sheath assembly 10 which includes dilator 30 to access a blood vessel, para [0028]-[0029]) having a first body region with a first flexibility profile (see region 32a, Fig 1; stiffness section 32a hence inherently having a first flexibility, para [0034]), a second body region with a second different flexibility profile (see second region 32b having a second different flexibility, Fig 1; multiple stiffness sections 32a-b which become less rigid, para [0034]), wherein the first body region and the second body region have a same diameter (see how 32a and 32b have a same diameter, Fig 1).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

# PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: BENJAMIN D. CASHDOLLAR
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

RECEIVED
PATENT DOCKETING

JAN 11 2024

PERKINS COIE LLP

**PCT**

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

| Date of mailing *(day/month/year)* | JAN 04 2024 |
|---|---|

| Applicant's or agent's file reference | FOR FURTHER ACTION |
|---|---|
| 111552-8042WO00 | See paragraph 2 below |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/US 23/66538 | 03 May 2023 (03.05.2023) | 04 May 2022 (04.05.2022) |

International Patent Classification (IPC) or both national classification and IPC
IPC - INV. A61M 29/00 (2023.01)
ADD. A61M 25/00 (2023.01)
CPC - INV. A61M 29/00, A61M 25/0662
ADD. A61M 2025/0687, A61M 2025/0681, A61B 2017/347

Applicant INARI MEDICAL, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

| Name and mailing address of the ISA/US | Date of completion of this opinion | Authorized officer |
|---|---|---|
| Mail Stop PCT, Attn. ISA/US<br>Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | 07 September 2023 (07.09.2023) | Kari Rodriquez<br>PCT Help Desk<br>Telephone No. 571-272-4300 |

Form PCT/ISA/237 (cover sheet) (revised July 2022)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 23/66536

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b)).

3. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of a sequence listing:

a. ☐ forming part of the international application as filed.

b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13*ter*.1(a)).

☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.

4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.

5. Additional comments:

Form PCT/ISA/237 (Box No. I) (revised July 2022)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 23/66538

**Box No. IV Lack of unity of invention**

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:

   ☐ paid additional fees.

   ☐ paid additional fees under protest and, where applicable, the protest fee.

   ☐ paid additional fees under protest but the applicable protest fee was not paid.

   ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-8 directed to a dilator comprising a coupling component, a tip, and body regions between the coupling component and tip having different flexibilities.

Group II: Claims 9-19 and 25-33 directed to a vascular access system comprising a valve, a catheter and a dilator.

Group III: Claims 20-24 directed to a method of treating clot material using a vascular access system.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical features of a dilator comprising a tip, a coupling component, a first body region between the tip and the coupling component with a first flexibility profile, a second body region between the first body region and the tip with a second flexibility profile greater than the first flexibility profile, not required by the claims of Groups II or III.

The invention of Group II includes the special technical features of a catheter defining a lumen and coupled to the valve; wherein the dilator is configured to be positioned within the lumen through the valve, not required by the claims of Group I or III.

The invention of Group III includes the special technical features of positioning a dilator within a vascular access system such that a valve of the vascular access system releasably engages a notch of the dilator to inhibit further movement of the dilator relative to the vascular access system; activating a button of the valve to release the notch from the valve to allow further movement of the dilator relative to the vascular access system; and moving the dilator relative to the vascular access system and/or the vascular access system relative to the dilator, not required by the claims of Group I or II.

COMMON TECHNICAL FEATURES

Groups I-III share the common technical features of a dilator for use in a vascular access system. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2013/0123705 A1 to W.L. Gore & Associates, Inc. (hereinafter 'Gore').

Gore discloses a dilator for use in a vascular access system (introducer assembly for a vascular treatment site including a dilator, para [0026]).

-*- Continued in Supplemental Box -*-

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-8

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 23/66538

**Box No. V** **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | None | YES |
| | Claims | 1-8 | NO |
| Inventive step (IS) | Claims | None | YES |
| | Claims | 1-8 | NO |
| Industrial applicability (IA) | Claims | 1-8 | YES |
| | Claims | None | NO |

2. Citations and explanations:
Claims 1-5 lack novelty under PCT Article 33(2) as being anticipated by US 2009/0312786 A1 to Trask et al. (hereinafter 'Trask').

As to claim 1, Trask discloses a dilator (see 30, Fig 1; dilator 30, para [0028]), comprising:
a tip (see tip 36, Fig 1);
a coupling component (see hub 31, Fig 1; hub 31 to interact with a sheath 40, para [0032]);
a first body region between the tip and the coupling component (see region 32a between 31 and 36, Fig 1), wherein the first body region has a first flexibility profile (stiffness section 32a hence inherently having a first flexibility, para [0034]); and
a second body region between the first body region and the tip (see region 32b between 32a and 36, Fig 1), wherein the second body region has a second flexibility profile greater than the first flexibility profile (multiple stiffness sections 32a-b become less rigid toward the distal end 33 hence the more distal section 32b is more flexible than 32a, para [0034]),
wherein the first body region and the second body region have a same diameter (see how 32a and 32b have a same diameter, Fig 1).

As to claim 2, Trask discloses the dilator of claim 1 wherein the first body region has a first stiffness (stiffness section 32a hence inherently having a first stiffness, para [0034]), wherein the second body region has a second stiffness (stiffness section 32b hence inherently having a second stiffness, para [0034]), and wherein the first stiffness is greater than the second stiffness (multiple stiffness sections 32a-b become less rigid toward the distal end 33 hence the more proximal section 32a is stiffer than 32b, para [0034]).

As to claim 3, Trask discloses the dilator of claim 1 wherein the first body region has a first durometer (the proximal end hence 32a has a durometer of 50-80 shore D, para [0034]), wherein the second body region has a second durometer (the distal end hence 32b has a durometer of 30-70 shore D, para [0034]), and wherein the second durometer is less than the first durometer (see how the distal end has a lower durometer than the proximal end, para [0034]).

As to claim 4, Trask discloses the dilator of claim 1 wherein the first body region comprises a first material (the first section 32a has a first material blend, para [0038]), and wherein the second body region comprises a second material different than the first material (the second section 32b has a second different material blend, para [0038]).

As to claim 5, Trask discloses the dilator of claim 1, further comprising a third body region between the tip and the coupling component (the dilator may have at least two stiffness sections between the proximal and distal ends hence including a third stiffness section, para [0008]), wherein the third body region has a third flexibility profile different than the first flexibility profile or the second flexibility profile (multiple stiffness sections that become less rigid toward's the distal end hence the third region has a different flexibility than the other regions, para [0008]).

Claims 1 and 6-8 lack novelty under PCT Article 33(2) as being anticipated by US 2016/0220741 A1 to Route 92 Medical, Inc. (hereinafter 'Route').

As to claim 1, Route discloses a dilator (see 340, Fig 1; dilator 340, para [0044], para [0017]), comprising:
a tip (see tip 346, Fig 1, distal tip 346, para [0092]);
a coupling component (see 348, Fig 1; proximal luer adapter 348, para [0092]);
a first body region between the tip and the coupling component (see a first red region between 346 and 348, see Supplemental Fig 1), wherein the first body region has a first flexibility profile (340 has stiffer materials toward the more proximal sections hence the proximal red region has a first flexibility profile, para [0093]); and
a second body region between the first body region and the tip (see a second blue region between the red region and 346, see Supplemental Fig 1), wherein the second body region has a second flexibility profile greater than the first flexibility profile (340 has more flexible materials toward the distal end hence the distal blue region has a greater flexibility profile than the proximal red region, para [0093]),
wherein the first body region and the second body region have a same diameter (see how the red region and the blue region have the same diameter, see Supplemental Fig 1; tubular dilator 340, para [0091]).

-*-Continued in Supplemental Box-*-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 23/66538

**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-*-Box IV - Lack of unity of invention -*-

Groups II-III further share the common technical features of a vascular access system comprising a valve, wherein the valve is configured to releasably engage a notch of the dilator to inhibit movement of the dilator relative to the vascular access system when the dilator is inserted through the valve and into the vascular access system. However, this shared technical feature does not represent a contribution over prior art as being anticipated by

Gore discloses a vascular access system (see introducer sheath 10, Fig 2; introducer sheath 10, para [0014]) comprising a valve (see valve 400, Fig 2; valve 400, para [0014]), wherein the valve is configured to releasably engage a notch of the dilator (see a locking knob 500 on the valve 400 to releasably engage a notch surface 104 of dilator 100, Fig 2-3; dilator tool 100, para [0014]; 100 includes hub 102 with annular bearing surface 104, para [0015]; lock knob 500 includes a radially extending rib 520 to engage 104 to axially constrain 500 and 102 relative to each other, para [0016]; locking mechanism 300 such as knob 500 to allow selective locking of the tool 100 to the valve 400, para [0014]-[0015]) to inhibit movement of the dilator relative to the vascular access system when the dilator is inserted through the valve and into the vascular access system (the mechanism is actuable between locked and unlocked positions to releasably axially lock 100 to the valve 400 of sheath 100, para [0015]).

Groups I-II further share the common technical features of a dilator for use in a vascular access system having a first body region with a first flexibility profile, a second body region with a second different flexibility profile, wherein the first body region and the second body region have a same diameter. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2009/0312786 A1 to Trask et al. (hereinafter 'Trask').

Trask discloses a dilator for use in a vascular access system (see dilator 30 for use in a vascular access sheath assembly 10, Fig 1; sheath assembly 10 which includes dilator 30 to access a blood vessel, para [0028]-[0029]) having a first body region with a first flexibility profile (see region 32a, Fig 1; stiffness section 32a hence inherently having a first flexibility, para [0034]), a second body region with a second different flexibility profile (see second region 32b having a second different flexibility, Fig 1; multiple stiffness sections 32a-b which become less rigid, para [0034]), wherein the first body region and the second body region have a same diameter (see how 32a and 32b have a same diameter, Fig 1).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

-*-Box V.2 - Citations and Explanations-*-

As to claim 6, Route discloses the dilator of claim 1, further comprising a notch positioned between the tip and the coupling component (the distal dilator portion can include detents on an outer surface configured to lock with corresponding features on an inner surface of a lumen, para [0016]; see additional views of a dilator 1340 including distal region 1360 between the tip 1346 and proximal coupling component, Fig 12A; dilator 1340 as described elsewhere, para [0094]; the entire dilator 1340 can be tubular and portion 1360 can include detents on an outer surface to lock with correspondingly shaped features of a catheter, para [0085], para [0016]).

As to claim 7, Route discloses the dilator of claim 6 wherein the notch is positioned between the first body region and the second body region (see how region 1360 including at least one of the notches is between the proximal body region and distal body region, Fig 12A, para [0017]).

As to claim 8, Route discloses the dilator of claim 6 wherein the notch is a first notch, the dilator further comprising a second notch positioned on a proximal or a distal side of the first notch (multiple detents to provide multiple points of locking connection hence further comprising a second notch either proximal or distal to the first notch, para [0017], para [0085]).

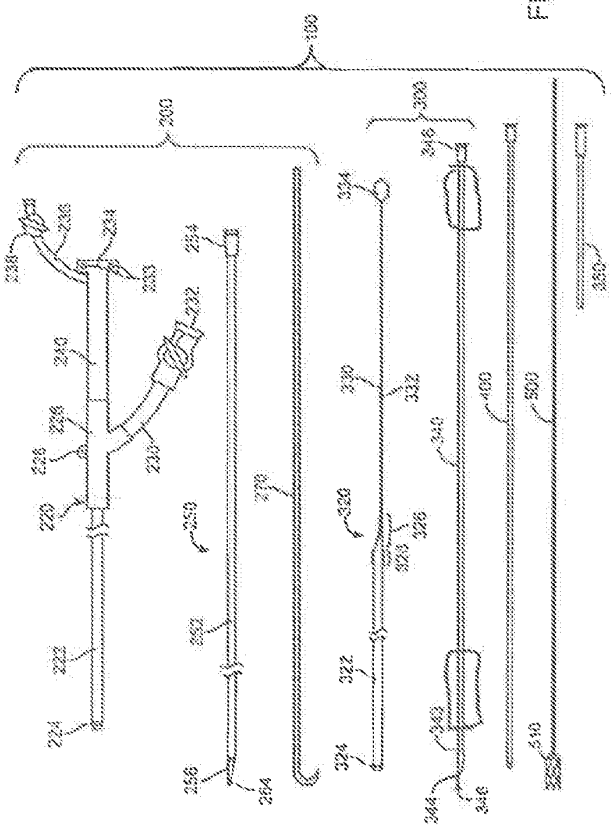
Claims 1-8 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Supplemental Fig 1

FIG. 1




Form PCT/ISA/237 (Supplemental Box) (July 2009)

# SEARCH HISTORY

| | |
|---|---|
| **Application Number** | PCT/US 23/66538 |
| **Search Conducted By** | JBT |
| **Search Approved By** | SCL |

| | |
|---|---|
| **CPC/IPC Classifications Searched** | CPC - INV. A61M 29/00, A61M 25/0662; ADD. A61M 2025/0687, A61M 2025/0681, A61B 2017/347<br>IPC(8) - INV. A61M 29/00; ADD. A61M 25/00 (2023.01) |
| **Date Conducted** | 07 September 2023 (07.09.2023) |

| | |
|---|---|
| **Documentation Searched** | CPC - INV. A61M 29/00, A61M 25/0662; ADD. A61M 2025/0687, A61M 2025/0681, A61B 2017/347<br>IPC(8) - INV. A61M 29/00; ADD. A61M 25/00 (2023.01) |
| **Search Terms Used** | Vary*, different, gradient, increas*, decreas*, stiffness, flexib*, durometer, dilator, shaft, tube, notch, notches, indent*, groove%, hardness, vascular, sheath, catheter |
| **Date Conducted** | 07 September 2023 (07.09.2023) |

| | |
|---|---|
| **Electronic Database Searched** | PatBase |
| **Files Searched** | Full-text: AU BE BR CA CH CN DE DK EP ES FI FR GB IN JP KR SE TH TW US WO<br>Bibliographic: (Europe) AT BA BE BG CH CS CY CZ DD DK EE ES FI GE GR HR HU IE IS IT LT LU LV MC MD MT NL NO PL PT RO RS SE SI SK SM TR UA YU (Asia) EA GC HK ID IL IN KZ MN MY PH RU SG SU TH TJ TW UZ VN (North America) CA CR CU DO GT HN MX NI PA SV TT (South America) AR BR CL CO EC PE UY (Australasia) AU NZ (Africa) AP DZ EG KE MA MW OA ZA ZM ZW |
| **Date Conducted** | 07 September 2023 (07.09.2023) |

**Search Logic:**

| # | Search query | Results |
|---|---|---|
| 1 | PN=(US2009312786 AA) | 1 |
| 2 | CTB 1 or CTF 1 | 67 |
| 3 | 2 and FT=((vary* or different or gradient or increas* or decreas*) NEAR (stiffness or flexib* or durometer)) | 25 |
| 4 | 3 and FT=((dilator or shaft or tube) NEAR (notch or notches or indent* or groove%)) | 5 |
| 5 | 3 and FT=(dilator% WP ((vary* or different or gradient or increas* or decreas*) NEAR | |

(stiffness or flexib* or durometer))) 8
6 PN=(US2016220741 AA) 1
7 PN=(US2016220741 AA) 1
8 CTB 7 or CTF 7 891
9 8 and FT=(dilator% WP ((vary* or different or gradient or increas* or decreas*) NEAR (stiffness or flexib* or durometer))) 19
10 9 and FT=((dilator or shaft or tube) NEAR (notch or notches or indent* or groove%)) 4
11 CPC=A61M 2025/0687 196
12 11 and FT=(dilator% WP ((vary* or different or gradient or increas* or decreas*) NEAR (stiffness or flexib* or durometer))) 16
13 12 and FT=stiffness 12
14 12 and FT=(durometer or hardness) 9
15 12 and FT=((dilator or shaft or tube) NEAR (notch or notches or indent* or groove%)) 2
16 IC=A61M 29/00 12,954
17 CPC=(A61M 29/00 or A61M 25/0662 or A61M 2025/0681 or A61B 2017/347) 4,673
18 16 or 17 15,782
19 18 and FT=(dilator% WP ((vary* or different or gradient or increas* or decreas*) NEAR (stiffness or flexib* or durometer))) 155
20 19 and FT=stiffness 105
21 19 and FT=(durometer or hardness) 62
22 19 and FT=((dilator or shaft or tube) NEAR (notch or notches or indent* or groove%)) 31
23 22 not (15 or 4) 27
24 A61M 25/00 120
25 24 and FT=(dilator% WP ((vary* or different or gradient or increas* or decreas*) NEAR (stiffness or flexib* or durometer))) 1
26 IC=A61M 25/00 42,855
27 26 and FT=(dilator% WP ((vary* or different or gradient or increas* or decreas*) NEAR (stiffness or flexib* or durometer))) 128
28 27 and FT=((dilator or shaft or tube) NEAR (notch or notches or indent* or groove%)) 23
29 28 and FT=((vascular or sheath or catheter) NEAR dilator%) 20
30 FT=((vascular or sheath or catheter) NEAR dilator%) 4,044
31 30 and FT=(dilator% WP ((vary* or different or gradient or increas* or decreas*) NEAR (stiffness or flexib* or durometer))) 176
32 31 and FT=((dilator or shaft or tube) NEAR (notch or notches or indent* or groove%)) 28

| | |
|---|---|
| **Electronic Database Searched** | Google |
| **Files Searched** | Google Web |
| **Date Conducted** | 07 September 2023 (07.09.2023) |
| **Search Logic:** | |
| variable stiffness vascular access dilator<br>About 126,000 results<br><br>inari medical vascular access dilator | |

About 34,100 results

vascular dilator flexible distal portion
About 1,600,000 results

| | |
|---|---|
| Electronic Database Searched | Google |
| Files Searched | Patents (US Patents/Published Applications, EPO publications, International, China, Germany, Canada) |
| Date Conducted | 07 September 2023 (07.09.2023) |
| Search Logic: | |

dilator with varying flexibility
About 8,770 results

vascular catheter and dilator
About 7,410 results

dilator to lock to valve
About 4,020 results

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

## U.S. PATENTS AND PUBLICATIONS

| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|---|---|---|---|---|---|
| | 1. | 3785380 | 01-15-1974 | Brumfield | |
| | 2. | 6908455 | 06-21-2005 | Hajianpour | |
| | 3. | 7837630 | 11-23-2010 | Nieoson et al. | |
| | 4. | 11832837 | 12-05-2023 | Hauser | |
| | 5. | 11832838 | 12-05-2023 | Hauser | |
| | 6. | 11833023 | 12-05-2023 | Hauser | |
| | 7. | 11839393 | 12-12-2023 | Hauser | |
| | 8. | 11844921 | 12-19-2023 | Merritt et al. | |
| | 9. | 11849963 | 12-26-2023 | Quick | |
| | 10. | 20130190701 | 07-25-2013 | Kirn | |
| | 11. | 20170143880 | 05-25-2017 | LUXON et al. | |
| | 12. | 20170172591 | 06-22-2017 | Ulm, III | |
| | 13. | 20210128182 | 05-06-2021 | Teigen et al. | |
| | 14. | 20210316127 | 10-14-2021 | Buck et al. | |
| | 15. | 20230389932 | 12-07-2023 | Ozenne et al. | |
| | 16. | 20230390045 | 12-07-2023 | Merritt et al. | |
| | | | | | |

## FOREIGN PATENT DOCUMENTS

| Examiner Initial* | Cite No | Foreign Document Number[3] | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[5] |
|---|---|---|---|---|---|---|
| | | | | | | |

## NON-PATENT LITERATURE DOCUMENTS

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

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

| EXAMINER SIGNATURE | | | |
|---|---|---|---|
| Examiner Signature | | Date Considered | |

*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.

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

## CERTIFICATION STATEMENT

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

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

**OR**

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

☐ See attached certification statement.

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

☒ None

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

### COPIES OF REFERENCES

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

## SIGNATURE

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

| | | | |
|---|---|---|---|
| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2024-01-17 |
| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

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

UNITED STATES
PATENT AND TRADEMARK OFFICE

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

# ELECTRONIC ACKNOWLEDGEMENT RECEIPT

| APPLICATION # | RECEIPT DATE / TIME | ATTORNEY DOCKET # |
|---|---|---|
| **17/498,642** | **01/17/2024 01:33:17 PM Z ET** | **111552-8023.US02** |

## Title of Invention

SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

## Application Information

| | | | |
|---|---|---|---|
| APPLICATION TYPE | Utility - Nonprovisional Application under 35 USC 111(a) | PATENT # | - |
| CONFIRMATION # | 1040 | FILED BY | Julie Willie |
| PATENT CENTER # | 63981338 | FILING DATE | 10/11/2021 |
| CUSTOMER # | 25096 | FIRST NAMED INVENTOR | Richard Quick |
| CORRESPONDENCE ADDRESS | - | AUTHORIZED BY | Matthew Williams |

## Documents

**TOTAL DOCUMENTS: 1**

| DOCUMENT | PAGES | DESCRIPTION | SIZE (KB) |
|---|---|---|---|
| IDS.pdf | 3 | Information Disclosure Statement (IDS) Form (SB08) | 126 KB |

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

## Digest

| DOCUMENT | MESSAGE DIGEST(SHA-512) |
|---|---|
| IDS.pdf | 7452E37157B264BD9476E33F7891AD8FF46CE21A1B111B97BA8ECEC1CE44E38E4B8DCE5F5DAC138C00787C3B9B299110B8 |

E568183538D54802FD50F3C516C7DE

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

**New Applications Under 35 U.S.C. 111**

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

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

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

**New International Application Filed with the USPTO as a Receiving Office**

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NUMBER | FILING or 371(c) DATE | GRP ART UNIT | FIL FEE REC'D | ATTY.DOCKET.NO | TOT CLAIMS | IND CLAIMS |
|---|---|---|---|---|---|---|
| 17/498,642 | 10/11/2021 | 3771 | 3380 | 111552-8023.US02 | 21 | 2 |

**CONFIRMATION NO. 1040**

**UPDATED FILING RECEIPT**

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

*OC00000006497017*

Date Mailed: 11/28/2023

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

**Please verify the accuracy of the data presented on this receipt.** If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

**Inventor(s)**

Richard Quick, Mission Viejo, CA;
Benjamin Edward Merritt, San Clemente, CA;
John Coleman Thress, Capistrano Beach, CA;
Paul Lubock, Monarch Beach, CA;
Thomas M. Tu, Louisville, KY;

**Applicant(s)**

Inari Medical, Inc., Irvine, CA;

**Power of Attorney:** The patent practitioners associated with Customer Number 25096

**Domestic Priority data as claimed by applicant**

This application is a CON of 16/258,344 01/25/2019 PAT 11,154,314
which claims benefit of 62/622,691 01/26/2018

Foreign Applications for which priority is claimed (You may be eligible to benefit from the Patent Prosecution Highway program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

**Permission to Access Application via Priority Document Exchange:** Yes

**Permission to Access Search Results:** Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

**If Required, Foreign Filing License Granted:** 10/20/2021

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/498,642**

**Projected Publication Date:** 08/04/2022

**Non-Publication Request:** No

**Early Publication Request:** No

**Title**

SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

**Preliminary Class**

606

**Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications:** No

## PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific

countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

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## Title 35, United States Code, Section 184

## Title 37, Code of Federal Regulations, 5.11 & 5.15

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

**NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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www.uspto.gov

| APPLICATION NUMBER | FILING OR 371(C) DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO./TITLE |
|---|---|---|---|
| 17/498,642 | 10/11/2021 | Richard Quick | 111552-8023.US02 |

**CONFIRMATION NO. 1040**

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

**37 CFR 1.48 ACKNOWLEDGEMENT LETTER**

*OC000000064970018*

Date Mailed: 11/28/2023

## NOTICE OF ACCEPTANCE OF REQUEST UNDER 37 CFR 1.48(a)

This is in response to the applicant's request under 37 CFR 1.48(a) submitted on 11/21/2023.

The request under 37 CFR 1.48(a) to correct the inventorship, to correct or update the name of an inventor, or to correct the order of names of joint inventors is accepted.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/sstephanos/

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

| U.S. PATENTS AND PUBLICATIONS | | | | | |
|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | 1. | 5391152 | 02-21-1995 | Patterson et al. | |
| | 2. | 20210404464 | 12-30-2021 | Patoskie | |
| | 3. | 5971958 | 10-26-1999 | Zhang | |
| | 4. | 3860006 | 01-14-1975 | Patel | |
| | 5. | 20130150793 | 06-13-2013 | Beissel et al. | |
| | 6. | 20230270991 | 08-31-2023 | Merritt et al. | |
| | 7. | 20190015298 | 01-17-2019 | Beatty et al. | |
| | 8. | 20180055999 | 03-01-2018 | Bare et al. | |
| | 9. | 20040019310 | 01-29-2004 | Hogendijk | |
| | 10. | 20080312681 | 12-18-2008 | Ansel et al. | |
| | 11. | 20170143359 | 05-25-2017 | Nguyen et al. | |
| | 12. | 20170143938 | 05-25-2017 | Ogle et al. | |
| | 13. | 20170281204 | 10-05-2017 | Garrison et al. | |
| | 14. | 8021351 | 09-20-2011 | Boldenow et al. | |
| | 15. | 1101890 | 06-30-1914 | TUNSTEAD | |
| | 16. | 10953195 | 03-23-2021 | Jalgaonkar et al. | |
| | 17. | 20210205577 | 07-08-2021 | Jalgaonkar et al. | |
| | 18. | 3416531 | 12-17-1968 | EDWARDS | |
| | 19. | 4981478 | 01-01-1991 | Evard et al. | |
| | 20. | 7815608 | 10-19-2010 | Schafersman et al. | |
| | 21. | 9662129 | 05-30-2017 | Galdonik et al. | |
| | 22. | 8070694 | 12-06-2011 | Galdonik et al. | |
| | 23. | 10058339 | 08-28-2018 | Galdonik et al. | |
| | 24. | 9532792 | 01-03-2017 | Galdonik et al. | |
| | 25. | 20200121334 | 04-23-2020 | Galdonik et al. | |
| | 26. | 11596768 | 03-07-2023 | Stern et al. | |
| | 27. | 10926060 | 02-23-2021 | Stern et al. | |
| | 28. | 11224450 | 01-18-2022 | Chou et al. | |
| | 29. | 11065019 | 07-20-2021 | Chou et al. | |
| | 30. | 11576691 | 02-14-2023 | Chou et al. | |
| | 31. | 2022033888 | 02-03-2022 | Schnall-Levin et al. | |

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

| U.S. PATENTS AND PUBLICATIONS | | | | | |
|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | 32. | 20220370761 | 11-24-2022 | Chou et al. | |
| | 33. | 20230059721 | 02-23-2023 | Chou et al. | |
| | 34. | 20230122587 | 04-20-2023 | Chou et al. | |
| | 35. | 11305094 | 04-19-2022 | Carrison et al. | |
| | 36. | 10485952 | 11-26-2019 | Carrison et al. | |
| | 37. | 10456555 | 10-29-2019 | Carrison et al. | |
| | 38. | 11383064 | 07-12-2022 | Carrison et al. | |
| | 39. | 11185664 | 11-30-2021 | Carrison et al. | |
| | 40. | 11224721 | 01-18-2022 | Carrison et al. | |
| | 41. | 11395903 | 07-26-2022 | Carrison et al. | |
| | 42. | 20200046940 | 02-13-2020 | Carrison et al. | |
| | 43. | 20210138194 | 05-13-2021 | Carrison et al. | |
| | 44. | 7122034 | 10-17-2006 | Belhe et al. | |
| | 45. | 5639276 | 06-17-1997 | Weinstock et al. | |
| | 46. | 7481805 | 01-27-2009 | Magnusson | |
| | 47. | 9241669 | 01-26-2016 | Pugh et al. | |
| | 48. | 10384034 | 08-20-2019 | Carrison et al. | |
| | 49. | 9265512 | 02-23-2016 | Carrison et al. | |
| | 50. | 20110152889 | 06-23-2011 | Ashland | |
| | 51. | 20230310138 | 10-05-2023 | Merritt et al. | |
| | 52. | 20230310137 | 10-05-2023 | Merritt et al. | |
| | 53. | 20230310751 | 10-05-2023 | Merritt et al. | |
| | 54. | 20030023263 | 01-30-2003 | Krolik et al. | |
| | 55. | 20030135151 | 07-17-2003 | Deng | |
| | 56. | 20200022711 | 01-23-2020 | Look et al. | |
| | 57. | 6017335 | 01-25-2000 | Burnham | |
| | 58. | 20040039351 | 02-26-2004 | Barrett | |
| | 59. | 20140180055 | 06-26-2014 | Glynn et al. | |
| | 60. | 20230329734 | 10-19-2023 | Marchand et al. | |
| | 61. | 5242461 | 09-07-1993 | Kortenbach et al. | |
| | 62. | 11806033 | 11-07-2023 | Marchand et al. | |

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
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| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

| U.S. PATENTS AND PUBLICATIONS | | | | | |
|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | 63. | 3438607 | 04-15-1969 | Williams et al. | |
| | 64. | 4401107 | 08-30-1983 | Harber et al. | |
| | 65. | 4634421 | 01-06-1987 | Hegemann | |
| | 66. | 5484418 | 01-16-1996 | Quiachon et al. | |
| | 67. | 20080087853 | 04-17-2008 | Kees | |
| | 68. | 10648268 | 05-12-2020 | Jaffrey et al. | |
| | 69. | 20230320834 | 10-12-2023 | Merritt et al. | |
| | 70. | 2784717 | 03-12-1957 | E.O. Thompson | |
| | 71. | 9884387 | 02-06-2018 | Plha | |
| | 72. | 20230338131 | 10-26-2023 | Merritt et al. | |
| | 73. | 20230338130 | 10-26-2023 | Merritt et al. | |
| | 74. | 2010114017 | 05-06-2010 | Lenker et al. | |
| | 75. | 6589264 | 07-08-2003 | Barbut et al. | |
| | 76. | 20230355259 | 11-09-2023 | Marchand et al. | |
| | 77. | 20230355256 | 11-09-2023 | Dinh | |
| | 78. | 20230355938 | 11-09-2023 | Merritt et al. | |
| | 79. | 20230363883 | 11-16-2023 | Merritt et al. | |
| | 80. | 20230363776 | 11-16-2023 | Quick | |
| | 81. | 20170113005 | 04-27-2017 | LINDER et al. | |
| | 82. | 20110309037 | 12-22-2011 | LEE | |
| | 83. | 20080294096 | 11-27-2008 | Uber, III et al. | |
| | 84. | 20130270161 | 10-17-2013 | KUMAR et al. | |
| | 85. | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Foreign Document Number[3] | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[5] |
| | 1. | CN106178227 | 12-07-2016 | Shanghai Microport Medical Group Co., Ltd. | | |
| | 2. | WO2023154612 | 08-17-2023 | Inari Medical, Inc. | | |
| | 3. | WO2018065092 | 04-12-2018 | PRINZESSIN VON ISENBURG, Sarah | | |

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
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| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initial* | Cite No | Foreign Document Number[3] | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[5] |
|---|---|---|---|---|---|---|
| | 4. | EP3013404 | 04-15-2020 | NorMedix Inc. | | |
| | 5. | EP3583972 | 12-25-2019 | Covidien LP | | |
| | 6. | EP3589348 | 01-08-2020 | Covidien LP | | |
| | 7. | EP4137070 | 02-22-2023 | ROUTE 92 MEDICAL INC. | | |
| | 8. | EP3620204 | 03-11-2020 | ROUTE 92 MEDICAL INC. | | |
| | 9. | WO2023192925 | 10-05-2023 | Inari Medical, Inc. | | |
| | 10. | WO2019173475 | 09-12-2019 | Innovative Cardiovascular Solutions, LLC | | |
| | 11. | WO2023215779 | 11-09-2023 | Inari Medical, Inc. | | |
| | 12. | | | | | |

**NON-PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T[5] |
|---|---|---|---|
| | | International Search Report and Written Opinion for International App. No. PCT/US23/60927; Date of Filing: January 19, 2023, Applicant: Inari Medical, Inc., Date of Mailing: July 20, 2023, 12 pages. | |
| | | Extended European Search Report issued for EP Application No. 20877370.5, Date of Mailing: October 17, 2023, 11 pages. | |
| | | International Search Report and Written Opinion for International App. No. PCT/US23/65128; Date of Filing: March 30, 2023, Applicant: Inari Medical, Inc., Date of Mailing: November 14, 2023, 14 pages. | |
| | | | |

**EXAMINER SIGNATURE**

| Examiner Signature | | Date Considered | |
|---|---|---|---|

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

**CERTIFICATION STATEMENT**

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

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

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

**OR**

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

☐ See attached certification statement.

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

☒ None

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

**COPIES OF REFERENCES**

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

## SIGNATURE

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

| | | | |
|---|---|---|---|
| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2023-11-21 |
| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

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

Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
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# REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
## (Submitted Only via EFS-Web)

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Application Number | 17/498,642 | Filing Date | 2021-10-11 | Docket Number (if applicable) | 111552.8023.US02 | Art Unit | 3771 |
| First Named Inventor | Richard Quick | | | Examiner Name | Tuan Van Nguyen | | |

**This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.**
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

### SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☐ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

### MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

### FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 500665

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| Signature of Registered U.S. Patent Practitioner | | | |
|---|---|---|---|
| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2023-11-21 |
| Name | Matthew S. Williams | Registration Number | 77516 |

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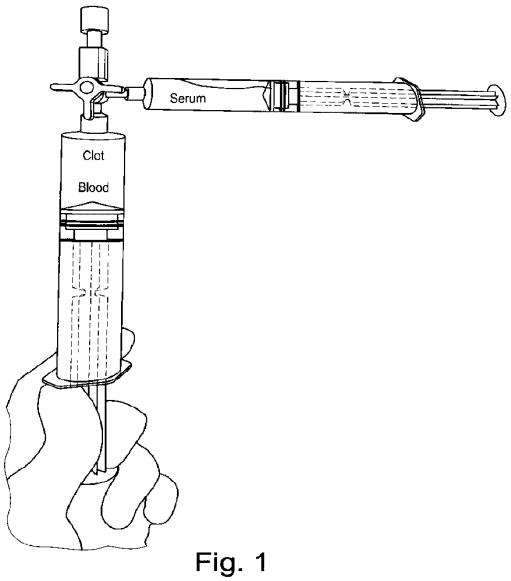



Fig. 1

(57) Abstract: The present invention is based on the idea of extracorporeally simulating a wound in order to obtain wound healing/regenerative growth factor mixtures. The invention provides a method for separating the growth factors that are released from cells upon coagulation (coagulation-induced signaling phase) from the growth factors that are secreted by cells under hypoxia (hypoxia-induced signaling phase), then mixing the two phases at defined ratios to obtain a novel composition. Peripheral blood is obtained and allowed to clot or centrifuged to induce clotting. The serum is removed completely or partially and replaced with fresh medium of volume equal or less than the volume of serum removed. The clot is incubated in fresh medium at a temperature of 10 to 40°C, under hypoxia ( 1 - 10% O2) for 1 to 7 days. The clot conditioned medium is then collected and mixed with the serum at a defined ratio to obtain the composition. Compositions comprising adjustable concentrations of growth factors derived from blood serum (coagulation-induced phase) and clot-conditioned medium (hypoxia-induced phase) can be added to suitable carriers, and can be topically applied or injected into a subject in order to aid wound healing, skin regeneration or rejuvenation.

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# COMPOSITIONS COMPRISING ADJUSTABLE CONCENTRATIONS OF GROWTH FACTORS DERIVED FROM BLOOD SERUM AND CLOT HYPOXIA-CONDITIONED MEDIUM AND METHODS OF THEIR PRODUCTION

## FIELD OF THE INVENTION

The present invention relates to compositions prepared from blood and blood serum. The compositions contain defined and adjustable concentrations of growth factors. The invention also concerns therapeutic and cosmetic methods in which these compositions are used. The invention further relates to methods and kits for producing these compositions.

## BACKGROUND OF THE INVENTION

Blood coagulation is necessary directly after injury to prevent excessive bleeding. At this stage, initiation of new blood vessel formation (angiogenesis) would be logically counterproductive, since newly formed vessels are fragile and unstable. Hemostasis and angiogenesis are therefore two tightly controlled processes, which ensures that angiogenesis is only triggered once hemostasis has been completed. This is evident during wound healing, where angiogenesis only begins three days after wounding. This temporal regulation of the hemostatic and angiogenic phases is achieved through the spatiotemporally-controlled release of protein growth factors by cells into the wound microenvironment.

Following activation of coagulation, the fibrin clot entraps platelets at the site of injury, forming a hemostatic plug, which is gradually replaced by capillary-rich granulation tissue, and eventually collagen, leading to restoration of the original extracellular matrix (Reinke JM, Sorg H. *Wound repair and regeneration.* Eur Surg Res 2012; 49(1):35-43). Clot hypoxia potentiates the platelet-derived pro-angiogenic signaling generated through coagulation. Platelet activation and release of factors stored in their granules has been utilized as a strategy for obtaining angiogenic compositions based on platelet concentrates, such as platelet-rich plasma (PRP) and PRP gel/ platelet-rich fibrin matrix (PRFM). However, in addition to pro-angiogenic mediators, certain factors released by platelets (e.g. PF-4, TSP-1) are strongly anti-angiogenic. Such factors

certainly play an important role in the aforementioned natural regulation of the hemostatic and angiogenic phases during wound healing. When present in excess (i.e. supraphysiological concentrations, such as those found in platelet concentrates), however, these factors might negatively impact the angiogenic effectiveness of platelet-rich products, by competing with or negating the effect of pro-angiogenic factors. This could explain the limited success of PRP products as chronic wound therapies to date.

Hypoxia is the primary angiogenic stimulus in physiological as well as pathological processes. Cell accumulation in the maturing wound bed or within a growing thrombus exacerbates the already compromised $O_2$ supply, by increasing local aerobic demand. Cell-mediated hypoxic conditioning of the hemostastic microenvironment results in an upregulated expression of a range of angiogenic growth factors such as VEGF, ANG, IL8, MMP-9 that are secreted by cells. This effect could be further potentiated though the simultaneous hypoxia-induced downregulation in the expression of anti-angiogenic factors, such as Thrombospondin 1 (TSP1).

*In vitro* hypoxic preconditioning of cells has been proposed to be a promising strategy for generating complex, yet physiological, angiogenic factor protein mixtures which can be delivered to ischaemic tissues (e.g. wounds, ulcers, burns) to aid re-perfusion, repair and regeneration. Among the various cell types that are suitable for hypoxic stress stimulation, peripheral blood cells (PBCs) represent an ideal autologous cell type, since their easy harvest and ample availability means that the need for lengthy cell population expansion cycles, required for example when using biopsy-harvested skin fibroblasts, is circumvented. PBCs can therefore be cultured directly after being obtained from the patient. Previous studies have shown that peripheral blood mononuclear cells (PBMCs) respond to stress (e.g. hypoxia/ischaemia, inflammation) by upregulating a wide range of angiogenic growth factors, such as VEGF, bFGF, IL-8, MMP-9, and have the ability to induce angiogenesis *in vitro* and *in vivo*. For example, it has been demonstrated that preconditioning PBMCs to hypoxia increases their survival and angiogenic potency upon implantation into ischaemic hindlimbs of mice. Also, intravenous administration of culture supernatant from irradiated apoptotic PBMCs confers cytoprotection to cardiomyocytes and inhibits tissue remodeling in rat and porcine acute myocardial infarction (AMI) models, while emulsions containing PBMC supernatant enhance wound closure. In various patient trials it was shown that transplantation of autologous mononuclear cells, from

peripheral blood or bone marrow, increases leg perfusion in critical limb ischaemia, improves cardiac function after AMI, and accelerates the healing of refractory skin ulcers. These findings provide strong evidence that peripheral blood is a suitable source of angiogenic factor producing cells.

Conditioned culture media containing protein growth factors secreted by cells that are cultured under normoxia or hypoxia are well known in the art, and have been proposed as suitable compositions for inducing tissue repair and regeneration. Hypoxia conditioned plasma, i.e. plasma derived after extracorporeal conditioning of anticoagulated blood under physiological temperature (37°C) and physiological hypoxia (1-10% $O_2$), represents a special form of conditioned culture medium, in that its composition (concentrations and ratios of factors) is stoichiometrically (i.e. precisely) defined by the patient's peripheral blood cell type and number/count, in contrast to conditioned media typically obtained by *ex vivo/in vitro* reconstituted culture methods. This confers an important advantage when considering the inter-individual variation present in terms of gene expression and growth factor-induced cellular responses, and forms the basis for its utilization as an autologous therapy.

## TECHNICAL PROBLEMS UNDERLYING THE PRESENT INVENTION

As mentioned above, during wound healing the onset of hypoxia-induced angiogenesis is temporally distinct from the early inflammatory phase, in which platelets are primarily involved in hemostasis (angiogenesis is typically induced 3 to 4 days after wounding) (Reinke & Sorg, 2012, *supra*). While platelets might play a regulatory role, rather than a directly stimulatory role in new vessel formation, their contribution to the initiation, progression and completion of the wound healing process is self-evident. A key premise of this invention is that an optimal wound healing composition should comprise both the coagulation-induced, as well as the hypoxia-induced growth factor signalling phases. In nature, these two phases occur sequentially, i.e. the coagulation-mediated phase is induced immediately upon/soon after wounding through the release of growth factors by activated platelets, followed by the induction of the hypoxia-mediated phase which depends on growth factor production by blood cells and other cells present within or migrating into the wound. Previously described methods for producing conditioned

culture media, including compositions comprising conditioned blood products, fail however to provide a way to segregate these two phases, as all the factors are released into the same (culture) medium (e.g. conditioned plasma or conditioned serum). A cumulative mixture is therefore obtained that contains all the required growth factors, but their concentrations and ratios can neither be controlled/adjusted, nor do they correlate with the concentrations/ratios at which these factors are progressively encountered with a natural wound.

This invention solves this problem by providing a method for first separating the two phases, in order to then be able to mix them at defined ratios in order to obtain tailor-made compositions that can eventually recapitulate the natural sequential expression of the two wound healing phases. The invention further solves this problem by providing a kit-of parts comprising the two phases in separate containers and a kit for preparing and separating the two phases.

## SUMMARY OF THE INVENTION

In a first aspect the present invention relates to a kit-of-parts comprising:

(a) a hypoxia-conditioned medium derived from blood; and

(b) a serum

in separate containers.

In a second aspect the present invention relates to a solution of growth factors comprising a mixture of

(a) a hypoxia-conditioned medium derived from blood; and

(b) a serum.

In a third aspect the present invention relates to a method for preparing a kit-of parts, said method comprising the steps:

(i) providing a blood sample from a subject;

(ii) allowing the blood sample of step (i) to clot or inducing clotting in the blood sample of step (i), thereby obtaining a composition comprising a blood clot and serum;

(iii) removing at least a part of the serum from the composition obtained in step (ii) and determining the volume of the serum removed;

(iv) adding medium to the blood clot, wherein the volume of the added medium is equal to or less than the volume of the serum removed in step (iii);

(v) incubating the clot in said medium at a temperature between 10°C and 40°C under hypoxic conditions for 1 to 7 days, thereby obtaining a hypoxia-conditioned medium;

(vi) collecting at least a part of the hypoxia-conditioned medium obtained in step (v); and

(vii) preparing a kit-of-parts comprising:

(a) the hypoxia-conditioned medium collected in step (vi) and

(b) at least a part of the serum removed in step (iii).

In a fourth aspect the present invention relates to a method for producing a solution of growth factors, said method comprising the steps:

(i) providing a blood sample from a subject;

(ii) allowing the blood sample of step (i) to clot or inducing clotting in the blood sample of step (i), thereby obtaining a composition comprising a blood clot and serum;

(iii) removing at least a part of the serum from the composition obtained in step (ii) and determining the volume of the serum removed;

(iv) adding medium to the blood clot, wherein the volume of the added medium is equal to or less than the volume of the serum removed in step (iii);

(v) incubating the clot in said medium at a temperature between 10°C and 40°C under hypoxic conditions for 1 to 7 days, thereby obtaining a hypoxia-conditioned medium;

(vi) collecting at least a part of the hypoxia-conditioned medium obtained in step (v);

(vii) mixing the hypoxia-conditioned medium collected in step (vi) with at least a part of the serum removed in step (iii), thereby obtaining the solution of growth factors.

In a fifth aspect the present invention relates to a method for preparing a kit-of parts, said method comprising the steps:

(i) providing a first blood sample from a subject;

(ii) allowing the blood sample of step (i) to clot or inducing clotting in the blood sample of step (i), thereby obtaining a first composition comprising a blood clot and serum;

(iii) removing at least a part of the serum from the first composition obtained in step (ii) and determining the volume of the serum removed;

(iv) adding medium to the blood clot, wherein the volume of the added medium is equal to or less than the volume of the serum removed in step (iii);

(v) incubating the clot in said medium at a temperature between 10°C and 40°C under hypoxic conditions for 1 to 7 days, thereby obtaining a hypoxia-conditioned medium;

(vi) collecting at least a part of the hypoxia-conditioned medium obtained in step (v);

(vii) providing a second blood sample from a subject;

(viii) allowing the blood sample of step (vii) to clot or inducing clotting in the blood sample of step (vii), thereby obtaining a second composition comprising a blood clot and serum;

(ix) recovering at least a part of the serum from the second composition obtained in step (viii); and

(x) preparing a kit-of-parts comprising:

(a) the hypoxia-conditioned medium collected in step (vi) and

(b) the serum recovered in step (ix).

In a sixth aspect the present invention relates to a method for producing a solution of growth factors, said method comprising the steps:

(i) providing a first blood sample from a subject;

(ii) allowing the blood sample of step (i) to clot or inducing clotting in the blood sample of step (i), thereby obtaining a first composition comprising a blood clot and serum;

(iii) removing at least a part of the serum from the first composition obtained in step (ii) and determining the volume of the serum removed;

(iv) adding medium to the blood clot, wherein the volume of the added medium is equal to or less than the volume of the serum removed in step (iii);

(v) incubating the clot in said medium at a temperature between 10°C and 40°C under hypoxic conditions for 1 to 7 days, thereby obtaining a hypoxia-conditioned medium;

(vi) collecting at least a part of the hypoxia-conditioned medium obtained in step (v);

(vii) providing a second blood sample from a subject;

(viii) allowing the blood sample of step (vii) to clot or inducing clotting in the blood sample of step (vii), thereby obtaining a second composition comprising a blood clot and serum;

(ix) recovering at least a part of the serum from the second composition obtained in step (viii), thereby obtaining a serum; and

(x) mixing the hypoxia-conditioned medium collected in step (vi) with at least a part of the serum recovered in step (ix), thereby obtaining the solution of growth factors.

In a seventh aspect the present invention relates to a kit-of-parts prepared by the method of the third or fifth aspect.

In an eighth aspect the present invention relates to a solution of growth factors produced by the method of the fourth or sixth aspect.

In a ninth aspect the present invention relates to a composition comprising

(a) the solution of the second or of the eighth aspect; and

(b) a carrier.

In a tenth aspect the present invention relates to a solution of the second aspect or of the eighth aspect or to a composition of the ninth aspect for use in medicine.

In an eleventh aspect the present invention relates to a solution of the second aspect or of the eighth aspect or to a composition of the ninth aspect for use in the improvement of tissue blood perfusion, for use in the stimulation of angiogenesis, for use in the treatment of skin that has been debrided, for use in the treatment of excessive scarring, for use in the treatment of grafts, for use in the treatment of flaps, for use in the treatment of wounds, and/or for use in the treatment of tissue damage.

In a twelfth aspect the present invention relates to a cosmetic, non-therapeutic use of the solution of the second aspect or of the eighth aspect or of the composition of the ninth aspect.

In a thirteenth aspect the present invention relates to a kit for preparing serum and/or hypoxia-conditioned medium derived from blood, said kit comprising:

(a) a first syringe,

(b) a second syringe,

(c) optionally a third syringe,

(d) optionally a fourth syringe,

(e) a three-way valve,

(f) a filter,

(g) a cap,

(h) optionally a container containing sterile medium,

(i) optionally a catheter or butterfly cannula,

(j) optionally a sticking plaster,

(k) optionally a rack into which the first syringe can be placed and maintained in upright position, and

(l) optionally a spatula.

In a fourteenth aspect the present invention relates to a use of the kit of the thirteenth aspect in a method according to any one of the third, fourth, fifth, or sixth aspect.

This summary of the invention does not necessarily describe all features of the present invention. Other embodiments will become apparent from a review of the ensuing detailed description.

## DESCRIPTION OF THE FIGURES

**Fig. 1**: Serum Separation. After a clot has formed in the first syringe (shown on the left side of the photograph), serum is withdrawn into the second syringe (shown at the top of the photograph).

**Fig. 2**: Addition of air and medium. A filter was connected to the three way valve. Air was drawn into the first syringe through the filter. Then, the filter was covered with a cap. A third syringe filled with sterile medium was connected to the three-way valve. This is the situation shown in the photograph. Next, the three way valve will be turned so that the connection to the filter will be blocked and the first syringe and the third syringe will be connected. The medium will be pushed from the third syringe into the first syringe.

**Fig. 3**: Collection of new mixture (conditioned medium and serum). The filter was removed and a fourth empty syringe was attached to the three way valve. The second syringe containing the serum was reconnected to the three way valve. Conditioned medium from the first syringe was pushed into the fourth syringe. The three valve was turned so that the first syringe is blocked and the second syringe and the fourth syringe are connected. This is the situation shown in the photograph. Next, serum will be pushed into the fourth syringe, thereby producing a mixture of conditioned medium and serum.

DETAILED DESCRIPTION OF THE INVENTION

**Definitions**

Before the present invention is described in detail below, it is to be understood that this invention is not limited to the particular methodology, protocols and reagents described herein as these may vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to limit the scope of the present invention which will be limited only by the appended claims. Unless defined otherwise, all technical and scientific terms used herein have the same meanings as commonly understood by one of ordinary skill in the art to which this invention belongs.

Preferably, the terms used herein are defined as described in "A multilingual glossary of biotechnological terms: (IUPAC Recommendations)", Leuenberger, H.G.W, Nagel, B. and Kölbl, H. eds. (1995), Helvetica Chimica Acta, CH-4010 Basel, Switzerland).

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated member, integer or step or group of members, integers or steps but not the exclusion of any other member, integer or step or group of members, integers or steps.

Several documents (for example: patents, patent applications, scientific publications, manufacturer's specifications, instructions etc.) are cited throughout the text of this specification. Nothing herein is to be construed as an admission that the invention is not entitled to antedate such disclosure by virtue of prior invention. Some of the documents cited herein are characterized as being *"incorporated by reference"*. In the event of a conflict between the definitions or teachings of such incorporated references and definitions or teachings recited in the present specification, the text of the present specification takes precedence.

As used herein, "hypoxic conditions" refer to oxygen concentrations of 10% or less.

As used herein, a "hypoxia-conditioned medium" refers to a solution obtainable by incubating a blood clot in a solution under hypoxic conditions for a certain amount of time and by subsequently removing the blot clot from the solution. Typically, the solution is a medium suitable for culturing blood cells. Typically, the incubation is carried out under hypoxic

conditions at a temperature between 10°C and 40°C for 1 to 7 days. Under these conditions, the cells present in the blood clot secrete certain growth factors into the solution. Accordingly, the "hypoxia-conditioned medium" contains growth factors produced by the cells present in the blood clot. The expressions "hypoxia-conditioned medium", "clot-conditioned medium", and "clot hypoxia-conditioned medium" are used interchangeably herein.

As used herein, the term "serum" refers to a fraction of blood that is free from blood cells and clotting factors. Typically, serum can be obtained by centrifuging a coagulated blood sample.

**Embodiments of the Invention**

The present invention will now be further described. In the following passages different aspects of the invention are defined in more detail. Each aspect defined below may be combined with any other aspect or aspects unless clearly indicated to the contrary. In particular, any feature indicated as being preferred or advantageous may be combined with any other feature or features indicated as being preferred or advantageous.

In a first aspect the present invention is directed to a kit-of-parts comprising: (a) a hypoxia-conditioned medium derived from blood; and (b) a serum in separate containers.

In a second aspect the present invention is directed to a solution of growth factors comprising a mixture of (a) a hypoxia-conditioned medium derived from blood; and (b) a serum.

In some embodiments of the first aspect or the second aspect, the hypoxia-conditioned medium is derived from whole blood.

In some embodiments of the first aspect or the second aspect, the hypoxia-conditioned medium has a lower concentration of Platelet Factor 4 (PF4) than the serum. In preferred embodiments of the first aspect or the second aspect, the hypoxia-conditioned medium contains PF4 in a concentration between 0 ng/ml and 15,000 ng/ml, preferably between 5 ng/ml and 5,000 ng/ml.

In some embodiments of the first aspect or the second aspect, the hypoxia-conditioned medium contains at least one angiogenesis-related growth factor selected from the group consisting of VEGF, TSP1, IL8, Angiogenin (ANG), MMP-9, MMP-8, TIMP-1, and PDGF.

In some embodiments of the first aspect or the second aspect, the hypoxia-conditioned medium has a higher concentration of Vascular Endothelial Growth Factor (VEGF) than the serum. In preferred embodiments of the first aspect or the second aspect, the VEGF concentration in the hypoxia-conditioned medium is greater than 100 pg/ml; preferably in the range of 100 pg/ml to 500 ng/ml, more preferably in the range of 500 pg/ml to 50,000 pg/ml.

In some embodiments of the first aspect or the second aspect, the hypoxia-conditioned medium and/or the serum are derived from one or more blood samples obtained from the same subject.

In some other embodiments of the first aspect or the second aspect, the hypoxia-conditioned medium is derived from one or more blood samples obtained from a first subject and the serum is derived from one or more blood samples obtained from a second subject, wherein the first subject and the second subject are not the same subject.

In some embodiments of the first aspect or the second aspect, the hypoxia-conditioned medium and/or the serum is free of cells.

In some embodiments of the second aspect, the solution is free of cells.

In a third aspect the present invention is directed to a method for preparing a kit-of parts, said method comprising the steps:

(i) providing a blood sample from a subject;

(ii) allowing the blood sample of step (i) to clot or inducing clotting in the blood sample of step (i), thereby obtaining a composition comprising a blood clot and serum;

(iii) removing at least a part of the serum from the composition obtained in step (ii) and determining the volume of the serum removed;

(iv) adding medium to the blood clot, wherein the volume of the added medium is equal to or less than the volume of the serum removed in step (iii);

(v) incubating the clot in said medium at a temperature between 10°C and 40°C under hypoxic conditions for 1 to 7 days, thereby obtaining a hypoxia-conditioned medium;

(vi) collecting at least a part of the hypoxia-conditioned medium obtained in step (v); and

(vii) preparing a kit-of-parts comprising:

(a) the hypoxia-conditioned medium collected in step (vi) and

(b) at least a part of the serum removed in step (iii).

In a fourth aspect the present invention is directed to a method for producing a solution of growth factors, said method comprising the steps:

(i) providing a blood sample from a subject;

(ii) allowing the blood sample of step (i) to clot or inducing clotting in the blood sample of step (i), thereby obtaining a composition comprising a blood clot and serum;

(iii) removing at least a part of the serum from the composition obtained in step (ii) and determining the volume of the serum removed;

(iv) adding medium to the blood clot, wherein the volume of the added medium is equal to or less than the volume of the serum removed in step (iii);

(v) incubating the clot in said medium at a temperature between 10°C and 40°C under hypoxic conditions for 1 to 7 days, thereby obtaining a hypoxia-conditioned medium;

(vi) collecting at least a part of the hypoxia-conditioned medium obtained in step (v);

(vii) mixing the hypoxia-conditioned medium collected in step (vi) with at least a part of the serum removed in step (iii), thereby obtaining the solution of growth factors.

In a fifth aspect the present invention is directed to a method for preparing a kit-of parts, said method comprising the steps:

(i) providing a first blood sample from a subject;

(ii) allowing the blood sample of step (i) to clot or inducing clotting in the blood sample of step (i), thereby obtaining a first composition comprising a blood clot and serum;

(iii) removing at least a part of the serum from the first composition obtained in step (ii) and determining the volume of the serum removed;

(iv) adding medium to the blood clot, wherein the volume of the added medium is equal to or less than the volume of the serum removed in step (iii);

(v) incubating the clot in said medium at a temperature between 10°C and 40°C under hypoxic conditions for 1 to 7 days, thereby obtaining a hypoxia-conditioned medium;

(vi) collecting at least a part of the hypoxia-conditioned medium obtained in step (v);

(vii) providing a second blood sample from a subject;

(viii) allowing the blood sample of step (vii) to clot or inducing clotting in the blood sample of step (vii), thereby obtaining a second composition comprising a blood clot and serum;

(ix) recovering at least a part of the serum from the second composition obtained in step (viii); and

(x) preparing a kit-of-parts comprising:

(a) the hypoxia-conditioned medium collected in step (vi) and

(b) the serum recovered in step (ix).

In a sixth aspect the present invention is directed to a method for producing a solution of growth factors, said method comprising the steps:

(i) providing a first blood sample from a subject;

(ii) allowing the blood sample of step (i) to clot or inducing clotting in the blood sample of step (i), thereby obtaining a first composition comprising a blood clot and serum;

(iii) removing at least a part of the serum from the first composition obtained in step (ii) and determining the volume of the serum removed;

(iv) adding medium to the blood clot, wherein the volume of the added medium is equal to or less than the volume of the serum removed in step (iii);

(v) incubating the clot in said medium at a temperature between 10°C and 40°C under hypoxic conditions for 1 to 7 days, thereby obtaining a hypoxia-conditioned medium;

(vi) collecting at least a part of the hypoxia-conditioned medium obtained in step (v);

(vii) providing a second blood sample from a subject;

(viii) allowing the blood sample of step (vii) to clot or inducing clotting in the blood sample of step (vii), thereby obtaining a second composition comprising a blood clot and serum;

(ix) recovering at least a part of the serum from the second composition obtained in step (viii), thereby obtaining a serum; and

(x) mixing the hypoxia-conditioned medium collected in step (vi) with at least a part of the serum recovered in step (ix), thereby obtaining the solution of growth factors.

In some embodiments of the third aspect, the fourth aspect, the fifth aspect, or the sixth aspect, clotting is induced in method step (ii) by centrifuging the blood sample provided in step (i).

In some embodiments of the fifth aspect or the sixth aspect, clotting is induced in method step (viii) by centrifuging the blood sample provided in step (vii).

In some embodiments of the fifth aspect or the sixth aspect, the first blood sample and the second blood sample were obtained from the same subject.

In some other embodiments of the fifth aspect or the sixth aspect, the first blood sample was obtained from a first subject and the second blood sample was obtained from a second subject, wherein the first subject and the second subject are not the same subject.

While exposing PBCs to hypoxia is an effective method for inducing angiogenic factor upregulation, it faces the common problem that generally hinders the application of hypoxia-based therapies, namely the limited availability of $O_2$-controlled incubators/chambers in clinical settings. A promising approach to overcome this limitation is to allow PBCs to regulate their $O_2$ microenvironment, instead of exposing them to an artificial one, i.e. hypoxia produced within an incubator. It has been demonstrated that cell-mediated hypoxia can be achieved in the core of 3D collagen matrix depots, seeded at high density with dermal fibroblasts or vascular smooth muscle cells, by adjusting the total cell number and cell distribution within the depot (Cheema, U., Brown, R. A., Alp, B., and MacRobert, A. J., *Spatially defined oxygen gradients and vascular endothelial growth factor expression in an engineered 3D cell model*, Cellular and Molecular Life Sciences 65 (2008) 177-186, herein incorporated by reference in its entirety). In this work, a VEGF response was elicited by cells exposed to low levels of $O_2$ (~3% $O_2$), primarily within the construct core. Also, grafting cord blood mesenchymal stem cells as spheroids in ischaemic hind limbs of mice was shown to improve therapeutic efficacy due to enhanced cell survival and paracrine activity, effects mediated by hypoxic cell preconditioning within spheroid cultures (Bhang, S. H., Lee, S., Shin, J. Y., Lee, T. J., and Kim, B. S., *Transplantation of cord blood*

*mesenchymal stem cells as spheroids enhances vascularization*, Tissue Eng Part A 18 (2012) 2138-2147, herein incorporated by reference in its entirety). In this study, culturing cells as monolayer, where cells were not exposed to hypoxia, abrogated these effects. These findings therefore indicate that cell-mediated hypoxia is a good alternative to externally-controlled (i.e. incubator) hypoxia. PBC pericellular $O_2$ tension, being a function of cellular $O_2$ consumption, will predictably depend on the level of aerobic metabolism, as well as the population cell number/viability. Both these parameters are directly related to the PBC seeding density, which is initially determined by the ratio of blood volume to cross sectional surface area of the blood container. While lower ratios (e.g. <0.25 ml/cm$^2$) would guarantee uniform cell distribution/spread, and would therefore be more suitable to external (i.e. incubator-controlled) hypoxia, higher ratios (e.g. 0.25 - 50 ml/cm$^2$, preferably 0.25 - 5 ml/cm$^2$) would produce a higher cell density, therefore aiding the induction of persisting cell-mediated hypoxia.

Accordingly, in some embodiments of the third aspect, the fourth aspect, the fifth aspect, or the sixth aspect, the hypoxic conditions in the medium in step (v) are achieved through cell-mediated oxygen consumption within a normoxic incubator and/or within an oxygen-regulated incubator.

It is well established that cellular metabolic activity correlates with protein synthetic activity. Angiogenic factor expression by cultured PBCs will also depend on the ambient temperature, a direct controller of cellular metabolism. Culturing PBCs under physiological temperature (37°C) is therefore preferable, as this will promote higher growth factor production. Accordingly, in some embodiments of the third aspect, the fourth aspect, the fifth aspect, or the sixth aspect, the incubation in step (v) is carried out at a temperature between 20°C to 40°C, preferably between 25°C and 40°C, more preferably between 30°C and 40°C, even more preferably between 35°C and 40°, and most preferably at about 37°C.

In some embodiments of the third aspect, the fourth aspect, the fifth aspect, or the sixth aspect, the incubation in step (v) is carried out at an oxygen concentration of between 1 and 10%, preferably between 1% and 5%.

In some embodiments of the third aspect, the fourth aspect, the fifth aspect, or the sixth aspect, the volume of the medium added in step (iv) is between 1/200 and 2/3 of the volume of the serum removed in step (iii), for example 1/200, 1/100, 1/20, 1/10, 1/5, 1/2 or 2/3.

In some embodiments of the third aspect, the fourth aspect, the fifth aspect, or the sixth aspect, step (vi) comprises the repeated collection of hypoxia-conditioned medium by carrying out the following steps:

(1) collecting at least a part of the hypoxia-conditioned medium at a first time point;

(2) adding medium to the blot clot, thereby replacing the hypoxia-conditioned medium collected in step (1),

(3) continuing incubation,

(4) collecting at least a part of the hypoxia-conditioned medium at a second time point, and

(5) optionally repeating steps (2) to (4) between 1 time and 5 times.

In preferred embodiments of the third aspect, the fourth aspect, the fifth aspect, or the sixth aspect, the volume of the medium added in step (iv) and/or the medium added in step (2) is equal to or less than the volume of the serum removed in step (iii).

In further preferred embodiments of the third aspect, the fourth aspect, the fifth aspect, or the sixth aspect, the total volume of the medium added in step (iv) and the medium added in step (2) is equal to or less than the volume of the serum removed in step (iii).

In further preferred embodiments of the third aspect, the fourth aspect, the fifth aspect, or the sixth aspect, the solution of growth factors obtained in step (vii) of the fourth aspect or in step (x) of the sixth aspect is obtained by mixing a given volume of hypoxia-conditioned medium ($V_{hcm}$) with a volume of serum ($V_s$) that fulfils the following inequality:

$$V_s \leq \frac{V_{hcm} * V_{s_{total}}}{V_{hcm_{total}}} - V_{hcm}$$

wherein $V_s$ is the volume of serum that can be used for mixing,

wherein $V_{hcm}$ is the volume of hypoxia-conditioned medium used for mixing,

wherein $V_{s_{total}}$ is the total volume of the serum removed in step (iii),

wherein $V_{hcm_{total}}$ is the total volume of the medium added in step (iv), and

wherein additionally the following condition applies: $V_{hcm_{total}} \leq V_{s_{total}}$.

In some embodiments of the third aspect, the fourth aspect, the fifth aspect, or the sixth aspect, the medium is selected from the group consisting of serum-containing culture medium, serum-free culture medium, a solution that is isotonic with blood, a culture medium with

glucose, a culture medium without glucose, a culture medium with albumin and a culture medium without albumin.

In a seventh aspect the present invention is directed to a kit-of-parts prepared by the method of the third aspect or the fifth aspect.

In an eighth aspect the present invention is directed to a solution of growth factors produced by the method of the fourth or the sixth aspect.

In a ninth aspect the present invention is directed to a composition comprising (a) the solution of the second aspect or the solution of the eighth aspect; and (b) an excipient.

In some embodiments of the ninth aspect, the composition is a pharmaceutical composition. In preferred embodiments, the excipient is a pharmaceutically acceptable excipient.

In some embodiments of the ninth aspect, the composition is a cosmetic composition. In preferred embodiments, the excipient is a cosmetically acceptable excipient.

In some embodiments of the ninth aspect, the excipient is fibrinogen. In some embodiments, the fibrinogen is exogenous fibrinogen, i.e. fibrinogen obtained from a different subject than the subject to which the composition is applied or administered.

In some embodiments of the ninth aspect, the composition further comprises: (c) a carrier. Preferably, the carrier is a pharmaceutically acceptable carrier or a cosmetically acceptable carrier. In preferred embodiments, the carrier is in the form of a cream, an emollient, an ointment, a gel, a sol-gel, a spray, a powder, a mesh, a sponge, a patch, a dressing, nanoparticles, microparticles, nanofibers or microfibers. In further preferred embodiments, the carrier comprises one or more substances selected from the group consisting of proteins (e.g. collagen, elastin, fibrin, or fibronectin), polysaccharides (e.g. alginate, chitin, or cellulose), glycosaminoglycan (e.g. hyaluronic acid, dermatan sulphate, keratin sulphate, chondroitin sulphate, heparan sulphate, or heparin sulphate), and synthetic polymers (e.g. polyglycolic acid, polylactic acid, polycaprolactone, or polylactic co-glycolic acid).

Without wishing to be bound by any particular theory, the inventors believe that using fibrinogen as excipient or using particular carriers provides the following advantages: Spatial

factor gradients promote chemotactic migration of cells, including endothelial cells towards a target site, and are important for stimulation of directional angiogenesis. To achieve such gradients, growth factors could be loaded onto suitable polymeric carriers that can be topically applied to a wound or be locally injected intradermally/subcutaneously through gel or sol-gel vehicles. Gradual factor release from the vehicle establishes a spatial gradient. In addition to using exogenous gels and sol-gels, localized delivery could be achieved through the addition of exogenous fibrinogen (autologous or of allogeneic/xenogenic origin) to a composition, and combining this solution with thrombin/calcium in order to induce the formation of a fibrin gel-matrix similar to the one that forms upon coagulation. The *in vivo*-formed fibrin matrix then sequesters the factors at the site of administration, by specific binding (e.g. VEGF) and/or passive trapping, and ensures their controlled release as it occurs within a wound. This also helps avoiding unwanted side-effects such as vascular leakage and ectopic angiogenesis. A further functionality of such factor-loaded matrices is that they can serve as scaffolds for migrating host cells (e.g. fibroblasts, endothelial cells) at a defect site, hence promoting tissue repair and regeneration.

In a tenth aspect the present invention is directed to a solution of the second aspect or a solution of the eighth aspect or a composition of the ninth aspect for use in medicine.

In an eleventh aspect the present invention is directed to a solution of the second aspect or a solution of the eighth aspect or a composition of the ninth aspect for use in the improvement of tissue blood perfusion, for use in the stimulation of angiogenesis, for use in the treatment of skin that has been debrided (e.g. by mechanical, chemical, or laser debridement, microdermabrasion, or needling), for use in the treatment of excessive scarring (including treatment of acne, keloids and hypertrophic scars), for use in the treatment of grafts (e.g. skin grafts or fat grafts), for use in the treatment of flaps (e.g. local flaps or free flaps), for use in the treatment of wounds (e.g. diabetic ulcers, arterial ulcers, venous-stasis wounds, decubital ulcers, radiation-induced wounds, steroid-induced wounds, ischaemic wounds, post-wounding and post-grafting ischaemic tissue, incisions, lacerations, abrasions or burns), and/or for use in the treatment of tissue damage (e.g. tissue damage caused by disorders selected from the group

consisting of diabetes; peripheral artery disease; vascular occlusive disease; atherosclerosis; myointimal hyperplasia; thromboangiitis obliterans; thrombotic disorders; mesenteric ischemia; limb ischemia; peripheral artery stenosis; vasculitis; infarctions including cerebral and myocardial infarctions; traumatic injuries; bone fractures; osteoporosis; arthritis (including osteoarthritis); rheumatism; cartilage rupture or detachment; torn or ruptured tendons; spinal injuries; muscular dystrophies; amyotrophic lateral sclerosis; cancer; AIDS; central nerve injury; peripheral nerve injury; central nerve degeneration; and peripheral nerve degeneration).

In an alternative wording, the eleventh aspect of the present invention is directed to the use of a solution of the second aspect or a solution of the eighth aspect or a composition of the ninth aspect in the preparation of a pharmaceutical composition for the improvement of tissue blood perfusion, for the stimulation of angiogenesis, for the treatment of skin that has been debrided (e.g. by mechanical, chemical, or laser debridement, microdermabrasion, or needling), for the treatment of excessive scarring (including treatment of acne, keloids and hypertrophic scars), for the treatment of grafts (e.g. skin grafts or fat grafts), for the treatment of flaps (e.g. local flaps or free flaps), for the treatment of wounds (e.g. diabetic ulcers, arterial ulcers, venous-stasis wounds, decubital ulcers, radiation-induced wounds, steroid-induced wounds, ischaemic wounds, post-wounding and post-grafting ischaemic tissue, incisions, lacerations, abrasions or burns), and/or for the treatment of tissue damage (e.g. tissue damage caused by disorders selected from the group consisting of diabetes; peripheral artery disease; vascular occlusive disease; atherosclerosis; myointimal hyperplasia; thromboangiitis obliterans; thrombotic disorders; mesenteric ischemia; limb ischemia; peripheral artery stenosis; vasculitis; infarctions including cerebral and myocardial infarctions; traumatic injuries; bone fractures; osteoporosis; arthritis (including osteoarthritis); rheumatism; cartilage rupture or detachment; torn or ruptured tendons; spinal injuries; muscular dystrophies; amyotrophic lateral sclerosis; cancer; AIDS; central nerve injury; peripheral nerve injury; central nerve degeneration; and peripheral nerve degeneration).

In another alternative wording, the eleventh aspect of the present invention is directed to a method for the improvement of tissue blood perfusion, for the stimulation of angiogenesis, for

the treatment of skin that has been debrided (e.g. by mechanical, chemical, or laser debridement, microdermabrasion, or needling), for the treatment of excessive scarring (including treatment of acne, keloids and hypertrophic scars), for the treatment of grafts (e.g. skin grafts or fat grafts), for the treatment of flaps (e.g. local flaps or free flaps), for the treatment of wounds (e.g. diabetic ulcers, arterial ulcers, venous-stasis wounds, decubital ulcers, radiation-induced wounds, steroid-induced wounds, ischaemic wounds, post-wounding and post-grafting ischaemic tissue, incisions, lacerations, abrasions or burns), and/or for the treatment of tissue damage (e.g. tissue damage caused by disorders selected from the group consisting of diabetes; peripheral artery disease; vascular occlusive disease; atherosclerosis; myointimal hyperplasia; thromboangiitis obliterans; thrombotic disorders; mesenteric ischemia; limb ischemia; peripheral artery stenosis; vasculitis; infarctions including cerebral and myocardial infarctions; traumatic injuries; bone fractures; osteoporosis; arthritis (including osteoarthritis); rheumatism; cartilage rupture or detachment; torn or ruptured tendons; spinal injuries; muscular dystrophies: amyotrophic lateral sclerosis; cancer; AIDS; central nerve injury; peripheral nerve injury; central nerve degeneration; and peripheral nerve degeneration), said method comprising the step of administering a therapeutic amount of a solution of the second aspect or a solution of the eighth aspect or a composition of the ninth aspect to a subject in need thereof.

In some embodiments of the eleventh aspect, the solution or the composition is for autologous administration.

In some embodiments of the eleventh aspect, the solution or the composition is for allogeneic application.

In some embodiments of the eleventh aspect, the solution or the composition is for epidermal administration.

In some embodiments of the eleventh aspect, the solution or the composition is for intradermal administration.

In some embodiments of the eleventh aspect, the solution or the composition is for subcutaneous administration.

In a twelfth aspect the present invention is directed to a cosmetic, non-therapeutic use of the solution of the second aspect or the solution of the eighth aspect or of the composition of the ninth aspect.

In some embodiments of the twelfth aspect, the use is for improving the appearance of skin (e.g. skin that has been altered through chronological ageing or photodamage), for stimulating new hair growth, for augmenting soft tissue, for reducing wrinkles, for skin rejuvenation, for improving the appearance of scars, for reducing excessive skin pigmentation, and/or for improving pigmentation in skin with reduced pigmentation.

In an alternative wording, the twelfth aspect of the present invention is directed to a cosmetic, non-therapeutic method for improving the appearance of skin (e.g. skin that has been altered through chronological ageing or photodamage), for stimulating new hair growth, for augmenting soft tissue, for reducing wrinkles, for skin rejuvenation, for improving the appearance of scars, for reducing excessive skin pigmentation, and/or for improving pigmentation in skin with reduced pigmentation, said method comprising the step of administering an effective amount of a solution of the second aspect or a solution of the eighth aspect or a composition of the ninth aspect to a subject in need of such cosmetic treatment.

In a thirteenth aspect the present invention is directed to a kit for preparing serum and/or hypoxia-conditioned medium derived from blood, said kit comprising:

(a) a first syringe,
(b) a second syringe,
(c) optionally a third syringe,
(d) optionally a fourth syringe,
(e) a three-way valve,
(f) a filter, and
(g) a cap.

In preferred embodiments of the thirteenth aspect, the first syringe has a volume of about 30 ml. In further preferred embodiments of the thirteenth aspect, the first syringe is certified for incubation at 37°C for 1 to 7 days. In further preferred embodiments of the thirteenth aspect, the

first syringe is labelled with the word 'UP' (or 'TOP' or a similar expression) at the end with the opening and labelled with the word 'DOWN' (or 'BOTTOM' or a similar expression) at the end with the plunger.

In preferred embodiments of the thirteenth aspect, the second syringe has a volume of about 10 ml.

In preferred embodiments of the thirteenth aspect, the third syringe has a volume of about 10 ml.

In preferred embodiments of the thirteenth aspect, the fourth syringe has a volume of about 10 ml.

In preferred embodiments of the thirteenth aspect, the first, the second and (if present) the third and fourth syringes are removably connectable to the three-way valve, e.g. by Luer lock connections.

In preferred embodiments of the thirteenth aspect, the kit comprises at least one filter (e.g. 1 filter, 2 filters, 3 filters, 4 filters, 5 filters, 6 filters, 7 filters, 8 filters, 9 filters, or 10 filters). In particularly preferred embodiments, the kit comprises at least two filters. In more preferred embodiments, the kit comprises at least three filters. In even more preferred embodiments, the kit comprises at least four filters. In most preferred embodiments, the kit comprises at least five filters. In preferred embodiments of the thirteenth aspect, the filter is a 0.2 µm filter or the filters are 0.2 µm filters. In further preferred embodiments of the thirteenth aspect, the filter is / the filters are removably connectable to the three-way valve and/or to any of the four syringes, e.g. by Luer lock connections.

In preferred embodiments of the thirteenth aspect, the cap is removably connectable to the three-way valve and/or to any one of the four syringes and/or to any one of the filters, e.g. by Luer lock connections.

In some embodiments of the thirteenth aspect, the kit further comprises a container containing sterile medium. In preferred embodiments, the sterile medium is selected from the group consisting of serum-containing culture medium, serum-free culture medium, a solution that is isotonic with blood, a culture medium with glucose, a culture medium without glucose, a culture medium with albumin and a culture medium without albumin.

In some embodiments of the thirteenth aspect, the kit further comprises a catheter (e.g. Vasuflo-Int) or a butterfly cannula.

In some embodiments of the thirteenth aspect, the kit further comprises a sticking plaster (i.e. an adhesive bandage in American English), e.g. Band-Aid™ or Elastoplast™.

In some embodiments of the thirteenth aspect, the kit further comprises a rack into which the first syringe can be placed and maintained in upright position.

In some embodiments of the thirteenth aspect, the kit further comprises a spatula. The spatula may be used to mix serum or hypoxia-conditioned medium prepared by using the kit with skincare products.

In a fourteenth aspect the present invention is directed to a use of the thirteenth aspect in a method according to any one of the third, fourth, fifth, or sixth aspect.

## BEST MODE FOR CARRYING OUT THE INVENTION

The solution of the invention can be produced by a method comprising the steps of obtaining a blood sample, preferably from a peripheral vein, and allowing the blood to clot or centrifuging the blood to induce clotting, and removing the serum completely or partially, preferably without disturbing the clot, then replacing the serum with fresh medium , and incubating the clot in fresh medium at a temperature of 10 to 40°C (preferably at 37°C) under hypoxia (1-10% $O_2$, preferably 1-5% $O_2$) for 1 to 7 days (preferably 1-4 days), and collecting the conditioned medium and mixing it with the serum at a defined ratio to obtain a solution of the invention.

The fresh medium used for clot incubation can be a suitable cell culture medium such as serum-containing or serum-free culture medium, a solution that is isotonic with blood, a culture medium with or without glucose, a culture medium with or without albumin. The serum, clot conditioned medium and/or the mixed solution can be filtered to remove cells or cellular material. During the incubation period (i.e. 1 to 7 days) the serum can be frozen (-10°C to -80°C) and stored, then thawed for mixing. The mixed composition can also be frozen (-10°C to -80°C) for up to 12 months while maintaining (at least part of) its bioactivity. The mixed composition can be also lyophilized or desiccated and reconstituted in a buffer.

This method allows for precise control of the concentration of protein growth factors in clot conditioned medium by controlling the volume of fresh medium added after serum removal. Preferably, the serum is replaced with a fresh medium of volume equal to or less than the volume of the serum obtained/removed in order to increase the concentration of the factors secreted by clotted blood cells into the conditioned medium above the concentration that would be achieved if the factors were secreted directly into the original serum volume during conditioning. In this way the factors can be concentrated by 1.5 fold, 2 fold, 5 fold, 10 fold, 20 fold, 100 fold, 200 fold or more. For example VEGF, which has an average concentration in serum of 60-700 pg/ml could be concentrated up to 500 ng/ml. This large increase in factor concentration is significantly higher than the increase that can be achieved by conditioning blood cells under hypoxia. The concentration of factors released in the serum can be indirectly adjusted by mixing it with clot conditioned medium. Serum will contain a significantly higher concentration of platelet-derived factors, such as anti-angiogenic factor PF4 that is normally present in serum at ca. 3000 – 15000 ng/ml, than clot conditioned medium. The preferred mixing volume ratio of clot conditioned medium to serum is such that the concentration of factors in the clot conditioned medium is never diluted, as a result of mixing, below what it would have been if the clot-derived factors were secreted directly into the original serum volume during conditioning. Therefore, the priority is to maintain a high concentration of the hypoxia-induced pro-angiogenic factors such as VEGF (produced into conditioned medium), while at the same time also delivering platelet-derived factors (released into serum) at naturally occurring concentrations.

Clot conditioned medium can be collected at defined points in time from the start of incubation, e.g. at 1, 2, 3, 4, 5, 6, or 7 days and replaced by new fresh medium, thus allowing the incubation to continue. Through this, different compositions can be obtained that comprise different factor concentrations and ratios, since it is known that hypoxia-induced factor expression by cells varies over time. These compositions then recapitulate the natural sequential expression of the wound healing phases.

It is understood that the coagulation-induced and hypoxia-induced signalling phases generated within a wound are unique/specific to the individual. In order to maintain this specificity when producing compositions, the blood serum and clot used for conditioning are preferably derived from the same subject. Nonetheless, the mixed (cell-free) composition can be

applied to the same subject from whom the blood was obtained (autologous composition) or to a different subject (allogeneic composition).

The composition comprising the two phases can be administered to prevent or treat tissue damage by being topically applied onto a wound or injected intradermally/subcutaneously. The composition can be combined with grafts such as skin and fat grafts in order to improve their take, by increasing blood supply to the graft. The composition can also be used in cosmetic applications in order to improve the appearance of skin that has been altered through chronological ageing or photodamage, and also stimulate new hair growth.

When using the kit for preparing serum and/or hypoxia-conditioned medium derived from blood described herein, the invention can be carried out by performing the following methods:

Method for withdrawing blood and allowing blood sample to clot

1. Sterilize skin and insert intravenous catheter (e.g. Vasuflo®Int) or Butterfly cannula into peripheral vein.

2. Connect the first Syringe* (e.g. Omnifix®, 30 ml) to a three-way valve (e.g. Discofix®) and connect the three-way valve to a first sterile filter (e.g. 0.2 µm Sterifix®) in a sterile field (*syringe certified for incubation under 37°C for 1-7 days. Syringe may be marked with Up and Down).

3. Connect the first syringe (with attached three-way valve and attached filter) to the catheter or cannula and withdraw blood (ca.10-20 ml).

4. Remove catheter or cannula and place plaster on skin.

5. Disconnect the first syringe from the catheter or cannula, and dispose catheter or cannula in a sharps container. The three-way valve and the first filter remain connected to the first syringe.

6. **While holding the first syringe with blood upright** (opening pointing upwards), draw air (ca. 1-10 ml) through the first filter into the first syringe.

7. Disconnect first filter from three-way valve and discard first filter.

8. While holding first syringe upright place cover (e.g. Combi Stopper) onto the three-way valve, and place first syringe into a holding stand or rack in the upright position.

Method for obtaining serum and mixing serum into skincare product

1. Following incubation of blood under 37°C for 1-7 days, remove first syringe from incubator, **always holding it in the upright position.**

2. Remove cover from three-way valve and connect second sterile filter (e.g. 0.2 μm Sterifix®) to the three-way valve.

3. Push plunger of first 30 ml syringe upwards (while holding the first syringe in the upright position) to expel all air through the second filter.

4. Disconnect second filter and discard it.

5. While holding the first syringe in the upright position attach the second, 10 ml Luer-Lock syringe onto 3-way valve and push the plunger of the first, 30 ml syringe so that serum enters the second 10 ml syringe.

6. Collect the complete serum volume, without disturbing the clot in the first 30 ml syringe.

7. Detach the second 10 ml syringe from first 30 ml syringe and safely dispose the first 30 ml syringe.

8. Attach 0.2 μm filter (i.e. third filter) onto second 10 ml syringe and filter serum while adding it to the skincare product. If the filter gets blocked, replace this with another available filter (i.e. fourth filter).

9. Mix serum into skincare product with spatula.

Method for obtaining serum and hypoxia-conditioned medium:

Step 1

1. After taking blood from peripheral vein, allow the blood to clot or centrifuge the blood to induce clotting, while keeping the first syringe* in the upright position**, as described above in section *"Method for withdrawing blood and allowing blood sample to clot"* (*syringe certified for incubation under 37°C for 1-7 days. **Syringe marked with Up and Down indicators: UP corresponds to syringe opening, DOWN corresponds to plunger. Maintain upright position through Steps 1 and 2).

2. Expel air from first syringe as described in paragraphs 1 to 4 of section *"Method for obtaining serum and mixing serum into skincare product"*.

3. Connect a second syringe to the three-way valve. Withdraw the serum into second syringe, without disturbing the clot in the blood-containing syringe (Fig. 1). Disconnect second syringe from three-way valve and store serum-containing second syringe (under low temperature; e.g. frozen between -80°C and -10°C).

4. Place new filter (i.e. a third filter; e.g. 0.2 µm Sterifix®) onto 3 way valve of blood-containing first syringe and draw air through the third filter into the first syringe. Remove filter from 3-way valve and discard filter. Place cover (e.g. a cap) onto the three-way valve.

5. Connect a third syringe containing sterile medium onto 3 way valve, and add medium to the blood-containing first syringe (Fig. 2). Remove third syringe from three-way valve.

6. Place blood-containing first syringe into a holding stand in the upright position. Incubate the first syringe at 37°C for 1-7 days.

Step 2

1. Following incubation of blood under 37°C for 1-7 days, remove first syringe from incubator, always holding it in the upright position. Remove cover from three-way valve and connect fourth sterile filter (e.g. 0.2 µm Sterifix®) to the three-way valve. Push plunger of blood-containing first syringe upwards to expel all air through the fourth filter.

2. Disconnect fourth filter, discard it, and attach an empty fourth syringe onto the 3 way valve.

3. Connect the serum-containing second syringe onto 3 way valve.

4. Collect a defined volume of conditioned medium and serum into the empty fourth syringe to obtain new mixture (Fig. 3).

This new mixture can be filtered using a new 0.2 µm filter (i.e. fifth filter) and can be mixed into a skincare product using a spatula.

Conventionally, blood is not incubated in clinical settings. This is primarily only done in case of blood culture to detect bacterial growth (septic patient). In contrast to this process, here it is important that no contamination of the blood occurs during the incubation phase, since blood-derived growth factors will be used therapeutically. Air must be introduced into the blood-containing syringe because this guarantees blood cell viability, under low oxygen tension (hypoxic) conditions, i.e. avoidance of pathological hypoxia/anoxia (i.e. oxygen tension below

1%, which would reduce factor production by blood cells). In order to ensure that the air introduced into the syringe is sterile, air must be drawn in through the filter. In addition, to avoid growth of pathogens inside the filter and a potential retro-aspiration into the serum or the conditioned medium, the filter should be removed prior to incubation.

Another novel concept is the utilization of the syringe directionally: conventionally, once blood is taken, the way the syringe is positioned is not defined. In the setting of the invention, the first syringe containing blood must always be kept upright (opening up, plunger down) following blot clotting, during the incubation phase and afterwards. The reason for this is to ensure that white blood cells in and around the clot remain in direct contact with the medium, thus getting sufficient nutrients and secreting growth factors into the medium, instead of into the red blood cell layer. Additionally, this prevents mixing of the medium containing the growth factors with red blood cells. Since the white blood cells and clot always end up above the red blood cell layer, having the plunger of the first syringe at the bottom, allows the expulsion of the medium out of the first syringe by pushing the plunger upwards.

The present invention particularly relates to the following 39 items:

1. A kit-of-parts comprising:
   (a) a hypoxia-conditioned medium derived from blood; and
   (b) a serum
   in separate containers.
2. A solution of growth factors comprising a mixture of
   (a) a hypoxia-conditioned medium derived from blood; and
   (b) a serum.
3. The kit-of parts of item 1 or the solution of item 2, wherein the hypoxia-conditioned medium has a lower concentration of Platelet Factor 4 (PF4) than the serum.
4. The kit-of parts of item 1 or 3 or the solution of item 2 or 3, wherein the hypoxia-conditioned medium contains PF4 in a concentration between 0 ng/ml and 15,000 ng/ml, preferably between 5 ng/ml and 5,000 ng/ml.
5. The kit-of parts of any one of item 1, 3 or 4 or the solution of any one of items 2 to 4, wherein the hypoxia-conditioned medium contains at least one angiogenesis-related growth factor selected from the group consisting of VEGF, TSP1, IL8, Angiogenin (ANG), MMP-9, MMP-8, TIMP-1, and PDGF.
6. The kit-of parts of any one of item 1 or 3 to 5 or the solution of any one of items 2 to 5, wherein the hypoxia-conditioned medium has a higher concentration of Vascular Endothelial Growth Factor (VEGF) than the serum.
7. The kit-of parts of any one of item 1 or 3 to 6 or the solution of any one of items 2 to 6, wherein the VEGF concentration in the hypoxia-conditioned medium is larger than 100 pg/ml.
8. The kit-of parts of any one of item 1 or 3 to 7 or the solution of any one of items 2 to 7, wherein the hypoxia-conditioned medium and/or the serum are derived from one or more blood samples obtained from the same subject.
9. The kit-of parts of any one of item 1 or 3 to 7 or the solution of any one of items 2 to 7, wherein the hypoxia-conditioned medium is derived from one or more blood samples obtained from a first subject and the serum is derived from one or more blood samples

obtained from a second subject, wherein the first subject and the second subject are not the same subject.

10. The kit-of parts of any one of item 1 or 3 to 9 or the solution of any one of items 2 to 9, wherein the hypoxia-conditioned medium and/or the serum is free of cells.

11. The solution of any one of items 2 to 10, wherein said solution is free of cells.

12. A method for preparing a kit-of parts, said method comprising the steps:

(i) providing a blood sample from a subject;

(ii) allowing the blood sample of step (i) to clot or inducing clotting in the blood sample of step (i) thereby obtaining a composition comprising a blood clot and serum;

(iii) removing at least a part of the serum from the composition obtained in step (ii) and determining the volume of the serum removed;

(iv) adding medium to the blood clot, wherein the volume of the added medium is equal to or less than the volume of the serum removed in step (iii);

(v) incubating the clot in said medium at a temperature between 10°C and 40°C under hypoxic conditions for 1 to 7 days, thereby obtaining a hypoxia-conditioned medium;

(vi) collecting at least a part of the hypoxia-conditioned medium obtained in step (v); and

(vii) preparing a kit-of-parts comprising:

(a) the hypoxia-conditioned medium collected in step (vi) and

(b) at least a part of the serum removed in step (iii).

13. A method for producing a solution of growth factors, said method comprising the steps:

(i) providing a blood sample from a subject;

(ii) allowing the blood sample of step (i) to clot or inducing clotting in the blood sample of step (i), thereby obtaining a composition comprising a blood clot and serum;

(iii) removing at least a part of the serum from the composition obtained in step (ii) and determining the volume of the serum removed;

(iv) adding medium to the blood clot, wherein the volume of the added medium is equal to or less than the volume of the serum removed in step (iii);

(v) incubating the clot in said medium at a temperature between 10°C and 40°C under hypoxic conditions for 1 to 7 days, thereby obtaining a hypoxia-conditioned medium;

(vi) collecting at least a part of the hypoxia-conditioned medium obtained in step (v);

(vii) mixing the hypoxia-conditioned medium collected in step (vi) with at least a part of the serum removed in step (iii), thereby obtaining the solution of growth factors.

14. A method for preparing a kit-of parts, said method comprising the steps:

(i) providing a first blood sample from a subject;

(ii) allowing the blood sample of step (i) to clot or inducing clotting in the blood sample of step (i), thereby obtaining a first composition comprising a blood clot and serum;

(iii) removing at least a part of the serum from the first composition obtained in step (ii) and determining the volume of the serum removed;

(iv) adding medium to the blood clot, wherein the volume of the added medium is equal to or less than the volume of the serum removed in step (iii);

(v) incubating the clot in said medium at a temperature between 10°C and 40°C under hypoxic conditions for 1 to 7 days, thereby obtaining a hypoxia-conditioned medium;

(vi) collecting at least a part of the hypoxia-conditioned medium obtained in step (v);

(vii) providing a second blood sample from a subject;

(viii) allowing the blood sample of step (vii) to clot or inducing clotting in the blood sample of step (vii), thereby obtaining a second composition comprising a blood clot and serum;

(ix) recovering at least a part of the serum from the second composition obtained in step (viii); and

(x) preparing a kit-of-parts comprising:

(a) the hypoxia-conditioned medium collected in step (vi) and

(b) the serum recovered in step (ix).

15. A method for producing a solution of growth factors, said method comprising the steps:

(i) providing a first blood sample from a subject;

(ii) allowing the blood sample of step (i) to clot or inducing clotting in the blood sample of step (i), thereby obtaining a first composition comprising a blood clot and serum;

(iii) removing at least a part of the serum from the first composition obtained in step (ii) and determining the volume of the serum removed;

(iv) adding medium to the blood clot, wherein the volume of the added medium is equal to or less than the volume of the serum removed in step (iii);

(v) incubating the clot in said medium at a temperature between 10°C and 40°C under hypoxic conditions for 1 to 7 days, thereby obtaining a hypoxia-conditioned medium;

(vi) collecting at least a part of the hypoxia-conditioned medium obtained in step (v);

(vii) providing a second blood sample from a subject;

(viii) allowing the blood sample of step (vii) to clot or inducing clotting in the blood sample of step (vii), thereby obtaining a second composition comprising a blood clot and serum;

(ix) recovering at least a part of the serum from the second composition obtained in step (viii), thereby obtaining a serum; and

(x) mixing the hypoxia-conditioned medium collected in step (vi) with at least a part of the serum recovered in step (ix), thereby obtaining the solution of growth factors.

16. The method of item 14 or item 15, wherein the first blood sample and the second blood sample were obtained from the same subject.

17. The method of any one of items 12 to 16, wherein the hypoxic conditions in the medium in step (v) are achieved through cell-mediated oxygen consumption within a normoxic incubator and/or within an oxygen-regulated incubator.

18. The method of any one of items 12 to 17, wherein the incubation in step (v) is carried out at an oxygen concentration of between 1 and 10%.

19. The method of any one of items 12 to 18, wherein the volume of the medium added in step (iv) is between 1/200 and 2/3 of the volume of the serum removed in step (iii).

20. The method of any one of items 12 to 19, wherein step (vi) comprises the repeated collection of hypoxia-conditioned medium by carrying out the following steps:

(1) collecting at least a part of the hypoxia-conditioned medium at a first time point;

(2) adding medium to the blot clot, thereby replacing the hypoxia-conditioned medium collected in step (1),

(3) continuing incubation,

(4) collecting at least a part of the hypoxia-conditioned medium at a second time point, and

(5) optionally repeating steps (2) to (4) between 1 time and 5 times.

21. The method of item 20, wherein the volume of the medium added in step (iv) and/or the medium added in step (2) is equal to or less than the volume of the serum removed in step (iii), preferably the total volume of the medium added in step (iv) and the medium added in step (2) is equal to or less than the volume of the serum removed in step (iii).

22. The method of any one of items 12 to 21, wherein the solution of growth factors obtained in step (vii) of item 13 or in step (x) of item 15 is obtained by mixing a given volume of hypoxia-conditioned medium ($V_{hcm}$) with a volume of serum ($V_s$) that fulfils the following inequality:

$$V_s \leq \frac{V_{hcm} * V_{s_{total}}}{V_{hcm_{total}}} - V_{hcm}$$

wherein $V_s$ is the volume of serum that can be used for mixing,

wherein $V_{hcm}$ is the volume of hypoxia-conditioned medium used for mixing,

wherein $V_{s_{total}}$ is the total volume of the serum removed in step (iii),

wherein $V_{hcm_{total}}$ is the total volume of the medium added in step (iv), and

wherein $V_{hcm_{total}} \leq V_{s_{total}}$.

23. The method of any one of items 12 to 22, wherein the medium is selected from the group consisting of serum-containing culture medium, serum-free culture medium, a solution that is isotonic with blood, a culture medium with glucose, a culture medium without glucose, a culture medium with albumin and a culture medium without albumin.

24. A kit-of-parts prepared by the method of any one of items 12, 14 or 16 to 20.

25. A solution of growth factors produced by the method of any one of items 13, 15 or 16 to 20.

26. A composition comprising

(a) the solution of any one of items 2 to 11 or 25; and

(b) an excipient.

27. The composition of item 26, wherein the composition is a pharmaceutical composition or a cosmetic composition.

28. The composition of item 26 or 27, wherein the excipient is fibrinogen.

29. The composition of any one of items 26 to 28, wherein the composition further comprises:

(c) a carrier.

30. The composition of item 29, wherein the carrier is in the form of a cream, an emollient, an ointment, a gel, a sol-gel, a spray, a powder, a mesh, a sponge, a patch, a dressing, nanoparticles, microparticles, nanofibers or microfibers.

31. The composition of item 29 or 30, wherein the carrier comprises one or more substances selected from the group consisting of proteins, polysaccharides, glycosaminoglycan, and synthetic polymers.

32. A solution of any one of items 2 to 11 or 25 or a composition of any one of items 26 to 31 for use in medicine.

33. A solution of any one of items 2 to 11 or 25 or a composition of any one of items 26 to 31 for use in the improvement of tissue blood perfusion, for use in the stimulation of angiogenesis, for use in the treatment of skin that has been debrided, for use in the treatment of excessive scarring, for use in the treatment of grafts, for use in the treatment of flaps, for use in the treatment of wounds, and/or for use in the treatment of tissue damage.

34. The solution for use or the composition for use according to item 32 or 33, wherein the solution or the composition is for autologous administration or for allogeneic application.

35. The solution for use or the composition for use according to any one of items 32 to 34, wherein the solution or the composition is for epidermal administration, intradermal administration or for subcutaneous administration.

36. A cosmetic, non-therapeutic use of the solution of any one of items 2 to 11 or 25 or of the composition of any one of items 26 to 31.

37. The cosmetic, non-therapeutic use of item 36, wherein said use is for improving the appearance of skin, for stimulating new hair growth, for augmenting soft tissue, for reducing wrinkles, for skin rejuvenation, for improving the appearance of scars, for reducing excessive skin pigmentation, and/or for improving pigmentation in skin with reduced pigmentation.

38. A kit for preparing serum and/or hypoxia-conditioned medium derived from blood, said kit comprising:

(a) a first syringe,
(b) a second syringe,
(c) optionally a third syringe,
(d) optionally a fourth syringe,
(e) a three-way valve,
(f) a filter,
(g) a cap,
(h) optionally a container containing sterile medium,
(i) optionally a catheter or butterfly cannula,
(j) optionally a sticking plaster,
(k) optionally a rack into which the first syringe can be placed and maintained in upright position, and
(l) optionally a spatula.

39. A use of the kit of item 38 in a method according to any one of items 12 to 23.

CLAIMS

1. A kit-of-parts comprising:

(a) a hypoxia-conditioned medium derived from blood; and

(b) a serum

in separate containers.

2. A solution of growth factors comprising a mixture of

(a) a hypoxia-conditioned medium derived from blood; and

(b) a serum.

3. The kit-of parts of claim 1 or the solution of claim 2, wherein

- the hypoxia-conditioned medium has a lower concentration of Platelet Factor 4 (PF4) than the serum, and/or
- the hypoxia-conditioned medium contains PF4 in a concentration between 0 ng/ml and 15,000 ng/ml, preferably between 5 ng/ml and 5,000 ng/ml, and/or
- the hypoxia-conditioned medium contains at least one angiogenesis-related growth factor selected from the group consisting of VEGF, TSP1, IL8, Angiogenin (ANG), MMP-9, MMP-8, TIMP-1, and PDGF, and/or
- the hypoxia-conditioned medium has a higher concentration of Vascular Endothelial Growth Factor (VEGF) than the serum, and/or
- the VEGF concentration in the hypoxia-conditioned medium is greater than 100 pg/ml, and/or
- the hypoxia-conditioned medium and/or the serum are derived from one or more blood samples obtained from the same subject, and/or
- the hypoxia-conditioned medium is derived from one or more blood samples obtained from a first subject and the serum is derived from one or more blood samples obtained from a second subject, wherein the first subject and the second subject are not the same subject, and/or
- the hypoxia-conditioned medium and/or the serum is free of cells.

4. A method for preparing a kit-of parts, said method comprising the steps:

(i) providing a blood sample from a subject;

(ii) allowing the blood sample of step (i) to clot or inducing clotting in the blood sample of step (i) thereby obtaining a composition comprising a blood clot and serum;

(iii) removing at least a part of the serum from the composition obtained in step (ii) and determining the volume of the serum removed;

(iv) adding medium to the blood clot, wherein the volume of the added medium is equal to or less than the volume of the serum removed in step (iii);

(v) incubating the clot in said medium at a temperature between 10°C and 40°C under hypoxic conditions for 1 to 7 days, thereby obtaining a hypoxia-conditioned medium;

(vi) collecting at least a part of the hypoxia-conditioned medium obtained in step (v); and

(vii) preparing a kit-of-parts comprising:

(a) the hypoxia-conditioned medium collected in step (vi) and

(b) at least a part of the serum removed in step (iii).

5. A method for producing a solution of growth factors, said method comprising the steps:

(i) providing a blood sample from a subject;

(ii) allowing the blood sample of step (i) to clot or inducing clotting in the blood sample of step (i), thereby obtaining a composition comprising a blood clot and serum;

(iii) removing at least a part of the serum from the composition obtained in step (ii) and determining the volume of the serum removed;

(iv) adding medium to the blood clot, wherein the volume of the added medium is equal to or less than the volume of the serum removed in step (iii);

(v) incubating the clot in said medium at a temperature between 10°C and 40°C under hypoxic conditions for 1 to 7 days, thereby obtaining a hypoxia-conditioned medium;

(vi) collecting at least a part of the hypoxia-conditioned medium obtained in step (v);

(vii) mixing the hypoxia-conditioned medium collected in step (vi) with at least a part of the serum removed in step (iii), thereby obtaining the solution of growth factors.

6. A method for preparing a kit-of parts, said method comprising the steps:

(i) providing a first blood sample from a subject;

(ii) allowing the blood sample of step (i) to clot or inducing clotting in the blood sample of step (i), thereby obtaining a first composition comprising a blood clot and serum;

(iii) removing at least a part of the serum from the first composition obtained in step (ii) and determining the volume of the serum removed;

(iv) adding medium to the blood clot, wherein the volume of the added medium is equal to or less than the volume of the serum removed in step (iii);

(v) incubating the clot in said medium at a temperature between 10°C and 40°C under hypoxic conditions for 1 to 7 days, thereby obtaining a hypoxia-conditioned medium;

(vi) collecting at least a part of the hypoxia-conditioned medium obtained in step (v);

(vii) providing a second blood sample from a subject;

(viii) allowing the blood sample of step (vii) to clot or inducing clotting in the blood sample of step (vii), thereby obtaining a second composition comprising a blood clot and serum;

(ix) recovering at least a part of the serum from the second composition obtained in step (viii); and

(x) preparing a kit-of-parts comprising:

(a) the hypoxia-conditioned medium collected in step (vi) and

(b) the serum recovered in step (ix).

7. A method for producing a solution of growth factors, said method comprising the steps:

(i) providing a first blood sample from a subject;

(ii) allowing the blood sample of step (i) to clot or inducing clotting in the blood sample of step (i), thereby obtaining a first composition comprising a blood clot and serum;

(iii) removing at least a part of the serum from the first composition obtained in step (ii) and determining the volume of the serum removed;

(iv) adding medium to the blood clot, wherein the volume of the added medium is equal to or less than the volume of the serum removed in step (iii);

(v) incubating the clot in said medium at a temperature between 10°C and 40°C under hypoxic conditions for 1 to 7 days, thereby obtaining a hypoxia-conditioned medium;

(vi) collecting at least a part of the hypoxia-conditioned medium obtained in step (v);

(vii) providing a second blood sample from a subject;

(viii) allowing the blood sample of step (vii) to clot or inducing clotting in the blood sample of step (vii), thereby obtaining a second composition comprising a blood clot and serum;

(ix) recovering at least a part of the serum from the second composition obtained in step (viii), thereby obtaining a serum; and

(x) mixing the hypoxia-conditioned medium collected in step (vi) with at least a part of the serum recovered in step (ix), thereby obtaining the solution of growth factors.

8. A kit-of-parts prepared by the method of any one of claims 4 or 6.

9. A solution of growth factors produced by the method of any one of claims 5 or 7.

10. A composition comprising

(a) the solution of any one of claims 2 to 3 or 9;

(b) an excipient, preferably fibrinogen; and

(c) optionally a carrier.

11. A solution of any one of claims 2 to 3 or 9 or a composition of claim 10 for use in medicine; preferably for use in the improvement of tissue blood perfusion, for use in the stimulation of angiogenesis, for use in the treatment of skin that has been debrided, for use in the treatment of excessive scarring, for use in the treatment of grafts, for use in the treatment of flaps, for use in the treatment of wounds, and/or for use in the treatment of tissue damage.

12. A cosmetic, non-therapeutic use of the solution of any one of claims 2 to 3 or 9 or of the composition of claim 10.

13. The cosmetic, non-therapeutic use of claim 12, wherein said use is for improving the appearance of skin, for stimulating new hair growth, for augmenting soft tissue, for reducing wrinkles, for skin rejuvenation, for improving the appearance of scars, for reducing excessive skin pigmentation, and/or for improving pigmentation in skin with reduced pigmentation.

14. A kit for preparing serum and/or hypoxia-conditioned medium derived from blood, said kit comprising:

(a) a first syringe,

(b) a second syringe,

(c) optionally a third syringe,

(d) optionally a fourth syringe,

(e) a three-way valve,

(f) a filter,

(g) a cap,

(h) optionally a container containing sterile medium,

(i) optionally a catheter or butterfly cannula,

(j) optionally a sticking plaster,

(k) optionally a rack into which the first syringe can be placed and maintained in upright position, and

(l) optionally a spatula.

15. A use of the kit of claim 14 in a method according to any one of claims 4 to 7.

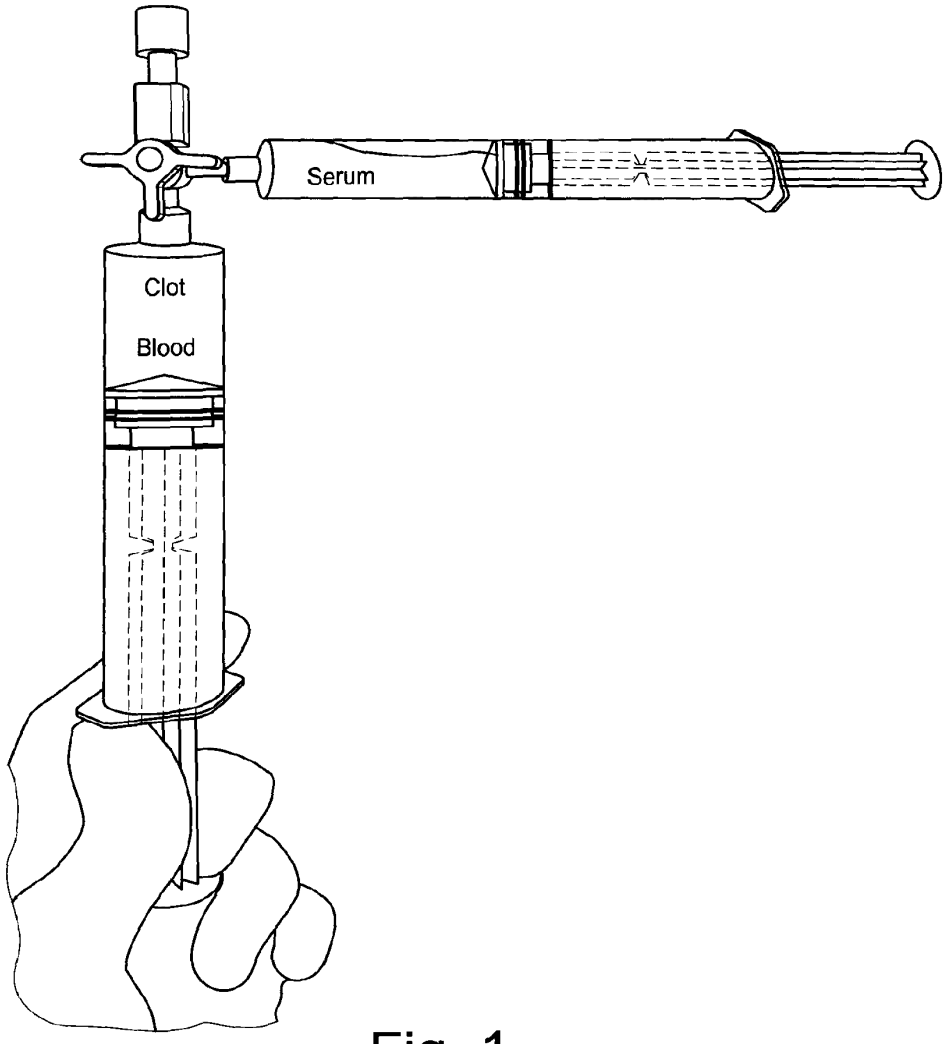



Fig. 1

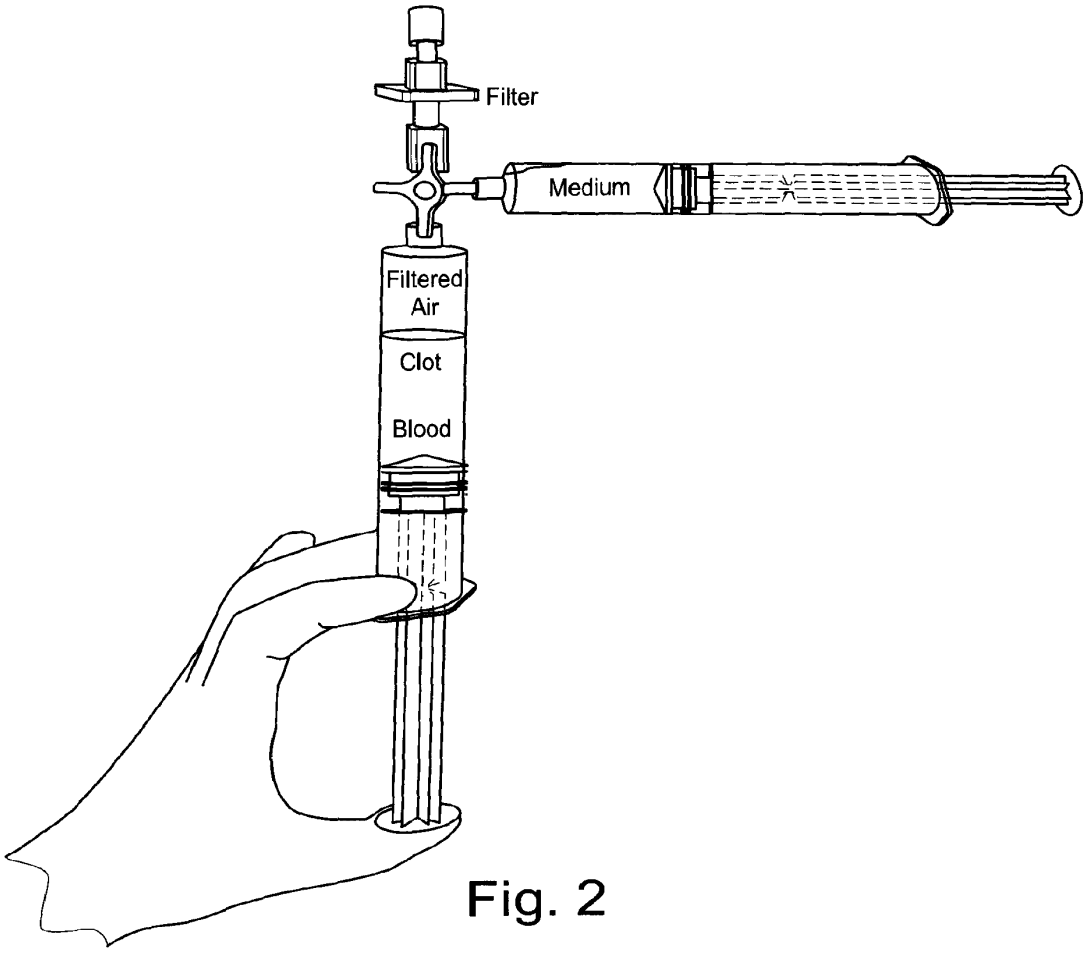



Fig. 2

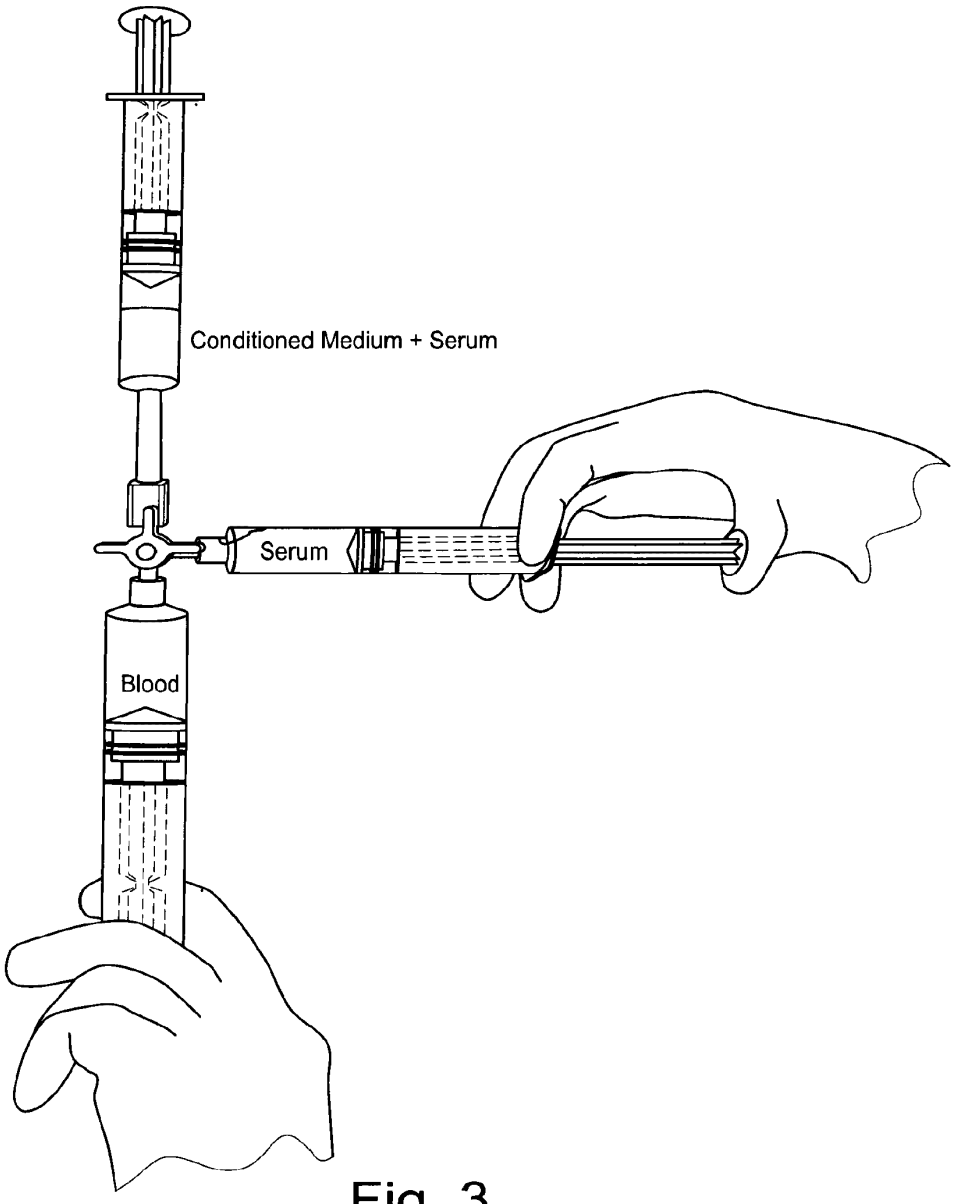



Fig. 3

# INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/001167

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61K35/14
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61K

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, BIOSIS, CHEM ABS Data, COMPENDEX, EMBASE, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br>Y | US 2015/023911 A1 (SCHILLING ARNDT [DE] ET AL) 22 January 2015 (2015-01-22)<br>paragraphs [0017], [0050], [0056], [0110], [0135]<br>----- | 1-13<br>4-7 |
| X | SUSHMITA ROY ET AL: "Hypoxia improves expansion potential of human cord blood-derived hematopoietic stem cells and marrow repopulation efficiency", EUROPEAN JOURNAL OF HAEMATOLOGY., vol. 88, no. 5, 17 May 2012 (2012-05-17), pages 396-405, XP055349633, DK ISSN: 0902-4441, DOI: 10.1111/j.1600-0609.2012.01759.x abstract<br>-----<br>-/-- | 1-3,8-13 |

[X] Further documents are listed in the continuation of Box C.

[X] 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 |
|---|---|
| 12 December 2017 | 02/03/2018 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Pilling, Stephen |

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Form PCT/ISA/210 (second sheet) (April 2005)

## INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/001167

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | EP 2 198 873 A1 (APOSCIENCE AG [AT])<br>23 June 2010 (2010-06-23)<br>abstract<br>paragraphs [0029], [0044] | 1-3,8-13 |
| X | BADER A M ET AL: "Hypoxic preconditioning increases survival and pro-Angiogenic capacity of human cord blood mesenchymal stromal cells in vitro",<br>PLOS ONE 20150918 PUBLIC LIBRARY OF SCIENCE USA,<br>vol. 10, no. 9,<br>18 September 2015 (2015-09-18),<br>XP002767667,<br>ISSN: 1932-6203<br>abstract<br>"Cells and cell culture" on 2nd page | 1-3,8-13 |
| X | YENG CHIA-HONG ET AL: "Attenuating spinal cord injury by conditioned medium from human umbilical cord blood-derived CD34+cells in rats",<br>TAIWANESE JOURNAL OF OBSTETRICS AND GYNECOLOGY, ELSEVIER (SINGAPORE) PTE LTD, HONG KONG BRANCH, HONG KONG, HK,<br>vol. 55, no. 1,<br>27 February 2016 (2016-02-27), pages 85-93, XP029435929,<br>ISSN: 1028-4559, DOI: 10.1016/J.TJOG.2015.12.009<br>abstract<br>"Cell culture and CM" on page 86 | 1-3,8-13 |
| X | WO 2014/046417 A1 (MEDIPOST CO LTD [KR])<br>27 March 2014 (2014-03-27)<br>abstract<br>page 6, line 31 - page 7, line 15<br>page 8, line 5 - line 10 | 1-3,8-13 |
| Y | WO 2014/147092 A1 (KHORIONYX [FR])<br>25 September 2014 (2014-09-25)<br>abstract<br>page 5, line 17 - page 6, line 8 | 4-7 |

1

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2017/001167

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

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

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

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

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

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

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

see additional sheet

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

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

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

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

1-13

**Remark on Protest**

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/** 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-13

a kit/growth-factor solution comprising a hypoxia-conditioned medium derived from blood and a serum.

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2. claims: 14, 15

a kit for preparing serum and/or hypoxia-conditioned medium derived from blood, said kit comprising: (a) a first syringe, (b) a second syringe, (c) optionally a third syringe, (d) optionally a fourth syringe, (e) a three-way valve, (f) a filter (g) a cap, (h) optionally a container containing sterile medium, (i) optionally a catheter or butterfly cannula, (j) optionally a sticking plaster, (k) optionally a rack into which the first syringe can be placed and maintained in upright position, and (l) optionally a spatula.

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## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2017/001167

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| US 2015023911 A1 | 22-01-2015 | AU 2013214187 A1 | 10-07-2014 |
| | | EP 2809333 A1 | 10-12-2014 |
| | | US 2015023911 A1 | 22-01-2015 |
| | | WO 2013113821 A1 | 08-08-2013 |
| EP 2198873 A1 | 23-06-2010 | AU 2009336668 A1 | 07-07-2011 |
| | | BR PI0922174 A2 | 29-12-2015 |
| | | CA 2746862 A1 | 15-07-2010 |
| | | CN 102256608 A | 23-11-2011 |
| | | EP 2198873 A1 | 23-06-2010 |
| | | EP 2379085 A1 | 26-10-2011 |
| | | ES 2429518 T3 | 15-11-2013 |
| | | JP 5869343 B2 | 24-02-2016 |
| | | JP 2012512842 A | 07-06-2012 |
| | | NZ 593364 A | 30-11-2012 |
| | | RU 2011129676 A | 27-01-2013 |
| | | US 2012045418 A1 | 23-02-2012 |
| | | WO 2010079086 A1 | 15-07-2010 |
| | | ZA 201104349 B | 29-02-2012 |
| WO 2014046417 A1 | 27-03-2014 | KR 20140038236 A | 28-03-2014 |
| | | WO 2014046417 A1 | 27-03-2014 |
| WO 2014147092 A1 | 25-09-2014 | EP 2781224 A1 | 24-09-2014 |
| | | EP 2976098 A1 | 27-01-2016 |
| | | JP 2016514716 A | 23-05-2016 |
| | | KR 20150131378 A | 24-11-2015 |
| | | US 2016279293 A1 | 29-09-2016 |
| | | WO 2014147092 A1 | 25-09-2014 |

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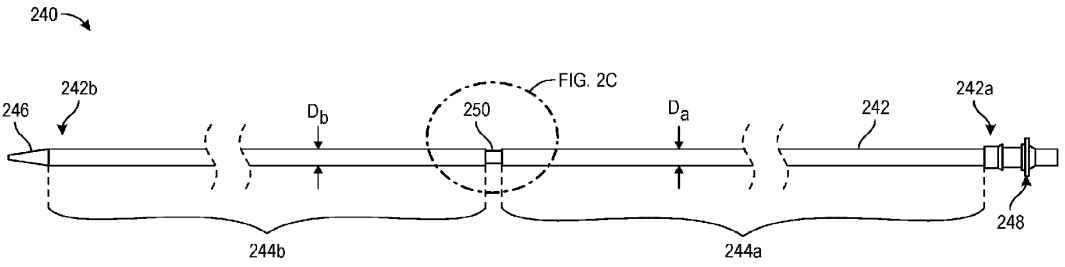



*FIG. 2A*

(57) Abstract: Disclosed herein are dilators for vascular access systems, and associated devices and methods. In some embodiments, a dilator includes an elongate body having a diameter that is generally constant or uniform along the length of the body. The diameter can be sized to correspond with a catheter of a vascular access system, such that the dilator can be positioned within the catheter with little or no gaps or spacing between the dilator and an interior of the catheter. Additionally, or alternatively, the body of the dilator can include multiple body regions, each having one or more respective mechanical properties. In these and other embodiments, the dilator can be configured to interface with at least a portion of the vascular access system. For example, the dilator can include one or more notches configured to couple the dilator to the vascular access system via a valve of the vascular access system.

*[Continued on next page]*

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# DILATOR FOR VASCULAR ACCESS SYSTEMS, AND ASSOCIATED DEVICES AND METHODS

## CROSS-REFERENCE TO RELATED APPLICATION(S)

**[0001]** This application claims benefit of U.S. Patent Application No. 63/338,266, filed May 4, 2022 and U.S. Patent Application No. 63/397,649, filed August 12, 2022, each of which is herein incorporated by reference in its entirety.

## TECHNICAL FIELD

**[0002]** The present technology generally relates to dilators for vascular access systems, and associated devices and methods.

## BACKGROUND

**[0003]** Thrombosis is the local coagulation or clotting of the blood in a part of the circulatory system, and a thrombus is a blood clot formed in situ within the vascular system. A venous thrombus is a blood clot that forms within a vein. A common type of venous thrombosis is a deep vein thrombosis (DVT), which is the formation of a blood clot within a deep vein (e.g., predominantly in the legs). Nonspecific signs of a thrombosis may include pain, swelling, redness, warmness, and engorged superficial veins.

**[0004]** If the thrombus breaks off (embolizes) and flows towards the lungs, it can become a life-threatening pulmonary embolism (PE) (e.g., a blood clot in the lungs). In addition to the loss of life that can arise from PE, DVT can cause significant health issues such as post thrombotic syndrome, which can cause chronic swelling, pressure, pain, and ulcers due to valve and vessel damage. Further, DVT can result in significant health-care costs either directly or indirectly through the treatment of related complications and inability of patients to work.

**[0005]** Existing methods for treating DVT and PE often involve treating the DVT or PE with a catheter system that is advanced through the patient's vasculature, such as along a venous access path. Such catheter systems—especially those having a large size (e.g., greater than 16 French)—often include a navigation component, such as a smaller catheter or a dilator, that may be used to dilate the patient's vasculature and guide a large catheter to a target treatment site. For example, the larger catheter may be inserted over the navigation component, using the navigation component as a "rail" to guide the larger catheter to the target treatment site.

**[0006]** However, during advancement of a catheter through the vasculature, the navigation component and/or the catheter can experience considerable force or resistance from the patient's vasculature. In some instances, this may result in practitioners unintentionally injuring patients by over-advancing large catheters along navigation components. Furthermore, the force against the navigation component can cause the navigation component to move or backslide relative to the catheter. If the navigation component bends or flexes relative to the catheter, it can hinder a practitioner's ability to advance the navigation component and catheter together through the patient's vasculature. If the navigation component backslides far enough through the catheter, the edge of the catheter can be exposed and may cause damage to a percutaneous access site or the vasculature of the patient.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0007]** Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

**[0008]** Figure 1 is a partially schematic side view of a vascular access system configured in accordance with the present technology.

**[0009]** Figures 2A and 2B are a side view and a side cross-sectional view, respectively, of a dilator configured in accordance with embodiments of the present technology.

**[0010]** Figure 2C is an enlarged perspective view of region 2C of the dilator shown in Figure 2A in accordance with embodiments of the present technology.

**[0011]** Figures 3A and 3B are side cross-sectional views of the dilator of Figures 2A-2C positioned within a valve of the vascular access system of Figure 1 in accordance with embodiments of the present technology.

**[0012]** Figures 4A and 4B are perspective views of the dilator of Figures 2A–2C positioned within the vascular access system of Figure 1 in accordance with embodiments of the present technology.

## DETAILED DESCRIPTION

**[0013]** The present technology is generally directed to navigation components ("dilators") for vascular access systems, and associated devices and methods. In some embodiments, a dilator includes an elongate body having a diameter that is generally constant or uniform along

the length of the body. The diameter can be sized to correspond with a catheter of a vascular access system, such that the dilator can be positioned within the catheter with little or no gaps or spacing between the dilator and the interior of the catheter. In these and other embodiments, the body of the dilator can include multiple body regions, each having one or more respective mechanical properties. In at least some embodiments, for example, the dilator includes a first body region having a first flexibility profile and a second body region having a second flexibility profile greater than the first flexibility profile, such that the second body region is more flexible than the first body region. The second body region can be distal from the first body region, such that the less flexible/stiffer first body region can provide a portion of the dilator against which force can be applied to advance the dilator through the patient's vasculature, and the less stiff/more flexible second body region can provide improved navigation response and/or control while advancing the dilator through the patient's vasculature.

**[0014]** Currently existing dilators may be tapered or sloped to provide flexibility. For example, the diameter of a tapered dilator can decrease toward the tapered dilator's distal tip, with the decreased diameter providing increased flexibility toward the distal tip. However, these tapered dilators can be difficult to secure relative to vascular access devices such as catheters. For example, the tapered shape of these dilators can lead to gaps or spacing between the tapered dilator and the catheter when the tapered dilator is positioned within the catheter, which can allow the tapered dilators to bend or flex within the catheter during use. This bending or flexing can reduce control and/or navigational precision during a procedure. In contrast to the current sloped dilators, the dilators of the present technology can have generally constant or uniform diameters that improve these dilators' fit within vascular access devices, and/or may reduce or prevent unwanted flexing or bending of these dilators during a procedure. Additionally, or alternatively, the respective mechanical properties of the body regions of the dilators can be selected to improve these dilators' flexibility.

**[0015]** Additionally or alternatively, the dilator can be configured to interface with at least a portion of the vascular access system. In some embodiments, the dilator includes one or more notches. Each of the notches can extend at least partially or fully around a longitudinal axis of the body of the dilator, and can be configured to couple the dilator to the vascular access system via a valve of the vascular access system. For example, the valve can include one or more internal components or tethers configured to open and/or close a path through the valve. When the dilator is positioned within the valve with one of the notches aligned with the tether, the tether can be inserted at least partially into the notch to thereby create a resistive force or

interference fit that inhibits or prevents further movement of the dilator relative to the valve (and/or movement of the valve relative to the dilator). Each of the notches can be spaced along the length of the dilator such that, when coupled via the valve, each notch can be associated with a different position of the dilator relative to the vascular access system and/or a different length of the dilator that extends beyond the vascular access system. Because each notch can inhibit further movement of the dilator and/or the vascular access system relative to one another, the positions of the one or more notches can be configured to inhibit or prevent over-insertion of the dilator, and/or can provide a user with increased control over an amount of the dilator that extends beyond the vascular access system.

**[0016]** Certain details are set forth in the following description and in Figures 1–4B to provide a thorough understanding of various embodiments of the present technology. In other instances, well-known structures, materials, operations, and/or systems often associated with intravascular procedures, clot removal procedures, catheters, and the like are not shown or described in detail in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. Those of ordinary skill in the art will recognize, however, that the present technology can be practiced without one or more of the details set forth herein, and/or with other structures, methods, components, and so forth.

**[0017]** The terminology used below is to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain examples of embodiments of the technology. Indeed, certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

**[0018]** The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope unless expressly indicated. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles and features without departing from the present technology. In addition, those of ordinary skill in the art will appreciate that further

embodiments of the present technology can be practiced without several of the details described below.

**[0019]** With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

**[0020]** Figure 1 is a partially schematic side view of a vascular access system 100 ("the system 100") configured in accordance with embodiments of the present technology. The system 100 can also be referred to as an aspiration assembly, a clot treatment system, a clot removal system, a thrombectomy system, an introducer sheath assembly, and/or the like. In the illustrated embodiment, the system 100 includes a tubing assembly 110 fluidly coupled to a catheter 120 via a valve 130. In some embodiments, the catheter 120 is an elongate member configured to be inserted into and through a patient's vasculature and used to, for example, treat clot material therein. In other embodiments, the catheter 120 can be an introducer sheath configured to be inserted through the skin and tissue tract of the patient to provide an access site through which other components (e.g., other catheters used to treat clot material) can traverse to easily access the vasculature. Accordingly, while referred to as "catheter 120," the catheter 120 can comprise an introducer sheath, an access sheath, and/or another type of elongate member configured to be inserted through the skin and tissue tract and/or to traverse the vasculature of a patient. In general, the system 100 (i) can include features generally similar or identical to those of the clot treatment systems described in detail in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety, and/or (ii) can be used to treat/remove clot material from a patient (e.g., a human patient) using any of the methods described in detail therein.

**[0021]** In the illustrated embodiment, the catheter 120 includes a proximal region or portion 122a and a distal tip region or portion 122b opposite the proximal region 122a. The proximal region 122a can include a proximal terminus 126a of the catheter 120, and the distal tip region 122b can include a distal terminus 126b of the catheter 120. The catheter 120 further

defines a lumen 124 (shown using dashed-line in Figure 1) extending entirely therethrough from the proximal region 122a to the distal tip region 122b. The lumen 124 and/or the catheter 120 can at least partially define a longitudinal axis X of the system 100.

**[0022]** The valve 130 is fluidly coupled to the lumen 124 of the catheter 120 and can be integral with or coupled to the proximal region 122a of the catheter 120 such that these components move together. In some embodiments, the valve 130 is a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in a proximal direction P through the valve 130 as various components such as dilators, delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and so on are inserted through the valve 130 to be delivered through the catheter 120 to a treatment site in a blood vessel. The valve 130 can include a branch or side port 102 configured to fluidly couple the lumen 124 of the catheter 120 to the tubing assembly 110. In some embodiments, the valve 130 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety.

**[0023]** In the illustrated embodiment, the tubing assembly 110 fluidly couples the catheter 120 to a pressure source 104, such as a syringe. The pressure source 104 can be configured to generate (e.g., form, create, charge, build-up) a vacuum (e.g., negative relative pressure) and store the vacuum for subsequent application to the catheter 120. The tubing assembly 110 can include one or more tubing sections 112 (individually labeled as a first tubing section 112a and a second tubing section 112b), at least one fluid control device 114 (e.g., a valve), and at least one connector 116 (e.g., a Toomey tip connector) for fluidly coupling the tubing assembly 110 to the pressure source 104 and/or other suitable components. In some embodiments, the fluid control device 114 is a stopcock that is fluidly coupled to (i) the side port 102 of the valve 130 via the first tubing section 112a and (ii) the connector 116 via the second tubing section 112b. The fluid control device 114 is externally operable by a user to regulate the flow of fluid therethrough and, specifically, from the lumen 124 of the catheter 120 to the pressure source 104. In some embodiments, the connector 116 is a quick-release connector (e.g., a quick disconnect fitting) that enables rapid coupling/decoupling of the catheter 120 and the fluid control device 114 to/from the pressure source 104.

**[0024]** During a clot treatment procedure, at least a portion of the system 100, such as the distal terminus 126b and/or distal tip region 122b of the catheter 120, can be inserted through

the vasculature of a patient. In some embodiments, the system 100 is inserted through an introducer sheath that traverses the skin and tissue of the patient to provide an access site. When the catheter 120 is positioned at a desired position relative to clot material (e.g., a pulmonary embolism, deep vein thrombosis) within the patient, a user can first close the fluid control device 114 before generating a vacuum in the pressure source 104 by, for example, withdrawing the plunger of a syringe coupled to the connector 116. In this manner, a vacuum is charged within the pressure source 104 (e.g., a negative pressure is maintained) before the pressure source 104 is fluidly connected to the lumen 124 of the catheter 120. To aspirate the lumen 124 of the catheter 120, the user can open the fluid control device 114 to fluidly connect the pressure source 104 to the catheter 120 and thereby apply or release the vacuum stored in the pressure source 104 to the lumen 124 of the catheter 120. Opening the fluid control device 114 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing assembly 110 and the catheter 120, thereby generating a suction pulse throughout the catheter 120 that can aspirate the clot material into the catheter 120. In particular, the suction is applied at the distal tip region 122b of the catheter 120 to suck/aspirate at least a portion of the clot material proximate the distal tip region 122b into the lumen 124 of the catheter 120. Additionally, or alternatively, the catheter 120 can act as an introducer sheath and can be inserted through the skin and tissue of a patient and partially into a vessel to provide an access point through which other medical instruments can be delivered and/or otherwise used to treat the patient.

**[0025]** Figures 2A and 2B are a side view and a side cross-sectional view, respectively, of a navigation component or dilator 240 configured in accordance with embodiments of the present technology. The dilator 240 is configured to be inserted into and advanced together with the catheter 120 of Figure 1. The dilator 240 includes a generally elongate body 242 having a proximal region or portion 242a, a distal tip region or portion 242b opposite the proximal region 242a, and one or more body segments or regions 244 (individually identified as a first body region 244a and a second body region 244b) extending at least partially between the proximal region 242a and the distal tip region 242b. The dilator 240 can further include a tip 246 (e.g., an atraumatic tip) in or near the distal tip region 242b, a coupling component 248 in or near the proximal region 242a, and one or more notches 250 (e.g., insertion positioning features). The coupling component 248 can include a twist-lock connector, a luer connector, and/or another suitable coupling component, and can be configured to couple or lock the dilator 240 to a valve of a vascular access system, such as the valve 130 of the system 100 of Figure 1. In the illustrated embodiment, the tip 246 is distal from the second body region 244b and the coupling component

248 is proximal from the first body region 244a. In other embodiments, the second body region 244b can include all or part of the tip 246, and/or the first body region 244a can include and/or be positioned within all or part of the coupling component 248. The notch 250 is described in further detail below with reference to Figure 2C.

**[0026]** In some embodiments, the body 242, the tip 246, and/or the coupling component 248 can be hollow, as shown in Figure 2B, such that a guide wire (not shown) can be positioned within the dilator 240 and used to aid the navigation thereof. In such embodiments, each of the body regions 244 can have a respective thickness T, individually labeled in Figure 2B as a first thickness $T_a$ and a second thickness $T_b$. The first and second thicknesses $T_{a-b}$ can be the same or different, and/or each thickness $T_{a-b}$ may be constant or variable along all or part of the length of the respective body region 244a-b.

**[0027]** The first body region 244a, the second body region 244b, the tip 246, and/or the coupling component 248 can each be formed from one or more polymers, and/or other suitable materials. For example, the first and second body regions 244a-b can be formed from the same or different materials.

**[0028]** Each of the body regions 244a-b can have a respective outer dimension or diameter D, individually labeled as a first diameter $D_a$ and a second diameter $D_b$. In some embodiments, the diameters $D_{a-b}$ of the body regions 244a-b can be different from each other and/or vary along their respective lengths, such that the first and second body regions 244a-b, and/or one or more portions thereof, can have different diameters. In the illustrated embodiment, the first and second diameters $D_{a-b}$ are generally similar or identical such that the body 242 of the dilator 240 has a substantially uniform diameter. In these and other embodiments, one or more of the diameters $D_{a-b}$ can correspond to and/or be less than an inner dimension of a catheter, such as an inner diameter of the lumen 124 of the catheter 120 (Figure 1). Accordingly, the dilator 240 can be positioned within the catheter 120 (e.g., via the valve 130) with at least a portion of the tip 246 extending distally beyond the distal terminus 126b of the catheter 120 (Figure 1).

**[0029]** Each of the body regions 244 can have one or more respective mechanical properties, such as a hardness, stiffness, durometer, flexibility, rigidity, Young's modulus, density, and/or the like. The mechanical properties (e.g., varying durometer) can give the body regions 244 different flexibility profiles. In some embodiments, individual ones of the body regions 244 can include one or more coils, braids, and/or other structures configured to increase or decrease the flexibility profile, e.g., relative to one or more other body regions 244. In at least

some embodiments, the first body region 244a has a first flexibility profile and the second body region 244b has a second flexibility profile greater than the first flexibility profile such that the second body region 244b is less stiff/more flexible than the first body region 244a. For example, in the illustrated embodiment the first body region 244a has a first durometer and the second body region 244b has a second durometer less (e.g., less stiff/more flexible) than the first durometer. In some aspects of the present technology, the less-stiff second body region 244b can improve the navigability of the dilator 240 while traveling through vasculature, while the more-stiff first body region 244a can improve control of and/or force transfer to (e.g., the "pushability" and/or column strength of) the dilator 240 while navigating through the vasculature. Although the dilator 240 shown in Figures 2A and 2B includes two body regions 244a-b, in other embodiments the dilator 240 can include more body regions 244, and each of the body regions 244 can have one or more respective mechanical properties greater than, equal to, or less than one or more of the other body regions 244. Accordingly, in some embodiments the dilator 240 includes two or more body regions 244 having the same diameter but different stiffnesses, durometers, flexibilities, etc.

**[0030]** Figure 2C is an enlarged perspective view of region 2C of Figure 2A in accordance with embodiments of the present technology. In the illustrated embodiment, the notch 250 defines/comprises a recessed area extending at least partially or fully around the body 242 of the dilator 240, such as circumferentially around a longitudinal axis Y of the body 242. Accordingly, the notch 250 can define a third diameter $D_c$ of the dilator 240 that can be less than the first diameter $D_a$ and/or the second diameter $D_b$. In the illustrated embodiment, the notch 250 is positioned between the first body region 244a and the second body region 244b. In other embodiments, the notch 250 can be positioned at least partially within one or both of the body regions 244a-b. In these and other embodiments, the dilator 240 can include a plurality of notches 250, individual ones of which can be positioned at least partially between the first and second body regions 244a-b, at least partially within the first body region 244a, at least partially within the second body region 244b, or at another suitable position along the dilator 240.

**[0031]** Figures 3A and 3B are side cross-sectional views of the dilator 240 positioned within the valve 130 in accordance with embodiments of the present technology. More specifically, in Figure 3A the dilator 240 is at a first position within the valve 130, and in Figure 3B the dilator 240 has been moved (e.g., distally) to a second position within the valve 130, as shown by arrow A. In Figures 3A and 3B, the dilator 240 includes the notch 250 ("first notch 250") and an additional second notch 350 positioned proximally from the first notch 250. The

second notch 350 can be at least generally similar or identical in structure and/or function to the first notch 250.

**[0032]** Referring to Figures 3A and 3B together, the valve 130 includes a first or distal aperture 332a, a second or proximal aperture 332b, and a central lumen 334 extending therebetween. The distal aperture 332a can be fluidly coupled to a catheter, such as the catheter 120 of Figure 1. The valve 130 further includes a filament or tether 336 operably coupled to one or more actuators or buttons 338 (individually identified as a first button 338a and a second button 338b in Figures 3A and 3B). The tether 336 can be configured to open and/or close the central lumen 334 of the valve 130, e.g., to form a substantially fluid-impermeable seal that inhibits or prevents fluid communication between the distal and proximal apertures 332a-b. In the illustrated embodiment, for example, the buttons 338 are biased outwardly by springs 339 (individually identified as a first spring 339a and a second spring 339b in Figures 3A and 3B) to a first position shown in Figure 3A. When the buttons 338a-b are in the first position, the buttons 338a-b draw the tether 336 taught to constrict and seals the central lumen 334. A user can depress the buttons 338 to a second position shown in Figure 3B against the biasing force of the springs 339 to relax the tether 336 and thereby unconstrict and unseal the central lumen 334. In general, the valve 130 (i) can include at least some features that are generally similar or identical to those of the hemostasis valves described in detail in U.S. Patent No. 11,000,682, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety, and/or (ii) can be used to treat/remove clot material from a patient (e.g., a human patient) using any of the methods described in detail therein.

**[0033]** In some embodiments, the tether 336 is configured to releasably couple the dilator 240 to the valve 130 by interfacing with one of the notches 250, 350. For example, in the illustrated embodiment the tether 336 constricts around the central lumen 334 when the buttons 338a-b are in the first position, as shown in Figure 3A. Accordingly, when the dilator 240 is inserted through the proximal aperture 332b, the first notch 250 can be positioned in alignment with the tether 336 to thereby allow at least part of the tether 336 to be driven toward and/or into the first notch 250 and create a resistive force/interference fit that couples the dilator 240 to the valve 130. The resistive force/interference fit inhibits or prevents further movement (e.g., proximal and/or distal movement) of the dilator 240 relative to the valve 130.

**[0034]** The dilator 240 can be uncoupled from the valve 130 by actuating/pressing one or more of the buttons 338, as shown in Figure 3B, to move the tether 336 radially outward away from the longitudinal axis of the central lumen 334 and radially outwardly from/out of the first notch 250. Pressing/actuating one or more of the buttons 338 can thereby allow further movement (e.g., proximal and/or distal movement) of the dilator 240 relative to the valve 130. In some embodiments, the resistive force/interference fit can be overcome by applying increased force to the dilator 240 and/or the valve 130, e.g., to displace the tether 336 from the first notch 250 and allow further movement of the dilator 240 and/or the valve 130 relative to each other without pressing/actuating one or more of the buttons 338. In Figure 3B, the dilator 240 has been moved further distally through the valve 130 from a proximal position (Figure 3A) to a more distal position. In some embodiments, the dilator 240 can be advanced further distally until the second notch 350 is positioned in alignment with the tether 336. When the second notch 350 is aligned with the tether 336, the tether 336 can be driven radially into the second notch 350, as described previously with reference to the first notch 250, and thereby again couple the dilator 240 to the valve 130.

**[0035]** Referring to Figures 1–3B together, the dilator 240 can be inserted distally through the valve 130 (e.g., via the proximal aperture 332b) and extend fully through the lumen 124 past the distal terminus 126b of the catheter 120, such that the tip 246 of the dilator 240 is positioned beyond the distal terminus 126b of the catheter 120. The notch 250 can be configured to control the position of the dilator 240 relative to the catheter 120, e.g., during insertion. For example, when the dilator 240 is inserted (e.g., distally) through the valve 130 into the catheter 120, the notch 250 can interface with (e.g., releasably couple to) the tether 336 to thereby create a resistive force or interference fit that at least inhibits or prevents further movement (e.g., proximal and/or distal movement) of the dilator 240 relative to the catheter 120. A magnitude of the resistive force/interference fit between the notch 250 and the valve 130 (e.g., the tether 336) can correspond to the difference in size between the third diameter $D_c$ and another diameter of a body region of the dilator 240, such as the first diameter $D_a$ of the first body region 244a and/or the second diameter $D_b$ of the second body region 244b.

**[0036]** Generally, a difference in size between the third diameter $D_c$ and a diameter of a body region positioned proximal and adjacent to the notch 250 (e.g., the first diameter $D_a$ of the first body region 244a) can be associated with a resistive force/interference fit that inhibits or prevents further distal movement of the dilator 240 through the system 100 (e.g., through the catheter 120) and/or further proximal movement of the system 100 over the dilator 240.

Additionally, a difference in size between the third diameter $D_c$ and a diameter of a body region positioned distal and adjacent to the notch 250 (e.g., the second diameter $D_b$ of the second body region 244b) can be associated with a resistive force/interference fit that at inhibits or prevents further proximal movement of the dilator 240 through the system 100 and/or further distal movement of the system 100 over the dilator 240. For example, if the difference between third diameter $D_c$ and the first diameter $D_a$ is between about 0.1mm and about 0.5mm, the resistive force/interference fit can be relatively slight and partially prevent further (distal) movement of the dilator 240 and/or further (proximal) movement of the system 100. In such embodiments, the resistive force/interference fit may provide a tactile indication or sensation (e.g., a "clicking" sound or sensation perceptible to a user) associated with the relative positions of the dilator 240 and the system 100, and any resistance/interference to further movement may be overcome by applying increased force to the dilator 240 and/or the system 100 to decouple the notch 250 and the valve 130 (e.g., the tether 336). As another example, if the difference between the third diameter $D_c$ and the first diameter $D_a$ is greater than 0.5mm, the resistive force/interference fit can be relatively substantial and fully prevent further (distal) movement of the dilator 240 and/or further (proximal) movement of the system 100. In such embodiments, the resistive force/interference fit may be overcome by actuating one or more of the buttons 338 of the valve 130 to release the dilator 240. Dilators with greater diameters can include notches having a greater depth (e.g., corresponding to a greater difference between the third diameter $D_c$ and the first and/or second diameters $D_a$, $D_b$) than dilators with a comparatively lesser depth, and greater notch depths are expected to provide increased resistive forces/interference fits than lesser notch depths.

**[0037]** In some embodiments, the magnitude of the resistive force/interference fit is based at least partially on a spring force applied by the valve 130 (e.g., via the springs 339a-b) to the dilator 240. For example, springs with a relatively high spring constant are expected to provide a greater resistive force than springs with a comparatively lower spring constant.

**[0038]** With the dilator 240 positioned within the catheter 120, the dilator 240 and the catheter 120 can together be inserted into a patient (e.g., a human patient) during a clot treatment procedure. For example, the dilator 240 and the catheter 120 can be inserted into and advanced together through a blood vessel of the patient to a target location in the blood vessel. In some embodiments, after the dilator 240 has been inserted through the catheter 120, because the dilator 240 and the catheter 120 can move relative to one another, the catheter 120 can be advanced (e.g., distally, telescopically, etc.) over the dilator 240, e.g., using the dilator 240 as a guide or

"rail" to position the catheter 120 at or near the target location. With the catheter 120 positioned at or near the target location, the dilator 240 can then be retracted (e.g., proximally) through the catheter 120 to allow for other intravascular medical devices to be introduced into the patient via the catheter 120 and/or for aspiration of the catheter 120.

**[0039]** In some aspects of the present technology, the uniform diameter and varying stiffness of the dilator 240 is expected to improve the control and advancement characteristics of the dilator 240 and the catheter 120. For example, the uniform diameter of the dilator 240 is expected to better match the inner dimension of the lumen 124 of the catheter 120 which, in turn, can reduce or eliminate gaps or spacing between the dilator 240 and the catheter 120. Reducing/eliminating these gaps can at least partially inhibit or prevent the dilator 240 from flexing or buckling within the catheter 120 when navigating through a patient's vasculature, which can improve control of the dilator's movement during a procedure. Additionally, or alternatively, the uniform diameter of the dilator 240 is expected to improve the durability (e.g., crush resistance) of the catheter 120 when the dilator 240 is positioned within the catheter 120. For example, reducing/eliminating the gaps can also reduce the size of, or eliminate entirely, one or more crush zones associated with the gaps or spacing between the dilator 240 and the catheter 120 and in which the catheter 120 can be crushed or buckled during use. Furthermore, the variable mechanical properties of the dilator's body regions 244a-b can improve the dilator's flexibility and/or response to forces exerted on the dilator 240 (e.g., by a practitioner and/or from the catheter 120) during a procedure. In these and other embodiments, the notch 250 is expected to further improve the control and advancement characteristics of the dilator 240 and/or the system 100. For example, the magnitude of the resistive force/interference fit between the notch 250 and the valve 130 (e.g., the tether 336) can be configured to inhibit or prevent over-insertion of the dilator 240, which may damage a patient's vasculature. Additionally, or alternatively, the tactile feedback or sensation provided by the interference fit between the notch 250 and the valve 130 can provide (e.g., to a user) an indication of the relative position of the dilator 240 within the system 100.

**[0040]** Figures 4A and 4B are perspective views of the dilator 240 positioned within the system 100, in accordance with embodiments of the present technology. More specifically, Figure 4A shows the dilator 240 in a first position or state 401a, and Figure 4B shows the dilator 240 in a second position or state 401b. In Figures 4A and 4B, the coupling component 248 of the dilator 240 includes one or more luer-coupling features 452 (individually identified as a first luer-coupling feature 452a and a second luer-coupling feature 452b in Figures 4A and 4B) and/or

one or more stopping features 454 (individually identified as a first stopping feature 454a and a second stopping feature 454b). Individual ones of the stopping features 454 can be spaced apart and/or positioned proximally from one or more of the luer-coupling features 452.

**[0041]** Referring to Figure 4A, the dilator 240 can be inserted through the system 100 until the dilator 240 is coupled to the valve 130 via the notch 250 (Figures 2A-3B), as described previously herein with reference to Figures 3A and 3B. With the dilator 240 and the system 100 in the first state 401a, a first length L1 of the dilator 240 can extend distally beyond the distal terminus 126b of the catheter 120. In the illustrated embodiment, the first length L1 includes the tip 246 and a portion of the body 242. Additionally, or alternatively, the first length L1 can extend from about 1 cm to about 5 cm beyond the distal terminus 126b. In the first state 401a, the dilator 240 and the catheter 120 can be in a "standard" or "vascular access" mode or configuration in which the catheter 120 and the dilator 240 can be inserted into and/or used to navigate through a patient's vasculature, e.g., to a target location, as described previously herein. The dilator 240 may then be removed from the catheter 120 so that the system 100 can be used to treat and/or remove clot material from within the patient.

**[0042]** Referring to Figure 4B, the dilator 240 can be advanced from the first state 401a to the second state 401b by advancing the dilator 240 distally through the system 100 and/or retracting the system 100 proximally over the dilator 240. In the second state 401b, a second length L2 of the dilator 240 can extend distally beyond the distal terminus 126b. The second length L2 can be greater than the first length L1. In at least some embodiments, for example, the second length L2 is between about 5cm and about 20cm, such as at least 15cm, or another suitable length therebetween. In the second state 401b, the dilator 240 and the catheter 120 can be in a "rail" or "telescoping delivery" mode or configuration in which the catheter 120 can be advanced into and/or through the patient's vasculature while sliding along and/or otherwise moving over (e.g., telescopically over) the dilator 240. In at least some embodiments, telescopically inserting the catheter 120 over the dilator 240 can include moving from the second state 401b to and/or toward the first state 401a (Figure 4A). In these and other embodiments, once the dilator 240 and/or the catheter 120 are position at or near a target location, the dilator 240 may then be removed from the catheter 120 the so that the system 100 can be used to treat and/or remove clot material from within the patient.

**[0043]** In some embodiments, one or more of the luer-coupling features 452 (Figure 4A) can be coupled to the valve 130 in the second state 401b, for example, to at least partially or

fully prevent further movement (e.g., unintended movement) of the catheter 120 and/or the dilator 240 relative to each other. Additionally, or alternatively, one or more of the stopping features 454 can contact or abut the valve 130 in the second state 401b, to thereby inhibit or prevent (i) further distal movement of the dilator 240 relative to the system 100 and/or (ii) further proximal movement of the system 100 relative to the dilator 240.

**[0044]** As described in detail above, the dilator 240 can include more than one notch (e.g., including the second notch 350 shown in Figures 3A and 3B). Each of the notches can be spaced along the length of the dilator 240 such that, when coupled via the valve 130, each notch can be associated with a different position of the dilator 240 relative to the system 100 and/or a different length of the dilator 240 (e.g., between the first and second lengths L1, L2) that extends beyond the distal terminus 126b. For example, referring to Figures 3A–4B together, the second notch 350 is positioned proximal of the first notch 250 such that the dilator extends farther past the distal terminus 126b of the catheter 120 when the valve 130 is coupled to (e.g., locked to) the dilator 240 at the second notch 350.

**[0045]** Because each notch can inhibit further movement of the dilator 240 and/or the system 100 relative to each other, the positions of one or more of the notches can be configured to inhibit or prevent over-insertion of the dilator 240, and/or can provide a user with increased control over the amount of the dilator 240 that extends beyond the distal terminus 126b. Additionally, when the dilator 240 includes multiple notches, the dilator 240 can be configured to be transitioned between more than the two states 401a-b shown in the illustrated embodiment. For example, the dilator 240 can be configured to be transitioned between at least three, four, five, or more different states.

Examples

**[0046]** Several aspects of the present technology are set forth in the following examples:

1. A dilator, comprising:

a tip;

a coupling component;

a first body region between the tip and the coupling component, wherein the first body region has a first flexibility profile; and

a second body region between the first body region and the tip, wherein the second body region has a second flexibility profile greater than the first flexibility profile,

wherein the first body region and the second body region have a same diameter.

2. The dilator of example 1 wherein the first body region has a first stiffness, wherein the second body region has a second stiffness, and wherein the first stiffness is greater than the second stiffness.

3. The dilator of example 1 or example 2 wherein the first body region has a first durometer, wherein the second body region has a second durometer, and wherein the second durometer is less than the first durometer.

4. The dilator of any of examples 1-3 wherein the first body region comprises a first material, and wherein the second body region comprises a second material different than the first material.

5. The dilator of any of examples 1-4, further comprising a third body region between the tip and the coupling component, wherein the third body region has a third flexibility profile different than the first flexibility profile or the second flexibility profile.

6. The dilator of any of examples 1-5, further comprising a notch positioned between the tip and the coupling component.

7. The dilator of example 6 wherein the notch is positioned between the first body region and the second body region.

8. The dilator of example 6 or example 7 wherein the notch is a first notch, the dilator further comprising a second notch positioned on a proximal or a distal side of the first notch.

9. A vascular access system, comprising:

a valve having a proximal end and a distal end;

a catheter defining a lumen and coupled to the valve; and

a dilator configured to be positioned within the lumen through the valve, wherein the dilator includes—

a first body region having a first flexibility profile; and

a second body region having a second flexibility profile less than the first flexibility profile,

wherein the first body region and the second body region have a same diameter.

10. The vascular access system of example 8 wherein the first body region has a first stiffness, wherein the second body region has a second stiffness, and wherein the first stiffness is greater than the second stiffness.

11. The dilator of example 9 or example 10 wherein the first body region has a first durometer, wherein the second body region has a second durometer, and wherein the second durometer is less than the first durometer.

12. The vascular access system of any of examples 9-11 wherein the first body region comprises a first material, and wherein the second body region comprises a second material different than the first material.

13. The vascular access system of any of examples 9-12, wherein the dilator further includes a notch configured to extend at least partially around a longitudinal axis of the dilator, wherein the valve is configured to be releasably coupled to the dilator via the notch.

14. The vascular access system of example 13 wherein the notch defines a recessed region of the dilator having a notch diameter less than the diameter of the first body region and the second body region.

15. The vascular access system of example 13 or example 14 wherein the valve includes a tether, and wherein the tether is configured to be positioned at least partially within the notch to releasably couple the dilator to the valve.

16. The vascular access system of example 15 wherein the tether is biased in a first direction to releasably couple the dilator to the valve, the valve further comprising a button operably coupled to the tether and configured to move the tether in a second direction, opposite the first direction, to cause the tether to uncouple the dilator from the valve.

17. The vascular access system of any of examples 13–16 wherein the notch is a first notch, and wherein the dilator further includes a second notch positioned on a proximal side or a distal side of the notch.

18. The vascular access system of example 17 wherein the catheter includes a distal terminus, wherein a first length of the dilator extends beyond the distal terminus when the first notch is coupled to the valve, and wherein a second length of the dilator extends beyond the distal terminus when the second notch is coupled to the valve.

19. The vascular access system of example 18 wherein the second length is greater than the first length.

20. A method of treating clot material within a patient, the method comprising:

positioning a dilator within a vascular access system such that a valve of the vascular access system releasably engages a notch of the dilator to inhibit further movement of the dilator relative to the vascular access system;

actuating a button of the valve to release the notch from the valve to allow further movement of the dilator relative to the vascular access system; and

moving the dilator relative to the vascular access system and/or the vascular access system relative to the dilator.

21. The method of example 20 wherein moving the dilator relative to the vascular access system includes advancing the dilator through the vascular access system to increase a length of the dilator that extends beyond a distal terminus of the vascular access system.

22. The method of example 20 wherein moving the vascular access system relative to the dilator includes advancing the vascular access system over the dilator to decrease a length of the dilator that extends beyond a distal terminus of the vascular access system.

23. The method of any of examples 20-22 wherein the notch is a first notch, the method further comprising:

positioning the dilator within the vascular access system such that the valve releasably engages a second notch of the dilator; and

applying a force to the dilator and/or the vascular access system to release the second notch from the valve.

24. The method of example 23 wherein applying the force to release the second notch from the valve includes applying the force to release the second notch from the valve without actuating the button.

25. A vascular access system, comprising:

a dilator extending along a longitudinal axis, wherein the dilator has a varying flexibility profile at least partially along the longitudinal axis, and wherein the dilator defines a notch extending at least partially circumferentially about the longitudinal axis;

a valve having a proximal end and a distal end; and

a catheter coupled to the valve and defining a lumen;

wherein the valve is configured to be releasably coupled to the dilator via the notch to inhibit movement of the dilator relative to the catheter when at least a portion of the dilator is inserted through the valve into the lumen of the catheter.

26. The vascular access system of example 25 wherein the dilator includes a body region having a diameter, and wherein the notch includes a recessed region of the dilator having a notch diameter less than the diameter of the body region.

27. The vascular access system of example 25 or example 26 wherein the valve includes a tether, and wherein the tether is configured to be positioned at least partially within the notch to releasably couple the dilator to the valve.

28. The vascular access system of example 27 wherein the tether is biased in a first direction to releasably couple the dilator to the valve, the valve further comprising a button operably coupled to the tether and configured to move the tether in a second direction, opposite the first direction, to move the tether at least partially out of the notch to uncouple the dilator from the valve.

29. The vascular access system of any of examples 25-28 wherein the notch is a first notch, wherein the portion of the dilator is a first portion, wherein the dilator further defines a second notch extending at least partially circumferentially about the longitudinal axis, and wherein the valve is configured to be releasably coupled to the dilator via the second notch to inhibit movement of the dilator relative to the catheter when at least a second portion of the dilator is inserted through the valve into the lumen of the catheter.

30. The vascular access system of example 29 wherein the catheter includes a distal terminus, wherein a first length of the dilator extends beyond the distal terminus when the first notch is coupled to the valve, and wherein a second length of the dilator extends beyond the distal terminus when the second notch is coupled to the valve.

31. The vascular access system of example 30 wherein the second length is greater than the first length.

32. The vascular access system of any of examples 25-31 wherein the dilator includes a proximal body region having a first flexibility profile and a distal body region having a second flexibility profile greater than the first flexibility profile, wherein the notch is positioned at least partially between the proximal body region and the distal body region.

33. The vascular access system of claim 25 wherein the dilator has a varying durometer at least partially along the longitudinal axis.

**[0047]** The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

**[0048]** From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures

and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

**[0049]** Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A dilator, comprising:

a tip;

a coupling component;

a first body region between the tip and the coupling component, wherein the first body region has a first flexibility profile; and

a second body region between the first body region and the tip, wherein the second body region has a second flexibility profile greater than the first flexibility profile,

wherein the first body region and the second body region have a same diameter.

2. The dilator of claim 1 wherein the first body region has a first stiffness, wherein the second body region has a second stiffness, and wherein the first stiffness is greater than the second stiffness.

3. The dilator of claim 1 wherein the first body region has a first durometer, wherein the second body region has a second durometer, and wherein the second durometer is less than the first durometer.

4. The dilator of claim 1 wherein the first body region comprises a first material, and wherein the second body region comprises a second material different than the first material.

5. The dilator of claim 1, further comprising a third body region between the tip and the coupling component, wherein the third body region has a third flexibility profile different than the first flexibility profile or the second flexibility profile.

6. The dilator of claim 1, further comprising a notch positioned between the tip and the coupling component.

7. The dilator of claim 6 wherein the notch is positioned between the first body region and the second body region.

8. The dilator of claim 6 wherein the notch is a first notch, the dilator further comprising a second notch positioned on a proximal or a distal side of the first notch.

9. A vascular access system, comprising:

a valve having a proximal end and a distal end;

a catheter defining a lumen and coupled to the valve; and

a dilator configured to be positioned within the lumen through the valve, wherein the dilator includes—

a first body region having a first flexibility profile; and

a second body region having a second flexibility profile less than the first flexibility profile,

wherein the first body region and the second body region have a same diameter.

10. The vascular access system of claim 9 wherein the first body region has a first stiffness, wherein the second body region has a second stiffness, and wherein the first stiffness is greater than the second stiffness.

11. The vascular access system of claim 9 wherein the first body region has a first durometer, wherein the second body region has a second durometer, and wherein the second durometer is less than the first durometer.

12. The vascular access system of claim 9 wherein the first body region comprises a first material, and wherein the second body region comprises a second material different than the first material.

13. The vascular access system of claim 9, wherein the dilator further includes a notch configured to extend at least partially around a longitudinal axis of the dilator, wherein the valve is configured to be releasably coupled to the dilator via the notch.

14. The vascular access system of claim 13 wherein the notch defines a recessed region of the dilator having a notch diameter less than the diameter of the first body region and the second body region.

15. The vascular access system of claim 13 wherein the valve includes a tether, and wherein the tether is configured to be positioned at least partially within the notch to releasably couple the dilator to the valve.

16. The vascular access system of claim 15 wherein the tether is biased in a first direction to releasably couple the dilator to the valve, the valve further comprising a button operably coupled to the tether and configured to move the tether in a second direction, opposite the first direction, to cause the tether to uncouple the dilator from the valve.

17. The vascular access system of claim 13 wherein the notch is a first notch, and wherein the dilator further includes a second notch positioned on a proximal side or a distal side of the notch.

18. The vascular access system of claim 17 wherein the catheter includes a distal terminus, wherein a first length of the dilator extends beyond the distal terminus when the first notch is coupled to the valve, and wherein a second length of the dilator extends beyond the distal terminus when the second notch is coupled to the valve.

19. The vascular access system of claim 18 wherein the second length is greater than the first length.

20. A method of treating clot material within a patient, the method comprising:

positioning a dilator within a vascular access system such that a valve of the vascular access system releasably engages a notch of the dilator to inhibit further movement of the dilator relative to the vascular access system;

actuating a button of the valve to release the notch from the valve to allow further movement of the dilator relative to the vascular access system; and

moving the dilator relative to the vascular access system and/or the vascular access system relative to the dilator.

21. The method of claim 20 wherein moving the dilator relative to the vascular access system includes advancing the dilator through the vascular access system to increase a length of the dilator that extends beyond a distal terminus of the vascular access system.

22. The method of claim 20 wherein moving the vascular access system relative to the dilator includes advancing the vascular access system over the dilator to decrease a length of the dilator that extends beyond a distal terminus of the vascular access system.

23. The method of claim 20 wherein the notch is a first notch, the method further comprising:

positioning the dilator within the vascular access system such that the valve releasably engages a second notch of the dilator; and

applying a force to the dilator and/or the vascular access system to release the second notch from the valve.

24. The method of claim 23 wherein applying the force to release the second notch from the valve includes applying the force to release the second notch from the valve without actuating the button.

25. A vascular access system, comprising:

a dilator extending along a longitudinal axis, wherein the dilator has a varying flexibility profile at least partially along the longitudinal axis, and wherein the dilator defines a notch extending at least partially circumferentially about the longitudinal axis;

a valve having a proximal end and a distal end; and

a catheter coupled to the valve and defining a lumen;

wherein the valve is configured to be releasably coupled to the dilator via the notch to inhibit movement of the dilator relative to the catheter when at least a portion of the dilator is inserted through the valve into the lumen of the catheter.

26. The vascular access system of claim 25 wherein the dilator includes a body region having a diameter, and wherein the notch includes a recessed region of the dilator having a notch diameter less than the diameter of the body region.

27. The vascular access system of claim 25 wherein the valve includes a tether, and wherein the tether is configured to be positioned at least partially within the notch to releasably couple the dilator to the valve.

28. The vascular access system of claim 27 wherein the tether is biased in a first direction to releasably couple the dilator to the valve, the valve further comprising a button operably coupled to the tether and configured to move the tether in a second direction, opposite the first direction, to move the tether at least partially out of the notch to uncouple the dilator from the valve.

29. The vascular access system of claim 25 wherein the notch is a first notch, wherein the portion of the dilator is a first portion, wherein the dilator further defines a second notch extending at least partially circumferentially about the longitudinal axis, and wherein the valve is configured to be releasably coupled to the dilator via the second notch to inhibit movement of the dilator relative to the catheter when at least a second portion of the dilator is inserted through the valve into the lumen of the catheter.

30. The vascular access system of claim 29 wherein the catheter includes a distal terminus, wherein a first length of the dilator extends beyond the distal terminus when the first notch is coupled to the valve, and wherein a second length of the dilator extends beyond the distal terminus when the second notch is coupled to the valve.

31. The vascular access system of claim 30 wherein the second length is greater than the first length.

32. The vascular access system of claim 25 wherein the dilator includes a proximal body region having a first flexibility profile and a distal body region having a second flexibility profile greater than the first flexibility profile, wherein the notch is positioned at least partially between the proximal body region and the distal body region.

33. The vascular access system of claim 25 wherein the dilator has a varying durometer at least partially along the longitudinal axis.

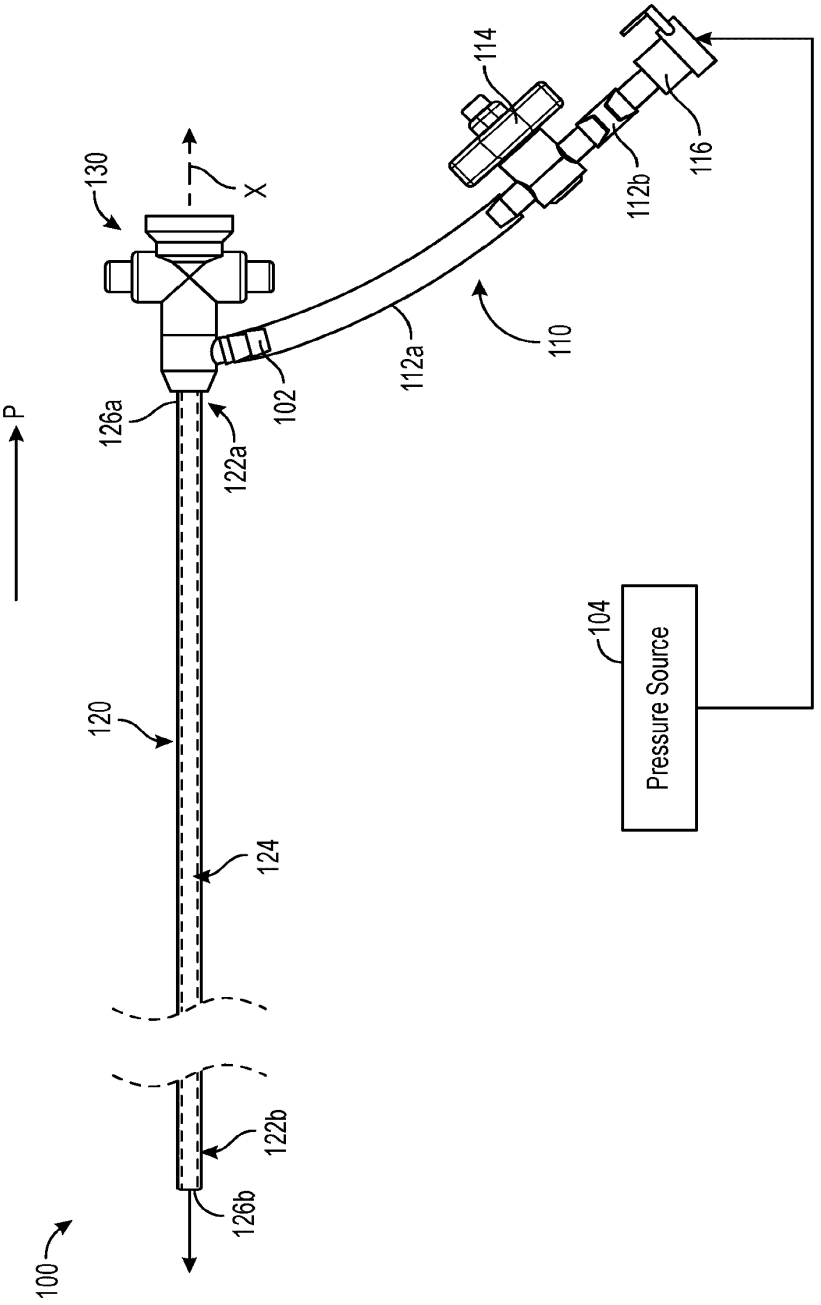

130
X
114
116
112b
110
112a
102
126a
122a
P
104
Pressure Source
120
124
122b
126b
100

*FIG. 1*

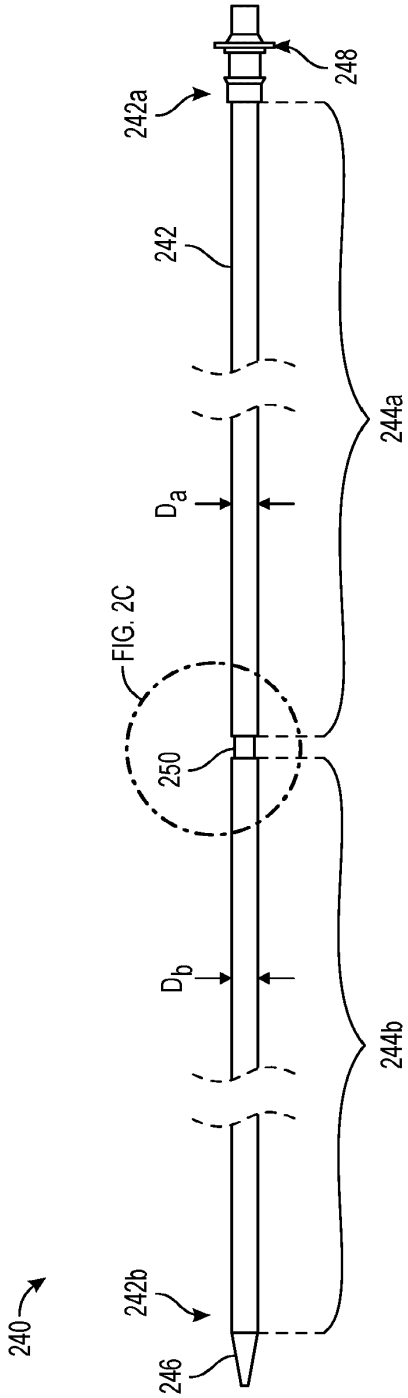

240
242b
246
244b
$D_b$
250
FIG. 2C
$D_a$
242
242a
248
244a

*FIG. 2A*

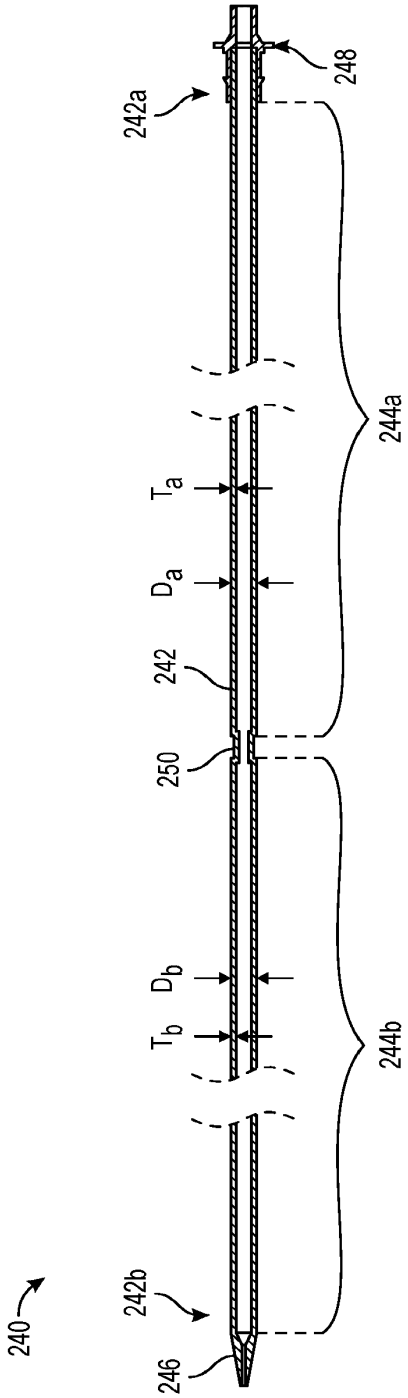

240
242b
246
244b
$T_b$
$D_b$
250
242
$D_a$
$T_a$
242a
248
244a

*FIG. 2B*

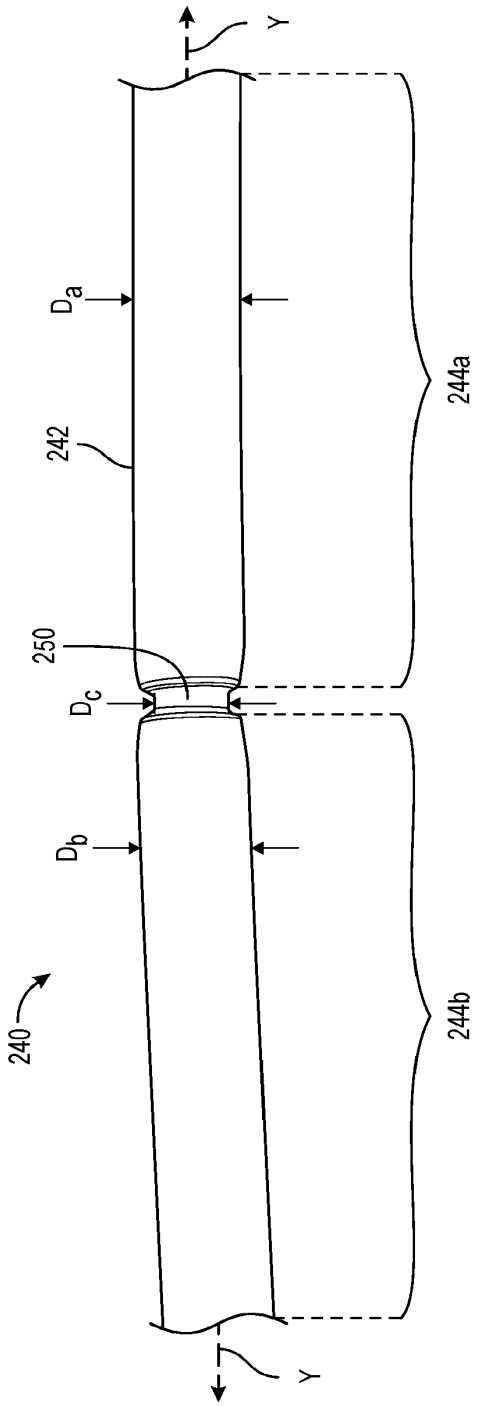



*FIG. 2C*

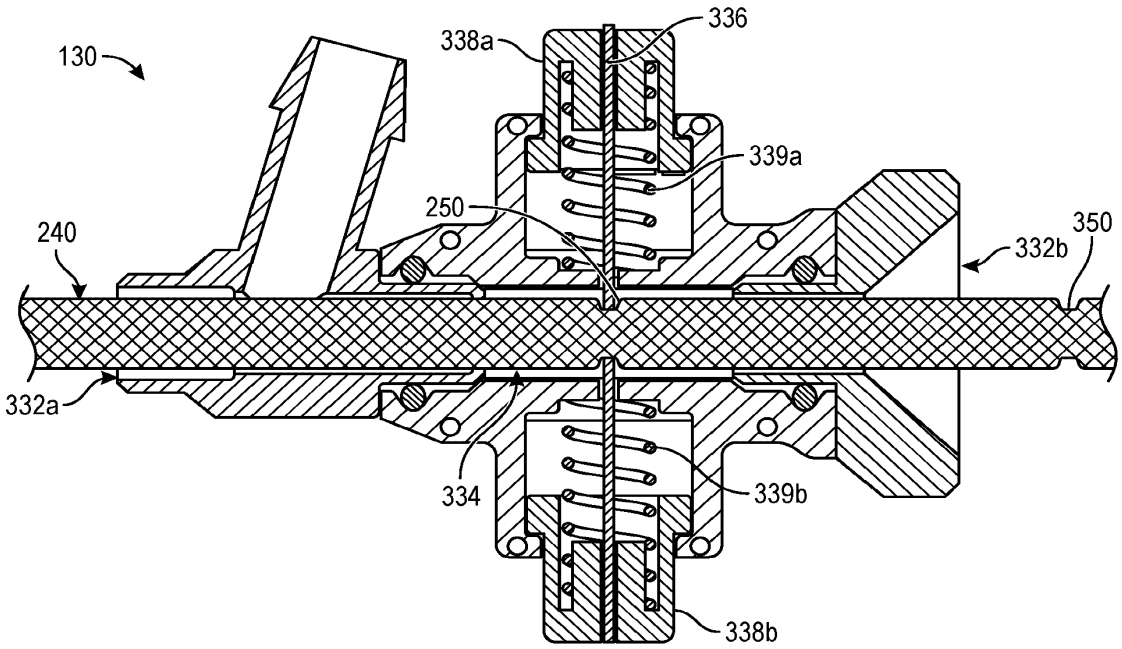

130
338a
336
339a
250
240
350
332b
332a
334
339b
338b

*FIG. 3A*

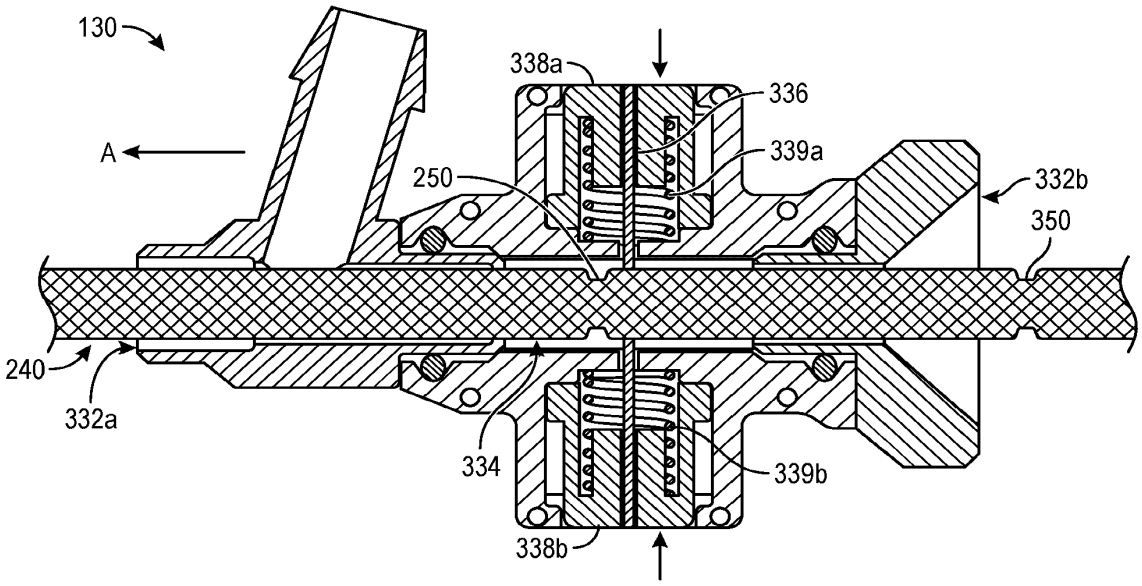

130
338a
336
A
339a
250
332b
350
240
332a
334
339b
338b

*FIG. 3B*

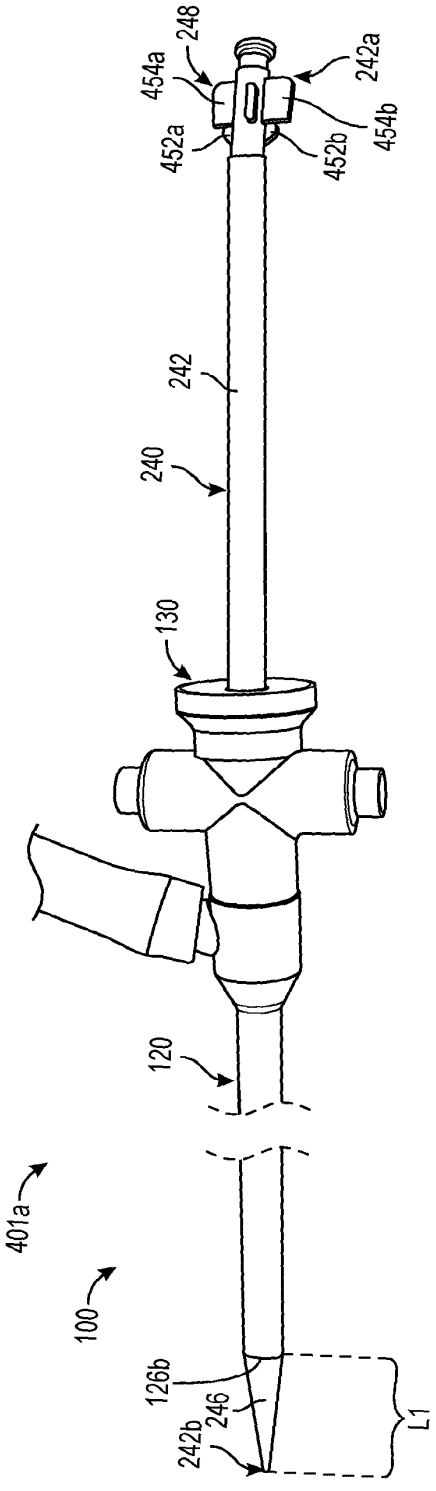

248
454a
242a
452a
452b
454b
242
240
130
120
401a
100
126b
246
242b
L1

FIG. 4A

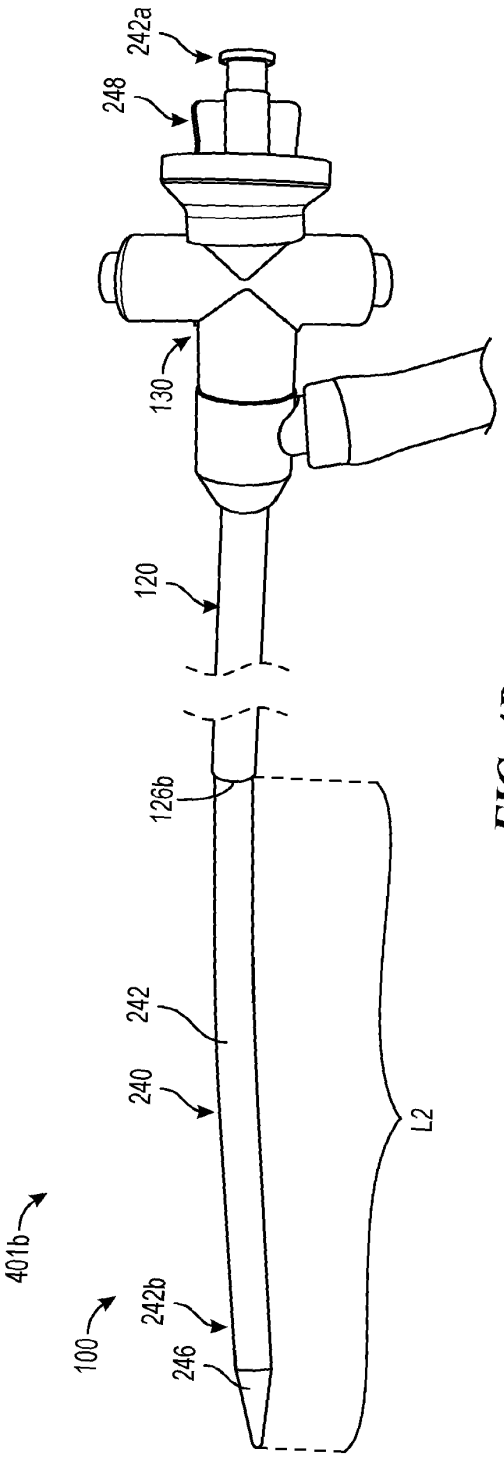

242a
248
130
120
126b
242
240
L2
401b
100
242b
246

FIG. 4B

# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: BENJAMIN D. CASHDOLLAR
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

RECEIVED
PATENT DOCKETING

JUL 25 2023

PERKINS COIE LLP

# PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

| | |
|---|---|
| Date of mailing *(day/month/year)* | JUL 20 2023 |
| Applicant's or agent's file reference<br>111552-8033WO00 | FOR FURTHER ACTION See paragraphs 1 and 4 below |
| International application No.<br>PCT/US 23/60927 | International filing date *(day/month/year)* 19 January 2023 (19.01.2023) |
| Applicant INARI MEDICAL, INC. | |

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   **Filing of amendments and statement under Article 19:**
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   **When?** The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   **How?** Directly to the International Bureau preferably through ePCT, or on paper to:
   The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland

   **For more detailed instructions,** see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   The applicant may **submit comments on an informal basis on the written opinion of the International Searching Authority** to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

   Shortly after the expiration of **18 months from the priority date, the international application will be published** by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, within **20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

   Within **22 months from the priority date, the applicant may request that a supplementary international search be carried out** by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

| | |
|---|---|
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US<br>Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | Authorized officer<br>Karl Rodriquez<br>Telephone No. PCT Helpdesk: 571-272-4300 |

Form PCT/ISA/220 (revised January 2020)

PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| Applicant's or agent's file reference | FOR FURTHER ACTION |
|---|---|
| 111552-8033WO00 | see Form PCT/ISA/220 as well as, where applicable, item 5 below. |

| International application No. | International filing date *(day/month/year)* | (Earliest) Priority Date *(day/month/year)* |
|---|---|---|
| PCT/US 23/60827 | 19 January 2023 (19.01.2023) | 08 February 2022 (08.02.2022) |

Applicant
INARI MEDICAL, INC.

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language**, the international search was carried out on the basis of:
      ☒ the international application in the language in which it was filed.
      ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☒ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,
   a. the figure of the drawings to be published with the abstract is Figure No. 2A
      ☒ as suggested by the applicant.
      ☐ as selected by this Authority, because the applicant failed to suggest a figure.
      ☐ as selected by this Authority, because this figure better characterizes the invention.
   b. ☐ none of the figures is to be published with the abstract.

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 23/60927

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

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

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

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

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

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

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-13 directed to a cap assembly for a catheter.

Group II: Claims 14-36 directed to a vascular access system and associated methods of use.

-*-Continued in extra sheet-*-

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

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

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

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-13

**Remark on Protest**

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 23/60927

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61M 25/18, A61M 39/10 (2023.01)
ADD.

CPC - INV. A61M 25/0097, A61M 39/1011

ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | CN 106178227 A (Shanghai Microport Medical Group Co., Ltd.); 7 December 2016 (07.12.2016); entire document, especially | 1-2, 5, 7-11 |
| X<br>--<br>Y | US 5,391,152 A (PATTERSON); 21 February 1995 (21.02.1995); entire document, especially Abstract, Figs. 7-9; col. 4, in 42-46; col. 5, in 24-55. | 1, 3-4, 6, 12<br><br>13 |
| Y | US 2021/0404464 A1 (S.P.M. Flow Control, Inc.); 30 December 2021 (30.12.2021); entire document, especially Abstract, para. [0008], [0071], [0074]. | 13 |
| A | US 5,971,958 A (ZHANG); 26 October 1999 (26.10.1999); entire document. | 1-13 |
| A | US 3,860,036 A (PATEL); 14 January 1975 (14.01.1975); entire document. | 1-13 |
| A | US 2013/0150793 A1 (BEISSEL et al.); 13 June 2013 (13.06.2013); entire document. | 1-13 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 12 April 2023 (12.04.2023) | JUL 20 2023 |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | Authorized officer<br>Kari Rodriquez<br>Telephone No. PCT Helpdesk: 571-272-4300 |

INARI_017426

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 23/60827

-*-Box No. III - Lack of unity-*-

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical features of [a first cap including a locking member], wherein [the locking member] includes an end portion and [a tab] positioned proximate the end portion; and [a second cap including a locking feature], wherein the locking feature includes a slot extending at least partially through [the second cap], in [the locked position], [the locking feature is configured to receive the locking member] through the slot [such that the tab engages a portion of the second cap] to inhibit movement of the [first cap] relative to [the second cap], not required in Group II.

The invention of Group II includes the special technical features of a vascular access system, comprising: a valve having a proximal end and a distal end; a catheter defining a lumen and coupled to the distal end of the valve, the catheter defining a longitudinal axis of the vascular access system; a dilator configured to extend at least partially through the valve and the lumen; wherein [the cap assembly] includes (i) [a] valve [cap] connected to the proximal end of the valve and [including a coupling feature], and (ii) [a] dilator [cap] coupled to the dilator and [including a] coupling tab insertable into the coupling feature], wherein [in the locked configuration, the coupling feature is configured to receive the coupling tab such that the coupling tab engages a portion of the] valve [cap] to inhibit movement of the dilator relative to the valve along the longitudinal axis, not required in Group I.

COMMON TECHNICAL FEATURES

The inventions of Groups I-II share the technical features of a cap assembly, the cap assembly including first cap including a locking member, wherein the locking member includes a tab, and a second cap including a locking feature, wherein the cap assembly is movable between a locked configuration and an unlocked configuration, wherein in the locked configuration, the locking feature is configured to receive the locking member such that the tab engages a portion of the second cap to inhibit movement, and the first cap is configured to rotate relative to the second cap to move the tab out of engagement with the second cap to move the first cap from the locked position to an unlocked position. The common technical features are known in prior art as shown in US 5,391,152 A to Patterson (hereinafter 'Patterson'). Therefore, Groups I-II lack unity since the shared technical features do not represent a contribution over:

Patterson teaches a cap assembly (hubs of catheter assembly complementary and rotatably engageable, Abstract, Figs. 7-9), the cap assembly including:
a first cap (hub 25, Fig. 7, col. 5, ln 24-29) including a locking member (locking member defined by first tab 29, Fig. 7, col. 5, ln 29-34), wherein the locking member includes a tab (pin 100 axially disposed on distal end of first tab 29, Fig. 7, col. 5, ln 29-31), and
a second cap (hub 35, Fig. 7-9, col. 5, ln 24-29) including a locking feature (locking element of hub 35 including first projection 150 and first slot 105, Fig. 7-9, col. 5, ln. 31-34),
wherein the cap assembly is movable between a locked configuration and an unlocked configuration (dilator hub 25 and introducer hub 35 are releasably interlocked, col. 5, ln 24-29),
wherein in the locked configuration, the locking feature is configured to receive the locking member (mechanically interlocked by inserting tab 29 with pin 100 into enlarged open end of slot 105, col. 5, ln 45-49) such that the tab engages a portion of the second cap to inhibit movement (once tab 29 with pin 100 us engaged with slot 105, axial disengagement is precluded by projection 150, col. 5, ln 50-55), and
wherein the first cap is configured to rotate relative to the second cap to move the tab out of engagement with the second cap to move the first cap from the locked position to an unlocked position (dilator hub 25 and introducer hub 35 are releasably interlocked to provide resistance to rotational disengagement, col. 5, ln 24-29; resistance posed by interfering portions of slot 105 inhibits accidental rotational disengagement [in the opposite circumferential direction], col. 5, ln 53-55, col. 4, ln 42-46; unlocked position, Fig. 7; implicitly, hubs 25 and 35 can be intentionally rotated in the opposite circumferential direction to overcome the resistance posed and to release the interlock).

As the common features were known in the art at the time of the invention, they cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

# PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: BENJAMIN D. CASHDOLLAR
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

RECEIVED
PATENT DOCKETING
JUL 25 2023
PERKINS COIE LLP

# PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

| | |
|---|---|
| Date of mailing *(day/month/year)* | JUL 20 2023 |
| Applicant's or agent's file reference<br>111552-8033WO00 | FOR FURTHER ACTION<br>See paragraph 2 below |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/US 23/60927 | 19 January 2023 (19.01.2023) | 08 February 2022 (08.02.2022) |

International Patent Classification (IPC) or both national classification and IPC
IPC - INV. A61M 25/18, A61M 39/10 (2023.01)
ADD.
CPC - INV. A61M 25/0097, A61M 39/1011
ADD.

Applicant INARI MEDICAL, INC.

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [X] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

| Name and mailing address of the ISA/US | Date of completion of this opinion | Authorized officer |
|---|---|---|
| Mail Stop PCT, Attn: ISA/US<br>Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | 12 April 2023 (12.04.2023) | Kari Rodriquez<br>PCT Help Desk<br>Telephone No. 571-272-4300 |

Form PCT/ISA/237 (cover sheet) (revised July 2022)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 23/60927

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b)).

3. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of a sequence listing:

a. ☐ forming part of the international application as filed.

b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13ter.1(a)),

☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.

4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.

5. Additional comments:

INARI_017429

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 23/60927

**Box No. IV Lack of unity of invention**

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:

   ☐ paid additional fees.

   ☐ paid additional fees under protest and, where applicable, the protest fee.

   ☐ paid additional fees under protest but the applicable protest fee was not paid.

   ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-13 directed to a cap assembly for a catheter.

Group II: Claims 14-36 directed to a vascular access system and associated methods of use.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical features of [a first cap including a locking member], wherein [the locking member] includes an end portion and [a tab] positioned proximate the end portion; and [a second cap including a locking feature], wherein the locking feature includes a slot extending at least partially through [the second cap], in [the locked position], [the locking feature is configured to receive the locking member] through the slot [such that the tab engages a portion of the second cap] to inhibit movement of the [first cap] relative to [the second cap], not required in Group II.

The invention of Group II includes the special technical features of a vascular access system, comprising: a valve having a proximal end and a distal end; a catheter defining a lumen and coupled to the distal end of the valve, the catheter defining a longitudinal axis of the vascular access system; a dilator configured to extend at least partially through the valve and the lumen; wherein [the cap assembly] includes (i) [a] valve [cap] connected to the proximal end of the valve and [including a coupling feature], and (ii) [a] dilator [cap] coupled to the dilator and [including a] coupling tab insertable into the coupling feature], wherein [in the locked configuration, the coupling feature is configured to receive the coupling tab such that the coupling tab engages a portion of the] valve [cap] to inhibit movement of the dilator relative to the valve along the longitudinal axis, not required in Group I.

-*-Continued in Supplemental Box-*-

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-13

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 23/60927

**Box No. V** **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | 13 | YES |
| | Claims | 1-12 | NO |
| Inventive step (IS) | Claims | None | YES |
| | Claims | 1-13 | NO |
| Industrial applicability (IA) | Claims | 1-13 | YES |
| | Claims | None | NO |

2. Citations and explanations:

Claims 1-2, 5, and 7-11 lack novelty under PCT Article 33(2) as being anticipated by CN 108178227 A to Shanghai Microport Medical Group Co., Ltd. (hereinafter 'Shanghai').

Regarding claim 1, Shanghai teaches a cap assembly for a catheter (device that locks and unlocks catheter sheaths and dilators, Abstract, Fig. 4; Note: all Citations to Shanghai are to the translation of Shanghai), the cap assembly comprising:
a first cap (dilator seat 1, Fig. 4, pg. 11) including a locking member (claw buckle 9, Fig. 4, pg. 12), wherein the locking member includes an end portion (distal end portion of arm of claw buckle 9, Fig. 4) and a tab positioned proximate the end portion (distal tab extending from a distal end of the arm of claw buckle 9, Fig. 4); and
a second cap (sheath seat 5, Fig. 4, pg. 11) including a locking feature (recess in seat 5 for receiving claw buckle 9, Fig. 4, pg. 12), wherein the locking feature includes a slot extending at least partially through the second cap (Fig. 4), and wherein---
the first cap is configured to be secured to the second cap in a locked position (push claw buckle 9 into sheath seat 5 to achieve locking, pg. 11), in the locked position, the locking feature is configured to receive the locking member through the slot such that the tab engages a portion of the second cap to inhibit movement of the first cap relative to the second cap (claw buckle 9 and inverted buckle 10 snap to achieve locking, Fig. 8, pg. 11), and
the first cap is configured to rotate relative to the second cap to move the tab out of engagement with the second cap to move the first cap from the locked position to an unlocked position (during the separation process, turn dilator seat 1 clockwise or counterclockwise so that it is separated from the sheath seat 5 until the claw buckle 9 is detached from the inverted buckle 10, Fig. 9, pg. 12).

Regarding claim 2, Shanghai teaches the cap assembly of claim 1 wherein the first cap includes an upper surface (upper surface of dilator seat 1, Fig. 4), and wherein the locking member extends from the upper surface in a direction generally perpendicular to the upper surface (Fig. 4), and wherein the end portion of the locking member is opposite the upper surface (Fig. 4).

Regarding claim 5, Shanghai teaches the cap assembly of claim 1 wherein the locking member is flexible (claw buckle 9 can move axially and elastically deform radially inward, Fig. 4, pg. 12), and wherein the second cap is configured to bend the locking member when the first cap moves between the unlocked position and the locked position (buckle 10 of sheath seat 5 to deform the claw buckle 9, Figs. 4, 8, 6, pg. 11).

Regarding claim 7, Shanghai teaches the cap assembly of claim 1 wherein the locking feature includes an angled insertion surface (angled upper surface of buckle 10, Fig. 4) positioned to engage and deflect the locking member when the first cap moves from the unlocked position toward the locked position (Fig. 4; claw buckle 9 can move axially and elastically deform radially inward, pg. 11; intended use, the angled upper surface of buckle 10 can elastically deform the buckle 9 inward for locking).

Regarding claim 8, Shanghai teaches the cap assembly of claim 7 wherein the cap assembly includes a longitudinal axis (Fig. 4), and where the insertion surface is angled to bend the locking member inward toward the longitudinal axis (Fig. 4, pg. 11).

Regarding claim 9, Shanghai teaches the cap assembly of claim 1 wherein the locking feature includes a radial removal surface (lower angled surface of buckle 10, Fig. 4), and wherein the radial removal surface is angled to deflect the tab inward when the first cap is rotated relative to the second cap (Fig. 4; claw buckle 9 can move axially and elastically deform radially inward, pg. 11; claw 9 is detached from the inverted buckle 10 for separation, pg. 12; intended use, the angled lower surface of buckle 10 can elastically deform the buckle 9 inward for unlocking).

Regarding claim 10, Shanghai teaches the cap assembly of claim 1 wherein the locking feature includes an axial removal surface positioned proximate the slot (lower angled surface of buckle 10 proximate to the recess in sheath seat 5, Fig. 4) and angled to move the first cap away from the second cap when the first cap is rotated relative to the second cap (Fig. 4; claw buckle 9 can move axially and elastically deform radially inward, pg. 11; claw 9 is detached from the inverted buckle 10 for separation, pg. 12; intended use, the angled lower surface of buckle 10 can elastically deform the buckle 9 inward for unlocking).

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**Supplemental Box**

**In case the space in any of the preceding boxes is not sufficient.**
Continuation of:
-*-Box No. IV.3 - Lack of unity-*-

COMMON TECHNICAL FEATURES

The inventions of Groups I-II share the technical features of a cap assembly, the cap assembly including first cap including a locking member, wherein the locking member includes a tab, and a second cap including a locking feature, wherein the cap assembly is movable between a locked configuration and an unlocked configuration, wherein in the locked configuration, the locking feature is configured to receive the locking member such that the tab engages a portion of the second cap to inhibit movement, and the first cap is configured to rotate relative to the second cap to move the tab out of engagement with the second cap to move the first cap from the locked position to an unlocked position. The common technical features are known in prior art as shown in US 5,391,152 A to Patterson (hereinafter 'Patterson'). Therefore, Groups I-II lack unity since the shared technical features do not represent a contribution over

Patterson teaches a cap assembly (hubs of catheter assembly complementary and rotatably engageable, Abstract, Figs. 7-9), the cap assembly including:
a first cap (hub 25, Fig. 7, col. 5, ln 24-29) including a locking member (locking member defined by first tab 29, Fig. 7, col. 5, ln 29-34), wherein the locking member includes a tab (pin 100 axially disposed on distal end of first tab 29, Fig. 7, col. 5, ln 29-31), and
a second cap (hub 35, Fig. 7-9, col. 5, ln 24-29) including a locking feature (locking element of hub 35 including first projection 150 and first slot 105, Fig. 7-9, col. 5, ln. 31-34),
wherein the cap assembly is movable between a locked configuration and an unlocked configuration (dilator hub 25 and introducer hub 35 are releasably interlocked, col. 5, ln 24-29),
wherein in the locked configuration, the locking feature is configured to receive the locking member (mechanically interlocked by inserting tab 29 with pin 100 into enlarged open end of slot 105, col. 5, ln 45-49) such that the tab engages a portion of the second cap to inhibit movement (once tab 29 with pin 100 us engaged with slot 105, axial disengagement is precluded by projection 150, col. 5, ln 50-55), and
wherein the first cap is configured to rotate relative to the second cap to move the tab out of engagement with the second cap to move the first cap from the locked position to an unlocked position (dilator hub 25 and introducer hub 35 are releasably interlocked to provide resistance to rotational disengagement, col. 5, ln 24-29; resistance posed by interfering portions of slot 105 inhibits accidental rotational disengagement [in the opposite circumferential direction], col. 5, ln 53-55, col. 4, ln 42-46; unlocked position, Fig. 7; implicitly, hubs 25 and 35 can be intentionally rotated in the opposite circumferential direction to overcome the resistance posed and to release the interlock).

As the common features were known in the art at the time of the invention, they cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-*-Box No. V.2 - Citations and explanations-*-

Regarding claim 11, Shanghai teaches the cap assembly of claim 1 wherein:
the first cap includes an upper surface (upper surface as dilator seat 1, Fig. 4), and the locking member extends from the upper surface in a direction perpendicular to the upper surface (Fig. 4);
the locking member is flexible (claw buckle 9 can move axially and elastically deform radially inward, Fig. 4, pg. 12) and configured to deflect when the first cap moves between the unlocked position and the locked position (buckle 10 of sheath seat 5 to deform the claw buckle 9, Figs. 4, 9, 6, pg. 11);
the tab defines a retaining surface (recess defined between distal tab of claw buckle and arm of claw buckle, Fig. 4) positioned to contact at least a portion of the second cap in the locked position (positioned to contact lower angled surface of buckle 10 in locked position, Fig. 6); and
the locking feature includes--
a locking surface positioned to at least partially contact the retaining surface of the tab in the locked position (projection of buckle to contact recess of claw buckle in locked position, Fig. 6),
an insertion surface (angled upper surface of buckle 10, Fig. 4) positioned to be at least partially aligned with the locking member (Fig. 4) and angled to deflect the locking member inward when the first cap moves from the unlocked position toward the locked position (Fig. 4; claw buckle 9 can move axially and elastically deform radially inward, pg. 11; intended use, the angled upper surface of buckle 10 can elastically deform the buckle 9 inward for locking),
a radial removal surface positioned proximate the tab of the locking member in the locked position (upper angled surface of claw buckle 9, Fig. 6), wherein the radial removal surface is angled to move the tab radially inward when the first cap moves from the locked position toward the unlocked position (Fig. 4; claw buckle 9 can move axially and elastically deform radially inward, pg. 11; claw 9 is detached from the inverted buckle 10 for separation, pg. 12; intended use, the angled surface of the claw together with the buckle 10 may cause the claw 9 to move inward during unlocking), and
an axial removal surface positioned proximate the slot (lower angled surface of buckle 10 proximate to the recess in sheath seat 5, Fig. 4) and angled to move the first cap longitudinally away from the second cap when the first cap moves from the locked positioned toward the unlocked position (Fig. 4; claw buckle 9 can move axially and elastically deform radially inward, pg. 11; claw 9 is detached from the inverted buckle 10 for separation, pg. 12; intended use, the angled lower surface of buckle 10 together with the angled surface of the claw can elastically deform the buckle 9 inward for unlocking).

Claims 1, 3-4, 6, and 12 lack novelty under PCT Article 33(2) as being anticipated by US 5,391,152 A to Patterson.

Regarding claim 1, Patterson teaches a cap assembly for a catheter (hubs of catheter assembly complementary and rotatably engageable, Abstract, Figs. 7-9), the cap assembly comprising:
a first cap (hub 25, Fig. 7, col. 5, ln 24-29) including a locking member (locking member defined by first tab 29, Fig. 7, col. 5, ln 29-34), wherein the locking member includes an end portion (distal end of first tab 29, Fig. 7) and a tab positioned proximate the end portion (pins 100 axially disposed on distal end of first tab 29, Fig. 7, col. 5, ln 29-31); and
a second cap (hub 35, Fig. 7-9, col. 5, ln 24-29) including a locking feature (locking element of hub 35 including first projection 150 and first slot 105, Fig. 7-9, col. 5, ln. 31-34) wherein the locking feature includes a slot extending at least partially through the second cap (slot 105, Fig. 7-9), and wherein---
the first cap is configured to be secured to the second cap in a locked position (hub 25 and hub 35 may be mechanically interlocked, col. 5, ln 45-49), in the locked position, the locking feature is configured to receive the locking member through the slot (mechanically interlocked by inserting tab 29 with pin 100 into enlarged open end of slot 105, col. 5, ln 45-49) such that the tab engages a portion of the second cap (projection 150 of hub 35 is complimentary with pin 100, col. 5, ln 30-34) to inhibit movement of the first cap relative to the second cap (once tab 29 with pin 100 us engaged with slot 105, axial disengagement is precluded by projection 150, col. 5, ln 50-55), and
the first cap is configured to rotate relative to the second cap to move the tab out of engagement with the second cap to move the first cap from the locked position to an unlocked position (dilator hub 25 and introducer hub 35 are releasably interlocked to provide resistance to rotational disengagement, col. 5, ln 24-29, resistance posed by interfering portions of slot 105 inhibits accidental rotational disengagement [in the opposite circumferential direction], col. 5, ln 53-55, col. 4, ln 42-46; unlocked position, Fig. 7; implicitly, hubs 25 and 35 can be intentionally rotated in the opposite circumferential direction to overcome the resistance posed and to release the interlock).

Regarding claim 3, Patterson teaches the cap assembly of claim 1 wherein the tab extends perpendicularly from the locking member (pin 100 extends perpendicularly from distal end of tab 29, Fig. 7).

Regarding claim 4, Patterson teaches the cap assembly of claim 1 wherein the tab defines a retaining surface (pin 100 defines recess between pin 100 and tab 29, Fig. 7) positioned to contact at least a portion of the second cap when the first cap is coupled to the second cap (receive projection 150, Fig. 7, col. 5, ln 31-34).

Regarding claim 6, Patterson teaches the cap assembly of claim 1 wherein the locking feature includes a locking surface (projection 150, Fig. 7, col. 5, ln 31-34) positioned to at least partially contact the tab of the locking member when the first cap is coupled to the second cap (projection 150 of hub 35 is complimentary with pin 100, col. 5, ln 30-34; once tab 29 with pin 100 are engaged with slot 105, axial disengagement is precluded by projection 150, col. 5, ln 50-55).

Regarding claim 12, Patterson teaches the cap assembly of claim 1 wherein the locking member is a first locking member (Fig. 7), wherein the locking feature is a first locking feature (Fig. 7-9), wherein the first cap includes one or more second locking members (second tab 29, Fig. 7), wherein the second cap includes one or more second locking features (second projection 150 and second slot 105, Fig. 7-9), and wherein individual ones of the second locking members are configured to receive and secure corresponding ones of the second locking members in the locked position (mechanically interlocked by inserting tab 29 with pin 100 into enlarged open end of slot 105, col. 5, ln 45-49) such that the tab engages a portion of the second cap (projection 150 of hub 35 is complimentary with pin 100, col. 5, ln 30-34).

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**Supplemental Box**

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Claim 13 lacks an inventive step under PCT Article 33(3) as being obvious over Patterson in view of US 2021/0404464 A1 to S.P.M Flow Control, Inc. (hereinafter 'Flow').

Regarding claim 13, Patterson teaches the cap assembly of claim 1. While Patterson teaches dilator hub 25 and introducer hub 35 are releasably interlocked to provide resistance to rotational disengagement, Patterson fails to teach wherein the locking feature is configured to be rotationally agnostic such that rotation of the first cap relative to the second cap in a first direction and a second direction opposite the first direction moves the tab out of engagement with the second cap to move the first cap from the locked position to an unlocked position.

Flow teaches a system (Abstract) wherein a locking feature is configured to be rotationally agnostic (moving from a first position to a second position in either a clockwise direction or a counterclockwise direction, para. [0071]) such that rotation of a first element relative to a second element in a first direction and a second direction opposite to the the first direction moves a tab out of engagement with the second cap to move the first cap from the locked position to an unlocked position (plug 198 can be rotated within port 166 in a clockwise direction or a counterclockwise direction from the locked position to the unlocked position, para. [0074]; unlocked position wherein the at least one key is aligned with the keyhole, Abstract, locked position where a sidewall of the keyway blocks the key from backing out, para. [0008]). It would have been obvious to one of ordinary skill in the art that the assembly of Patterson could have been modified as claimed in view of Flow to allow for quick detachment of the locking elements of Patterson.

Claims 1-13 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

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(54) Title: CLOT TREATMENT SYSTEMS WITH DILATOR LOCKING MECHANISMS, AND ASSOCIATED DEVICES AND METHODS

(57) Abstract: Disclosed herein are vascular access systems with dilator locking mechanisms, and associated devices and methods. In some embodiments, the dilator locking mechanisms include a first cap coupled to a dilator component and a second cap coupled to the vascular access system. The first cap can include one or more locking members. The second cap can include one or more locking features, each configured to be releasably coupled to one of the locking members. In operation, the dilator component can be inserted into the vascular access system, and at least a portion of one or more of the locking members can be aligned with and inserted into the corresponding locking feature to, e.g., couple the first cap and the second cap. The interaction between first and second caps when coupled can at least partially prevent the dilator from moving relative to the vascular access system.

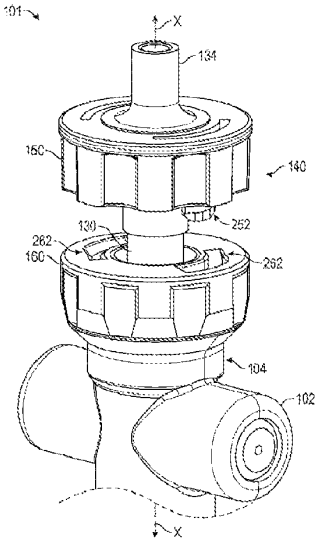



*FIG. 2A*

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# CLOT TREATMENT SYSTEMS WITH DILATOR LOCKING MECHANISMS, AND ASSOCIATED DEVICES AND METHODS

## CROSS-REFERENCE TO RELATED APPLICATION

**[0001]** This application claims the benefit of U.S. Provisional Patent Application No. 63/307,766 filed February 8, 2022, and titled "CLOT TREATMENT SYSTEMS WITH DILATOR LOCKING MECHANISMS, AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety.

## TECHNICAL FIELD

**[0002]** The present technology generally relates to vascular access systems, such as clot treatment systems, including locking mechanisms for releasably locking a dilator to a catheter to facilitate their joint navigation through a patient's skin, tissue, and vasculature.

## BACKGROUND

**[0003]** Thrombosis is the local coagulation or clotting of the blood in a part of the circulatory system, and a thrombus is a blood clot formed in situ within the vascular system. A venous thrombus is a blood clot that forms within a vein. A common type of venous thrombosis is a deep vein thrombosis (DVT), which is the formation of a blood clot within a deep vein (e.g., predominantly in the legs). Nonspecific signs of a thrombosis may include pain, swelling, redness, warmness, and engorged superficial veins.

**[0004]** If the thrombus breaks off (embolizes) and flows towards the lungs, it can become a life-threatening pulmonary embolism (PE) (e.g., a blood clot in the lungs). In addition to the loss of life that can arise from PE, DVT can cause significant health issues such as post thrombotic syndrome, which can cause chronic swelling, pressure, pain, and ulcers due to valve and vessel damage. Further, DVT can result in significant health-care costs either directly or indirectly through the treatment of related complications and inability of patients to work.

**[0005]** Existing methods for treating DVT and PE often involve treating the DVT or PE with a catheter system that is advanced through the patient's vasculature, such as along a venous access path. Such catheter systems—especially those having a large size (e.g., greater than 16 French)—often include a dilator component that is inserted through a catheter and used to

dilate the vasculature while the catheter is navigated to a target treatment site. Similarly, such systems are often used in conjunction with an introducer sheath that acts as a resealable access point through which the DVT and PE catheter systems can traverse to easily access the vasculature. The introducer sheath provides a stable tract and prevents excessive manipulation of devices with the access site, and can be inserted through the skin and tissue tract with a dilator component interested therein.

**[0006]** However, during advancement of a catheter through the vasculature, the dilator component and/or the catheter can experience considerable force or resistance from the patient's vasculature. Similarly, during insertion of an introducer sheath, the dilator component and/or the introducer sheath can experience considerable force or resistance from the patient's skin and tissue. In some instances, the force against the dilator component can cause the dilator component to retract or backslide within the catheter/introducer sheath. If the dilator retracts far enough, the edge of the catheter/introducer sheath can be exposed and may cause damage to a percutaneous access site or the vasculature of the patient.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0007]** Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

**[0008]** Figure 1 is a partially schematic side view of a vascular access system including a cap assembly and configured in accordance with the present technology.

**[0009]** Figure 2A–2C are a partially-exploded isometric view, a side cross-sectional view, and an enlarged view, respectively, of the cap assembly of Figure 1 in accordance with embodiments of the present technology.

**[0010]** Figures 3A–3C are a perspective view, a cross-sectional view, and a bottom view, respectively, of a first cap of the cap assembly of Figure 1 in accordance with embodiments of the present technology.

**[0011]** Figures 4A–4C are a perspective view, a cross-sectional view, and a bottom view, respectively, of a second cap of the cap assembly of Figure 1 in accordance with embodiments of the present technology.

**[0012]** Figures 5A and 5B are respective bottom views of the cap assembly of Figure 1 in accordance with embodiments of the present technology.

**[0013]** Figures 6A–6C are top views of respective second caps in accordance with additional embodiments of the present technology.

**[0014]** Figure 7 is a top view of a second cap in accordance with additional embodiments of the present technology.

**[0015]** Figure 8 is a perspective view of a cap-locking valve in accordance with embodiments of the present technology.

## DETAILED DESCRIPTION

**[0016]** The present technology is generally directed to vascular access systems with dilator locking mechanisms, and associated devices and methods. In some of the embodiments described in detail below, a dilator locking mechanism includes a first cap coupled to a dilator and a second cap coupled to a catheter (e.g., an aspiration catheter, an introducer/access sheath) of, for example, a clot treatment system. The first cap can include one or more locking members, and the second cap can include one or more locking features corresponding to one or more of the locking members. Each of the locking members (first cap) can be aligned with and inserted at least partially into the corresponding locking feature (second cap) to, for example, couple the first cap to the second cap. Because the first cap is coupled to the dilator, the interaction between the first and second caps when coupled can secure the dilator relative to the catheter to inhibit or even prevent the dilator from moving proximally and/or distally relative to the catheter.

**[0017]** In some embodiments, the locking features are configured to deflect the locking members into a locked position when the locking members are inserted therein. In these and other embodiments, the first cap can be rotated relative to the second cap (and/or the second cap rotated relative to the first cap) to move the locking members from the locked position to an unlocked position to uncouple the dilator locking mechanism and allow the dilator to move relative to the catheter of the vascular access system.

**[0018]** Current dilator locking mechanisms may involve a direct connection between the associated dilator and vascular access system. For example, such locking mechanisms may require that the dilator be fully advanced through the clot treatment system and then rotated to secure the dilator. With this style of mechanism, it may be difficult for an operator to distinguish (e.g., visually) between situations where the dilator is (i) fully inserted into and secured to the clot treatment system and (ii) fully inserted into but not secured to the clot

treatment system. In contrast to these current mechanisms, the dilator locking mechanisms of the present technology can be located at or near a proximal end of the clot treatment system, such that a user of the clot treatment system (e.g., a physician) can easily observe the first and second caps to determine whether the dilator is secured to the clot treatment system by observing the relative positions and/or alignment of the first and second caps.

**[0019]** Certain details are set forth in the following description and in Figures 1–8 to provide a thorough understanding of various embodiments of the present technology. In other instances, well-known structures, materials, operations, and/or systems often associated with intravascular procedures, clot removal procedures, catheters, and the like are not shown or described in detail in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. Those of ordinary skill in the art will recognize, however, that the present technology can be practiced without one or more of the details set forth herein, and/or with other structures, methods, components, and so forth.

**[0020]** The terminology used below is to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain examples of embodiments of the technology. Indeed, certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

**[0021]** The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope unless expressly indicated. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles and features without departing from the present technology. In addition, those of ordinary skill in the art will appreciate that further embodiments of the present technology can be practiced without several of the details described below.

**[0022]** With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter

subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

**[0023]** Figure 1 is a partially schematic side view of a vascular access system 100 ("the system 100") configured in accordance with embodiments of the present technology. The system 100 can also be referred to as an aspiration assembly, a clot treatment system, a clot removal system, a thrombectomy system, an introducer sheath assembly, and/or the like. In the illustrated embodiment, the system 100 includes a tubing assembly 110 fluidly coupled to a catheter 120 via a valve 102. In some embodiments, the catheter 120 is an elongate member configured to be inserted into and through a patient's vasculature and used to, for example, treat clot material therein. In other embodiments, the catheter 120 can be an introducer sheath configured to be inserted through the skin and tissue tract of the patient to provide an access site through which other components (e.g., other catheters used to treat clot material) can traverse to easily access the vasculature. Accordingly, while referred to as "catheter 120," the catheter 120 can comprise an introducer sheath, an access sheath, and/or another type of elongate member configured to be inserted through the skin and tissue tract and/or to traverse the vasculature of a patient. In general, the system 100 (i) can include features generally similar or identical to those of the clot treatment systems described in detail in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety, and/or (ii) can be used to treat/remove clot material from a patient (e.g., a human patient) using any of the methods described in detail therein.

**[0024]** In the illustrated embodiment, the catheter 120 includes a proximal region or portion 122 and a distal tip region or portion 124 opposite the proximal region 122. The catheter 120 further defines a lumen 121 (shown in dashed-line in Figure 1) extending entirely therethrough from the proximal region 122 to the distal tip region 124. The lumen 121 and/or the catheter 120 can at least partially define a longitudinal axis X of the system 100. The proximal region 122 can include a proximal terminus 126 of the catheter 120, and the distal tip region 124 can include a distal terminus 128 of the catheter 120.

**[0025]** The valve 102 is fluidly coupled to the lumen 121 of the catheter 120 and can be integral with or coupled to the proximal region 122 of the catheter 120 such that these components move together. In some embodiments, the valve 102 is a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in a proximal direction P through the valve 102 as various components such as dilators, delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and so on are inserted through the valve 102 to be delivered through the catheter 120 to a treatment site in a blood vessel. In the illustrated embodiment, for example, a dilator 130 is inserted through the valve 102 and positioned within the catheter 120. The valve 102 includes a branch or side port 106 configured to fluidly couple the lumen 121 of the catheter 120 to the tubing assembly 110. In some embodiments, the valve 102 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety.

**[0026]** In the illustrated embodiment, the tubing assembly 110 fluidly couples the catheter 120 to a pressure source 108, such as a syringe. The pressure source 108 can be configured to generate (e.g., form, create, charge, build-up) a vacuum (e.g., negative relative pressure) and store the vacuum for subsequent application to the catheter 120 (e.g., after the dilator 130 has been removed from the catheter 120). The tubing assembly 110 can include one or more tubing sections 112 (individually labeled as a first tubing section 112a and a second tubing section 112b), at least one fluid control device 114 (e.g., a valve), and at least one connector 116 (e.g., a Toomey tip connector) for fluidly coupling the tubing assembly 110 to the pressure source 108 and/or other suitable components. In some embodiments, the fluid control device 114 is a stopcock that is fluidly coupled to (i) the side port 106 of the valve 102 via the first tubing section 112a and (ii) the connector 116 via the second tubing section 112b. The fluid control device 114 is externally operable by a user to regulate the flow of fluid therethrough and, specifically, from the lumen 121 of the catheter 120 to the pressure source 108. In some embodiments, the connector 116 is a quick-release connector (e.g., a quick disconnect fitting) that enables rapid coupling/decoupling of the catheter 120 and the fluid control device 114 to/from the pressure source 108.

**[0027]** In the illustrated embodiment, the dilator 130 is inserted through the valve 102 in a distal direction D and extends fully through the lumen 121 and past the distal terminus 128 of the catheter 120, such that a distal tip 132 (e.g., an atraumatic tip) of the dilator 130 is positioned beyond the distal terminus 128 of the catheter 120. The dilator 130 and the system

100 can together define a catheter or introducer assembly 101 that can be inserted into a patient (e.g., a human patient) during a clot treatment procedure. For example, the dilator 130 and the system 100 can be inserted into and advanced together through a blood vessel of the patient to a target location in the blood vessel. The dilator 130 can then be retracted proximally (e.g., in the proximal direction P) through the system 100 to allow for other intravascular medical devices to be introduced into the patient via the system 100 and/or for aspiration of the catheter 120. For example, in some embodiments the system 100 and/or the catheter assembly 101 can be used in any of the clot removal procedures disclosed in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety.

**[0028]** The catheter assembly 101 can include a locking mechanism or cap assembly 140 (which can also be referred to as a locking cap assembly, a dilator locking mechanism, a dilator coupling mechanism, and/or the like) configured to releasably couple and secure the dilator 130 to the system 100. The cap assembly 140 can lock the dilator 130 to the valve 102 and the catheter 120 to inhibit or even prevent the dilator 130 from moving within the catheter 120 in the proximal direction P and/or the distal direction D when the catheter assembly 101 is advanced through the vasculature of a patient. More specifically, for example, the cap assembly 140 can inhibit or even prevent the distal tip 132 of the dilator 130 from moving proximally toward the distal terminus 128 of the catheter 120 when the catheter assembly 101 is advanced through the vasculature of the patient.

**[0029]** In the illustrated embodiment, the cap assembly 140 includes (i) a first or proximal cap 150 coupled to or integrally formed with the dilator 130 (via, e.g., a coupling element or luer connector 134) opposite the distal tip 132 and (ii) a second or distal cap 160 coupled to a proximal portion 104 of the valve 102. The first cap 150 can be releasably coupled/locked to the second cap 160. Accordingly, inserting the dilator 130 into the catheter 120 can include moving the first cap 150 toward the second cap 160. In some embodiments, the first cap 150 can mate with the second cap 160 to lock the dilator 130 to the valve 102 when the dilator 130 is fully seated within the system 100. In some aspects of the present technology, a user can easily determine the state of the dilator 130 (e.g., how far the dilator 130 is inserted into the catheter 120 and/or whether the dilator 130 is secured to the system 100) by viewing the cap assembly 140. Additional details regarding the cap assemblies of the present technology, including the cap assembly 140, are discussed in detail below with reference to Figures 2A–8.

**[0030]** During a clot treatment procedure, the catheter assembly 101 can be inserted through the vasculature of a patient (e.g., through an introducer sheath that traverses the skin and tissue of the patient to provide an access site) with the cap assembly 140 locking the dilator 130 to the valve 102 and the catheter 120. When the catheter 120 is positioned at a desired position relative to clot material (e.g., a pulmonary embolism, deep vein thrombosis) within the patient, the cap assembly 140 can be unlocked and the dilator 130 withdrawn from the catheter 120. Then, a user can first close the fluid control device 114 before generating a vacuum in the pressure source 108 by, for example, withdrawing the plunger of a syringe coupled to the connector 116. In this manner, a vacuum is charged within the pressure source 108 (e.g., a negative pressure is maintained) before the pressure source 108 is fluidly connected to the lumen 121 of the catheter 120. To aspirate the lumen 121 of the catheter 120, the user can open the fluid control device 114 to fluidly connect the pressure source 108 to the catheter 120 and thereby apply or release the vacuum stored in the pressure source 108 to the lumen 121 of the catheter 120. Opening of the fluid control device 114 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing assembly 110 and the catheter 120, thereby generating a suction pulse throughout the catheter 120 that can aspirate the clot material into the catheter 120. In particular, the suction is applied at the distal tip region 124 of the catheter 120 to suck/aspirate at least a portion of the clot material proximate the distal tip region 124 into the lumen 121 of the catheter 120. In other embodiments, where the catheter 120 is an introducer sheath, the introducer assembly 101 can be inserted through the skin and tissue of a patient and partially into a vessel to provide an access point for other medical instruments.

**[0031]** Figure 2A is a partially-exploded isometric view of cap assembly 140 of Figure 1 in accordance with embodiments of the present technology. In the illustrated embodiment, the cap assembly 140 is in an unlocked position in which the first cap 150 is not secured to the second cap 160 such that the dilator 130 is free to move relative to the valve 102 and the catheter 120 (Figure 1). The first cap 150 can include one or more coupling or locking members 252 extending (e.g., downwardly, distally, and/or toward the second cap 160) in a direction parallel or generally parallel to the longitudinal axis X. In the illustrated embodiment, the first cap 150 includes two of the locking members 252 (one of the locking members 252 is obscured in Figure 2A) positioned on opposite sides of the first cap 150 (e.g., 180-degrees apart). The second cap 160 can include one or more coupling or locking features 262 that extend through the second cap 160 at least partially about the longitudinal axis X. In the illustrated embodiment, the locking members 252 are projections and the locking features 262

are corresponding grooves or openings. In other embodiments, the first cap 150 can include more or fewer of the locking members 252 and/or the second cap 160 can include more or fewer of the locking features 262. For example, the first cap 150 can include one or more than two of the locking members 252, and the second cap 160 can include the same number of the locking features 262. In the illustrated embodiment, the first cap 150 and the second cap 160 have circular shapes. In other embodiments, the first cap 150 and/or the second cap 160 can have a triangular, square, rectangular, rectilinear, curvilinear, or any other suitable shape. In at least some embodiments, the first cap 150 and the second cap 160 can have a same shape. In other embodiments, the first cap and the second cap can have different shapes.

**[0032]** Each of the locking members 252 can be relatively flexible and configured to undergo elastic or generally elastic deformations. Additionally, each of the locking features 262 can be configured (e.g., shaped and sized) to bend or deflect the corresponding locking members 252 inwardly (toward the longitudinal axis X) to facilitate locking/coupling of the first cap 150 to the second cap 160. In the illustrated embodiment, individual ones of the locking features 262 are configured (e.g., shaped, sized, positioned) to releasably receive a corresponding one of the locking members 252. In general, to secure (e.g., couple, lock) the first cap 150 to the second cap 160, the locking members 252 can be at least partially aligned with and inserted into the corresponding locking features 262. Once inserted, the outward bias of the locking members 252 can cause the locking members 252 to engage the corresponding locking features 262 (and/or another portion of the valve 102) to secure the first cap 150 to the second cap 160. In some embodiments, aligning the locking members 252 with the corresponding locking features 262 can include rotating the first cap 150 (e.g., about the longitudinal axis X) relative to the second cap 160.

**[0033]** In operation, inserting the dilator 130 into the valve 102 and the catheter 120 includes moving the first cap 150 toward the second cap 160. While moving the dilator 130 through the valve 102, the user can rotate the first cap 150 such that individual ones of the locking members 252 are at least partially aligned with the corresponding ones of the locking features 262. With the locking members 252 and the corresponding locking features 262 in this orientation, the user can bring the first cap 150 into contact with the second cap 160 to insert the locking members 252 into the corresponding locking features 262 and secure the first cap 150 to the second cap 160.

**[0034]** More specifically, Figure 2B is a side cross-sectional view of the cap assembly 140 of Figure 2A in accordance with embodiments of the present technology. Figure 2C is an enlarged view of a region 2C of Figure 2B in accordance with embodiments of the present technology. The cap assembly 140 is in a locked position in Figures 2B and 2C in which the first cap 150 is secured to the second cap 160 such that the dilator 130 is locked in position relative to the valve 102 and the catheter 120 (Figure 1). Referring to Figures 2B and 2C together, each of the locking features 262 of the second cap 160 can include a channel or slot 264 defined at least partially by a first or inner wall 263 and a second or outer wall 265 spaced radially apart from the inner wall 263. In the locked position shown in Figures 2B and 2C, the locking members 252 are inserted into the corresponding locking features 262 such that at least a portion of the locking members 252 are positioned in the slots 264 of the corresponding locking features 262 between the inner wall 263 and the outer wall 265.

**[0035]** Referring to Figure 2B, in some embodiments the second cap 160 includes an opening 261 sized, positioned, and/or otherwise configured to allow the dilator 130 to pass through the second cap 160. The first cap 150 is secured to the dilator 130 and can include an opening 251 configured to receive the dilator 130 and a connected or integral luer connector 134. In the illustrated embodiment, for example, the opening 251 is at least partially defined by one or more luer coupling members 253. Each of the luer coupling members 253 can be positioned radially inward relative to one or more of the locking members 252. Additionally, each of the luer coupling members 253 can be generally flexible and configured to undergo elastic or generally elastic deformations. The luer connector 134 can include a first or distal flange 236 and a second or proximal flange 238 opposite and spaced apart from the distal flange 236. The dilator 130 and the luer connector 134 can be inserted through the opening 251 such that the distal flange 236 contacts individual ones of the luer coupling members 253 to cause the luer coupling members 253 to bend or deflect radially outward away from the luer connector 134. Once the distal flange 236 has moved distally past the luer coupling members 253, the luer coupling members 253 can return to their original (e.g., unbent) configuration, as shown in Figure 2B. With the luer connector 134 and the luer coupling members 253 in the respective positions shown in Figure 2B, at least a portion of the first cap 150 (e.g., the luer coupling members 253) can be positioned between the distal flange 236 and the proximal flange 238 to secure the dilator 130 to the first cap 150. In other embodiments, the dilator 130 can be secured to the first cap 150 in other manners.

**[0036]** Referring to Figure 2C, each of the locking features 262 in the second cap 160 can further include a first surface 266 (which can also be referred to as a proximal, deflecting, angled, and/or insertion surface) and a second surface 268 (which can also be referred to as a distal, retaining, and/or locking surface). The second surface 268 can extend from the outer wall 265 toward the inner wall 263 in an inward direction perpendicular or generally perpendicular to the inner and/or outer walls 263, 265. The first surface 266 can extend upwardly at an incline from the second surface 268 and away from the inner wall 263, to, for example, form an acute interior angle with the second surface 268. In other embodiments, the first and second surfaces 266, 268 can be positioned on the inner wall 263 opposite the outer wall 265, or have any other suitable configuration.

**[0037]** Each of the locking members 252 can include a tab 254. Each tab 254 can be positioned at or near a distal end of the associated locking members 252. In the illustrated embodiment, the tab 254 extends outward and/or perpendicularly from the associated locking member 252 (e.g., toward the outer wall 265). In other embodiments, one or more of the tabs 254 can extend inward from the associated locking member 252 (e.g., toward the inner wall 263), or in any other suitable direction. The tab 254 can define a stopping or retaining surface 256. When the first cap 150 is coupled to the second cap 160, as shown in Figure 2C, the retaining surface 256 is at least partially aligned with and/or parallel to the second surface 268. The alignment of the retaining surface 256 with the second surface 268 can prevent, or at least partially prevent, the first cap 150 from moving (e.g., upwardly and/or proximally) relative to the second cap 160 which, in turn, can couple or "lock" the first cap 150 and the second cap 160 to one another. In Figure 2C, the retaining surface 256 and the second surface 268 are shown as being spaced apart for the sake of illustration; those of ordinary skill in the art will understand that, in other embodiments, at least part of the retaining surface 256 can contact at least part of the second surface 268 to prevent, or at least partially prevent, the first cap 150 from moving relative to the second cap 160.

**[0038]** Referring to Figures 2A–2C together, to couple the dilator 130 to the valve 102, a user can position the locking members 252 of the first cap 150 such that the tabs 254 are at least partially aligned with the slots 264 of the second cap 160 and/or contacting the first surfaces 266 of the corresponding locking features 262. The user can then move the first cap 150 toward the second cap 160 to cause the tabs 254 to translate along the corresponding first surfaces 266 inwardly in a first direction D1 (Figure 2C; e.g., toward the longitudinal axis X in Figure 2A). The movement of the tabs 254 in the first direction D1 can cause a corresponding

bend or deflection in the locking members 252. Continued movement of the first cap 150 toward the second cap 160 can move the tabs 254 past the corresponding first surfaces 266; once past the first surfaces 266, the locking members 252 can move in a second direction D2 (Figure 2C; e.g., away from the longitudinal axis X in Figure 2A) opposite the first direction D1. The movement of the locking members 252 in the second direction D2 can be due at least partially to the elastic or generally elastic deformation properties of the locking members 252. As the locking members 252 move in the second direction D2, each of the retaining surfaces 256 can be at least partially aligned with the second surface 268 of the corresponding locking features 262 to secure the first cap 150 and the second cap 160. That is, the tabs 254 can be advanced past and snap inward behind the corresponding second surfaces 268, which retain the tabs 254 and the first cap 150 in the locked position, e.g., as described previously herein.

**[0039]** Figures 3A–3C are a perspective view, a cross-sectional view, and a bottom view, respectively, of the first cap 150 in accordance with embodiments of the present technology. Referring to Figures 3A–3C together, the first cap 150 can have a longitudinal axis Y and, when the first cap 150 is coupled to the valve 102 and the catheter 120 (Figure 1), the longitudinal axis Y can be the same as (e.g., colinear with) the longitudinal axis X (Figures 1 and 2A). In the illustrated embodiment, the first cap 150 is bilaterally and/or radially symmetric relative to the longitudinal axis Y. In other embodiments, the first cap 150 can be configured to have any other symmetry and/or be asymmetrical. Referring to Figure 3B, each of the locking members 252 can be deflectable at least in the first direction D1 (e.g., outwardly and/or away from the longitudinal axis Y). Each of the luer coupling members 253 can be oppositely deflectable compared to the locking members 252 (e.g., at least in the second direction D2). Each of the locking members 252 and/or the luer coupling members 253 can extend away from an upper surface 357 of the first cap 150 (e.g., downwardly and/or in a direction parallel or generally parallel to the longitudinal axis Y). Referring to Figure 3C, each of the locking members 252 and/or the luer coupling members 253 can be curved or arcuate and extend at least partially around the longitudinal axis Y. In at least some embodiments, the curvature of one or more of the locking members 252 and/or the luer coupling members 253 is concentric with the opening 251.

**[0040]** Figures 4A–4C are a perspective view, a cross-sectional view, and a bottom view, respectively, of the second cap 160 of the cap assembly 140 of Figure 1 in accordance with embodiments of the present technology. Referring to Figures 4A–4C together, the second cap 160 can have a longitudinal axis Z and when the second cap 160 is coupled to the valve 102

and the catheter 120 (Figure 1), the longitudinal axis Z can be the same as (e.g., colinear with) the longitudinal axis X (Figures 1 and 2A). Additionally, when the first cap 150 (Figures 1–3C) is coupled to the second cap 160, the longitudinal axis Z can be the same as (e.g., colinear with) the longitudinal axis Y (Figures 3A–3C). Each of the locking features 262 and/or one or more of the elements thereof (e.g., the slot 264, the first surface 266, etc.) can be curved or arcuate and extend at least partially around the longitudinal axis Z.

**[0041]** Referring to Figures 4A and 4B together, each of the locking features 262 can include an axial removal surface 470. Each of the axial removal surfaces 470 can be adjacent to the slot 264, opposite an end wall 469 of the slot 264 and at least partially between the first surface 266 and the inner wall 263. Additionally, each of the axial removal surfaces 470 can be inclined upwardly (e.g., along the longitudinal axis Z and/or toward an upper surface 467 of the second cap 160). Accordingly, when the locking members 252 are positioned in the slots 264, the axial removal surfaces 470 can drive the locking members 252 axially and/or upwardly there along, as described in detail below with reference to Figures 5A and 5B.

**[0042]** Referring to Figure 4C, each of the locking features 262 can further include a radial removal surface 472. Each of the radial removal surfaces 472 can be positioned at least partially within the associated slot 264 and extend (e.g., downwardly, distally) from the associated second surface 268 (from the perspective shown in Figure 4C, the radial removal surfaces 472 extend away from the page toward the viewer). Additionally, each of the radial removal surfaces 472 can be angled relative to the outer wall 265 and/or the inner wall 263. In the illustrated embodiment, for example, each of the radial removal surfaces 472 extend inward away from the outer wall 265 and toward the inner wall 263 and/or the longitudinal axis Z. Accordingly, when the locking members 252 are positioned in the slots 264 and brought into contact with the radial removal surfaces 472, the radial removal surfaces 472 can drive the locking members 252 inwardly there along, as described in detail below with reference to Figures 5A and 5B.

**[0043]** The slots 264 can have a slot dimension S defined at least partially by the slot end wall 469 and the axial removal surface 470. The slot dimension S can be an angle, an arc length, or any other suitable dimension. Because the locking members 252 can be inserted along the length of the slot 264, an increased slot dimension S can reduce the difficulty of aligning the first cap 150 with the second cap 160. Additionally, or alternatively, the slot dimension S can at least partially define an amount that the first cap 150 can rotate while at least partially

coupled to the second cap 160. For example, a relatively high slot dimension (e.g., a greater arc length) can correspond to a relatively increased degree of rotation of the first cap 150, and a relatively low slot dimension can correspond to a relatively decreased degree of rotation of the first cap 150.

**[0044]** Figures 5A and 5B are respective bottom views of the cap assembly of Figure 1 in accordance with embodiments of the present technology. In Figure 5A, the cap assembly 140 is in the locked position with the locking members 252 of the first cap 150 positioned in the corresponding locking features 262 of the second cap 160 such that the first cap 150 is coupled to the second cap 160. In Figure 5B, the cap assembly 140 is in the unlocked position in which the first cap 150 has been rotated in a direction R relative to the second cap 160 and/or about the longitudinal axes Y and/or Z to uncouple the first cap 150 from the second cap 160. In the illustrated embodiment, the direction R is a clockwise direction when viewed from the bottom of the cap assembly 140 (e.g., a counter-clockwise direction when viewed from the top of the cap assembly 140). In other embodiments, the first cap 150 and/or the second cap 160 can be configured such that the direction R is a counter-clockwise direction when viewed from the bottom of the cap assembly 140 (e.g., a clockwise direction when viewed from the top of the cap assembly 140).

**[0045]** Referring to Figures 5A and 5B together, rotating the first cap 150 in the direction R (Figure 5B) can move the tabs 254 toward the corresponding radial removal surfaces 472 until one or more of the tabs 254 at least partially contact the corresponding radial removal surface 472. In response to the rotation in the direction R, the radial removal surfaces 472 can deflect each of the tabs 254 inward in the direction D1, as shown in Figure 5B. This deflection of the tabs 254 causes a corresponding inward deflection in the associated locking members 252. In some aspects of the present technology, the radial removal surfaces 472 at least partially prevent the first cap 150 from being accidentally or unintentionally disconnected from the second cap 160 until a force (e.g., torque) sufficient to deflect the locking members 252 inward is applied to the first cap 150.

**[0046]** With the tabs 254 in the position shown in Figure 5B, continued rotation of the first cap 150 in the direction R causes the tabs 254 to contact the corresponding axial removal surfaces 470 (Figures 4A and 4B). Each of the locking members 252 can translate upwardly across the corresponding axial removal surface 470 and cause the first cap 150 to move away from the second cap 160 in a direction generally along the longitudinal axis Z (e.g., to the unlocked

position shown in Figure 2A). Continued rotation of the first cap 150 can fully uncouple the first cap 150 and the second cap 160. However, it will be appreciated that, with the tabs 254 deflected inwardly in the position shown in Figure 5B, the first cap 150 can be moved away from the second cap 160 without further rotation to decouple the first cap 150 from the second cap 160.

**[0047]** Accordingly, in some aspects of the present technology the locking features 262 include (i) the insertion surface 266 for deflecting one or more of the tabs 254 inward during insertion and/or in response to axial movement, (ii) the radial removal surface 472 for deflecting the tabs 254 inward (e.g., radially inward) during removal and/or in response to rotary movement, and (iii) the axial removal surface 470 for moving the tabs 254 upward (e.g., axially upward) during removal and/or in response to rotary movement. The insertion surface 266 can be positioned to align with the corresponding tab 254 when the cap assembly 140 is in the unlocked position. During insertion, the tab 254 can move toward, contact, and translate inwardly along the insertion surface 266. The radial removal surface 472 can be positioned proximate the tab 254 when the cap assembly 140 is in the locked position. During removal, the tab 254 can move (e.g., rotate) toward, contact, and translate inwardly along the radial removal surface 472. The cap assembly 140 can transition from the locked position toward the unlocked position as the tab 254 translates along the radial removal surface 472. Additionally, the tab 254 can move toward the axial removal surface 470 as it translates along the radial removal surface 472. The axial removal surface 470 can be angled upwardly, away from the radial removal surface 472. Accordingly, during removal, the tab 254 can move (e.g., rotate) toward, contact, and translate upward along the axial removal surface 470. Translating the tab 254 along the axial removal surface 470 can return the cap assembly 140 to the unlocked position.

**[0048]** Figures 6A–6C are top views of respective second caps in accordance with additional embodiments of the present technology. Each of the second caps 660a-c can be generally similar to the second cap 160 of Figures 1–2C and 4A-5B. However, referring to Figure 6A, the second cap 660a includes a reduced slot dimension S1, such that the second cap 660a does not allow the first cap (not shown) to rotate while remaining coupled to the second cap 660a and/or any rotation of the first cap begins the decoupling process described above. Referring to Figure 6B, the second cap 660b includes an increased slot dimension S2 that allows the first cap (not shown) to rotate up to 60 degrees relative to the second cap 660b while still remaining coupled to the second cap 660b and/or before the rotation of the first cap begins the decoupling

process described above. Referring to Figure 6C, the second cap 660c does not include one or more of inner walls 263 (Figures 2B, 2C, and 4A–4C), such that the opening 661 and one or more of the slots 664 are connected or are otherwise not separated by inner walls.

**[0049]** Figure 7 is a top view of a second cap 760 configured in accordance with additional embodiments of the present technology. At least some aspects of the second cap 760 can be at least generally similar or identical in structure and/or function to one or more of the second caps 160, 660a-c described in detail previously herein. In the illustrated embodiment, the second cap 760 further includes one or more rotationally agnostic locking features 762 ("locking features 762"). In the illustrated embodiment, each of the locking features 762 includes an outer wall 765 and two radial removal surfaces 772 positioned e.g., on left and right sides of the outer wall 765. The second cap 760 can further include axial removal surfaces 770 positioned on the left and right sides of the locking features 762 and/or aligned with the radial removal surfaces 772 thereof. Accordingly, when a locking member of a first cap (e.g., the locking members 252 of the first cap 150 of Figure 2A) is received within one of the locking features 762, the first cap can be rotated in the direction R or opposite the direction R (e.g., counterclockwise or clockwise) to drive the locking member against one of the radial removal surfaces 772 and uncouple the first cap and the second cap 760. Continued rotation of the first cap can translate the locking members of the first cap along the axial removal surfaces 770. This rotationally agnostic configuration of the locking features 762 is expected to allow the first cap to be quickly and easily uncoupled from the second cap 760. The locking features 762 can be aligned with and/or positioned distally of a respective first surface 766, and the locking members of a first cap (e.g., the locking members 252 of the first cap 150 of Figure 2A) can contact and be driven radially inward by the first surfaces 766 to couple with the locking features 762.

**[0050]** In some embodiments, the second cap 760 can include one or more support surfaces 774positioned radially inward of one of the first surfaces 766, e.g., between the axial removal surfaces 770 associated with one of the locking features 762. Each of the support surfaces 774 can be configured to contact at least part of a coupling member of a first cap, e.g., after the first cap is coupled/locked to the second cap 760. In some embodiments, one or more of the support surfaces 774 can be curved or concave. Accordingly, when the first cap is coupled to the second cap 760 and/or the coupling members of the first cap contact the support surfaces 774, the curvature/concavity of the support surfaces 774 can at least partially prevent rotation of the

first cap relative to the second cap 760, e.g., in addition to or in lieu of the resistance to rotation of the first cap provided by the radial removal surfaces 772.

**[0051]** Figure 8 is a perspective view of a cap-locking valve 880 configured in accordance with embodiments of the present technology. The cap-locking valve 880 can include a valve 802 and an integrated locking feature 860. The valve 802 can include at least some aspects that are at least generally similar or identical in structure and/or function to the valve 102 of Figure 1. In at least some embodiments, for example, the valve 802 can be a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in a proximal direction through the valve 802 as various components such as dilators, delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and so on are inserted through the valve 802.

**[0052]** The integrated locking feature 860 can be formed in the valve at or near a proximal end of the valve 802 or at another suitable position on/in the valve 802. The integrated locking feature 860 can include at least some aspects that are at least generally similar or identical in structure and/or function to one or more of the second caps 160, 660a-c, 760 described herein. In the illustrated embodiment, for example, the integrated locking feature 860 includes at least some features that are at least generally similar in structure and/or function to the second cap 760 of Figure 7. In other embodiments, the integrated locking feature 860 can have another suitable configuration. In these and other embodiments, the integrated locking feature 860 can be directly integrated into the valve 802 rather than being included in a separate cap or other component releasably couplable to the valve 802.

**[0053]** Several aspects of the present technology are set forth in the following examples:

1. A cap assembly for a catheter, the cap assembly comprising:

a first cap including a locking member, wherein the locking member includes an end portion and a tab positioned proximate the end portion; and

a second cap including a locking feature, wherein the locking feature includes a slot extending at least partially through the second cap, and wherein—

the first cap is configured to be secured to the second cap in a locked position,

in the locked position, the locking feature is configured to receive the locking member through the slot such that the tab engages a portion of the

second cap to inhibit movement of the first cap relative to the second cap, and

the first cap is configured to rotate relative to the second cap to move the tab out of engagement with the second cap to move the first cap from the locked position to an unlocked position.

2. The cap assembly of example 1 wherein the first cap includes an upper surface, and wherein the locking member extends from the upper surface in a direction generally perpendicular to the upper surface, and wherein the end portion of the locking member is opposite the upper surface.

3. The cap assembly of example 1 or example 2 wherein the tab extends perpendicularly from the locking member.

4. The cap assembly of any one of examples 1–3 wherein the tab defines a retaining surface positioned to contact at least a portion of the second cap when the first cap is coupled to the second cap.

5. The cap assembly of any one of examples 1–4 wherein the locking member is flexible, and wherein the second cap is configured to bend the locking member when the first cap moves between the unlocked position and the locked position.

6. The cap assembly of any one of examples 1–5 wherein the locking feature includes a locking surface positioned to at least partially contact the tab of the locking member when the first cap is coupled to the second cap.

7. The cap assembly of any one of examples 1–6 wherein the locking feature includes an angled insertion surface positioned to engage and deflect the locking member when the first cap moves from the unlocked position toward the locked position.

8. The cap assembly of example 7 wherein the cap assembly includes a longitudinal axis, and where the insertion surface is angled to bend the locking member inward toward the longitudinal axis.

9. The cap assembly of any one of examples 1–8 wherein the locking feature includes a radial removal surface, and wherein the radial removal surface is angled to deflect the tab inward when the first cap is rotated relative to the second cap.

10. The cap assembly of any one of examples 1–9 wherein the locking feature includes an axial removal surface positioned proximate the slot and angled to move the first cap away from the second cap when the first cap is rotated relative to the second cap.

11. The cap assembly of any one of examples 1–10 wherein:

the first cap includes an upper surface, and the locking member extends from the upper surface in a direction perpendicular to the upper surface;

the locking member is flexible and configured to deflect when the first cap moves between the unlocked position and the locked position;

the tab defines a retaining surface positioned to contact at least a portion of the second cap in the locked position; and

the locking feature includes—

a locking surface positioned to at least partially contact the retaining surface of the tab in the locked position,

an insertion surface positioned to be at least partially aligned with the locking member and angled to deflect the locking member inward when the first cap moves from the unlocked position toward the locked position,

a radial removal surface positioned proximate the tab of the locking member in the locked position, wherein the radial removal surface is angled to move the tab radially inward when the first cap moves from the locked position toward the unlocked position, and

an axial removal surface positioned proximate the slot and angled to move the first cap longitudinally away from the second cap when the first cap moves from the locked positioned toward the unlocked position.

12. The cap assembly of any one of examples 1–11 wherein the locking member is a first locking member, wherein the locking feature is a first locking feature, wherein the first cap includes one or more second locking members, wherein the second cap includes one or more second locking features, and wherein individual ones of the second locking members are

configured to receive and secure corresponding ones of the second locking members in the locked position.

13. The cap assembly of any one of examples 1-12 wherein the locking feature is configured to be rotationally agnostic such that rotation of the first cap relative to the second cap in a first direction and a second direction opposite the first direction moves the tab out of engagement with the second cap to move the first cap from the locked position to an unlocked position.

14. A vascular access system, comprising:

a valve having a proximal end and a distal end;

a catheter defining a lumen and coupled to the distal end of the valve, the catheter defining a longitudinal axis of the vascular access system;

a dilator configured to extend at least partially through the valve and the lumen; and

a cap assembly movable between a locked configuration and an unlocked configuration, wherein the cap assembly includes (i) a valve cap connected to the proximal end of the valve and including a coupling feature, and (ii) a dilator cap coupled to the dilator and including a coupling tab insertable into the coupling feature, wherein—

in the locked configuration, the coupling feature is configured to receive the coupling tab such that the coupling tab engages a portion of the valve cap to inhibit movement of the dilator relative to the valve along the longitudinal axis, and

the dilator cap is configured to rotate relative to the valve cap to move the coupling tab out of engagement with the valve cap to move the cap assembly from the locked configuration toward the unlocked configuration.

15. The vascular access system of example 14 wherein the coupling tab is flexible, wherein the coupling feature is configured to deflect the coupling tab toward the longitudinal axis when the cap assembly moves from the unlocked configuration toward the locked configuration.

16. The vascular access system of example 14 or example 15 wherein the dilator cap includes a coupling member extending in a direction generally parallel to the dilator and having a distal end, and wherein the coupling tab is positioned proximate the distal end of the coupling member.

17. The vascular access system of any one of examples 14–16 wherein valve cap has a valve cap longitudinal axis, and wherein the coupling feature is curved circumferentially at least partially about the valve cap longitudinal axis.

18. The vascular access system of any one of examples 14–17 wherein the coupling feature includes a coupling surface positioned to at least partially contact the coupling tab of the dilator cap when the cap assembly is in the locked configuration.

19. The vascular access system of example 18 wherein the coupling feature includes an insertion surface positioned to engage and deflect the coupling tab toward the longitudinal axis when the cap assembly moves from the unlocked configuration toward the locked configuration.

20. The vascular access system of example 19 wherein the insertion surface is positioned proximally from the coupling surface.

21. The vascular access system of example 19 or example 20 wherein the insertion surface forms an acute interior angle relative to the coupling surface.

22. The vascular access system of any one of examples 14–21 wherein the coupling feature includes a radial removal surface configured to move the coupling tab radially inward toward the longitudinal axis when the cap assembly moves from the locked configuration toward the unlocked configuration.

23. The vascular access system of any one of examples 14–22 wherein the coupling feature includes (i) a slot configured to receive the coupling tab, and (ii) an axial removal surface positioned proximate the slot and angled to move the dilator cap away from the valve cap along the longitudinal axis when the dilator cap is rotated relative to the valve cap.

24. The vascular access system of any of examples 14-22 wherein the coupling feature includes an outer wall and a pair of radial removal surfaces positioned on left and right sides of the outer wall, and wherein—

in the locked configuration, the coupling tab is positioned between the pair of radial removal surfaces, and

rotation of the dilator cap in a left or right direction relative to the valve cap moves the cap assembly from the locked configuration toward the unlocked configuration.

25. The vascular access system of any one of examples 14-24 wherein the valve cap is integrally formed with proximal end of the valve.

26. The vascular access system of any one of examples 14-24 wherein the valve cap is releasably coupled to the proximal end of the valve.

27. A method of using a vascular access system, the method comprising:

aligning a first cap of the vascular access system with a second cap of the vascular access system, wherein the first cap is coupled to a dilator of the vascular access system, wherein the second cap is coupled to a catheter of the vascular access system, and wherein aligning the first cap with the second cap includes aligning at a locking member of the first cap with a locking feature of the second cap; and

coupling the first cap to the second cap to inhibit the dilator from moving relative to the catheter of the vascular access system, wherein coupling the first cap to the second cap includes inserting the locking member into the locking feature such that the locking feature drives the locking member past a locking surface of the locking feature, and wherein the locking surface is configured to engage the locking member to inhibit longitudinal movement of the first cap relative to the second cap.

28. The method of example 27 wherein coupling the first cap to the second cap further includes positioning the dilator at least partially within the catheter.

29. The method of example 27 or example 28 wherein coupling the first cap to the second cap further includes inserting the dilator fully through the catheter.

30. The method of any one of examples 27–29 wherein aligning the locking member of the first cap with the locking feature of the second cap includes aligning a tab of the locking member with an insertion surface of the locking feature.

31. The method of example 30 wherein moving the first cap toward the second cap includes (i) positioning the tab of the locking member to contact the insertion surface of the locking feature and (ii) translating the tab across the insertion surface to deflect the tab.

32. The method of any one of examples 27–31, further comprising rotating the first cap relative to the second cap to uncouple the first cap from the second cap after coupling the first cap to the second cap.

33. The method of example 32 wherein rotating the first cap includes translating at least a portion of the locking member across a radial removal surface of the locking feature, wherein the radial removal surface is angled to deflect the locking member when the first cap is rotated relative to the second cap.

34. The method of example 32 or example 33 wherein rotating the first cap includes moving the first cap longitudinally away from the second cap.

35. The method of example 34 wherein moving the first cap away from the second cap includes translating the locking member across an axial removal surface of the locking feature, wherein the axial removal surface is angled to move the first cap away from the second cap as the locking member translates across the axial removal surface.

36. The method of any one of examples 32-35 wherein rotating the first cap relative to the second cap to uncouple the first cap from the second cap includes rotating the first cap in a first direction or a second direction opposite the first direction to uncouple the first cap from the second cap.

**[0054]** The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

**[0055]** From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

**[0056]** Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A cap assembly for a catheter, the cap assembly comprising:

a first cap including a locking member, wherein the locking member includes an end portion and a tab positioned proximate the end portion; and

a second cap including a locking feature, wherein the locking feature includes a slot extending at least partially through the second cap, and wherein—

the first cap is configured to be secured to the second cap in a locked position,

in the locked position, the locking feature is configured to receive the locking member through the slot such that the tab engages a portion of the second cap to inhibit movement of the first cap relative to the second cap, and

the first cap is configured to rotate relative to the second cap to move the tab out of engagement with the second cap to move the first cap from the locked position to an unlocked position.

2. The cap assembly of claim 1 wherein the first cap includes an upper surface, and wherein the locking member extends from the upper surface in a direction generally perpendicular to the upper surface, and wherein the end portion of the locking member is opposite the upper surface.

3. The cap assembly of claim 1 wherein the tab extends perpendicularly from the locking member.

4. The cap assembly of claim 1 wherein the tab defines a retaining surface positioned to contact at least a portion of the second cap when the first cap is coupled to the second cap.

5. The cap assembly of claim 1 wherein the locking member is flexible, and wherein the second cap is configured to bend the locking member when the first cap moves between the unlocked position and the locked position.

6. The cap assembly of claim 1 wherein the locking feature includes a locking surface positioned to at least partially contact the tab of the locking member when the first cap is coupled to the second cap.

7. The cap assembly of claim 1 wherein the locking feature includes an angled insertion surface positioned to engage and deflect the locking member when the first cap moves from the unlocked position toward the locked position.

8. The cap assembly of claim 7 wherein the cap assembly includes a longitudinal axis, and where the insertion surface is angled to bend the locking member inward toward the longitudinal axis.

9. The cap assembly of claim 1 wherein the locking feature includes a radial removal surface, and wherein the radial removal surface is angled to deflect the tab inward when the first cap is rotated relative to the second cap.

10. The cap assembly of claim 1 wherein the locking feature includes an axial removal surface positioned proximate the slot and angled to move the first cap away from the second cap when the first cap is rotated relative to the second cap.

11. The cap assembly of claim 1 wherein:

the first cap includes an upper surface, and the locking member extends from the upper surface in a direction perpendicular to the upper surface;

the locking member is flexible and configured to deflect when the first cap moves between the unlocked position and the locked position;

the tab defines a retaining surface positioned to contact at least a portion of the second cap in the locked position; and

the locking feature includes—

a locking surface positioned to at least partially contact the retaining surface of the tab in the locked position,

an insertion surface positioned to be at least partially aligned with the locking member and angled to deflect the locking member inward when the first cap moves from the unlocked position toward the locked position,

a radial removal surface positioned proximate the tab of the locking member in the locked position, wherein the radial removal surface is angled to move the tab radially inward when the first cap moves from the locked position toward the unlocked position, and

an axial removal surface positioned proximate the slot and angled to move the first cap longitudinally away from the second cap when the first cap moves from the locked positioned toward the unlocked position.

12. The cap assembly of claim 1 wherein the locking member is a first locking member, wherein the locking feature is a first locking feature, wherein the first cap includes one or more second locking members, wherein the second cap includes one or more second locking features, and wherein individual ones of the second locking members are configured to receive and secure corresponding ones of the second locking members in the locked position.

13. The cap assembly of claim 1 wherein the locking feature is configured to be rotationally agnostic such that rotation of the first cap relative to the second cap in a first direction and a second direction opposite the first direction moves the tab out of engagement with the second cap to move the first cap from the locked position to an unlocked position.

14. A vascular access system, comprising:

a valve having a proximal end and a distal end;

a catheter defining a lumen and coupled to the distal end of the valve, the catheter defining a longitudinal axis of the vascular access system;

a dilator configured to extend at least partially through the valve and the lumen; and

a cap assembly movable between a locked configuration and an unlocked configuration, wherein the cap assembly includes (i) a valve cap connected to the proximal end of the valve and including a coupling feature, and (ii) a dilator cap coupled to the dilator and including a coupling tab insertable into the coupling feature, wherein—

in the locked configuration, the coupling feature is configured to receive the coupling tab such that the coupling tab engages a portion of the valve cap to inhibit movement of the dilator relative to the valve along the longitudinal axis, and

the dilator cap is configured to rotate relative to the valve cap to move the coupling tab out of engagement with the valve cap to move the cap assembly from the locked configuration toward the unlocked configuration.

15. The vascular access system of claim 14 wherein the coupling tab is flexible, wherein the coupling feature is configured to deflect the coupling tab toward the longitudinal axis when the cap assembly moves from the unlocked configuration toward the locked configuration.

16. The vascular access system of claim 14 wherein the dilator cap includes a coupling member extending in a direction generally parallel to the dilator and having a distal end, and wherein the coupling tab is positioned proximate the distal end of the coupling member.

17. The vascular access system of claim 14 wherein valve cap has a valve cap longitudinal axis, and wherein the coupling feature is curved circumferentially at least partially about the valve cap longitudinal axis.

18. The vascular access system of claim 14 wherein the coupling feature includes a coupling surface positioned to at least partially contact the coupling tab of the dilator cap when the cap assembly is in the locked configuration.

19. The vascular access system of claim 18 wherein the coupling feature includes an insertion surface positioned to engage and deflect the coupling tab toward the longitudinal axis when the cap assembly moves from the unlocked configuration toward the locked configuration.

20. The vascular access system of claim 19 wherein the insertion surface is positioned proximally from the coupling surface.

21. The vascular access system of claim 19 wherein the insertion surface forms an acute interior angle relative to the coupling surface.

22. The vascular access system of claim 14 wherein the coupling feature includes a radial removal surface configured to move the coupling tab radially inward toward the longitudinal axis when the cap assembly moves from the locked configuration toward the unlocked configuration.

23. The vascular access system of claim 14 wherein the coupling feature includes (i) a slot configured to receive the coupling tab, and (ii) an axial removal surface positioned proximate the slot and angled to move the dilator cap away from the valve cap along the longitudinal axis when the dilator cap is rotated relative to the valve cap.

24. The vascular access system of claim 14 wherein the coupling feature includes an outer wall and a pair of radial removal surfaces positioned on left and right sides of the outer wall, and wherein—

in the locked configuration, the coupling tab is positioned between the pair of radial removal surfaces, and

rotation of the dilator cap in a left or right direction relative to the valve cap moves the cap assembly from the locked configuration toward the unlocked configuration.

25. The vascular access system of claim 14 wherein the valve cap is integrally formed with proximal end of the valve.

26. The vascular access system of claim 14 wherein the valve cap is releasably coupled to the proximal end of the valve.

27. A method of using a vascular access system, the method comprising:

aligning a first cap of the vascular access system with a second cap of the vascular access system, wherein the first cap is coupled to a dilator of the vascular access system, wherein the second cap is coupled to a catheter of the vascular access system, and wherein aligning the first cap with the second cap includes aligning at a locking member of the first cap with a locking feature of the second cap; and

coupling the first cap to the second cap to inhibit the dilator from moving relative to the catheter of the vascular access system, wherein coupling the first cap to the

second cap includes inserting the locking member into the locking feature such that the locking feature drives the locking member past a locking surface of the locking feature, and wherein the locking surface is configured to engage the locking member to inhibit longitudinal movement of the first cap relative to the second cap.

28. The method of claim 27 wherein coupling the first cap to the second cap further includes positioning the dilator at least partially within the catheter.

29. The method of claim 27 wherein coupling the first cap to the second cap further includes inserting the dilator fully through the catheter.

30. The method of claim 27 wherein aligning the locking member of the first cap with the locking feature of the second cap includes aligning a tab of the locking member with an insertion surface of the locking feature.

31. The method of claim 30 wherein moving the first cap toward the second cap includes (i) positioning the tab of the locking member to contact the insertion surface of the locking feature and (ii) translating the tab across the insertion surface to deflect the tab.

32. The method of claim 27, further comprising rotating the first cap relative to the second cap to uncouple the first cap from the second cap after coupling the first cap to the second cap.

33. The method of claim 32 wherein rotating the first cap includes translating at least a portion of the locking member across a radial removal surface of the locking feature, wherein the radial removal surface is angled to deflect the locking member when the first cap is rotated relative to the second cap.

34. The method of claim 32 wherein rotating the first cap includes moving the first cap longitudinally away from the second cap.

35. The method of claim 34 wherein moving the first cap away from the second cap includes translating the locking member across an axial removal surface of the locking feature, wherein the axial removal surface is angled to move the first cap away from the second cap as the locking member translates across the axial removal surface.

36. The method of claim 32 wherein rotating the first cap relative to the second cap to uncouple the first cap from the second cap includes rotating the first cap in a first direction or a second direction opposite the first direction to uncouple the first cap from the second cap.

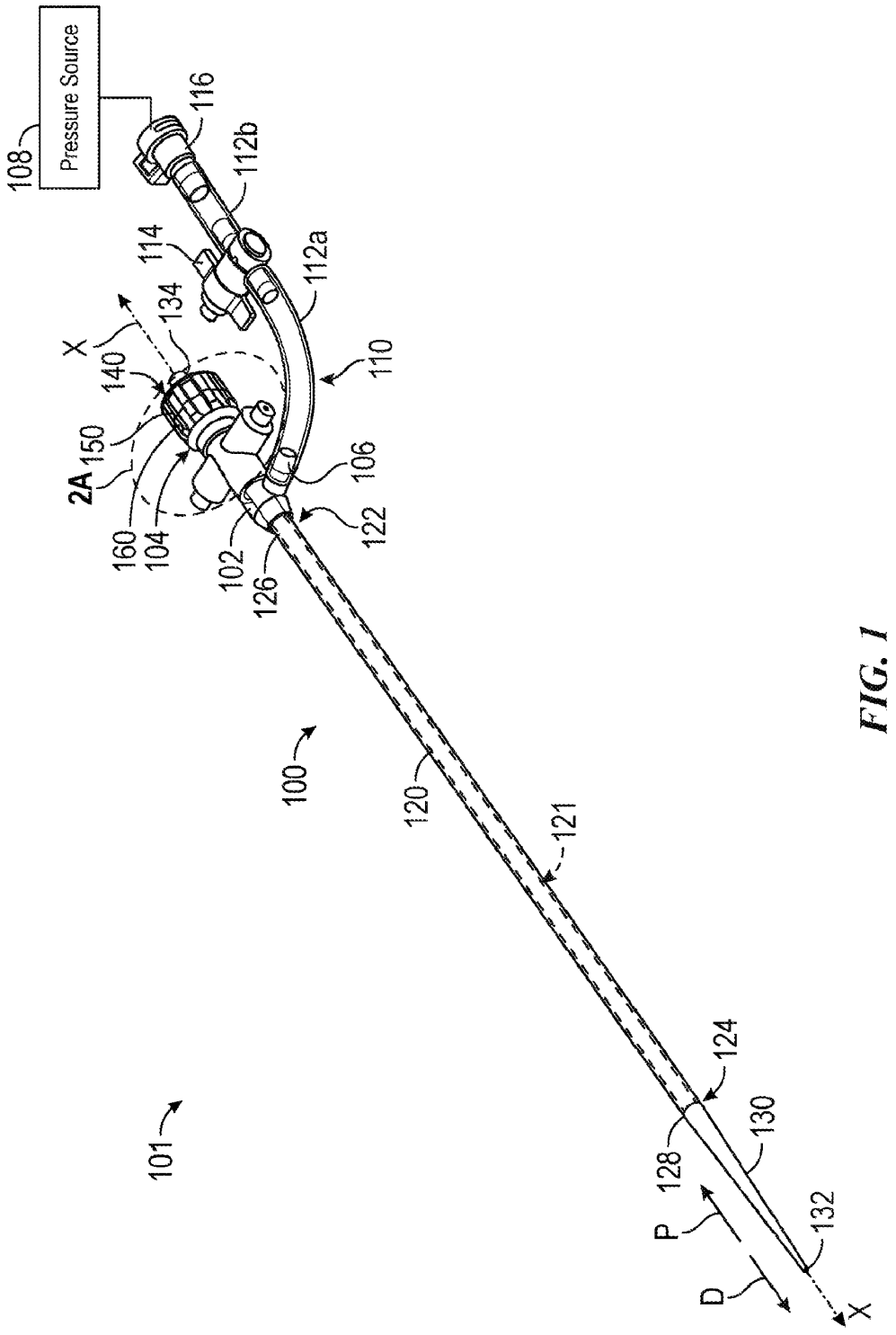

Pressure Source
108
116
112b
114
112a
134
X
140
110
150
2A
106
160
104
122
102
126
100
120
121
101
124
130
128
P
132
D
X

*FIG. 1*

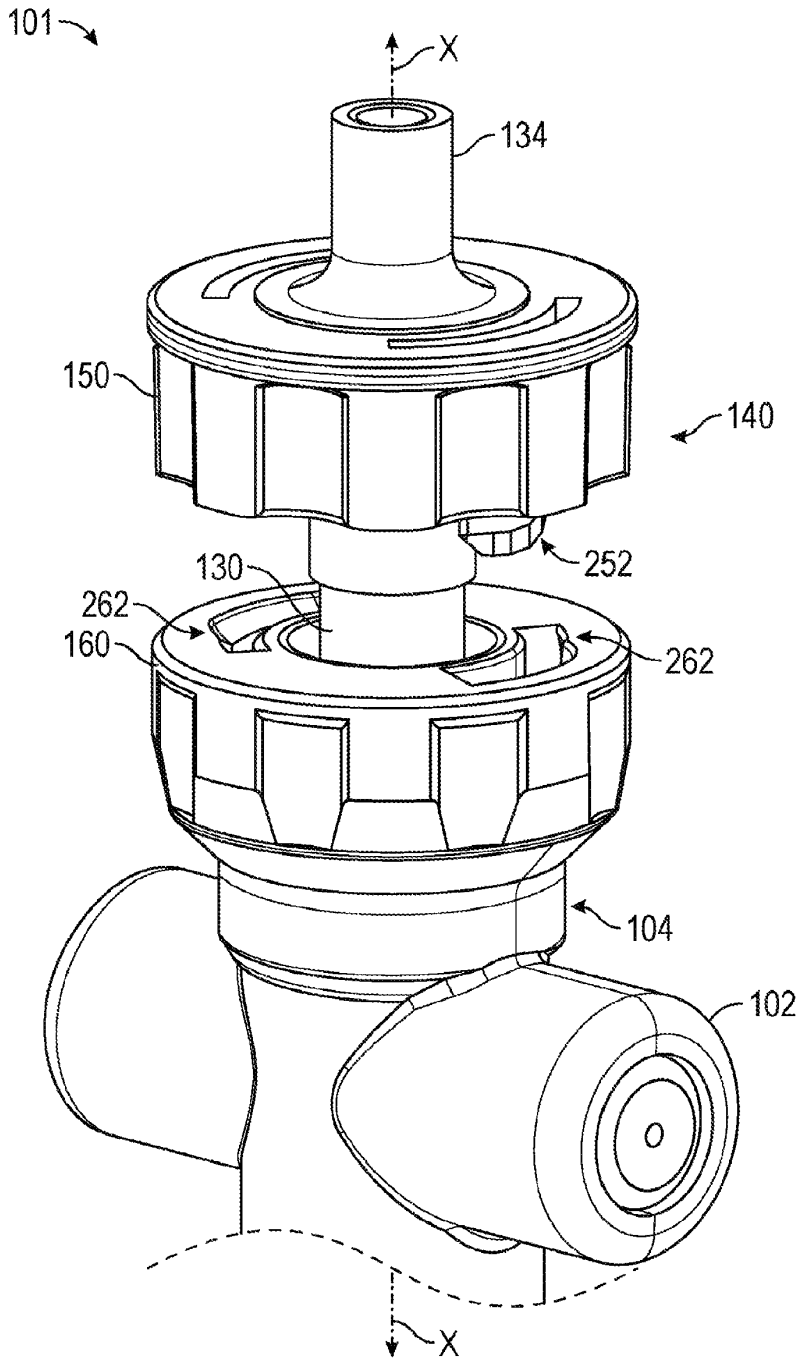



*FIG. 2A*

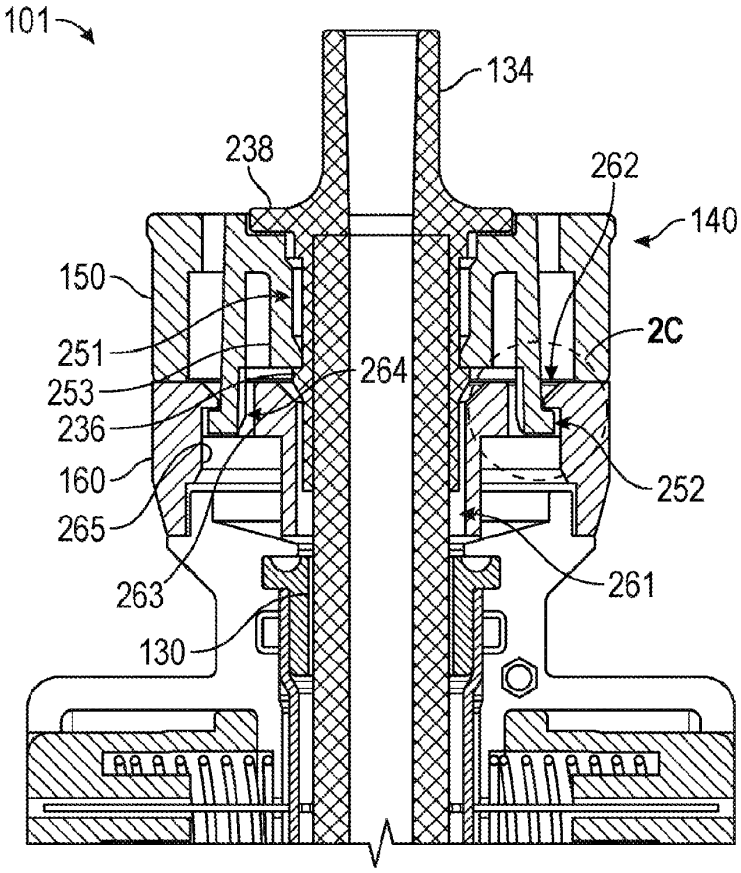

101
134
238
262
140
150
2C
251
264
253
236
160
265
252
263
261
130

*FIG. 2B*

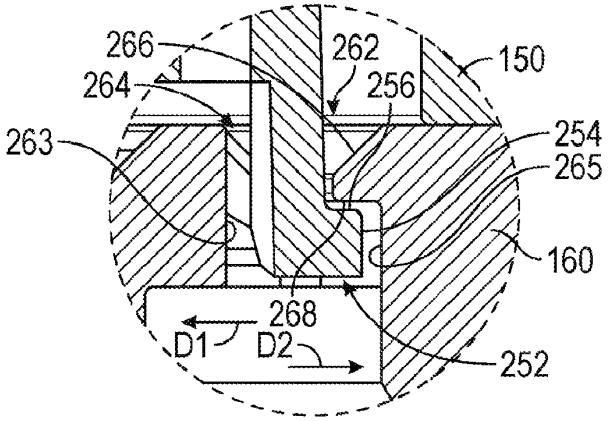

266
262
150
264
256
263
254
265
160
268
D1
D2
252

*FIG. 2C*

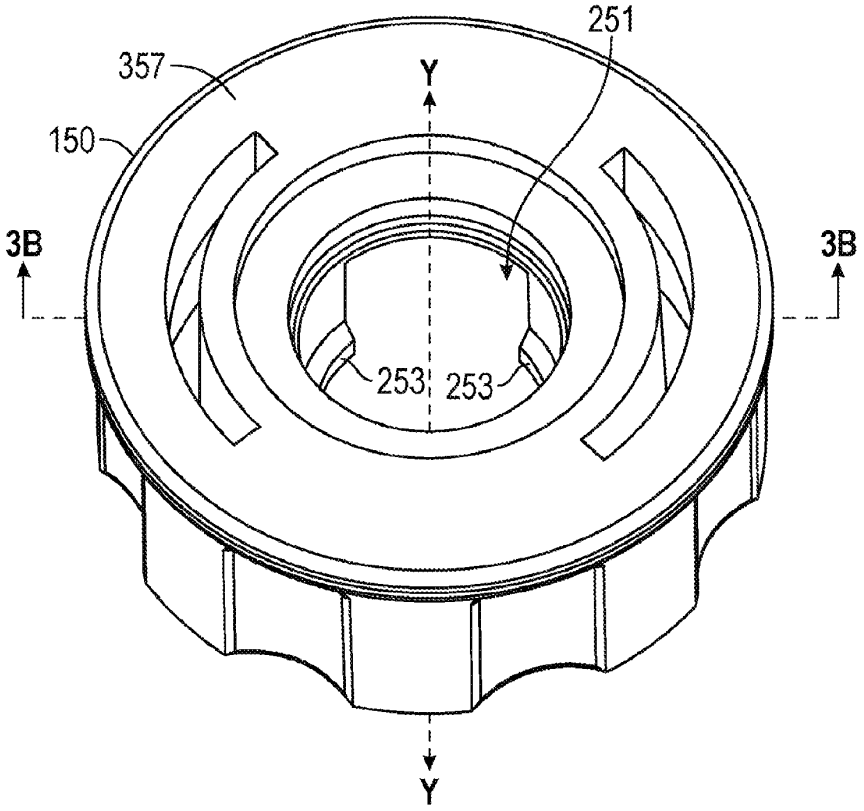

251
357
Y
150
3B
3B
253
253
Y

*FIG. 3A*

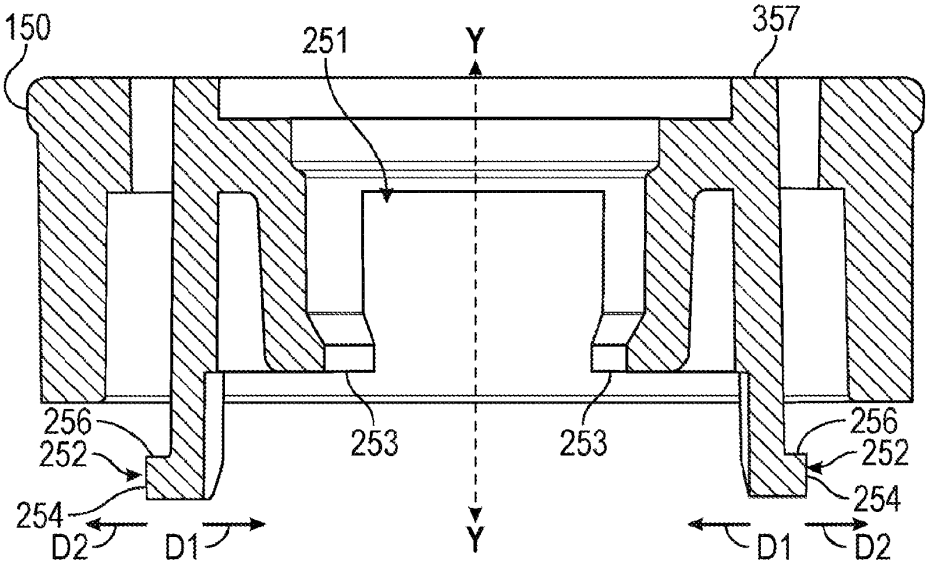

150
251
Y
357
256
252
253
253
256
252
254
254
D2
D1
Y
D1
D2

*FIG. 3B*

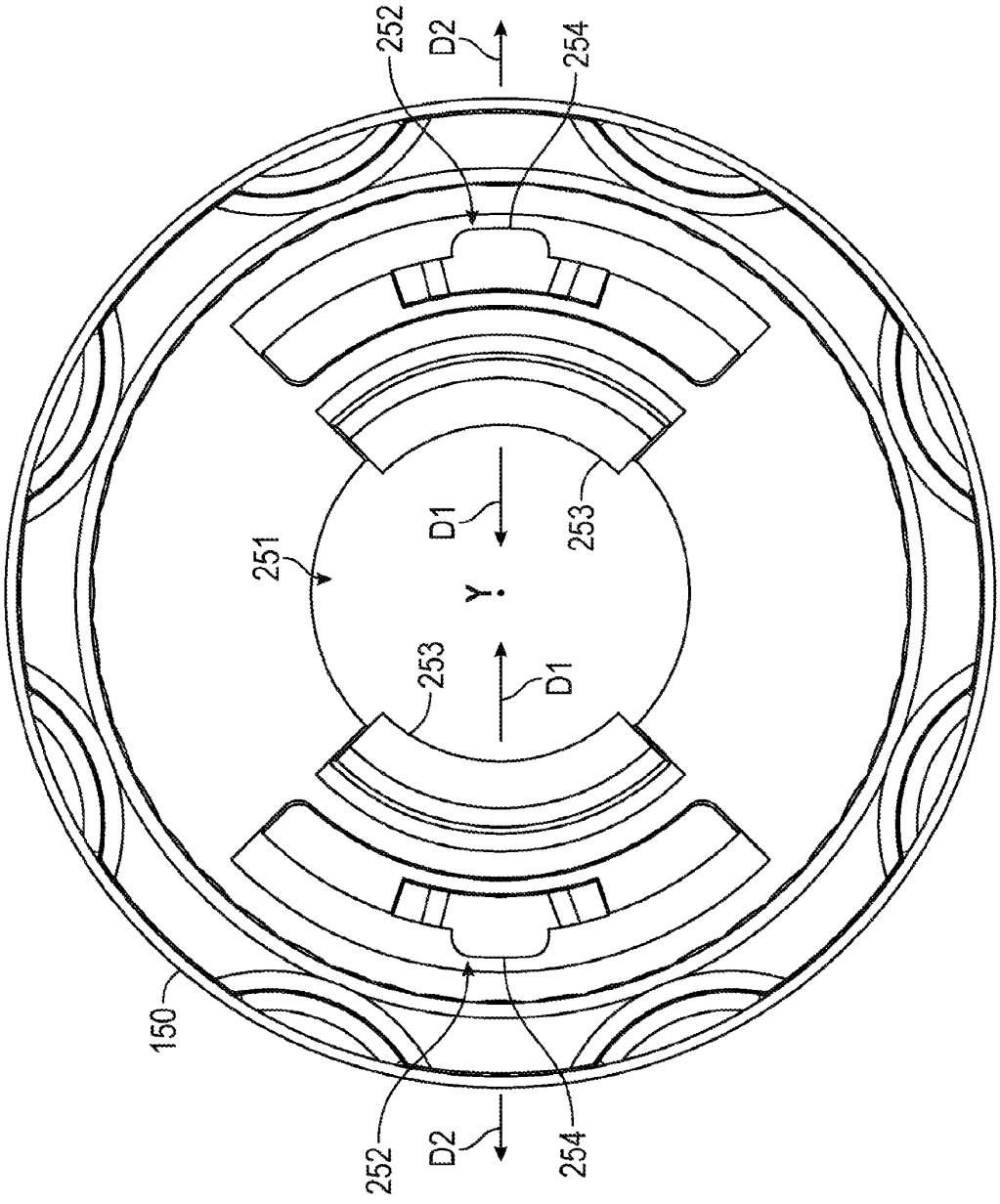



FIG. 3C

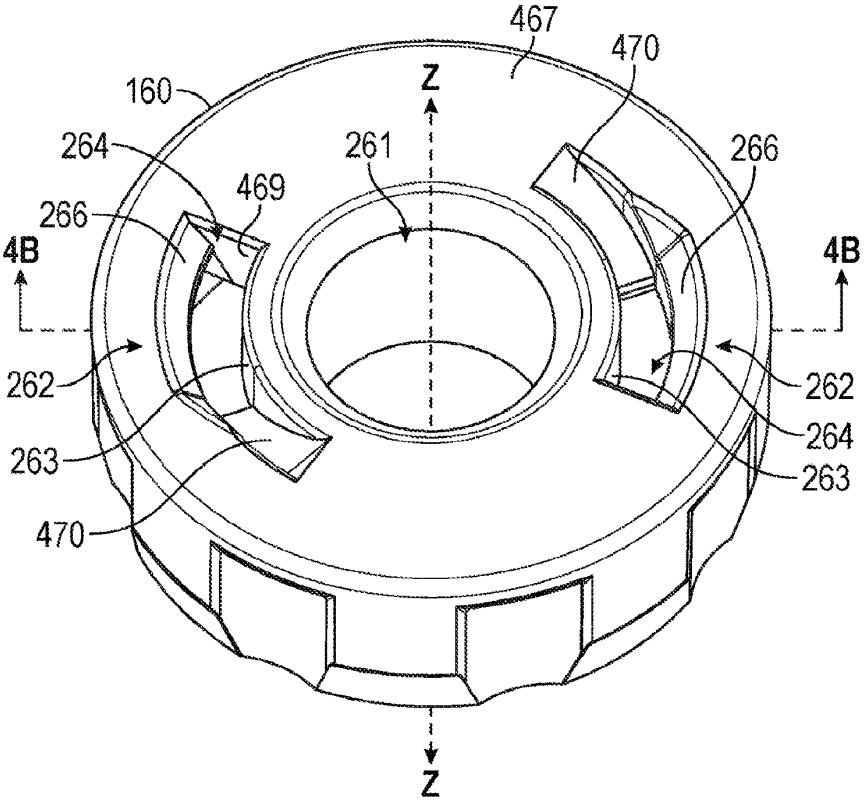

467
470
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Z
264
261
266
469
266
4B
4B
262
262
264
263
263
470
Z

*FIG. 4A*

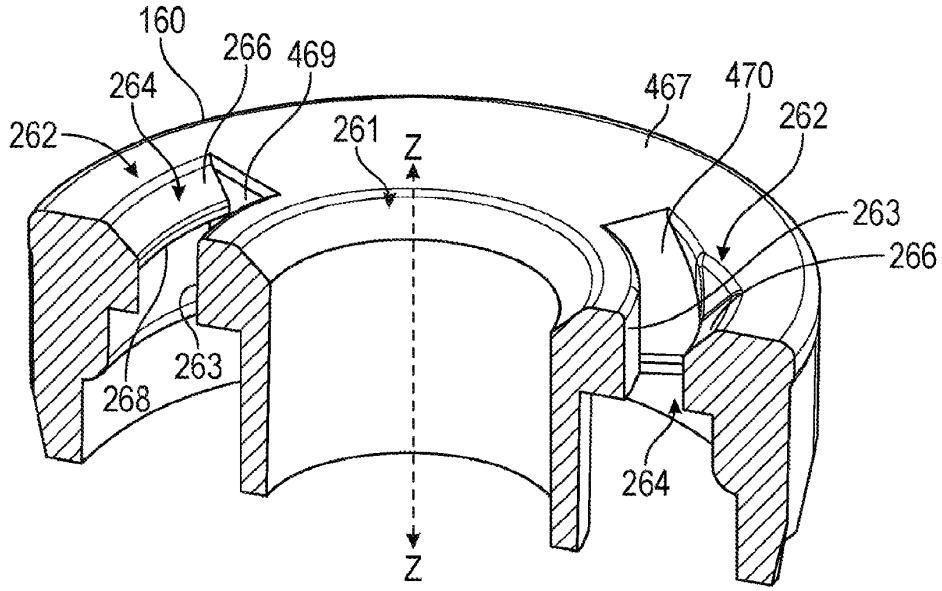

160
266
469
264
467
470
262
262
261
Z
263
266
263
268
264
Z

*FIG. 4B*

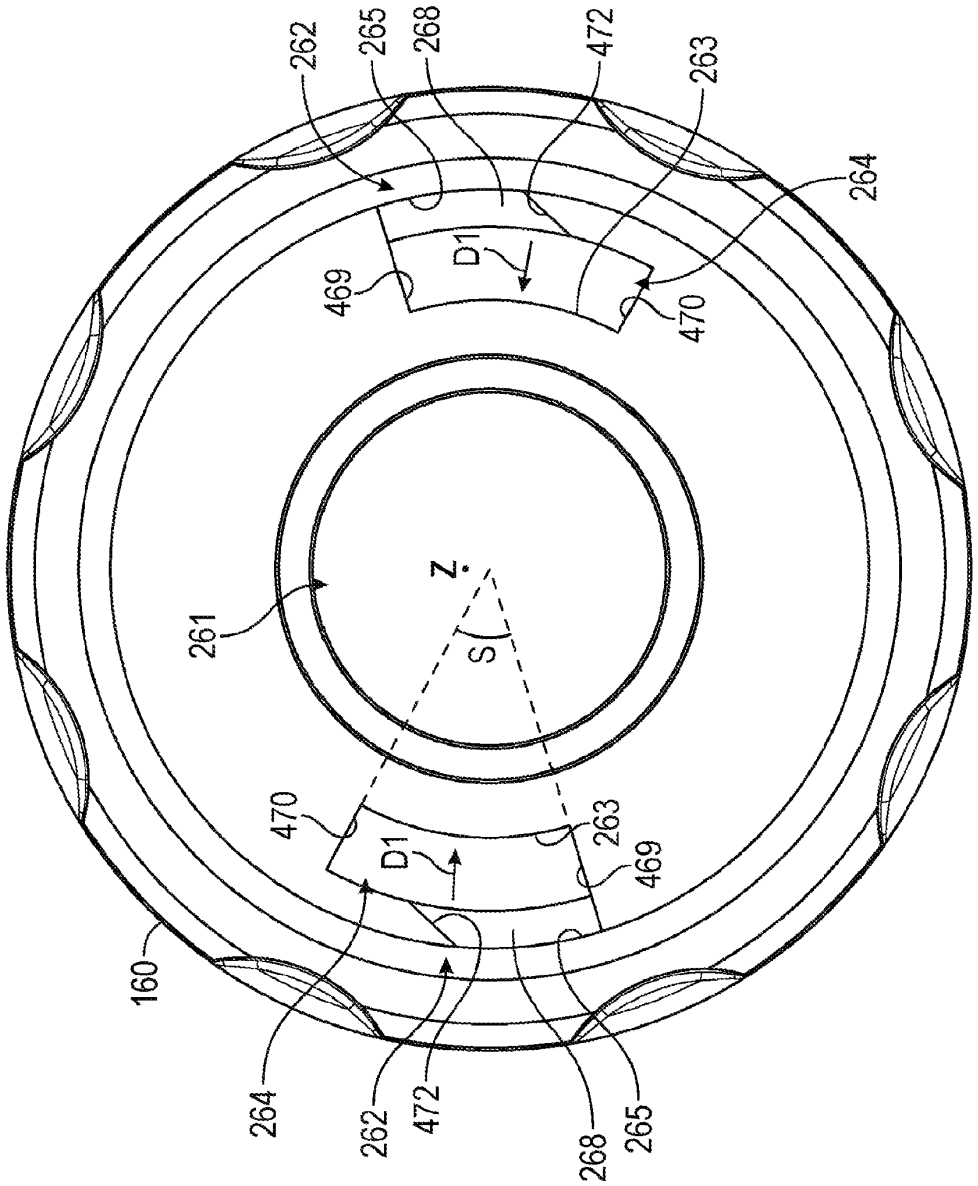

262
265
268
472
263
264
469
D1
470
261
Z
S
470
D1
263
469
160
264
262
472
268
265

FIG. 4C

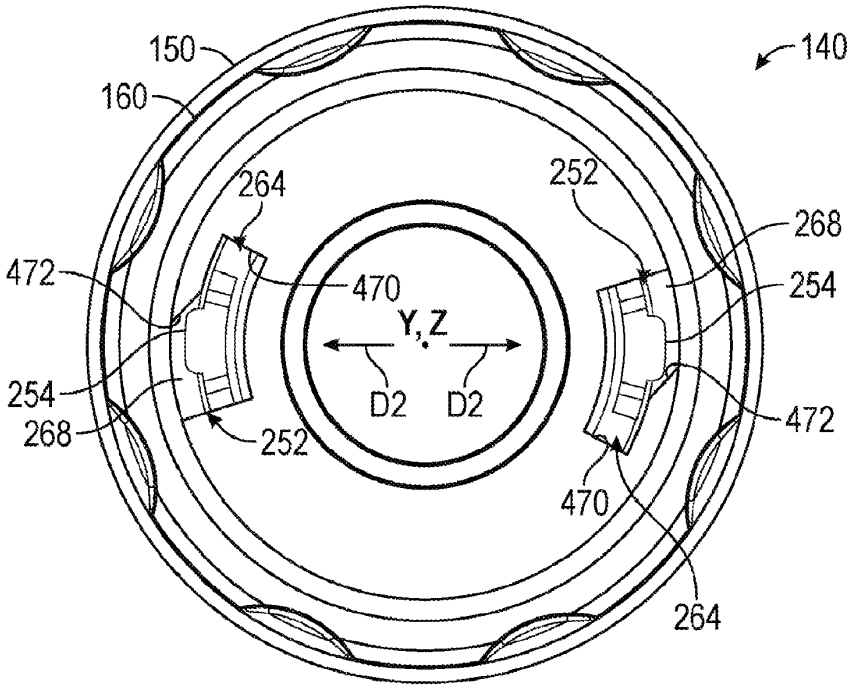

150
160
140
264
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268
472
470
Y, Z
254
D2
D2
254
268
252
472
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264

*FIG. 5A*

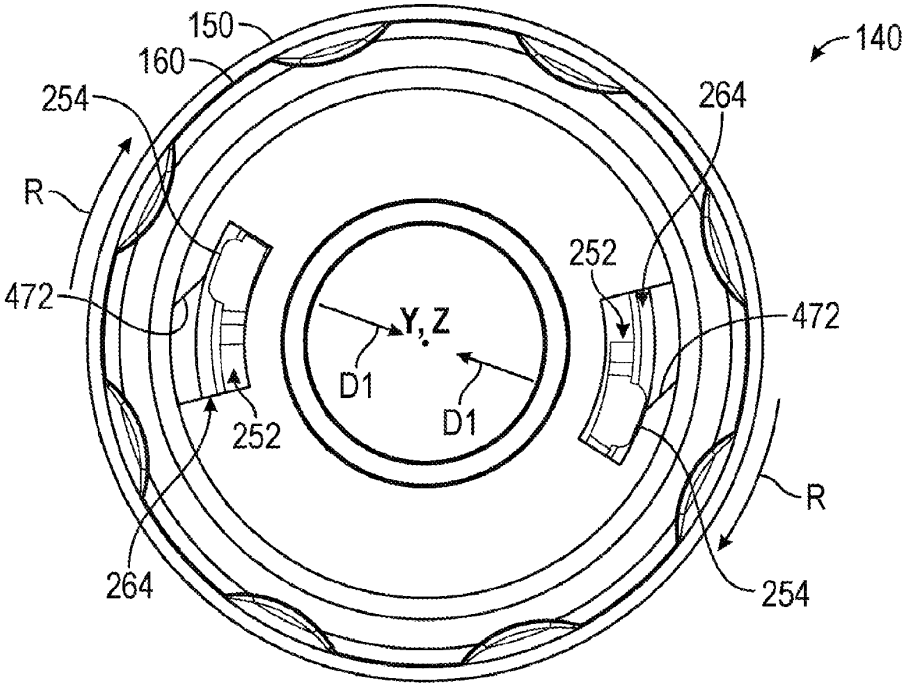

150
160
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264
R
252
472
Y, Z
472
D1
D1
252
R
264
254

*FIG. 5B*

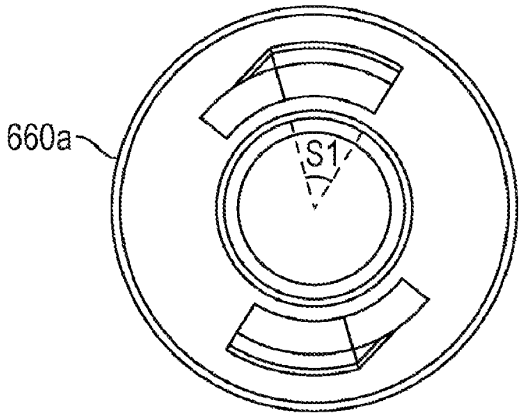



*FIG. 6A*

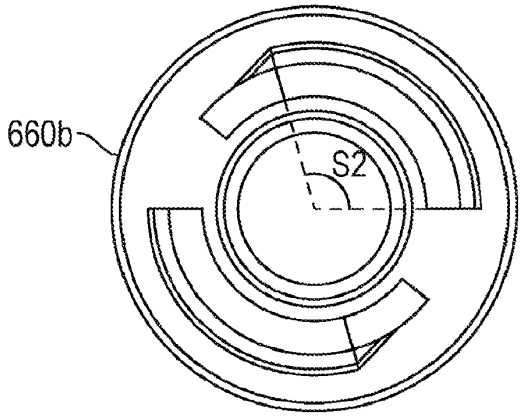



*FIG. 6B*

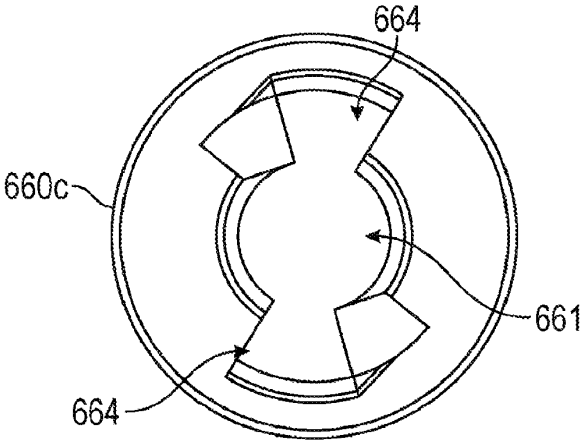



*FIG. 6C*

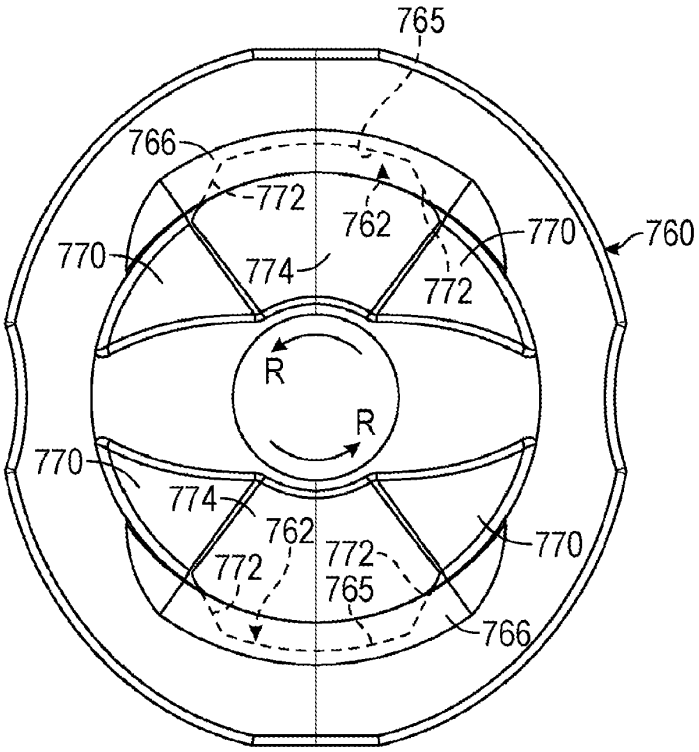

765
766
772
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774
772
R
R
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774
762
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770
772
765
766

*FIG. 7*

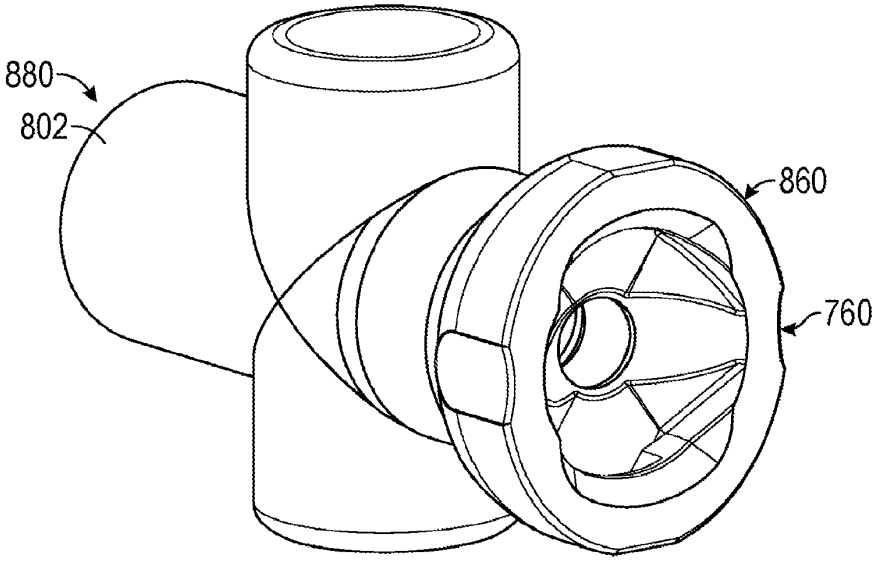

880
802
860
760

*FIG. 8*

Espacenet

# Bibliographic data: EP3589348 (A1) — 2020-01-08

## FLEXIBLE TIP CATHETER

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**Applicant(s):** COVIDIEN LP [US] ± (Covidien LP)

**Classification:** - international: ***A61M25/00***
- cooperative: **A61B17/22031 (US)**; **A61M25/001 (US)**; **A61M25/0012 (EP, US)**; **A61M25/0045 (EP, US)**; **A61M25/005 (EP, US)**; **A61M25/0052 (US)**; **A61M25/0054 (EP, US)**; **A61M25/0068 (US)**; **A61M25/008 (US)**; **A61M25/0097 (US)**; **A61M25/0108 (US)**; A61B2017/22035 (US); A61B2017/22079 (US); A61M2025/0036 (EP); A61M2025/0042 (EP); A61M2025/0059 (EP); A61M2025/0062 (EP); A61M2205/0222 (EP, US); A61M25/0108 (EP)

**Application number:** EP20180724347 20180301 Global Dossier

**Priority number(s):** US201715448028 20170302 ; WO2018US20410 20180301

**Also published as:** CN110430913 (A) CN110430913 (B) US10926060 (B2) US11596768 (B2) US2018250498 (A1) more

**Abstract not available for EP3589348 (A1)**
**Abstract of corresponding document: US2018250498 (A1)**



In some examples, a catheter includes an elongated body comprising proximal and distal portions. The distal portion of the elongated body comprises an inner liner that includes a proximal liner section and a distal liner section that include different materials, and an outer jacket positioned over the inner liner. The distal liner section has a first hardness and the proximal liner section has a second hardness, where the first hardness is less than the second hardness.

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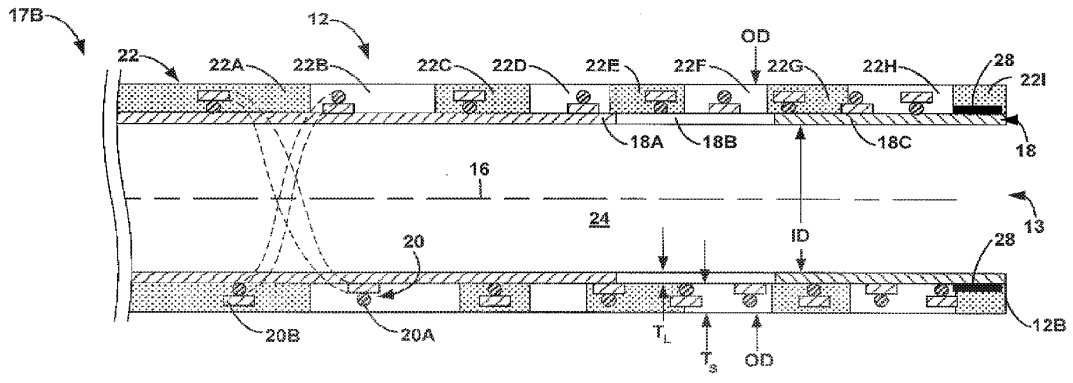



FIG. 2

(57) Abstract: In some examples, a catheter includes an elongated body comprising proximal and distal portions. The distal portion of the elongated body comprises an inner liner that includes a proximal liner section and a distal liner section that include different materials, and an outer jacket positioned over the inner liner. The distal liner section has a first hardness and the proximal liner section has a second hardness, where the first hardness is less than the second hardness.

*[Continued on next page]*

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# FLEXIBLE TIP CATHETER

## TECHNICAL FIELD

**[0001]** This disclosure relates to a medical catheter.

## BACKGROUND

**[0002]** A medical catheter defining at least one lumen has been proposed for use with various medical procedures. For example, in some cases, a medical catheter may be used to access and treat defects in blood vessels, such as, but not limited to, lesions or occlusions in blood vessels.

## SUMMARY

**[0003]** In some aspects, the disclosure describes examples catheters that includes an inner liner and an outer jacket, where a distal section of the inner liner is more flexible than a more proximal section of the inner liner. The relatively flexible distal portion of the inner liner may provide the catheter with a relatively flexible tip and improved navigability though a tortuous vasculature of a patient (e.g., better kink resistance at the tip). In some examples, the outer jacket also decreases in relative hardness moving distally toward the distal end of the catheter, which may also help improve navigability of the catheter though a tortuous vasculature of a patient. In some examples, the catheters described herein may be configured to resist geometric deformation when the distal end of the catheter body is engaged with a guidewire. This disclosure also describes example methods of forming catheters and methods of using catheters.

**[0004]** Clause 1: In one example, a catheter that includes an elongated body that includes proximal and distal portions, the distal portion of the elongated body having an inner liner that includes a proximal liner section and a distal liner section that include different materials, and an outer jacket positioned over the inner liner. The distal liner section having a first hardness, the proximal liner section having a second hardness, where the first hardness is less than the second hardness.

**[0005]** Clause 2: In some examples of the catheter of clause 1, the catheter includes a support element positioned between the inner liner and the outer jacket.

**[0006]** Clause 3: In some examples of the catheter of clause 2, the support element includes a braided structure including at least two strands to different diameters.

**[0007]** Clause 4: In some examples of the catheter of clause 3, the braided structure includes at least one flat or half-round wire and at least one round wire.

**[0008]** Clause 5: In some examples of the catheter of clause 4, the braided structure includes four flat or half-round wires woven against four round wires.

**[0009]** Clause 6: In some examples of the catheter of any of clauses 2 to 5, the support element is embedded in at least one of the inner liner or the outer jacket.

**[0010]** Clause 7: In some examples of the catheter of any of clauses 2 to 6, the support element includes at least one of a metal braid or a metal coil.

**[0011]** Clause 8: In some examples of the catheter of any of clauses 1 to 7, the distal liner section includes a thermoplastic elastomer.

**[0012]** Clause 9: In some examples of the catheter of any of clauses 1 to 8, the distal liner section further includes a slip agent.

**[0013]** Clause 10: In some examples of the catheter of clause 9, the slip agent includes an amide derived from a monosaturated fatty acid and is mixed with the polyolefin elastomer in an amount of about 0.5 weight percent (wt.%).

**[0014]** Clause 11: In some examples of the catheter of any of clauses 1 to 10, the proximal liner section includes a fluoropolymer.

**[0015]** Clause 12: In some examples of the catheter of any of clauses 1 to 11, the distal liner section includes a polyolefin elastomer and a slip agent, and the proximal liner section includes polytetrafluoroethylene (PTFE).

**[0016]** Clause 13: In some examples of the catheter of any of clauses 1 to 12, the proximal liner section extends to a proximal end of the elongated body.

**[0017]** Clause 14: In some examples of the catheter of any of clauses 1 to 13, the inner liner further includes an intermediate liner section defining a hardness less than that of the proximal liner section and greater than the distal liner section.

**[0018]** Clause 15: In some examples of the catheter of clause 14, the intermediate liner section includes a polyolefin elastomer and a slip agent.

**[0019]** Clause 16: In some examples of the catheter of clause 14 or 15, the intermediate liner section and the distal liner section collectively define an axial length of at least about 0.2 cm extending along a central axis of the elongated body.

**[0020]** Clause 17: In some examples of the catheter of any of clauses 1 to 16, the distal liner section is less lubricious than the proximal liner section.

**[0021]** Clause 18: In some examples of the catheter of any of clauses 1 to 17, the distal liner section includes a radial thickness of about 0.0015 inches (about 38 micrometers).

**[0022]** Clause 19: In some examples of the catheter of any of clauses 1 to 18, the distal liner section defines a lumen having a diameter of about 0.89 mm to about 2.24 mm.

**[0023]** Clause 20: In some examples of the catheter of any of clauses 1 to 19, the catheter includes a radiopaque marker band disposed over the distal liner section.

**[0024]** Clause 21: In some examples of the catheter of any of clauses 1 to 20, the outer jacket includes a proximal jacket section and a distal jacket section, the proximal jacket section having a greater hardness than the distal jacket section.

**[0025]** Clause 22: In some examples of the catheter of clause 21, the catheter includes a plurality of intermediate jacket sections positioned between the proximal jacket section and the distal jacket section, the outer jacket defines a hardness gradient of decreasing hardness moving distally from the proximal jacket section to a distal most intermediate jacket section of the plurality of intermediate jacket sections.

**[0026]** Clause 23: In some examples of the catheter of clause 22, the proximal jacket section and the plurality of intermediate jacket sections together define sequential sections of different hardnesses.

**[0027]** Clause 24: In some examples of the catheter of clause 22 or 23, the proximal jacket section defines a Shore D hardness of about 63–85.

**[0028]** Clause 25: In some examples of the catheter of any of clauses 22 to 24, the plurality of intermediate jacket sections includes at least one jacket section including a polyether block amide, at least one jacket section including a polyolefin elastomer, and at least one jacket section including a polyurethane elastomer.

**[0029]** Clause 26: In some examples of the catheter of any of clauses 22 to 25, the hardness gradient region transitions from a Shore D hardness of about 72 to a Shore A hardness of about 30.

**[0030]** Clause 27: In some examples of the catheter of clause 26, the plurality of intermediate jacket sections includes at least four intermediate jacket sections.

**[0031]** Clause 28: In some examples of the catheter of clause 27, the distal most intermediate jacket section includes a polyurethane elastomer, and a proximal most intermediate jacket section includes a polyether block amide.

**[0032]** Clause 29: In some examples of the catheter of any of clauses 22 to 28, the distal jacket section defines a harness between about a Shore A hardness of 30 and about a Shore D hardness of 55.

**[0033]** Clause 30: In some examples of the catheter of any of clauses 22 to 29, the proximal jacket section includes a polyamide and the distal jacket section includes a polyolefin elastomer.

**[0034]** Clause 31: In some examples of the catheter of any of clauses 1 to 30, the distal portion of the elongated body defines a wall thickness of less than about 0.15 mm.

**[0035]** Clause 32: In some examples of the catheter of any of clauses 1 to 31, the catheter includes a tie layer positioned between the inner liner and the outer jacket.

**[0036]** Clause 33: In some examples of the catheter of clause 32, the catheter includes a support element positioned between over the tie layer.

**[0037]** Clause 34: In one example, a method of forming an elongated body of a catheter, the method including positioning an inner liner over a mandrel, the inner liner includes a proximal liner section and a distal liner section including different materials, the distal liner section has a first hardness less than a second hardness of the proximal liner section; and positioning an outer jacket over the inner liner.

**[0038]** Clause 35: In some examples of the method of clause 34, the method includes forming the inner liner, wherein forming the inner liner includes extruding a mixture including a first polyolefin elastomer and a slip agent to from the distal liner section, and bonding the distal liner section to the proximal liner section to form the inner liner.

**[0039]** Clause 36: In some examples of the method of clause 34, the method includes forming the inner liner by extruding a mixture including a first polyolefin elastomer and a slip agent to from the distal liner section; extruding a mixture including a second polyolefin elastomer to form an intermediate liner section; and bonding a first end of the intermediate liner section to the proximal liner section and a second end of the intermediate liner section to the distal liner section to form the inner liner.

**[0040]** Clause 37: In some examples of the method of any of clauses 34 to 36, the method includes positioning a support element over the inner liner, the support element includes at least one of a wire braid or a wire coil.

**[0041]** Clause 38: In some examples of the method of clause 37, positioning the support element includes weaving or wrapping a plurality of metal wires over the inner liner while the inner liner is on the mandrel, the plurality of metal wires at least two wires of different diameters.

**[0042]** Clause 39: In some examples of the method of clause 37 or 38, positioning the support element includes weaving four flat or half-round wires against four round wires to form the wire braid.

**[0043]** Clause 40: In some examples of the method of any of clauses 37 to 39, the method includes heat setting the support element on a mandrel prior to positioning the support element over the inner liner.

**[0044]** Clause 41: In some examples of the method of any of clauses 34 to 40, the method includes positioning a radiopaque marker over the distal liner section prior to positioning the outer jacket over the inner liner and the support element.

**[0045]** Clause 42: In some examples of the method of any of clauses 34 to 41, positioning the outer jacket over the inner liner includes positioning a proximal jacket section over the inner liner, and positioning a plurality of intermediate jacket sections over the inner liner such that the outer jacket defines a hardness gradient of decreasing hardness moving distally from the proximal jacket section to a distal most intermediate jacket section of the plurality of intermediate jacket sections.

**[0046]** Clause 43: In some examples of the method of clause 42, positioning the outer jacket over the inner liner further includes positioning a distal jacket section over the inner liner such that the outer jacket includes a sequential arrangement of the proximal jacket section, the plurality of intermediate jacket sections, and the distal jacket section; and bonding contacting portions of the proximal jacket section, the plurality of intermediate jacket sections, and the distal jacket section to one another.

**[0047]** Clause 44: In some examples of the method of clause 43, the distal jacket section defines a hardness that is greater than that of the distal most intermediate jacket section.

**[0048]** Clause 45: In one example, a method for treating a thrombus within a vasculature of a patient, the method including inserting the catheter of any of clauses 1 to 33 into the vasculature of the patient; and aspirating the thrombus using the catheter.

**[0049]** The details of one or more aspects of the disclosure are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the techniques described in this disclosure will be apparent from the description and drawings, and from the claims.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0050]** FIG. 1 is a conceptual side elevation view of an example catheter, which includes an elongated body and a hub.

**[0051]** FIG. 2 is a conceptual axial cross-sectional view of the distal portion of the elongated body of FIG. 1, where the cross-section is taken through a center of the elongated body along a longitudinal axis.

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**[0052]** FIG. 3 is another conceptual axial cross-sectional view of a distal portion of another example catheter, which includes an elongated body and a hub.

**[0053]** FIG. 4 is a flow diagram of an example method of forming a catheter described herein.

## DETAILED DESCRIPTION

**[0054]** In some examples, a medical catheter ("catheter") described herein includes a relatively flexible elongated body that is configured to be navigated through vasculature of a patient, e.g., tortuous vasculature in a brain of the patient. The elongated body of the catheter is configured to exhibit a relatively high level of structural integrity while defining a thin-walled construction. In this way, the catheter may maintain a relatively low profile (e.g., a relatively small outer diameter), while still providing a relatively large inner lumen (also referred to as a working channel in some examples), through which distal tissue sites may be accessed, e.g., to deliver a medical device or therapeutic agent, to remove a thrombus or other target from the patient's body, or any combination thereof.

**[0055]** The described catheters may include a relatively flexible distal portion that can be configured to be navigated through vasculature of a patient, e.g., tortuous vasculature in a brain of the patient, where the distal portion may exhibit increased flexibility relative to a proximal portion of the catheter. In some examples, the elongated body includes an inner liner and an outer jacket, and the increased flexibility of the distal portion may be at least partially (e.g., partially or fully) attributable to the configuration of the inner liner. For example, in some cases, a distal section of the inner liner may be more flexible than a more proximal section of the inner liner. In this way, the inner liner, as well as the catheter, may be a variable stiffness catheter that increases in flexibility towards a distal end of the catheter. For example, the inner liner may have sections of different hardnesses (e.g., sections of different materials) such that the distal-most section of the inner liner has a decreased hardness compared to a more proximal section of the inner liner. In some examples, the inner liner may include a plurality of inner liner sections that define a hardness gradient that decreases from a proximal-most section of the inner liner to a distal-most section of the inner liner.

**[0056]** Additionally, in some examples, the outer jacket within the distal portion of the catheter may likewise define sections of different materials and hardnesses such that a distal section of the outer jacket has a decreased hardness compared to a more proximal section of the outer jacket. In some examples, sections of "different materials" may

include sections of similar polymeric constructions whose relative amounts and/or additive have been altered to result in sections of different relative hardnesses. In some examples, the outer jacket may include a plurality of intermediate jacket sections (e.g., four or more intermediate jacket sections) positioned between a proximal jacket section and a distal jacket section such that the outer jacket defines a hardness gradient that decreases from the proximal jacket section to the distal most intermediate jacket section.

**[0057]** The elongated body of the catheter can be configured to exhibit a relatively high level of flexibility, pushability, torqueability, and/or structural integrity. In some examples, the elongated body of the catheter includes an inner liner, a support element (e.g. metal coil or braid), and an outer jacket, which can interact to provide a relatively flexible elongated body of the catheter with sufficient structural integrity (e.g., columnar strength) to permit the elongated body of the catheter to be advanced through the vasculature via a pushing force applied to a proximal portion of the elongated body of the catheter, e.g. without buckling, kinking, or otherwise undesirably deforming (e.g., ovalization). In addition, in some examples, the elongated body of the catheter has a columnar strength and flexibility that allow at least a distal portion of the elongated body of the catheter to be navigated from a femoral artery, through the aorta of the patient, and into the intracranial vascular system of the patient, e.g., to reach a relatively distal treatment site, including the middle cerebral artery (MCA), the Circle of Willis, and tissue sites more distal than the MCA and the Circle of Willis. The MCA and, consequently, vasculature distal to the MCA may be relatively difficult to access due to the carotid siphon or vertebral artery anatomy that must be traversed to reach such locations.

**[0058]** In some examples, the catheter may be a guide catheter that acts as a conduit to help support a microcatheter. In other examples, the catheter may be a microcatheter. In either example, the elongated body of the catheter of the catheter may define an inner lumen, which may be configured to receive one or more medical devices, deliver a therapeutic agent to a distal tissue site, remove thrombus (e.g., by aspiration) from the patient's vasculature, and the like or any combination thereof. Example therapeutic agents include, but are not limited to, an oxygenated medium or a pharmaceutical agent, which may be, for example, a vasodilator such as nifedipine or sodium nitroprusside, or a tissue plasminogen activator (t-PA), which can be used to breakdown blood clots.

**[0059]** In examples in which the inner lumen defined by the elongated body of the catheter is used to remove thrombus from vasculature, the catheter may be referred to as an aspiration catheter. A vacuum may be applied to a proximal end of the elongated body

of the catheter to draw a thrombus into the inner lumen, e.g., by a suction pump. An aspiration catheter may be used in a medical procedure to treat an ischemic insult, which may occur due to occlusion of a blood vessel that deprives brain tissue of oxygen-carrying blood. In some examples, in addition to being configured to be navigated to relatively distal tissue sites, an aspiration catheter may also include a distal tip configuration that is configured to substantially maintain its shape, even in the presence of the vacuum force applied to the catheter during the aspiration process.

**[0060]** The catheters described herein may be advanced to a target location within vasculature of the patient in cooperation with a guidewire, an inner catheter, or both, which may aid in the navigation (e.g., steering and manipulation) of the catheter through the vasculature. For example, an inner lumen of the catheter body may be configured to receive a guidewire or an inner catheter, such that the catheter body may be guided through vasculature over the guidewire or the inner catheter. As described in further detail below, in some examples, a distal tip of the catheter body is configured to resist geometric deformation from forces applied to the distal tip by the guidewire or inner catheter. This resistance to geometric deformation may help improve the ease with which the catheter body may be guided to a relatively distal tissue site, e.g., through relatively tight turns in the vasculature.

**[0061]** Although primarily described as being used to reach relatively distal vasculature sites, the relatively thin-walled and kink resistant catheters described herein may readily be configured to be used with other target tissue sites. For example, the catheters may be used to access tissue sites throughout the coronary and peripheral vasculature, the gastrointestinal tract, the urethra, ureters, Fallopian tubes and other body lumens.

**[0062]** FIG. 1 is a conceptual side view of an example catheter 10, which includes elongated body 12 and a hub 14 positioned at a proximal end 12A of elongated body 12. In some examples, catheter hub 14 may define an opening through which an inner lumen 24 (shown in FIG. 2) of elongated body 12 may be accessed and, in some examples, closed. For example, catheter hub 14 may include a luer connector for connecting to another device, a hemostasis valve, or another mechanism or combination of mechanisms for establishing connections between catheter 10 and other devices. In other examples, the proximal end of catheter 10 can include another structure in addition to or instead of hub 14.

**[0063]** Elongated body 12 extends from proximal end 12A to distal end 12B, and defines a proximal portion 17A and a distal portion 17B. Elongated body 12 may define at least

one inner lumen 24 (shown in FIG. 2) that extends the length of elongated body 12. In the example shown in FIG. 1, proximal end 12A of elongated body 12 is received within hub 14 and can be mechanically connected to hub 14 via an adhesive, welding, or another suitable technique or combination of techniques. Opening 15 defined by hub 14 and located at proximal end 14A of hub 14 is aligned with the inner lumen 24 (shown in FIG. 2) of elongated body 12, such that the inner lumen 24 of elongated body 12 may be accessed via opening 15. In some examples, catheter 10 may include a strain relief body 11, which may be a part of hub 14 or may be separate from hub 14.

**[0064]** In some cases, a clinician may steer catheter 10 through the vasculature of a patient by pushing or rotating hub 14 to navigate distal portion 17B of elongated body 12 through the vasculature of a patient. The clinician may apply torque to hub 14 and/or proximal portion 17A of the catheter 10 (or at least a portion of elongated body 12 that is more proximal than distal portion 17B implanted in the patient) in order to rotate distal portion 17B of catheter 10.

**[0065]** As described further below, in some examples, elongated body 12 includes an inner liner, support element, and outer jacket, which may configure elongated body 12 to better transmit the torque applied to a relatively proximal portion to a relatively distal portion of elongated body 12, resist kinking or otherwise undesirable deformation upon rotation of catheter 10, and/or exhibit a high degree of responsiveness from the relatively proximal portion 17A of elongated body 12. In addition, distal portion 17B of elongated body 12 may be configured to provide increased flexibility to assist the navigation of catheter 10 through the extensive curvatures of a vasculature, which can be relatively tortuous in some anatomical regions.

**[0066]** In some examples, catheter 10 may be a guide catheter that acts as a conduit to help support a microcatheter. In other examples, catheter 10 may be a microcatheter. In either example, elongated body 12 of catheter 10 may define at least one inner lumen 24 (e.g., one inner lumen, two inner lumens, three inner lumens or more than three inner lumens), which may be configured to receive one or more medical devices, serve as a conduit for the delivery of a medical device, deliver a therapeutic agent to a distal tissue site, remove thrombus (e.g., by aspiration) from the patient's vasculature, and the like or any combination thereof. Example therapeutic agents include, but are not limited to, an oxygenated medium or a pharmaceutical agent, which may be, for example, a vasodilator such as nifedipine or sodium nitroprusside, or a tissue plasminogen activator (t-PA), which can be used to breakdown blood clots. In examples in which inner lumen 24

defined by elongated body 12 is used to remove thrombus from vasculature, catheter 10 may be referred to as an aspiration catheter. A vacuum may be applied to proximal end 12A of elongated body 12 (e.g., at opening 15) to draw a thrombus into inner lumen 24. An aspiration catheter may be used in a medical procedure to treat an ischemic insult, which may occur due to occlusion of a blood vessel that deprives brain tissue of oxygen-carrying blood. In some examples, in addition to being configured to be navigated to relatively distal tissue sites, an aspiration catheter may also include a distal tip that is configured to substantially maintain its shape, even in the presence of the vacuum force applied to the catheter during the aspiration process.

**[0067]** In some examples, elongated body 12 may be used to access relatively distal vasculature locations in a patient, such as the MCA in a brain of a patient. The MCA, as well as other vasculature in the brain or other relatively distal tissue sites (e.g., relative to the vasculature access point), may be relatively difficult to reach with a catheter, due at least in part to the tortuous pathway (e.g., comprising relatively sharp twists and/or turns) through the vasculature to reach these tissue sites.

**[0068]** Distal portion 17B of catheter 10 may be configured to be relatively flexible compared to proximal portion 17A of elongated body 12 to allow for improved navigability of elongated body 12 through a tortuous vasculature of a patient. FIG. 2 shows a conceptual axial cross-sectional view of distal portion 17B of catheter 10 of FIG. 1, where the cross-section is taken through a center of elongated body 12 along a longitudinal axis 16. As shown in FIG. 2, elongated body 12 includes an inner liner 18, a support element 20, and an outer jacket 22.

**[0069]** Inner liner 18 comprises a proximal section (proximal liner section 18A), an optional intermediate section (intermediate liner section 18B), and a distal section (distal liner section 18C) formed from of different materials such that distal liner section 18C has a lower hardness and higher flexibility compared to proximal liner section 18A. Reducing the hardness and increasing the flexibility of the distal liner section 18C compared to proximal liner section 18A may improve the navigability of catheter 10 without compromising or reducing the structural integrity (e.g., kink resistance) of elongated body 12. In some examples, distal portion 17B of catheter 10 may also include at least one support element 20 such as a braid or coil formed over inner liner 18 and embedded within or located beneath an outer jacket 22. Support element 20 can be formed from any suitable material, such as, but not limited to, a metal, a polymer, a fiber, or any combination thereof. As described further below, outer jacket 22 may include

regions of different hardnesses such that outer jacket 22 defines a hardness gradient where the hardness of the outer jacket 22 generally decreases moving distally over distal portion 17B.

**[0070]** In some examples, inner liner 18 extends from proximal end 12A to distal end 12B of elongated body 12 with proximal liner section 18A extending along a substantial portion of elongated body 12 (e.g., extend to proximal end 12A). Inner liner 18 defines inner lumen 24 of elongated body 12, inner lumen 24 extending from proximal end 12A to distal end 12B and defining a passageway extending from proximal end 12A to distal opening 13 at distal end 12B of elongated body 12. Inner lumen 24 may be sized to receive a medical device (e.g., another catheter, a guidewire, an embolic protection device, a stent, a thrombectomy device, or any combination thereof), a therapeutic agent, or the like.

**[0071]** Inner liner 18 may be composed of different materials including, for example, one or more thermoplastic elastomers such as polyolefin elastomers, thermoplastic polyolefins, fluoropolymers such as polytetrafluoroethylene (PTFE), perfluoroalkyoxy alkane (PFA), fluorinated ethylene propylene (FEP), or the like. The different materials may include sections of similar polymeric constructions whose relative amounts and/or additive have been altered to result in sections of different relative hardnesses. In some examples, inner liner 18 can be formed as independent tubular sections that are subsequently joined together using any suitable technique, such as an adhesive, fusing/welding, or any combination thereof.

**[0072]** Proximal liner section 18A may include of materials that exhibit high lubricity and a Shore D hardness (ASTM D2240) of about 50–65. In some examples, proximal liner section 18A may include a non-etched PTFE, e.g., may consist essentially of a non-etched PTFE. PTFE may exhibit a relatively high lubricity, such that the inner surface of proximal liner section 18A may exhibit a relatively low friction coefficient to facilitate the introduction and passage of a medical device (e.g., another catheter, a guidewire, an embolic protection device, a stent, a thrombectomy device, or any combination thereof) through inner lumen 24. In some examples, proximal liner section 18A may include PTFE such as Teflon® PTFE 640 available from The Chemours Company, Inc. having a Shore D hardness of about 58D.

**[0073]** Distal liner section 18C may include of materials that exhibit lower hardness and higher flexibility compared to proximal liner section 18A to improve the navigability the catheter 10 within the vasculature of a patient. In some examples, distal liner section 18C

may include a thermoplastic elastomer having a Shore D hardness of about 11 to about 47. In some examples, distal liner section 18C may include one or more polyolefins including, for example, a polyolefin elastomers such as Engage™ polyolefin elastomers available from the Dow Chemical Company of Midland, Michigan. In some examples, distal liner section 18C may include polyolefin elastomer ethylene butane such as Engage™ 7270 having a Shore D hardness of about 26.

**[0074]** In some examples, distal liner section 18C may be positioned directly adjacent to proximal liner section 18A, thereby excluding the presence of an intermediate liner section. Alternatively, distal portion 17B may include an optional intermediate liner section 18B to provide a stepped change in hardnesses between proximal liner section 18A and distal liner section 18C. In some such examples, intermediate liner section 18B may have a Shore D hardness of about 12 to about 47. In some examples, intermediate liner section 18C may include one or more polyolefins including, for example, a polyolefin elastomers such as Engage™ 8440 having a Shore D hardness of about 36.

**[0075]** In some examples, the polymers used to form intermediate or distal liner sections 18B, 18C may exhibit a higher coefficient of friction compared to the harder polymers (e.g., PTFE) that form proximal liner section 18A. To improve the lubricity of the softer polymers forming intermediate or distal liner sections 18B, 18C, one or more of intermediate and distal liner sections 18B, 18C may include one or more slip agents. The one or more slip agents may help increase the lubricity of the respective liner section which can help improve the navigability of catheter 10 by facilitating the smooth passage of distal portion 17B over a guide catheter or guidewire. Suitable slip agents may include, for example, an amide derived from a monosaturated fatty acid such as Ampacet 100329 slip concentrate available from Ampacet Corporation of Tarrytown, New York. Ampacet 100329 is characterized as 5 weight percent (wt.%) erucamide in metallocene linear low-density polyethylene. The slip agent may be added to the polymeric materials that from intermediate or distal liner sections 18B, 18C in an amount of about 0.1 wt.% to about 1 wt.% (e.g., 1–10 wt.% of Ampacet 100329 is added to distal liner section 18C corresponding to 0.1–1 wt.% of the erucamide slip agent being added). The slip agent may be mixed and extruded along with the thermoplastic elastomer (e.g., a polyolefin elastomer ethylene butane such as, but not limited to, Engage™ 7270 or 8440) used to form intermediate or distal liner sections 18B, 18C.

**[0076]** In some examples the slip agent, while being thoroughly mixed with the thermoplastic elastomer prior to extrusion, may migrate towards the exterior wall of the

structure used to form the section of inner liner 18 (e.g., the inner wall of intermediate or distal liner sections 18B, 18C defining lumen 24) during the extrusion process and solidification of the material used to form at least part of inner liner 18. The migration towards the exterior wall of the structure may be due to the incompatibility between the thermoplastic elastomer and the slip agent. This structure used to form one or more sections of inner liner 18 may be referred to as a liner structure. The resulting migration of the slip agent within the liner structure may help increase the lubricity of the inner wall of the resultant section of inner liner 18. In some examples, while the polymers used to form intermediate or distal liner sections 18B, 18C may include a slip agent to improve the lubricity of the respective liner section, intermediate or distal liner sections 18B, 18C may still define a lower coefficient of friction compared to polymeric materials used to form proximal liner section 18A (e.g., PTFE).

**[0077]** Intermediate and distal liner sections 18B, 18C may be of any suitable length (e.g., distance extending along the direction of longitudinal axis 16). In some examples, the combined length of intermediate and distal liner sections 18B, 18C may be from about 5 cm centimeters (cm) to about 45 cm, such as from about 15 cm to about 30 cm. In some examples, the length of distal liner section 18C may be greater than the length of intermediate liner 18B. For example, the length of intermediate liner section 18B may be about 15 cm and the length of distal liner section 18C may be about 20 cm. In other examples, the length of distal liner section 18C may be less than the length of intermediate liner 18B. For example, the length of intermediate liner section 18B may be about 20 cm and the length of distal liner section 18C may be about 10 cm.

**[0078]** Elongated body 12 may include one or more support elements 20 positioned over inner liner 18. In some examples, support element 20 may include at least one braided structure, coil structure, or combinations thereof. Support element 20 may be structurally configured to be relatively flexible, pushable, navigable, and relatively kink- and buckle-resistant, so that elongated body 12 may resist buckling when a pushing force is applied to a relatively proximal portion of catheter 10 to advance elongated body 12 distally through vasculature, and so that it may resist kinking when traversing around a tight turn in the vasculature. Unwanted kinking and/or buckling of elongated body 12 may otherwise hinder a clinician's efforts to push the elongated body 12 distally, e.g., past a turn. In some examples, support element 20 may be tailored to increase the structural integrity of elongated body 12 while allowing elongated body 12 to remain relatively flexible. For example, support element 20, together with inner liner 18, and outer jacket

22, may help distribute pushing and rotational forces along a length of elongated body 12, while also providing structural support to help prevent kinking or buckling of elongated body 12 upon bending or rotation of elongated body 12. As a result, a clinician may apply pushing forces, rotational forces, or both, to a proximal portion of elongated body 12, and such forces may cause a distal portion of elongated body 12 to advance distally, rotate, or both, respectively.

**[0079]** In some examples, support element 20 may include a braided structure having wires or filaments of different diameters, different cross-sectional shapes, different materials, or any combination thereof. For example, as shown in FIG. 2, support element 20 may include a combination of round wires 20A and flat wires 20B. Round wires 20A may be substantially circular in cross-section and flat wires 20B may be a quadrilateral in cross-section, where the cross-sections are taking in a direction orthogonal to the longitudinal axis of the respective wire when the wire is substantially straight. The cross-sectional dimension of the wire (e.g., the diameter) can sometimes be referred to as the size of the wire. For example, a 0.0015 inch round wire 20A may have a circular cross-sectional diameter of about 0.0015 inches and a 0.001 x 0.008 inch flat wire 20B may have cross-sectional diameters of about 0.001 inches and about 0.008 inches.

**[0080]** In some examples, the braided structure may include a wire braid including round wires 20A woven against flat wires 20B, such that there is no cross braiding of the respective round wires 20A or flat wires 20B. In some such examples, support element 20 may include 0.0015 inch or 0.002 inch round wires 20A and 0.001 x 0.002 inch, 0.001 x 0.005 inch, or 0.001 x 0.008 inch flat wires 20B, or combinations thereof. For example, support element 20 may include round wires 20A that have a cross-sectional diameter of about 0.0015 inches (e.g., about 38 μm) and flat wires 20B with a cross-sectional diameter of about 0.001 x 0.005 inches (e.g., about 25 x 125 μm); round wires 20A that have a cross-sectional diameter of about 0.002 inches (e.g., about 50 μm) and flat wires 20B with a cross-sectional diameter of about 0.001 x 0.005 inches (e.g., about 25 x 125 μm); round wires 20A that have a cross-sectional diameter of about 0.002 inches (e.g., about 50 μm) and flat wires 20B with a cross-sectional diameter of about 0.001 x 0.008 inches (e.g., about 25 x 200 μm); or round wires 20A that have a cross-sectional diameter of about 0.0015 inches (e.g., about 38 μm) and flat wires 20B with a cross-sectional diameter of about 0.001 x 0.008 inches (e.g., about 25 x 200 μm). In some examples the wire braid may include 8 wires (e.g., four round wires 20A woven against four flat wires

20B), 16 wires (e.g., eight round wires 20A woven against eight flat wires 20B), or the like.

**[0081]** In some examples, the braided combination of round wires 20A and flat wires 20B may provide elongated body 12 with better ovalization resistance and tensile strength compared to other catheter designs (e.g., a support element consisting of only one metal coil or a braid consisting of only round wires). For example, including support element 20 made of an eight-wire braid (e.g., four 0.002 inches round wires 20A woven against four 0.001 x 0.008 inch flat wires 20B such that the round wires 20A do not cross another round wire 20A) may provide for greater kink and ovalization resistance compared to a single coil construction of comparable thickness without adding to the thickness or the tubular wall. Additionally, the combination of round wires 20A and flat wires 20B may define a relatively thin jacket thickness ($T_S$) and/or sidewall thickness (e.g., $T_S + T_L$) while still providing a high tensile strength with kink resistance and pushability.

**[0082]** Though support element 20 is primarily described as a braided structure of different diameter wires, in some examples, support element 20 may comprise a wire braid of similarly sized wires (e.g. wires with similar cross-sectional sizes), round or flat filaments made of synthetic or polymeric materials (e.g., non-metal wires), or combinations thereof. For example, support element 20 may include a 16 wire braid comprising of only 0.001 x 0.002 inches (e.g., about 25 x 50 μm) flat wires.

**[0083]** In some examples, in addition to or instead of a braided structure, support element 20 may include one or more coil structures. The coil structures (e.g., wire coils) may exhibit columnar strength (e.g., kink resistance) and/or hoop strength (e.g., resistance to ovalization) compared to other catheter designs. The one or more coil structures forming support element 20 may each define a plurality of turns in the shape of a helical coil, each coil defining a central axis substantially aligned or coincident with longitudinal axis 16. In some examples, wherein support element 20 includes more one or more coil structures, the coils may be interspaced with each other in a longitudinal direction (in a direction along longitudinal axis 16) such that the helical coils are wound in the same direction (e.g., a right-handed wind or a left-handed wind) with one turn (e.g., one full circumvolution about inner liner 18) of a respective coil is positioned between an adjacent turn of the other coil so that the turns of both coils are longitudinally offset from one another along the length of elongated body 12 and the coils do not overlap along the length of elongated body 12. In some examples, the interspaced arrangement of the more

than one coil structures may allow for improved rotational responsiveness and structural integrity.

**[0084]** In other examples, support element 20 may include both a coil structures and braided structure (e.g., a wire braid over a wire coil or vise versa). For example, support element 20 may include an inner stainless steel wire coil made of either a round wire (e.g., 0.0015 inch round wire coil) or a flat wire (e.g., 0.001 x 0.002 inch, 0.001 x 0.005 inch, or 0.001 x 0.008 inch flat wires). A wire braid can be positioned over the inner wire coil (e.g., an 8 or 16 wire braid that includes 0.0005 x 0.002 inch flat wires).

**[0085]** In some examples, support element 20 may be formed using braids or coils made of metal wires. Any suitable sized metal wire may be used for form the metal coils or metal braids. In some examples, the metal wires used to form support element 20 may have one or two cross-sectional diameters each measuring between about 0.0005 inches to about 0.008 inches (e.g., about 13 μm to about 200 μm). The metal wires may include round wires (e.g., circular cross-section), half-round wires (e.g., oval cross-section), flat wires (e.g., rectangular cross-section), or any suitable combination thereof. In some examples where support element 20 includes one or more wire coils, the coils may include round wires having a cross-sectional diameter of about 0.002 inches (e.g., about 50 μm). In some examples, support element 20 may include a braided structure that includes one or more round wires, half-round/flat wires, or combinations thereof.

**[0086]** In some examples, support element 20 may define a variable pitch along the length of elongated body 12. As used herein, the "pitch" is used to refer to the length along axis 16 for a single wire (e.g., a single round wire 20A) to complete one revolution around axis 16. For example, a wire coil having a pitch equal to the cross-sectional diameter of the wire means that the wire will be tightly coiled such that each loop of the wire is in continuous contact with an adjacent loop. In some examples, the pitch of support element 20 may decrease moving distally within distal portion 17B. In some examples, support element 20 may define a variable pick braid along the length of elongated body 12. As used herein, the term "pick" is used to refer to the number of overlaps or "picks" along axis 16 defining the density of the braid. For example, a braid having a high picks-per-inch value may have round wires 20A overlapping opposing flat wires 20B with increased frequency along axis 16. In some examples, the pick count of support element 20 may increase moving distally within distal portion 17B.

**[0087]** In some examples, support element 20 may be an etched or cut hypotube such as a spirally cut hypotube. In such examples, the hypotube may define a smaller diameter

compared to inner liner 18. The hypotube may be radially expanded (e.g., partially uncoiled) to fit over the inner liner.

**[0088]** Suitable materials for support element 20 may include, for example, one or more metals such as nickel titanium alloy (e.g., Nitinol, tertiary Nitinols), stainless steel, tungsten, titanium, gold, platinum, palladium, tantalum, silver, or a nickel-chromium alloy, a cobalt-chromium alloy, or the like. In such examples, support element may include stainless steel wires, which may provide increased strength to elongated body 12 (e.g., to increase the resistance of elongated body 12 to kinking. In some examples, support element 20 may be selected to include a radiopaque material(s) to allow elongated body 12 to be easily observed by the clinician as catheter 10 is advanced through the vasculature of a patient. In some examples support element 20 may be cladded with one or more materials, for example, to improve the radiopacity of the element without altering the underlying structural characteristics of the base wire (e.g., Nitinol wire cladded in gold).

**[0089]** In some examples, support element 20 may include non-metal materials such as one or more synthetic fibers including, for example, at least one of a para-aramid material, liquid crystal polymer (LCP), poly(p-phenylene-2,6-benzobisoxazole), polyether amides, polycarbonates, PTFE, PEEK, ultra-high molecular weight polyethylene, polyethylene naphthalate, polyester, carbon fiber a glass-fiber reinforced polymer, a carbon-fiber reinforced polymer, or the like. In some examples, support element 20 may include one or more polymers including, for example, polycarbonate, polyimide, polyetherimide, polyphenylene sulfide, polyether-ether-ketone, one or more fluoropolymers such as polytetrafluoroethylene, poly(ethene-cotetrafluoroethene), fluorinated ethylene propylene, polyvinylidene fluoride, or the like, one or more thermoplastic polymers such as polyether block amide, a polyamide, a polyamide-based polymer (e.g., nylon), a polyurethane, a polyolefin, PEBAX, polypropylene, a thermoplastic elastomer, one or more thermoset polymers, or the like. In some examples, support element 20 may include substantially hard and/or rigid based polymer materials including, for example, Kevlar, LCP, nylon, ultra high molecular weight polyethylene, FPEN, polyester, glass-fiber reinforced or carbon-fiber reinforced polymers, or the like that may be used to provide columnar and or hoop strength to elongated body 12. In some examples, forming support element 20 using a thermoplastic polymer may help improve the flexibility of the elongated body 12. In some examples, the round wires 20A and/or flat wires 20B of support element 20 described above may be replaced with

similarly sized components formed from one or more of the synthetic/polymeric materials described above.

**[0090]** Elongate body 12 includes outer jacket 22 positioned over support element 20 and inner liner 18, the support element 20 being positioned between inner liner 18 and outer jacket 22 in at least some portions of elongated body 12. In some examples, outer jacket 22 may include various regions of different hardnesses such that outer jacket 22 defines a hardness gradient where the hardness of the outer jacket 22 generally decreases moving distally along elongate body 12. For example, outer jacket 22 may define hardness gradient within distal portion 17B that transitions from a Shore D hardness of about 85 at a proximal section (e.g., proximal jacket section 22A) to a Shore A hardness (ASTM D2240) of about 30 at a distal section (e.g., intermediate jacket section 22H just proximal to distal jacket section 22I).

**[0091]** In some examples, the described hardness gradient of outer jacket 22 may be a step gradient, where the hardness changes sequentially dependent on the composition of the outer jacket within a specific section. For example, each outer jacket section (e.g., proximal jacket section 22A, one or more intermediate jacket sections 22B–22H, and distal jacket section 22I) may be formed from different materials that provide different relative hardnesses for each respective section. In some examples, the different materials may include sections of similar polymeric constructions whose relative amounts and/or additives have been altered to result in sections of different relative hardnesses.

**[0092]** In some examples, proximal jacket section 22A may include polymeric materials that exhibit a Shore D hardness of about 63 to 85. An example polymeric material for proximal jacket section 22A may include polyamides such as Grilamid® TR 55 (polyamide 12) (available from EMS-Grivory of Sumter, South Carolina) having a Shore D hardness of about 85 or polyamides such as Grilamid® L 25 (polyamide 12) available from EMS-Grivory having a Shore D hardness of about 72.

**[0093]** In the example shown in FIG. 2, distal portion 17B of elongated body 12 may include one or more intermediate jacket sections 22B–22H. In some examples, intermediate jacket sections 22B–22H may include polymeric materials of decreasing hardness, such that the hardness of outer jacket 22 decreases from a Shore D hardness of about 72 within intermediate jacket section 22B to a Shore D hardness of about 26 within intermediate jacket section 22H. Example polymeric materials for intermediate jacket sections 22B–22H may include for example polyether block amide such as Pebax® commercially available from Arkema Group of Colombes, France, polyurethane

elastomers such as PolyBlend 1100™ available from AdvanSource Biomaterials of St. Wilmington, Massachusetts, polyolefin elastomers (e.g., Engage™ polyolefin elastomer available from Dow Chemical Company of Midland, Michigan), thermoplastic polyurethanes such as Pellethane® TPU available from The Lubrizol Corporation of Wickliffe, Ohio, or the like. In some examples, intermediate jacket section 22B may include a polyether block amide (e.g., Pebax® 72D) having a Shore D hardness of about 72, intermediate jacket section 22C may include a polyether block amide (e.g., Pebax® 63D) having a Shore D hardness of about 63, intermediate jacket section 22D may include a polyether block amide (e.g., Pebax® 55D) having a Shore D hardness of about 55, intermediate jacket section 22E may include a polyether block amide or a polyolefin elastomer (e.g., Pebax® 40D, Pebax® 45D, or Engage™ 8480) having a Shore D hardness of about 40–45, intermediate jacket section 22F may include a polyether block amide or a polyolefin elastomer (e.g., Pebax® 35D, or Engage™ 8440G) having a Shore D hardness of about 35–36, intermediate jacket section 22G may include a polyether block amide or a polyolefin elastomers having (e.g., Pebax® 25D or Engage™ 7270) a Shore D hardness of about 25–26, and intermediate jacket section 22H may include a polyurethane elastomer (e.g., PolyBlend 1100™) having a Shore A hardness of about 30.

**[0094]** In some examples, distal jacket section 22I may be configured to have a higher lubricity compared to other sections of outer jacket 22 to provide for improved navigability of elongated body 12 through a tortious vasculature of a patient relative to an elongated body that includes a distal jacket section having the same lubricity as the more proximal jacket sections. In some examples, distal jacket section 22I may have the same or lower hardness compared to distal most intermediate jacket section 22H. In such examples, the jacket hardness gradient may be characterized as extending from proximal jacket section 22A to distal jacket section 22I. In other examples, jacket section 22I may have a hardness less than that of proximal jacket section 22A, but more than the hardness of the distal most intermediate jacket section (e.g., intermediate jacket section 22H). In some examples, distal jacket section 22I may exhibit a Shore D hardness of about 26 to about 55. In some such examples the increased hardness of distal jacket section 22I may provide better support for radiopaque marker 28. Example polymeric materials for distal jacket section 22H may include for example polyolefin elastomers such as polyolefin elastomer ethylene butane (e.g., Engage™ 7270) having a Shore D hardness of about 26.

**[0095]** Intermediate and distal jacket sections 22B–22I may be of any suitable length (e.g., distance extending along the direction of central axis 16). In some examples, the

combined length of intermediate and distal jacket sections 22B–22I may be about 10 cm to about 40 cm, in some examples about 20 cm. In some examples, each intermediate jacket section 22B may individually range in length from between about 0 cm to about 25 cm. The choice of length for the different intermediate jacket sections may be dependent in part on the location of the target treatment cite with in the vasculature of a patient. For example, in examples where catheter 10 must navigate particularly tortuous sections of vasculature, the relatively intermediate jacket sections may be sized such that the more flexible jacket sections are the ones passing through the corresponding tortuous confines of the vasculature. In some non-limiting examples, intermediate jacket section 22B may be about 2 to about 10 cm (e.g., about 5 cm), intermediate jacket section 22C may be about 2 cm to about 10 cm (e.g., about 8 cm), intermediate jacket section 22D may be about 0 cm to about 8 cm (e.g., about 6 cm), intermediate jacket section 22E may be about 0 cm to about 6 cm (e.g., about 1 cm), intermediate jacket section 22F may be about 0 cm to about 4 cm (e.g., about 1 cm), intermediate jacket section 22G may be about 1 cm to about 3 cm (e.g., about 1 cm), intermediate jacket section 22H may be about 4 cm to about 30 cm (e.g., about 25 cm), and distal jacket section 22I may be about 0.05 cm to about 1 cm (e.g., about 0.2 cm).

**[0096]** In some examples, at least a portion of an outer surface of outer jacket 22 includes one or more coatings, such as, but not limited to, an anti-thrombogenic coating, which may help reduce the formation of thrombi in vivo, an anti-microbial coating, and/or a lubricating coating. The lubricating coating may be configured to reduce static friction and/ kinetic friction between elongated body 12 and tissue of the patient as elongated body 12 is advanced through the vasculature of the patient. The lubricating coating can be, for example, a hydrophilic coating. In some examples, the entire working length of elongated body 12 (from distal portion 14B of hub 14 to distal end 12B) may be coated with the hydrophilic coating. In other examples, only a portion of the working length of elongated body 12 may be coated with the hydrophilic coating. This may provide a length of elongated body 12 distal to distal end 14B of hub 14 with which the clinician may grip elongated body 12, e.g., to rotate elongated body 12 or push elongated body 12 through the vasculature of the patient.

**[0097]** Due to the construction of elongated body 12, the thickness of the wall of elongated body 12 (measured in a direction orthogonal to longitudinal axis 16) may be relatively thin thereby providing a relatively large inner diameter ("ID" of FIG. 2) for a given outer diameter ("OD" of FIG. 2) of elongated body 12. In some examples, the

thickness of the inner liner along distal liner section 18C (e.g., "$T_L$" of FIG. 2) may be about 0.0005 to about 0.003 inches (e.g., about 12.5 micrometers (μm) to about 76 μm). In some examples, the corresponding thickness of outer jacket 22 (e.g., "$T_S$" of FIG. 2) may be about 0.0015 inches to about 0.005 inches (e.g., about 38 μm to about 127 μm), such as about 0.003 inches, to create a total wall thickness of elongated body 12 within distal portion 17B (e.g., $T_L$+$T_S$) of about 0.003 inches to about 0.006 inches (e.g., about 76 μm to about 152 μm).

**[0098]** The thickness of wall of elongated body 12 can be, for example, the thickness of inner liner 18 plus the thickness of outer jacket 22. In some examples, support element 20 may be embedded within one or both of inner liner 18 or outer jacket 22, such that a thickness of support element 20 does not contribute to the overall thickness of the wall of elongated body 12. However, in other examples, support element 20 may be only be partially embedded within one or both of inner liner 18 or outer jacket 22 or not embedded in inner liner 18 or outer jacket 22, such that a thickness of support element 20 at least partially contributes to the overall thickness of the wall of elongated body 12.

**[0100]** In some examples, due to the construction of elongated body 12, thickness of the wall of elongated body 12 may remain relatively thin while still providing greater flexibility within distal portion 17B and kink resistance compare compared to a catheter having a comparable ID/OD design and formed with a uniform liner material (e.g., a catheter constructed with only a single PTFE liner) and/or uniform outer jacket material. Additionally or alternatively, the construction of elongated body 12 with proximal and distal liner sections 18A, 18C may remain highly pushabile and torqueabile by the clinician compared to a catheter with distal liner section 18C extended along the entire length of elongated body 12.

**[0101]** In some examples, inner liner 18 may have different thickness. For example, proximal liner section 18A may have a thickness of about 0.001 inches (e.g., about 25 μm) and distal liner section 18C may have a thickness of about 0.001 inches to about 0.0015 inches (e.g., about 38 μm). In some examples, increasing the thickness of the liner sections 18 may increase the pushability, stiffness, and/or kink-resistance of the elongated member 12.

**[0102]** The inner diameter (ID) of elongated body 12 will depend on the size of vasculature and chosen size of catheter 10 to be passed through such vasculatures. In some examples, the inner diameter (ID) of catheter 10 as defined by distal liner section 18C (e.g., diameter at distal portion 17B) may be about 0.89 millimeters (mm) to about

2.24 mm. In some examples, the ID formed by distal liner section 18C may be about 2.0 mm (e.g., about 0.080 inches). In some examples, the inner diameter (ID) or elongated body 12 defined by inner liner 18 may vary along the length of elongated body 12.

**[0103]** In some examples, elongate body 12 may include one or more marker bands 28 that may be in the form of a full or partial ring of material more radiopaque than the material forming elongated body 12. In some examples, marker band 28 may include radiopaque materials that allow elongated body 12 (e.g., distal end 12B) to be easily observed by the clinician as catheter 10 is advanced through the vasculature of a patient. Suitable radiopaque materials may include, for example, gold, platinum/iridium alloy, palladium, or the like. In some examples, marker band 28 may be positioned over distal liner section 18C and attached to distal jacket section 22I (e.g., adhered to distal jacket section 22I or inner liner 18, or both, or embedded within distal jacket section 22I). In addition, in some examples, marker band 28 may be positioned over support element 20, such that marker band 28 is positioned between a part of support element 20 and outer jacket 22.

**[0104]** Elongated body 12 has a suitable working length for accessing a target tissue site within the patient from a vascular access point. In some examples the working length of elongated body 12 may be measured from hub distal end 14B of hub 14 (marked by the distal end of optional strain relief body 11) to distal end 12B of elongated body 12 along longitudinal axis 16. The working length of catheter 10 may depend on the location of the target tissue and/or the medical procedure for which catheter 10 is used. For example, if catheter 10 is a distal access catheter or other catheter used to access vasculature in a brain of a patient from a femoral artery access point at the groin of the patient, catheter 10 may have a working length of about 120 cm to about 135 cm, such as about 132 cm, although other lengths may be used. In other examples, or for other applications, the working length of elongated body 12 may have different lengths.

**[0105]** In some examples, elongated body 12 may define an outer diameter taper (e.g., gradient, gradation, segmented gradient or gradation, or the like) along its working length of elongated body 12. An outer diameter (OD) taper may assist with the navigability and/or maneuverability of elongated body 12 through the vasculature of a patient. In some examples, the outer diameter taper may define a continuous transition gradient from an outer diameter of elongated body 12 defined at hub distal end 14B the outer diameter at distal end 12B of elongated body 12. In other examples, the outer diameter of elongated body 12 may define a discontinuous transition (e.g., a gradation or discrete

step-downs) in outer diameter to define the outer diameter taper. The size of each discontinuous transition (e.g., each discrete step-downs) in the outer diameter may be selected to reduce the number of edges/ridges on the outer surface of elongated body 12 that may potentially catch on anatomical features within the vasculature as elongated body 12 is advanced through vasculature.

**[0106]** In some examples, at least a part (e.g., only part of the working length or the entire working length) of elongated body 12 may define a constant outer diameter. In such examples, support element 20 of elongated body 12 may be configured to provide sufficient support to elongated body 12 to allow the outer diameter of the elongate body 12 to remain relatively small along the length of elongated body 12 to facilitate distal flexibility about distal portion 17B while still retaining sufficient strength an pushability about proximal portion 17A. Additionally, or alternatively, a relatively small outer diameter (OD) of elongated body 12 may allow for easier to navigability of the catheter 10 through tortuous vasculature of a patient. In addition, the relatively large inner diameter (ID) of the elongated body 12 may provide for more efficient and/or more effective aspiration of thrombus from the vasculature compared to catheter bodies having smaller inner diameters, e.g., due to a larger aspiration force that can be applied to the catheter, due to the larger catheter inner lumen for receiving the thrombus, or both. In addition to, or instead of, providing benefits when used to aspirate a thrombus from the vasculature, the relatively large inner diameter (ID) for a given outer diameter (OD) may accommodate a larger range of medical devices and a larger range of fluid volumes. Thus, the thin-walled elongated body 12 defining a relatively large inner diameter (ID) for a given outer diameter (OD) may be used with a larger range of medical procedures.

**[0107]** In some examples, by maintaining a relatively small outer diameter (OD) of elongated body 12 at distal portion 17B, which leads elongated body 12 through vasculature, elongated body 12 may better traverse through tortuous vasculature with still maintaining a relatively high level of proximal pushability due to support element 20.

**[0108]** In some examples, proximal portion 17A of elongated body 12 may define a relatively large outer diameter to provide better proximal support for elongated body 12, which may help increase the navigability and maneuverability of elongated body 12 through the vasculature of a patient. In some cases, proximal portion 17A may not be introduced into low profile or tortuous arteries, such that the cross-sectional size of proximal portion 17A may be increased in favor of proximal support without adversely affecting the ability of elongated body 12 to reach relatively distal tissue sites.

**[0109]** In some examples, the outer diameter of elongated body 12 may taper from about 6 French (e.g., 6 French or nearly 6 French) at proximal end 12A to about 5 French (e.g., 5 French or nearly 5 French) at the distal portion 17B. In other examples, the outer diameter of elongated body 12 may taper from about 4 French (e.g., 4 French or nearly 4 French) at proximal end 12A to about 5 French (e.g., 3 French or nearly 3 French) at the distal portion 17B. In other examples, the outer diameter of elongated body 12 may remain substantially constant (e.g., constant or nearly constant) in the range of about 3 French to about 6 French. In some examples, the outer diameter of elongated body 12 may be larger than 6 French, for example 8 French. The measurement term French, abbreviated Fr or F, is three times the diameter of a device as measured in millimeters (mm). Thus, an 8 French diameter is about 2.67 mm, a 6 French diameter is about 2 mm, a 5 French diameter is about 1.67 mm, a 4 French diameter is about 1.33 mm, and a 3 French diameter is about 1 mm. In some examples, the outer diameter of elongated body 12 may be between about 1 mm to about 2.67 mm.

**[0110]** In some examples, catheter 10 may be advanced to a target location within vasculature of the patient in cooperation with a guide member (not shown) such as a guidewire, an inner catheter, both a guidewire and an inner catheter, or the like, which may aid in the navigation (e.g., steering and manipulation) of elongated body 12 through the vasculature. For example, at least part of inner lumen 24 of elongated body 12 may be configured to receive a guide member or an inner catheter, such that elongated body 12 may be guided through vasculature over the guide member or the inner catheter. In some examples, the design of distal portion 17B of elongated body 12 (e.g., the region defined by distal opening 13) may be configured to resist geometric deformation (e.g., kinking, ovalization, or the like) from forces applied to the distal tip by the guidewire or inner catheter. This resistance to geometric deformation may help improve the ease with which elongated body 12 may be guided to a relatively distal tissue site, e.g., through relatively tight turns in the vasculature and/or the responsiveness of catheter 10 as a clinician guides the distal tip of elongated body 12 through the vasculature of a patient.

**[0111]** In some examples, elongated body 12 may include a tie-layer (not shown) disposed between inner liner 18 and outer jacket 22 configured to help bind the two layers together. The tie-layer may include polymeric materials with good binding capabilities including, for example, thermoplastic polyurethanes such as Pellethane® 2363-80A.

**[0112]** FIG. 3 is a conceptual axial cross-sectional view of another example of a distal portion 32 of an example catheter 30 (e.g., distal portion 17B of catheter 10). The distal

portion of catheter 30 includes an inner liner 34 that include a proximal liner section 34A and distal liner section 34B, a support element 38, and an outer jacket 36 that includes a proximal jacket section 36A, intermediate jacket sections 36B–36F, and a distal jacket section 36G, and a marker band 39 embedded within or located beneath distal jacket section 36G.

**[0113]** In some examples, support element 38 may include a support structure similar to support element 20 described above. For example, support element 38 may include a single round wire coil as shown in FIG. 3, a wire braid, or a combination of both. For example, support element 38 may include a singular wire coil comprising 0.002 inch stainless steel round wires. In other examples, support element 38 may include a flat wire braid comprising 16 0.001 x 0.002 inch stainless steel flat wires. In other examples, support element 38 may include a flat wire braid comprising 8 0.0005 x 0.002 inch stainless steel flat wires positioned over 0.0015 inch stainless steel round wire coil.

**[0114]** As described above, distal liner section 34B may define a lower relative hardness compared to proximal liner section 34A to provide greater flexibility within the distal portion 32 of catheter 30. In some examples, proximal liner section 34A may include PTFE and distal liner section 34B may include a thermoplastic elastomer (e.g., polyolefin elastomer ethylene butane such as Engage™ 7270) and slip agent (e.g., 5 wt.% Ampacet 100329). In some examples, distal liner section 34B may define an overall axial length of about 10 cm to about 20 cm, for example between about 16.5 cm to about 17.5 cm.

**[0115]** Outer jacket 36 may define a hardness gradient extending that decreases from proximal jacket section 36A to distal most intermediate jacket section 36F. In some examples, proximal jacket section 36A may include polyamides (e.g., Grilamid® TR 55) having a Shore D hardness of about 85D extending to the proximal end of the elongated body, intermediate jacket section 36B may include a polyether block amide (e.g., Pebax® 72D) having a Shore D hardness of about 72 and an axial length of about 8.2 cm, intermediate jacket section 36C may include a polyether block amide (e.g., Pebax® 63D) having a Shore D hardness of about 63 and an axial length of about 4.1 cm, intermediate jacket section 36D may include a polyether block amide (e.g., Pebax® 55D) having a Shore D hardness of about 55 and an axial length of about 6.1 cm, intermediate jacket section 36E may include a polyether block amide (e.g., Pebax® 40D) having a Shore D hardness of about 40 and an axial length of about 5.8 cm, intermediate jacket section 36F may include a polyether block amide (e.g., Pebax® 25D) having a Shore D hardness of about 25 and an axial length of about 14.9 cm, and distal jacket section 36G may include

a polyolefin elastomer (e.g., Engage™ 7270) having a Shore D hardness of about 26 and axial length of about 0.2 cm.

**[0116]** The catheters described herein can be formed using any suitable technique. FIG. 4 is a flow diagram of an example method of forming a catheter as described herein. The technique of FIG. 4 is described with respect to catheter 10 of FIG. 1 however the techniques may be used to form other catheters or the catheters described herein (e.g., catheters 10, 30) may be formed using techniques other than those describe in FIG. 4.

**[0117]** In accordance with the technique shown in FIG. 4, inner liner 18 (e.g., proximal, intermediate, and distal liner sections 18A, 18B, 18C) may be positioned over mandrel (40). The respective sections of inner liner 18 may be fabricated using any suitable technique. In some examples, the respective sections of inner liner 18 may be formed using an extrusion process in which the polymeric materials and, if applicable, slip agent, are mechanically mixed together and heated to the melting point of the underlying polymeric material and passed through a tubular extrusion process to form a tubular body having the desire thickness and diameter profiles. In some examples, the respective sections of inner liner 18 (e.g., proximal, intermediate, and distal liner sections 18A, 18B, 18B) may be positioned over a mandrel followed by being subsequently joined together (e.g., fused).

**[0118]** As discussed above, in some examples, elongated body 12 may taper from proximal portion 17A (FIG. 1) having a first outer diameter to distal portion 17B having a second outer diameter. In these examples, the mandrel may define a corresponding change in outer diameter and the respective sections of inner liner 18 may be approximately sized to exhibit the changes in diameter. In other examples, inner and outer diameters of elongated body 12 may remain substantially constant (e.g., constant or nearly constant). In such examples, the mandrel may define a substantially constant diameter.

**[0119]** In some examples, after positioning inner liner 18 over the mandrel, inner liner 18 may be heat shrunk onto the mandrel such that inner liner 18 conforms to the outer surface of the mandrel and acquire the tapered profile (if applicable) of the mandrel. In such examples, the respective sections of inner liner 18 may be sized such that the inner diameter of the respective liner sections 18 as slightly oversized to facilitate placement of the liner sections on the mandrel prior to the heat shrink process. In other examples, however, heat shrinking may not be necessary. For example, in addition to, or instead of, heat shrinking, the respective sections of inner liner 18 may be longitudinally stretched

over the mandrel in order to substantially conform to the outer surface of the mandrel. In either example, inner liner 18 may define a constant inner diameter or may have different inner diameters, e.g., corresponding to the outer diameters defined by the mandrel.

**[0120]** After positioning inner liner 18 over a mandrel, at least one support element 20 may be positioned over inner liner 18 (42). The at least one support element may include one or more of a wire coil, wire braid, or combinations thereof. In some examples, support element 20 may include a wire braid that includes four round wires 20A (e.g., 0.001 inch round wires) woven against four flat wires 20B (e.g., 0.001 x 0.002 inch flat wires), such that the respective round wires 20A are not cross woven against each other and the respective flat wires 20B are likewise not cross woven against each other. For example, the braided support element 20 is woven such that a single round wire 20A does not cross the other three round wires.

**[0121]** In some examples, the structural configuration of support element 20 may be at least partially defined prior to being positioned over inner liner 18. For example, a shape memory wire (e.g., NiTi alloy) or a wire of an otherwise heat-settable metal, alloy, or polymer base may be wound over a different mandrel where the wires are heat set to define at least one of the desired pitch, spacing, wind diameter, tapering profile, or length of support element 20.

**[0122]** After being heat set, the one or more wires of support element 20 may then be subsequently unwound from the mandrel onto a reel or a bobbin (not shown), and then re-wound/woven over inner liner 18. In some examples, defining some or all of the structural characteristics of support element 20 prior to positioning support element 20 over inner liner 18 may help control the structural characteristics of support element 20 (e.g., gap spacings, pitch, etc.), as well as control product consistency and uniformity of the support element 20 used in multiple catheters. In addition, shape-setting wires of support element 20 on a separate, heat-resistant mandrel enables the construction of the elongated body 12 using the support element 20 on a mandrel made of, for example, PTFE or other lubricious, non-heat resistant materials.

**[0123]** Support element 20 may be secured in place relative to inner liner 18 using any suitable technique. For example, support element 20 may be adhered to inner liner 18. In some examples, an adhesive may be positioned over inner liner 18 prior to positioning support element 20 over inner liner 18. In addition to, or instead of, an adhesive, outer jacket 22 may be used to secure support element 20 to inner liner 18. In examples in which support element 20 includes a cut hypotube, the hypotube may be defined to have a

diameter less than the outer diameter of inner liner 18. As the hypotube is positioned on inner liner 18, the diameter of the hypotube may be expanded thereby creating a gap between adjacent turns of the hypotube, which may receive one or more other coil members in the created spacing.

**[0124]** In some examples, in addition to positioning support element 20 over inner liner 18, one or more optional marker bands 28 may be positioned over inner liner 18. In some examples, marker band 28 may be positioned over distal liner section 18C in close proximity to distal end 12B of elongated body 12 to assist with the positioning of distal end 12B within the vasculature of a patient. In addition, one or more marker bands 28 can be adhered to inner liner 18, outer jacket 22, or both inner liner 18 and outer jacket 22, or may be held in place within elongated body 12 because of being positioned between inner liner 18 and outer jacket 22.

**[0125]** In the technique of FIG. 4 also includes positioning outer jacket 22 over support element 20 (44), including any optional marker bands 28, and inner liner 18. In some examples, the various sections of outer jacket 22 (e.g., proximal jacket section 22A, intermediate jacket sections 22B–22H, and distal jacket section 22I) may independently formed (e.g., extruded) and slid over inner liner 18 and support element 20 in the desired arrangement. The various sections of outer jacket 22 may then be heat-shrunk onto inner liner 18 and support element 20. In some examples, the heat shrinking of outer jacket 22 may help secure the respective positions of support element 20 along elongated body 12. This may help minimize the wall thickness of elongated body 12 and, therefore, increase the inner diameter of elongated body 12 for a given outer diameter by limiting the inclusion of addition layer within the wall construction of elongated body 12. In addition, the absence of additional layers (e.g., an adhesive/tie layer) that joins inner liner 18 to outer jacket 22 may contribute to an increased flexibility of catheter 10. In some examples, during the heat-shrink process, the various sections of outer jacket 22 may also be bonded (e.g., fused) together.

**[0126]** In some examples, the various sections outer jacket 22 may be adhered to an outer surface of support element 20 using, for example, an adhesive/polymer that may be applied to outer surface of support element 20 prior to positioning outer jacket 22 over support element 20 and then cured after outer jacket 22 is positioned. Additionally or alternatively, the outer surface of inner liner 18 may be initially etched (e.g., chemically or mechanically roughened) to improve the bonding our inner liner 18 to outer jacket 22.

**[0127]** Once elongated body 12 is formed, hub 14 may be attached to proximal end 14A of elongated body 12 using any suitable technique, such as an adhesive, fusing, or any combination thereof.

**[0128]** In some examples, catheter 10 may be a part of an assembly that includes, e.g., a guide member. The guide member may be used to guide catheter 10 to a target tissue site within the vasculature of a patient. In some examples, a method of using catheter 10 comprises introducing a guide member or an inner catheter into vasculature (e.g., an intracranial blood vessel) of a patient via an access point (e.g., a femoral artery), and guiding elongated body 12 over the guide member. Once distal end 12B of elongated body 12 is positioned at the target tissue site, which may be proximal to thromboembolic material (e.g., a thrombus), the thromboembolic material be removed from the vasculature via elongated body 12. For example, the thromboembolic material may be aspirated from the vasculature by at least applying a vacuum force to inner lumen 24 of elongated body 12 via hub 14 (and/or proximal end 12A), which may cause the thromboembolic material to be introduced into inner lumen 24 via distal opening 13. Optionally, the vacuum or aspiration can be continued to thereby draw the thromboembolic material proximally along the inner lumen 24, all or part of the way to the proximal end 12A or hub 14.

**[0129]** As another example, the thromboembolic material may be removed from the vasculature using another technique, such as via an endovascular retrieval device delivered through the inner lumen 24 of the elongated body 12. In such a method the elongated body 12 can be inserted into the vasculature (for example using any technique disclosed herein) and the retrieval device advanced through the inner lumen 24 (or through another catheter, such as a microcatheter, inserted into the vasculature through the inner lumen 24) so that the device engages the thromboembolic material. The retrieval device and the material engaged thereby (together with any other catheter or microcatheter) can then be retracted into the inner lumen 24 and removed from the patient. Optionally, aspiration can be performed with or through the elongated body 12 during retraction of the retrieval device and thromboembolic material into the elongated body 12. The vasculature can comprise the neurovasculature, peripheral vasculature or cardiovasculature. The thromboembolic material may be located using any suitable technique, such as fluoroscopy, intravascular ultrasound or carotid Doppler imaging techniques.

**[0130]** Various examples have been described. These and other examples are within the scope of the following claims.

**WHAT IS CLAIMED IS:**

1. A catheter comprising:

an elongated body including proximal and distal portions, the distal portion of the elongated body comprising:

an inner liner comprising a proximal liner section and a distal liner section comprising different materials, wherein the distal liner section has a first hardness less than a second hardness of the proximal liner section; and

an outer jacket positioned over the inner liner.

2. The catheter of claim 1, further comprising a support element positioned between the inner liner and the outer jacket.

3. The catheter of claim 2, wherein the support element comprises a braided structure comprising at least two strands of different diameters.

4. The catheter of claim 3, wherein the braided structure comprises at least one flat or half-round wire and at least one round wire.

5. The catheter of claim 4, wherein the braided structure comprises four flat or half-round wires woven against four round wires.

6. The catheter of any of claims 2 to 5, wherein the support element is embedded in at least one of the inner liner or the outer jacket.

7. The catheter of any of claims 2 to 6, wherein the support element comprises at least one of a metal braid or a metal coil.

8. The catheter of any of claims 1 to 7, wherein the distal liner section comprises a thermoplastic elastomer.

9. The catheter of any of claims 1 to 8, wherein the distal liner section further comprises a slip agent.

10. The catheter of claim 9, wherein the slip agent comprises an amide derived from a monosaturated fatty acid and is mixed with the polyolefin elastomer in an amount of about 0.5 weight percent (wt.%).

11. The catheter of any of claims 1 to 10, wherein the proximal liner section comprises a fluoropolymer.

12. The catheter of any of claims 1 to 11, wherein the distal liner section comprises a polyolefin elastomer and a slip agent, and the proximal liner section comprises polytetrafluoroethylene (PTFE).

13. The catheter of any of claims 1 to 12, wherein the proximal liner section extends to a proximal end of the elongated body.

14. The catheter of any of claims 1 to 13, wherein the inner liner further comprises an intermediate liner section defining a hardness less than that of the proximal liner section and greater than the distal liner section.

15. The catheter of claim 14, wherein the intermediate liner section comprises a polyolefin elastomer and a slip agent.

16. The catheter of claim 14 or 15, wherein the intermediate liner section and the distal liner section collectively define an axial length of at least about 0.2 cm extending along a central axis of the elongated body.

17. The catheter of any of claims 1 to 16, wherein the distal liner section is less lubricious than the proximal liner section.

18. The catheter of any of claims 1 to 17, wherein the distal liner section comprises a radial thickness of about 0.0015 inches (about 38 micrometers).

19. The catheter of any of claims 1 to 18, wherein the distal liner section defines a lumen having a diameter of about 0.89 mm to about 2.24 mm.

20. The catheter of any of claims 1 to 19, further comprising a radiopaque marker band disposed over the distal liner section.

21. The catheter of any of claims 1 to 20, wherein the outer jacket comprises a proximal jacket section and a distal jacket section, the proximal jacket section having a greater hardness than the distal jacket section.

22. The catheter of claim 21, further comprising a plurality of intermediate jacket sections positioned between the proximal jacket section and the distal jacket section, wherein the outer jacket defines a hardness gradient of decreasing hardness moving distally from the proximal jacket section to a distal most intermediate jacket section of the plurality of intermediate jacket sections.

23. The catheter of claim 22, wherein the proximal jacket section and the plurality of intermediate jacket sections together define sequential sections of different hardnesses.

24. The catheter of claim 22 or 23, wherein the proximal jacket section defines a Shore D hardness of about 63–85.

25. The catheter of any of claims 22 to 24, wherein the plurality of intermediate jacket sections comprises:

at least one jacket section comprising a polyether block amide;

at least one jacket section comprising a polyolefin elastomer; and

at least one jacket section comprising a polyurethane elastomer.

26. The catheter of any of claims 22 to 25, wherein the hardness gradient region transitions from a Shore D hardness of about 72 to a Shore A hardness of about 30.

27. The catheter of claim 26, wherein the plurality of intermediate jacket sections comprises at least four intermediate jacket sections.

28. The catheter of claim 27, wherein the distal most intermediate jacket section comprises a polyurethane elastomer, and a proximal most intermediate jacket section comprises a polyether block amide.

29. The catheter of any of claims 22 to 28, wherein the distal jacket section defines a harness between about a Shore A hardness of 30 and about a Shore D hardness of 55.

30. The catheter of any of claims 22 to 29, wherein the proximal jacket section comprises a polyamide and the distal jacket section comprises a polyolefin elastomer.

31. The catheter of any of claims 1 to 30, wherein the distal portion of the elongated body defines a wall thickness of less than about 0.15 mm.

32. The catheter of any of claims 1 to 31, further comprising a tie layer positioned between the inner liner and the outer jacket.

33. The catheter of claim 32, further comprising a support element positioned over the tie layer.

34. A method of forming an elongated body of a catheter, the method comprising:

positioning an inner liner over a mandrel, wherein the inner liner comprises a proximal liner section and a distal liner section comprising different materials, wherein the distal liner section has a first hardness less than a second hardness of the proximal liner section; and

positioning an outer jacket over the inner liner.

35. The method of claim 34, further comprising forming the inner liner, wherein forming the inner liner comprises:

extruding a mixture comprising a first polyolefin elastomer and a slip agent to from the distal liner section; and

bonding the distal liner section to the proximal liner section to form the inner liner.

36. The method of claim 34, further comprising forming the inner liner, wherein forming the inner liner comprises:

extruding a mixture comprising a first polyolefin elastomer and a slip agent to from the distal liner section; and

extruding a mixture comprising a second polyolefin elastomer to form an intermediate liner section; and

bonding a first end of the intermediate liner section to the proximal liner section and a second end of the intermediate liner section to the distal liner section to form the inner liner.

37. The method of any of claims 34 to 36, further comprising positioning a support element over the inner liner, wherein the support element comprises at least one of a wire braid or a wire coil.

38. The method of claim 37, wherein positioning the support element comprises weaving or wrapping a plurality of metal wires over the inner liner while the inner liner is on the mandrel, wherein the plurality of metal wires at least two wires of different diameters.

39. The method of claim 37 of 38, wherein positioning the support element comprises weaving four flat or half-round wires against four round wires to form the wire braid.

40. The method of any of claims 37 to 39, further comprising heat setting the support element on a mandrel prior to positioning the support element over the inner liner.

41. The method of any of claims 34 to 40, further comprising positioning a radiopaque marker over the distal liner section prior to positioning the outer jacket over the inner liner and the support element.

42. The method of any of claims 34 to 41, wherein positioning the outer jacket over the inner liner comprises:

positioning a proximal jacket section over the inner liner; and

positioning a plurality of intermediate jacket sections over the inner liner,

wherein the outer jacket defines a hardness gradient of decreasing hardness moving distally from the proximal jacket section to a distal most intermediate jacket section of the plurality of intermediate jacket sections.

43. The method of claim 42, wherein positioning the outer jacket over the inner liner further comprises:

positioning a distal jacket section over the inner liner, wherein the outer jacket includes a sequential arrangement of the proximal jacket section, the plurality of intermediate jacket sections, and the distal jacket section; and

bonding contacting portions of the proximal jacket section, the plurality of intermediate jacket sections, and the distal jacket section to one another.

44. The method of claim 43, wherein the distal jacket section defines a hardness that is greater than that of the distal most intermediate jacket section.

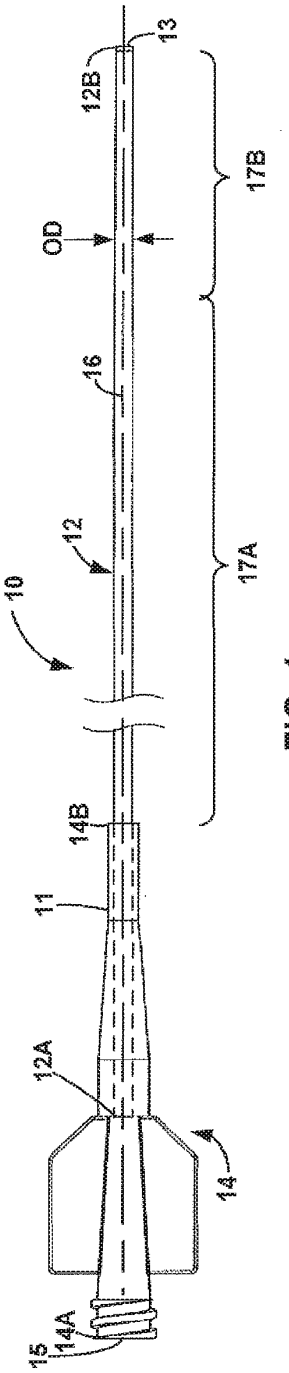

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12B
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FIG. 1

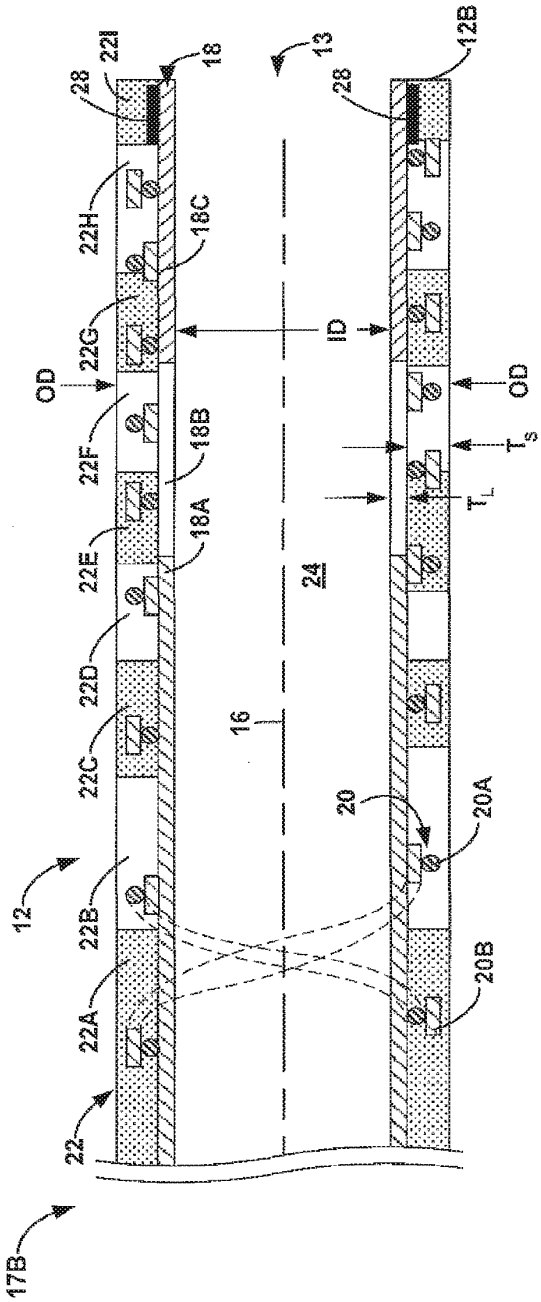

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22
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FIG. 2

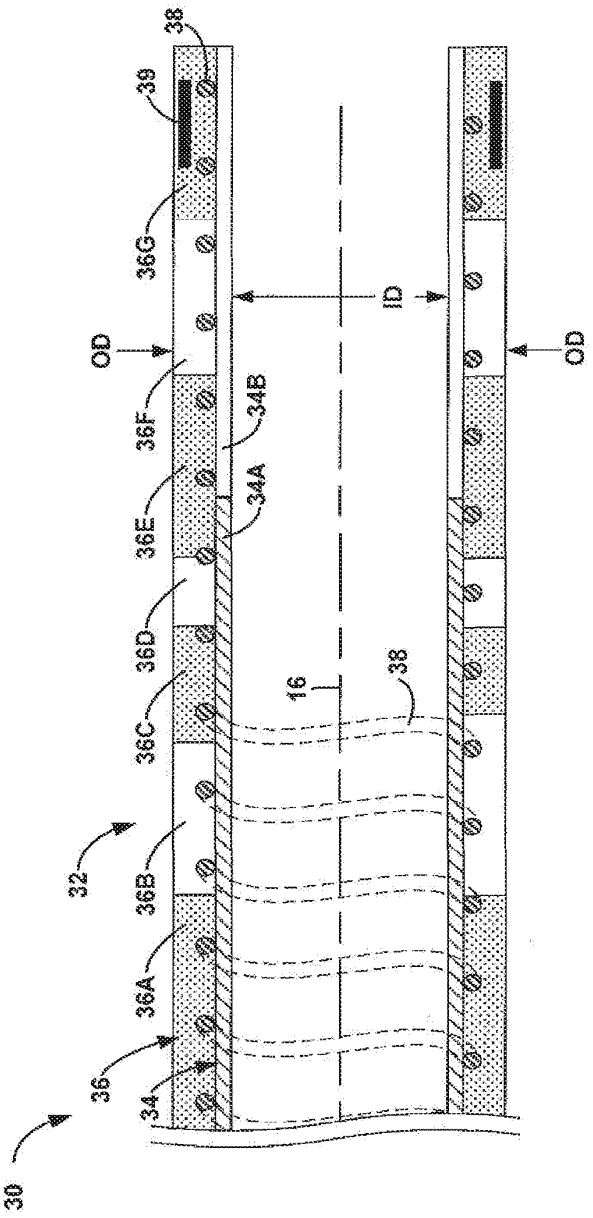



FIG. 3

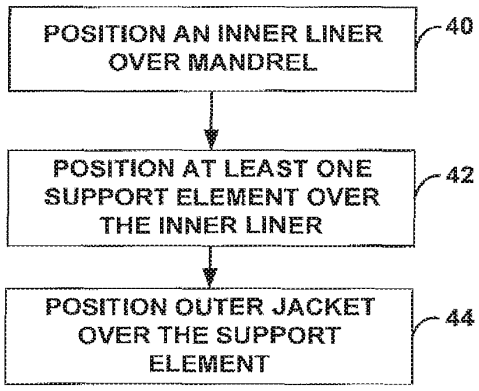

POSITION AN INNER LINER OVER MANDREL
40
POSITION AT LEAST ONE SUPPORT ELEMENT OVER THE INNER LINER
42
POSITION OUTER JACKET OVER THE SUPPORT ELEMENT
44

FIG. 4

# INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/020410

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/00
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | WO 03/004085 A2 (SCIMED LIFE SYSTEMS INC [US]) 16 January 2003 (2003-01-16) page 2, line 11 - page 4, line 27; figures 1, 4A | 1-44 |
| X | WO 2017/004194 A1 (BOSTON SCIENT SCIMED INC [US]) 5 January 2017 (2017-01-05) paragraphs [0046] - [0049]; figure 3 | 1-44 |
| X | WO 2007/050718 A1 (BOSTON SCIENT SCIMED INC [US]; GRIFFIN STEPHEN [US]; LIM ELAINE [US];) 3 May 2007 (2007-05-03) page 10, line 6 - page 11, line 12; figure 3 | 1-44 |
| X | US 6 622 367 B1 (BOLDUC LEE R [US] ET AL) 23 September 2003 (2003-09-23) column 22, line 45 - column 23, line 64; figure 31 | 1-44 |

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

☒ See patent family annex.

* Special categories of cited documents :

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"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

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| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 31 July 2018 | 07/08/2018 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Dydenko, Igor |

1

Form PCT/ISA/210 (second sheet) (April 2005)

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2018/020410

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| WO 03004085 A2 | 16-01-2003 | AT 518558 T | 15-08-2011 |
| | | CA 2452570 A1 | 16-01-2003 |
| | | EP 1401525 A2 | 31-03-2004 |
| | | JP 4667745 B2 | 13-04-2011 |
| | | JP 2005527244 A | 15-09-2005 |
| | | US 2003009150 A1 | 09-01-2003 |
| | | WO 03004085 A2 | 16-01-2003 |
| WO 2017004194 A1 | 05-01-2017 | EP 3297717 A1 | 28-03-2018 |
| | | US 2017000977 A1 | 05-01-2017 |
| | | WO 2017004194 A1 | 05-01-2017 |
| WO 2007050718 A1 | 03-05-2007 | AT 517651 T | 15-08-2011 |
| | | EP 1940498 A1 | 09-07-2008 |
| | | US 2007100285 A1 | 03-05-2007 |
| | | US 2011082443 A1 | 07-04-2011 |
| | | US 2013046285 A1 | 21-02-2013 |
| | | WO 2007050718 A1 | 03-05-2007 |
| US 6622367 B1 | 23-09-2003 | US 6622367 B1 | 23-09-2003 |
| | | US 2004103516 A1 | 03-06-2004 |
| | | US 2005245897 A1 | 03-11-2005 |

Form PCT/ISA/210 (patent family annex) (April 2005)

(19) Europäisches Patentamt
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(11) EP 3 620 204 A1

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*A61M 25/06* *(2006.01)*

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(30) Priority: **04.02.2015 US 201562111841 P**
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(62) Document number(s) of the earlier application(s) in accordance with Art. 76 EPC:
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## (54) RAPID ASPIRATION THROMBECTOMY SYSTEM

(57) There is provided a dilator (1340) for facilitation of intraluminal medical procedures within the neurovasculature. The dilator (1340) comprises a flexible distal dilator portion (1360) having a proximal end region and a distal end region having a distal tapered tip (1346), a single lumen, and an outer diameter, wherein the single lumen extends longitudinally through the dilator portion to a distal opening at the distal tapered tip (1346). The dilator (1340) further comprises a spine (1362) extending proximally from the proximal end region of the dilator portion (1360), wherein the spine (1362) is made of a different material than the dilator portion (1360) and has a single lumen that communicates with the single lumen of the dilator portion (1360).

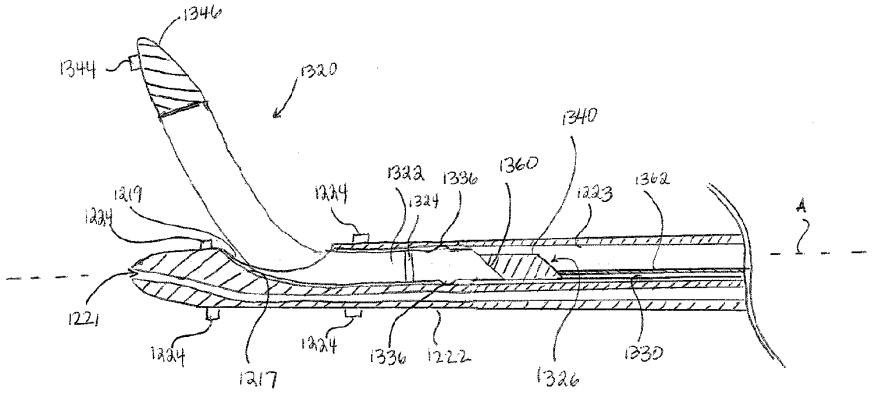



Fig. 12C

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## Description

### CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This application claims priority to U.S. Provisional Application Serial No. 62/111,481, filed February 4, 2015, and U.S. Provisional Application Serial No. 62/142,637, filed April 3, 2015.

**[0002]** This application is also related to the following U.S. Patent Applications: (1) US Patent Application Serial Number 14/576,953, filed December 19, 2014; and (2) US Patent Application Serial Number 14/569,365, filed December 12, 2014; (3) US Patent Application Serial Number 14/537,316, filed November 10, 2014; (4) US Patent Application Serial Number 14/221,917, filed March 21, 2014.

### BACKGROUND

**[0003]** The present disclosure relates generally to medical methods and devices for the treatment of acute ischemic stroke. More particularly, the present disclosure relates to methods and systems for navigating complex anatomy to perform rapid and safe aspiration and removal of cerebral occlusions.

**[0004]** Acute ischemic stroke is the sudden blockage of adequate blood flow to a section of the brain, usually caused by thrombus or other emboli lodging or forming in one of the blood vessels supplying the brain. If this blockage is not quickly resolved, the ischemia may lead to permanent neurologic deficit or death. The timeframe for effective treatment of stroke is within 3 hours for intravenous (IV) thrombolytic therapy and 6 hours for site-directed intra-arterial thrombolytic therapy or up to 8 hours for interventional recanalization of a blocked cerebral artery. Re-perfusing the ischemic brain after this time period has no overall benefit to the patient, and may in fact cause harm due to the increased risk of intracranial hemorrhage from fibrinolytic use. Even within this time period, there is strong evidence that the shorter the time period between onset of symptoms and treatment, the better the results. Unfortunately, the ability to recognize symptoms, deliver patients to stroke treatment sites, and finally to treat these patients within this timeframe is rare. Despite treatment advances, stroke remains the third leading cause of death and the leading cause of serious, long-term disability in the United States.

**[0005]** Endovascular treatment of acute stroke is comprised of either the intra-arterial administration of thrombolytic drugs such as recombinant tissue plasminogen activator (rtPA), mechanical removal of the blockage, or a combination of the two. As mentioned above, these interventional treatments must occur within hours of the onset of symptoms. Both intra-arterial (IA) thrombolytic therapy and interventional thrombectomy involve accessing the blocked cerebral artery via endovascular techniques and devices.

**[0006]** Like IV thrombolytic therapy, IA thrombolytic therapy alone has the limitation in that it may take several hours of infusion to effectively dissolve the clot. Interventional thrombectomy therapies have involved capturing and removing the clot using snares, coils or temporary stents (also known as retrievable stent devices), and suctioning the clot with or without adjunct disruption of the clot. Retrievable stent devices are also utilized to restore flow quickly to the vessel during the intervention. Hybrid procedures are also utilized, combining retrievable stent devices and aspiration via the guide catheter or via intermediate catheters to aid in the removal of the clot and reduce the risk of distal emboli. Finally, balloons or stents have been used to create a patent lumen through the clot when clot removal or dissolution was not possible.

**[0007]** To access the cerebral anatomy, guide catheters or guide sheaths are used to guide interventional devices to the target anatomy from an arterial access site, typically the femoral artery. Balloon guide catheters are often used to enable proximal carotid artery occlusion during periods of the procedure which may potentially liberate a high level of emboli. The proximal occlusion has the effect of arresting forward flow and increasing aspiration efficiency through the lumen of the guide catheter. The length of the guide is determined by the distance between the access site and the desired location of the guide distal tip. Interventional devices such as guidewires, microcatheters, and intermediate catheters used for sub-selective guides and aspiration, are inserted through the guide and advanced to the target site. Often, devices are used in a co-axial fashion, namely, a guidewire inside a microcatheter inside an intermediate catheter is advanced as an assembly to the target site in a stepwise fashion with the inner, most atraumatic elements, advancing distally first and providing support for advancement of the outer elements. The length of each element of the coaxial assemblage takes into account the length of the guide, the length of proximal connectors on the catheters, and the length needed to extend from the distal end. Thus, for example, the working length of an intermediate catheter is typically 20-40 cm longer than the working length of a guide, and the working length of a microcatheter is typically 10-30 cm longer than the working length of the intermediate catheter. The guidewire is typically longer than the microcatheter by another 20-50 cm.

**[0008]** Some exemplary issues with current technology include the time required or even the ability to access the site of the occlusion, the time required to restore flow or the inability to fully, or even partially, restore flow to the vessel, the occurrence of distal emboli during the procedure, which has potentially negative neurologic effect and procedural complications such as perforation and intracerebral hemorrhage. There is a need for a system of devices and methods that enable rapid access, optimized aspiration of the clot, distal protection throughout all stages of the procedure, which potentially liberate emboli, and safe and rapid exchange of devices as needed to fully restore flow to the blocked cerebral vessel.

## SUMMARY

**[0009]** In one aspect, there is disclosed an intravascular access system for facilitation of intraluminal medical procedures within the neurovasculature through an access sheath. The system includes an aspiration or support catheter having a flexible, distal luminal portion having an inner diameter defining a lumen extending between a proximal opening at a proximal end of the luminal portion and a distal opening at a distal end of the luminal portion. The catheter has a rigid spine coupled to at least the proximal end of the luminal portion and extending proximally therefrom. The system includes a dilator having a flexible, distal dilator portion sized to be received within the lumen of the luminal portion; and a rigid, dilator spine extending proximally from the dilator portion.

**[0010]** The dilator spine can align side-by-side with the spine of the catheter. The distal dilator portion can have a tapered distal tip. The dilator can have a length at least as long as a length of the catheter such that a distal tip of the dilator protrudes from the distal opening of the luminal portion. The dilator can be generally tubular along at least a portion of the length. A proximal end of the catheter spine can include a gripping feature configured for a user to grasp in order to move the catheter through an access sheath. A proximal end of the dilator spine can include a tab configured to be locked with the gripping feature on the catheter spine. When the catheter and the dilator are in a locked configuration they can be advanced as a single unit through the access sheath. The gripping feature and the dilator tab can be removably coupled such that in a locked configuration the dilator tab engages the gripping feature and in an unlocked configuration the dilator tab disengages from the gripping feature. The dilator tab can be affixed to the dilator or can be slideable on the dilator to accommodate different relative positions between the dilator and the catheter. The distal dilator portion can include one or more detents on an outer surface configured to lock with correspondingly-shaped surface features on an inner surface of the luminal portion lumen through which the dilator portion extends. The dilator spine and the catheter spine can have a similar stiffness and kink-resistance. The dilator can have a visual marker on a distal end and/or a proximal end of the distal tip. A distal end region of the dilator can be more flexible and increasingly stiffen towards a proximal end region of the dilator. The catheter spine and dilator spine can be configured to cause bi-directional sliding movement of the luminal portion through a lumen of an access sheath and navigate the luminal portion into a cerebral vessel to reach a treatment site.

**[0011]** In an interrelated aspect, disclosed is an intravascular access system for facilitation of intraluminal medical procedures within the neurovasculature having an access sheath and an aspiration or support catheter. The access sheath has a sheath body having an inner diameter defining a lumen between a proximal end and a distal end of the sheath body. The sheath body has at least one opening from the lumen near a distal end region of the sheath body. The aspiration or support catheter includes a flexible, distal luminal portion having an outer diameter sized for insertion through the lumen of the access sheath, an inner diameter defining a lumen extending between a proximal opening at a proximal end of the luminal portion and a distal opening at a distal end of the luminal portion, and a length between the proximal opening and the distal opening. The aspiration or support catheter includes a rigid spine coupled to at least the proximal end of the luminal portion and extending proximally therefrom. The rigid spine is configured to cause bi-directional sliding movement of the luminal portion through the lumen of the access sheath and out the at least one opening to navigate the luminal portion into a cerebral vessel to reach a treatment site. A portion of the outer diameter of the luminal portion fluidly seals with the inner diameter of the access sheath when the distal end of the luminal portion extends into the cerebral vessel to reach the treatment site.

**[0012]** The luminal portion and the sheath body can be concentrically aligned and the lumen of the luminal portion and the lumen of the sheath body form a contiguous aspiration lumen from the distal end of the luminal portion to the proximal end of the sheath body. The contiguous aspiration lumen can be used to aspirate fluid and debris from the distal opening of the luminal portion. The contiguous aspiration lumen can be to deliver materials through the distal opening of the luminal portion. The contiguous aspiration lumen can form a step-up in diameter where the lumen of the luminal portion empties into the lumen of the sheath body. The lumen of the luminal portion can be shorter than the lumen of the sheath body. The luminal portion and the sheath body can form an overlap region when the luminal portion extends distally beyond the at least one opening of the sheath body. The outer diameter of the luminal portion can approach the inner diameter of the lumen of the sheath body such that a seal is formed by the overlap region. The seal can be configured to enable sealing against a vacuum of up to 25 inHg, or up to 28 inHg. The seal within the overlap region can be configured to enable sealing against a pressure of up to 300 mmHg or up to 600 or up to 700 mmHg. The seal can be located distal a proximal end of the luminal portion and proximal to the at least one opening of the sheath body.

**[0013]** The system can further include a sealing element positioned on an external surface of the luminal portion. The sealing element can include a stepped up diameter or protruding feature in the overlap region. The sealing element can include one or more external ridge features. The one or more ridge features can be compressible when the luminal portion is inserted into the lumen of the sheath body. The sealing element can include one or more inclined surfaces biased against an inner surface of the sheath body lumen. The sealing element can include one or more expandable members actuated to seal. The sheath body can have an outer

diameter suitable for insertion into the carotid artery. The outer diameter of the sheath body can be between 5Fr and 7Fr.

**[0014]** The sheath body can have a length between the proximal end and the distal end suitable for locating the distal end of the sheath body at the petrous portion of an internal carotid artery from a transfemoral approach. The length of the sheath body can be between 80 cm and 105 cm. The length of the luminal portion can be between 10 cm and 25 cm. The length of the luminal portion can be less than a length of the sheath body such that as the catheter is retracted into the sheath body a seal remains between an overlap region of the luminal portion and the inner diameter of the sheath body.

**[0015]** The spine can be longer than an entire length of the sheath body. The luminal portion can include three or more layers including an inner lubricious liner, a reinforcement layer, and an outer jacket layer. The outer jacket layer can be composed of discreet sections of polymer with different durometers, compositions, and/or thicknesses to vary the flexibility along the length of the distal luminal portion. The outer diameter of the distal luminal portion can be sized for navigation into cerebral arteries. The inner diameter of the distal luminal portion can be between 0.040" and 0.088". The outer diameter of the luminal portion can approach the inner diameter of the sheath body creating a sealed area at an overlap region while still allowing the catheter to move through the sheath body. The catheter can be tapered towards the distal opening such that a distal-most end of the luminal portion has a smaller outer diameter compared to a more proximal region of the luminal portion near where the luminal portion seals with the sheath body. The distal end region of the sheath body can include an occlusion element. The distal end region of the sheath body can include an expanding distal tip. The at least one opening from the lumen can include a side opening located a distance away from a distal tip of the sheath body. The distal tip of the sheath body further can include a ramp feature configured to direct at an angulation the catheter away from a longitudinal axis of the sheath body lumen out through the at least one opening.

**[0016]** The spine can be longer than an entire length of the sheath body. The spine can be a wire having an outer dimension from 0.014" to 0.018". The spine can be a hypotube having a guide-wire passageway extending therethrough. The spine can be a ribbon having an outer dimension from 0.010" to 0.025" thick. The ribbon can be curved along at least a portion of an arc. The spine can be configured to rotate the luminal portion around a longitudinal axis of the access sheath. The spine can be eccentrically coupled to the luminal portion and the spine extend proximally from the luminal portion to outside the proximal end of the sheath body. The proximal end of the luminal portion can have an angled cut. The angled cut can be generally planar or curved. The sheath body can have one or more visual markers on the distal end region of the sheath body. The distal luminal portion can have one or more visual markers at a distal end region of the luminal portion, a proximal end region of the luminal portion or both. The one or more visual markers on the sheath body and the one or more visual markers on the luminal portion can be visually distinct. The spine can have one or more visual markers. The one or more visual markers of the spine can indicate overlap between the distal luminal portion and the sheath body. The one or more visual markers of the spine can be positioned so that when the visual marker of the spine is aligned with a portion of the access sheath, the catheter is positioned at a distal-most position with minimal overlap length needed to create a seal between the catheter and the sheath body.

**[0017]** The system can further include a dilator having a flexible, distal dilator portion having a distal tip and sized to be received within the luminal portion of the catheter. The dilator can be a tubular element along at least a portion of its length. The dilator can be a solid rod formed of malleable material configured to be shaped by a user. The dilator can further include a rigid, dilator spine extending proximally from the dilator portion. The dilator spine can be coaxial and can have a lumen extending through it. The dilator spine can be eccentric. When in use, the dilator spine can align side-by-side with the spine of the catheter. The distal tip of the dilator can be tapered. The dilator can have a length at least as long as a length of the catheter such that the distal tip protrudes from the distal opening of the luminal portion. A proximal end of the spine can include a gripping feature configured for a user to grasp in order to move the catheter through the access sheath. A proximal end of the dilator spine can include a tab configured to be locked with the gripping feature on the catheter spine. When the catheter and dilator are in a locked configuration they can be advanced as a single unit through the sheath body. The gripping feature and the dilator tab can be removably coupled such that in a locked configuration the dilator tab engages the gripping feature and in an unlocked configuration the dilator tab disengages from the gripping feature. The dilator tab can be affixed to the dilator and/or can be slideable on the dilator to accommodate different relative positions between the dilator and the catheter.

**[0018]** The distal dilator portion can include one or more detents on an outer surface configured to lock with correspondingly-shaped surface features on an inner surface of the luminal portion lumen through which the dilator portion extends. The dilator spine and the catheter spine can have a similar stiffness and kink-resistance. The dilator can have a visual marker on a distal end and/or a proximal end of the distal tip. A distal end region of the dilator can be more flexible and increasingly stiffens towards the proximal end region of the dilator.

**[0019]** The access sheath can further include a connector that connects the proximal end of the sheath body to a proximal hemostasis valve. The proximal hemostasis valve can have an adjustable opening sized large enough to allow removal of the catheter without dislodging any

clots thereon. When in use with the access sheath, the rigid spine of the catheter can extend proximally from the luminal portion through the access sheath lumen and out the proximal hemostasis valve of the access sheath. The connector can provide a connection of the proximal end of the sheath body to an aspiration line. The connector can have a large bore inner lumen and connects to a large-bore aspiration line. The aspiration line can connect to an aspiration source. The aspiration source can be an active aspiration source. The aspiration line can connect to a forward drip or flush line. The access sheath can further include a proximal extension portion such that when the distal luminal portion of the catheter is withdrawn from the sheath body lumen it remains within the proximal extension portion. The inner diameter of the luminal portion can be sized to permit placement of an interventional device through the luminal portion.

**[0020]** Other features and advantages should be apparent from the following description of various implementations, which illustrate, by way of example, the principles of the invention.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0021]**

FIG. 1 is an exploded view of a system of devices for accessing and removing a cerebral occlusion to treat acute ischemic stroke from a femoral artery access site;

FIG. 2A shows components of the system of FIG. 1 in position in a patient from the transfemoral approach to treat the occlusion;

FIG. 2B is a detailed view of a portion of the system of FIG. 2A taken along circle BB;

FIG. 3 shows components of the system of FIG. 1 being used via a transcarotid access site;

FIG. 4 shows an implementation of an access sheath;

FIG. 5 shows an implementation of a proximal portion of the access sheath of FIG. 4 provided as a separate, removable component;

FIG. 6 shows an implementation of a connector to minimize flow resistance through the access sheath of FIG. 4 into the proximal portion;

FIG. 7 shows an implementation of an access sheath having an occlusion balloon;

FIGs. 8A-8B show implementations of sealing elements between the access sheath body and luminal portion of a catheter extending therethrough;

FIG. 9 shows an implementation of a microcatheter and retrievable stent device positioned through a spined catheter;

FIGs. 10A-10C show implementations of expandable portions on retrievable stent devices;

FIG. 11 shows an implementation of an aspiration system for use with the systems described herein;

FIG. 12A shows an implementation of a spined catheter system for use with the systems described herein;

FIG. 12B shows the spined catheter system of FIG. 12A having a spined dilator extending through a lumen of a spined catheter;

FIG. 12C shows the spined catheter system of FIG. 12A extended through a side opening of an implementation of an access sheath;

FIG. 13 is a cross-sectional view taken about line A-A of FIG. 12B;

FIG. 14 is a cross-sectional view taken about line B-B of FIG. 12B;

FIG. 15A shows an implementation of a spined aspiration catheter-dilator system having a spined catheter and a spined dilator in a locked configuration;

FIG. 15B shows the spined aspiration catheter-dilator system having the spined catheter and the spined dilator in an unlocked configuration;

FIG. 16 shows an implementation of a spined catheter system extending distally to an access sheath to treat an embolus in a cerebral vessel.

## DETAILED DESCRIPTION

**[0022]** One of the major drawbacks to current acute stroke intervention procedures is the amount of time required to restore blood perfusion to the brain. This time includes the time it takes to access the occlusive site or sites in the cerebral artery, and the time it takes to completely remove the occlusion in the artery. Because it is often the case that more than one attempt must be made to completely remove the occlusion, reducing the number of attempts as well as reducing the time required to exchange devices for additional attempts is an important factor in minimizing the overall time. Additionally, each attempt is associated with potential procedural risk due to device advancement in the delicate cerebral vasculature.

**[0023]** Disclosed herein are methods and devices that

enable safe and rapid access to the complex neurovascular anatomies of the cerebral and intracranial arteries and removal of the occlusion. The methods and devices include one or more access devices, catheters, and thrombectomy devices to remove the occlusion. Methods and devices are also disclosed to provide active aspiration and/or passive flow reversal for the purpose of facilitating removal of the occlusion as well as minimizing distal emboli. The system offers the user a degree of flow control so as to address the specific hemodynamic requirements of the cerebral vasculature. The systems described herein provide superior ease of use in that a single operator may operate the disclosed systems using single-point continuous aspiration for rapid and safe exchange without switching. The higher efficiency of aspiration force through the systems described herein reduces distal embolic debris and increases the rate of "one-pass" thrombectomy.

**[0024]** It should be appreciated that while some embodiments are described with specific regard to aspirating a neurovascular anatomy, the embodiments are not so limited and may also be applicable to other uses. For example, the spined aspiration catheter and one or more components of the access systems described herein may be used to deliver working devices to a target vessel of a coronary anatomy, or other vasculature anatomy. It should be appreciated that where the phrase "aspiration catheter" is used herein that such a catheter may be used for other purposes besides or in addition to aspiration, such as the delivery of fluids to a treatment site or as a support catheter providing a conduit that facilitates and guides the delivery or exchange of other devices such as a guidewire or interventional devices. Alternatively, the access systems need not be limited only to the vasculature can be useful for access of other parts of the body outside the vasculature. It should also be appreciated that reference throughout this specification to a particular feature, structure, configuration, characteristic or implementation or embodiment may be combined in any suitable manner. The use of relative terms throughout the description may denote a relative position or direction. For example, "distal" may indicate a first direction away from a reference point. Similarly, "proximal" may indicate a location in a second direction opposite to the first direction. However, such terms are provided to establish relative frames of reference, and are not intended to limit the use or orientation of an anchoring delivery system to a specific configuration described in the various embodiments below.

**[0025]** FIG. 1 shows a system of devices for accessing and removing a cerebral occlusion to treat acute ischemic stroke from a femoral artery access site. The system 100 includes an access sheath 220, sheath dilator 250, guidewire 270, one or more spined aspiration or support catheters 320, dilator 340, microcatheter 400, and a retrievable stent device 500, each of which will be described in more detail below. Further, the system 100 can include one or more arterial access sheath system 200 that includes an access sheath 220, one or more sheath dilators 250 and a sheath guidewire 270. The system 100 can include one or more spined catheter systems 300 including a spined aspiration or support catheter 320, a tapered dilator 340, and alternatively a catheter clearing tool 350. The spine catheter system 300 can incorporate nested spined catheters to provide for extended reach into distal sites. The system 100 can include an access sheath system 200, a tapered catheter system 300, a microcatheter 400, and a retrievable stent device 500.

**[0026]** FIG. 2A shows some elements of the system in position in the patient from the transfemoral approach to treat the occlusion. The access sheath 220 can be inserted through a femoral artery insertion site positioned with the distal tip of the access sheath 220 at or near the petrous portion of the internal carotid artery ICA. The spined aspiration catheter 320 can be positioned with the distal tip at the face of the occlusion in the artery. In some implementations, the access sheath 220 can be inserted through a direct puncture in the wall of the common carotid artery and advanced into the internal carotid artery rather than via a transfemoral approach (see FIG. 3).

**[0027]** As seen more clearly in detailed FIG. 2B, the access sheath 220 can have a sheath body 222 and an inner lumen 223 extending between a proximal end and a distal end region of the sheath body 222. The spined aspiration catheter 320 is sized to extend through the inner lumen 223 of the access sheath 220 such that a distal end region of the catheter 320 extends beyond a distal end region of the access sheath 220. The catheter 320 is shown in FIG. 2B exiting the lumen 223 of the sheath body 222 through a distal opening 221. It should be appreciated, however, that the sheath body 222 may have one or more side openings near a distal end region of the body 222 through which the catheter 320 can extend (see FIG. 12C) as will be described in more detail below.

**[0028]** Still with respect to FIG. 2B, the spined aspiration catheter 320 can include a relatively flexible, distal luminal portion 322 coupled to a stiff and kink-resistant proximal spine 330. The distal luminal portion 322 can have an inner lumen 323 extending between a proximal end and a distal end of the luminal portion 322. The lumen 323 of the catheter 320 can have a first inner diameter and the lumen 223 of the access sheath 220 can have a second, larger inner diameter. The lumens 223, 323 are fluidly connected and contiguous such that fluid flow into and/or out of the system is possible, such as by applying suction from an aspiration source coupled to the system via a connector 226 on the access sheath 220. An overlap region 120 between the distal section of the sheath body 222 and the luminal portion 322 of the catheter 320 is sized and configured to create a seal that enables a continuous aspiration lumen from the distal tip region of the spined catheter 320 to the proximal sheath connector 226. If the sheath body 222 has a side opening through which the distal luminal portion 322 of the catheter 320 extends, the seal created at the overlap region 120 be-

tween the sheath body 222 and the luminal portion 322 is located proximal to the side opening.

**[0029]** Key dimensions that affect aspiration force through a tube include radius (r), pressure (P), viscosity (n) and length (L) where Flow = $Q = \pi r^4(\Delta P)/8nL$. Changes in radius increase flow to the $4^{th}$ power and length is inversely proportional to flow. As will be described in more detail below, the aspiration catheter has an over-the-wire portion that is a fraction of the overall distance required to reach the target site. This configuration greatly speeds up the time required to retract and re-advance the catheter. Further, the systems described herein can provide for a markedly increased radius and luminal area for aspiration of the clot and markedly shorter length, particularly compared to prior systems where the aspiration lumen runs along the entire inner diameter of the aspiration catheter. In the systems described herein, the majority of the aspiration lumen has a radius of the procedural sheath. The catheter 320 is smaller in diameter than the guide, but steps up in luminal diameter upon reaching the lumen of the access sheath 220 allowing for a greater aspiration force to be applied to a majority of the length of the luminal system. Further, the overall length of this narrow diameter region of the catheter 320 is much shorter compared to the overall length of the access sheath. The proximal spine 330 of the catheter 320 has a length and structure that extends through the lumen 223 of the access sheath 220 to a proximal end of the system such that it can be used to advance and retract the catheter 320 through the lumen 223 of the sheath 220. The spine 330 of the aspiration catheter 320, however, takes up only a fraction of the luminal space the system resulting in increased luminal area for aspiration. Increased luminal area for aspiration increases the time it takes to aspirate the occlusion and increases the possibility of removing the occlusion in a single aspiration attempt. The stepped up luminal diameter also increases the annular area available for forward flushing of contrast, saline, or other solutions while devices such as microcatheters or tapered dilators are coaxially positioned in the spined catheter 320 and access sheath 220. This can increase the ease and ability to perform angiograms during device navigation.

**[0030]** Current stroke interventions pose a risk of distal emboli being released. During the effort to remove or dissolve clot blockages in the cerebral artery, for example, there is a significant risk of thrombus fragmentation creating embolic particles that can migrate downstream into either the occluded vessel or other vessels and compromise cerebral perfusion. In carotid artery stenting procedures (CAS), embolic protection devices and systems are commonly used to reduce the risk of embolic material from entering the cerebral vasculature. The types of devices include intravascular distal filters, and reverse flow or static flow systems. Unfortunately, because of the delicate anatomy and access challenges as well as the need for rapid intervention, these types of embolic protection systems are not used in interventional treatment of acute ischemic stroke. The period of a stroke intervention when flow is restored is normally considered an important time as the brain is now being perfused by blood. However, it is also a period of embolic risk. While there is blockage in the artery, there is no flow. Therefore any embolic debris created by crossing the occlusion with guidewire and/or microcatheter, or deployment of a retrievable stent device across the occlusion, remains stagnant. However, when flow is restored to the artery, the emboli can now flow antegrade to distal vascular territories.

**[0031]** A second period of embolic risk occurs when the retrievable stent device is being pulled back into the guide or catheter. In prior methods and devices, aspiration is applied to the intermediate catheter during retrievable stent device retraction into the catheter, or the catheter and retrievable stent device are pulled back together into the guide, while simultaneously applying aspiration to the guide catheter. Two points of aspiration, through the catheter and through the guide, may both be utilized to reduce risk of distal emboli during the critical step of drawing the occlusion through the guide and out of the patient. Often, two people are required to enable two points of aspiration, or aspiration is performed sequentially from first the catheter and then the guide, which may lead to interruption in aspiration or sub-optimal aspiration. In the disclosed systems and methods, reverse flow may be applied to the target site during device advancement, at the critical time of flow restoration, and during the entire time that the occlusion is being removed, with a single point of aspiration.

**[0032]** In an aspect of the disclosure, the level of aspiration may be modified from a low level to achieve adequate protection from distal emboli, to a higher level to provide effective aspiration removal of the occlusion. This aspect allows distal protection without high levels of blood loss, yet allows a strong aspiration force as needed to remove the occlusion.

**[0033]** In another aspect, there are disclosed methods and devices for additionally providing active aspiration or passive retrograde flow during the procedure to remove thrombus and to minimize distal emboli. The system offers the user a degree of blood flow control so as to address the specific hemodynamic requirements of the cerebral vasculature. The system may include a flow controller, which allows the user to control the timing and mode of aspiration.

**[0034]** In another aspect, there are disclosed methods and devices for additionally providing flushing steps to minimize emboli entrapment in the system and increased visibility of particulates in the system during use.

**[0035]** The following descriptions provide detailed implementations and benefits of each aspect of the disclosed invention.

**[0036]** Referring again to FIG. 1 illustrating an implementation of an access sheath 220. The sheath 220 can include a sheath body 222 that is the insertable portion of the sheath 220 (i.e. the portion that inserts into the patient), a proximal connector 226, an aspiration line 230,

a proximal hemostasis valve 234 and a flush line 236. The sheath 220 may also include a proximal extension portion 240, and may also include a valve on the connector 226 to fluidly isolate the sheath body 222 from the proximal portion 240 of the access sheath 220. The access sheath 220 may come in a kit with one or more dilators 250, and a sheath guidewire 270.

**[0037]** The diameter of the sheath body 222 is suitable for insertion into the carotid artery, with an inner lumen 223 that is suitably sized for providing a passageway for catheters to treat the occlusion. In an implementation, the sheath body 222 can have an inner diameter of about 0.074" and an outer diameter of about 0.090", corresponding to a 5 French sheath size, an inner diameter of about 0.087" and an outer diameter of about 0.104", corresponding to a 6 French sheath size, or an inner diameter of about 0.100" and an outer diameter of about 0.177", corresponding to a 7 French sheath size. The length of the sheath body 222 is configured to enable the distal tip of the sheath body 222 to be positioned as far distal as the petrous portion of the internal carotid artery. In an implementation, the sheath body 222 length is suitable for a transfemoral approach, in the range 80 to 90 cm or up to about 100 cm or up to about 105 cm. In an implementation, the sheath body 222 length is suitable for a transcarotid approach to the petrous ICA, in the range 20 to 25 cm. In an implementation, the sheath body 222 length is suitable for a transcarotid approach to the CCA or proximal ICA, in the range 10-15 cm. The sheath body 222 is configured to assume and navigate the bends of the vasculature and be subject to high aspiration forces without kinking, collapsing, or causing vascular trauma.

**[0038]** The sheath body 222 can be constructed in two or more layers. An inner liner can be constructed from a low friction polymer such as PTFE (polytetrafluoroethylene) or FEP (fluorinated ethylene propylene) to provide a smooth surface for the advancement of devices through the inner lumen. An outer jacket material can provide mechanical integrity to the inner liner and may be constructed from materials such as PEBAX, thermoplastic polyurethane, polyethylene, nylon, or the like. A third layer can be incorporated that can provide reinforcement between the inner liner and the outer jacket. The reinforcement layer can prevent flattening or kinking of the inner lumen of the sheath body 222 to allow unimpeded device navigation through bends in the vasculature as well as aspiration or reverse flow. The sheath body 222 can be circumferentially reinforced. The reinforcement layer can be made from metal such as stainless steel, Nitinol, Nitinol braid, helical ribbon, helical wire, cut stainless steel, or the like, or stiff polymer such as PEEK. The reinforcement layer can be a structure such as a coil or braid, or tubing that has been laser-cut or machine-cut so as to be flexible. In another implementation, the reinforcement layer can be a cut hypotube such as a Nitinol hypotube or cut rigid polymer, or the like.

**[0039]** The flexibility of the sheath body 222 can vary over its length, with increasing flexibility towards the distal portion of the sheath body 222. The variability in flexibility may be achieved in various ways. For example, the outer jacket may change in durometer and/or material at various sections. A lower durometer outer jacket material can be used in a distal section of the sheath compared to other sections of the sheath. Alternately, the wall thickness of the jacket material may be reduced, and/or the density of the reinforcement layer may be varied to increase the flexibility. For example, the pitch of the coil or braid may be stretched out, or the cut pattern in the tubing may be varied to be more flexible. Alternately, the reinforcement structure or the materials may change over the length of the sheath body 222. In an implementation, the distal-most section has a flexural stiffness (E*I) in the range 50 to 300 N-mm2 and the remaining portion of the sheath body 222 has a flexural stiffness in the range 500 to 1500 N-mm2 , where E is the elastic modulus and I is the area moment of inertia of the device. In another implementation, there is a transition section between the distal-most flexible section and the proximal section, with one or more sections of varying flexibilities between the distal-most section and the remainder of the sheath body 222. In this implementation, the distal-most section is about 2 cm to about 5 cm, the transition section is about 2 cm to about 10 cm and the proximal section takes up the remainder of the sheath length.

**[0040]** The tip of the sheath body 222 may include one or more distal radiopaque markers 224 (see FIG. 1). In an implementation, the radiopaque tip marker 224 is a metal band, for example platinum iridium alloy, embedded near the distal end of the sheath body 222. Alternately, the access sheath tip material may be a separate radiopaque material, for example a barium polymer or tungsten polymer blend. The distal region of the sheath body 222 is also the area of the overlap region 120 that allows a seal between the catheter 320 and the sheath body 222, creating a continuous aspiration lumen. Thus, the outer diameter of the luminal portion 322 of the aspiration catheter 320 approaches the inner diameter of the distal region of the sheath body 222 lumen 223 such that a seal is formed. The relative location of the seal formed may vary depending on where the aspiration catheter 320 exits the lumen 223 of the sheath body 222 and the location of the openings from the sheath body 222, as described in more detail below. For example, if the sheath body 222 has an opening at the distal tip the location of the seal may be closer to the distal end of the sheath body 222 compared to if the sheath body 222 has one or more side openings in the distal end region of the sheath body 222 through which the catheter 320 exits the lumen 223.

**[0041]** Referring again to FIG. 1, the access sheath 220 also can include a connector 226 that connects a proximal end of the sheath body 222 to the proximal hemostasis valve 234, and also provides a connection to the aspiration line 230. This connector 226 can have a large bore inner lumen, and connects to a large-bore aspiration line 230. In an implementation, the inner lumen

of the connector 226 is at least .080". In an implementation, the inner lumen of the aspiration line 230 is at least .080". The aspiration line 230 can terminate in a stopcock, female Luer connector, or other connector 232 that allows connection to an aspiration source. In an implementation, the aspiration source is an active aspiration source such as a syringe or a pump. In another implementation, the aspiration source is a reverse flow shunt line such as that described in US Patent Number 8,157,760 and US Patent Publication Number 2010/0217276, which are both incorporated by reference. The large bore aspiration line 230 can be constructed to be resistant to collapse. For example, the aspiration line 230 can be a thick-walled polymer tubing or a reinforced polymer tubing. The aspiration line valve 232 enables the line 230 to be opened or closed. In one implementation, the valve 232 also allows connection of one or more additional fluid lines, for connecting a forward drip or a flush line for contrast or saline injections. As an example, the valve 232 may be a stopcock manifold commonly used in interventional procedures to allow multiple connections. The connector 226 may also include means to secure the access sheath 220 to the patient to reduce the risk of sheath dislodgement during the case. For example, the connector 226 may include one or more suture eyelets 233.

**[0042]** With reference still to FIG. 1, the proximal end of the access sheath 220 can terminate in a proximal hemostasis valve 234. This valve 234 allows the introduction of devices through the sheath 220 into the vasculature, while preventing or minimizing blood loss and preventing air introduction into the access sheath 220. The hemostasis valve 234 can include a flush line 236 or a connection to a flush line 236 so that the sheath 220 can be flushed with saline or radiopaque contrast during the procedure as desired. The flush line 236 can also be used as a second point of aspiration during portions of the procedure as described more fully below. The hemostasis valve 234 can be a static seal-type passive valve, or an adjustable-opening valve such as a Tuohy-Borst valve or rotating hemostasis valve (RHV). The hemostasis valve 234 can be integral to the access sheath 220, or the access sheath 220 can terminate on the proximal end in a female Luer adaptor to which a separate hemostasis valve 234 component, such as a passive seal valve, a Tuohy-Borst valve or rotating hemostasis valve may be attached. In an implementation, the valve 234 has an adjustable opening that is open large enough to allow removal of devices that have adherent clot on the tip without causing the clot to dislodge at the valve 234 during removal. Alternately, the valve 234 is removable and is removed when the catheter tip is being removed from the sheath 220 to prevent clot dislodgement at the valve 234.

**[0043]** Referring again to FIG. 1, the arterial sheath system 200 can include one or more sheath dilators 250 and a sheath guidewire 270. The sheath guidewire 270 can be inserted first into the artery using standard vascular access techniques such as a micropuncture technique or Modified Seldinger technique. The sheath dilator 250 allows for smooth insertion of the access sheath 220 through a puncture site in the arterial wall. The dilator 250 can be inserted into the access sheath 220 and then the two components can be inserted together over the sheath guidewire 270 into the artery The distal end 256 of the dilator 250 can be generally tapered to allow the dilator 250 to dilate the needle puncture site as it is being inserted through the arterial wall into the artery. The tapered distal end 256 can be generally between 6 and 12 degrees total included angle (relative to a longitudinal axis of the dilator), with a radiused leading edge.

**[0044]** An inner lumen of the dilator 250 can accommodate the sheath guidewire 270, and can have an inner diameter of between .037" to .041" to correspond to a sheath guidewire 270 of between .035" to .038". Alternately, the inner lumen of the dilator 250 can be between .020" to .022" to accommodate a sheath guidewire 270 of between .014" to .018". Alternately, the dilator 250 can be a two part dilator with an inner dilator and an outer dilator. The outer dilator can have an inner diameter of between .037" to .041", and the inner dilator can have an inner diameter of between .020" to .022". In use, the sheath 220 can be inserted into the artery with the outer dilator with a sheath guidewire 270 between .035" and .038". The sheath guidewire 270 may then be removed and replaced with the inner dilator and a smaller guidewire of between .014" and .018", and the access sheath 220 can then be advanced further distally to the desired site in the carotid artery.

**[0045]** To insert the arterial sheath 220 initially over the sheath guidewire 270 into the artery, the dilator taper 256 can have a certain stiffness and taper angle to provide the adequate dilating force on the arterial puncture site. However, to safely reach the petrous portion of the ICA, it may be desirable to have a sheath dilator 250 with a softer and/or longer taper at a distal end than that used for initial arterial access. In an implementation, the access sheath system 200 can include two or more tapered dilators. The first tapered dilator can be used with the arterial access device to gain entry into the artery, and is thus sized and constructed in a manner similar to standard introducer sheath dilators. Example materials that may be used for the tapered dilator include, for example, high density polyethylene, 72D PEBAX, 90D PEBAX, or equivalent stiffness and lubricity material. A second tapered dilator may be supplied with a softer distal section or a distal section that has a lower bending stiffness relative to the distal section of the first tapered dilator, and/or a longer taper length. That is, the second dilator has a distal region that is softer, more flexible, or articulates or bends more easily than a corresponding distal region of the first dilator. The distal region of the second dilator thus bends more easily than the corresponding distal region of the first dilator. In an implementation, the distal section of the first dilator has a bending stiffness in the range of 50 to 100 N-mm2 and the distal section of the

second dilator has a bending stiffness in the range of 5 to 15 N-mm2. The second dilator (which has a distal section with a lower bending stiffness) may be exchanged with the initial, first dilator such that the access sheath 220 may be advanced into the internal carotid artery and around curvature in the artery without undue force or trauma on the vessel due to the softer distal section of the second dilator.

**[0046]** The distal section of the soft, second dilator may be, for example, 35 or 40D PEBAX, with a proximal portion made of, for example 72D PEBAX. An intermediate mid portion or portions may be included on the second dilator to provide a smooth transition between the soft distal section and the stiffer proximal section. In an implementation, both dilators have an inner diameter of between .037" to .041". In an alternate implementation, the first dilator has an inner diameter of between .037" to .041" and the second dilator has an inner diameter of between .020" to .022". In yet another implementation, the second dilator is a two part dilator with an inner dilator and an outer dilator, as described above. In an implementation, one or both dilators may have radiopaque tip markers 224 so that the dilator tip position is visible on fluoroscopy. In one variation, the radiopaque marker 224 is a section of tungsten loaded PEBAX or polyurethane that is heat welded to the distal tip of the dilator. Other radiopaque materials may similarly be used to create a radiopaque marker 224 at the distal tip.

**[0047]** In an implementation, the access sheath 220 includes a proximal extension 240 that extends between the connector 226 and the proximal hemostasis valve 234. In the transcarotid configuration of the system, it may be desirable to move the proximal hemostasis valve 234 away from the distal tip of the access sheath 220, effectively elongating or lengthening the proximal portion of the access sheath that is outside the body while maintaining the length of the insertable sheath body portion 222. This allows the user to insert devices into the proximal hemostasis valve 234 of the access sheath 220 from a point further away from the target site and therefore away from the x-ray source and/or image intensifier used to image the target site fluoroscopically, thereby minimizing radiation exposure of the user's hands and also his or her entire body. In this implementation, the proximal extension 240 can be in the range between 10 and 25 cm, or between 15 and 20 cm. In either the transcarotid or transfemoral configuration, it may also be desirable to provide a section of the access sheath 220 that is fluidly connected to the access sheath aspiration line, but which may extend proximally from the aspiration line connection. This will allow users to pull devices out of the flow of blood from the sheath tip to the aspiration line, without completely removing the device from the access sheath 220.

**[0048]** In an alternate implementation, it may also be desirable to intermittently isolate this proximal portion 240 from the sheath body 222. In an implementation, as shown in FIG. 4, the connector 226 includes a valve 242 that can close off the fluid connection between the sheath body 222 and the proximal portion 240 of the access sheath 220, including the aspiration line 230, proximal extension 240 and proximal hemostasis valve 234. This can allow the distal portion of a catheter, retrievable stent device, or other thrombectomy device to be pulled into this proximal extension portion 240, the valve 242 closed to fluidly isolate the sheath body 222 from the proximal portion of the sheath, and then the proximal hemostasis valve 234 to be widely opened or removed, or the entire proximal extension portion 240 of the sheath 220 removed, without arterial bleeding from the sheath 220. The proximal extension 240 can be at least as long as the distal luminal portion 222 of the spined catheter 320 so that the distal luminal portion 322 may be pulled entirely into the proximal extension 240 and the valve 242 closed off before the proximal hemostasis valve 234 is widely opened to remove the catheter 320 entirely from the sheath 220.

**[0049]** Alternately, after the thrombectomy device or other interventional device is pulled into this proximal extension portion 240 and the sheath body 222 closed off via the valve 242, a portion of the thrombectomy device, such as the distal luminal portion 322 of the aspiration catheter 320, may remain in the proximal extension 240 and be flushed or otherwise cleared by creating flow from the flush line to the aspiration lines to dislodge clot without fully removing the device 320 from the access sheath 220. This ability to flush and clear the thrombectomy device without fully removing the thrombectomy device may reduce bleeding, time, and risk of air emboli during the steps between thrombectomy attempts. Also, withdrawing the thrombectomy device into the proximal extension 240 without fully removing it from the sheath body 222 while flushing and clearing also minimizes operator and staff exposure to blood and debris associated with device cleansing. In any of these implementations, the proximal extension tubing is clear so that the flush solution and presence/absence of embolic debris or air is clearly visible through the tubing.

**[0050]** The proximal extension portion 240 of the access sheath 220 can be provided as a separate, removable component that can be attached to any sheath with a standard connection on the proximal end. As shown in FIG. 5, a proximal component 280 includes a connector 285 that can attach to a proximal hub 15 of a standard sheath 10. The coupled components can create an assembly with the configuration and features of access sheath 220. In this implementation, the user can select from any of several already available sheaths of appropriate length, shape, and mechanical characteristics for the procedure, and perform the steps of the procedure described in this disclosure. The removable proximal component 280 can include the Y-arm connector 226, aspiration line 230, proximal extension 240, proximal hemostasis valve 234 and flush line 236, along with the valve connectors 232 and 238 terminating the aspiration

line 230 and flush line 236 respectively. A connector 285 can couple to the proximal connector 226 on the sheath 220. In an implementation as shown in FIG. 6, the connector 285 is configured to minimize the flow resistance through the sheath 10 and into the proximal portion 280. For example, instead of a standard male-female Luer connection, the connector 285 can include an adaptor 60 with an inner lumen and surface that matches a standard female Luer connector 62 typically found on sheaths, a seal element 64 that seals between the adaptor 60 and the sheath female Luer 62, and a rotating nut 66 that engages the thread elements of the female Luer 62 and couples the adaptor 60 and Luer 62 together such that the seal 64 is compressed and can seal against fluid and air vacuum and pressure. Again with respect to FIG.5, the proximal component 280 may also include a valve 242 on the Y-arm connector 226, so that when the proximal component 280 is attached to a sheath 10, the proximal section may be selectively open or closed to fluid connection with the sheath 10. A similar type of connection can be made for connector 232 connecting the sheath aspiration line 230 to an aspiration source.

**[0051]** In a preferred implementation, the proximal connection has a proximal extension length of about 22 cm, a Y-arm connector of about 7 cm, and a proximal hemostasis valve of length about 5 cm for a total length of about 34 cm.

**[0052]** It may be desirable to transiently occlude the carotid artery during the intervention to arrest antegrade flow of emboli during portions of the procedure. In an implementation, as shown in FIG. 7, the access sheath 220 includes an occlusion balloon 246 on the distal tip of the sheath body 222. An additional lumen in sheath body 222 can be connected to an inflation line 248 and fluidly connects the balloon 246 to the inflation line 248. An inflation device is attached to inflation line 248 to inflate the occlusion balloon 246. In this implementation, the balloon 246 is inflated when carotid artery occlusion is desired.

**[0053]** In some instances it is desirable to keep the sheath tip as small as possible during sheath insertion to minimize the diameter of the arterial puncture, but to expand the opening of the sheath 220 after it has been inserted into the vessel. At least one purpose of this feature is to minimize the effect or creation of distal emboli during pull back of an aspiration catheter 320 or other thrombectomy device into the sheath 220. During a thrombectomy procedure, the thrombus may be "pulled back" into a distal opening 221 of the sheath 220 on a device that has captured the thrombus. If the distal tip of the sheath 220 is enlarged relative to its initial size, or flared into a funnel shape, the chance of pieces of the thrombus breaking off and causing emboli is minimized because the larger size or funnel shape of the sheath tip is more likely to accommodate the emboli being drawn into it without being split into multiple pieces. This creates a better clinical outcome for the patient. In an implementation of the access sheath, the distal portion of the sheath body 222 is a material and/or construction such that the tip can be expanded after the sheath 220 is inserted into the artery and positioned in its desired location. In an implementation, the distal region of the sheath has an ID of about 0.087" can be enlarged to a diameter of about 0.100" to 0.120" although the size may vary and/or be flared.

**[0054]** Examples of expanding distal tip constructions include covered braided tips that can be shortened to expand. Another example of an expanding distal tip construction is an umbrella or similar construction that can open up with mechanical actuation or elastic spring force when unconstrained. Other mechanisms of expandable diameter tubes are well known in the art. One particular implementation is a sheath made of material that is deformable when expanded using a high pressure balloon. Co-pending U. S. Patent Publication number 2015/0173782, filed on December 19, 2014, describes exemplary devices and is incorporated herein by reference in its entirety. Construction of such features are described in co-pending Publication number 2015/0173782.

**[0055]** The distal end region of the sheath body 222 also may vary in the location, size and number of openings. The sheath body 222 may incorporate one or more openings near the distal end region of the sheath 220 that allow for fluid flow between the lumen 223 of the sheath body 222 and the vasculature within which the sheath 220 is positioned. The one or more openings can be sized to allow at least the luminal portion 322 of the aspiration catheter 320 to extend therethrough. The one or more openings may be sized larger than the outer diameter of the luminal portion 322 such that the one or more openings form an elongate mouth, slot or notch in a distal end region of the sheath body 222. The one or more openings may be formed within a region of the side wall of the sheath body 222 just proximal to the distal end, such that the opening is located at least 0.25 mm, 0.5 mm, 1.0 mm, 1.5 mm, 2.0 mm, 2.5 mm, 3.0 mm, 3.5 mm, or 4.0 mm or greater from the distal end of the sheath body 222. The one or more openings may be a plurality of openings forming a porous region near the distal end region of the sheath body 222 wherein at least one of the pluralities of openings is sized large enough to allow one or more components of the system to exit the lumen 223 of the sheath body 222. In some implementations, the one or more openings includes a distal opening 221 from the lumen 223 of the sheath body 222 (see FIGs. 4 and 12C). In some implementations, the one or more openings includes an elongate, distal mouth forming a side opening 1219 on a first side of the sheath body 222 located near a distal end region (see FIG. 12C). The side opening 1219 may be located at least 0.25 mm or more from the distal end of the sheath body 222. The side opening 1219 may having a diameter that is at least as large as the outer diameter of the distal luminal portion 322 of the spined catheter 320. Preferably, the side opening 1219 has a diameter that is at least 1.5x, 2x, 2.5x, or

3x as large as the outer diameter of the distal luminal portion 322. In another implementation, the sheath body 222 includes a pair of side openings 1219 on opposing and/or adjacent sides of the sheath body 222 near the distal end region. In another implementation, the sheath body 222 includes a distal opening 221 from the lumen 223 and one or more elongate side openings 1219 from the lumen 223. It should be appreciated that the sheath body 222 can be rotated around the longitudinal axis A such that the one or more side openings 1219 are positioned to allow for distal extension of the catheter 320 from the side openings 1219 in a desired direction relative to the longitudinal axis A of the sheath 220. Inclusion of a wide-mouthed side opening 1219 can allow for a range of exit angles for the catheter 320 from a position substantially (i.e. very nearly) parallel to the sheath body 222 to a position that is at an angle to the sheath body 222, for example substantially perpendicular or at a right angle to the sheath body 222, as well as greater than 90° angle. This arrangement can be critically important in situations where there is severe angulation within the vessel being traversed or where a bifurcation is present. Often, tortuous segments in vessels and bifurcations have severe angulations to 90° or greater angle up to 180°. Classic severe angulation points in the vasculature can include the aorto-iliac junction, the left subclavian artery takeoff from the aorta, the brachiocephalic (innominate) artery takeoff from the ascending aorta as well as many other peripheral locations.

**[0056]** Referring again to FIG. 1, as mentioned above the catheter system 300 can include a spined aspiration catheter 320 having a flexible, distal luminal portion 322 and a rigid, proximal spine 330. The outer diameter of the distal luminal portion 322 as well as the flexibility and lubricity of the luminal portion 322 paired with the rigid spine 330 allow for the spined aspiration catheter 320 to navigate to the site of occlusions in the cerebral vasculature compared to other systems configured to navigate the cardiac vasculature. The systems described herein can reach occlusions in a region of the anatomy that has a long, tortuous access route. The route may contain stenosis plaque material in the aortic arch and carotid and brachiocephalic vessel origins, presenting a risk of embolic complications. Further, cerebral vessels are usually more delicate and prone to perforation than coronary or other peripheral vasculature. The catheter systems described herein can provide for neurovascular interventional procedures more easily due to its ability to overcome these access challenges. The catheter systems described herein are designed for navigating tortuosity rather than pushing through it. U.S. Patent Publication Number 2015/0174368, filed on December 12, 2014, and U.S. Patent Publication Number 2015/0173782, filed on December 19, 2014, describe features of catheter devices that can navigate the tortuous anatomy of the cerebral arteries.

**[0057]** The length of the distal luminal portion 322 can vary. In some implementations, the length of the distal luminal portion 322 extends from a region near the distal tip of the access sheath body 222 to the site of the occlusion in the carotid artery, forming a proximal overlap region 120 with the distal end of the access sheath 220 (see FIG. 2B). Taking into account the variation in occlusion sites and sites where the access sheath distal tip may be positioned, the length of the distal luminal portion 322 may range from about 10 cm to about 25 cm. The length of the distal luminal portion 322 is less than the length of the sheath body 222 of the access sheath 220, such that as the spined aspiration catheter 320 is retracted into the sheath body 222 there remains a seal between the overlap region 328 of the spined aspiration catheter 320, and the inner diameter of the sheath body 222.

**[0058]** The catheter systems described herein can incorporate multiple spined catheters that are nested inside one another to allow for an extended reach into the tortuous anatomy. For example, a first spined catheter 320 having an outer diameter sized to be received within the lumen of the sheath body 222 may have a second spined catheter 320 extending through the inner lumen of the first spined catheter 320. The second spined catheter 320 can be extended using its proximal spine beyond a distal end of the first spined catheter 320 such that the smaller diameter second spined catheter 320 can reach a more distal region of the vasculature, particularly one having a narrower dimension. In this implementation, the first spined catheter 320 can act as a support catheter for the second spined catheter 320. The second spined catheter 320 can have an inner lumen that fluidly communicates with the inner lumen of the first spined catheter 320 that fluidly communicates with an inner lumen of the sheath body 222 forming a contiguous aspiration lumen.

**[0059]** In an implementation, the distal luminal portion 322 of the catheter 320 is constructed to be flexible and lubricious, so as to be able to be safely navigated to the target site, and kink resistant and collapse resistant when subjected to high aspiration forces, so as to be able to effectively aspirate the clot, with sections of increasing flexibility towards the distal end. In an implementation, the distal luminal portion 322 includes three or more layers, including an inner lubricious liner, a reinforcement layer, and an outer jacket layer. The outer jacket layer may be composed of discreet sections of polymer with different durometers, composition, and/or thickness to vary the flexibility along the length of the distal luminal portion 322. In an implementation the lubricious inner liner is a PTFE liner, with one or more thicknesses along variable sections of flexibility. In an implementation, the reinforcement layer is a generally tubular structure formed of, for example, a wound ribbon or wire coil or braid. The material for the reinforcement structure may be stainless steel, for example 304 stainless steel, nitinol, cobalt chromium alloy, or other metal alloy that provides the desired combination of strengths, flexibility, and resistance to crush. In an implementation, the reinforcement structure includes multiple materials and/or designs, again to vary the flexibility along the length of the

distal luminal portion 322. In an implementation, the outer surface of the catheter 320 is coated with a lubricious coating such as a hydrophilic coating. In some implementations the coating may be on an inner surface and/or an outer surface to reduce friction during tracking. The coating may include a variety of materials as is known in the art. The spine portion 330 may also be coated to improve tracking through the access sheath 220. Suitable lubricious polymers are well known in the art and may include silicone and the like, hydrophilic polymers such as high-density polyethylene (HDPE), polytetrafluoroethylene (PTFE), polyarylene oxides, polyvinylpyrolidones, polyvinylalcohols, hydroxy alkyl cellulosics, algins, saccharides, caprolactones, and the like, and mixtures and combinations thereof. Hydrophilic polymers may be blended among themselves or with formulated amounts of water insoluble compounds (including some polymers) to yield coatings with suitable lubricity, bonding, and solubility.

**[0060]** The outer diameter of the distal luminal portion 322 can be sized for navigation into cerebral arteries. It is desirable to have a catheter having an inner diameter that is as large as possible that can be navigated safely to the site of the occlusion, in order to optimize the aspiration force. A suitable size for the inner diameter may range between .040" and .075" or may range between 0.040" and 0.088", depending on the patient anatomy and the clot size and composition. The outer diameter should be as small as possible while still maintaining the mechanical integrity of the catheter 320. However, at the overlap region 120, the outer diameter (OD) of the catheter 320 approaches the inner diameter (ID) of the access sheath 220, so as to create a sealed area at the overlap region 120 whilst still enabling the catheter 320 to be inserted easily through the sheath 220 and positioned at the desired site. In an implementation, the catheter 320 and access sheath 220 are sized to match at the overlap region 120 with no change in catheter 320 outer diameter (see FIG. 2B). In an implementation, the difference between the catheter OD and the access sheath ID at the overlap region is .002" or less. In another implementation, the difference is .003" or less. In an implementation, the catheter 320 is tapered towards the distal tip of the distal luminal portion 322 such that the distal-most end of the catheter has a smaller outer diameter compared to a more proximal region of the catheter near where it seals with the access sheath. In another implementation, the catheter OD steps up at an overlap portion 328 to more closely match the sheath inner diameter (see FIG. 1). This implementation is especially useful in a system with more than one catheter suitable for use with a single access sheath size. It should be appreciated where the catheter OD of the spined catheter 320 matches the sheath inner diameter or the difference is 0.002" or less, a seal to fluid being injected or aspirated can be achieved by the overlap portion 328 such that no increase in catheter OD is necessary. A seal to fluid being injected or aspirated between the catheter and the sheath can be achieved by the overlap between their substantially similar dimensions without incorporating any separate sealing structure or seal feature.

**[0061]** In another implementation as shown in Figure 8A and 8B, there is a sealing element 336 positioned on the external surface of the proximal end of the distal luminal portion 322. The sealing element 336 can be one or more external ridge features, and can be compressed when the catheter 320 is inserted into the lumen of the access sheath 220. The ridge geometry can be such that the sealing element 336 behaves as an O-ring, quad ring, or other piston seal design. Figure 8B shows a similar configuration, with the sealing element 336 having a wiper seal configuration such as an inclined surface that is biased against an inner surface of access sheath body 222. Alternately, the seal element 336 may be an inflatable or expandable member such as a balloon or covered braid structure that can be inflated or expanded and provide sealing between the two devices at any time, including after the catheter 320 is positioned at the desired site. An advantage to this implementation is that there is no sealing force being exerted on the catheter 320 during catheter positioning, but rather is applied or actuated to seal after the catheter 320 is positioned.

**[0062]** It should be appreciated that the shape of the proximal end region of the distal luminal portion 322 may have an angled cut compared to the straight cut shown in the FIGs. 8A-8B. It should also be appreciated that the spine 330 may be coupled to a proximal end region of the catheter 320 and/or may extend along at least a portion of the distal luminal portion 322 such that the spine 330 couples to the distal luminal portion 322 a distance away from the proximal end. The spine 330 can be coupled to the portion 322 by a variety of mechanisms including bonding, welding, gluing, sandwiching, stringing, tethering, or tying one or more components making up the spine 330 and/or portion 322. In some implementations, the spine 330 and luminal portion 322 are coupled together by sandwiching the spine 330 between layers of the distal luminal portion 322. For example, the spine 330 can be a hypotube or rod having a distal end that is skived, ground or cut such that the distal end can be laminated or otherwise attached to the layers of the catheter portion 322 near a proximal end region. The region of overlap between the distal end of the spine 330 and the portion 322 can be at least about 1 cm. This type of coupling allows for a smooth and even transition from the spine 330 to the luminal portion 322.

**[0063]** In an implementation, the overlap region is configured to enable sealing against a vacuum of up to 25 inHg, or up to 28 inHg. In an implementation, the overlap region 120 is configured to enable sealing against a pressure of up to 300 mmHg or up to 600 mmHg or up to 700 mmHg with minimal to no leakage. In addition, there may be features that prevent excessive advancement of the spined aspiration catheter 320 beyond the distal end of the access sheath 220. In any implementation that involves a stepped up diameter or protruding feature at the overlap region 328 of the spined aspiration catheter 320,

the access sheath body 222 may include an undercut at the tip that prevents the proximal overlap portion of the spined aspiration catheter 320 to exit the sheath body 222.

**[0064]** The distal luminal portion 322 of the catheter 320 can have a radiopaque marker 324 at the distal tip to aid in navigation and proper positioning of the tip under fluoroscopy (see FIG. 1). Additionally, the proximal overlap region 328 of the catheter 320 may have one or more proximal radiopaque markers 1324 (see FIG. 12C) so that the overlap region 120 can be visualized as the relationship between the access sheath distal marker 224 and the catheter proximal marker 1324. In an implementation, the two markers (marker 324 at distal tip and a more proximal marker 1324) are distinct so as to minimize confusion of the fluoroscopic image, for example the catheter proximal marker 1324 may be a single band and the sheath tip marker 224 may be a double band.

**[0065]** The spine 330 of the spined aspiration catheter 320 is coupled to a proximal end region of the distal luminal portion 322. The spine 330 is configured to allow distal advancement and proximal retraction of the catheter 320 through the lumen 223 of the access sheath 220. In an implementation, the length of the spine 330 is longer than the entire length of the access sheath 220 (from distal tip to proximal valve), such as by about 5 cm to 15 cm. As shown in FIG. 1, the spine 330 can include a mark 332 to indicate the overlap between the distal luminal portion 322 of the catheter 320 and the sheath body 222. The mark 332 can be positioned so that when the mark 332 is aligned with the sheath proximal valve 234 during insertion of the catheter 320 through the sheath 220, the spined aspiration catheter 320 is positioned at the distal-most position with the minimal overlap length needed to create the seal between the spined aspiration catheter 320 and the access sheath 220. The spine 330 can include a gripping feature such as a tab 334 on the proximal end to make the spine easy to grasp and advance or retract. The tab 334 can coupled with one or more other components of the system 300, such as a dilator configured to extend through the lumen 323 of the distal luminal portion 322 as will be described in more detail below. The proximal tab 334 can be designed to be easily identifiable amongst the other devices existing in the sheath proximal valve 234, such as guidewires 270 or retrievable stent device wires 500. In an implementation, the spine 330 is colored a bright color, or marked with a bright color, to make it easily distinguishable from guidewire, retrievable stent tethers, or the like.

**[0066]** The spine 330 can be configured with sufficient stiffness to allow advancement and retraction of the distal luminal portion 322 of the spined aspiration catheter 320, yet also be flexible enough to navigate through the cerebral anatomy as needed. Further, the outer diameter of the spine 330 is sized to avoid taking up too much luminal area in the lumen 223 of the access sheath 220 and sheath body 222. In an implementation, the spine 330 is a round wire, with dimensions from .014" to .018". In another implementation, the spine 330 is a ribbon with dimensions ranging from .010" to .015" thick, and .015" thick to .025" thick. The ribbon can have a variety of cross-sectional shapes such as a flat ribbon or curved ribbon forming a c-shape or other shape along an arc. In another implementation, the spine 330 is a hypotube. In an implementation, the spine 330 material is a metal such as a stainless steel or nitinol as well as a plastic such as any of a variety of polymers.

**[0067]** One or more components of the systems described herein may be made from a metal, metal alloy, polymer, a metal-polymer composite, ceramics, combinations thereof, and the like, or other suitable materials. Some examples of suitable metals and metal alloys include stainless steel, such as 304V, 304L, and 316LV stainless steel; mild steel; nickel-titanium alloy such as linear-elastic and/or super-elastic nitinol; other nickel alloys such as nickel-chromium-molybdenum alloys (e.g., UNS: N06625 such as INCONEL® 625, UNS: N06022 such as HASTELLOY® C-22®, UNS: N10276 such as HASTELLOY® C276®, other HASTELLOY® alloys, and the like), nickel-copper alloys (e.g., UNS: N04400 such as MONEL® 400, NICKELVAC® 400, NICORROS® 400, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nickel-molybdenum alloys (e.g., UNS: N10665 such as HASTELLOY® ALLOY B2®), other nickel-chromium alloys, other nickel-molybdenum alloys, other nickel-cobalt alloys, other nickel-iron alloys, other nickel-copper alloys, other nickel-tungsten or tungsten alloys, and the like; cobalt-chromium alloys; cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like); platinum enriched stainless steel; titanium; combinations thereof; and the like; or any other suitable material.

**[0068]** The junction between the distal luminal portion 322 of the catheter 320 and the proximal spine 330 can be configured to allow a smooth transition of flexibility between the two portions so as not to create a kink or weak point, and also allow smooth passage of devices such as guidewires and microcatheters through the continuous inner lumen created by the lumen 223 of the access sheath 220 and the lumen 323 of the luminal portion 322 of the catheter 320. In an implementation, the distal luminal portion 322 has a transition section 326 (see FIG. 1) near where the portion 322 couples to the spine 330 that has an angled cut such that there is no abrupt step transition from the sheath 220 inner lumen 223 to the catheter 320 inner lumen 323. The angled cut can be generally planer. In an alternate implementation, the angled cut is curved or stepped to provide a more gradual transition zone. The distal luminal portion 322 and the spine 330 may be joined by a weld bond, a mechanical bond, an adhesive bond, or some combination thereof. The distal end of the spine 330 may have features that facilitate a mechanical joint during a weld, such as a textured surface, protruding features, or cut-out features. During a heat weld process, the features would facilitate

a mechanical bond between the polymer distal luminal portion 322 and the spine 330. In another implementation, such as the catheter system 1300 shown in FIGs. 12A-12B having a spined catheter 1320 and a dilator 1340 extending therethrough, a smooth transition of flexibility between the two portions is formed so as not to kink or create a weak point during advancement of the system 1300. Loss of this smooth flexibility transition can occur upon removal of the dilator 1340 from the spined catheter 1320. The spine 1330 can be intended primarily to withdraw the spined catheter 1320 where risk of kink or weak spot formation is markedly lower.

**[0069]** Because the spined aspiration catheter 320 does not have a lumen that runs its entire length 320 due to the presence of the spine 330 on its proximal end region, traditional flushing and preparation steps, either before use or during the procedure should the lumen of the catheter become clogged, are ineffective. In a traditional single lumen catheter, a syringe is attached to the proximal adaptor of the catheter and the inner lumen may be forcefully flushed with solution. The spined catheter 320 can be supplied with an accessory catheter flushing and clearing device 350 (see FIG. 1). This device 350 may be a tube with a rounded or tapered tip on a distal end and a female Luer connection on the proximal end. The Luer connector allows a syringe to be connected to the device 350. The blunt or tapered tip enables the device 350 to be inserted into either the distal or proximal end of the luminal portion 322 of the catheter 320, without risk of damaging the catheter 320, and the syringe actuated to flush the device. The OD of the clearing device 350 is closely matched with the ID of the luminal portion 322 of the spined catheter 320, such that the spined aspiration catheter 320 may be flushed with enough force to clear out the catheter of debris and aspirated occlusive material. The device 350 may also be used to mechanically clear out any entrapped thrombus in a plunger-type action, the working length of the device 350 can be at least as long as the distal luminal portion 322 of the catheter 320, so that it may be inserted through the entire lumen 323 of the distal luminal portion 322. Flushing may occur in conjunction with plunging the device 350, to more effectively clear the catheter 320 of entrapped thrombus or other embolic material.

**[0070]** In an alternate implementation, the aspiration catheter 320 is a single lumen catheter, for example, the type of catheter described in co-pending application U.S. Patent Publication Number 2015/0174368, filed December 12, 2014. In such an implementation, the catheter may be supplied with or coupled with a tapered co-axial dilator 340 that is generally tubular and has a tapered distal portion that provides a smooth transition between the catheter and a guidewire positioned within the catheter.

**[0071]** The spined aspiration catheter 320 can be navigated through the vasculature over an appropriately-sized microcatheter and guidewire. Alternately, the spined catheter 320 can be supplied with a co-axial dilator 340 (see FIG. 1). The dilator 340 is sized and shaped to be inserted through the internal lumen 323 of the distal luminal portion 322 of the catheter 320 in a coaxial fashion, such that a proximal end region of the dilator 340 aligns side-by-side with the spine 330 of the catheter 320 when in use. The dilator 340 can have a tapered distal tip 346. The length of the dilator 340 can be at least as long as the spined aspiration catheter 320 allowing for the distal tapered tip 346 as a minimum to protrude from the distal end of the luminal portion 322 of the spined catheter 320. The dilator 340 can have an outer diameter that forms a smooth transition to the distal tip of the catheter, and the distal tapered tip 346 that provides a smooth transition down to the guidewire that extends out the inner lumen of the dilator 340. The dilator 340 can be generally tubular along at least a portion of its length. In an implementation, the tapered dilator 340 is designed to accommodate a guidewire that may be in the range of 0.014" and 0.018" diameter for example. In this implementation, the inner luminal diameter may be between .020" and .024". The tapered distal tip 346 may be in range from 1.5 cm to 3 cm.

**[0072]** It should be appreciated that the dilators described herein for use with the spined catheters can vary in their configuration. For example, as described above the dilator 340 can be a co-axial dilator 340 that is generally tubular and has a tapered distal portion that provides a smooth transition between the catheter 320 and a guidewire positioned within the catheter 320. The tubular body of the dilator 340 can extend along the entire length of the catheter 320. Alternatively, the dilator 340 can incorporate a proximal spine that aligns side-by-side with the spine of the catheter 320. The proximal spine can be positioned co-axial or eccentric to a distal end region of the dilator 340. The co-axial proximal spine of the dilator 340 can have a lumen extending through it. Alternatively, the dilator 340 can be a solid rod having no lumen. The solid rod dilator can be formed of a malleable material that skives down to have a narrow outer diameter (e.g. 0.010" - 0.014") such that the dilator can be shaped to whatever angle or shape is desired by the user, similar to how a guidewire may be used. In this configuration, the catheter system does not include a guidewire or microcatheter. Such a dilator has a benefit over a microcatheter in that it can have an outer diameter that is 0.003" - 0.010" smaller than the inner diameter of the spined catheter 320.

**[0073]** The dilator 340 may have a proximal female Luer adaptor 348 at a proximal end to allow the dilator 340 to be flushed with a syringe. The dilator 340 may also incorporate a clip feature at a proximal end allowing the dilator 340 to be the material of the dilator 340 can be flexible enough and the taper distal tip 346 can be long enough to create a smooth transition between the flexibility of the guidewire and the flexibility of the catheter. This configuration can facilitate advancement of the catheter 320 through the curved anatomy and into the target cerebral vasculature. In an implementation, the distal end

of the dilator 340 has a radiopaque marker 344 and/or a marker 343 at the proximal end of the taper distal tip 346. The marker material may be a platinum/iridium band, a tungsten, platinum, or tantalum-impregnated polymer, or other radiopaque marker.

**[0074]** The dilator 340 can be constructed to have variable stiffness between the distal and proximal ends of the dilator 340. For example, the distal most section that extends beyond the distal end of the luminal portion 322 of the catheter 320 can be made from a more flexible material, with increasingly stiffer materials towards the more proximal sections. In some implementations, the dilator 340 can be a spined dilator having a proximal spine as will be described in more detail below. The proximal end of the dilator 340 can include a tab 1364 that allows the dilator 340 to lock with the tab 334 on the proximal end of the spine 330 of the catheter 320, such that the two components (the spined catheter 320 and the dilator 340) may be advanced as a single unit over the guidewire (see FIG. 12A). In some implementations, the tab 334 of the catheter 320 can form a ring having a central opening extending therethrough. The tab 1364 of the dilator 340 can have an annular detent with a central post. The central post of the tab 1364 can be sized to insert through the central opening of the tab 334 such that the ring of the tab 334 is received within the annular detent of tab 1364 forming a singular grasping element for a user to advance and/or withdraw the catheter system through the access sheath. The tab 1364 may be affixed to the dilator 340, or may be slideable on the dilator 340 to accommodate different relative positions between the dilator 340 and the spined catheter 320.

**[0075]** FIGs. 12A-16 provide additional views of a spined aspiration catheter and dilator system 1300 as described elsewhere herein. FIGs. 12A-12B show the spined aspiration catheter 1320 having a dilator 1340 extending through an aspiration lumen 1323 of the distal luminal portion 1322. As described elsewhere herein, the catheter 1320 can have a proximal spine 1330 having a tab 1334 and a distal luminal portion 1322 having an aspiration lumen 1323. The spine 1330 can extend between the distal luminal portion 1322 and the tab 1334. The dilator 1340 can be received within the aspiration lumen 1323 of the spined catheter 1320. The dilator 1340 can include a distal dilator portion 1360 and a proximal spine 1362. The dilator portion 1360 can extend between a distal tip 1346 of the dilator 1340 to the start of the proximal spine 1362. When engaged with the catheter 1320, the dilator portion 1360 of the dilator 1340 may extend through an entire length of the distal luminal portion 1322 of the catheter 1320 such that the dilator tip 1346 extends a fixed distance beyond a distal end of the distal luminal portion 1322 of the catheter 1320 providing a smooth transition for improved tracking. The dilator tip 1346 can be tapered as described elsewhere herein and can be soft, atraumatic and flexible to the vessel wall to facilitate endovascular navigation to an embolus in a tortuous anatomy compared to dilators typically used for percutaneous arterial access, which are meant to bluntly dissect through tissue and artery wall.

**[0076]** The dilator 1340 is shown in a locked configuration with the catheter 1320 configured for improved tracking through a tortuous and often diseased vasculature in acute ischemic stroke. The dilator portion 1360 can include one or more detents on an outer surface of the dilator portion 1360. The detents can be located near a proximal end region and/or a distal end region of the dilator portion 1360. The detents are configured to lock with correspondingly-shaped surface features on the inner surface of the lumen 1323 through which the dilator portion 1360 extends. The dilator 1340 can include a dilator tab 1364 on a proximal end of the proximal spine 1362 of the dilator 1340, which as discussed above can be configured to connect and lock with a corresponding feature on the proximal end region of the catheter spine 1330, for example via one or more detents or other surface features. Thus, the dilator 1340 and the catheter 1320 can have more than a single point of locking connection between them. The proximal spine 1362 of the dilator 1340 can extend between the dilator portion 1360 and the tab 1364 of the dilator 1340. The dilator portion 1360 can be a tubular element as described elsewhere herein that forms a guidewire lumen running a length of the dilator portion 1360 (and an entire length of the distal luminal portion 1322 of the spined catheter 1320). It should be appreciated that the entire dilator 1340 can be tubular element configured to receive a guidewire through the spine 1362 as well as the dilator portion 1360. The proximal end of the dilator portion 1360, i.e., the transition section 1326 between the dilator portion 1360 and the proximal spine 1362, may include a "step up" to smooth the transition between the distal luminal portion 1322 of the catheter 1320 and the dilator portion 1360 of the dilator 1340. The transition section 1326 can incorporate an angled cut such that there is no abrupt step transition from the sheath 1220 inner lumen 1223 to the catheter 1320 inner lumen 1323. Accordingly, the spined aspiration catheter-dilator 1300 may be smooth to the vascular wall it interfaces with.

**[0077]** The proximal spine 1362 of the dilator 1340 may have a similar stiffness and character as the spine 1330 of catheter 1320. More particularly, one or both of the spines 1362, 1330 may be stiff and/or kink resistant. Furthermore, one or both of the spines 1362, 1330 may have a stiffness to allow pushing the distal portions, i.e., the combined distal luminal portion 1322 and dilator portion 1360, through an access sheath or a guide-sheath while producing a very low profile. In an embodiment, one or both of the spines 1362, 1330 includes a stiff wire.

**[0078]** The catheter tab 1334 and the dilator tab 1364 can be removably connected with one another. More particularly, the tabs 1334, 1364 may have a locked configuration and an unlocked configuration. In the locked configuration, the dilator tab 1364 can be engaged with the catheter tab 1334. In the unlocked configuration, the dilator tab 1364 may be disengaged from the catheter tab

1334. The dilator tab 1364 may attach, e.g., click or lock into, the catheter tab 1334 in a fashion as to maintain the relationships of corresponding section of the spined dilator 1340 and the spined catheter 1320 in the locked configuration. Such locking may be achieved by, e.g., using a detent on the dilator tab 1364 that snaps into place within a recess formed in the catheter tab 1334, or vice versa. In some implementations, the spine 1330 of the spined catheter 1320 can run alongside or within a specialized channel of the dilator spine 1362. The channel can be located along a length of the dilator spine 1362 and have a cross-sectional shape that matches a cross-sectional shape of the catheter spine 1330 such that the spine 1330 of the catheter 1320 can be received within the channel and slide smoothly along the channel bi-directionally. Once the spined catheter 1320 and spined dilator 1340 are fixed, the combined system, i.e., the spined aspiration catheter-dilator 1300 may be delivered to a target site, for example through the lumen 223 of the access sheath 220 described elsewhere herein.

**[0079]** Referring to FIG. 12B, a spined aspiration catheter-dilator 1300 having a spined catheter 1320 and a spined dilator 1340 in an unlocked configuration is illustrated in accordance with an embodiment. When the spined aspiration catheter-dilator 1300 is positioned at the target site, as discussed herein, the dilator tab 1364 can be unlocked from the catheter tab 1334. The spined dilator 1340 may be withdrawn and the spined catheter 1320 may be used, e.g., for aspiration or for wire or balloon delivery.

**[0080]** Referring to FIG. 13, a cross-sectional view, taken about line A-A of FIG. 12B, of a spined catheter 1320 coaxially aligned with a spined dilator 1340 is illustrated in accordance with an embodiment. The cross-section illustrates a portion of the catheter-dilator having the dilator portion 1360 received within the aspiration lumen 1323 of distal luminal portion 1322. The lumen 1323 may have an inner diameter in a range up to 0.072 inches, although a larger or smaller inner diameter is possible (larger or smaller possible). The wall of the distal luminal portion 1322 may resist kinking or ovalizing to provide maximum diameter for aspiration. The dilator portion 1360 may be received in the distal luminal portion 1322 in a slip fit. Thus, in an embodiment, an outer dimension of the dilator portion 1360 may be less than the inner diameter of the distal luminal portion 1322. For example, the lumen 1323 may have a diameter of 0.072 inches and the dilator portion 1360 may have an outer dimension of 0.070 inches.

**[0081]** Referring to FIG. 14, a cross-sectional view, taken about line B-B of FIG. 12B, of a spined catheter 1320 after removal of a spined dilator 1340 is illustrated in accordance with an embodiment. The cross-section illustrates the distal luminal portion 1322 after the dilator portion 1360 has been retracted and/or removed. The distal luminal portion 1322 has an inner wall 1321 defining the lumen 1323. The lumen 1323 may be circular, as shown, or may have any other shape. In an embodiment, the effective diameter of the lumen 1323 ranges up to 0.072 inches.

**[0082]** Referring to FIG. 15A, a spined aspiration catheter-dilator system 1300 having a spined catheter 1320 and a spined dilator 1340 in a locked configuration is illustrated in accordance with an embodiment. In an embodiment, the spine 1330 and dilator 1340 may have an outer dimension that is substantially similar over an entire length. For example, rather than converging to a smaller dimension between the dilator portion 1360 and the dilator spine 1362, the dilator spine 1362 may have a same dimension as the dilator portion 1360. Thus, a catheter-dilator having a substantially same cross-sectional area over at least a majority of its length may be provided. As discussed above, the spine dilator 1340 and the spine catheter 1320 may have corresponding tabs 1334, 1364 that engage in a locked configuration and disengage in an unlocked configuration.

**[0083]** Referring to FIG. 15B, a spined aspiration catheter-dilator having a spined catheter 1320 and a spined dilator 1340 in an unlocked configuration is illustrated in accordance with an embodiment. The spined dilator 1340 may be removed from the spined catheter 1320 in a manner similar to that described above. In an embodiment, the spined aspiration catheter-dilator may have a similar cross-sectional area over a majority of its length, and thus, the shapes of the spined catheter 1320 and the spined dilator 1340 may be complimentary. For example, the spine 1330 may have a cross-sectional area along an arc, such as a quarter circle, and thus, a cross-sectional area of the dilator spine 1362 may be three quarters of a circle. As such, the spine 1330 may conform to the dilator spine 1362 to provide an overall cross-sectional area of a full circle.

**[0084]** Referring to FIG. 16, a schematic view of a spined catheter 1320 having a distal luminal portion 1322 having an inner lumen 1323 located in a neurovascular anatomy is illustrated in accordance with an embodiment. Used in conjunction with an access sheath 1220 having a sheath body 1222 and an inner lumen 1232, in an embodiment where the spined catheter 1320 reaches the ICA and the distance to embolus E is consistently felt to be less than 20 cm, one would see that the distal luminal portion 1322 having a length of 25 cm would allow for an overlap region 1120 with the access sheath 1220 to create a seal. The overlap region 1120 may have a length of a few centimeters, and the may vary depending on the distance from the embolus E to the distal end of the distal luminal portion 1322, e.g., depending on how far the spined catheter 1320 is advanced relative to the access sheath 1220.

**[0085]** As described elsewhere herein, the luminal area available for aspiration of the embolus is greater using the spined catheter 1320 as compared to an aspiration system having a conventional large bore catheter in an access sheath. More particularly, the combined volume of the luminal area of the spined catheter 1320 and the luminal area of the access sheath 1220 proximal to the

distal luminal portion 1322 is greater than the luminal area of the large bore catheter along the entire length of the system. Thus, the likelihood of removing the embolus in a single aspiration attempt may be increased. More particularly, the stepped up luminal diameter along the spine 1330 may enable a greater aspiration force to be achieved resulting in improved aspiration of the embolus. The stepped up luminal diameter may also increase the annular area available for forward flushing of contrast, saline, or other solutions while devices such as microcatheters or tapered inner members are coaxially positioned in the spined catheter and access sheath. Thus, the ease and ability to perform angiograms during device navigation may be improved.

**[0086]** The disclosed systems may be supplied with ancillary devices that are particularly configured to be used with the system. It should be appreciated that reference to one implementation of an access sheath system or aspiration catheter system is not intended to be limited and that the ancillary devices described herein can be used with any of the systems having any of a variety or combination of features described herein. For example, where an access sheath is described below it should be appreciated that one or more features of any of the access sheaths or access sheath systems described herein can be incorporated. Similarly, where a spined catheter is described below one or more featured of any of the spined catheters or spined catheter systems described herein can be incorporated.

**[0087]** In an implementation, the system includes a microcatheter 400 (see FIG. 1). The microcatheter 400 can be configured to be particularly suited for navigation in the cerebral vasculature. The microcatheter 400 may be used in place of the tapered dilator 340 to help navigate the spined catheter 320 to the desired site. As such, it may include means at the proximal end to lock the spine 330 to the microcatheter 400, so that so that the two components (the spined catheter 320 and the microcatheter 400) may be advanced as a single unit over the guidewire. In some instances the microcatheter 400 is advanced ahead of the catheter 320, to provide support as the catheter 320 is advanced, or to cross the occlusion and perform an angiogram distal to the occlusion. In this case, the length of the microcatheter 400 can be longer than the spined catheter 320 by about 10 to 20 cm. The microcatheter 400 may also be used to deliver a retrievable stent device 500 to the occlusion. In this case, the microcatheter 400 can have an inner diameter suitable for delivery of the retrievable stent device 500, for example, in the range .021" to .027" and with a PTFE inner liner. The microcatheter 400 can be at least about 5-10 cm longer or at least about 5 - 20 cm longer than the overall length of the spined catheter 320 to allow the microcatheter 400 to extend beyond the distal end of the aspiration catheter 320 during navigation.

**[0088]** In an implementation, the system includes a retrievable stent device 500 with a distal expandable section 510, which is sized and configured to be delivered through the microcatheter 400, as shown in FIG. 9. The retrievable stent device 500 may be used in conjunction with the other components of the system to aid in removal of the occlusion. The retrievable stent device 500 may also be used to quickly restore flow to the occluded artery during the thrombectomy procedure. Examples of retrievable stent devices include the Solitaire Revascularization Device (Medtronic) or the Trevo Stentriever (Stryker).

**[0089]** In a method of use, the retrievable stent device 500 is used to assist in bringing thrombus into the catheter 320 during an aspiration step, or clearing the catheter 320 that may become clogged during the aspiration step. In an implementation, the retrievable stent device 500 is configured to be particularly suited for performing these functions. For example, as shown in FIG. 10A, the distal end of the expandable portion 510 of the device 500 has multiple struts or elements 520 that come together at the distal tip to close off the distalmost end, such that the device allows blood flow across the device, but captures the thrombus pieces as the device 500 is pulled into the catheter 320, and subsequently through the catheter 320 and out the distal end. Alternately, the distal end 520 is a filter element or a balloon element.

**[0090]** In another example, in FIG. 10B, the retrievable stent device 500 includes two or more segments with one or more proximal segments 510a configured to be expanded in the catheter distal inner lumen while one or more distal segments 510b are expanded across the occlusion as is done with prior retrievable stent devices. Alternately, as seen in FIG. 10C, the retrievable stent device 500 has a very long expandable portion 510, such that a proximal portion of the expandable portion may be expanded in the catheter distal inner lumen while the distal portion is expanded across the occlusion. In all these implementations, the proximal end of expandable section 510 has minimal structural elements that will allow the expandable section to be pulled easily into the lumen of the catheter 320, and out of the access sheath 320, so as minimize impediment of thrombus aspiration through the device. In these examples, the expandable portion 510 is still engaged with the clot even when the clot is aspirated into the catheter 320, and if the catheter 320 becomes corked, the device 500 is well-positioned to clear the clot when it is pulled back. Once the retrievable stent device 500 has been removed from the luminal portion 322 of the catheter 320, additional aspiration can be applied to the site through the catheter 320 if it is still partially or fully occluded. This step would not be possible if the catheter 320 remained clogged; the catheter would have to be removed and cleared outside the patient before being reinserted for additional aspiration. This configuration of retrievable stent device 500 can be used with either a conventional single lumen aspiration catheter, or a spined aspiration catheter 320.

**[0091]** The implementations of device 500 as shown in FIGs. 10A-10C may be used with known thrombectomy devices and methods to address the issue of cathe-

ters clogging during thrombus aspiration.

**[0092]** In an implementation, the system includes an aspiration source 600, as shown in FIG. 2A or FIG. 3. The aspiration source 600 can be attached to the aspiration line 230 on the access sheath 220. Examples of aspiration source 600 include a syringe or an active aspiration pump. The aspiration source 600 may be connected to a delivery location, such as a receptacle. The receptacle and source of aspiration 600 may be separate, such as a mechanical or electromechanical fluid pump whose outlet is connected to a blood collection reservoir or may be combined into a single device such as a syringe or syringe pump. Alternately, the blood collection reservoir is connected to a source of vacuum such as a hospital vacuum line or an air vacuum pump, and is thus the receptacle as well as the source of aspiration. A filter and/or a check valve may be coupled with the aspiration source. The pump may be a positive displacement pump such as a diaphragm or piston pump, a peristaltic pump, centrifugal pump, or other fluid pump mechanism known in the art.

**[0093]** In an implementation, the aspiration source is a variable state or multi-state aspiration source, and includes a mechanism to control the level of aspiration, for example by modifying the vacuum level in the vacuum pump, by modifying the power to the motor of a positive displacement, peristaltic or centrifugal pump, or modifying the syringe pull back speed in the syringe or syringe pump. Alternately, the aspiration rate may be varied by providing an element with variable resistance to flow, for example parallel flow paths that can switch between a high and low flow resistance path, flow orifices or lumens that can be variably opened, or other means to vary flow resistance. In an example, the aspiration source is configured to have two levels of aspiration: a high level of aspiration to be used when the catheter is in contact with the thrombotic material, to aspirate the thrombotic occlusion, and a low level of aspiration to be used during steps in the procedure that are high risk of causing distal emboli, for example crossing the lesion or when flow is restored to the vessel when a retrievable stent device is expanded.

**[0094]** In another example, as shown in FIG. 11, the aspiration source 600 further includes a flow sensor 275 that senses flow in the aspiration line 230, coupled to a controller that controls the level of aspiration. The aspiration source 600 can increase in aspiration level when the flow rate is slow and decrease when the flow rate is increased. In this manner, the force is greatest when the catheter is clogged or partially clogged, but decreases to a minimal level when there is free flow to ensure protection from distal emboli but limit the volume of aspirated blood. In this manner, the system optimizes the thrombus aspiration while limiting the amount of blood aspirated. Alternately, the aspiration source 600 can include a vacuum gauge. When the flow in the catheter 320 is blocked or restricted the pump creates a higher level of vacuum. In this example the aspiration force may be configured to rise when higher vacuum is detected.

**[0095]** In yet another aspiration source implementation, the aspiration source 600 provides a cyclic level of aspiration force, for example, an aspiration force that cycles between a high level of vacuum to a lower level of vacuum at a set frequency, or from a high level of vacuum to no vacuum, or from a high level of vacuum to a pressure source. A cyclic aspiration mode may provide a jackhammer type force on the thrombus and increase the ability to aspirate the thrombus through the catheter. The cyclic aspiration force may be enabled through solenoid valves, a programmable pump motor, or the like. In an implementation, cyclic aspiration is applied only when clogged or restricted flow is detected in the aspiration line, either through low flow or high vacuum, as discussed above, and at other times, the aspiration source reverts to a low level of flow, or be turned off. This configuration may be controlled by the user, or controlled automatically via a feedback loop to the aspiration source.

**[0096]** In an implementation, the system includes a mechanism for passive reverse flow that is configured to be connected to the aspiration line on the access sheath. For example, the aspiration line is connected to a lower pressure site such as a central vein, or an external receptacle set to zero or negative pressure.

**[0097]** In an implementation as shown in FIG. 11, the flush line 236 may be connected via stopcock 238 to a syringe 286 that may hold saline fluid or radiopaque contrast. Additionally the flush line 236 may be connected to a flush source 288, for example, a pressurized bag of saline. A valve 292 can control flow from the flush source 288 to the flush line 236. When the valve 292 is opened to the flush line 236 a pressurized source of fluid is provided. In an implementation, the valve 292 is coupled via a mechanical or electromechanical coupler 295 to the aspiration source 600 such that the valve 292 is only open when the aspiration source 600 is on. Alternately, the valve 292 is coupled to a flow sensor 275 in the aspiration line 230, such that the valve 292 is only on when there is flow in the direction towards the aspiration source 600. In these implementations, the flow rate of the flush source 288 is configured to flow just enough to keep the proximal extension 240 clear of blood but not so high as to cause flow to work against the aspiration flow and limit aspiration of thrombus. An advantage of this implementation is that the proximal extension 240 remains clear of blood and any emboli or air that is in the proximal extension 240 is clearly visible. This provides a feedback to the user on when and if to flush the catheter with saline or contrast via syringe 286.

**[0098]** In another implementation, the valve 292 is coupled either mechanically or electromechanically to the valve 242 that connects the sheath body 222 to the proximal portion 240 of the sheath 220. The coupling 290 can be configured such that the valve 292 can only be opened when the valve 242 is closed. This feature allows the proximal extension 240 to be cleared of blood via a flush step, without risk of flushing emboli back through the

catheter into the vasculature. The coupling 290 may be configured in one of several ways For example, the coupling 290 may always open the valve 238 when the valve 242 is closed, or the coupling may prevent the valve 238 from opening unless valve 242 is closed but that does not automatically open.

**[0099]** In an implementation, the valve 292 is a variable state valve that allows different levels of flush flow rate. In this example, the valve 292 is configured to allow a slow flush when the aspiration source is on a low setting, a higher level of flush when the aspiration source is on a high setting. In an implementation, the valve allows yet a higher level of flush when the valve 242 is closed. These configurations allow a continuous removal of debris and/or clear visibility of the proximal portion of the access sheath and minimizes the risk of distal emboli or air entering the vasculature during the steps of the procedure. For example, during the step when the distal tip of catheter is being removed from the proximal hemostasis valve 234, any clot that was captured on the tip of the catheter may be liberated when the catheter is pulled through the valve, but with the continuous flush the liberated emboli would be flushed into the aspiration line and not remain in the sheath where it might be re-injected into the vasculature, for example during a contrast injection after the catheter is removed.

**[0100]** Again with respect to FIG. 1, the system 100 may include a kit of multiple devices. In an implementation, the kit includes an access sheath system 200 wherein the access sheath system includes an access sheath, one or more tapered sheath dilators, and one or more sheath guidewires. In another implementation, the system 100 includes an access sheath system 200 and one or more spined catheter systems 300 with one or more inner diameters. In an implementation, the spined catheter system 300 includes a spined aspiration catheter 320 and a tapered dilator 340. In an implementation, the spined catheter system 300 also includes a catheter clearing tool 350. In yet another implementation, the system 100 includes an access sheath system 200, a tapered catheter system 300, a microcatheter 400, and a retrievable stent device 500.

**[0101]** In an implementation configured for transcarotid access, the kit includes an access sheath 220, wherein the insertable sheath body 222 length is about 23 cm, the proximal extension 240 is about 22 cm, the connector 226 is about 7 cm and the proximal hemostasis valve 234 is about 5 cm, for an overall access sheath length of about 57 cm. In an implementation, the kit also includes a spined aspiration catheter 320 wherein the catheter distal luminal portion 322 is about 20 cm, the transition section 326 is about 2-4 cm, and the spine section 330 is about 65 cm, for an overall spined catheter length of about 88 cm. In another implementation, the kit also includes a tapered dilator 340 with a working length of 93 cm. In another implementation, the kit also includes a microcatheter 400 with a working length of about 198 cm and a retrievable stent device 500 with an overall length of 128 cm.

**[0102]** In an implementation configured for transfemoral access, the kit includes an access sheath system 220, wherein the insertable sheath body 222 length is about 90 cm, the proximal extension 240 is about 22 cm, the connector 226 is about 7 cm and the proximal hemostasis valve 234 is about 5 cm, for an overall access sheath length of about 124 cm. The proximal portion of the access sheath may be a removable proximal portion 280. In an implementation, the kit also includes a spined aspiration catheter 320, wherein the catheter distal luminal portion 322 is about 20 cm, the transition section 326 is about 2-4 cm, the spine section 330 is about 132 cm, for an overall spined catheter length of about 155 cm. In another implementation, the kit also includes a tapered dilator 340 with a working length of 160 cm. In another implementation, the kit also includes a microcatheter 400 with a working length of about 165 cm and a retrievable stent device 500 with an overall length of 195 cm.

**[0103]** In another implementation, the kit includes an access sheath 220 with a removable proximal portion 280, and a single lumen aspiration catheter. In another implementation, the kit includes only the proximal portion 280 that can be attached to any introducer sheath suitable for the procedure. In this implementation, the kit may also include a spined aspiration catheter 320 or a single lumen aspiration catheter.

**[0104]** In any of these implementations, the kit may also include an aspiration source, for example a pump, an attachment to a vacuum pump, a syringe, a syringe that is attachable to a syringe pump, or the like. The kit may also include means for automatic flushing, for example coupling means 290 or 292.

**[0105]** As described elsewhere herein, it should be appreciated that reference to one implementation of an access sheath system or catheter system is not intended to be limited and that the kits described herein can incorporate any of the systems and/or ancillary devices described herein as having any of a variety of features. For example, where an access sheath is described as being a part of a kit it should be appreciated that one or more features of any of the access sheaths or access sheath systems described herein can be incorporated. Similarly, where a spined catheter is described as being part of a kit one or more featured of any of the spined catheters or spined catheter systems described herein can be incorporated.

**[0106]** FIGs. 2A and 3 illustrates methods of use. As shown in FIG. 2A, an access sheath 220 is inserted using standard vascular access sheath into the femoral artery, and advanced until the sheath tip is positioned at a site as distal as safely possible in the internal or common carotid artery. In FIG. 3, the access sheath 220 is inserted directly into the common carotid artery, and advanced until the sheath tip is positioned at a site as distal as safely possible in the internal carotid artery. In either scenario, the sheath may be advanced initially to the common carotid artery or proximal internal carotid artery, and

then the dilator and is exchanged for a softer dilator before advancing the sheath more distally into the internal carotid artery. The sheath is then secured to the patient using a suture through the eyelet on the sheath connector. The sheath aspiration line 230 is connected to an aspiration source 600 such as a syringe or aspiration pump. The sheath aspiration line may also be connected via a stopcock or stopcock manifold to a forward flush line (such as a pressurized saline bag).

**[0107]** Once the sheath tip is positioned at the desired location, it is secured to the patient. A spined catheter, tapered dilator, and guidewire are pre-assembled in a co-axial configuration and introduced through the sheath proximal hemostasis valve into the carotid artery. The spined aspiration catheter 320 is advanced through access sheath and positioned until the distal tip is at the treatment site. The devices are advanced using standard interventional techniques until the distal catheter tip is at the proximal face of the occlusion. A mark 332 on the spine 330 ensures that there is still an overlap region 120 between the distal luminal portion 322 of the catheter and the access sheath body 222. At this point, the tapered dilator 340 and guidewire can be removed. In an alternate implementation, a microcatheter 400 is used in place of the tapered dilator 340 to help navigate the catheter 320 to the occlusion. During the procedure, the forward flush is opened to the aspiration lumen to keep the lumen clear before or between periods of aspiration. At any point during device navigation, aspiration may be initiated from the aspiration source 600 at a level suitable for distal embolic protection, for example when the guidewire or microcatheter 400 is crossing the occlusion.

**[0108]** Once the distal tip of the spined aspiration catheter 320 is at the face of the clot, aspiration is initiated at a level suitable for aspiration thrombectomy, which is a higher level than for distal embolic protection. The catheter 320 may remain in aspiration mode against the clot for some period of time, as deemed suitable by the user. Depending on the results of the aspiration thrombectomy maneuver (as observed by flow though the aspiration line and/or resistance to backwards force on the spine of the catheter), the user may determine that the clot has been completely aspirated, or if not, the user may choose to move the catheter 320 back and forth to aspirate the clot in situ, or to slowly retract the catheter 320 into the sheath 220. If flow is restored to the artery via aspiration of the clot through the catheter 320 and sheath 220, a final angiogram may be performed and the catheter 320 can be retracted. If however, thrombus occludes the catheter tip and cannot be removed, the catheter 320 is pulled back, with some or all of the occlusion attached through suction force to the tip of the catheter 320.

**[0109]** In the latter scenario, aspiration is maintained at the tip of the catheter 320 the entire time the catheter 320 is being pulled into the access sheath 220. Once the catheter 320 has been completely retracted into the access sheath 220, the catheter 320 can be quickly removed from the sheath body 222 while aspiration is maintained on the sheath 220. It should be appreciated that the catheter 320 may be withdrawn into the sheath body 222 after extending through the distal opening 219 at the distal tip of the sheath body 222. Alternatively, the catheter 320 may be extending through a side opening 219 near a distal end region of the sheath body 222 such that withdrawal of the catheter 320 into the sheath body 220 occurs through this side opening 219. At some time during catheter retraction, depending on if the catheter 320 is clogged with occlusive material, the aspiration level may be changed from a high level desirable for aspiration thrombectomy to a lower level desirable for distal embolic protection. By providing the ability to maintain aspiration continuously from either the catheter tip or the sheath tip or the sheath distal region, and providing the means to change aspiration levels and maintain asp, the procedure optimizes the ability to aspiration clot while minimizing distal emboli and minimizing blood loss from aspiration. If desired, aspiration may also be initiated at the flush line 236 of the proximal valve 234, to reduce chance of distal embolization during removal of the catheter tip with possibly adhered clot through the proximal valve 234.

**[0110]** The spined aspiration catheter 320 may be removed completely from the proximal hemostasis valve 234 of the sheath 220. Alternately, if the access sheath 220 has a proximal extension 240, the distal luminal portion 322 may be pulled into the proximal extension portion 240. In the latter scenario, once pulled in, the catheter 320 and sheath 220 may be flushed to remove potential embolic material without removing the catheter 320 completely from the sheath 220. A vigorous flush from the proximal valve flush line 236 simultaneous with aspiration from the aspiration line 230 creates a flush environment for the catheter 320 and sheath 220. If desired, a catheter clearing tool 350 may be inserted into the sheath proximal valve 234 and used at this time to clear the inner lumen 323 of the catheter 320. If the access sheath 220 has a connector valve 242, the proximal portion 240 may be closed off from the sheath body 222 during this stage, so that there is no risk of flushing embolic material into the sheath body 222 and thence into the artery.

**[0111]** Alternately, the valve 242 may be closed off and aspiration paused while the proximal valve 242 is opened or removed and the catheter 320 is completely removed from the sheath 220. Closing the valve 242 limits the blood loss from the sheath 220 as the catheter 320 is removed. The catheter 320 may then be flushed onto the table or into a bowl or other receptacle, using the cleaning tool 350. The proximal extension portion 240 may also be flushed by providing a flush source 288 from the proximal valve flush line 236 simultaneous with aspiration from the aspiration line 230, or by opening a side port on the aspiration line 230 to flush to the table or into a bowl or other receptacle. If desired, an angiogram may be performed to assess flow through the treated artery. If the procedure dictates, the catheter 320 or another catheter may be re-advanced as above over a guidewire and tapered dilator 340 or microcatheter 400 to the site of the

occlusion to attempt another aspiration thrombectomy step. The flushing of the catheters and proximal extension portion 240 of the access sheath 220 minimizing the risk of distal emboli during these subsequent steps.

**[0112]** In another exemplary method, a retrievable stent device 500 can be used in conjunction with aspiration to remove the thrombotic occlusion. FIG. 9 illustrates this method of use through either a transcarotid or transfemoral access site. In this scenario, the access sheath 220 can be positioned as above and advanced until the sheath tip is positioned at a site as distal as safely possible in the internal carotid artery. The spined aspiration catheter 320 can be then pre-loaded onto a microcatheter 400 and guidewire, and the co-axial assembly can be introduced via the access sheath 220 into the carotid artery and advanced into the cerebral vasculature. The microcatheter 400 and guidewire can be advanced across occlusion. The tip of the spined aspiration catheter 320 can be advanced as distal as possible but proximal to the clot.

**[0113]** At this point, the guidewire can be removed and the retrievable stent device 500 inserted through the microcatheter 400 until it too is positioned across the occlusion. The microcatheter 400 can be pulled back to deploy the stent. At any point during device navigation, aspiration may be initiated from the aspiration source at a level suitable for distal embolic protection, for example when the guidewire or microcatheter 400 is crossing the occlusion, or prior to stent deployment. By having aspiration initiated before stent deployment, any emboli that was liberated while crossing the lesion is not carried downstream on restoration of flow in the artery, but is rather captured into the catheter tip. While the retrievable stent device 500 is deployed, aspiration may be maintained. It is typically deployed for several minutes before retraction of the stent is attempted, to maximize the engagement of the stent struts to the occlusion. Then, the retrievable stent device 500 can be pulled into the spined catheter 320 and continued to be retracted until it has been completely removed from the proximal valve of the access sheath 220.

**[0114]** Alternately, the stent device 500 can be pulled into the distal portion of the spined catheter 320, and the stent device 500 and spined catheter 320 can be pulled back together out of the access sheath 220. Aspiration may be increased to a higher level during stent and/or catheter retraction steps, to optimize aspiration of clot and minimize distal emboli. If the access sheath 220 has a proximal extension 240 with a valve on the connector, the device 500 can be pulled into the proximal extension 240 and the valve closed, and then the proximal hemostasis valve 234 may be opened widely and the stent device 500 or the stent device/spined catheter combination may be pulled out. The proximal extension section 240 may then be flushed via the valve flush line 236 and the aspiration line 230 before the same or alternate devices are reinserted for another thrombectomy attempt, if the procedure dictates.

**[0115]** Alternately after placement of an aspiration catheter 320, a long or segmented stent retriever 500 can be positioned as above with a microcatheter 400 such that part of the expandable portion 510 is across the thrombus and part is in the distal segment 322 of the catheter 320, and then expanded. After the expandable portion 510 is expanded aspiration can be initiated so that thrombus either is suctioned completely out of the vessel and catheter 320 into the aspiration source 600, or is suctioned into the distal tip and/or distal lumen 323 of the catheter 320. At that point, the long or segmented stent retriever 500 can be carefully pulled into the catheter 320, while maintaining aspiration. During this time clot that has been clogging the catheter 320 and/or debris that is liberated during this step should be aspirated into the catheter 320. Complete removal of the stent retrieval device 500 from the working channel 323 of the catheter 320 should free up the lumen 323 from occlusive material.

**[0116]** In any of these scenarios, the aspiration source may be a variable or multi-state aspiration source that is configured to maximize the aspiration force on the thrombotic occlusion while minimizing blood loss during periods of free flow in the catheter.

**[0117]** In another exemplary method, the access sheath 220 has an occlusion balloon 246. As seen in FIG. 7, the balloon 246 may be inflated during steps of the procedure that are high risk for distal emboli, for example retraction of the stent device 500 or the spined catheter 320 with adhered clot. The balloon 246 has the effect of stopping antegrade flow and increasing the force of aspiration in the carotid artery, thus increasing the aspiration of clot and reducing the risk of distal emboli.

**[0118]** In another exemplary method, the access sheath 220 has an expandable distal tip. In this method, the distal tip may be expanded sometime after the access sheath tip has been positioned at the desired site, but before retraction of the spined catheter 320 into the access sheath 220. This method would reduce the chance of distal emboli caused by the release of clot that was adhered to the distal tip of the spined catheter 320, as the distal tip is pulled into the tip of the sheath 220. Instead, the access sheath tip that is expanded or flared out acts as a funnel to capture the entire clot.

**[0119]** In another exemplary method and as discussed briefly above, the access sheath 1220 has a side opening 1219 (best shown in FIG. 12C). In this method, the spined catheter 1320 having a spined dilator 1340 extending through lumen 1323 of the distal luminal portion 1322 of the catheter 1320 can be advanced distally through the lumen 1223 of the access sheath 1220 towards the distal end region of the sheath body 1222. The distal tip of the distal luminal portion 1322 of the spined catheter 1320 (which may having the spined dilator extending through the distal luminal portion 1322 and forming a distal-most end to the catheter system) may exit the lumen 1223 via the side opening 1219 and then be further advanced distally beyond the distal tip of the access sheath 1220. A ramp feature 1217 or other internal feature can be incor-

porated at a distal end region of the lumen 1223 to provide a surface against which the tip of the dilator can be deflected to guide the catheter 1320 away from a longitudinal axis A of the lumen 1223 of the sheath body 1222 towards the side opening 1219 to achieve a smooth transition or exit from the lumen 1223. The distal tip 1346 of the dilator 1340 can abut against the ramp feature 1217 and be directed at a slight angulation away from the longitudinal axis of the sheath body 1222 towards the side opening 1219. As described elsewhere herein, the sheath body 1222 and thus the side opening 1219 can be rotated around the longitudinal axis A such that the one or more side openings 1219 are positioned to allow for distal extension of the catheter 1320 from the side openings 1219 in a desired direction relative to the longitudinal axis A of the sheath 1220. This will often be dictated by the anatomy encountered by the operator. Also as mentioned elsewhere herein, an overlap region 1120 is formed between the distal luminal portion 1322 of the catheter and the access sheath body 1222. A sealing element 1336 can be positioned on the external surface of the distal luminal portion 1322, for example, near a proximal end region of the distal luminal portion 1322 and may be located within the overlap region 1120. The seal formed can allow for full transmission of aspiration force through the contiguous lumen formed by the lumen 1323 of the luminal portion 1322 and the lumen 1223 of the access sheath body 1222 upon withdrawal of the dilator 1340 from the lumen 1323 of the luminal portion 1322.

**[0120]** In another exemplary method, the aspiration source 600 is connected to a blood collection reservoir that maintains the integrity of the blood in such a way that the blood can be safely returned to the patient at the conclusion of the thrombectomy portion of the procedure, either directly or through subsequent treatment of the blood such as cell washing and/or blood filtration. In another exemplary method, the aspiration source is connected to a blood shunt that is connected in turn to a device such as a venous sheath or a venous return catheter that enables blood to be returned to the patient during the procedure and not requiring a blood reservoir. In another exemplary method, the blood is collected in a reservoir and subsequently discarded at the end of the procedure.

**[0121]** In another exemplary method, the access sheath 1220 is delivered as described elsewhere herein from a femoral insertion site to a right or left subclavian artery or an external carotid artery. The access sheath 1220 may be delivered to a carina of a bifurcation between a target vessel having the embolus, such as the internal carotid artery (ICA), and another vessel, such as the external carotid artery (ECA). Once the access sheath 1220 is in position a working device such as a splined aspiration catheter 1320 can be delivered through the lumen 1223 of the access sheath 1220 into the target vessel. The lumen 1223 of the access sheath 1220 and the lumen 1323 of the catheter 1320 are contiguous and form a stepped up diameter for aspiration as described elsewhere herein. An overlap region 1120 is maintained between the catheter 1320 extending distally from the lumen 1223 of the access sheath 1220. It should be appreciated that the catheter 1320 can extend distally from the lumen 1223 of the access sheath 1220 through an opening 1221 at the distal tip of the access sheath 1220 or a side opening 1119 near the distal region of the access sheath 1220. The body 1222 of the access sheath 1220 may be oriented to provide optimum placement of the side opening 1119 relative to the anatomy. The overlap region 1120 between the distal luminal portion 1322 of the catheter 1320 and the access sheath body 1222 can create a seal and allow for full transmission of aspirating force through the contiguous lumen formed by the lumen 1323 of the luminal portion 1322 and the lumen 1223 of the access sheath body 1222, as well as providing a seal for delivery of fluids to the target vessel such as angiographic contrast injection, saline, one or more drugs or other materials directly into the neurovascular anatomy. The spined aspiration catheter 1320 can create a more powerful aspiration force by allowing for the working lumen 1223 of the access sheath 1220 to provide a majority of the aspiration column. As described elsewhere herein, the dimension of the lumen 1323 of the distal luminal portion 1322 of the aspiration catheter 1320 may be less than the diameter of the lumen 1223 of the access sheath 1220, which is reduced only by a diameter of the spine 1330 extending therethrough. The increased diameter of the lumen can create a larger aspiration column than, e.g., an aspiration column of a large bore catheter having a similar overall length. The spined aspiration catheter 1320 may also be used as a supportive delivery catheter, for example, where the operator wants to reach the petrous carotid or other hard to reach landmarks within the cerebral vasculature. More particularly, after delivering the spined aspiration catheter 1320 into the target vessel through the working lumen 1223 of the access sheath 1220, a secondary working device such as a guidewire, microcatheter, stent retriever, etc. may be delivered through the lumen 1323 into a more distal anatomy to perform other procedural operations as described elsewhere herein.

**[0122]** While this specification contains many specifics, these should be construed as descriptions of features specific to particular implementations. Certain features that are described in this specification in the context of separate implementations can also be implemented in combination in a single implementation. Conversely, various features that are described in the context of a single implementation can also be implemented in multiple implementations separately or in any suitable sub-combination. Moreover, although features may be described above as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination may be directed to a sub-combination or a variation of a sub-combination.

Similarly, while operations are depicted in the drawings in a particular order, this should not be understood as requiring that such operations be performed in the particular order shown or in sequential order, or that all illustrated operations be performed, to achieve desirable results.

## STATEMENTS

**[0123]**

1. An intravascular access system for facilitation of intraluminal medical procedures within the neurovasculature through an access sheath, the system comprising:

an aspiration or support catheter comprising:

a flexible, distal luminal portion having an inner diameter defining a lumen extending between a proximal opening at a proximal end of the luminal portion and a distal opening at a distal end of the luminal portion; and a rigid spine coupled to at least the proximal end of the luminal portion and extending proximally therefrom; and

a dilator comprising:

a flexible, distal dilator portion sized to be received within the lumen of the luminal portion; and
a rigid, dilator spine extending proximally from the dilator portion.

2. The system of statement 1, wherein, when in use, the dilator spine aligns side-by-side with the spine of the catheter.
3. The system of statements 1 or 2, wherein the distal dilator portion has a tapered distal tip.
4. The system of any of statements 1-3, wherein the dilator has a length at least as long as a length of the catheter such that a distal tip of the dilator protrudes from the distal opening of the luminal portion.
5. The system of any of statements 1-4, wherein the dilator is generally tubular along at least a portion of the length.
6. The system of any of statements 1-5, wherein a proximal end of the catheter spine includes a gripping feature configured for a user to grasp in order to move the catheter through an access sheath.
7. The system of statement 6, wherein a proximal end of the dilator spine includes a tab configured to be locked with the gripping feature on the catheter spine.
8. The system of statement 7, wherein when the catheter and the dilator are in a locked configuration they are advanced as a single unit through the access sheath.
9. The system of statements 7 or 8, wherein the gripping feature and the dilator tab are removably coupled such that in a locked configuration the dilator tab engages the gripping feature and in an unlocked configuration the dilator tab disengages from the gripping feature.
10. The system of any of statements 7-9, wherein the dilator tab is affixed to the dilator.
11. The system of any of statements 7-9, wherein the dilator tab is slideable on the dilator to accommodate different relative positions between the dilator and the catheter.
12. The system of any of the preceding statements, wherein the distal dilator portion comprises one or more detents on an outer surface configured to lock with correspondingly-shaped surface features on an inner surface of the luminal portion lumen through which the dilator portion extends.
13. The system of any of the preceding statements, wherein the dilator spine and the catheter spine have a similar stiffness and kink-resistance.
14. The system of any of the preceding statements, wherein the dilator has a visual marker on a distal end and/or a proximal end of the distal tip.
15. The system of any of the preceding statements, wherein a distal end region of the dilator is more flexible and increasingly stiffens towards a proximal end region of the dilator.
16. The system of any of the preceding statements, wherein the catheter spine and dilator spine are configured to cause bi-directional sliding movement of the luminal portion through a lumen of an access sheath and navigate the luminal portion into a cerebral vessel to reach a treatment site.
17. An intravascular access system for facilitation of intraluminal medical procedures within the neurovasculature, the system comprising:

an access sheath having a sheath body comprising an inner diameter defining a lumen between a proximal end and a distal end of the sheath body, and at least one opening from the lumen near a distal end region of the sheath body; and
an aspiration or support catheter comprising:

a flexible, distal luminal portion having an outer diameter sized for insertion through the lumen of the access sheath, an inner diameter defining a lumen extending between a proximal opening at a proximal end of the luminal portion and a distal opening at a distal end of the luminal portion, and a length between the proximal opening and the distal opening; and
a rigid spine coupled to at least the proximal end of the luminal portion and extending

proximally therefrom,

wherein the rigid spine is configured to cause bi-directional sliding movement of the luminal portion through the lumen of the access sheath and out the at least one opening to navigate the luminal portion into a cerebral vessel to reach a treatment site, and

wherein a portion of the outer diameter of the luminal portion fluidly seals with the inner diameter of the access sheath when the distal end of the luminal portion extends into the cerebral vessel to reach the treatment site.

18. The system of statement 17, wherein the luminal portion and the sheath body are concentrically aligned and the lumen of the luminal portion and the lumen of the sheath body form a contiguous aspiration lumen from the distal end of the luminal portion to the proximal end of the sheath body.

19. The system of statement 18, wherein the contiguous aspiration lumen is usable to aspirate fluid and debris from the distal opening of the luminal portion.

20. The system of statements 18 or 19, wherein the contiguous aspiration lumen is usable to deliver materials through the distal opening of the luminal portion.

21. The system of any of statements 17-20, wherein the contiguous aspiration lumen forms a step-up in diameter where the lumen of the luminal portion empties into the lumen of the sheath body.

22. The system of any of statements 17-21, wherein the lumen of the luminal portion is shorter than the lumen of the sheath body.

23. The system of any of statements 17-22, wherein the luminal portion and the sheath body form an overlap region when the luminal portion extends distally beyond the at least one opening of the sheath body.

24. The system of statement 23, wherein the outer diameter of the luminal portion approaches the inner diameter of the lumen of the sheath body such that a seal is formed by the overlap region.

25. The system of statement 24, wherein the seal is configured to enable sealing against a vacuum of up to 25 inHg, or up to 28 inHg.

26. The system of statement 24, wherein the seal within the overlap region is configured to enable sealing against a pressure of up to 300 mmHg.

27. The system of any of statements 24-26, wherein the seal is located distal a proximal end of the luminal portion and proximal to the at least one opening of the sheath body.

28. The system of any of statements 24-27, further comprising a sealing element positioned on an external surface of the luminal portion.

29. The system of statement 28, wherein the sealing element includes a stepped up diameter or protruding feature in the overlap region.

30. The system of statement 28, wherein the sealing element comprises one or more external ridge features.

31. The system of statement 30, wherein the one or more ridge features are compressible when the luminal portion is inserted into the lumen of the sheath body.

32. The system of statement 28, wherein the sealing element comprises one or more inclined surfaces biased against an inner surface of the sheath body lumen.

33. The system of statement 28, wherein the sealing element comprises one or more expandable members actuated to seal.

34. The system of any statements 17-33, wherein the sheath body has an outer diameter suitable for insertion into the carotid artery.

35. The system of statement 34, wherein the outer diameter of the sheath body is between 5Fr and 7Fr.

36. The system of any of statements 17-35, wherein the sheath body has a length between the proximal end and the distal end suitable for locating the distal end of the sheath body at the petrous portion of an internal carotid artery from a transfemoral approach.

37. The system of statement 36, wherein the length of the sheath body is between 80 cm and 105 cm.

38. The system of any of statements 17-37, wherein the length of the luminal portion is between 10 cm and 25 cm.

39. The system of any of statements 17-38, wherein the length of the luminal portion is less than a length of the sheath body such that as the catheter is retracted into the sheath body a seal remains between an overlap region of the luminal portion and the inner diameter of the sheath body.

40. The system of any of statements 17-39, wherein the spine is longer than an entire length of the sheath body.

41. The system of any of statements 17-40, wherein the luminal portion includes three or more layers including an inner lubricious liner, a reinforcement layer, and an outer jacket layer.

42. The system of statement 41, wherein the outer jacket layer is composed of discreet sections of polymer with different durometers, compositions, and/or thicknesses to vary the flexibility along the length of the distal luminal portion.

43. The system of any of statements 17-42, wherein the outer diameter of the distal luminal portion is sized for navigation into cerebral arteries.

44. The system of any of statements 17-43, wherein the inner diameter of the distal luminal portion is between 0.040" and 0.088".

45. The system of any of statements 17-44, wherein the outer diameter of the luminal portion approaches the inner diameter of the sheath body creating a sealed area at an overlap region while still allowing the catheter to move through the sheath body.

46. The system of any of statements 17-45, wherein the catheter is tapered towards the distal opening such that a distal-most end of the luminal portion has a smaller outer diameter compared to a more proximal region of the luminal portion near where the luminal portion seals with the sheath body.
47. The system of any of statements 17-46, wherein the distal end region of the sheath body comprises an occlusion element.
48. The system of any of statements 17-47, wherein the distal end region of the sheath body comprises an expanding distal tip.
49. The system of any of statements 17-48, wherein the at least one opening from the lumen comprises a side opening located a distance away from a distal tip of the sheath body.
50. The system of any of statements 17-49, wherein a distal tip of the sheath body further comprises a ramp feature configured to direct at an angulation the catheter away from a longitudinal axis of the sheath body lumen out through the at least one opening.
51. The system of any of statements 17-50, wherein the spine is longer than an entire length of the sheath body.
52. The system of any of statements 17-51, wherein the spine is a wire having an outer dimension from 0.014" to 0.018".
53. The system of any of statements 17-52, wherein the spine is a hypotube having a guide-wire passageway extending therethrough.
54. The system of any of statements 17-53, wherein the spine is a ribbon having an outer dimension from 0.010" to 0.025" thick.
55. The system of statement 54, wherein the ribbon is curved along at least a portion of an arc.
56. The system of any of statements 17-55, wherein the spine is configured to rotate the luminal portion around a longitudinal axis of the access sheath.
57. The system of any of statements 17-56, wherein the spine is eccentrically coupled to the luminal portion and the spine extends proximally from the luminal portion to outside the proximal end of the sheath body.
58. The system of any of statements 17-57, wherein the proximal end of the luminal portion has an angled cut.
59. The system of statement 58, wherein the angled cut is generally planar or is curved.
60. The system of any of statements 17-59, wherein the sheath body has one or more visual markers on the distal end region of the sheath body.
61. The system of any of statements 17-60, wherein the distal luminal portion has one or more visual markers at a distal end region of the luminal portion, a proximal end region of the luminal portion or both.
62. The system of statements 60 or 61, wherein the one or more visual markers on the sheath body and the one or more visual markers on the luminal portion are visually distinct.
63. The system of any of statements 60-62, wherein the spine has one or more visual markers.
64. The system of statement 63, wherein the one or more visual markers of the spine indicates overlap between the distal luminal portion and the sheath body.
65. The system of statements 63 or 64, wherein the one or more visual markers of the spine is positioned so that when the visual marker of the spine is aligned with a portion of the access sheath, the catheter is positioned at a distal-most position with minimal overlap length needed to create a seal between the catheter and the sheath body.
66. The system of any of statements 17-65, further comprising a dilator comprising a flexible, distal dilator portion having a distal tip and sized to be received within the luminal portion of the catheter.
67. The system of statement 66, wherein the dilator is a tubular element along at least a portion of its length.
68. The system of statement 66, wherein the dilator is a solid rod formed of malleable material configured to be shaped by a user.
69. The system of statement 66, wherein the dilator further comprises a rigid, dilator spine extending proximally from the dilator portion.
70. The system of statement 69, wherein the dilator spine is coaxial.
71. The system of statement 70, wherein the coaxial dilator spine has a lumen extending through it.
72. The system of statement 69, wherein the dilator spine is eccentric.
73. The system of any of statements 69-72, wherein when in use the dilator spine aligns side-by-side with the spine of the catheter.
74. The system of any of statements 66-73, wherein the distal tip is tapered.
75. The system of statement 74, wherein the dilator has a length at least as long as a length of the catheter such that the distal tip protrudes from the distal opening of the luminal portion.
76. The system of any of statements 69-75, wherein a proximal end of the spine includes a gripping feature configured for a user to grasp in order to move the catheter through the access sheath.
77. The system of statement 76, wherein a proximal end of the dilator spine includes a tab configured to be locked with the gripping feature on the catheter spine.
78. The system of statement 77, wherein when the catheter and dilator are in a locked configuration they are advanced as a single unit through the sheath body.
79. The system of statements 77 or 78, wherein the gripping feature and the dilator tab are removably coupled such that in a locked configuration the dilator

tab engages the gripping feature and in an unlocked configuration the dilator tab disengages from the gripping feature.

80. The system of any of statements 77-79, wherein the dilator tab is affixed to the dilator.

81. The system of any of statements 77-79, wherein the dilator tab is slideable on the dilator to accommodate different relative positions between the dilator and the catheter.

82. The system of any of statements 66-81, wherein the distal dilator portion comprises one or more detents on an outer surface configured to lock with correspondingly-shaped surface features on an inner surface of the luminal portion lumen through which the dilator portion extends.

83. The system of any of statements 69-82, wherein the dilator spine and the catheter spine have a similar stiffness and kink-resistance.

84. The system of any of statements 66-83, wherein the dilator has a visual marker on a distal end and/or a proximal end of the distal tip.

85. The system of any of statements 66-84, wherein a distal end region of the dilator is more flexible and increasingly stiffens towards the proximal end region of the dilator.

86. The system of any of statements 17-85, wherein the access sheath further comprises a connector that connects the proximal end of the sheath body to a proximal hemostasis valve.

87. The system of statement 86, wherein the proximal hemostasis valve has an adjustable opening sized large enough to allow removal of the catheter without dislodging any clots thereon.

88. The system of statement 86 or 87, wherein, when in use with the access sheath, the rigid spine of the catheter extends proximally from the luminal portion through the access sheath lumen and out the proximal hemostasis valve of the access sheath.

89. The system of any of statements 86-88, wherein the connector provides a connection of the proximal end of the sheath body to an aspiration line.

90. The system of any of statements 86-89, wherein the connector has a large bore inner lumen and connects to a large-bore aspiration line.

91. The system of statement 89 or 90, wherein the aspiration line connects to an aspiration source.

92. The system of statement 91, wherein the aspiration source is an active aspiration source.

93. The system of any of statements 89-92, wherein the aspiration line connects to a forward drip or flush line.

94. The system of any of statements 17-93, wherein the access sheath further comprises a proximal extension portion such that when the distal luminal portion of the catheter is withdrawn from the sheath body lumen it remains within the proximal extension portion.

95. The system of any of statements 17-94, wherein the inner diameter of the luminal portion is sized to permit placement of an interventional device through the luminal portion.

## Claims

1. A dilator (340, 1340) for facilitation of intraluminal medical procedures within the neurovasculature, the dilator (340, 1340) comprising:

   a flexible distal dilator portion (1360) having a proximal end region and a distal end region (346, 1346) having a distal tapered tip (346, 1346), a single lumen, and an outer diameter, wherein the single lumen extends longitudinally through the dilator portion (1360) to a distal opening at the distal tapered tip (346, 1346); and
   a spine (1362) extending proximally from the proximal end region of the dilator portion (1360), wherein the spine is made of a different material than the dilator portion and has a single lumen that communicates with the single lumen of the dilator portion (1360).

2. The dilator of claim 1, further including a first radiopaque marker (344) at a distal end of the distal tapered tip (346, 1346).

3. The dilator of claim 1 or claim 2, further including a second radiopaque marker (343) at a proximal end of the distal tapered tip (346, 1346).

4. The dilator of claim 2 or 3, wherein the flexible distal dilator portion is made of polymer.

5. The dilator of claim 1 or 4, wherein the spine is made of metal.

6. The dilator of claim 1 or 5, wherein the distal dilator portion has a variable stiffness between the distal end region and the proximal end region, wherein the distal end region of the distal dilator portion is made of a more flexible material than the proximal end region with increasingly stiffer material moving proximally.

7. The dilator of claim 1 or 2, wherein the outer diameter is generally tubular along at least a portion of the flexible distal dilator portion.

8. The dilator of claim 7, wherein the tubular portion extends along the entire length of the dilator.

9. The dilator of claim 7, wherein the outer diameter is sized to be received within a lumen of a catheter, the lumen having an inner diameter sized to receive the dilator in a slip fit, optionally wherein the outer diam-

eter of the dilator is about 1.778 mm and the inner diameter of the catheter is about 1.828 mm

**10.** The dilator of claim 1, 2 or 3 wherein the distal tapered tip (346, 1346) has a length between 1.5 cm and 3 cm.

**11.** The dilator of any of the preceding claims further including a proximal female luer adaptor (348) at a proximal end of the proximal end region of the flexible distal dilator portion.

**12.** The dilator of claim 1, wherein the spine has an outer diameter that is equal to the outer diameter of the flexible distal dilator portion.

**13.** The dilator of claim 1, wherein the spine has an outer diameter that is less than the outer dimeter of the flexible distal dilator portion.

**14.** The dilator of claim 1 or 2, wherein the lumen of the flexible distal dilator portion is sized to accommodate a guidewire having a diameter between 0.356 mm and 0.457 mm, or, wherein the inner luminal diameter of the flexible distal dilator portion is between 0.508 mm and 0.620 mm.

**15.** The dilator of claim 1 or 2, wherein the outer diameter of the flexible distal dilator portion (1360) is sized to be received within a lumen of a catheter (320, 1320) and form a smooth transition between the flexible distal dilator portion and the lumen of the catheter (320, 1320).

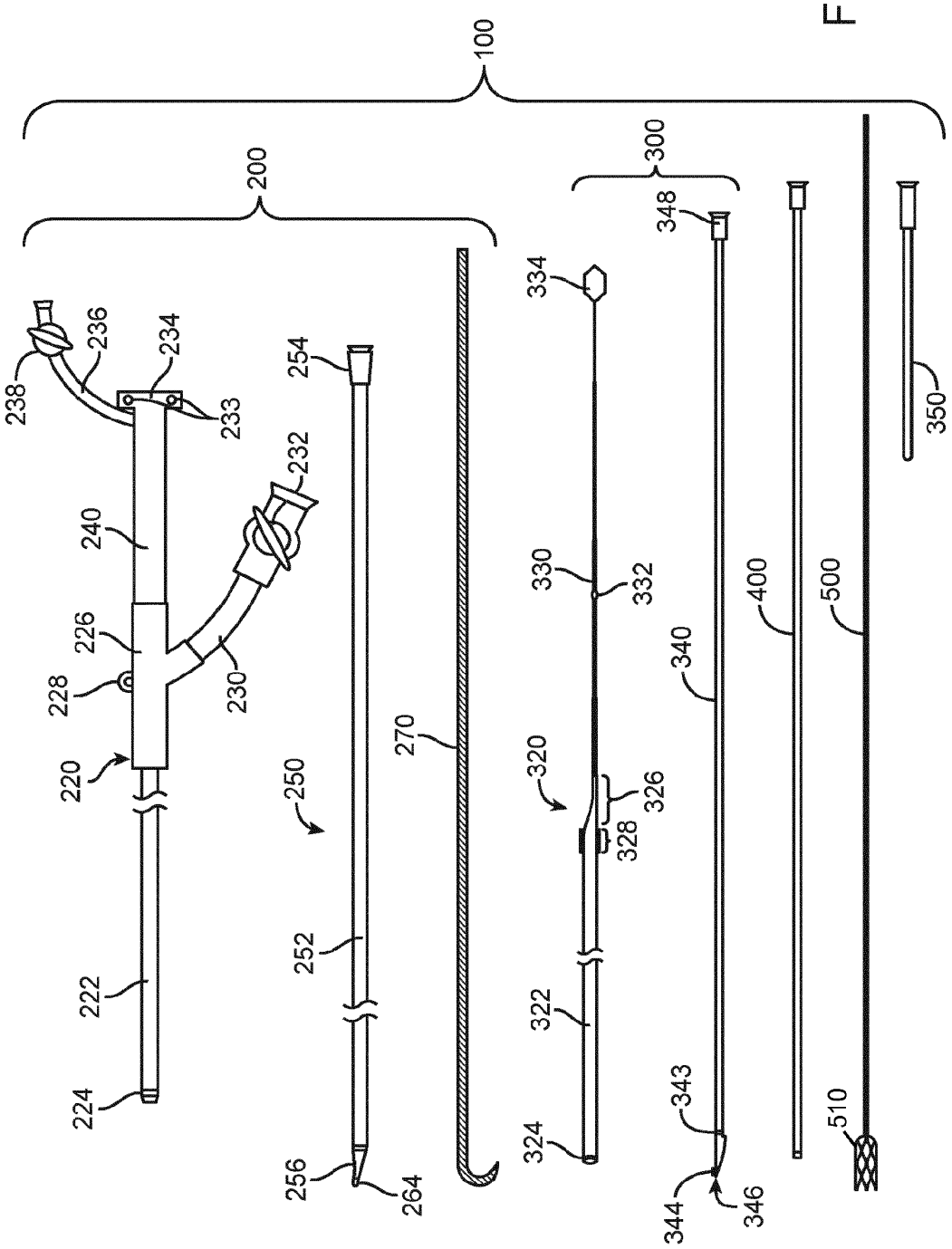

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FIG. 1

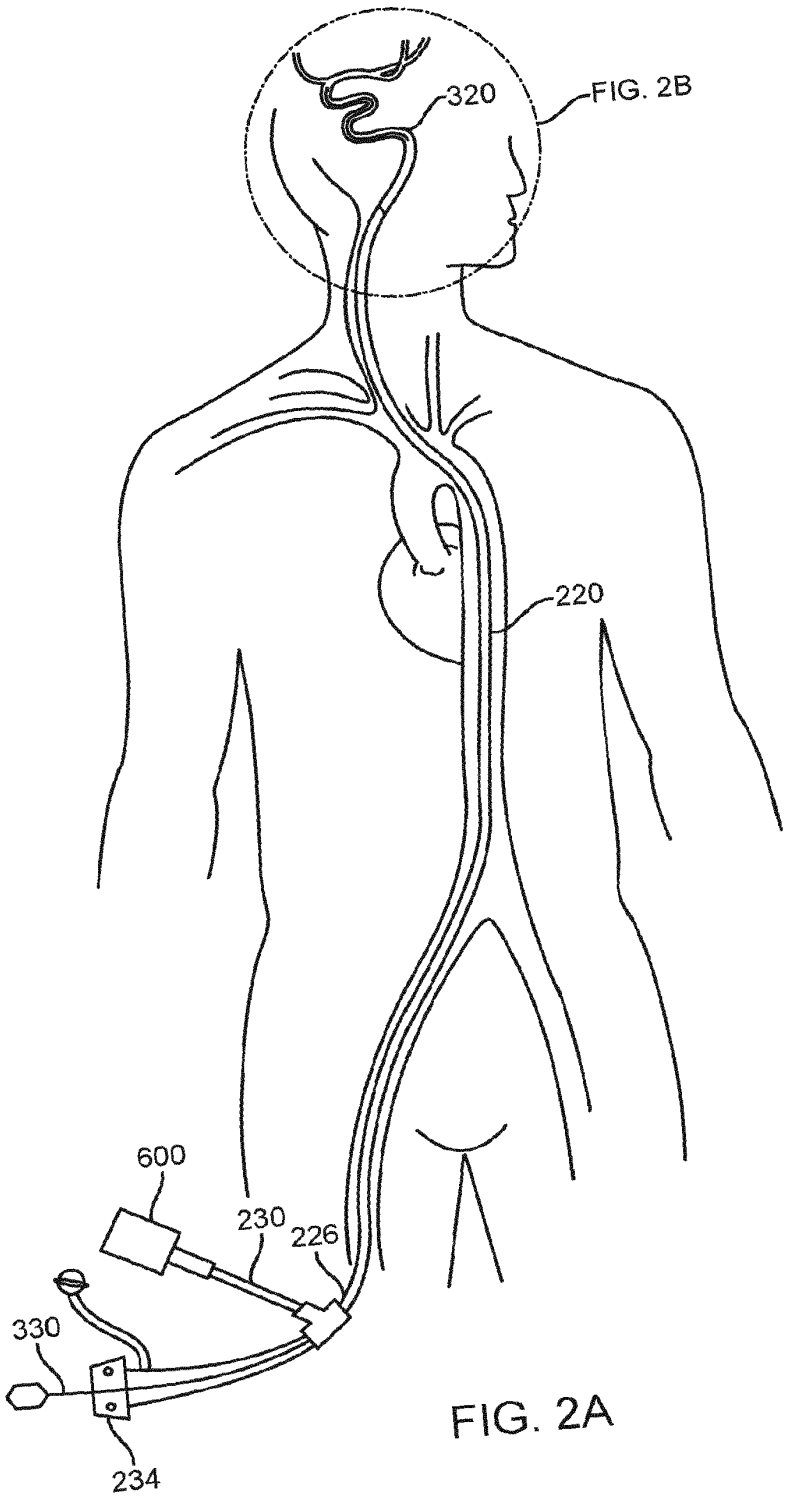



FIG. 2A

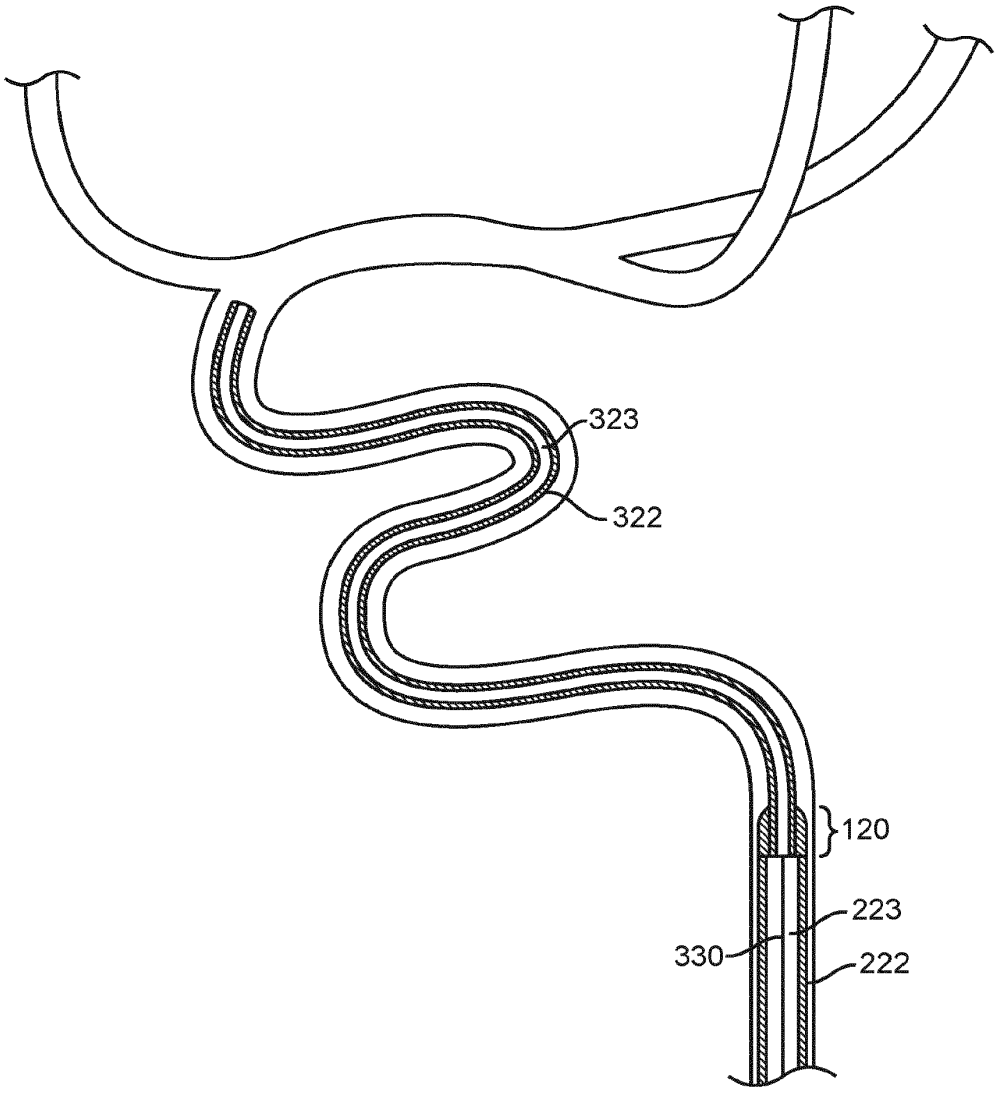



FIG. 2B

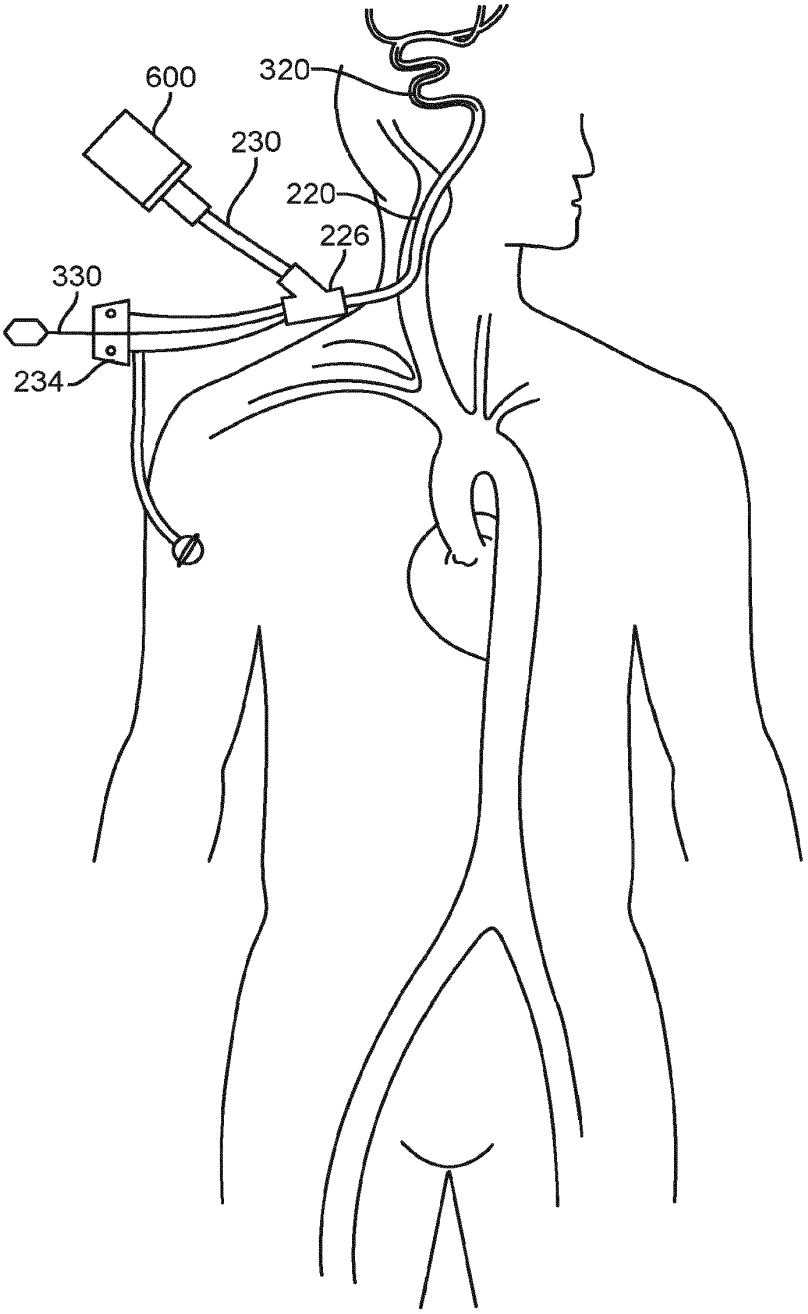



FIG. 3

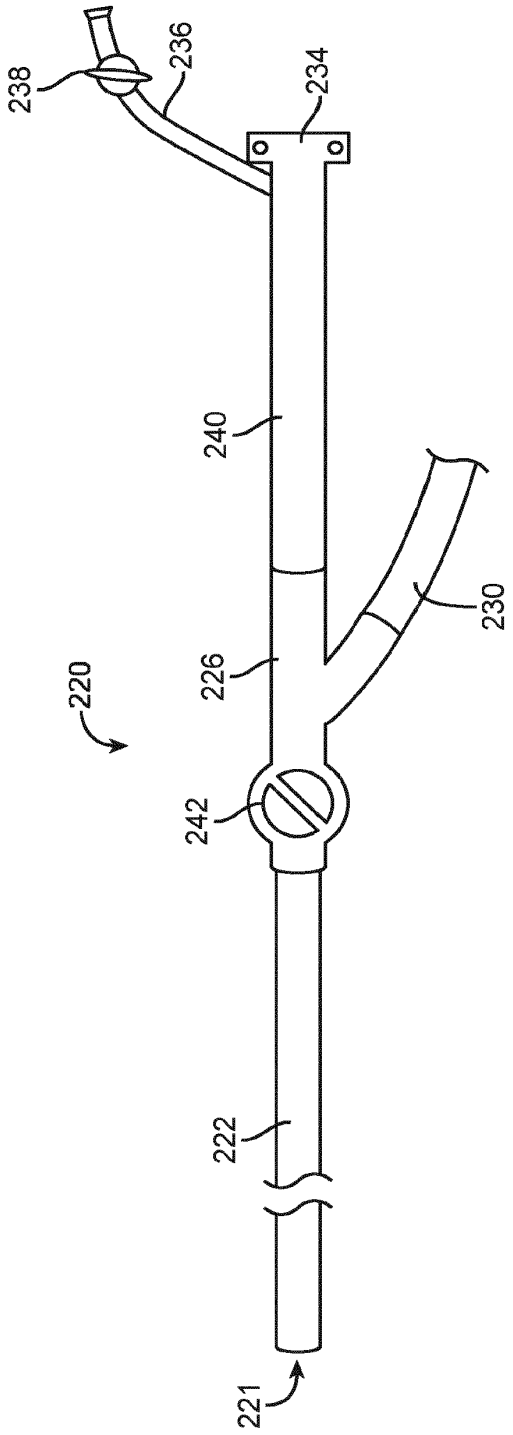



FIG. 4

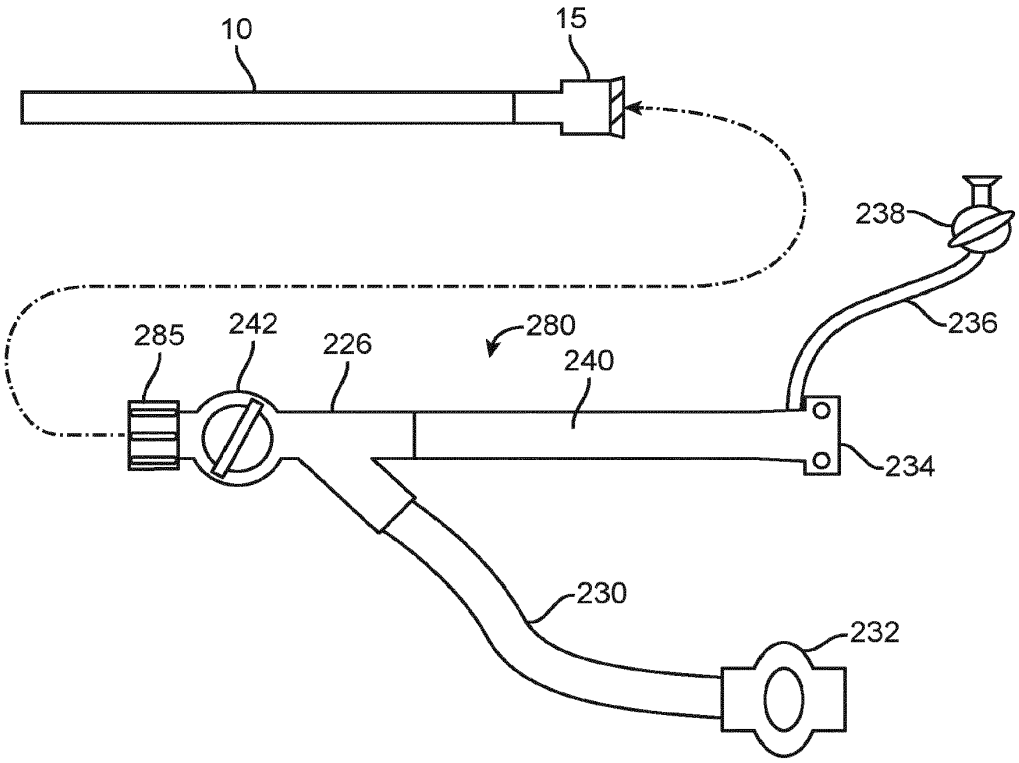



FIG. 5

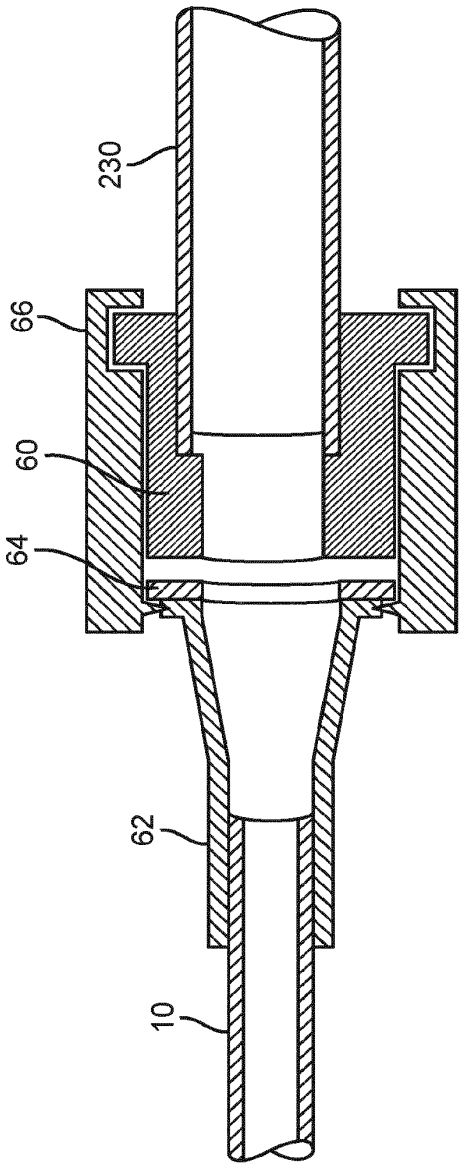



FIG. 6

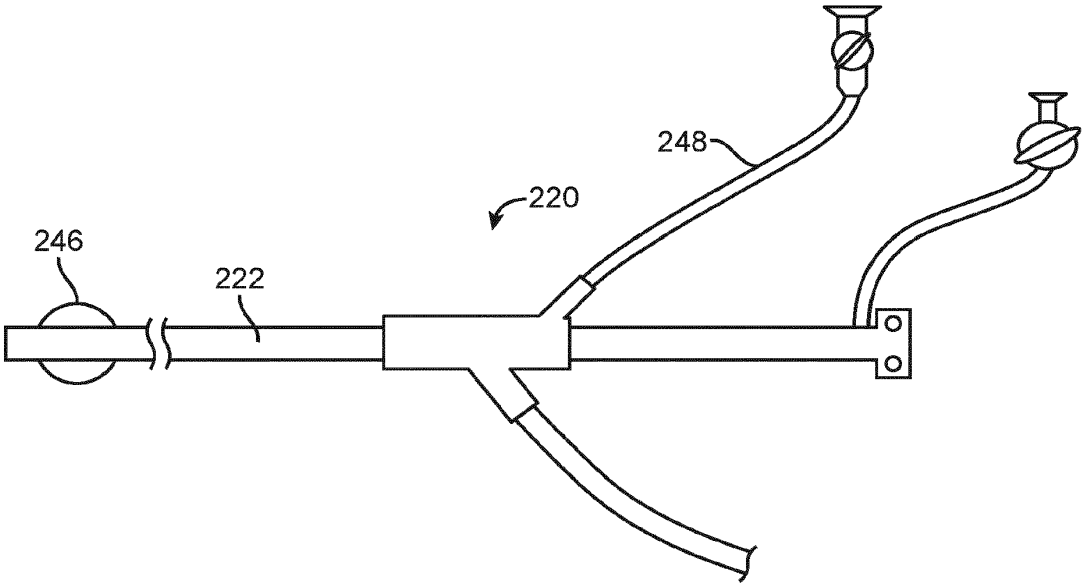



FIG. 7

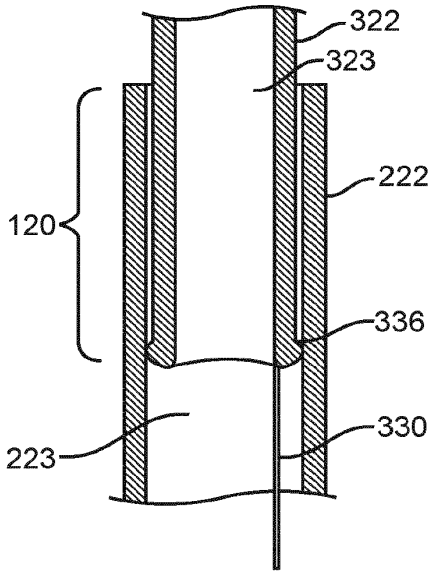



FIG. 8A

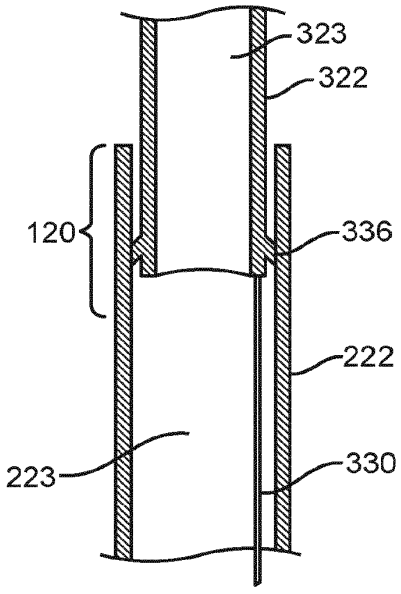



FIG. 8B

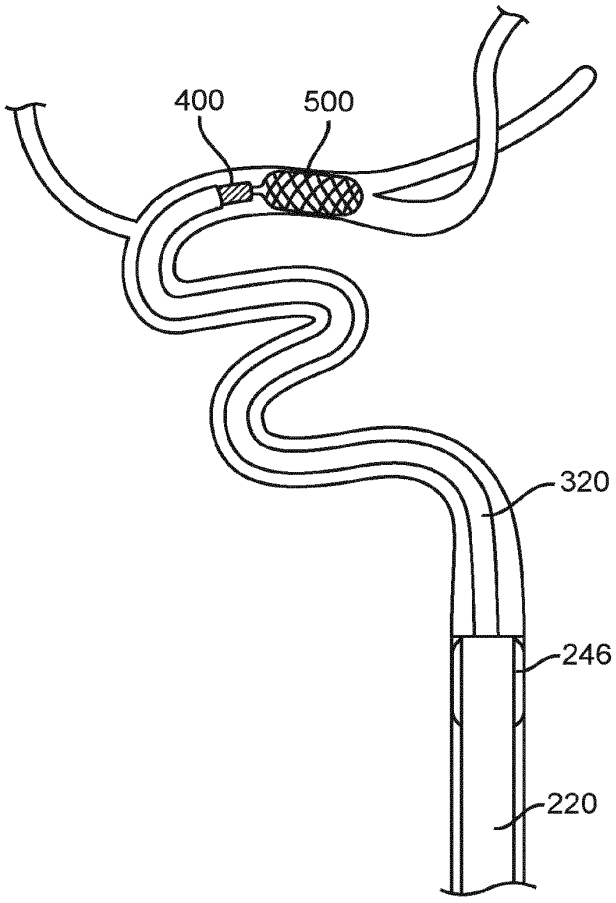



FIG. 9

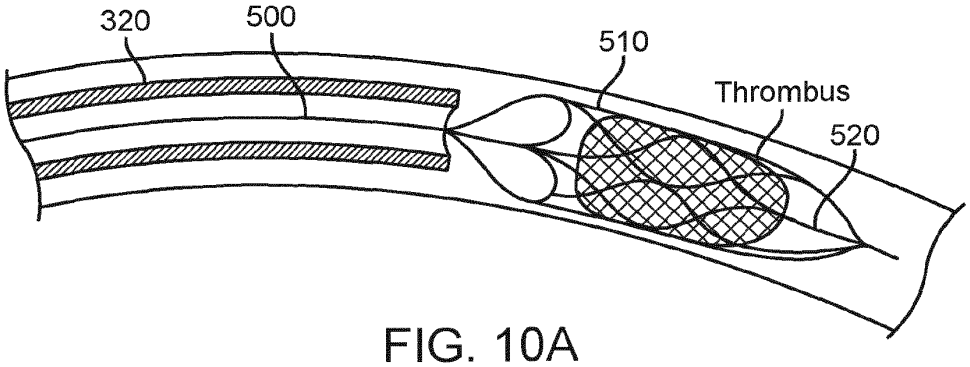



FIG. 10A

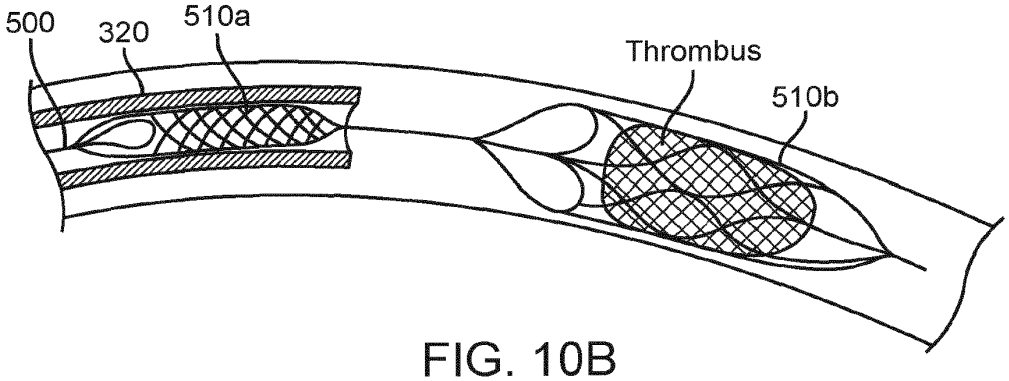



FIG. 10B

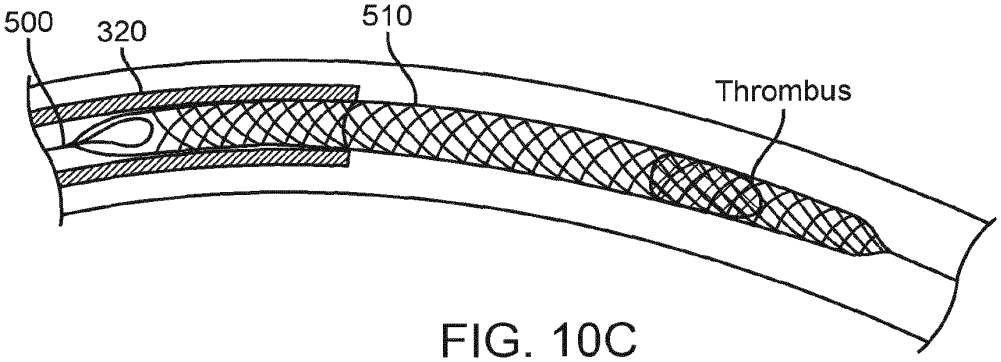



FIG. 10C

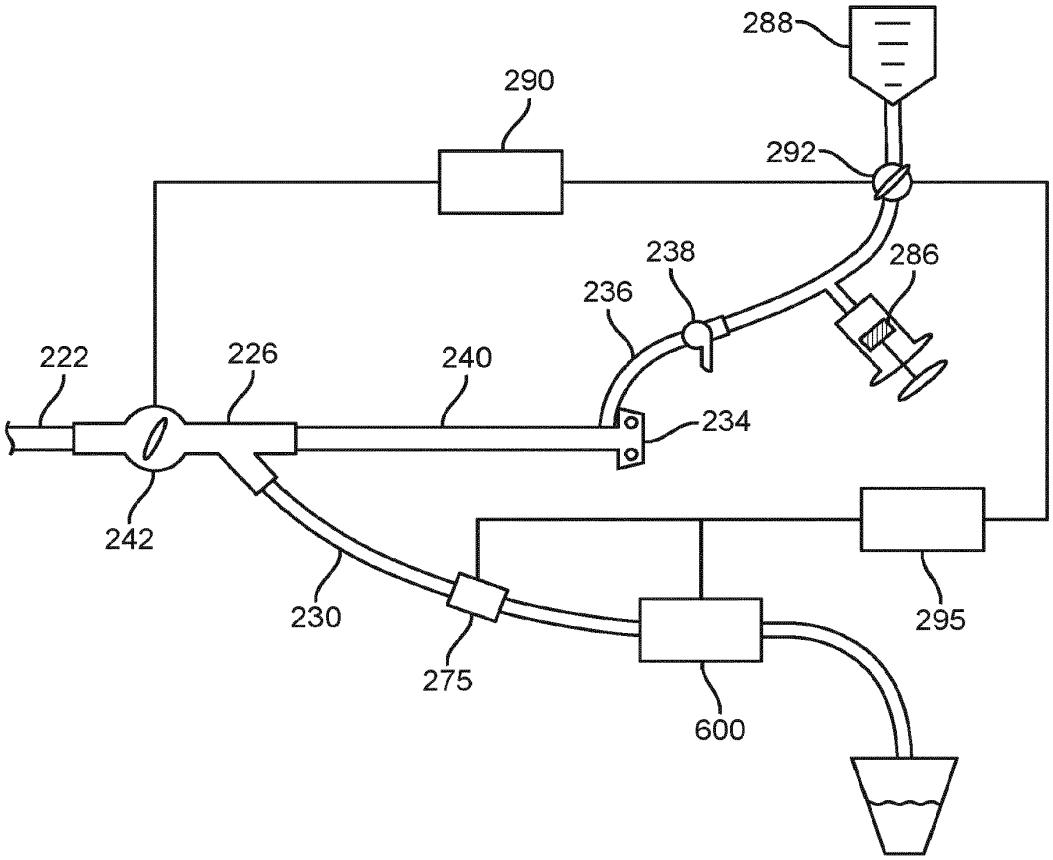



FIG. 11

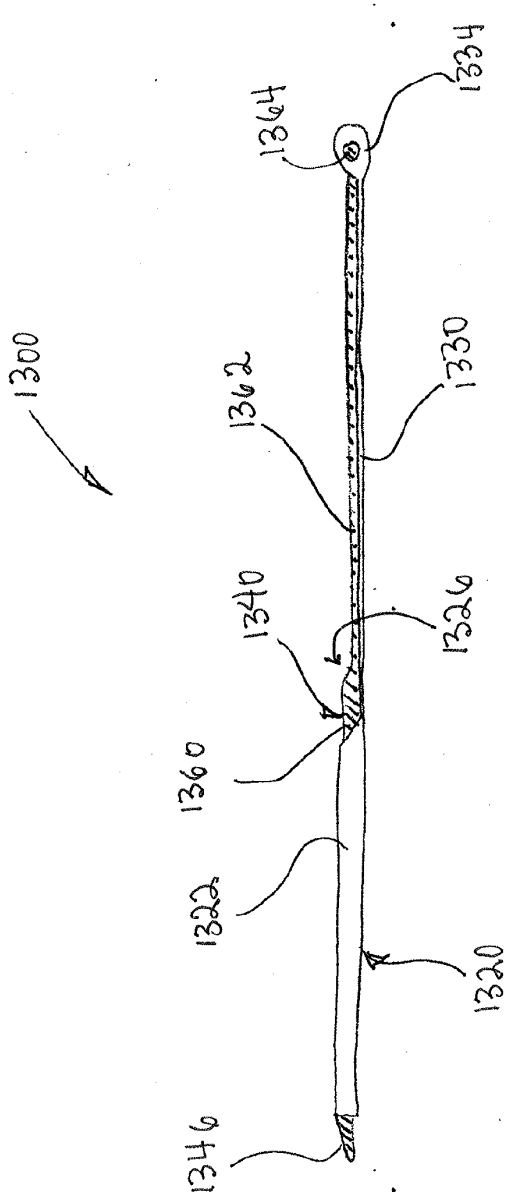



FIG. 12A

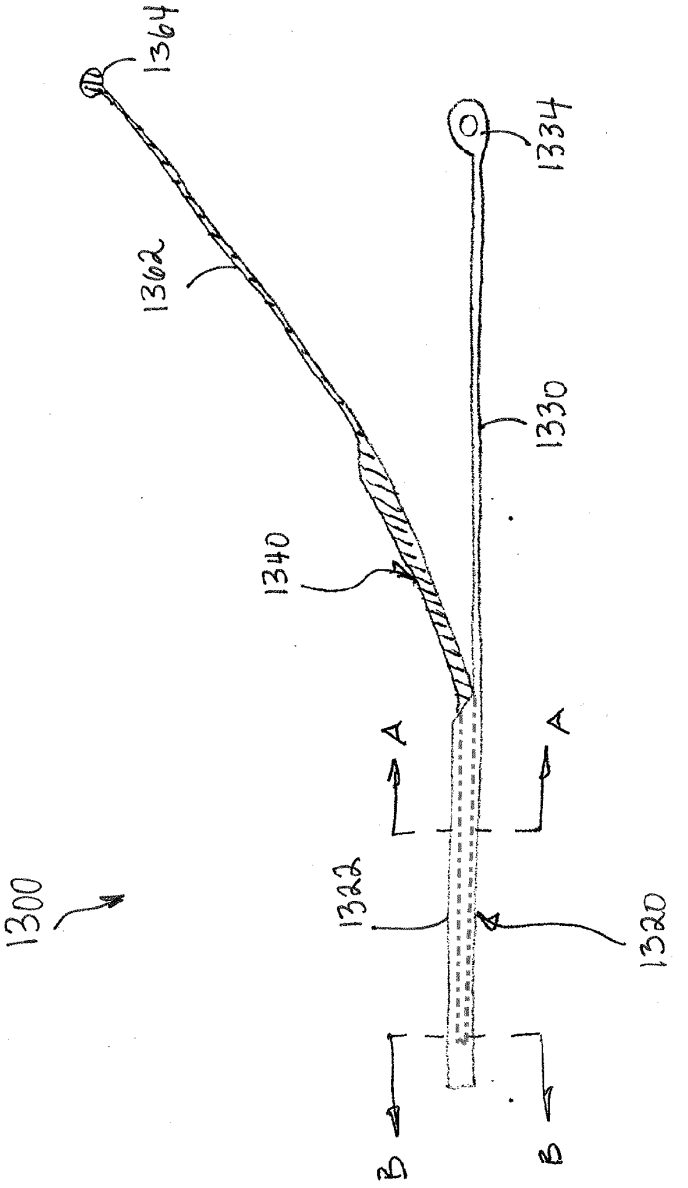



FIG. 12B

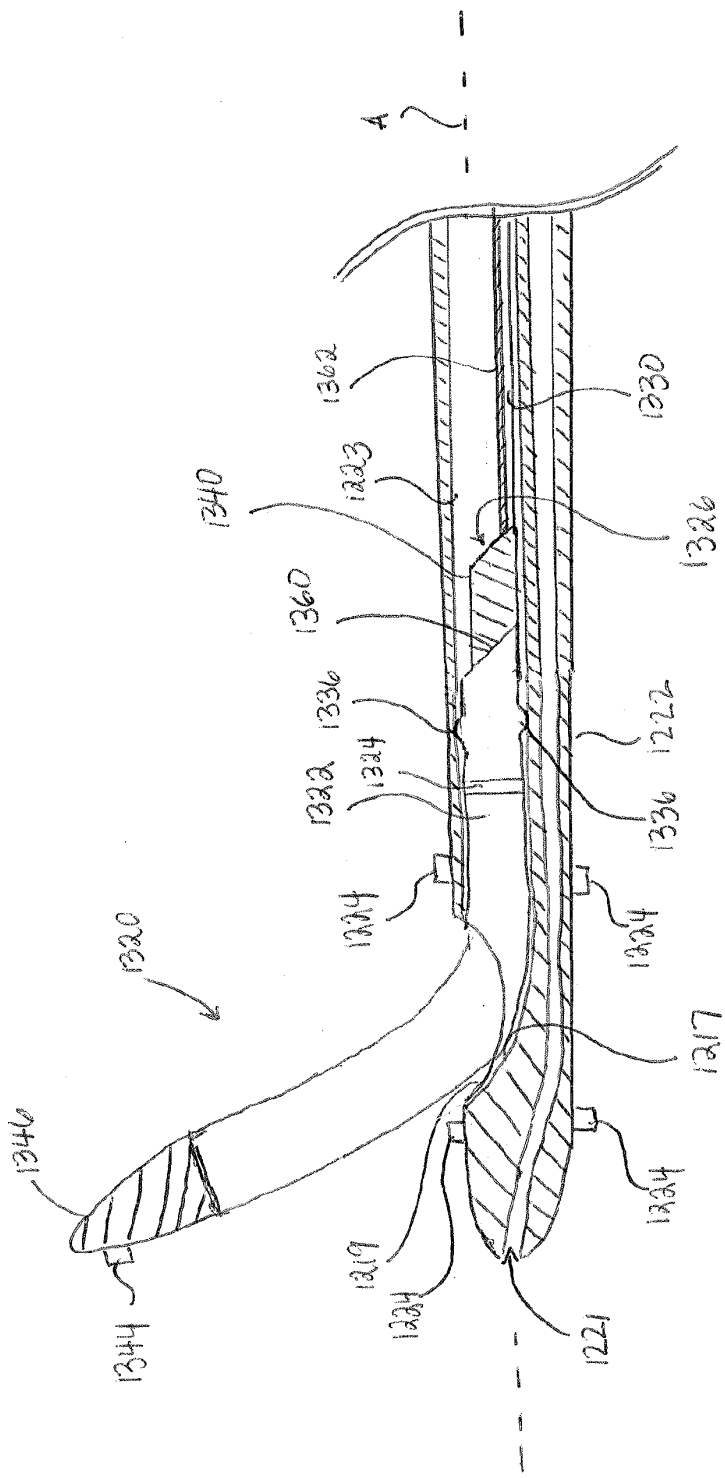
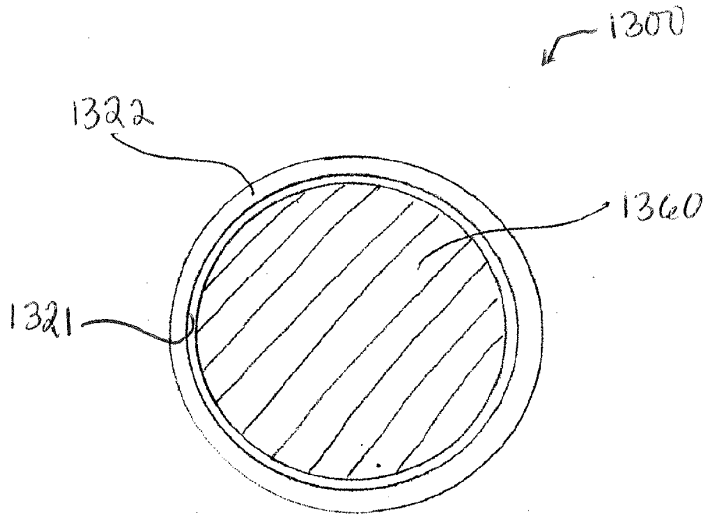
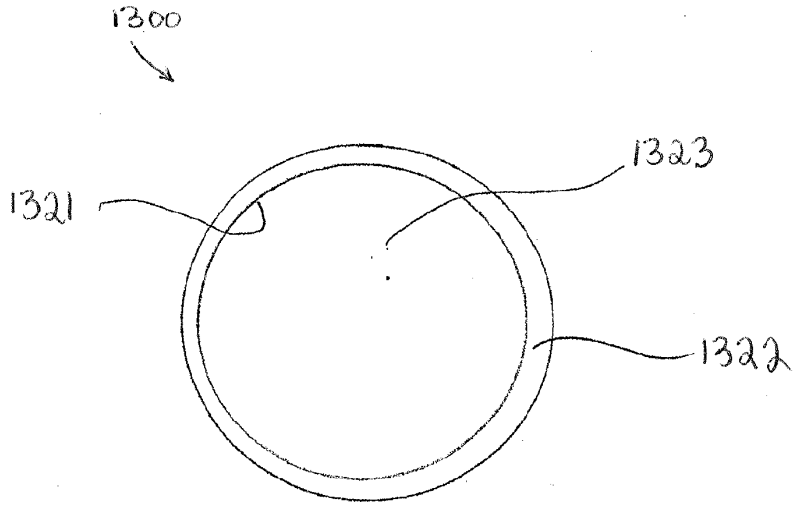

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FIG. 12C




A - A
FIG. 13




B - B
FIG. 14

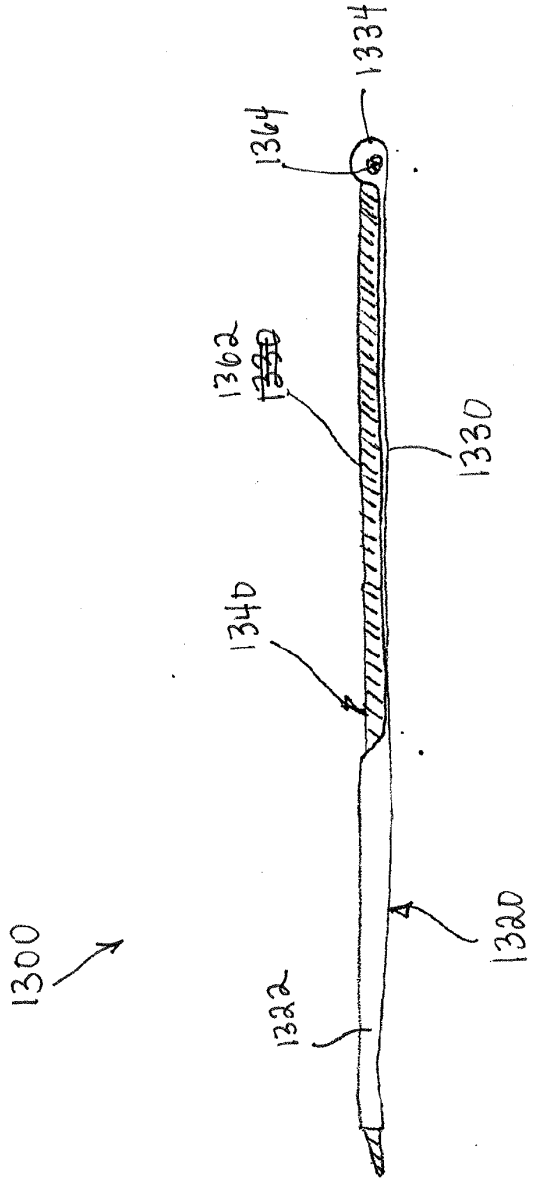



FIG. 15A

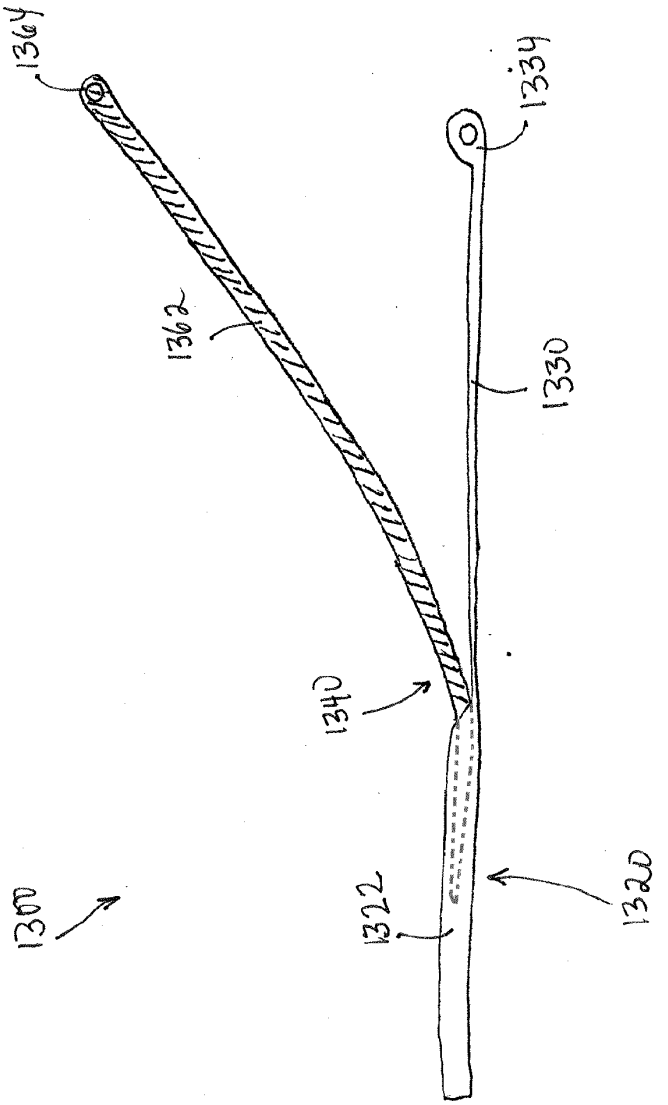



FIG. 15B

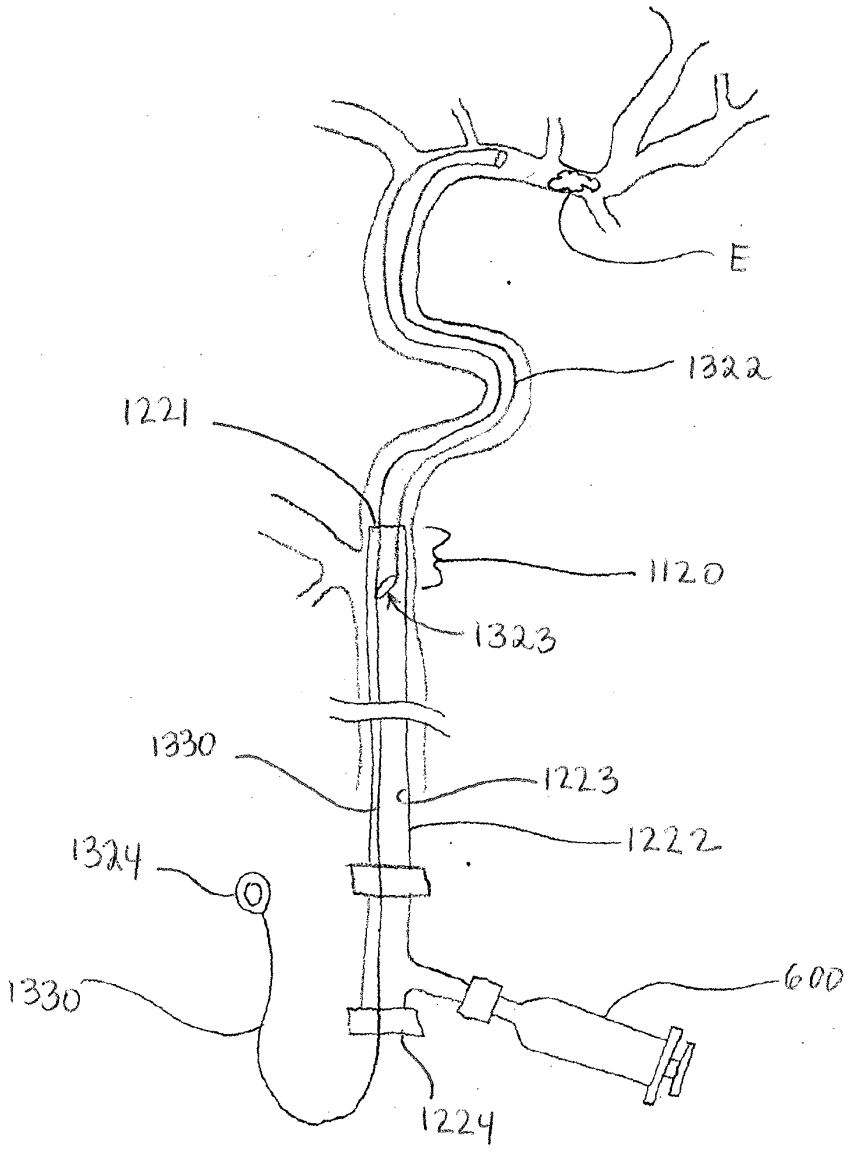



FIG. 16

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# EUROPEAN SEARCH REPORT

Application Number
EP 19 20 5500

## DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document with indication, where appropriate, of relevant passages | Relevant to claim | CLASSIFICATION OF THE APPLICATION (IPC) |
|---|---|---|---|
| X | US 2007/185522 A1 (DAVIES GARETH [CA] ET AL) 9 August 2007 (2007-08-09)<br>* figures 1, 5 *<br>* paragraph [0025] - paragraph [0033] * | 1-15 | INV.<br>A61M29/00<br>A61M25/01<br>A61B17/22 |
| X | US 2008/243222 A1 (SCHAFERSMAN JESSICA A [US] ET AL) 2 October 2008 (2008-10-02)<br>* figures 1,4 *<br>* paragraphs [0033], [0034] * | 1-15 | ADD.<br>A61B17/221<br>A61M25/06 |
| A | US 2003/050600 A1 (RESSEMANN THOMAS V [US] ET AL) 13 March 2003 (2003-03-13)<br>* figures 1A, 6A-I, 11E, 11G *<br>* paragraph [0086] - paragraph [0089] *<br>* paragraph [0095] - paragraph [0125] *<br>* paragraph [0208] - paragraph [0209] * | 1-15 | |

TECHNICAL FIELDS SEARCHED (IPC)

A61M
A61B

The present search report has been drawn up for all claims

| Place of search | Date of completion of the search | Examiner |
|---|---|---|
| The Hague | 29 November 2019 | Emirdag, Eda |

CATEGORY OF CITED DOCUMENTS

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29-11-2019

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| US 2007185522 A1 | 09-08-2007 | NONE | |
| US 2008243222 A1 | 02-10-2008 | NONE | |
| US 2003050600 A1 | 13-03-2003 | AU 2002327606 A1 | 25-02-2004 |
| | | EP 1531740 A1 | 25-05-2005 |
| | | JP 2005535380 A | 24-11-2005 |
| | | US 2003050600 A1 | 13-03-2003 |
| | | WO 2004014240 A1 | 19-02-2004 |

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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### Patent documents cited in the description


- US 62111481 **[0001]**
- US 62142637 **[0001]**
- US 57695314 **[0002]**
- US 56936514 **[0002]**
- US 53731614 **[0002]**
- US 22191714 **[0002]**
- US 8157760 B **[0041]**
- US 20100217276 A **[0041]**
- US 20150173782 A **[0054] [0056]**
- US 20150174368 A **[0056] [0070]**

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| APPLICATION # | RECEIPT DATE / TIME | ATTORNEY DOCKET # |
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| **17/498,642** | **11/21/2023 02:03:34 PM Z ET** | **111552-8023.US02** |

## Title of Invention

SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

## Application Information

| | | | |
|---|---|---|---|
| APPLICATION TYPE | Utility - Nonprovisional Application under 35 USC 111(a) | PATENT # | - |
| CONFIRMATION # | 1040 | FILED BY | JiYoung Anderson |
| PATENT CENTER # | 63340019 | FILING DATE | 10/11/2021 |
| CUSTOMER # | 25096 | FIRST NAMED INVENTOR | Richard Quick |
| CORRESPONDENCE ADDRESS | - | AUTHORIZED BY | Matthew Williams |

## Documents

**TOTAL DOCUMENTS: 16**

| DOCUMENT | PAGES | DESCRIPTION | SIZE (KB) |
|---|---|---|---|
| 2023-11-21 IDS SB08 - 111552-8023US2.pdf | 5 | Information Disclosure Statement (IDS) Form (SB08) | 157 KB |
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| RCE - 111552.8023.US02.pdf | 3 | Request for Continued Examination (RCE) | 1628 KB |
| FOR_CN106178227.pdf | 14 | Foreign Reference | 6121 KB |
| FOR-WO2018065092.pdf | 50 | Foreign Reference | 2030 KB |

| | | | |
|---|---|---|---|
| FOR-EP3013404.pdf | 15 | Foreign Reference | 591 KB |
| FOR_WO2023154612.pdf | 42 | Foreign Reference | 8876 KB |
| FOR-EP3583972.pdf | 21 | Foreign Reference | 1735 KB |
| FOR-EP3589348 - Counterpart WO2018160810.pdf | 44 | Foreign Reference | 2164 KB |
| FOR-EP4137070.pdf | 51 | Foreign Reference | 3226 KB |
| FOR-EP3620204.pdf | 50 | Foreign Reference | 3291 KB |
| FOR_WO2023192925.pdf | 54 | Foreign Reference | 2231 KB |
| FOR_WO2019173475.pdf | 114 | Foreign Reference | 5744 KB |
| FOR_WO2023215779.pdf | 33 | Foreign Reference | 1426 KB |
| NPL_EESR-EP20877370.5-Oct 17 2023 11 pages.pdf | 11 | Non Patent Literature | 1028 KB |
| NPL_ISR_WO_PCTUS20236 0927_JUL_20_2023_12page s.pdf | 12 | Non Patent Literature | 6286 KB |
| NPL_ISR-PCTUS23_65128 Nov 14 2023 - 14 pages.pdf | 14 | Non Patent Literature | 2410 KB |

## Digest

| DOCUMENT | MESSAGE DIGEST(SHA-512) |
|---|---|
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| | |
|---|---|
| RCE - 111552.8023.US02.pdf | 9F6B655E114EC36A704AC687F0854294A7911DCAC498D17011 37C0DC6BB4E67A111EE2E19EE0BA8866B1C24CB1AF398288 EFAB7019436337A60CB9DF890330CD |
| FOR_CN106178227.pdf | 5A5A25D3A129C1CA7F59548B3AA207B09B7B6674AE7508C5B 307B43967E2C3546C294514C3BCCDD7C3503E392643D94605 17231E240FA9368165728CF9E2C7B2 |
| FOR-WO2018065092.pdf | 8CD5C10DCA882A13C195ED6238D679A0D5AEC67FB86BA6D7 5814A5943F1911EE33A68A315B57F447D2CA9698FA33332063 CE1BB690E501F57728B93546A20BAD |
| FOR-EP3013404.pdf | 3D90324030CFADDE2E69B16548429204EED8FD4CB29E457F0 532D25D701134341C5E14FD142B0E42FBE19C633688FAC8C5 684757CE7C5BDF2AAA1DC4AAF01E4F |
| FOR_WO2023154612.pdf | 3C9F5C1AFA5DAF87353AD9ADE84FDB7C4BAED63CC5B03A1 BFA09D4C569B26851BF1F54043C003B047406BA9C85A53244E 46A60E8CA62C7AEE7F89CB62BFA557E |
| FOR-EP3583972.pdf | 1BCADA91406B3C917BB9CA44C5E41E850921CC779D2790C8 20A8D3F5730A239DFE5AB4A8A8412B60BFAC80E3ED5A3C2A 9F47BF7ADE74D0BD6052AB153471DDAD |
| FOR-EP3589348 - Counterpart WO2018160810.pdf | 5494011818D2C61C69D8661EAE176A54A8D2D22DE923F718F EAE2C688C0893E19C7F61304AD3589D55C2AA6C52E01FD238 5F346D5A7523F37569A5AA54BBEDE2 |
| FOR-EP4137070.pdf | 05C4C9A6AF9A250D312393DAF39AABE109571DE37245F17B6 5A86187121D449DC3060876A4DDD7C5E2023068B0EDE11F9E A19C9777D641BBE064B96725B094AA |
| FOR-EP3620204.pdf | 3BFC88107F2D2CC39249A1082F73A511741CFF801B44AAC79 7CAC8ED804966306DDC2052ED2BA49AEF1280DFC3B31D0DE 301B802ECD3EC774353D8A04CE3EE09 |
| FOR_WO2023192925.pdf | 505C8B0B5181623D59604F65A91F55E7362EC91ECCFAED65C DDADF834C815E200E02C38FF719F0C512F22B547F9B3C14DD 623B59C16DAB25BFB5A8A2FC85055F |

| | |
|---|---|
| FOR_WO2019173475.pdf | 46135CA36322848AC7713731C3C3A89B30E3CD582A0A4656E0<br>00533596F331158ECD136D065C986D6C15459727E80D1E8901<br>469442DD51ADE518ACC9FD2FBBD5 |
| FOR_WO2023215779.pdf | 0EE67AEBB7478EACB1D2C581BFBAE15FA09DD578F2F6E565<br>CEC2E1B7597A1CEFB22A6ED5F2B5B2B5BC4F6DF3EBF74B19<br>57BB3E7B39318CCC465AE16F63581612 |
| NPL_EESR-EP20877370.5-Oct 17 2023 11 pages.pdf | 965199476EC91E44333C0B2C98A43D4DB73CBBE22CD58A51<br>C5F767C071A88473B07F82C411A5BAB6F24DB4311E74FDAC8<br>03F906F3C960C97292C98BC16A40CF0 |
| NPL_ISR_WO_PCTUS2023609 27_JUL_20_2023_12pages.pdf | C3544C8CC4356AE50734DAA84C2B65A4258997E9E0E90E459<br>CCDABC6A995E67A4123E7F292B4D4D91AA981B64CDE45498<br>14DAB408B3E39575FF8CDA130EC4870 |
| NPL_ISR-PCTUS23_65128 Nov 14 2023 - 14 pages.pdf | B168B0F8F5BB4B99A99668BDBD61735258CF29A560AF704A0<br>6792410EC4553843A32D74FFC82399E5242863C55E578ED676<br>AD1F2E132E1CA1C100D7088CCE01A |

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

**New Applications Under 35 U.S.C. 111**

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

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

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

**New International Application Filed with the USPTO as a Receiving Office**

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

# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: BENJAMIN D. CASHDOLLAR
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

RECEIVED
PATENT DOCKETING

NOV 20 2023

PERKINS COIE LLP

# PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

| | |
|---|---|
| | Date of mailing *(day/month/year)* NOV 14 2023 |
| Applicant's or agent's file reference<br>111552-8037WO00 | FOR FURTHER ACTION See paragraphs 1 and 4 below |
| International application No.<br>PCT/US 23/65128 | International filing date *(day/month/year)* 30 March 2023 (30.03.2023) |
| Applicant INARI MEDICAL, INC. | |

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   **Filing of amendments and statement under Article 19:**
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   **When?** The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   **How?** Directly to the International Bureau preferably through ePCT, or on paper to:
   The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland

   **For more detailed instructions,** see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(*a*) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   **The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority** to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

   **Shortly after the expiration of 18 months from the priority date, the international application will be published** by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

   Within 19 **months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices. In respect of other designated Offices, the time limit of 30 **months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

   **Within 22 months from the priority date, the applicant may request that a supplementary international search be carried out** by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

| | |
|---|---|
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US<br>Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | Authorized officer<br>Kari Rodriquez<br><br>Telephone No. PCT Helpdesk: 571-272-4300 |

Form PCT/ISA/220 (revised January 2020)

PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| Applicant's or agent's file reference | FOR FURTHER ACTION |
|---|---|
| 111552-8037WO00 | see Form PCT/ISA/220 as well as, where applicable, item 5 below. |

| International application No. | International filing date *(day/month/year)* | (Earliest) Priority Date *(day/month/year)* |
|---|---|---|
| PCT/US 23/65128 | 30 March 2023 (30.03.2023) | 31 March 2022 (31.03.2022) |

Applicant
INARI MEDICAL, INC.

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☒ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 2A

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 23/65128

**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 -*-

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.:
1-17, 27-32

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 23/65128

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61M 5/178, A61M 5/315, A61B 5/153, A61B 17/22 (2023.01)
ADD. A61M 1/00 (2023.01)

CPC - INV. A61M 5/3145, A61B 5/150236, A61B 5/150244, A61M 1/67, A61M 1/81
ADD. A61B 5/153, A61B 2017/22079, A61M 5/178

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 2017/0113005 A1 (Human Med AG) 27 April 2017 (27.04.2017), entire document, especially Fig 1, para [0044]-[0045] | 1-4, 6-7, 10-12 |
| X | US 2011/0309037 A1 (Lee) 22 December 2011 (22.12.2011), entire document, especially Fig 6, Fig 7-10, para [0015]-[0018], para [0041], para [0044]-[0045], para [0065]-[0068], para [0071] | 1, 6, 8-9, 13-17 |
| X | US 2008/0294096 A1 (Uber, III et al.) 27 November 2008 (27.11.2008), entire document, especially Fig 3, Fig 18C, para [0227]-[0229], para [0223], para [0233], para [0351], para [0468]-[0471] | 1, 5, 27-32 |
| A | US 2020/0046368 A1 (Inari Medical, Inc) 13 February 2020 (13.02.2020), entire document | 1-17, 27-32 |
| A | US 2013/0270161 A1 (Kumar et al.) 17 October 2013 (17.10.2013), entire document | 1-17, 27-32 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 23 August 2023 | NOV 14 2023 |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | Authorized officer<br>Kari Rodriquez<br>Telephone No. PCT Helpdesk: 571-272-4300 |

INARI_017578

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/US 23/65128

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-17, 27-32 directed to a filtering syringe comprising a plunger with a lumen, a filter at a first end of the plunger, and a valve at a second end of the plunger.

Group II: Claims 18-23 directed to a system for aspirating clots from a blood vessel comprising a catheter and a filtering syringe.

Group III: Claims 24-26 directed to a method for removing clots from a blood vessel using a filtering syringe, a catheter, and a fluid control device.

Group IV: Claims 33-37 directed to a filtering syringe comprising a first plunger body including a filter and valve connected to a second plunger body defining an interior chamber.

The inventions listed as Groups I-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:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical features of a plunger assembly having a first end portion and a second end portion opposite the first end portion, wherein the plunger assembly includes a filter proximate to the first end portion, a port/valve proximate to the second end portion, and a lumen therebetween and fluidly coupling the filter and the port/valve; wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel, not required by the claims of Groups II-IV.

The invention of Group II includes the special technical features a filtering syringe including a tip configured to be coupled to the catheter, not required by the claims of Group I or III-IV.

The invention of Group III includes the special technical features of positioning a distal portion of a catheter proximate to the clot material within the blood vessel; coupling a filtering and pressure-generating syringe to the catheter via a fluid control device, wherein (i) opening of the fluid control device fluidly connects the filtering and pressure-generating syringe to the catheter, and (ii) closing the fluid control device fluidly disconnects the filtering and pressure-generating syringe from the catheter; activating the syringe to generate a vacuum while the fluid control device is closed; opening the fluid control device to apply the vacuum to the catheter to thereby aspirate at least a portion of the clot material into the catheter; and filtering blood from the portion of the clot material via a filter of the syringe, not required by the claims of Group I-II or IV.

The invention of Group IV includes the special technical features of the plunger assembly including a first body portion and a second body portion, wherein the first body portion includes a filter and a valve, and wherein the second body portion defines an interior chamber and is detachably couplable to the first body portion via the valve; wherein at least part of the first body portion and the second body portion are insertable within the chamber and slidable relative to the barrel, not required by the claims of Group I-III.

COMMON TECHNICAL FEATURES

The inventions of Groups I-IV share the technical features of a system for use in filtering clot material from blood, comprising: a syringe including at least one filter. Specifically, Groups I-IV are related as an apparatus (Groups I-II and IV) and methods for using the apparatus (Group III). The apparatus is known in prior art as shown in US 2008/0294086 A1 to Uber, III et al. (hereinafter "Uber").

Uber discloses system for use in filtering clot material from blood (see system comprising syringe 50 coupled with a patient's blood via catheter 315', Fig 3; see embodiment of 50 as syringe 2250 including filter 2556, Fig 18C; 50 is a syringe such as in Fig 18A-I, para [0229], 316 is an intravascular catheter, para [0233]; syringe with filter 2556 with pore size to allow liquid hence configured to filter clot material from blood, para [0466], para [0471]), comprising: a syringe (see syringe 2250, Fig 18C; syringe 2250, para [0468]) including at least one filter (see filter 2556, Fig 18C, filter 2556, para [0468]).

Groups II-III further share the common technical features of the system for use in filtering clot material from blood further comprising a catheter configured to be intravascularly positioned at a treatment site within a blood vessel. However, this shared technical feature does not represent a contribution over prior art as being anticipated by Human.

Uber discloses wherein the system for use in filtering clot material from blood further comprising a catheter (see 315', Fig 3) configured to be intravascularly positioned at a treatment site within a blood vessel (315 is an intravascular catheter, para [0233]).

Groups I and IV further share the common technical features of the syringe comprising a barrel defining a chamber; a plunger assembly comprising a filter and a valve, wherein at least a portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel. However, this shared technical feature does not represent a contribution over prior art as being anticipated by Human.

Uber discloses the syringe comprising a barrel defining a chamber (see barrel 2250 defining a chamber for plunger 2552, Fig 18C, syringe barrel, para [0466]); a plunger assembly (see plunger 2552, Fig 18C; plunger 2552, para [0468]) comprising a filter (see how 2552 comprises filter 2556, Fig 18C, filter 2556 replaces the rubber cover on the forward end of a conventional plunger, para [0468]) and a valve (see valve 2564 of plunger 2552, Fig 18C; exit outlet valve 2564 of plunger chamber 25554, para [0469]); wherein at least a portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel (see how the left end of 2552 is insertable within and slidable relative to 2550, Fig 18C; plunger 2552 may be drawn back and pushed forward in syringe 2550, para [0469]).

INARI_017579

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-IV lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

# PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: BENJAMIN D. CASHDOLLAR
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

RECEIVED
PATENT DOCKETING

NOV 20 2023

PERKINS COIE LLP

**PCT**

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

| | |
|---|---|
| Date of mailing *(day/month/year)* | NOV 14 2023 |
| Applicant's or agent's file reference<br>111552-8037WO00 | FOR FURTHER ACTION<br>See paragraph 2 below |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/US 23/65128 | 30 March 2023 (30.03.2023) | 31 March 2022 (31.03.2022) |

International Patent Classification (IPC) or both national classification and IPC
IPC - INV. A61M 5/178, A61M 5/315, A61B 5/153, A61B 17/22 (2023.01)
ADD. A61M 1/00 (2023.01)
CPC - INV. A61M 5/3145, A61B 5/150236, A61B 5/150244, A61M 1/67, A61M 1/81
ADD. A61B 5/153, A61B 2017/22079, A61M 5/178

Applicant INARI MEDICAL, INC.

1. This opinion contains indications relating to the following items:

- [x] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [x] Box No. IV Lack of unity of invention
- [x] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

| Name and mailing address of the ISA/US | Date of completion of this opinion | Authorized officer |
|---|---|---|
| Mail Stop PCT, Attn: ISA/US<br>Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | 23 August 2023 | Kari Rodriquez<br>PCT Help Desk<br>Telephone No. 571-272-4300 |

Form PCT/ISA/237 (cover sheet) (revised July 2022)

INARI_017581

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 23/65128

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(b)).

3. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of a sequence listing:

a. ☐ forming part of the international application as filed.

b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13ter.1(a)),

☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.

4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 23/65128

**Box No. IV Lack of unity of invention**

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:

   ☐ paid additional fees.

   ☐ paid additional fees under protest and, where applicable, the protest fee.

   ☐ paid additional fees under protest but the applicable protest fee was not paid.

   ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-17, 27-32 directed to a filtering syringe comprising a plunger with a lumen, a filter at a first end of the plunger, and a valve at a second end of the plunger.

Group II: Claims 18-23 directed to a system for aspirating clots from a blood vessel comprising a catheter and a filtering syringe

Group III: Claims 24-26 directed to a method for removing clots from a blood vessel using a filtering syringe, a catheter, and a fluid control device.

Group IV: Claims 33-37 directed to a filtering syringe comprising a first plunger body including a filter and valve connected to a second plunger body defining an interior chamber.

The inventions listed as Groups I-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:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical features of a plunger assembly having a first end portion and a second end portion opposite the first end portion, wherein the plunger assembly includes a filter proximate to the first end portion, a port/valve proximate to the second end portion, and a lumen therebetween and fluidly coupling the filter and the port/valve; wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel, not required by the claims of Groups II-IV.

The invention of Group II includes the special technical features a filtering syringe including a tip configured to be coupled to the catheter, not required by the claims of Group I or III-IV.

The invention of Group III includes the special technical features of positioning a distal portion of a catheter proximate to the clot material within the blood vessel; coupling a filtering and pressure-generating syringe to the catheter via a fluid control device, wherein (i) opening of the fluid control device fluidly connects the filtering and pressure-generating syringe to the catheter, and (ii) closing the fluid control device fluidly disconnects the filtering and pressure-generating syringe from the catheter; activating the syringe to generate a vacuum while the fluid control device is closed; opening the fluid control device to apply the vacuum to the catheter to thereby aspirate at least a portion of the clot material into the catheter; and filtering blood from the portion of the clot material via a filter of the syringe, not required by the claims of Group I-II or IV.

The invention of Group IV includes the special technical features of the plunger assembly including a first body portion and a second body portion, wherein the first body portion includes a filter and a valve, and wherein the second body portion defines an interior chamber and is detachably couplable to the first body portion via the valve; wherein at least part of the first body portion and the second body portion are insertable within the chamber and slidable relative to the barrel, not required by the claims of Group I-III.

-*- Continued in Supplemental Box -*-

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-17, 27-32

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 23/65128

**Box No. V** **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | 5, 11, 17 | YES |
| | Claims | 1-4, 6-10, 12-16, 27-32 | NO |
| Inventive step (IS) | Claims | None | YES |
| | Claims | 1-17 and 27-32 | NO |
| Industrial applicability (IA) | Claims | 1-17 and 27-32 | YES |
| | Claims | None | NO |

2. Citations and explanations:
Claims 1-4, 6-7, 10 and 12 lack novelty under PCT Article 33(2) as being anticipated by US 2017/0113005 A1 to Human Med AG (hereinafter 'Human').

As to claim 1, Human discloses a filtering syringe for treatment of clot material from within a blood vessel of a patient (see syringe 10 coupled to cannula 50 hence configured to filter clot material from within a blood vessel, Fig 1; cannula 50 may be mounted depending on application, para [0045]), the filtering syringe comprising
a barrel defining a chamber (see hollow barrel 12 defining a chamber, Fig 1; 12 is a hollow cylinder, para [0044]) configured to receive at least a portion of the clot material and blood from the patient (see how the chamber of 12 is configured to receive at least a portion of clot and blood material from a patient through cannula 50, Fig 1; fluid may be sucked into the chamber 12, para [0045]); and
a plunger assembly (see plunger 14 and piston 24, Fig 1, piston 24 connected to plunger 14, para [0044]) having a first end portion (see first end portion 22, Fig 1; sealing lips 22 of 14, para [0044]) and a second end portion opposite the first end portion (see opposite end portion 26, Fig 1), wherein the plunger assembly includes a filter proximate to the first end portion (see filter 30 proximate 22, Fig 1, plunger 14 includes filter 30, para [0044]), a port proximate to the second end portion (see port 32 proximate end 26, Fig 1; closeable medlis connection 32, para [0044]), and a lumen therebetween and fluidly coupling the filter and the port (see lumen 28 coupling 30 and 32, Fig 1; fluidic connection 28 extending through the plunger, para [0044]),
wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel (see how at least end 22 is insertable within the chamber of 12 and slidable, Fig 1; plunger 14 may be guided on inner surface 16 of chamber 12, para [0044]); and
wherein the filter is configured to allow at least part of the blood received within the chamber to separate from the portion of the clot material (the filter 30 has a transmission limit of 200 um hence is configured to allow at least a part of liquid blood to separate from larger clot material, para [0044]) and enter the lumen of the plunger assembly (see how 30 is fluidly connected to 28 hence is configured to allow a liquid part of blood to enter lumen 28, Fig 1; fluid can be sucked through plunger filter 30, para [0045]).

As to claim 2, Human discloses the filtering syringe of claim 1, further comprising a tip (see a left tip of 12, Fig 1) configured to fluidly couple the filtering syringe to a clot treatment system (see how the tip is configured to fluidly couple 12 to a cannula 50 which may be configured to aspirate blood and clots from a patient, Fig 1; negative pressure may be supplied at 32 to suck fluid in, para [0045]; means 34 for guiding fluid into the chamber of 12 includes cannula 50, para [0045]).

As to claim 3, Human discloses the filtering syringe of claim 1 wherein the filter has a circular, annular, cylindrical, and/or pleated shape (see how 30 has a circular shape similar to the shape of 12 and 14, Fig 1; 12 is a hollow cylinder, para [0044]).

As to claim 4, Human discloses the filtering syringe of claim 1 wherein the filter has a porosity between about 40 microns and about 200 microns (the transmission limit of 30 is about 200 um, para [0044]).

As to claim 6, Human discloses the filtering syringe of claim 1 wherein the filter is a first filter having a first porosity (see how 30 is a first filter, Fig 1; filter 30 having transmission limit of 200 um, para [0044]), the filtering syringe further comprising a second filter having a second porosity (see how 12 further has a second filter 52, Fig 1; prefilter 52 with transmission limit of 1.5 mm, para [0045]).

As to claim 7, Human discloses the filtering syringe of claim 6 wherein the first porosity is different than the first porosity (30 has a transmission limit of 200 um, para [0044]; 52 has a transmission limit of 1.5 mm, para [0045]).

As to claim 10, Human discloses the filtering syringe of claim 6 wherein the second filter is spaced apart from the first filter (see how 52 is spaced apart from 30, Fig 1).

As to claim 12, Human discloses the filtering syringe of claim 1 wherein the first end portion of the plunger assembly is a distal end portion of the plunger assembly (see distal end 22, Fig 1) and the second end portion is a proximal end portion of the plunger assembly (see proximal end 26, Fig 1), wherein the filter is positioned proximally from the distal end portion (see how 30 is to the right of sealing lips 22, Fig 1).

-*-Continued in Supplemental Box-*-

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-*-Box IV - Lack of unity of invention -*-

COMMON TECHNICAL FEATURES

The inventions of Groups I-IV share the technical features of a system for use in filtering clot material from blood, comprising: a syringe including at least one filter. Specifically, Groups I-IV are related as an apparatus (Groups I-II and IV) and methods for using the apparatus (Group III). The apparatus is known in prior art as shown in US 2006/0294096 A1 to Uber, III et al. (hereinafter 'Uber').

Uber discloses system for use in filtering clot material from blood (see system comprising syringe 50 coupled with a patient's blood via catheter 315', Fig 3; see embodiment of 50 as syringe 2550 including filter 2556, Fig 18C; 50 is a syringe such as in Fig 18A-I, para [0229]; 315 is an intravascular catheter, para [0233]; syringe with filter 2556 with pore size to allow liquid hence configured to filter clot material from blood, para [0468], para [0471]), comprising: a syringe (see syringe 2550, Fig 18C; syringe 2550, para [0468]) including at least one filter (see filter 2556, Fig 18C, filter 2556, para [0468]).

Groups II-III further share the common technical features of the system for use in filtering clot material from blood further comprising a catheter configured to be intravascularly positioned at a treatment site within a blood vessel. However, this shared technical feature does not represent a contribution over prior art as being anticipated by Human.

Uber discloses wherein the system for use in filtering clot material from blood further comprising a catheter (see 315', Fig 3) configured to be intravascularly positioned at a treatment site within a blood vessel (315 is an intravascular catheter, para [0233]).

Groups I and IV further share the common technical features of the syringe comprising a barrel defining a chamber; a plunger assembly comprising a filter and a valve; wherein at least a portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel. However, the shared technical feature does not represent a contribution over prior art as being anticipated by Human.

Uber discloses the syringe comprising a barrel defining a chamber (see barrel 2550 defining a chamber for plunger 2552, Fig 18C, syringe barrel, para [0468]); a plunger assembly (see plunger 2552, Fig 18C; plunger 2552, para [0468]) comprising a filter (see how 2552 comprises filter 2556, Fig 18C; filter 2556 replaces the rubber cover on the forward end of a conventional plunger, para [0468]) and a valve (see valve 2564 of plunger 2552, Fig 18C; exit outlet valve 2564 of plunger chamber 25564, para [0469]); wherein at least a portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel (see how the left end of 2552 is insertable within and slidable relative to 2550, Fig 18C; plunger 2552 may be drawn back and pushed forward in syringe 2550, para [0469]).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-IV lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

-*-Box V.2 - Citations and Explanations-*-

Claims 1, 6, 8-9 and 13-16 lack novelty under PCT Article 33(2) as being anticipated by US 2011/0309037 A1 to Lee.

As to claim 1, Lee discloses a filtering syringe for treatment of clot material from within a blood vessel of a patient (syringe having filtering device, para [0015]; filtering device pore diameter 10 to 100 um hence configured to filter clot material from blood, para [0018]), the filtering syringe comprising:
a barrel defining a chamber (see b defining a chamber, Fig 9) configured to receive at least a portion of the clot material and blood from the patient (see how b is connected to a cannula 100 hence is configured to receive a portion of clot material and blood when cannula 100 is inserted in a patient, Fig 6, b has cannula 100 attached and inserted into the patient, para [0041]); and
a plunger assembly (see plunger assembly, Fig 7; syringe piston shown in Fig 7, para [0065]) having a first end portion (see end portion 13, Fig 7, Fig 10) and a second end portion opposite the first end portion (see end 404, Fig 8), wherein the plunger assembly includes a filter proximate to the first end portion (see filter 60 proximate end 13, Fig 8, filter 60 of the syringe piston, para [0071]), a port proximate to the second end portion (see port at 400, Fig 8), and a lumen therebetween and fluidly coupling the filter and the port (see lumen 300 between 60 and the port at 400, Fig 8; central hole 300 penetrating the front end and rear end of the piston body, para [0066]);
wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel (see how at least end 13 is insertable and slidable relative to b, Fig 9-10); and
wherein the filter is configured to allow at least part of the blood received within the chamber to separate from the portion of the clot material (filtering device has pore diameter of 10 um to 100 um hence is configured to separate clot material from blood, para [0018]) and enter the lumen of the plunger assembly (see how 60 is positioned to allow blood from the chamber of b to enter the lumen of the plunger, Fig 10).

As to claim 6, Lee discloses the filtering syringe of claim 1 wherein the filter is a first filter having a first porosity (a first layer of 60 may comprise holes of about 100 um, para [0045]), the filtering syringe further comprising a second filter having a second porosity (a second layer of 60 hence a second filter may comprises holes of about 100 um, para [0045]).

As to claim 8, Lee discloses the filtering syringe of claim 6 wherein the first porosity is the same as the second porosity (multiple layers of filter each having holes of about 100 um, para [0045]).

As to claim 9, Lee discloses the filtering syringe of claim 6 wherein the second filter is positioned proximate the first end portion of the plunger assembly (see how 60 hence including the second filter layer is proximate 13, Fig 7).

-*-Continued in next Supplemental Box-*-

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-*-Supplemental Box - Box V.2 - Citations and Explanations-*-

As to claim 13, Lee discloses the filtering syringe of claim 1 wherein the chamber includes an inner surface (see an inner surface of b, Fig 10), and wherein first end portion of the plunger assembly is radially spaced apart from chamber (see how 13 is radially spaced from the inner surface of b, Fig 10) such that the barrel assembly and the plunger assembly at least partially define (i) a first chamber portion positioned on a first side of the first end portion of the plunger assembly (see a first chamber portion of b to the left of 13, Fig 10), (ii) a second chamber portion positioned on a second side of the first end portion of the plunger assembly, the second side opposite the first side (see a second chamber portion of b to the right of 13, Fig 10), and (iii) a gap fluidly coupling the first chamber portion and the second chamber portion (see how the left and right chamber portions relative to 13 are coupled by a gap between 13 and the inner surface of b, Fig 10).

As to claim 14, Lee discloses the filtering syringe of claim 13 wherein the filter is positioned in the second chamber portion (see how 50 is positioned in the chamber portion to the right of 13, Fig 10), wherein the first chamber portion is configured to receive at least the portion of the clot material from the patient (see how the left chamber portion is configured to receive at least a portion of blood and clot material from the patient via cannula 100, Fig 6), wherein the gap is configured to at least partially prevent the portion of the clot material from entering the second chamber portion (see how the gap between 13 and the inner surface of b is configured to prevent clot material larger than the gap size from entering the right chamber portion, Fig 10), and wherein the filter is configured to allow blood within the second chamber portion to enter the lumen (see how 50 is positioned to allow blood within the right chamber portion to enter the lumen of the plunger, Fig 10).

As to claim 15, Lee discloses the filtering syringe of claim 1 wherein the first end portion of the plunger assembly is configured to at least partially prevent contact between the filter and the portion of the clot material (see how 13 is to the left of 50 hence is configured to prevent contact between 50 and clot material, Fig 10).

As to claim 16, Lee discloses the filtering syringe of claim 1 wherein the plunger assembly defines a filter chamber configured to receive the filter (see how 50 is received in a chamber of the plunger, Fig 8), and wherein the first end portion of the plunger assembly includes one or more holes in fluid communication with the filter chamber (see holes in the tip portion 13 in fluid communication with the chamber with filter 50, Fig 7, Fig 10).

Claims 1 and 27-32 lack novelty under PCT Article 33(2) as being anticipated by US 2008/0294096 A1 to Uber, III et al. (hereinafter 'Uber').

As to claim 1, Uber discloses a filtering syringe for treatment of clot material from within a blood vessel of a patient (see syringe 50 configured to remove target material such as clots from a patient's vascular system via catheter 315', Fig 3; see embodiment of 50 as syringe 2550 including filter 2556, Fig 18C; 50 is a syringe such as in Fig 18A-I, para [0229]; 315 is an intravascular catheter, para [0233]; syringe with filter 2556, para [0471]), the filtering syringe comprising:
a barrel defining a chamber (see 2550 defining an inner chamber, Fig 18C; syringe 2550 with plunger within syringe barrel, para [0468]) configured to receive at least a portion of the clot material and blood from the patient (see how the chamber of 2550 is configured to receive a target material such as clots to the left of plunger 2552 due to filter 2556, Fig 18C; filter 2556 has pores sized so liquid may pass while other target material cannot, para [0468]); and
a plunger assembly (see plunger 2552, Fig 18C; plunger 2552, para [0468]) having a first end portion (see left end of 2552, Fig 18C) and a second end portion opposite the first end portion (see right end 2552, Fig 18C), wherein the plunger assembly includes a filter proximate to the first end portion (see filter 2556 proximate the left end of 2552, Fig 18C; filter 2556 on the forward end of the plunger, para [0468]), a port proximate to the second end portion (see port with valve 2564 proximate end 2552, Fig 18C; outlet valve 2564, para [0468]), and a lumen therebetween and fluidly coupling the filter and the port (see lumen 2554 between 2556 and 2564, Fig 18C; plunger chamber 2554, para [0468]),
wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel (see how at least the left end of 2552 is insertable within and slidable relative to 2550, Fig 18C; plunger 2552 may be drawn back and pushed forward, para [0468]); and
wherein the filter is configured to allow at least part of the blood received within the chamber to separate from the portion of the clot material and enter the lumen of the plunger assembly (holes of filter 2556 are sized such that liquid may pass through while larger material may not, para [0468]).

-*-Continued in next Supplemental Box-*-

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-*-Supplemental Box - Box V.2 - Citations and Explanations-*-

As to claim 27, Uber discloses a filtering syringe for removing target material from within a human patient (see syringe 50 configured to remove target material from a patient's vascular system via catheter 315', Fig 3; see embodiment of 50 as syringe 2550 including filter 2556, Fig 18C; 50 is a syringe such as in Fig 18A-I, para [0229]; 315 is an intravascular catheter, para [0233]; syringe with filter 2556, para [0471]), the filtering syringe comprising:
a barrel defining a chamber (see 2550 defining an inner chamber, Fig 18C; syringe 2550 with plunger within syringe barrel, para [0468]) configured to receive at least a portion of the target material and fluid from the human patient (see how the chamber of 2550 is configured to receive a target material to the left of plunger 2552 due to filter 2556, Fig 18C; filter 2556 has pores sized so liquid may pass while other target material cannot, para [0468]); and
a plunger assembly (see plunger 2552, Fig 18C; plunger 2552, para [0468]) having a first end portion (see left end of 2552, Fig 18C) and a second end portion opposite the first end portion (see right end 2582, Fig 18C), wherein the plunger assembly includes a filter proximate to the first end portion (see filter 2556 proximate the left end of 2552, Fig 18C; filter 2556 on the forward end of the plunger, para [0468]), a valve proximate to the second end portion (see valve 2564 proximate end 2582, Fig 18C; outlet valve 2564, para [0468]), and a lumen therebetween and fluidly coupling the filter and the valve (see lumen 2554 between 2556 and 2564, Fig 18C; plunger chamber 2554, para [0468]);
wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel (see how at least the left end of 2552 is insertable within and slidable relative to 2550, Fig 18C; plunger 2552 may be drawn back and pushed forward, para [0468]); and
wherein the filter is configured to allow at least part of the fluid received within the chamber to pass through the filter and enter the lumen of the plunger assembly (holes of filter 2556 are sized such that liquid may pass through, para [0468]).

As to claim 28, Uber discloses the filtering syringe of claim 27 wherein the fluid includes blood (315 is an intravascular catheter hence fluid entering the syringe from the catheter includes blood, para [0233], para [0468]).

As to claim 29, Uber discloses the filtering syringe of claim 27 wherein the target material includes clot material (315 is an intravascular catheter hence target material entering the syringe from the catheter that may not pass through the filter may include clots, para [0233], para [0468]).

As to claim 30, Uber discloses a filtering syringe for treating a human patient (see syringe 50 configured to treat a patient via catheter 315', Fig 3; see embodiment of 50 as syringe 2550 including filter 2556, Fig 18C; 50 is a syringe such as in Fig 18A-I, para [0229]; 315 is an intravascular catheter, para [0233]; syringe with filter 2556, para [0471]), comprising:
a barrel defining a chamber (see 2550 defining an inner chamber, Fig 18C; syringe 2550 with plunger within syringe barrel, para [0468]) configured to receive first material (see how liquid material received within 2550 may pass through filter 2556, Fig 18C; filter 2556 has pores sized so liquid may pass while other larger sized material cannot, para [0468]) and second material from within the human patient (see how the chamber of 2550 is configured to receive a larger sized material to the left of plunger 2552 due to filter 2556, Fig 18C; filter 2556 has pores sized so liquid may pass while other larger sized material cannot, para [0468]); and
a plunger assembly (see plunger 2552, Fig 18C; plunger 2552, para [0468]) having a first end portion (see left end of 2552, Fig 18C) having a first end portion (see left end of 2552, Fig 18C) and a second end portion opposite the first end portion (see right end 2582, Fig 18C), wherein the plunger assembly includes a filter proximate to the first end portion (see filter 2556 proximate the left end of 2552, Fig 18C; filter 2556 on the forward end of the plunger, para [0468]), a valve proximate to the second end portion (see valve 2564 proximate end 2582, Fig 18C; outlet valve 2564, para [0468]), and a lumen therebetween and fluidly coupling the filter and the valve (see lumen 2554 between 2556 and 2564, Fig 18C; plunger chamber 2554, para [0468]);
wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel (see how at least the left end of 2552 is insertable within and slidable relative to 2550, Fig 18C, plunger 2552 may be drawn back and pushed forward, para [0468]); and
wherein the filter is configured to (i) allow at least part of the first material received within the chamber to pass through the filter and enter the lumen of the plunger assembly (filter 2556 has pores sized so liquid may pass while other larger sized material cannot, para [0468]), and (ii) prevent at least part of the second material received within the chamber from passing through the filter (filter 2556 has pores sized so liquid may pass while other larger sized material cannot, para [0468]).

As to claim 31, Uber discloses the filtering syringe of claim 30 wherein the first material includes blood (315 is an intravascular catheter hence liquid material entering the syringe from the catheter includes blood, para [0233], para [0468]).

As to claim 32, Uber discloses the filtering syringe of claim 30 wherein the second material includes clot material (315 is an intravascular catheter hence larger sized material entering the syringe from the catheter that may not pass through the filter may include clots, para [0233], para [0468]).

-*-Continued in next Supplemental Box-*-

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**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-*-Supplemental Box - Box V.2 - Citations and Explanations-*-

Claim 5 lacks an inventive step under PCT Article 33(3) as being obvious over Uber.

As to claim 5, Uber discloses the filtering syringe of claim 1 but does not explicitly teach wherein the filter includes at least one of a polyester, a polyamide, and/or a hemocompatible material.
Uber teaches wherein the syringe may be used with an intravascular catheter (para [0223], para [0233]) such that the syringe receives material from a patient (material such as cells may be harvested directly into the syringe 50 from the patient, para [0227]), and wherein blood-contacting catheters may comprise hemocompatible material (coatings on blood-contacting catheters provide hemocompatibility, para [0351]), however Uber does not specify the material of the filter.
However, it would have been obvious to a person having ordinary skill in the art to modify the material of the filter such that it comprises a hemocompatible material in order to use the filtering syringe for applications involving blood from a patient.

Claim 11 lacks an inventive step under PCT Article 33(3) as being obvious over Human.

As to claim 11, Human discloses the filtering syringe of claim 1 but does not explicitly teach wherein the port includes a luer-activated valve.
Human teaches wherein the port includes a closeable media connection such as a shut-off valve (closeable media connection 32 can be a shut-off valve, para [0044]) for connection to a negative pressure source (32 is connected to negative pressure, para [0044] [0045]). Luer-activated valves are commonly known in the art in order to provide a valve which is only opened when connected to a luer connector and which is closed when not connected. Accordingly, it would have been obvious to a person having ordinary skill in the art to modify the port valve such that it comprises a luer-activated valve in order to provide a valve which is only opened when connected to a suitable luer connector of a negative pressure source.

Claim 17 lacks an inventive step under PCT Article 33(3) as being obvious over Lee.

As to claim 17, Lee discloses the filtering syringe of claim 16 but does not teach wherein the filter is an annular filter defining a central space, and wherein individual ones of the one or more holes are positioned to direct at least a portion of the clot material and/or the blood received from the patient into the central space.
Lee teaches wherein the filter is circular (see circular filter 50, Fig. 7; circular filter 50, para [0044]) comprising holes sized to filter larger sized material while passing fluid material (50 has holes of the size for filtering adipose cells and passing free oil, para [0044]]) and wherein the fluid material is passed to the plunger assembly lumen aligned with the center of the filter (see how material is passed through 50 to the central lumen of the plunger, Fig 10, see central lumen 360, Fig 8). Further, optimizing size, shape, and angle(s) is within the ordinary skill of one in the art. Accordingly, it would have been obvious to a person having ordinary skill in the art to have optimized the shape of the filter such that it comprises an annular filter defining a central space, wherein individual ones of the one or more holes are positioned to direct at least a portion of the fluid blood received from the patient into a central space of the filter sized to only pass the fluid material to the plunger assembly lumen.

Claims 1-17 and 27-32 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

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(54) **INTRODUCER SHEATH FOR RADIAL ARTERY ACCESS**
EINFÜHRSCHLEUSE FÜR RADIALEN ARTERIENZUGANG
GAINE D'INTRODUCTEUR POUR ACCÈS ARTÉRIEL RADIAL

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(56) References cited:
**EP-A2- 1 068 876**
**WO-A1-2013/003835**
**WO-A2-2005/072806**
**US-A- 5 938 587**
**US-B1- 6 197 014**
**US-B1- 6 689 120**

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EP 3 013 404 B1

## Description

### Field of the Invention

**[0001]** The present disclosure relates to an arterial sheath introducer. More specifically, the present disclosure relates to an arterial sheath introducer intended to facilitate introduction of interventional catheter devices through the skin and into the arterial system.

### Background of the Invention

**[0002]** Currently, vascular introducer sheaths used to access radial or femoral arteries suffer from various limitations. These include buckling or "roll-back" of the very distal tip upon entry into the skin. This is caused by a poor or abrupt transition or step between the introducer tip and the dilator that is inside the introducer to provide a transition from the guidewire to the sheath. Roll-back can also be caused by inadequate mechanical structure of the sheath tip.

**[0003]** Another limitation of current vascular introducer sheaths is the overall diameter of the introducer can be too large, such that excessive bleeding upon removal and/or arterial spasm during use can be caused. This limitation can be due to excessive wall thickness of the introducer related to current introducer construction methods.

**[0004]** A further limitation of current introducer is kinking or buckling during manipulation, insertion, or withdrawal of the catheter through the sheath or due to excessive cutaneous tissue thickness. The kinking and buckling of the introducer can be inherent in the construction and design of currently available introducer.

**[0005]** EP 1 068 876 A2 discloses a catheter inserted into, for example, a blood vessel for use and a method of manufacturing a catheter having a proximal end, a distal end and a tubular member defining an inner lumen extending between the proximal end and the distal end, the method comprising steps of: preparing a first linear member made of a first resin material and a second linear member made of a second resin material; disposing the first linear member in a dense spiral or mesh in a first region of the tubular member and in a sparse spiral or mesh in a second region of the tubular member; and disposing the second linear member in a sparse spiral or mesh in the first region of the tubular member and in a dense spiral or mesh in the second region of the tubular member.

**[0006]** US 6 689 120 B1 relates to an outer catheter being formed of a layered wall construction including a low friction polymeric inside tube, a polymeric outside tube, and a metallic reinforcement braid embedded in the wall between the inside and outside tubes.

### Summary of the Invention

**[0007]** In accordance with the present invention, there is provided a radial artery catheter introducer sheath as defined in claim 1.

**[0008]** In addition, further advantageous embodiments frollow from the dependent claims.

### Summary of the Disclosure

**[0009]** Examples of the disclosure include a radial artery catheter introducer sheath for introducing interventional catheters into the vasculature comprising: a main tubular shaft comprising a distal tip, a proximal end, an inner layer, a main structural layer and an outer layer; wherein the inner layer comprises one or more layers of polymer with a thickness of 0.0254 - 0.127 mm (0.001 - 0.005 inches), the main structural layer comprises one or more metallic helically wound multi-filar wires with a wall thickness of 0.0381 mm to 0.254 mm (0.0015 inches to 0.010 inches); wherein the outer layer comprises an outer polymer jacket that at least partially covers the inner layer at the distal tip, and the outer polymer jacket is coupled to the main structural layer; wherein the outer polymer jacket has a thickness of 0.0254 mm - 0.254 mm (0.001 inches to 0.010 inches); wherein the distal tip comprises 2 or more layers, these layers formed of the outer polymer and inner polymer, and the distal tip has a length of 1.27 mm and 7.62 mm (0.05 inches and 0.30 inches).

**[0010]** In an embodiment, the main tubular shaft can have an outer diameter of 1.524 mm to 4.064 mm (0.060 inches to 0.160 inches). The main tubular shaft can comprise an inner polymer layer, a main structural layer comprised of multi-filar wires that have been swaged into a rectangular cross-section and covered with a metallic wire braid and an outer polymer jacket. The distal tip can also comprise two or more layers, such as a layer of PTFE and a layer of Pebax.

**[0011]** This summary is an overview of some of the teachings of the present application and is not intended to be an exclusive or exhaustive treatment of the present subject matter. Further details are found in the detailed description and appended claims. Other aspects will be apparent to persons skilled in the art upon reading and understanding the following detailed description and viewing the drawings that form a part thereof, each of which is not to be taken in a limiting sense. The scope of the present invention is defined by the appended claims.

### Brief Description of the Figures

**[0012]** The invention may be more completely understood in connection with the following drawings, in which:

FIG. 1 is a view of an introducer, according to an embodiment.

FIG. 2 is a cross-section view of a portion of an introducer, according to an embodiment.

FIG. 3 is a view of an introducer along with other components it can be used with, according to an em-

bodiment.

FIG. 4 is a view of a cross section of an introducer, according to an embodiment.

FIG. 5 is a view of a cross section of an introducer, according to an embodiment.

FIG. 6 is a view of a cross section of an introducer, according to an embodiment.

FIG. 7 is a view of a cross section of an introducer, according to an embodiment.

**[0013]** While the invention is susceptible to various modifications and alternative forms, specifics thereof have been shown by way of example and drawings, and will be described in detail. It should be understood, however, that the invention is not limited to the particular embodiments described. but is as defined in the claims.

## Detailed Description of the Invention

**[0014]** The embodiments of the present invention described herein are not intended to be exhaustive or to limit the invention to the precise forms disclosed in the following detailed description. Rather, the embodiments are chosen and described so that others skilled in the art can appreciate and understand the principles and practices of the present invention.

**[0015]** References to "embodiments" throughout the description which are not under the scope of the eppended claims merely represent possible exemplary executions and are therefore not part of the present invention.

**[0016]** The invention is defined by the appended claims.

**[0017]** The device of this invention solves the problems associated with current vascular introducer sheaths by providing novel improved design, construction and materials.

**[0018]** Figure 1 shows an introducer 100. The introducer 100 can comprise a composite built main tubular shaft. The main tubular shaft can be configured to be slideable, such that an inner dilator can slide through the main tubular shaft. The main tubular shaft can be configured to closely fit an inner dilator for delivery through the skin and into an artery. An inner dilator can be mounted inside the introducer 100, such as during insertion, such as to allow a smooth transition from a guidewire to the introducer 100. In an embodiment, the main tubular shaft can have an outer diameter of 1.524 mm (0.060 inches) or more. In an embodiment, the main tubular shaft can have an outer diameter of 4.064 mm (0.160 inches) or less. In an embodiment, the main tubular shaft can have a length of 15 cm or more. In an embodiment, the main tubular shaft can have a length of 205 cm or less. The main tubular shaft can comprise a wound metal structural layer 1. The structural layer 1 can be jacked with a thin wall polymer. The structural layer 1 can comprise a multi-filar metallic helical wound structure. The multi-filar structure can comprise stainless steel.

**[0019]** In an embodiment, the structural layer 1 can comprise 12 or more filars. In an embodiment, the structural layer 1 can comprise 18 or fewer filars. In an embodiment, the multi-filar structure can be swaged such that each wire has a rectangular cross-section, such that it can result in a very close fitting wire matrix between adjacent wires. The multi-filar structure can comprise non-swaged wires. The multi-filar structure can comprise a wire with a round (such as circular, oval, or elliptical) cross-section. The multi-filar structure can comprise a wire with a square or rectangular cross-section. The multi-filar structure can comprise welded ends. The multi-filar structure can comprise a PTFE coating. In an embodiment, the multi-filar wires can comprise a PTFE coating prior to forming the multi-filar structure.

**[0020]** In an embodiment, the structural layer 1 can define a center lumen, such as to allow an inner dilator to pass through the introducer 100. The structural layer 1 can have a thickness of 0.0381 mm (0.0015 inches) or more. The structural layer 1 can have a thickness of 0.0762 mm (0.003 inches) or less. In an embodiment, the structural layer 1 can have a thickness of 0.254 mm (0.010 inches) or less. The structural layer 1 can provide a significant improvement in mechanical integrity of the sheath compared to existing introducer sheaths with respect to kinking, buckling, flexibility, radial strength and maintaining cross-sectional circularity of the sheath.

**[0021]** The introducer 100 can include a distal end and a proximal end 6. The distal end of the introducer 100 is curved, such as to conform to a portion of a patient's anatomy. The structural layer is curved to the desired shape and heat processed such that the structural layer holds the desired curve shape.

**[0022]** The introducer 100 can further comprise an outer layer 2. The outer layer can comprise an outer polymer jacket. The outer polymer jacket can substantially cover the outside surface of the structural layer 1. The outer polymer jacket can comprise one or more of the following: PTFE, Pebax, nylon and Polyurethane. In an embodiment, the outer polymer jacket 2 comprises one or more layers or segments of different polymers. In an embodiment, the outer polymer jacket comprises two or more layers of Pebax. The outer polymer jacket can comprise or be coated with a hydrophilic polymer. The outer polymer jacket can be coupled to the structural layer 1, such as by thermal polymer heat-shrinking or reflow. Heat shrinking the outer polymer jacket can allow the outer polymer jacket 2 to be formed tightly onto the structural layer 1. In an embodiment, the outer polymer jacket can have a thickness of 0.0254 mm (0.001 inches) or more. In an embodiment, the outer polymer jacket can have a thickness of 0.0762 mm (0.003 inches) or less. In an embodiment, the outer polymer jacket can have a thickness of 0.254 mm (0.010 inches) or less.

**[0023]** The introducer 100 can further comprise an inner layer 7. The inner layer 7 can comprise an inner polymer jacket. The inner polymer jacket can substantially cover a surface of the structural layer 1, such as the inner surface. The inner polymer jacket can comprise one or

more of the following: PTFE, Pebax, nylon and Polyurethane. In an embodiment, the inner polymer jacket comprises one or more layers or segments of different polymers. In an embodiment, the inner polymer jacket comprises two or more layers of Pebax. The inner polymer jacket can comprise or be coated with a hydrophilic polymer. The inner polymer jacket can be coupled to the structural layer 1, such as by thermal polymer reflow. In an embodiment, the inner polymer jacket can have a thickness of 0.0254 mm (0.001 inches) or more. In an embodiment, the inner polymer jacket can have a thickness of 0.127 mm (0.005 inches) or less. In an embodiment, the inner polymer jacket can have a thickness of 0.254 mm (0.010 inches) or less.

**[0024]** In an embodiment, the lamination of the structural layer 1, the outer layer 2, and the inner layer 7 does not include fusion of the outer layer 2 and the inner layer 7. In an embodiment, the inner layer 7 and the outer layer 2 can be fused between and through the structural layer 1. In other implementations the outer layer and the inner layer are not fused together.

**[0025]** In some implementations the material forming the introducer, taken along a cross section of the introducer perpendicular to the central axis of the introducer, is from 40 to 60 percent metal. In other implementations the material forming the introducer, taken along a cross section of the introducer perpendicular to the central axis of the introducer, is from 20 to 60 percent metal. Alternatively the material forming the introducer, taken along a cross section of the introducer perpendicular to the central axis of the introducer, is greater than 20 percent metal.

**[0026]** The introducer 100 can further comprise a distal tip 3. The distal tip 3 can be tapered, such that the portion of the distal tip 3 closer to the proximal end 6 of the introducer 100 has a larger outer diameter than the distal end of the distal tip 3. The outer diameter of the distal end of the distal tip 3 can be configured to closely hug the outer diameter of an inner dilator.

**[0027]** The length of the distal tip 3 can be at least 1.27 mm (0.05 inches). In an embodiment, the length of the distal tip 3 is 7.62 mm (0.30 inches) or less.

**[0028]** The distal tip 3 can comprise an inner tip layer and an outer tip layer. The inner tip layer can comprise PTFE and the outer tip layer can comprises Pebax. The distal tip 3 can comprise a gold coating. In an embodiment, the thickness of the gold coating is 0.5 mm or more. In an embodiment, the thickness of the gold coating is 2 mm or less. The distal tip 3 can comprise a composite of a thin sheath jacket layer on the inside of the tip and a reflowed polymer on the outside. A distal tip 3 comprising such a composite can results in a very close fitting (non-abrupt) transition from the inner dilator to the introducer 100, thus reducing potential introducer tip damage such as "roll-back" or buckling. The main tubular shaft can be coupled to the hemostatis valve 4.

**[0029]** As shown in FIG. 3, the introducer 100 can also be configured to be used with standard components and elements familiar with those skilled in the art such as a hemostatis valve 4, an inner dilator 5, proximal hemostasis adaptor, side-port luer extension for flushing and a skin attachment means at the proximal adaptor. In an embodiment, an infusion port can be attached to the hemostatis valve 4, such as to allow infusion of media through the introducer 100.

**[0030]** FIG. 4 shows a cross section of an introducer 100, according to an embodiment. FIG. 5 shows a cross section of a similar introducer 100. The introducer 100 can define a central lumen 8, such as to accommodate the passage of an object, such as a dilator. The introducer 100 can include a structural layer 1, an outer layer 2, and an inner layer 7. In an embodiment, the outer layer 2 can include two or more layers. In an embodiment, the inner layer 7 can include two or more layers.

**[0031]** FIG. 6 shows a cross section of an introducer 200, according to an embodiment. FIG. 7 shows a cross section of a similar introducer 200. The introducer 200 can define a central lumen 28, such as to accommodate the passage of an object, such as a dilator. The introducer 200 can include a structural layer 21, an outer layer 22, and an inner layer 27. In an embodiment, the outer layer 22 can include two or more layers, such as braid 29 and a polymer layer 30. The braid 29 can be positioned between the polymer layer 30 and the structural layer 21. In an embodiment, the braid 29 can include metal. In an embodiment, the polymer layer 30 can fuse together with the braid 29, such that portions of the polymer layer 30 are disposed between or around portions of the braid 29.

**[0032]** It should be noted that, as used in this specification and the appended claims, the singular forms "a," "an," and "the" include plural referents unless the content clearly dictates otherwise. Thus, for example, reference to a composition containing "a compound" includes a mixture of two or more compounds. It should also be noted that the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

**[0033]** It should also be noted that, as used in this specification and the appended claims, the phrase "configured" describes a system, apparatus, or other structure that is constructed or configured to perform a particular task or adopt a particular configuration to. The phrase "configured" can be used interchangeably with other similar phrases such as arranged and configured, constructed and arranged, constructed, manufactured and arranged, and the like.

## Claims

1. A radial artery catheter introducer sheath (100, 200) for introducing interventional catheters into the vasculature comprising:

   a main tubular shaft comprising a distal tip (3), a proximal end (6), a structural layer (1, 21), an

inner layer (7, 27), and an outer layer (2, 22);
wherein the structural layer (1, 21) comprises one or more metallic helically wound multi-filar wires with a wall thickness of 0.038 mm to 0.25 mm (0.0015 inches to 0.010 inches), and the structural layer is heat processed to retain a curved distal end, the distal end being curved to conform to a portion of a patient's anatomy;
wherein the outer layer (2, 22) comprises an outer polymer jacket that at least partially covers the structural layer and the outer polymer jacket is coupled to the structural layer, the outer polymer jacket having a thickness of 0.025 mm to 0.25 mm (0.001 inches to 0.010 inches);
wherein the inner layer (7, 27) comprises an inner polymer jacket that at least partially covers the structural layer and the inner polymer jacket is coupled to the structural layer;
wherein the inner polymer jacket has a thickness of 0.025 mm to 0.25 mm (0.001 inches to 0.010 inches); and
wherein the distal tip (3) comprises an outer polymer and the distal tip has a length of 1.27 mm to 7.62 mm (0.05 inches and 0.30 inches).

2. The introducer sheath of claim 1, wherein the metal helically wound multi-filar layer (1, 21) comprises stainless steel.

3. The introducer sheath of claim 1, wherein the multi-filar structure comprises 12 to 18 filars.

4. The introducer sheath of claim 1, wherein the multi-filar structure wire is swaged so as to impart a rectangular cross-section and intimate fitting contact between adjacent wires.

5. The introducer sheath of claim 1, wherein the main tubular shaft has an outer diameter of 1.52 mm to 2.92 mm (0.060 inches to 0.115 inches).

6. The introducer sheath of claim 1, wherein the outer polymer jacket (2, 22) comprises PTFE or nylon, or Pebax or two layers of Pebax.

7. The introducer sheath of claim 1, wherein the outer polymer jacket (2, 22) is coated with a hydrophilic polymer.

8. The introducer sheath of claim 1, wherein the distal tip (3) comprises an inner tip layer and an outer tip layer, wherein the inner tip layer comprises PTFE and the outer tip layer comprises Pebax.

9. The introducer sheath of claim 1, wherein the helically wound multi-filar wires comprise welded terminations.

10. The introducer sheath of claim 1, wherein the distal tip (3) comprises a gold coating, wherein the gold coating is between 0.5 mm to 2 mm.

11. The introducer sheath of claim 1, wherein the outer jacket layer (2, 22) is heat shrinkable and configured to be formed tightly onto the helically wound multi-filar structure.

12. The introducer sheath of claim 1, wherein the helically wound multi-filar structure wire has a rectangular cross-section or a circular cross-section or an oval or elliptical cross-section.

13. The introducer sheath of claim 1, wherein the proximal end (6) of the main tubular shaft is coupled to a hemostasis valve (4).

14. The introducer sheath of claim 1, wherein the helically wound multi-filar structure wires comprise a PTFE coating prior to forming into a multi-filar configuration.

15. The introducer sheath of claim 1, wherein the main tubular shaft has a length of 15 cm to 205 cm.

16. The introducer sheath of claim 12, wherein the multi-filar structure has an intimate fitting contact between adjacent wires.

17. The introducer sheath of claim 1, wherein the outer polymer jacket (2, 22) covers the structural layer (1, 21).

18. The introducer sheath of claim 1, wherein the outer layer (2, 22) and the inner layer (7, 27) are not fused together.

19. The introducer sheath of claim 1, wherein the material forming the introducer (100, 200), taken along a cross section of the introducer perpendicular to the central axis of the introducer, is from 40 to 60 percent metal or from 20 to 60 percent metal or greater than 20 percent metal.

20. The introducer sheath of claim 1, wherein the distal tip (3) comprises two or more layers of outer polymer.

**Patentansprüche**

1. Einführhülse für einen Radialarterienkatheter (100, 200) zum Einführen von interventionellen Kathetern in das Gefäßsystem, umfassend:

einen Hauptrohrschaft, umfassend eine distale Spitze (3), ein proximales Ende (6), eine Strukturschicht (1, 21), eine innere Schicht (7, 27) und

eine äußere Schicht (2, 22);
wobei die Strukturschicht (1, 21) einen oder mehrere metallische, spiralförmig gewickelte, multifilare Drähte mit einer Wanddicke von 0,038 mm bis 0,25 mm (0,0015 Zoll bis 0,010 Zoll) umfasst, und die Strukturschicht wärmebehandelt ist, um ein gekrümmtes distales Ende beizubehalten, wobei das distale Ende gekrümmt ist, um sich an einen Abschnitt der Anatomie eines Patienten anzupassen;
wobei die äußere Schicht (2, 22) einen äußeren Polymermantel umfasst, der die Strukturschicht zumindest teilweise bedeckt und der äußere Polymermantel mit der Strukturschicht gekoppelt ist, wobei der äußere Polymermantel eine Dicke von 0,025 mm bis 0,25 mm (0,001 Zoll bis 0,010 Zoll) aufweist;
wobei die innere Schicht (7, 27) einen inneren Polymermantel umfasst, der die Strukturschicht zumindest teilweise bedeckt und der innere Polymermantel mit der Strukturschicht gekoppelt ist;
wobei der innere Polymermantel eine Dicke von 0,025 mm bis 0,25 mm (0,001 Zoll bis 0,010 Zoll) aufweist; und
wobei die distale Spitze (3) ein äußeres Polymer umfasst und die distale Spitze eine Länge von 1,27 mm bis 7,62 mm (0,05 Zoll und 0,30 Zoll) aufweist.

2. Einführhülse nach Anspruch 1, wobei die spiralförmig gewickelte, multifilare Metallschicht (1, 21) Edelstahl umfasst.

3. Einführhülse nach Anspruch 1, wobei die multifilare Struktur 12 bis 18 Filare umfasst.

4. Einführhülse nach Anspruch 1, wobei der Draht mit multifilarer Struktur so verpresst ist, dass er einen rechteckigen Querschnitt und einen eng anliegenden Kontakt zwischen benachbarten Drähten vermittelt.

5. Einführhülse nach Anspruch 1, wobei der Hauptrohrschaft einen Außendurchmesser von 1,52 mm bis 2,92 mm (0,060 Zoll bis 0,115 Zoll) aufweist.

6. Einführhülse nach Anspruch 1, wobei der äußere Polymermantel (2, 22) PTFE oder Nylon oder Pebax oder zwei Schichten Pebax umfasst.

7. Einführhülse nach Anspruch 1, wobei der äußere Polymermantel (2, 22) mit einem hydrophilen Polymer beschichtet ist.

8. Einführhülse nach Anspruch 1, wobei die distale Spitze (3) eine innere Spitzenschicht und eine äußere Spitzenschicht umfasst, worin die innere Spitzenschicht PTFE umfasst und die äußere Spitzenschicht Pebax umfasst.

9. Einführhülse nach Anspruch 1, wobei die spiralförmig gewickelten multifilaren Drähte geschweißte Endverbindungen umfassen.

10. Einführhülse nach Anspruch 1, wobei die distale Spitze (3) eine Goldbeschichtung umfasst, wobei die Goldbeschichtung zwischen 0,5 mm und 2 mm liegt.

11. Einführhülse nach Anspruch 1, wobei die äußere Mantelschicht (2, 22) wärmeschrumpfbar und so konfiguriert ist, dass sie fest auf der spiralförmig gewickelten multifilaren Struktur ausgebildet ist.

12. Einführhülse nach Anspruch 1, wobei der spiralförmig gewickelte multifilare Strukturdraht einen rechteckigen Querschnitt oder einen kreisförmigen Querschnitt oder einen ovalen oder elliptischen Querschnitt aufweist.

13. Einführhülse nach Anspruch 1, wobei das proximale Ende (6) der Hauptrohrschaft mit einem Hämostaseventil (4) gekoppelt ist.

14. Einführhülse nach Anspruch 1, wobei die spiralförmig gewickelten multifilaren Strukturdrähte eine PTFE-Beschichtung umfassen, bevor sie zu einer multifilaren Konfiguration geformt werden.

15. Einführhülse nach Anspruch 1, wobei der Hauptrohrschaft eine Länge von 15 cm bis 205 cm aufweist.

16. Einführhülse nach Anspruch 12, wobei die multifilare Struktur einen eng anliegenden Kontakt zwischen benachbarten Drähten aufweist.

17. Einführhülse nach Anspruch 1, wobei der äußere Polymermantel (2, 22) die Strukturschicht (1, 21) bedeckt.

18. Einführhülse nach Anspruch 1, wobei die äußere Schicht (2, 22) und die innere Schicht (7, 27) nicht miteinander verschmolzen sind.

19. Einführhülse nach Anspruch 1, wobei das Material, das die Einführvorrichtung (100, 200) bildet, entlang eines Querschnitts der Einführvorrichtung senkrecht zur Mittelachse der Einführvorrichtung aufgenommen, von 40 bis 60 Prozent Metall oder von 20 bis 60 Prozent Metall oder mehr als 20 Prozent Metall ist.

20. Einführhülse nach Anspruch 1, wobei die distale Spitze (3) zwei oder mehr Schichten aus einem äußeren Polymer umfasst.

**Revendications**

1. Gaine d'introducteur de cathéter artériel radial (100, 200) pour introduire des cathéters interventionnels à l'intérieur du système vasculaire comprenant :

   une tige tubulaire principale comprenant une pointe distale (3), une extrémité proximale (6), une couche structurale (1, 21), une couche intérieure (7, 27), et une couche extérieure (2, 22) ;
   dans laquelle la couche structurale (1, 21) comprend un ou plusieurs fils multifilaires métalliques enroulés de manière hélicoïdale avec une épaisseur de paroi de 0,038 mm à 0,25 mm (0,0015 pouce à 0,010 pouce), et la couche structurale est traitée thermiquement pour retenir une extrémité distale courbée, l'extrémité distale étant courbée pour se conformer à une partie de l'anatomie d'un patient ;
   dans laquelle la couche extérieure (2, 22) comprend une chemise polymère extérieure qui recouvre au moins en partie la couche structurale et la chemise polymère extérieure est couplée à la couche structurale, la chemise polymère extérieure présentant une épaisseur de 0,025 mm à 0,25 mm (0,001 pouce à 0,010 pouce) ;
   dans laquelle la couche intérieure (7, 27) comprend une chemise polymère intérieure qui recouvre au moins en partie la couche structurale et la chemise polymère intérieure est couplée à la couche structurale ;
   dans laquelle la chemise polymère intérieure présente une épaisseur de 0,025 mm à 0,25 mm (0,001 pouce à 0,010 pouce) ; et
   dans laquelle la pointe distale (3) comprend un polymère extérieur et la pointe distale présente une longueur de 1,27 mm à 7,62 mm (0,05 pouce et 0,30 pouce).

2. Gaine d'introducteur selon la revendication 1, dans laquelle la couche multifilaire (1, 21) métallique enroulée de manière hélicoïdale comprend de l'acier inoxydable.

3. Gaine d'introducteur selon la revendication 1, dans laquelle la structure multifilaire comprend 12 à 18 fils.

4. Gaine d'introducteur selon la revendication 1, dans laquelle la structure multifilaire est estampée de manière à conférer une section transversale rectangulaire et un contact de montage intime entre des fils adjacents.

5. Gaine d'introducteur selon la revendication 1, dans laquelle la tige tubulaire principale présente un diamètre extérieur de 1,52 mm à 2,92 mm (0,060 pouce à 0,115 pouce).

6. Gaine d'introducteur selon la revendication 1, dans laquelle la chemise polymère extérieure (2, 22) comprend PTFE ou du nylon, ou Pebax ou deux couches de Pebax.

7. Gaine d'introducteur selon la revendication 1, dans laquelle la chemise polymère extérieure (2, 22) est revêtue d'un polymère hydrophile.

8. Gaine d'introducteur selon la revendication 1, dans laquelle la pointe distale (3) comprend une couche de pointe intérieure et une couche de pointe extérieure, dans laquelle la couche de pointe intérieure comprend PTFE et la couche de pointe extérieure comprend Pebax.

9. Gaine d'introducteur selon la revendication 1, dans laquelle les fils multifilaires enroulés de manière hélicoïdale comprennent des terminaisons soudées.

10. Gaine d'introducteur selon la revendication 1, dans laquelle la pointe distale (3) comprend un revêtement doré, dans lequel le revêtement doré est compris entre 0,5 mm et 2 mm.

11. Gaine d'introducteur selon la revendication 1, dans laquelle la couche de chemise extérieure (2, 22) est thermo-rétractable et configurée pour être formée étroitement sur la structure multifilaire enroulée de manière hélicoïdale.

12. Gaine d'introducteur selon la revendication 1, dans laquelle la structure multifilaire enroulée de manière hélicoïdale présente une section transversale rectangulaire ou une section transversale circulaire ou une section transversale ovale ou elliptique.

13. Gaine d'introducteur selon la revendication 1, dans laquelle l'extrémité proximale (6) de la tige tubulaire principale est couplée à un interrupteur de flux (4).

14. Gaine d'introducteur selon la revendication 1, dans laquelle les fils à structure multifilaire enroulés de manière hélicoïdale comprennent un revêtement PTFE avant d'être formés en une configuration multifilaire.

15. Gaine d'introducteur selon la revendication 1, dans laquelle la tige tubulaire principale présente une longueur de 15 cm à 205 cm.

16. Gaine d'introducteur selon la revendication 12, dans laquelle la structure multifilaire présente un contact de montage intime entre des fils adjacents.

17. Gaine d'introducteur selon la revendication 1, dans laquelle la chemise polymère extérieure (2, 22) recouvre la couche structurale (1, 21).

18. Gaine d'introducteur selon la revendication 1, dans laquelle la couche extérieure (2, 22) et la couche intérieure (7, 27) ne sont pas fondues ensemble.

19. Gaine d'introducteur selon la revendication 1, dans laquelle le matériau formant l'introducteur (100, 200), considéré le long d'une section transversale de l'introducteur perpendiculaire à l'axe central de l'introducteur, est de 40 à 60 pour cent du métal ou de 20 à 60 pour cent du métal ou à plus de 20 pour cent du métal.

20. Gaine d'introducteur selon la revendication 1, dans laquelle la pointe distale (3) comprend deux couches ou plus de polymère extérieur.

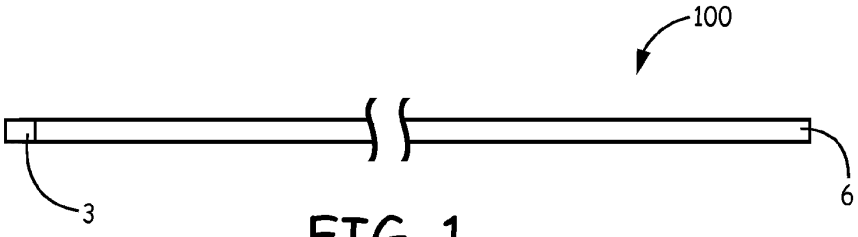



FIG. 1

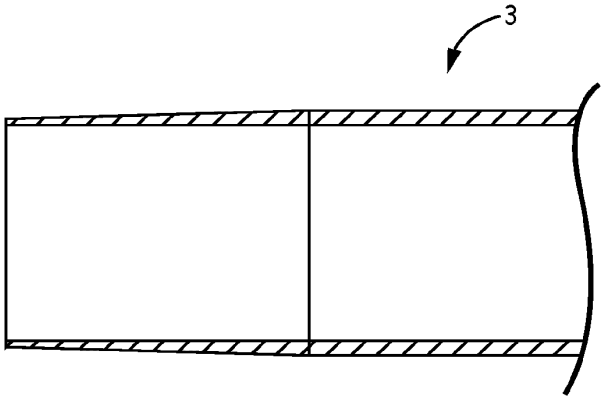



FIG. 2

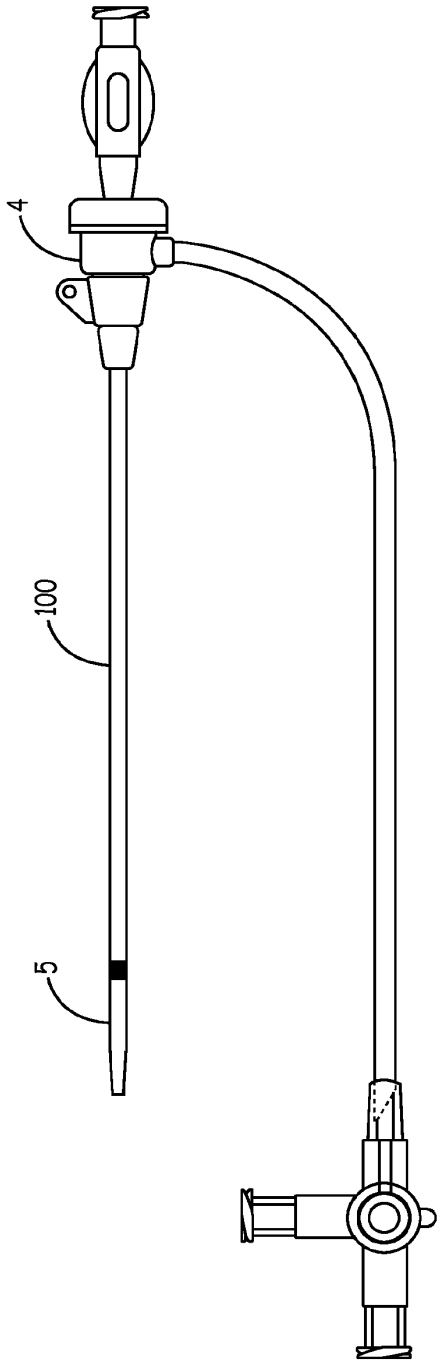



FIG. 3

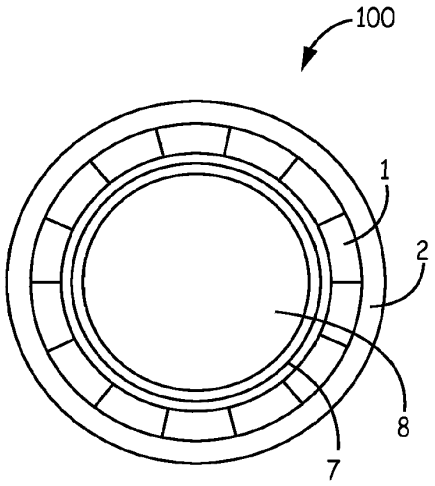



FIG. 4

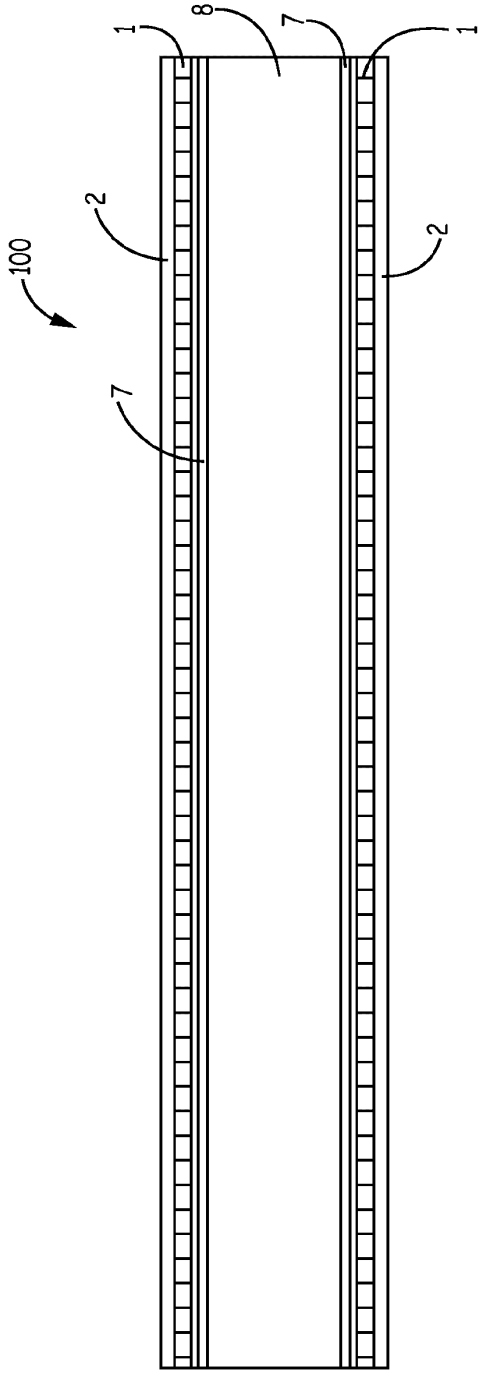



FIG. 5

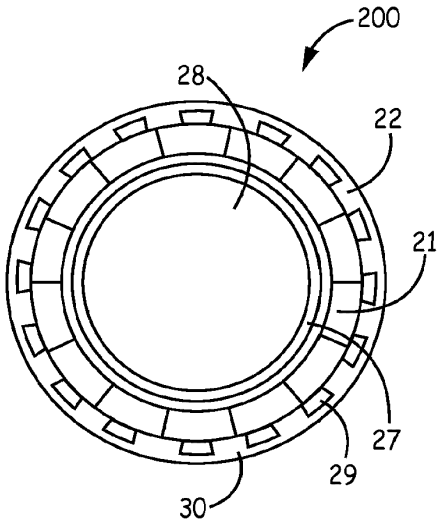



FIG. 6

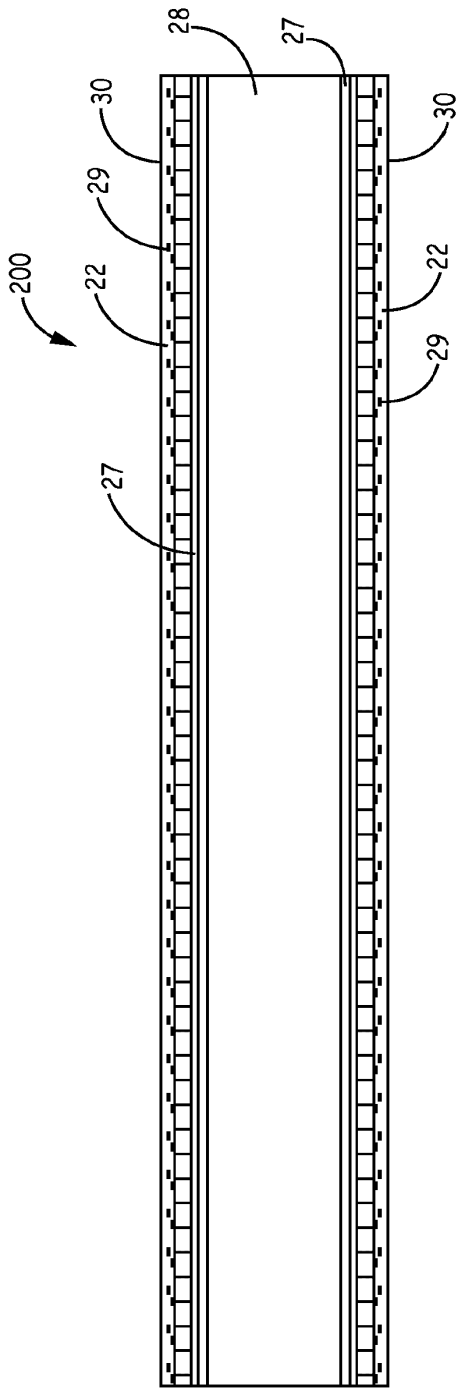



FIG. 7

## REFERENCES CITED IN THE DESCRIPTION

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### Patent documents cited in the description


- EP 1068876 A2 **[0005]**
- US 6689120 B1 **[0006]**

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## (54) FLEXIBLE TIP CATHETER

(57) A catheter may include an inner liner (28, 68, 108), at least one support structure (36, 38, 76, 78, 116, 118) over the inner liner, and an outer jacket (32, 72, 112) over the at least one support structure. In some examples, the catheter includes a tip jacket (46, 136) positioned over a distal portion of the outer jacket and extend beyond a distal-most part of the inner liner and a distal-most part of the outer jacket to define a single-layer catheter tip. In some examples, the at least one support structure may include a braid (38, 78, 118) and a coil (36, 76, 116). The catheter may include a marker band (40, 80, 120) over a distal portion of one of the braid or the coil. The other of the braid or the coil ends proximally of a proximal end of the marker band, such that the catheter includes a location with lower radial and/or flexural stiffness proximal of the marker band.

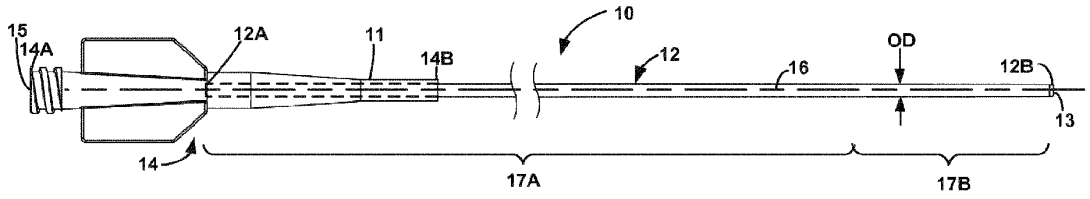



FIG. 1

EP 3 583 972 A2

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## Description

### TECHNICAL FIELD

**[0001]** This disclosure relates to a medical catheter.

### BACKGROUND

**[0002]** A medical catheter defining at least one lumen has been proposed for use with various medical procedures. For example, in some cases, a medical catheter may be used to access and treat defects in blood vessels, such as, but not limited to, lesions or occlusions in blood vessels.

### SUMMARY

**[0003]** In some aspects, the disclosure describes a medical catheter ("catheter") that includes at least one feature that reduces a chance of traumatic contact between a tip of the catheter and tissue, such as a wall of vasculature of a patient. In some examples, the catheter may include an inner liner, at least one support structure over the inner liner, an outer jacket over the at least one support structure, and a tip jacket. The tip jacket may be positioned over a distal portion of the outer jacket and extend beyond a distal-most part of the inner liner and a distal-most part of the outer jacket. The tip jacket thus may define a single-layer catheter tip. A radially outer surface of the tip jacket may taper radially inward as the tip jacket extends distally, which may reduce the cross-sectional area of the catheter at the distal tip of the catheter and aid navigation of the catheter through vasculature of a patient. Forming the distal tip of the catheter from a single layer of material (e.g., by at least excluding the inner liner and the outer jacket from the distal tip) may enable the distal tip to be more acutely tapered, which may also aid navigation of the catheter through vasculature of a patient. The material from which the tip jacket is formed may be the same or a lower durometer than the material from which the inner liner is formed and the material from which the outer jacket is formed. In this way, the tip jacket may be more atraumatic than a catheter in which the inner liner, the outer jacket, or both extend to a distal end of the catheter.

**[0004]** In some aspects, the disclosure describes a catheter that includes a physical configuration that results in a preferential bending location proximal of a marker band. The catheter may include an inner liner, a braid over the inner liner, a coil over the inner liner, and an outer jacket over the at least one support structure. The catheter also may include a marker band over a distal portion of one of the braid or the coil. The other of the braid or the coil ends proximally of a proximal end of the marker band. By ending one of the braid or the coil proximally of the proximal end of the marker band, the catheter includes a location with lower radial and/or flexural stiffness proximal of the marker band. Thus, the catheter may preferentially bend at this location in response to a distal tip of the catheter contacting an anatomical structure, such as a wall of vasculature of a patient. This may also contribute to navigability of the catheter through vasculature and make the catheter more atraumatic than a catheter that does not include the preferential bending location proximal of the marker band. In some examples, a catheter may include both a distal tip formed from a single, relatively soft tip jacket and a preferential bending location proximal of the marker band. In other examples, a catheter may include only one of the distal tip formed from a single, relatively soft tip jacket or the preferential bending location proximal of the marker band.

Clause 1: A catheter including an elongated body including proximal and distal portions, the distal portion of the elongated body comprising: an inner liner; at least one support structure positioned over the inner liner; an outer jacket positioned over the at least one support structure, wherein the outer jacket tapers radially inward distal of a distal-most part of the at least one support structure to bond to the inner liner; and a tip jacket positioned over a distal part of the outer jacket and extending beyond a distal-most part of the inner liner and the outer jacket to define a single-layer catheter tip, wherein the tip jacket comprises a material that is the same or a lower durometer than the inner liner and the same or a lower durometer than the outer jacket.

Clause 2: The catheter of clause 1, wherein the tip jacket comprises a polyurethane, a polyolefin elastomer, a poly(ether-*block*-amide), or combinations thereof.

Clause 3: The catheter of clause 1 or 2, wherein the tip jacket material has a durometer of 35D or less.

Clause 4: The catheter of any one of clauses 1 to 3, wherein the tip jacket is the only layer for the distal-most 0.3 to 0.8 millimeters of the catheter.

Clause 5: The catheter of any one of clauses 1 to 4, wherein the inner liner and the outer jacket extend distally past the distal-most part of the at least one support structure by about 0.2 millimeters to about 0.6 millimeters.

Clause 6: The catheter of any one of clauses 1 to 5, further comprising a marker band, wherein the marker band is positioned over the at least one support structure near the distal-most part of the at least one support structure.

Clause 7: The catheter of any one of clauses 1 to 6, wherein the at least one support structure comprises at least one of a braid or a coil.

Clause 8: The catheter of any one of clauses 1 to 7, wherein the at least one support structure comprises a braid and a coil.

Clause 9: The catheter of clause 8, wherein the braid is positioned over the coil.

Clause 10: The catheter of clause 8, wherein the coil is positioned over the braid.

Clause 11: The catheter of clause 8, further comprising a marker band, wherein the marker band is positioned over one of the braid or the coil near the distal-most part of the one of the braid or the coil, and wherein the other of the braid or the coil ends proximally of a proximal end of the marker band.

Clause 12: The catheter of clause 11, wherein the other of the braid or the coil ends at least about 0.5 millimeters proximally of the proximal end of the marker band.

Clause 13: An assembly comprising: the catheter of any one of clauses 1 to 12; and an aspiration pump connected to the catheter.

Clause 14: A method of forming an elongated body of a catheter, the method comprising: positioning at least one support structure over an inner liner; positioning an outer jacket over the at least one support structure, wherein a distal part of the outer jacket extends past a distal-most part of the at least one support structure to taper radially inward distal of the distal-most part of the at least one support structure and contact a distal part of the inner liner; and bonding at least the distal part of the outer jacket to the distal part of the inner liner; positioning a tip jacket over the distal part of the outer jacket, wherein the tip jacket extends beyond a distal-most part of the inner liner and the outer jacket to define a single-layer catheter tip, wherein the tip jacket comprises a material that is the same or a lower durometer than the inner liner and the same or a lower durometer than the outer jacket; and bonding the tip jacket to the outer jacket.

Clause 15: The method of clause 14, wherein the tip jacket comprises a polyurethane, a polyolefin elastomer, a poly(ether-*block*-amide), or combinations thereof.

Clause 16: The method of clause 14 or 15, wherein the tip jacket material has a durometer of 35D or less.

Clause 17: The method of any one of clauses 14 to 16, wherein the tip jacket is the only layer for the distal-most 0.3 to 0.8 millimeters of the catheter.

Clause 18: The method of any one of clauses 14 to 17, wherein the inner liner and the outer jacket extend past the distal-most part of the at least one support structure by about 0.2 millimeters to about 0.6 millimeters.

Clause 19: The method of any one of clauses 14 to 18, further comprising positioning a distal marker band over the at least one support structure near the distal-most part of the at least one support structure prior to positioning the outer jacket over the at least one support structure.

Clause 20: The method of any one of clauses 14 to 19, wherein the at least one support structure comprises at least one of a braid or a coil.

Clause 21: The method of any one of clauses 14 to 20, wherein the at least one support structure comprises a braid and a coil.

Clause 22: The method of clause 21, wherein positioning the at least one support structure over the inner liner comprises positioning the braid over the coil.

Clause 23: The method of clause 21, wherein positioning the at least one support structure over the inner liner comprises positioning the coil over the braid.

Clause 24: The method of clause 21, further comprising positioning a distal marker band over one of the braid or the coil, and wherein the other of the braid or the coil ends proximally of a proximal end of the marker band.

Clause 25: The method of clause 24, wherein the other of the braid or the coil ends at least about 0.5 mm proximally of the proximal end of the marker band.

Clause 26: A catheter comprising: an elongated body including proximal and distal portions, the distal portion of the elongated body comprising: an inner liner; a first support structure positioned over the inner liner; a second support structure positioned over the first support structure; a distal marker band positioned over a distal part of one of the first support structure or the second support structure, wherein the other of the first support structure or the second support structure ends proximally of a proximal end of the distal marker band; and an outer jacket positioned over the first support structure, the second support structure, and the marker band, wherein the outer jacket tapers radially inward distal of a distal-most part of the marker band to bond to the inner liner.

Clause 27: The catheter of clause 26, wherein the first support structure comprises a coil and the second support structure comprises a braid.

Clause 28: The catheter of clause 27, wherein a distal end of the braid is proximal to the proximal end of the distal marker band.

Clause 29: The catheter of clause 27, wherein a distal end of the coil is proximal to the proximal end of the distal marker band.

Clause 30: The catheter of clause 26, wherein the first support structure comprises a braid and the second support structure comprises a coil.

Clause 31: The catheter of clause 30, wherein a distal end of the braid is proximal to the proximal end of the distal marker band.

Clause 32: The catheter of clause 30, wherein a distal end of the coil is proximal to the proximal end of the distal marker band.

Clause 33: The catheter of any one of clauses 26 to 32, wherein the other of the first support structure or the second support structure ends at least about 0.5 millimeters proximally of the proximal end of the marker band.

Clause 34: The catheter of any one of clauses 26 to 33, wherein the other of the first support structure or the second support structure ends between about 0.5 millimeters and about 5 millimeters proximally of the proximal end of the marker band.

Clause 35: An assembly comprising: the catheter of any one of clauses 26 to 34; and an aspiration pump connected to the catheter.

Clause 36: A method of forming an elongated body of a catheter, the method comprising: positioning a first support structure over the inner liner; positioning a second support structure over the first support structure; positioning a distal marker band over a distal part of one of the first support structure or the second support structure, wherein the other of the first support structure or the second support structure ends proximally of a proximal end of the distal marker band; positioning an outer jacket over the first support structure, the second support structure, and the distal marker band, wherein a distal part of the outer jacket extends past a distal-most part of the marker band to taper radially inward distal of the distal-most part of the marker band and contact a distal part of the inner liner; and bonding at least the distal part of the outer jacket to the distal part of the inner liner.

Clause 37: The method of clause 36, further comprising: positioning a tip jacket over the distal part of the outer jacket, wherein the tip jacket extends beyond a distal most part of the inner liner and the outer jacket to define a single-layer catheter tip, wherein the tip jacket comprises a material that is the same or a lower durometer than the inner liner and the same or a lower durometer than the outer jacket; and bonding the tip jacket to the outer jacket.

Clause 38: The method of clause 36, wherein the first support structure comprises a coil and the second support structure comprises a braid.

Clause 39: The method of clause 38, wherein a distal end of the braid is proximal to the proximal end of the distal marker band.

Clause 40: The method of clause 38, wherein a distal end of the coil is proximal to the proximal end of the distal marker band.

Clause 41: The method of clause 37, wherein the first support structure comprises a braid and the second support structure comprises a coil.

Clause 42: The method of clause 41, wherein a distal end of the braid is proximal to the proximal end of the distal marker band.

Clause 43: The method of clause 41, wherein a distal end of the coil is proximal to the proximal end of the distal marker band.

Clause 44: The method of any one of clauses 37 to 43, wherein the other of the first support structure or the second support structure ends at least about 0.5 millimeters proximally of the proximal end of the marker band.

Clause 45: The method of any one of clauses 37 to 43, wherein the other of the first support structure or the second support structure ends between about 0.5 mm and about 5 mm proximally of the proximal end of the marker band.

Clause 46: A method comprising: inserting the catheter of any one of clauses 1 to 12 into vasculature of a patient; and aspirating a thrombus from the vasculature using the catheter.

Clause 47: A method comprising: inserting the catheter of any one of clauses 26 to 34 into vasculature of a patient; and aspirating a thrombus from the vasculature using the catheter.

**[0005]** The details of one or more aspects of the disclosure are set forth in the accompanying drawings and

the description below. Other features, objects, and advantages of the techniques described in this disclosure will be apparent from the description and drawings, and from the claims.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0006]**

FIG. 1 is a conceptual side elevation view of an example catheter, which includes an elongated body and a hub.

FIG. 2 is a conceptual axial cross-sectional view of the distal portion of the elongated body of FIG. 1, where the cross-section is taken through a center of the elongated body along a longitudinal axis of the elongated body.

FIG. 3 is another conceptual axial cross-sectional view of a distal portion of another example catheter, where the cross-section is taken through a center of the elongated body along a longitudinal axis of the elongated body.

FIG. 4 is another conceptual axial cross-sectional view of a distal portion of another example catheter, where the cross-section is taken through a center of the elongated body along a longitudinal axis of the elongated body.

FIG. 5 is a flow diagram of an example technique for forming a catheter described herein.

FIG. 6 is a flow diagram of an example technique for forming a catheter described herein.

## DETAILED DESCRIPTION

**[0007]** Medical catheters ("catheters") described herein include at least one feature that reduces a chance of traumatic contact between a tip of the catheter and a tissue, such as a wall of vasculature of a patient, aids navigability of the catheter through vasculature of a patient, or both. Catheters include at least internal lumen through which a medical device or a therapeutic substance may be delivered to a target location in a patient, through which material may be aspirated from a blood vessel or other part of a patient, or the like. The diameter of the internal lumen affects an outer diameter of the catheter. Catheters with larger internal lumen diameters (and thus larger external diameters) are increasingly being used to deliver treatment to target locations accessed through smaller, more distal, or tortuous vasculature. For example, catheters with larger external diameters may be used to treat acute ischemic stroke, pulmonary embolisms, or the like. The larger external diameter may present difficulties when tracking through tortuous distal vasculature, such as the internal carotid and middle cerebral arteries in the intracranial space. For example, larger diameter catheters may get caught on branching arteries while being advanced through the primary artery. Catheters with stiff or relatively blunt tips may increase a chance for traumatic contact between the catheter tip and walls of the vasculature.

**[0008]** In accordance with some aspects of this disclosure, a catheter may include an inner liner, at least one support structure over the inner liner, an outer jacket over the at least one support structure, and a tip jacket. The tip jacket may be positioned over a distal portion of the outer jacket and extend beyond a distal-most part of the inner liner and a distal-most part of the outer jacket (e.g., extend longitudinally beyond the distal-most part of the inner liner and the distal-most part of the outer jacket). The tip jacket thus may define a single-layer catheter tip. A radially outer surface of the tip jacket may taper radially inward as the tip jacket extends distally, which may reduce the cross-sectional area of the catheter at the distal tip of the catheter and aid navigation of the catheter through vasculature of a patient. Forming the distal tip of the catheter from a single layer of material may enable the distal tip to be more acutely tapered (e.g., without decreasing a cross-sectional dimension of an inner lumen of the catheter), which may also aid navigation of the catheter through vasculature of a patient. The material from which the tip jacket is formed may be the same or a lower durometer than the material from which the inner liner is formed and the material from which the outer jacket is formed. In this way, the tip jacket may be more atraumatic than a catheter in which the inner liner, the outer jacket, or both extend to a distal end of the catheter.

**[0009]** The disclosure also describes a catheter that includes a physical configuration that results in a preferential bending location proximal of a marker band. The catheter may include an inner liner, a braid over the inner liner, a coil over the inner liner, and an outer jacket over the at least one support structure. The catheter also may include a marker band over a distal portion of one of the braid or the coil. The other of the braid or the coil ends proximally to a proximal end of the marker band. By ending one of the braid or the coil proximally to the proximal end of the marker band, the catheter includes a location with lower radial and/or flexural stiffness proximal of the marker band. Thus, the catheter may preferentially bend at this location in response to a distal tip of the catheter contacting an anatomical structure, such as a wall of vasculature of a patient. This may also contribute to navigability of the catheter through vasculature and make the catheter more atraumatic than a catheter that does not include the preferential bending location proximal of the marker band.

**[0010]** In some examples, a catheter may include both a distal tip formed from a single, relatively soft tip jacket and a preferential bending location proximal of the marker band. In other examples, a catheter may include only one of the distal tip formed from a single, relatively soft tip jacket or the preferential bending location proximal of the marker band.

**[0011]** Although primarily described as being used to reach relatively distal vasculature sites, the catheters described herein may readily be configured to be used with

other target tissue sites. For example, the catheters may be used to access tissue sites throughout the coronary and peripheral vasculature, the gastrointestinal tract, the urethra, ureters, Fallopian tubes and other body lumens.

**[0012]** FIG. 1 is a conceptual side view of an example catheter 10, which includes elongated body 12 and a hub 14 positioned at a proximal end 12A of elongated body 12. In some examples, catheter hub 14 may define an opening through which an inner lumen 24 (shown in FIG. 2) of elongated body 12 may be accessed and, in some examples, closed. For example, catheter hub 14 may include a luer connector for connecting to another device, a hemostasis valve, or another mechanism or combination of mechanisms for establishing connections between catheter 10 and other devices. In other examples, the proximal end of catheter 10 can include another structure in addition to or instead of hub 14.

**[0013]** Elongated body 12 extends from proximal end 12A to distal end 12B and defines a proximal portion 17A and a distal portion 17B. Elongated body 12 may define at least one inner lumen that extends the length of elongated body 12. In the example shown in FIG. 1, proximal end 12A of elongated body 12 is received within or attached to hub 14 and can be mechanically connected to hub 14 via an adhesive, welding, friction fit, or another suitable technique or combination of techniques. Hub 14 defines an opening 15 located at proximal end 14A of hub 14. Opening 15 is substantially aligned with inner lumen 24 of elongated body 12, such that inner lumen 24 may be accessed via opening 15. In some examples, catheter 10 may include a strain relief body 11, which may be a part of hub 14 or may be separate from hub 14.

**[0014]** In some cases, a clinician may steer catheter 10 through the vasculature of a patient by pushing or rotating hub 14 to navigate distal portion 17B of elongated body 12 through the vasculature of a patient. The clinician may apply torque to hub 14 and/or proximal portion 17A of the catheter 10 (or at least a portion of elongated body 12 that is more proximal than distal portion 17B inserted in the patient) to rotate distal portion 17B of catheter 10.

**[0015]** As described further below, elongated body 12 includes an inner liner, at least one support structure, and an outer jacket, which may configure elongated body 12 to transmit the torque applied to a relatively proximal portion to a relatively distal portion of elongated body 12. In some examples, as shown in FIG. 2, at least distal portion 17B of elongated body 12 includes an inner liner, at least one support structure, and an outer jacket. Distal portion 17B of elongated body 12 also may include a tip jacket. The tip jacket may be positioned over a distal portion of the outer jacket and extend beyond a distal-most part of the inner liner and a distal-most part of the outer jacket (e.g., extend longitudinally beyond the distal-most part of the inner liner and the distal-most part of the outer jacket). The tip jacket thus may define a single-layer tip of catheter 10. A radially outer surface of the tip jacket may taper radially inward as the tip jacket extends distally, and the tip jacket may be formed from a material that is the same or a lower durometer than the material from which the inner liner is formed and the material from which the outer jacket is formed. In this way, the tip jacket may be more atraumatic than a catheter in which the inner liner, the outer jacket, or both extend to a distal end of catheter 10.

**[0016]** In some examples, in addition to or as an alternative to the single-layer tip jacket, catheter 10 includes a physical configuration that results in a preferential bending location proximal of a marker band of catheter 10. For example, as shown in FIGS. 3 and 4, catheter 10 may include an inner liner, a coil over the inner liner, a braid over the inner liner, and an outer jacket over the coil and the braid. Catheter 10 also may include a marker band. In some examples, the marker band is over a distal portion of one of the braid or the coil. The other of the braid or the coil ends proximally of a proximal end of the marker band. In other examples, both the braid and the coil end proximally of the proximal end of the marker band. By ending one of the braid or the coil proximally of the proximal end of the marker band, catheter 10 includes a location with lower radial and/or flexural stiffness proximal of the marker band. Catheter 10 may preferentially bend at this location in response to a distal tip of catheter 10 contacting an anatomical structure, such as a wall of vasculature of a patient, or otherwise encountering a force oriented oblique or transverse to the longitudinal axis of catheter 10. In other examples, the marker band is over both a distal portion of the braid and a distal portion of the coil.

**[0017]** In some examples, catheter 10 may be a guide catheter that acts as a conduit to help support a microcatheter. In other examples, catheter 10 may be a microcatheter. In either example, elongated body 12 of catheter 10 may define at least one inner lumen extending between proximal end 12A and distal end 12B of elongated body (e.g., one inner lumen, two inner lumens, three inner lumens, or more than three inner lumens). The at least one inner lumen may open to an exterior of elongated body 12 at distal opening 13. The at least one inner lumen may be configured to receive one or more medical devices, serve as a conduit for the delivery of a medical device to a distal tissue site, serve as a conduit for the delivery of a therapeutic agent to a distal tissue site, remove thrombus (e.g., by aspiration) from the patient's vasculature, or the like. Example therapeutic agents include, but are not limited to, an oxygenated medium or a pharmaceutical agent, which may be, for example, a vasodilator such as nifedipine or sodium nitroprusside, or a tissue plasminogen activator (t-PA), which can be used to break down blood clots.

**[0018]** In examples in which an inner lumen defined by elongated body 12 is used to remove thrombus from vasculature, catheter 10 may be referred to as an aspiration catheter. A vacuum may be applied to proximal end 12A of elongated body 12 (e.g., at opening 15) to draw a thrombus into the inner lumen via distal opening 13. An aspiration catheter may be used in a medical procedure

to treat an ischemic insult, which may occur due to occlusion of a blood vessel that deprives brain tissue of oxygen-carrying blood. In some examples, in addition to being configured to be navigated to relatively distal tissue sites, an aspiration catheter may also include a distal tip that is configured to substantially maintain its shape, even in the presence of the vacuum force applied to the catheter during the aspiration process.

**[0019]** In some examples, elongated body 12 may be used to access relatively distal vasculature locations in a patient, such as the internal carotid artery or middle cerebral artery (MCA) in a brain of a patient. The MCA, as well as other vasculature in the brain or other relatively distal tissue sites (e.g., relative to the vasculature access point), may be relatively difficult to reach with a catheter, due at least in part to the tortuous pathway (e.g., comprising relatively sharp twists and/orturns) through the vasculature to reach these tissue sites.

**[0020]** Distal portion 17B of catheter 10 may be configured to be relatively flexible to allow for navigability of elongated body 12 through a tortuous vasculature of a patient. Further, catheter 10 may include a distal tip at distal end 12B that is relatively atraumatic, e.g., due to inclusion of a relatively soft, single layer tip jacket, a preferential bending location proximal of a marker band of catheter 10, or both. FIG. 2 shows a conceptual axial cross-sectional view of distal portion 20B of an example catheter 20, where the cross-section is taken through a center of elongated body 22 along a longitudinal axis 26. As shown in FIG. 2, elongated body 22 includes an inner liner 28, at least one support structure, and an outer jacket 32.

**[0021]** Inner liner 28 may extend from a proximal end of catheter 20 (e.g., proximal end 12A of catheter 10 of FIG. 1) to near but proximal to a distal end 30 of catheter 20. In some examples, inner liner 28 is a unitary structure that includes a single material and single geometry along the length of inner liner 28. In other examples, inner liner 28 may include multiple sections, such as a proximal section, an optional intermediate section, and a distal section formed from different materials such that the distal liner section has a lower hardness and higher flexibility compared to the proximal liner section. Reducing the hardness and increasing the flexibility of the distal liner section compared to the proximal liner section may improve the navigability of catheter 20 without compromising or reducing the structural integrity (e.g., pushability) of elongated body 22.

**[0022]** Inner liner 28 defines inner lumen 24 of elongated body 22, inner lumen 24 extending from the proximal end of elongated body 22 (e.g., proximal end 12A of FIG. 1) to distal end 30 and defining a passageway extending from the proximal end to distal opening 34 at distal end 30 of elongated body 22. Inner lumen 24 may be sized to receive a medical device (e.g., another catheter, a guidewire, an embolic protection device, a stent, a thrombectomy device, or any combination thereof), a therapeutic agent, or the like. In some examples, inner lumen 24 has a constant cross-sectional dimension (e.g., a diameter) along a length of catheter 20. In other examples, inner lumen 24 has a varying cross-sectional diameter, e.g., lumen 24 may taper from a larger diameter in a proximal portion of catheter 20 to a smaller diameter in a more distal portion of catheter 20.

**[0023]** Inner liner 28 may be composed of one or more different materials including, for example, one or more thermoplastic elastomers such as polyolefin elastomers, thermoplastic polyolefins, fluoropolymers such as polytetrafluoroethylene (PTFE), perfluorocalkyoxy alkane (PFA), fluorinated ethylene propylene (FEP), or the like. In examples in which inner liner 28 include multiple sections, the different sections may include similar polymeric constructions whose relative amounts and/or additives have been altered to result in sections of different relative hardnesses. In some examples in which inner liner 28 includes multiple sections, the respective sections can be formed as independent tubular sections that are subsequently joined together using any suitable technique, such as an adhesive, fusing/welding, or any combination thereof.

**[0024]** In some examples, inner liner 28 may include materials that exhibit high lubricity and a Shore D hardness (ASTM D2240) of between about 25 and about 65, such as about 55. In some examples, inner liner 28 may include a non-etched PTFE, e.g., may consist essentially of a non-etched PTFE. PTFE may exhibit a relatively high lubricity, such that the inner surface of inner liner 28 may exhibit a relatively low coefficient of friction to facilitate the introduction and passage of a medical device (e.g., another catheter, a guidewire, an embolic protection device, a stent, a thrombectomy device, or any combination thereof) through inner lumen 24. In some examples, inner liner 28 may include PTFE such as Teflon® PTFE 640 available from The Chemours Company, Inc. having a Shore D hardness of about 58D. In some examples, inner liner 28 may include one or more polyolefins including, for example, a polyolefin elastomer such as Engage™ polyolefin elastomers available from the Dow Chemical Company of Midland, Michigan.

**[0025]** In some examples in which inner liner 28 includes a polyolefin or a relatively softer polymer, inner liner 28 may include one or more slip agents. The one or more slip agents may help increase the lubricity of inner liner 28 which can help improve the navigability of catheter 10 by facilitating the smooth passage of inner liner 28 over a guide catheter or guidewire. Suitable slip agents may include, for example, an amide derived from a monosaturated fatty acid such as Ampacet 100329 slip concentrate available from Ampacet Corporation of Tarrytown, New York. Ampacet 100329 is characterized as 5 weight percent (wt.%) erucamide in metallocene linear low-density polyethylene. The slip agent may be added to the polymeric materials that form inner liner 28 in an amount of about 0.1 wt.% to about 1 wt.%. The slip agent may be mixed and extruded along with the thermoplastic elastomer (e.g., a polyolefin elastomer ethylene butane)

used to form inner liner 28.

**[0026]** Elongated body 22 may include one or more support structures positioned over inner liner 28. In some examples, the one or more support structures may include a first support structure 36 and a second support structure 38. First support structure 36 may include a coil and second support structure 38 may include a braid, or vice versa, or first support structure 36 and second support structure 38 may each include coils, the coils being counter-wound relative to each other. First and second support structures 36 and 38 may be structurally configured to be relatively flexible, pushable, navigable, and relatively kink- and buckle- resistant, so that elongated body 22 may resist buckling when a pushing force is applied to a relatively proximal portion of catheter 20 to advance elongated body 22 distally through vasculature, and so that it may resist kinking when traversing around a tight turn in the vasculature. Unwanted kinking and/or buckling of elongated body 22 may otherwise hinder a clinician's efforts to push the elongated body 22 distally, e.g., past a turn.

**[0027]** In some examples, the structural characteristics of first and second support structures 36 and 38 may be tailored to increase the structural integrity of elongated body 22 while allowing elongated body 22 to remain relatively flexible. For example, first and second support structures 36 and 38, together with inner liner 28 and outer jacket 32, may help distribute pushing and rotational forces along a length of elongated body 22, while also providing structural support to help prevent kinking or buckling of elongated body 22 upon bending or rotation of elongated body 22. As a result, a clinician may apply pushing forces, rotational forces, or both, to a proximal portion of elongated body 22, and such forces may cause a distal portion of elongated body 22 to advance distally, rotate, or both, respectively. In some examples, rather than including both first and second support structures 36 and 38, catheter 20 may include only one of first and second support structures 36 and 38, e.g., may include only a braid or only a coil.

**[0028]** In some examples, second support structure 38 may include a braided structure having wires or filaments of different diameters, different cross-sectional shapes, different materials, or any combination thereof. In some cases, a braided combination of round wires and flat wires may provide elongated body 22 with better ovalization resistance and tensile strength compared to other catheter designs (e.g., a support structure consisting of only one metal coil or a braid consisting of only round wires). For example, including second support structure 38 made of an eight-wire braid (e.g., four round wires woven against four flat wires such that the round wires do not cross another round wire) may provide for greater kink and ovalization resistance compared to a single coil construction of comparable thickness without adding to the thickness or the tubular wall. Additionally, the combination of round wires and flat wires may contribute to a relatively thin jacket thickness and/or sidewall thickness for catheter 20 while still providing a high tensile strength with kink resistance and pushability.

**[0029]** Though second support structure 38 is primarily described as a braided structure of different diameter wires, in some examples, second support structure 38 may include a wire braid of similarly sized wires (e.g. wires with similar cross-sectional sizes), round or flat filaments made of synthetic or polymeric materials (e.g., non-metal wires), or combinations thereof.

**[0030]** In some examples, in addition to or instead of second support structure 38 including a braided structure, first support structure 36 may include a coil structure. The coil structure (e.g., wire coils) may exhibit columnar strength (e.g., kink resistance) and/or hoop strength (e.g., resistance to ovalization). The coil structure forming first support structure 36 may define a plurality of turns in the shape of a helical coil, the coil defining a central axis substantially aligned or coincident with longitudinal axis 26. In some examples in which first support structure 36 includes more than one coil structure, the coils may be interspaced with each other in a longitudinal direction (in a direction along longitudinal axis 26) such that the helical coils are wound in the same direction (e.g., a right-handed wind or a left-handed wind) with one turn (e.g., one full circumvolution about inner liner 28) of a respective coil is positioned between an adjacent turn of the other coil so that the turns of both coils are longitudinally offset from one another along the length of elongated body 22 and the coils do not overlap along the length of elongated body 22. In some examples, the interspaced arrangement of the more than one coil structures may allow for improved rotational responsiveness and structural integrity.

**[0031]** First and second support structures 36 and 38 may be formed from any suitable structural material, including, for example, a metal, an alloy, or a polymer. Suitable materials include, for example, one or more metals such as nickel titanium alloy (e.g., Nitinol, tertiary Nitinols), stainless steel, tungsten, titanium, gold, platinum, palladium, tantalum, silver, or a nickel-chromium alloy, a cobalt-chromium alloy, or the like. In some examples, one or both of first and second support structures 36 and 38 may be selected to include a radiopaque material(s) to allow elongated body 22 to be easily observed by the clinician as catheter 20 is advanced through the vasculature of a patient. In some examples one or both of first and second support structures 36 and 38 may be cladded with one or more materials, for example, to improve the radiopacity of the element without altering the underlying structural characteristics of the base wire (e.g., Nitinol wire cladded in gold).

**[0032]** In some examples, one or both of first and second support structures 36 and 38 may include non-metal materials such as one or more synthetic fibers including, for example, at least one of a para-aramid material, liquid crystal polymer (LCP), poly(p-phenylene-2,6-benzobisoxazole), polyether amides, polycarbonates, PTFE, PEEK, ultra-high molecular weight polyethylene, poly-

ethylene naphthalate, polyester, carbon fiber, a glass-fiber reinforced polymer, a carbon-fiber reinforced polymer, or the like. In some examples, one or both of first and second support structures 36 and 38 may include one or more polymers including, for example, polycarbonate, polyimide, polyetherimide, polyphenylene sulfide, polyether-ether-ketone, one or more fluoropolymers such as polytetrafluoroethylene, poly(ethene-cotetrafluoroethene), fluorinated ethylene propylene, polyvinylidene fluoride, or the like, one or more thermoplastic polymers such as polyether block amide, a polyamide, a polyamide-based polymer (e.g., nylon), a polyurethane, a polyolefin, PEBAX, polypropylene, a thermoplastic elastomer, one or more thermoset polymers, or the like. In some examples, one or both of first and second support structures 36 and 38 may include substantially hard and/or rigid based polymer materials including, for example, Kevlar, LCP, nylon, ultra-high molecular weight polyethylene, FPEN, polyester, glass-fiber reinforced or carbon-fiber reinforced polymers, or the like that may be used to provide columnar and or hoop strength to elongated body 22. In some examples, forming one or both of first and second support structures 36 and 38 using a thermoplastic polymer may help improve the flexibility of the elongated body 22.

**[0033]** Elongated body 12 also includes outer jacket 32 positioned over first and second support structures 36 and 38 and inner liner 28, the one or both of first and second support structures 36 and 38 being between inner liner 28 and outer jacket 32 in at least some portions of elongated body 22. In some examples, outer jacket 32 may include polymeric materials, such as, for example, a polyamide, a polyether block amide such as Pebax® commercially available from Arkema Group of Colombes, France, a polyurethane elastomer such as PolyBlend 1100™ available from AdvanSource Biomaterials of St. Wilmington, Massachusetts, a polyolefin elastomer (e.g., Engage™ polyolefin elastomer available from Dow Chemical Company of Midland, Michigan), a thermoplastic polyurethanes such as Pellethane® TPU available from The Lubrizol Corporation of Wickliffe, Ohio, or the like.

**[0034]** In the example of FIG. 2, distal end 50 of outer jacket 32 is substantially aligned (e.g., aligned so as to be coterminous or nearly aligned to the extent permitted by manufacturing variances) with distal end 48 of inner liner 28. This may be a result of the technique used to form catheter 20, which may include attaching outer jacket 32 to inner liner 28, then cutting outer jacket 32 and inner liner 28 in a single operation. In other examples, outer jacket 32 may extend slightly distal of distal end 48 of inner liner 28. The portion of outer jacket 32 that extends distal of distal end 48 of inner liner 28 may define the inner diameter for that portion of catheter 20.

**[0035]** In some examples, at least a portion of an outer surface of outer jacket 32 includes one or more coatings, such as, but not limited to, an anti-thrombogenic coating, which may help reduce the formation of thrombi in vivo, an anti-microbial coating, and/or a lubricating coating. The lubricating coating may be configured to reduce static friction and/ kinetic friction between elongated body 22 and tissue of the patient as elongated body 22 is advanced through the vasculature of the patient. The lubricating coating can be, for example, a hydrophilic coating. In some examples, the entire working length of elongated body 22 (from distal portion 14B of hub 14 (FIG. 1) to distal end 30) may be coated with the hydrophilic coating. In other examples, only a portion of the working length of elongated body 22 may be coated with the hydrophilic coating. This may provide a length of elongated body 22 distal to distal end 14B of hub 14 with which the clinician may grip elongated body 22, e.g., to rotate elongated body 22 or push elongated body 22 through the vasculature of the patient.

**[0036]** In some examples, elongate body 22 may include one or more marker bands, such as distal marker band 40, that may be in the form of a full or partial ring of material that is more radiopaque than all or some of the material forming the remainder of elongated body 22. In some examples, distal marker band 40 may include radiopaque materials that allow elongated body 22 (e.g., distal end 30) to be easily observed by the clinician as catheter 20 is advanced through the vasculature of a patient. Suitable radiopaque materials may include, for example, gold, platinum/iridium alloy, palladium, or the like. In some examples, distal marker band 40 may be positioned over a distal portion of first support structure 36, second support structure 38, or both.

**[0037]** Distal marker band 40 may be attached to inner liner 28, outer jacket 32, or both. For example, as shown in FIG. 2, a distal part 42 of outer jacket 32 may taper over a distal end of distal marker band 40 to attach to a distal part 44 of inner liner 28. The attachment of distal part 42 of outer jacket 32 to distal part 44 of inner liner 44 may help restrain first support structure 36, second support structure 38, and distal marker band 40 in place. In addition, in some examples, distal marker band 40 may be positioned over one or both of first support structure 36 or second support structure 38, such that distal marker band 40 is positioned between a part of one or both of first support structure 36 or second support structure 38 and outer jacket 32. In the example shown in FIG. 2, distal marker band 40 is positioned between first support structure 36 and outer jacket 32. This may enable distal marker band 40 to help maintain first support structure 36 in contact with inner liner 28, e.g., during manufacturing of catheter 20, may reduce an outer diameter of catheter 20 compared to a catheter in which distal marker band 40 is radially outward of both first support structure 36 and second support structure 38, or both.

**[0038]** Elongated body 22 has a suitable working length for accessing a target tissue site within the patient from a vascular access point. In some examples the working length of elongated body 22 may be measured from hub distal end 14B (FIG. 1; marked by the distal end of optional strain relief body 11) to distal end 30 of elon-

gated body 22 along longitudinal axis 26. The working length of elongated body 22 may depend on the location of the target tissue and/or the medical procedure for which catheter 20 is used. For example, if catheter 20 is a distal access catheter or other catheter used to access vasculature in a brain of a patient from a femoral artery access point at the groin of the patient, elongated body 22 may have a working length of about 120 cm to about 135 cm, such as about 132 cm, although other lengths may be used. In other examples, or for other applications, the working length of elongated body 22 may be different.

**[0039]** In some examples, elongated body 22 may define an outer diameter taper (e.g., gradient, gradation, segmented gradient or gradation, or the like) along its working length of elongated body 22. An outer diameter (OD) taper may assist with the navigability and/or maneuverability of elongated body 22 through the vasculature of a patient. In some examples, at least a part (e.g., only part of the working length or the entire working length) of elongated body 22 may define a constant outer diameter. In such examples, first and second support structures 36 and 38 of elongated body 22 may be configured to provide sufficient support to elongated body 22 to allow the outer diameter of the elongate body 22 to remain relatively small along the length of elongated body 22 for a given inner diameter of elongated body 22 to facilitate distal flexibility about distal portion 20B while still retaining sufficient strength and pushability about the proximal portion of elongated body 22. Additionally, or alternatively, a relatively small OD of elongated body 22 may allow for easier to navigability of the catheter 20 through tortuous vasculature of a patient.

**[0040]** In some examples, catheter 20 may be advanced to a target location within vasculature of the patient in cooperation with a guide member (not shown) such as a guidewire, an inner catheter, both a guidewire and an inner catheter, or the like, which may aid in the navigation (e.g., steering and manipulation) of elongated body 22 through the vasculature. For example, at least part of inner lumen 24 of elongated body 22 may be configured to receive a guide member, such that elongated body 22 may be guided through vasculature over the guide member or the inner catheter. In some examples, the design of distal portion 20B of elongated body 22 (e.g., the region defined by distal opening 34) may be configured to resist geometric deformation (e.g., kinking, ovalization, or the like) from forces applied to the distal tip by the guidewire or inner catheter. This resistance to geometric deformation may help improve the ease with which elongated body 22 may be guided to a relatively distal tissue site, e.g., through relatively tight turns in the vasculature and/or the responsiveness of catheter 20 as a clinician guides the distal tip of elongated body 22 through the vasculature of a patient.

**[0041]** In some examples, elongated body 22 may include tip jacket 46, which surrounds distal part 42 of outer jacket 32 and extends beyond a distal end 48 of inner liner 28 and a distal end 50 of outer jacket 32. In particular, tip jacket 46 extends longitudinally beyond distal end 48 of inner liner 28 and distal end 50 of outer jacket 32. Tip jacket 46 thus may define a single-layer tip of elongated body 22 of catheter 20 that excludes inner liner 28 and outer jacket 32.

**[0042]** A distal end of tip jacket 46 defines distal end 30 of catheter 20. Distal end 30 may be a length L1 from the distal end of marker band 40. The distance between the distal end of marker band 40 and distal end 30 may depend at least in part on the OD of catheter 20. For example, a catheter 20 with a larger OD may include a larger length L1, while a catheter 20 with a smaller OD may include a smaller length L1. In some examples, the length L1 between distal end 30 and the distal end of marker band 40 may be between about 0.5 mm and about 1.5 mm.

**[0043]** As shown in FIG. 2, tip jacket 46 may overlap the distal part 42 of outer jacket 32, the distal part 44 of inner liner 28, or both. A remaining portion of tip jacket 46 may define the only layer of elongate body 22 of catheter 20 distally of the overlap with the distal part 42 of outer jacket 32, the distal part 44 of inner liner 28, or both. This remaining portion of tip jacket 46 has a length L2. Length L2 may be related to length L1. For example, length L2 may be between about 1/3 and about 1/2 of L1. As such, in some examples, length L2 may be between about 0.1 mm and about 0.8 mm.

**[0044]** A radially outer surface of tip jacket 46 tapers radially inward as tip jacket 46 extends distally, which may reduce the cross-sectional area of elongate body 22 of catheter 20 near distal end 30 of catheter 20 and aid navigation of catheter 20 through vasculature of a patient. Forming the distal-most portion of catheter 20 from a single layer of material may enable the distal-most portion to be more acutely tapered, which may also aid navigation of catheter 20 through vasculature of a patient.

**[0045]** The material from which tip jacket 46 is formed may be the same or a lower durometer than the material from which inner liner 28 is formed and the material from which outer jacket 32 is formed. For example, tip jacket 46 may be formed from a polymeric material with a durometer that is less than 35D, such as between about 30A and about 35D, although in other examples, the material of tip jacket 46 may have a higher durometer than 35D, depending on the durometers of the materials from which inner liner 28 and outer jacket 32 are formed. In some examples, tip jacket 46 may be formed from a polyolefin elastomer; a poly(ether-*block*-amide), such as a poly(ether-*block-amide)* available under the trade designation PEBAX® from Arkema, Colombes, France; a thermoplastic polyurethane, such as a thermoplastic polyurethane elastomer available under the trade designation PolyBlend™ from AdvancSource Biomaterials, Wilmington, Massachusetts; an aromatic polyether-based thermoplastic polyurethane available under the trade designation Tecothane™ from The Lubrizol Corporation, Wickliffe, Ohio; a thermoplastic polyurethane available under the trade designation Pellethane® from

The Lubrizol Corporation; or mixtures thereof. A tip jacket 46 that is softer than the material from which inner liner 28 is formed and the material from which outer jacket 32 is formed may be less traumatic than a catheter in which inner liner 28, outer jacket 32, or both extend to distal end 30 of catheter 20.

**[0046]** In some examples, instead of or in addition to a tip jacket 46, a distal tip may include a preferential bending location proximal of a distal marker band. The preferential bending location also may facilitate guiding the catheter through vasculature of a patient and make the catheter less traumatic upon contacting tissue of the patient. FIG. 3 is a conceptual axial cross-sectional view of another example of a distal portion 60B of an example catheter 60 (e.g., distal portion 17B of catheter 10). Distal portion 60B of catheter 60 may be similar to or substantially the same as distal portion 20B of catheter 20 of FIG. 2, aside from the differences described herein. For example, distal portion 60B includes an elongate member 62 that defines a central axis 66 and includes an inner liner 68, a first support structure 76 over inner liner 68, a second support structure 78 over inner liner 68 and over part of the length of first support structure 76, an outer jacket 72, and a distal marker band 80. Distal portion 60B extends to distal end 70 of elongate body 62, which defines a distal opening 74 to inner lumen 64. Inner liner 68 extends to distal part 84, which defines distal end 88 of inner liner 68, and outer jacket 72 extends to distal part 82, which defines distal end 90 of outer jacket 72. Distal part 84 of inner liner 68 is attached to distal part 82 of outer jacket 72. For example, distal part 84 of inner liner 68 may be directly attached to distal part 82 of outer jacket 72 with no intervening layers.

**[0047]** Unlike catheter 20 of FIG. 2, in catheter 60 of FIG. 3, second support structure 78 ends proximal to a proximal end 94 of distal marker band 80. In particular, a distal end 92 of second support structure 78 is proximal to proximal end 94 of distal marker band 80. The space between distal end 92 of second support structure 78 and proximal end 94 of distal marker band 80 defines a gap 86, which may be at least partially filled with material from outer jacket 72. In some examples, both second support structure 78 and first support structure 76 end proximal to proximal end 94 of distal marker band 80. Gap 86 defines a location with lower radial and/orflexural stiffness than the portion of catheter 70 that includes both first support structure 76 and second support structure 78, as outer jacket 72 has a lower stiffness than second support structure 78. Thus, catheter 70 may preferentially bend at gap 86 in response to distal tip 70 of catheter 60 contacting an anatomical structure, such as a wall of vasculature of a patient, or in response to any force oblique or transverse to the longitudinal axis 66. This may also contribute to navigability of catheter 60 through vasculature and make catheter 60 more atraumatic than a catheter that does not include gap 86.

**[0048]** Gap 86 may define any suitable length L3. The length L3 may be proportional to the OD of elongate body 62, e.g., an elongate body 62 with a greater OD may include a longer length L3 and an elongate body 62 with a smaller OD may include a smaller length L3. In some examples, length L3 of gap 86 may be between about 0.5 mm and about 5 mm, such as between about 0.5 mm and about 1.5 mm. A distance L4 between proximal end 94 of distal marker band 80 and distal tip 70 of catheter 60 may be between about 2 mm and about 5 mm, and also may be proportional to the OD of elongate body 62.

**[0049]** In some examples, rather than second support structure 78, which is a braid, ending proximal of distal marker band 80 to define gap 86, a first support structure that is a coil may end proximal of the distal marker band. FIG. 4 is a conceptual axial cross-sectional view of another example of a distal portion 100B of an example catheter 100 (e.g., distal portion 17B of catheter 10). Distal portion 100B of catheter 100 may be similar to or substantially the same as distal portion 60B of catheter 60 of FIG. 3, aside from the differences described herein. For example, distal portion 100B includes an elongate member 102 that defines a central axis 106 and includes an inner liner 108, a first support structure 116 over inner liner 108, a second support structure 118 over inner liner 108 and over first support structure 116, an outer jacket 112, and a distal marker band 120. Distal portion 100B extends to distal end 110 of elongate body 102, which defines a distal opening 114 to inner lumen 104. Inner liner 108 extends to distal part 124, which defines distal end 128 of inner liner 108, and outer jacket 112 extends to distal part 122, which defines distal end 130 of outer jacket 112. Distal part 124 of inner liner 108 is attached to distal part 122 of outer jacket 12.

**[0050]** Unlike catheter 60 of FIG. 3, in catheter 100 of FIG. 4, first support structure 116 ends proximal to a proximal end 134 of distal marker band 120. In particular, a distal end of first support structure 116 is located proximal to proximal end 134 of distal marker band 120. The space between the distal end of first support structure 116 and proximal end 134 of distal marker band 120 defines a gap 126, which may be at least partially filled with material from outer jacket 112. Gap 126 defines a location with lower radial and/or flexural stiffness that the portion of catheter 100 that includes both first support structure 116 and second support structure 118, as outer jacket 112 has a lower radial and/or flexural stiffness than first support structure 116. Thus, catheter 100 may preferentially bend at gap 126 in response to distal tip 110 of catheter 100 contacting an anatomical structure, such as a wall of vasculature of a patient. This may also contribute to navigability of catheter 100 through vasculature and make catheter 100 more atraumatic than a catheter than that does not include gap 126.

**[0051]** Second support structure 118 extends distally past the distal end of first support structure 116. In the example shown in FIG. 4, a distal part 138 of second support structure 118 contacts inner liner 108 and is positioned between inner liner 108 and distal marker band 120. In this way, distal marker band 120 may compress

second support structure 118 to inner liner 108 and help maintain position of distal part 138 of second support structure 118 relative to inner liner 108. Further, second support structure 118 may compress a distal portion of first support structure 116 and help maintain position a distal end of first support structure 116 relative to inner liner 108.

**[0052]** In some examples, as shown in FIG. 4, catheter 100 may include both a distal tip formed from a single, relatively soft tip jacket 138 and a preferential bending location (e.g., gap 126) proximal of distal marker band 120. Tip jacket 138 may be similar to or substantially the same as tip jacket 46 of catheter 20 of FIG. 2.

**[0053]** The catheters described herein can be formed using any suitable technique. FIG. 5 is a flow diagram of an example method of forming a catheter as described herein. The technique of FIG. 5 is described with respect to catheter 20 of FIG. 2; however, the techniques may be used to form other catheters or the catheters described herein (e.g., catheter 100) may be formed using techniques other than those described in FIG. 5.

**[0054]** In the technique shown in FIG. 5, inner liner 28 may be positioned over a mandrel (142). Inner liner 28 may be fabricated using any suitable technique. In some examples, inner liner 28 may be formed using an extrusion process in which the polymeric materials and, if applicable, slip agent, are mechanically mixed together and heated to the melting point of the underlying polymeric material and passed through a tubular extrusion process to form a tubular body having the desired thickness and diameter profiles. In some examples in which inner liner 28 includes multiple sections, the respective sections may be positioned over a mandrel followed by being subsequently joined together (e.g., fused).

**[0055]** In some examples, after positioning inner liner 28 over the mandrel, inner liner 28 may be heat shrunk onto the mandrel such that inner liner 28 conforms to the outer surface of the mandrel and acquire a tapered profile (if applicable) of the mandrel. In some such examples in which inner liner 28 includes multiple sections, the respective sections of inner liner 28 may be sized such that the inner diameter of the respective liner sections are slightly oversized to facilitate placement of the liner sections on the mandrel prior to the heat shrink process. In other examples, however, heat shrinking may not be necessary. For example, in addition to, or instead of, heat shrinking, inner liner 28 may be longitudinally stretched over the mandrel to substantially conform to the outer surface of the mandrel. In either example, inner liner 28 may define a constant inner diameter or may have different inner diameters, e.g., corresponding to the outer diameters defined by the mandrel.

**[0056]** After positioning inner liner 28 over a mandrel (142), at least one support structure may be positioned over inner liner 28 (144). The at least one support structure may include one or more of a coil, a braid, or combinations thereof. In some examples, the at least one support structure may include a first support structure 36 and a second support structure 38. First support structure 36 may include a coil and second support structure 38 may include a braid. In some examples, second support structure 38 may be positioned over first support structure 36. In other examples, first support structure 36 may be positioned over second support structure 38.

**[0057]** In some examples, the structural configuration of the at least one support structure may be at least partially defined prior to being positioned over inner liner 28. For example, a shape memory wire (e.g., NiTi alloy) or a wire of an otherwise heat-settable metal, alloy, or polymer base may be wound over a different mandrel where the wires are heat set to define at least one of the desired pitch, spacing, wind diameter, tapering profile, or length of the at least one support structure.

**[0058]** After being heat set, the one or more wires of the at least one support structure may then be subsequently unwound from the mandrel onto a reel or a bobbin (not shown), and then re-wound/woven over inner liner 28. In some examples, defining some or all of the structural characteristics of the at least one support structure prior to positioning the at least one support structure over inner liner 28 may help control the structural characteristics of the at least one support structure (e.g., gap spacings, pitch, etc.), as well as control product consistency and uniformity of the at least one support structure used in multiple catheters. In addition, shape-setting wires of the at least one support structure on a separate, heat-resistant mandrel enables the construction of the elongated body 22 using the at least one support structure on a mandrel made of, for example, PTFE or other lubricious, non-heat resistant materials.

**[0059]** The at least one support structure may be secured in place relative to inner liner 28 using any suitable technique. For example, the at least one support structure may be adhered to inner liner 28. In some examples, an adhesive may be positioned over inner liner 28 prior to positioning the at least one support structure over inner liner 28. In addition to, or instead of, an adhesive, outer jacket 22, distal marker band 40, or both may be used to secure the at least one support structure to inner liner 28. For example, distal marker band 40 may be positioned over a distal part of first support structure 36 as shown in FIG. 2. In some examples, distal marker band 40 can be adhered to inner liner 28, first support structure 36, or both, or may be held in place within elongated body 22 because of being positioned between first support structure 36 and outer jacket 32.

**[0060]** In the technique of FIG. 5 also includes positioning outer jacket 32 over the at least one support structure (146), including the optional distal marker band 40, and inner liner 28. Distal part 42 of outer jacket 32 then may be bonded to distal part 44 of inner liner 28 (148). In some examples, to join distal part 42 of outer jacket 32 to distal part 44 of inner liner 28, outer jacket 22 may be heat-shrunk onto inner liner 28 and the at least one support structure, which may result in outer jacket 32 being bonded to inner liner 28 along a length of outer

jacket 32. In some examples, the heat shrinking of outer jacket 32 may help secure the respective positions of the at least one support structure along elongated body 22. For example, outer jacket 32 may extend through apertures defined in second support structure 38 and between coils or turns of first support structure 36 to contact and bond to inner liner 28 (e.g., using thermal bonding, an adhesive, or the like). Thus, although a gap is shown between coils or turns of first support structure 36 in FIG. 2, in some examples, these gaps may be filled with material from outer jacket 32, an adhesive, or a combination of adhesive and material from outer jacket 32. This may help minimize the wall thickness of elongated body 22 and, therefore, increase the ID of elongated body 22 for a given OD by limiting the inclusion of addition layer within the wall construction of elongated body 22. In addition, the absence of additional layers (e.g., an adhesive/tie layer) that joins inner liner 28 to outer jacket 32 may contribute to an increased flexibility of catheter 20.

**[0061]** Tip jacket 46 then may be positioned over distal part 42 of outer jacket 32 (150). Tip jacket 46 may be positioned to overlap a tapering portion of outer jacket 32 and may extend beyond distal end 50 of outer jacket 32. For example, tip jacket 46 may longitudinally extend beyond distal end 48 of inner liner 28 and distal end 50 of outer jacket 32. Tip jacket 46 then may be bonded to outer jacket 32 (152). For example, tip jacket 46 may be heat-shrunk onto distal part 42 of outer jacket 32. As shown in FIG. 2, a distal portion of tip jacket 46 may shrink to contact the mandrel and define a portion of the inner diameter of catheter 20. The distal portion of tip jacket 46 also may define a single layer tip of catheter 20. A radially outer surface of tip jacket 46 may taper radially inward as tip jacket 46 extends distally, and tip jacket 46 may be formed from a material that is the same or a lower durometer than the material from which inner liner 28 is formed and the material from which outer jacket 32 is formed. In this way, tip jacket 46 may be more atraumatic than a catheter 20 in which inner liner 28, outer jacket 32, or both extend to a distal end of catheter 20.

**[0062]** Once elongated body 22 is formed, hub 14 (FIG. 1) may be attached to the proximal end of elongated body 22 (e.g., proximal end 12A of elongated body 12 of FIG. 1) using any suitable technique, such as an adhesive, fusing, over-molding, or any combination thereof.

**[0063]** FIG. 6 is a flow diagram of another example method of forming a catheter as described herein. The technique of FIG. 6 is described with respect to catheter 60 of FIG. 3; however, the techniques may be used to form other catheters or the catheters described herein (e.g., catheter 100) may be formed using techniques other than those described in FIG. 6.

**[0064]** In the technique shown in FIG. 6, inner liner 68 may be positioned over a mandrel (162). This step may be similar to or substantially the same as step (142) of FIG. 5.

**[0065]** After positioning inner liner 68 over the mandrel (162), a first support structure 76 may be positioned over inner liner 68 (164). First support structure 76 may include a coil, a braid, or the like. In the example illustrated in FIG. 3, first support structure 76 includes a coil. In some examples, the structural configuration of first support structure 76 may be at least partially defined prior to being positioned over inner liner 68. For example, a shape memory wire (e.g., NiTi alloy) or a wire of an otherwise heat-settable metal, alloy, or polymer base may be wound over a different mandrel where the wires are heat set to define at least one of the desired pitch, spacing, wind diameter, tapering profile, or length of first support structure 76.

**[0066]** After being heat set, the one or more wires of first support structure 76 may then be subsequently unwound from the mandrel onto a reel or a bobbin (not shown), and then re-wound/woven over inner liner 68. In some examples, defining some or all of the structural characteristics of first support structure 76 prior to positioning first support structure 76 over inner liner 68 may help control the structural characteristics of first support structure 76 (e.g., gap spacings, pitch, etc.), as well as control product consistency and uniformity of first support structure 76 used in multiple catheters. In addition, shape-setting wires of first support structure 76 on a separate, heat-resistant mandrel enables the construction of the elongated body 62 using first support structure 76 on a mandrel made of, for example, PTFE or other lubricious, non-heat resistant materials.

**[0067]** In some examples, first support structure 76 may be secured in place relative to inner liner 68 using an adhesive. In other examples, first support structure 76 may be secured in place relative to inner liner 68 by another structure of elongate body 62, such as, for examples, distal marker band, second support structure 78, or outer jacket 72.

**[0068]** In the technique of FIG. 6 also includes positioning second support structure 78 over first support structure 76 (166). Second support structure 78 may include a coil, a braid, or the like. In the example illustrated in FIG. 3, second support structure 78 includes a braid. In some examples, second support structure 78 may be sized with an inner diameter slightly smaller than an outer diameter of first support structure 76 and may help maintain first support structure 76 in position relative to inner liner 68.

**[0069]** Distal marker band 80 is positioned over a distal part of one of first support structure 76 or second support structure 78 (168). In some examples, distal marker band 80 may be positioned over the distal part of one of first support structure 76 or second support structure 78 (168) after second support structure is positioned over first support structure 76 (166). The other of first support structure 76 or second support structure 78 may end proximal to distal marker band 80. In other examples, distal marker band 80 may be positioned over the distal part of first support structure 76 (168) before second support structure 78 is positioned over first support structure 76 (e.g., in examples in which second support structure 78 does

not cover a distal part of first support structure 76). Distal marker band 80 may help maintain position of the distal part of the one of first support structure 76 or second support structure 78 over which distal maker band 80 is positioned relative to inner liner 68. In some examples, distal marker band 80 may be adhered to the one of first support structure 76 or second support structure 78, inner liner 68, or both. In other examples, distal marker band 80 may simply be fit over the distal part of one of first support structure 76 or second support structure 78. For example, a distal end of the other of first support structure 76 or second support structure 78 may be proximal to a proximal end of distal marker band 80, thus defining gap 86. Gap 86 defines a location with lower radial and/or flexural stiffness than the portion of catheter 70 that includes both first support structure 76 and second support structure 78 due to the absence of one of first support structure 76 or second support structure 78. As discussed above, gap 86 may define any suitable length L3. The length L3 may be proportional to the OD of elongate body 62, e.g., an elongate body 62 with a greater OD may include a longer length L3 and an elongate body 62 with a smaller OD may include a smaller length L3. In some examples, length L3 of gap 86 may be between about 0.5 mm and about 5 mm. A distance L4 between proximal end 94 of distal marker band 80 and distal tip 70 of catheter 60 may be between about 2 mm and about 5 mm, and also may be proportional to the OD of elongate body 62.

**[0070]** Once distal marker band 80 is positioned over a distal part of one of first support structure 76 or second support structure 78 (168), outer jacket 72 is positioned over first support structure 76, second support structure 78, and distal marker band 80 (170). Distal part 82 of outer jacket 72 then may be bonded to distal part 84 of inner liner 68 (172). In some examples, to bond distal part 82 of outer jacket 72 to distal part 84 of inner liner 68, outer jacket 72 may be heat-shrunk onto inner liner 68, first support structure 76, second support structure 78, and distal marker band 80, which may result in outer jacket 72 being bonded to inner liner 68 along a length of outer jacket 72. In some examples, the heat shrinking of outer jacket 72 may help secure the respective positions of first support structure 76, second support structure 78, and distal marker band 80 along elongated body 62. For example, outer jacket 72 may extend through apertures defined in second support structure 78 and between coils or turns of first support structure 76 to contact and bond to inner liner 68. Thus, although a gap is shown between coils of first support structure 76 in FIG. 2, in some examples, these gaps may be filled with material from outer jacket 72, an adhesive, or a combination of adhesive and material from outer jacket 72. This may help minimize the wall thickness of elongated body 62 and, therefore, increase the ID of elongated body 62 for a given OD by limiting the inclusion of addition layer within the wall construction of elongated body 62. In addition, the absence of additional layers (e.g., an adhesive/tie layer) that joins inner liner 68 to outer jacket 72 may contribute to an increased flexibility of catheter 60.

**[0071]** In some examples, although not shown in FIG. 6, a tip jacket (e.g., tip jacket 136 of FIG. 4) then may be positioned over distal part 82 of outer jacket 72. The tip jacket may be positioned to overlap a tapering portion of outer jacket 72 and may extend beyond distal end 90 of outer jacket 72. The tip jacket then may be bonded to outer jacket 72. For example, the tip jacket may be heat-shrunk onto distal part 82 of outer jacket 72.

**[0072]** In some examples, any of catheter 10, catheter 20, catheter 60, or catheter 100 may be a part of an assembly that includes, e.g., a guide member/or an aspiration pump. In some examples, the aspiration pump may be connected to catheter 10, catheter 20, catheter 60, or catheter 100 by an intermediate tube. The guide member may be used to guide catheter 10 to a target tissue site within the vasculature of a patient. In some examples, a method of using catheter 10 comprises introducing a guide member or an inner catheter into vasculature (e.g., an intracranial blood vessel) of a patient via an access point (e.g., a femoral artery), and guiding elongated body 12 over the guide member. Once distal end 12B of elongated body 12 is positioned at the target tissue site, which may be proximal to thromboembolic material (e.g., a thrombus), the thromboembolic material may be removed from the vasculature via elongated body 12. For example, the thromboembolic material may be aspirated from the vasculature by at least applying a vacuum force to inner lumen 24 of elongated body 12 via hub 14 (and/or proximal end 12A), which may cause the thromboembolic material to be introduced into inner lumen 24 via distal opening 13. Optionally, the vacuum or aspiration can be continued to thereby draw the thromboembolic material proximally along the inner lumen 24, all or part of the way to the proximal end 12A or hub 14.

**[0073]** As another example, the thromboembolic material may be removed from the vasculature using another technique, such as via an endovascular retrieval device delivered through the inner lumen 24 of the elongated body 12. In such a method the elongated body 12 can be inserted into the vasculature (for example using any technique disclosed herein) and the retrieval device advanced through the inner lumen 24 (or through another catheter, such as a microcatheter, inserted into the vasculature through the inner lumen 24) so that the device engages the thromboembolic material. The retrieval device and the material engaged thereby (together with any other catheter or microcatheter) can then be retracted into the inner lumen 24 and removed from the patient. Optionally, aspiration can be performed with or through the elongated body 12 during retraction of the retrieval device and thromboembolic material into the elongated body 12. Optionally the retrieval device along with the thrombus could be pulled back into the tip of the catheter 10 under aspiration and then the retrieval device and catheter 10 withdrawn together as one unit toward and through a surrounding larger sheath or catheter. The vas-

culature can include neurovasculature, peripheral vasculature or cardiovasculature. The thromboembolic material may be located using any suitable technique, such as fluoroscopy, intravascular ultrasound or carotid Doppler imaging techniques.

## INVENTIVE STATEMENTS

**[0074]**

Statement 1. An assembly comprising:
a catheter comprising:
an elongated body including proximal and distal portions, the distal portion of the elongated body comprising:

an inner liner;
at least one support structure positioned over the inner liner;
an outer jacket positioned over the at least one support structure, wherein the outer jacket tapers radially inward distal of a distal-most part of the at least one support structure to bond to the inner liner; and
a tip jacket positioned over a distal part of the outer jacket and extending beyond a distal-most part of the inner liner and the outer jacket to define a single-layer catheter tip, wherein the tip jacket comprises a material that is the same or a lower durometer than the inner liner and the same or a lower durometer than the outer jacket; and

an aspiration pump connected to the catheter.

Statement 2. A catheter comprising:
an elongated body including proximal and distal portions, the distal portion of the elongated body comprising:

an inner liner;
a first support structure positioned over the inner liner;
a second support structure positioned over the first support structure;
a distal marker band positioned over a distal part of one of the first support structure or the second support structure, wherein the other of the first support structure or the second support structure ends proximally of a proximal end of the distal marker band; and
an outer jacket positioned over the first support structure, the second support structure, and the marker band, wherein the outer jacket tapers radially inward distal of a distal-most part of the marker band to bond to the inner liner.

Statement 3. The catheter of statement 2, wherein the first support structure comprises a coil and the second support structure comprises a braid.

Statement 4. The catheter of statement 3, wherein a distal end of the braid is proximal to the proximal end of the distal marker band.

Statement 5. The catheter of statement 3, wherein a distal end of the coil is proximal to the proximal end of the distal marker band.

Statement 6. The catheter of statement 2, wherein the first support structure comprises a braid and the second support structure comprises a coil.

Statement 7. The catheter of statement 6, wherein a distal end of the braid is proximal to the proximal end of the distal marker band.

Statement 8. The catheter of statement 6, wherein a distal end of the coil is proximal to the proximal end of the distal marker band.

Statement 9. The catheter of statement 2, wherein the other of the first support structure or the second support structure ends at least about 0.5 millimeters proximally of the proximal end of the marker band.

Statement 10. The catheter of statement 2, wherein the other of the first support structure or the second support structure ends between about 0.5 millimeters and about 5 millimeters proximally of the proximal end of the marker band.

**[0075]** Various examples have been described. These and other examples are within the scope of the following claims.

## Claims

1. A catheter comprising:
an elongated body including proximal and distal portions, the distal portion of the elongated body comprising:

an inner liner;
at least one support structure positioned over the inner liner;
an outer jacket positioned over the at least one support structure, wherein the outer jacket tapers radially inward distal of a distal-most part of the at least one support structure to bond to the inner liner; and
a tip jacket positioned over a distal part of the outer jacket and extending beyond a distal-most part of the inner liner and the outer jacket to define a single-layer catheter tip, wherein the tip

jacket comprises a material that is the same or a lower durometer than the inner liner and the same or a lower durometer than the outer jacket.

2. The catheter of claim 1, wherein the tip jacket comprises a polyurethane, a polyolefin elastomer, a poly(ether-*block*-amide), or combinations thereof.

3. The catheter of claim 1, wherein the tip jacket material has a durometer of 35D or less.

4. The catheter of claim 1, wherein the tip jacket is the only layer for the distal-most 0.3 to 0.8 millimeters of the catheter.

5. The catheter of claim 1, wherein the inner liner and the outer jacket extend distally past the distal-most part of the at least one support structure by about 0.2 millimeters to about 0.6 millimeters.

6. The catheter of claim 1, further comprising a marker band, wherein the marker band is positioned over the at least one support structure near the distal-most part of the at least one support structure.

7. The catheter of claim 1, wherein the at least one support structure comprises at least one of a braid or a coil.

8. The catheter of claim 1, wherein the at least one support structure comprises a braid and a coil.

9. The catheter of claim 8, wherein the braid is positioned over the coil.

10. The catheter of claim 8, wherein the coil is positioned over the braid.

11. The catheter of claim 8, further comprising a marker band, wherein the marker band is positioned over one of the braid or the coil near the distal-most part of the one of the braid or the coil, and wherein the other of the braid or the coil ends proximally of a proximal end of the marker band.

12. The catheter of claim 11, wherein the other of the braid or the coil ends at least about 0.5 millimeters proximally of the proximal end of the marker band.

13. An assembly comprising:
a catheter comprising:
an elongated body including proximal and distal portions, the distal portion of the elongated body comprising:

an inner liner;
a first support structure positioned over the inner liner;
a second support structure positioned over the first support structure;
a distal marker band positioned over a distal part of one of the first support structure or the second support structure, wherein the other of the first support structure or the second support structure ends proximally of a proximal end of the distal marker band; and
an outer jacket positioned over the first support structure, the second support structure, and the marker band, wherein the outer jacket tapers radially inward distal of a distal-most part of the marker band to bond to the inner liner; and

an aspiration pump connected to the catheter.

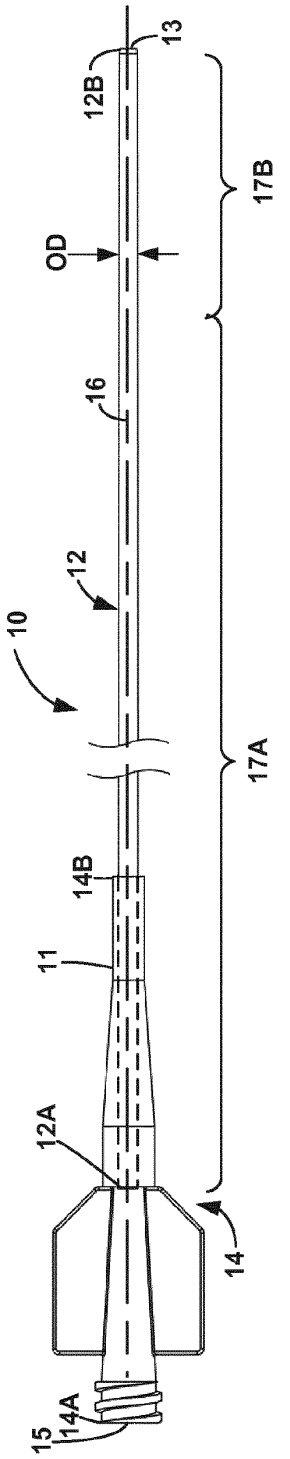

10
12
12A
12B
13
14
14A
14B
15
16
17A
17B
OD
11

FIG. 1

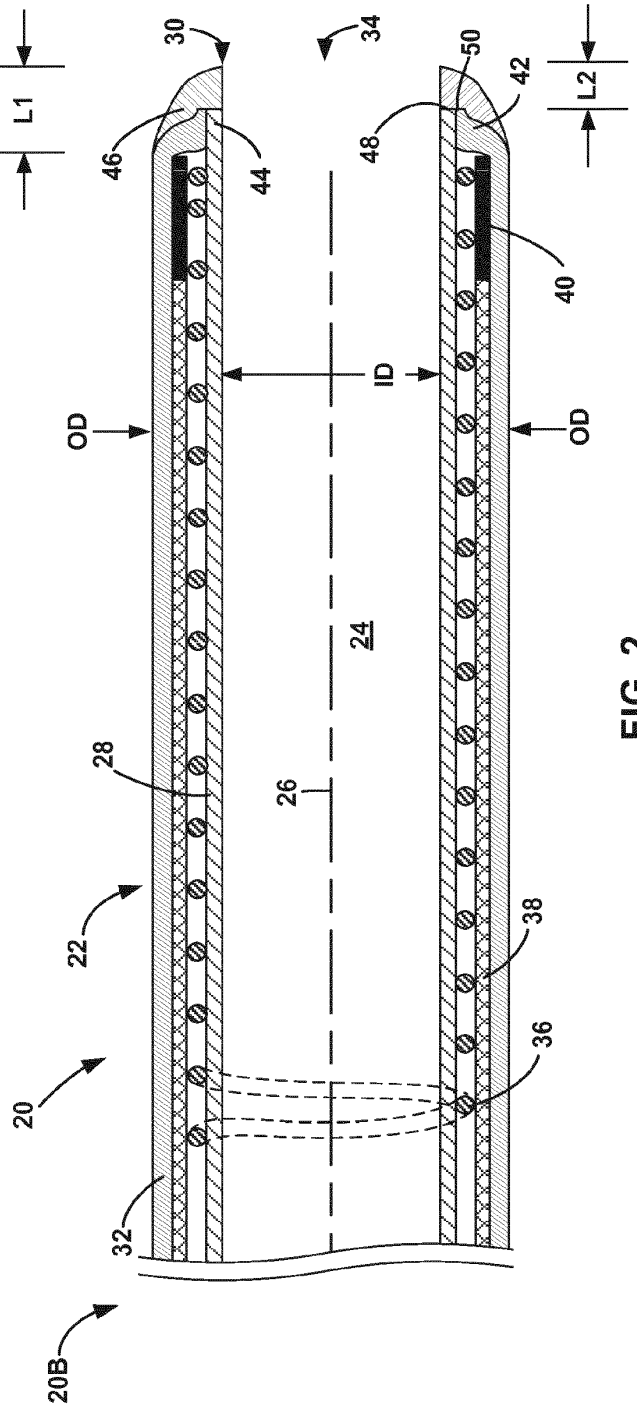

L1
L2
30
34
46
44
48
50
42
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OD
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OD
24
26
28
22
20
32
20B
38
36

FIG. 2

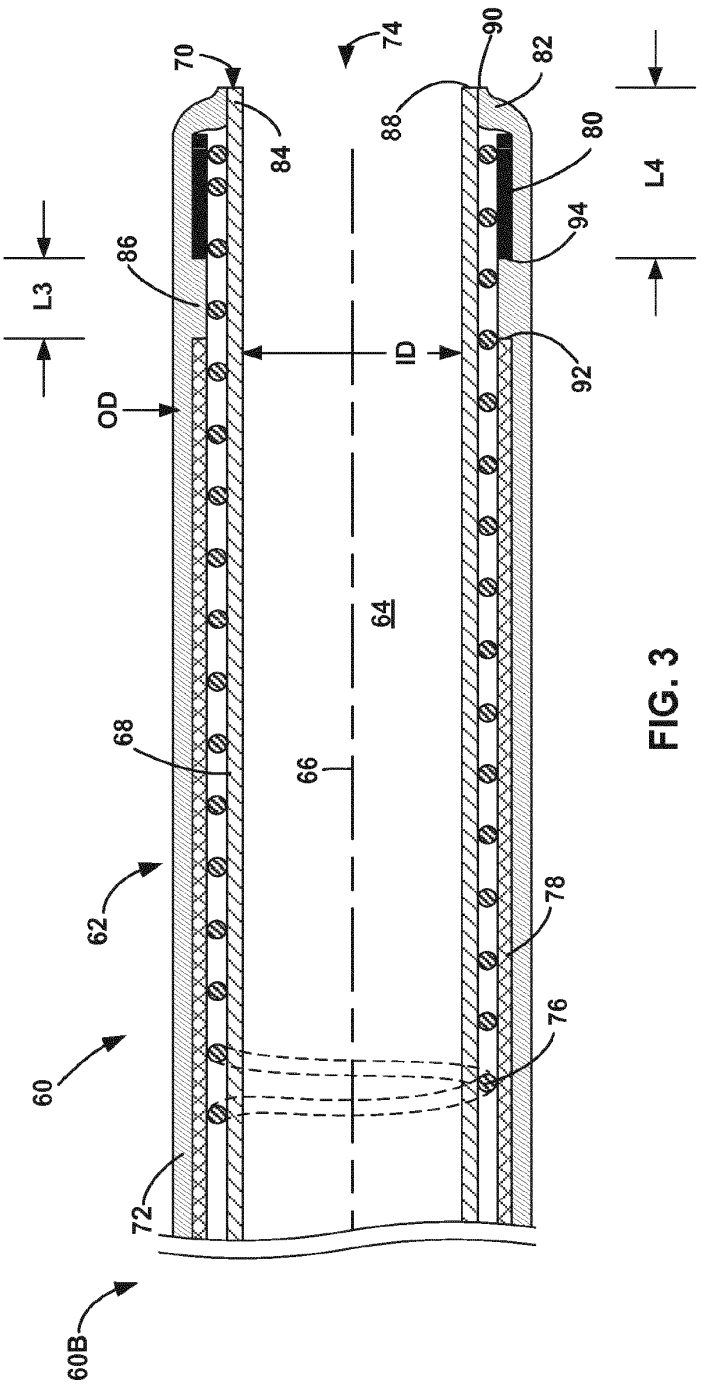



FIG. 3

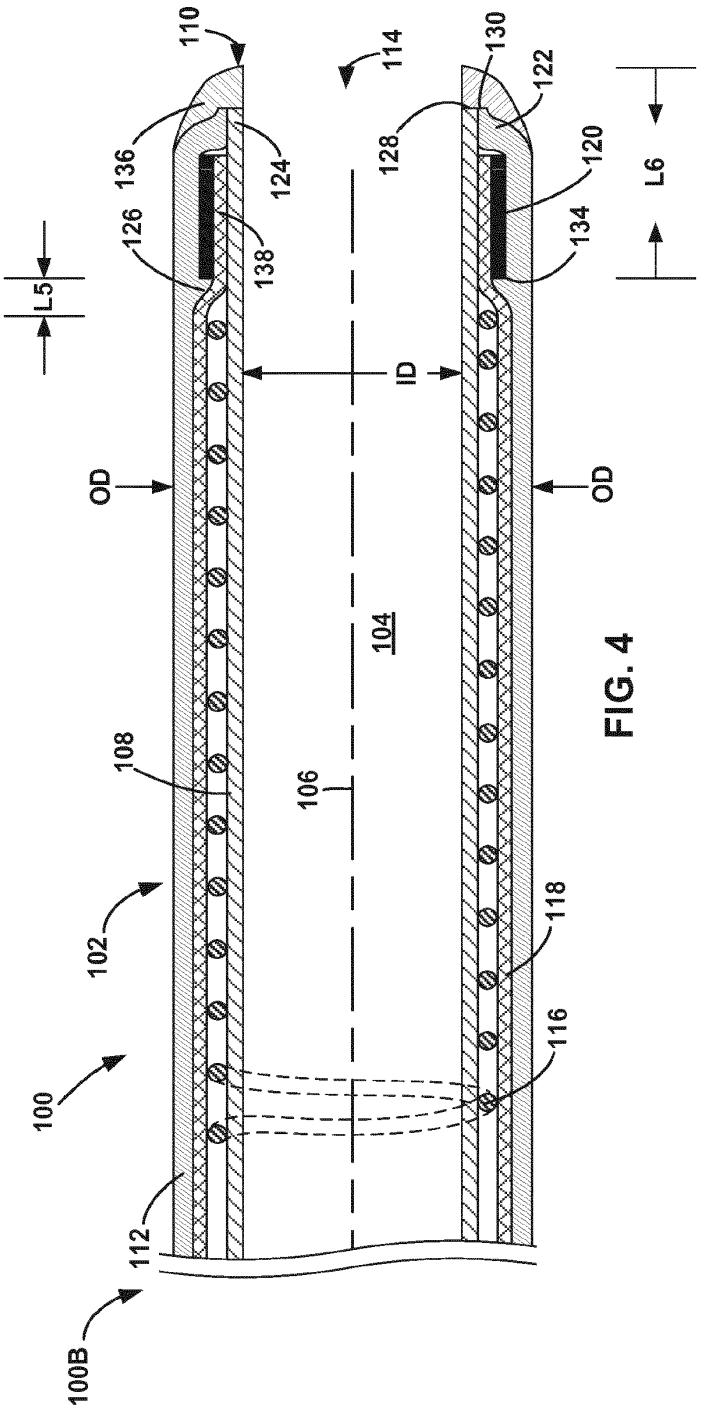

110
114
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122
136
124
128
120
L6
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138
134
L5
ID
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OD
104
108
106
102
118
116
100
112
100B

FIG. 4

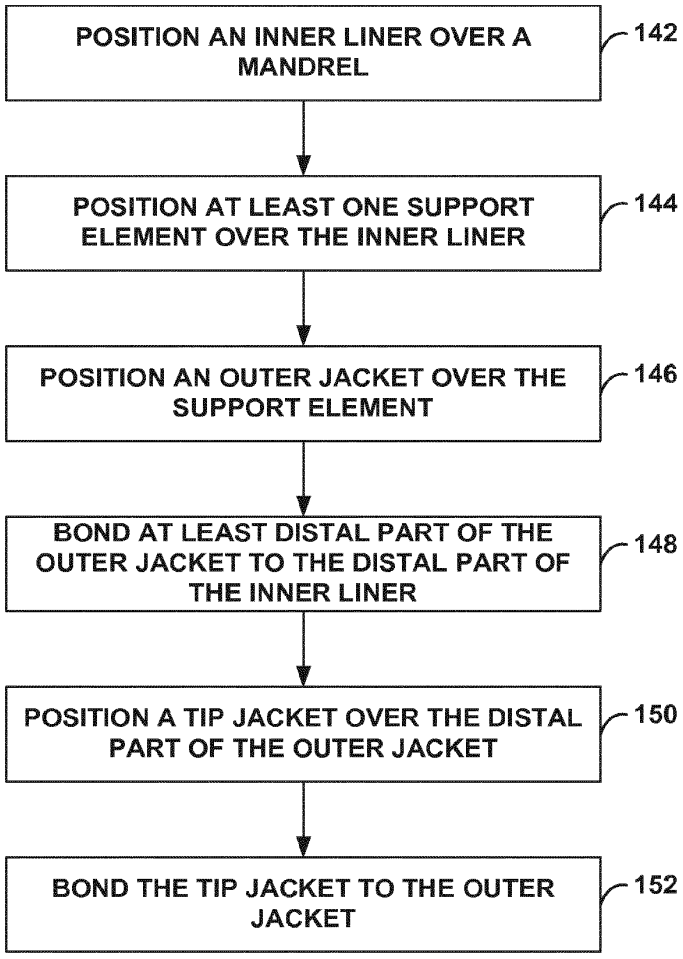

POSITION AN INNER LINER OVER A MANDREL
142
POSITION AT LEAST ONE SUPPORT ELEMENT OVER THE INNER LINER
144
POSITION AN OUTER JACKET OVER THE SUPPORT ELEMENT
146
BOND AT LEAST DISTAL PART OF THE OUTER JACKET TO THE DISTAL PART OF THE INNER LINER
148
POSITION A TIP JACKET OVER THE DISTAL PART OF THE OUTER JACKET
150
BOND THE TIP JACKET TO THE OUTER JACKET
152

FIG. 5

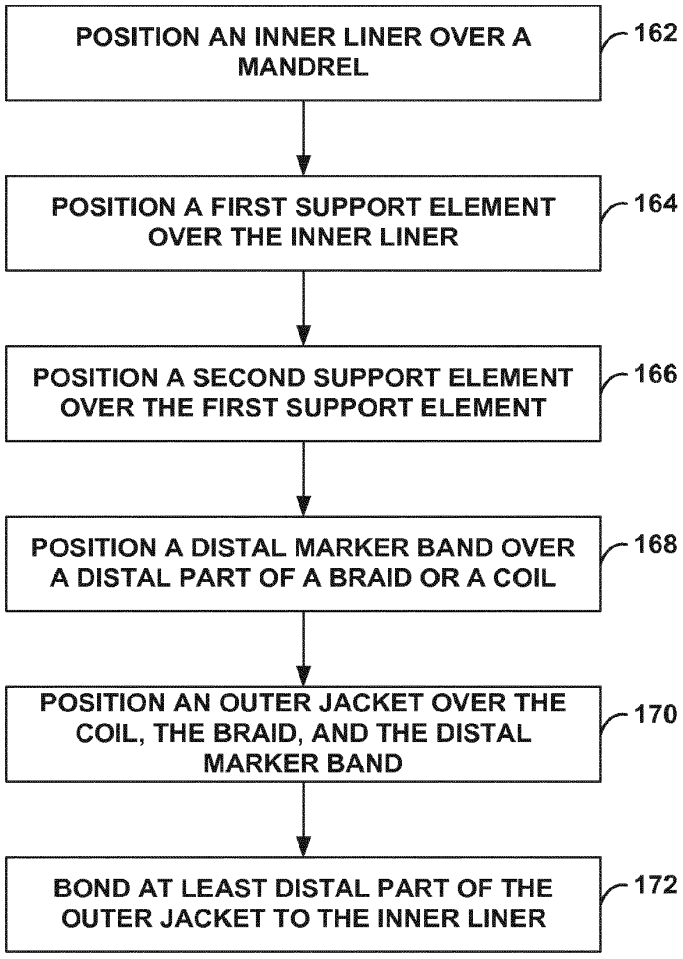

POSITION AN INNER LINER OVER A MANDREL
162
POSITION A FIRST SUPPORT ELEMENT OVER THE INNER LINER
164
POSITION A SECOND SUPPORT ELEMENT OVER THE FIRST SUPPORT ELEMENT
166
POSITION A DISTAL MARKER BAND OVER A DISTAL PART OF A BRAID OR A COIL
168
POSITION AN OUTER JACKET OVER THE COIL, THE BRAID, AND THE DISTAL MARKER BAND
170
BOND AT LEAST DISTAL PART OF THE OUTER JACKET TO THE INNER LINER
172

FIG. 6

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(54) Title: EMBOLIC PROTECTION DEVICE

(57) Abstract: The present invention includes an embolic protection device comprising a catheter having a self-expanding embolic filter that is disposed around the catheter proximal to a distal portion, wherein the embolic filter comprises a frame, and the frame defines an opening of the embolic filter that faces the distal end of the catheter; a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon the longitudinal retraction of the deployment mechanism; and a wire coupled to the frame for expanding the size or diameter of the embolic filter opening.

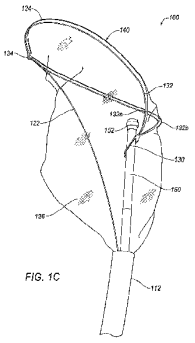



FIG. 1C

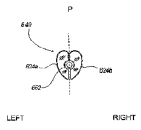



FIG. 6C

[Continued on next page]

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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))*

# EMBOLIC PROTECTION DEVICE

## CROSS REFERENCE TO RELATED APPLICATION

[0001] This PCT application claims the benefit of U.S. provisional application no. 62/639,618, filed on March 7, 2018, and U.S. provisional application no. 62/812,391, filed on March 1, 2019. Each of these documents is hereby incorporated by reference in its entirety.

## TECHNICAL FIELD

[0002] This application relates to embolic protection devices including a catheter and methods of using such embolic protection devices in medical procedures (e.g., closed-heart surgical procedures).

## BACKGROUND

[0003] Traditional pigtail catheters are used during percutaneous cardiac procedures where the positioning of various instruments and devices within the vasculature of a patient is important. These pigtail catheters comprise a curved distal end that can rest within the patient's anatomy (e.g., an artery (e.g., aorta)) and hold the catheter in place while other instrumentation and devices are delivered into the patient's vasculature. Some traditional pigtail catheters include a lumen and small apertures at their distal ends through which a contrast agent can be injected into a patient's vasculature for imaging the relevant portion of the patient's anatomy and identifying anatomical landmarks.

[0004] However, the use of traditional pigtail catheters in percutaneous cardiac procedures often results in serious and life-threatening complications for the patient. For example, cerebral embolism is a common complication in cardiac procedures, such as valve replacement and repair, where a traditional pigtail catheter is deployed. During such procedures, plaque, calcium, thrombi, or any combination thereof, in the vessels, valves, and/or cardiac chambers can be dislodged by the catheter or other medical devices introduced into the patient's vasculature. The dislodged plaque, calcium, thrombi or any combination thereof can be carried into the patient's brain via blood flow from the aorta and can cause blockages therein leading to an embolic event such as stroke. Approximately 2.9%-6.7% of patients undergoing transfemoral transcatheter aortic-valve implantation (TAVI) have a stroke within 30 days, and even more (4.5%-10.6%) have a stroke within a year, often leading to death. Furthermore, up to 85% of patients undergoing TAVI have evidence of embolic phenomenon to the brain based on neuroimaging studies. Although clinically silent, such embolic phenomena are associated with cognitive decline (Astraci 2011; Ghanem 2010; Kahlert 2010; Rodes-Caban 2011).

[0005] Presently, there are a few devices on the market designed to protect the brain, abdominal organs, and carotid arteries from emboli, and these devices suffer from various significant drawbacks. For instance, the Embrella Embolic Deflector®, available from Edwards Lifesciences of Irvine, California, employs a deflector that deflects emboli from the carotid arteries into the descending aorta, but the device does not trap the emboli, so emboli are free to travel to other areas of the body and cause deleterious complications. The EMBOL-X®, also available from Edwards Lifesciences, employs a filtering screen, but this device is designed for use in open heart procedures, which present additional medical risks and increased morbidity. Additionally, the use of multiple devices, for example a catheter for visualization and a separate filter device, lengthens the procedure time and increases the risk of complications to the patient.

## SUMMARY

[0006] These and other needs are met by the present invention, which presents an embolic protection device comprising a deployable embolic filter that is disposed around a catheter having a distal portion that can assume an arcuate configuration being at least a semi-circle, and having a wire that is operable to manipulate the embolic filter into a configuration that more fully engages a body lumen.

[0007] The combination of the catheter and the embolic filter in the same device may provide the benefits of both devices individually, as well as provide a synergistic effect. For example, the integration of the catheter and the embolic filter can decrease the duration of the medical procedure and reduce the occurrence of complications (e.g., complications caused by dislodged emboli). In other examples, the expansion of the embolic filter may help to anchor the catheter into position to provide a more accurate position of the catheter than if the position of the catheter is susceptible to the influences of blood flow, tissue movement, and the like. In a valve replacement procedure, anchoring of the catheter and more accurate positioning of the catheter may help ensure that the valve prosthesis is properly positioned and stabilized. In another example, the position of the catheter may ensure that the filter is being properly positioned.

[0008] In some aspects, the embolic protection device comprises a catheter, a self-expanding embolic filter coupled to the catheter, a pull wire for reorienting the filter by bending a frame of the filter, and an outer sheath movable with respect to the embolic filter and the catheter. The outer sheath holds the embolic filter in a collapsed configuration when surrounding the embolic filter and is proximally retracted to deploy the embolic filter. The outer sheath may recapture the embolic filter and any debris captured therein by being distally advanced. The filter and outer sheath might both be movable with respect to the catheter, for example to be

able to move the embolic filter longitudinally without having to move the entire catheter longitudinally. The pull wire is advantageous due to its ability to bend the frame, thereby facing the filter opening towards the distal end of the device and causing the embolic filter to more fully engage the body lumen.

**[0009]** In some aspects, the catheter has a proximal end and a distal end. A lumen extends from the proximal end of the catheter to the distal end of the catheter. In some embodiments, the lumen may be configured to house a guidewire.

**[0010]** In some aspects, the catheter is a pigtail catheter. A pigtail catheter is configured to curl at the distal end of the catheter, forming a generally arcuate shape that is at least a semi-circle. The pigtail may have a radiopaque marker viewable on x-rays or other medical imaging devices. The radiopaque marker is on the distal section of the curled pigtail in the form of a longitudinal marker, circumferential bands, or the like. The pigtail may additionally have one or more apertures to dispense drugs and/or contrast agents through the lumen.

**[0011]** In some aspects, a guidewire is inserted through the patient's skin and into a body lumen such as a femoral, radial, or brachial artery and steered near a target site. The guidewire is inserted into a lumen of the embolic protection device, and the embolic protection device is pushed or tracked over the guidewire to the target site. When the guidewire is retracted from at least the distal portion of the catheter, the catheter assumes a generally arcuate shape. The radiopaque marker on the catheter is used to visualize and position the catheter. Once the catheter is in position, the outer sheath is retracted to deploy the embolic filter and the pull wire is retracted to bend the frame of the filter to position the distal opening of the filter across the vessel. The user can then perform a procedure such as valve replacement, valve repair, radio frequency ablation, and the like. When the procedure is completed, the pull wire is advanced and the outer sheath is advanced to recapture the embolic filter and any debris trapped in the embolic filter. The device is then retracted from the vessel, with the catheter being atraumatic to vessels during retraction.

**[0012]** Another aspect is a method of capturing embolic debris during a closed-heart surgical procedure comprising inserting the distal end of the catheter of the embolic protection device into a body lumen. The method further comprises allowing the embolic filter to assume an expanded, deployed configuration and retracting the pull wire to bend the frame of the filter, so that a distal opening of the filter spans the body lumen.

**[0013]** In some aspects, the embolic protection device comprises a catheter, a self-expanding embolic filter coupled to the catheter, a push wire for reorienting the filter by bending a frame of the filter in a longitudinal direction and extending the frame in a radial direction, and an

outer sheath movable with respect to the embolic filter and the catheter. The outer sheath holds the embolic filter in a collapsed configuration when surrounding the embolic filter and is proximally retracted to deploy the embolic filter. The outer sheath may recapture the embolic filter and any debris captured therein by being distally advanced. The push wire is advantageous due to its ability to bend and extend the frame, thereby facing the filter opening towards the distal end of the device and causing the embolic filter to more fully engage the body lumen.

**[0014]** In some aspects, the catheter has a proximal end and a distal end. A lumen extends from the proximal end to the distal end along a longitudinal axis of the catheter. In some embodiments, the lumen may be configured to house a guidewire.

**[0015]** In some aspects, the catheter is a pigtail catheter. A pigtail catheter is configured to curl at the distal end of the catheter, forming a generally arcuate shape that is at least a semi-circle. The pigtail may have a radiopaque marker viewable on x-rays or other medical imaging devices. The radiopaque marker is on the distal section of the curled pigtail in the form of a longitudinal marker, circumferential bands, or the like. The pigtail may additionally have one or more apertures to dispense drugs and/or contrast agents through the lumen.

**[0016]** In some aspects, a guidewire is inserted through the patient's skin and into a body lumen such as a femoral, radial, or brachial artery and steered near a target site. The guidewire is inserted into a lumen of the embolic protection device, and the embolic protection device is pushed or tracked over the guidewire to the target site. When the guidewire is retracted from at least the distal portion of the catheter, the catheter assumes a generally arcuate shape. The radiopaque marker on the catheter is used to visualize and position the catheter. Once the catheter is in position, the outer sheath is retracted to deploy the embolic filter and the push wire is advanced to bend and extend the frame of the filter to position the distal opening of the embolic filter across the vessel. The user can then perform a procedure such as valve replacement, valve repair, radio frequency ablation, and the like. When the procedure is completed, the push wire is retracted and the outer sheath is advanced to recapture the embolic filter and any debris trapped in the embolic filter. The device is then retracted from the vessel, with the catheter being atraumatic to vessels during retraction.

**[0017]** Another aspect is a method of capturing embolic debris during a closed-heart surgical procedure comprising inserting the distal end of the catheter of the embolic protection device into a body lumen. The method further comprises allowing the embolic filter to assume an expanded, deployed configuration and advancing the push wire to bend and extend the frame of the filter, so that a distal opening of the filter spans the body lumen.

## BREF DESCRIPTION OF THE FIGURES

**[0018]** The following figures are provided by way of example and are not intended to limit the scope of the claimed invention.

**[0019]** FIGS. 1A and 1B illustrate partial side views of an embodiment of an embolic protection device of the present invention. In FIG. 1A, an embolic filter of the embolic protection device is illustrated in a collapsed (undeployed) configuration. In FIG. 1B, the embolic filter is illustrated in an expanded (deployed) configuration wherein a pull wire affixed to a frame of the embolic filter is advanced to a distal position so that the frame assumes it's self-expanded and undeflected (i.e., unbent) configuration.

**[0020]** FIG. 1C illustrates a side perspective view of an embodiment of an embolic filter of the present invention assuming a partially deflected (i.e., partially bent) configuration wherein the pull wire affixed to the frame of the embolic filter is partially longitudinally retracted to a proximal position.

**[0021]** FIG. 1D illustrates a transverse cross-sectional view of an embodiment of an embolic filter of the present invention assuming a fully deflected (e.g., fully bent) configuration wherein the pull wire is fully longitudinally retracted thereby deflecting the filter.

**[0022]** FIGS. 1E and 1F illustrate front views of an embodiment of an embolic filter frame of the present invention. In FIG. 1E, the filter frame is undeployed wherein the frame is collapsed and enclosed by an outer sheath. In FIG. 1F, the outer sheath is longitudinally retracted and the filter frame is deployed to its self-expanded configuration.

**[0023]** FIGS. 2A – 2B illustrate partial side views of an embodiment of an embolic protection device of the present invention comprising a shoulder.

**[0024]** FIGS. 3A – 3D illustrate partial side views of an embodiment of an embolic protection device of the present invention comprising an intermediate tube.

**[0025]** FIGS. 4A – 4C illustrate partial side views of an embodiment of an embolic protection device of the present invention comprising a deflector.

**[0026]** FIG. 5A illustrates an embodiment of an embolic protection device comprising a handle. FIG. 5B illustrates a distal portion of the embolic protection device comprising the embolic filter and pigtail catheter.

**[0027]** FIG. 6A illustrates a partial side view of an embodiment of an embolic protection device of the present invention with an embolic filter in a collapsed (undeployed) configuration.

**[0028]** FIGS. 6B and 6C illustrate a side view and a front end view of the embolic filter in an self-expanded (deployed) configuration, respectively, wherein a push wire coupled to a frame

of the embolic filter is retracted to a proximal position so that the frame assumes an undeflected (i.e., unbent) configuration.

**[0029]** FIGS. 6D and 6E illustrate a side view and a front end view of the embolic filter in an partially expanded configuration, respectively, wherein the push wire coupled to the frame of the embolic filter is longitudinally advanced to a first distal position so that the frame assumes a deflected (i.e., bent) configuration.

**[0030]** FIGS. 6E and 6F illustrate a side view and a front end view of the embolic filter in an fully expanded configuration, respectively, wherein the push wire coupled to the frame of the embolic filter is longitudinally advanced to a second distal position farther than the first distal position shown in FIG. 6C so that the frame assumes an extended configuration.

**[0031]** FIGS. 7A – 7C illustrate partial side views of an embodiment of an embolic protection device of the present invention having an actuating mechanism for operating an embolic filter.

**[0032]** FIGS. 8A and 8B illustrate an embodiment of an embolic protection device of the present invention having a handle for manually operating an embolic filter.

**[0033]** FIGS. 8C – 8F illustrate an example of the handle.

**[0034]** FIGS. 9A – 9E illustrate a stepwise method of using an embolic protection device of the present invention.

**[0035]** FIG. 10 illustrates the deflection and capture of embolic debris by an embolic protection device of the present invention comprising a deflector.

**[0036]** FIG. 11 illustrates the deflection and capture of embolic debris by an embolic protection device of the present invention wherein a second catheter device is present.

**[0037]** FIGS. 12A – 12D illustrate a stepwise method of using an embolic protection device of the present invention operating an embolic filter.

**[0038]** FIGS. 13A and 13B are photographs of distal portions of embolic protection devices of the present invention situated within a cadaver's vasculature according to Example 1. In FIG. 13A, the embolic protection device comprises a longitudinal groove in which a second catheter is inserted alongside the embolic protection device. In FIG. 13B, the second catheter is situated adjacent to the embolic protection device that lacks a longitudinal groove.

**[0039]** FIG. 14 is a bar graph of performance data of an embolic protection device of the present invention (the EPD-1 device) according to Example 2.

**[0040]** FIGS. 15A – 15J are images generated from diffusion-weighted magnetic resonance imaging (DW-MRI) of representative subjects according to Example 2.

**[0041]** FIG. 16A is a photograph of thrombi captured by an embolic protection device of the present invention (the EPD-1 device) according to Example 2.

[0042] FIG. 16B is a photograph of a collagenous fragment captured within the filter of the embolic protection device (the EPD-1 device) according to Example 2.

[0043] Like reference numerals in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0044] The present invention provides an embolic protection device and methods of using the embolic protection device for capturing embolic debris during surgical procedures.

[0045] I. DEFINITIONS

[0046] As used herein, the term "self-expanding" means to increase, spread out, or unfold from a collapsed state upon the withdrawal or removal of a restricting or confining force.

[0047] As used herein, the term "closed-heart" refers to any surgical procedure involving the heart, wherein the chest cavity is not opened.

[0048] As used herein, the term "woven" refers to any material that comprises a plurality of strands, wherein the strands are interlaced to form a net, mesh, or screen. Without limitation, examples of woven materials include netting or mesh comprising a polymer, metal, or metal alloy.

[0049] As used herein, the term "non-woven" refers to any material that comprises a continuous film. Non-woven material may be permeable, semi-permeable, or non-permeable. For example, permeable or semi-permeable non-woven material may optionally include one or more pores through which a fluid may pass.

[0050] As used herein, the term "alloy" refers to a homogenous mixture or solid solution produced by combining two or more metallic elements, for example, to give greater strength or resistance to corrosion. For example, alloys include brass, bronze, steel, nitinol, chromium cobalt, MP35N, 35NLT, elgiloy, and the like.

[0051] As used herein, "nitinol" and "nickel titanium" are used interchangeably to refer to an alloy of nickel and titanium.

[0052] As used herein, "chromium cobalt" refers to an alloy of chromium and cobalt.

[0053] As used herein, "MP35N" refers to an alloy of nickel and cobalt.

[0054] As used herein, "35NLT" refers to a cobalt-based alloy that may also comprise chromium, nickel, molybdenum, carbon, manganese, silicon, phosphorus, sulphur, titanium, iron, and boron.

[0055] As used herein, "elgiloy" refers to an alloy of cobalt, chromium, nickel, iron, molybdenum, and manganese.

[0056] As used herein, a "body lumen" refers to the inside space of a tubular structure in the body, such as an artery, intestine, vein, gastrointestinal tract, bronchi, renal tubules, and urinary collecting ducts. In some instances, a body lumen refers to the aorta.

[0057] II. EMBOLIC PROTECTION DEVICES

[0058] Although certain embodiments and examples are described below, those skilled in the art will recognize that the disclosure extends beyond the specifically disclosed embodiments and/or uses and obvious modifications and equivalents thereof. Thus, it is intended that the scope of the disclosure herein presented should not be limited by any particular embodiments described below.

[0059] For purposes of this disclosure, the terms "upper," "lower," "right," "left," "rear," "front," "vertical," "horizontal," and derivatives thereof shall relate to the invention as oriented in FIGS. 1B and 1F (or in FIGS. 6B and 6C). However, it is to be understood that the invention may assume various alternative orientations, except where expressly specified to the contrary. Also, for purposes of this disclosure, the term "coupled" (in all of its forms, couple, coupling, coupled, etc.) generally means the joining of two components (electrical or mechanical) directly or indirectly to one another. Such joining may be stationary in nature or movable in nature; may be achieved with the two components (electrical or mechanical) and any additional intermediate members being integrally formed as a single unitary body with one another or with the two components; and may be permanent in nature or may be removable or releasable in nature, unless otherwise stated.

[0060] FIGS. 1A and 1B illustrate embodiments of an embolic protection device 100. In these embodiments, the device 100 comprises a catheter 102 (e.g., a pigtail catheter) having a proximal end 114, a distal end 116, and a lumen 118 extending from the proximal end 114 to the distal end 116. The lumen 118 may be configured to house a guidewire 990 (see FIGS. 9A and 9B) that is longitudinally moveable through this lumen to coil or straighten the distal portion 104 of the catheter 102 depending on whether the guidewire is retracted (to coil the distal portion) or extended (to straighten the distal portion). In some embodiments, the catheter 102 includes a distal portion 104 configured to assume a generally arcuate shape being at least a semi-circle. A side wall of the catheter 102 may optionally include one or more apertures 108 in the distal portion 104 that are configured to deliver one or more fluids (e.g., imaging dye, contrast agent, oxygenated blood, saline, any combination thereof, or the like) to a body lumen 992 (see FIG. 9A). The apertures 108 (the plural intended to include embodiments in which the distal portion includes one aperture 108) are in fluid communication with the lumen 118. In some embodiments, the distal portion 104 of the catheter 102 includes one or more radiopaque markers 106. In some embodiments, the radiopaque markers 106 are wrapped around the circumference of the distal portion of the catheter and can have the same or different widths. In other embodiments, the radiopaque markers are co-linear with the lumen and extend to the distal end of the catheter. The device

100 further comprises a self-expanding embolic filter 110 defined by a frame 124 and a filter medium 126, and a deployment mechanism 112 (e.g., a longitudinally retractable outer sheath or a longitudinally retractable ring). The embolic filter 110 is disposed around the catheter 102.

**[0061]** As illustrated in FIG. 1B, in its deployed configuration, the embolic filter 110 includes a distal opening 140 that is defined by the frame 124, faces the distal end 116 of the catheter 102, and extends proximally from the distal opening 140 to a closed proximal end 142. The device 100 further comprises a pull wire 122 that is coupled to the frame 124 and can be retracted to deflect or bend the frame 124 and change the orientation and shape of the distal opening 140.

**[0062]** In some embodiments, retracting the pull wire 122 may cause the distal opening 140 of the embolic filter 110 to engage at least a portion of the interior body lumen 992 (see FIG. 9D) wall. FIG. 1B illustrates the pull wire 122 in an advanced, i.e., un-retracted or self-expanded, configuration with the frame oriented generally to extend in a distal longitudinal direction, albeit angled back somewhat (e.g., less than about 45 degrees) in a lateral direction. The catheter 102 may be partially surrounded towards its proximal end 114 by a support catheter 150 that terminates at a head 152, proximal to the distal portion 104 of the catheter 102. The support catheter 150 may be made of a thicker, stiffer material to add rigidity and provide a protective or supporting layer surrounding the catheter 102.

**[0063]** FIG. 1C illustrates the embolic filter 110 deployed (e.g., self-expanded) by retraction of the deployment mechanism (e.g., outer sheath) 112 with the frame 124 partially deflected, i.e., partially bent, by retraction of the pull wire 122. The pull wire 122 is coupled to the frame 124 at a distal coupling 134. The distal opening 140 is primarily defined by a first portion 132 of the frame 124. The first portion 132 of the frame 124 defines a shape of the distal opening 140 that is substantially elliptical (i.e., shaped like an ellipse), or alternatively, substantially oval-shaped or circular. In this embodiment, the portion 132 of the frame 124 may be substantially elliptical and may terminate a V-shaped point at its proximal end, i.e., the portion 132 of the frame 124 may invert its curvature at one end of its substantially elliptical shape (e.g., at its distal end) and come to a point at its proximal end. The distal opening 140 may substantially be defined by the frame 124, but may span across the frame 124 adjacent to the section of the frame 124 that comes to a point. The filter medium 126 may define a portion of the distal opening 140 where the filter medium 126 spans across the frame 124, i.e., adjacent to a point of attachment of the frame 124 to the catheter 102 or support catheter 150.

**[0064]** The attachment of the frame 124 to the support catheter 150 (or alternatively, directly to the catheter 102) is accomplished via a second portion 130 of the frame 124, which encircles the support catheter 150 (or catheter 102) and is at an angle with respect to the longitudinal axis of the catheter 102. The second portion 130 of the frame 124 may be fixed in its position by friction and by tension of the embolic filter 110 in the lateral and/or longitudinal directions. In other embodiments, the fixed attachment of the second portion 130 of the frame 124 to the support catheter 150 (or catheter 102) may also be accomplished via adhesives, welding, or the like.

**[0065]** The first portion 132 of the frame 124 may extend in a first lateral direction away from the catheter 102 and away from the second portion 130 of the catheter 102 and loop back across the catheter 102 and extend in the opposite lateral direction. In this embodiment, the first portion 132 of the frame 124 comprises two sides (132a, 132b) that each extend generally in a first lateral direction away from the catheter 102 and then loop back on opposite sides around the catheter 102 and extend generally in the opposite lateral direction before converging and meeting to form the substantially elliptical shape. As shown in FIG. 1F, the embolic filter 110 is symmetrical about the pull wire 122. For ease of discussion, the embolic filter 110 is referred as having a left side and a right side. Elements on the left side of the embolic filter 110 are mirrored by elements on the right side of the embolic filter 110.

**[0066]** When the pull wire 122 is in its advanced state (or partially, but not fully, retracted state), the frame 124 extends in a distal longitudinal direction as it extends from its attachment to the catheter 102 (or support catheter 150). When the pull wire 122 is in its retracted state (i.e., fully retracted) (see FIG. 1D and FIG. 9E), the frame 124 extends in a distal longitudinal direction near its point of attachment to the catheter 102, but then is bent such that it extends substantially perpendicular to the longitudinal axis of the catheter 102.

**[0067]** FIG. 1D presents a cross-sectional view of the distal opening 140 of the embolic filter 110 when the embolic filter 110 assumes an expanded configuration and when the pull wire 122 is in a fully retracted state, fully deflecting (or bending) the frame 124. The pull wire 122 deflects or bends the frame 124 in a proximal longitudinal direction and laterally outward. In a fully deflected configuration (i.e., when the pull wire 122 is fully retracted), the distal opening 140 of the embolic filter 110 may be substantially perpendicular to the longitudinal axis of the catheter 102 and may span laterally across the body lumen 992 (see FIGS. 9D and 9E), substantially perpendicular to the longitudinal axis of the body lumen 992. The fully deflected (or bent) configuration may allow the embolic filter 110 to more fully engage the body lumen 992. In this fully deflected configuration, the distal opening 140 is substantially perpendicular to the longitudinal axis of the catheter 102. In the fully deflected

configuration, the width, x, across the distal opening 140 may be increased compared to the corresponding dimension in the undeflected configuration. Likewise, in the fully deflected configuration, the length, y, across the distal opening 140 may be decreased compared to the corresponding dimension in the undeflected configuration. By increasing the width, x, in the bent configuration, the frame 124 defining the distal opening 140 may more fully engage the body lumen 992.

**[0068]** In the embodiments illustrated in each of FIGS. 1A – 1D, the catheter 102 extends through the distal opening 140 of the embolic filter 110, and the frame 124 extends away from the catheter 102 in a first lateral direction and then curves back around the catheter 102 in the opposite direction.

**[0069]** The embolic protection device 100, with the embolic filter 110 deployed, i.e., the deployment mechanism 112 is retracted), may assume an undeflected (FIG. 1B), partially deflected (FIG. 1C), or fully deflected (FIGS. 1D and 5E) configuration. These configurations are achieved by engaging the pull wire 122 to a fully advanced, partially retracted (or partially advanced), or fully retracted state. In the fully advanced state, the pull wire 122 is in a distal position. In the fully retracted state, the pull wire 122 is in a proximal position. When longitudinally retracted to a proximal position, the pull wire 122 is configured to deflect (or bend) the frame 124 so that the distal opening 140 of the filter 110 is substantially perpendicular to the longitudinal direction of the catheter 102 and the distal opening 140 faces the distal end 116 of the catheter 102. When longitudinally advanced to a distal position, the pull wire 122 is configured to position the frame 124 so that the distal opening 140 of the filter 110 defined by the frame 124 is substantially parallel or angled less than about 45 degrees with respect to longitudinal direction of the catheter 102.

**[0070]** In some embodiments, the distal opening 140 of the embolic filter 110 has a diameter of from about 2 cm to about 6 cm (e.g., from about 2.5 cm to about 5 cm or about 4.5 cm). The embolic filter 110 can comprise any suitable size or diameter to accommodate anatomic variability in patients' body lumens 992 (see FIG. 9C). In some embodiments, the embolic filter 110 is coupled to the catheter 102 at the proximal and/or distal ends of the embolic filter 110 and/or at any other points there between. For example, the embolic filter 110 may be coupled to the catheter 102 via the frame 124, specifically the second portion 130 of the frame 124 (distal attachment) and also coupled to the catheter 102 via the filter medium 126 at an attachment point within the sheath 112.

**[0071]** FIGS. 1E and 1F illustrate the frame 124 of the embolic filter 110. In the embodiment illustrated in FIG. 1E, the frame 124 is collapsed within the outer sheath 112, i.e., with the sheath 112 advanced over the frame 124. In the embodiment illustrated in FIG. 1F, the frame

124 is deployed outside the sheath 112, i.e., with the sheath 112 retracted. The pull wire 122 is coupled to the frame 124 at a distal coupling 134. The pull wire 122 may be coupled to the frame 124 at the distal coupling 134 by a variety of methods, including by means of a hole in the frame 124 through which the pull wire 122 is threaded and crimped to hold it in place. The distal coupling 134 may also include a variation in the curvature of the frame 124, i.e., by inverting the curvature of the frame 124 and coming to a point. This curvature, along with the curvature of the frame 124 adjacent to the point of attachment of the frame 124 to the catheter 102, may aid in collapsing the frame 124 in order to advance the sheath 112 over the embolic filter 110. In some embodiments, the frame 124 comprises a shape memory material (e.g., a metal alloy or polymer). Examples of shape memory materials include, without limitation, nitinol, chromium cobalt, and/or other metal alloys such as MP35N, 35NLT, elgiloy, and the like. In some embodiments, the frame 124 is laser cut from a tube or a sheet.

**[0072]** FIGS. 2A and 2B illustrate embodiments of an alternative deployment mechanism for an embolic protection device 200 comprising a catheter 202, an embolic filter 210, and a movable outer sheath 212. In some embodiments, the outer sheath 212 can include an optional lip 260 protruding inwardly from the distal end of the outer sheath 212. The catheter 202 can include one or more shoulders 262 (e.g., a distal shoulder 262a and a proximal shoulder 262b) protruding outwardly from an outer wall of the catheter 202. The lip 260 of the outer sheath 212 is configured to engage the shoulder or shoulders 262 of the catheter 202 to inhibit or prevent the outer sheath 212 from moving excessively in either the proximal or distal direction. The lip 260 and shoulder 262 may be arcuate, pronged, and combinations thereof, and the like.

**[0073]** In some embodiments, the outer sheath 212 and/or the catheter 202 comprise nubs and/or detents configured to provide information to the user about the longitudinal position of the outer sheath without inhibiting further movement. In some embodiments, the outer sheath 212 and the catheter 202 comprise lips 260, shoulders 262, and detents and nubs (e.g., to inhibit longitudinal movement of the outer sheath 212 excessively in either direction, and to provide information about the extent of movement of the outer sheath 212 relative to the catheter 202 (e.g., 1/2 retracted, 1/4 retracted, etc.)).

**[0074]** Benefits of the outer sheath 212 deployment mechanism may include its simplicity, ease of operation, and small number of moving parts. The embolic protection device 200 is well-suited for use in conjunction with delicate cardiac procedures having serious risks. As the duration of the procedure increases, the risk of complications typically increases as well. Therefore, it can be advantageous that the user be able to quickly and easily deploy and recapture the embolic filter 210. A more complicated device could be more difficult to

operate and could be more likely to malfunction or cause adverse effects. The ability to move the outer sheath 212 relative to the embolic filter 210 can advantageously allow the user to partially recapture the embolic filter 210, for example to adjust the width of the distal opening 140. In some embodiments, narrowing the distal opening 140 allows the user to introduce a second catheter or instrument to the patient's body lumen 992 (see FIG. 9D) and maneuver the second catheter or instrument around and past the catheter 202 and embolic filter 210, as described herein. In some embodiments, an embolic protection device as described herein may have a longitudinally extending groove (not shown) along its surface, e.g., along the catheter 102, along the support catheter 150 or along the deployment mechanism (e.g. outer sheath) 112. In such embodiments, a second catheter or instrument may be inserted while engaging the groove to guide the second device alongside the embolic protection device.

**[0075]** FIGS. 3A – 3D illustrate embodiments of an embolic protection device 300 in which an embolic filter 310 is movably coupled to a catheter 302 by way of a frame 324 and is longitudinally movable with respect to the catheter 302. In some embodiments, the embolic filter 310 is coupled to an intermediate tube 330 that at least partially circumferentially surrounds the catheter 302. The intermediate tube 330 is longitudinally movable with respect to the catheter 302. An outer sheath 312 is configured to at least partially circumferentially surround both the catheter 302 and the intermediate tube 330. The intermediate tube 330 and the outer sheath 312 can be moved simultaneously and independently. The longitudinal position of the embolic filter 310 with respect to the catheter 302 can be adjusted while the embolic filter 310 is in the collapsed configuration or in a deployed or partially deployed, expanded configuration. In some embodiments, the perimeter of the distal opening of the embolic filter 310 comprises one or more radiopaque markers to allow the user to visualize the position of the distal opening, for example, with respect to various anatomical landmarks. For example, if the user is performing a procedure on a patient's aortic valve and wants to prevent emboli from entering the cerebral arteries, the radiopaque markers can be used to ensure the distal opening of the embolic filter 310 is positioned in the ascending aorta upstream from the carotid arteries.

**[0076]** FIG. 3A illustrates the embolic filter 310 confined in a closed configuration by the outer sheath 312 and a distal end of intermediate tube 330 at position (a). If the intermediate tube 330 is held stationary at position (a), the outer sheath 312 can be retracted to deploy the embolic filter 310, as shown in FIG. 3C. If the intermediate tube 330 and outer sheath 312 are instead moved simultaneously, the embolic filter 310 remains confined by the outer sheath 312 while the longitudinal position of the embolic filter 310 is adjusted. For example,

FIG. 3B illustrates the embolic filter 310 still confined by outer sheath 312, while the intermediate tube 330 has been retracted so that the distal end of the intermediate tube 330 is at position (b). If the intermediate tube 330 is then held stationary at position (b), the outer sheath 312 can be retracted to deploy the embolic filter 310, as shown in FIG. 3D. The intermediate tube 330 and outer sheath 312 can be moved to adjust the longitudinal position of the embolic filter 310 in a deployed or partially deployed configuration. For example, the intermediate tube 330 and outer sheath 312 can be moved simultaneously to retract the intermediate tube 330 from the position as shown in FIG. 3C to position (b) as shown in FIG. 3D.

**[0077]** In addition to those described in detail herein, a wide variety of deployment mechanisms for embolic filters are possible. For example, a deployment system may comprise a portion of an annular sheath including inward end protrusions that are guided in tracks along the catheter body. Certain such embodiments may advantageously reduce the profile of the catheter. For another example, a deployment system may comprise a threaded sheath that longitudinally moves upon twisting by the user. For yet another example, a deployment system may comprise a plurality of annular bands that can capture the embolic filter longitudinally and/or circumferentially. Combinations of the deployment systems described herein and other deployment systems are also possible.

**[0078]** FIGS. 4A – 4C illustrate another embodiment of an embolic protection device 400 comprising a catheter 402, a deflector 460, an embolic filter 410, and a movable outer sheath 412. In some embodiments, the embolic protection device 400 is similar to embolic protection device 100 with the addition of the deflector 460.

**[0079]** Various types and designs of deflectors can be used with an embolic protection device such as embolic protection device 400. Such deflectors can have different shapes and/or sizes and can vary in where and how they are coupled to the catheter. For example, deflectors can be made in various sizes, for example to accommodate differences in patient anatomy. In some embodiments, the deflector comprises a shape memory material, for example including nitinol, chromium cobalt, and/or alloys such as MP35N, 35NLT, elgiloy, and the like. In some embodiments, the deflector comprises a porous membrane, for example a semi-permeable polyurethane membrane/material, mounted to a self-expanding frame, for example a frame comprising a shape memory material.

**[0080]** An example of the deflector 460 shown in FIGS. 4A – 4C has a generally butterfly or elliptical shape with two wings or petals 460a and 460b extending to either side of a central axis 464. The wings or petals 460a and 460b may be the same or different in size shape, material, and the like. The deflector 460 is coupled to a side of the catheter 402 via an

elongate member 462 that is coupled (e.g., by adhering, welding, soldering, coupling using a separate component, combinations thereof, and the like) at one end to the central axis 464 of the deflector 460 and at the other end to the catheter 402. In some embodiments, the elongate member 462 comprises a shape memory material, for example including nitinol, chromium cobalt, and/or alloys such as MP35N, 35NLT, elgiloy, and the like that is configured (e.g., shape set) to bias the deflector away from the catheter 402. The deflector 460 is configured to release to an open configuration, shown in FIGS. 4B and 4C, when not confined by, for example, an outer sheath 412. In some embodiments, the deflector 460 is configured to fold along the central axis 464 away from the elongate member 462 so that the wings or petals 460a and 460b come together and the deflector 460 can be contained in, for example, an outer sheath 412, as shown in FIG. 4A. As shown in FIG. 4A, the deflector 460 can initially be folded and contained in the outer sheath 412 such that the wings or petals 460a and 460b are positioned distal to the central axis 464. In some embodiments, the deflector 460 can initially be folded in the opposite direction such that the wings or petals 460a and 460b are positioned proximal to the central axis 464.

**[0081]** In some embodiments, the catheter 402 is a pigtail-type catheter as shown in FIGS. 4A and 4B and described herein. The catheter 402 includes a distal portion 404 configured to assume a generally arcuate shape being at least a semi-circle. In some embodiments, the distal portion 404 of the catheter 402 includes one or more radiopaque markers 406. A side wall of the catheter 402 may optionally include one or more apertures 408 in the distal portion 404 that are configured to deliver one or more fluids (e.g., imaging dye, contrast agent, oxygenated blood, saline, any combination thereof, or the like) to a body lumen.

**[0082]** The catheter 402 has a proximal end 414 and a distal end 416. As shown in the FIG. 4B, an example of the catheter 402 is partially surrounded towards its proximal end 414 by a support catheter 450 that terminates at a head 452, proximal to the distal portion 404 of the catheter 402. The support catheter 450 may be made of a thicker, stiffer material to add rigidity and provide a protective or supporting layer surrounding the catheter 402.

**[0083]** As illustrated in FIG. 4B, the embolic filter 410 comprises a frame 424 and a filter medium 426. In its deployed configuration, the embolic filter 410 includes a distal opening 440 defined by the frame 424, faces the distal end 416 of the catheter 402, and extends proximally from the distal opening 440 to a closed proximal end 442. The device 400 further comprises a pull wire 422 that is coupled to the frame 424 and can be retracted to deflect or bend the frame 424 and change the orientation and shape of the distal opening 440, in manner similar to that described above with reference to FIGS. 1B – 1D.

**[0084]** In some embodiments, the deflector 460 and embolic filter 410 can be coupled to another type of catheter, for example a catheter without a distal portion configured to assume an arcuate shape. The embolic filter 410 can be similar to the embolic filters 110 and 210 shown in FIGS. 1A – 1D; FIGS. 2A and 2B; and described herein. In some embodiments, the embolic filter 410 is coupled to the catheter 402 proximal to the deflector 460, for example as shown in FIGS. 4A – 4B. In some embodiments, the embolic filter 410 is coupled to the catheter 402 distal to the deflector 460. The embolic filter 410 is coupled so that it is disposed around the catheter 402. This configuration advantageously allows the embolic filter 410 to engage the interior body lumen 992 (see FIG. 9D) wall, as the position of the catheter 402 within the body lumen 992 (see FIG. 9D) may be affected by the deployed deflector 460.

**[0085]** The combination of the deflector 460 and the embolic filter 410 can advantageously provide additional protection against potential complications resulting from thrombi in the blood stream. For example, if the embolic filter 410 (e.g., the distal end of the embolic filter 410) is distal to the deflector 460, the embolic filter 410 can serve as the primary means of embolic protection and the deflector 460 can serve as the secondary means of embolic protection. If some blood is able to flow around the embolic filter 410 rather than through it, the deflector 460 serves as a secondary (or back-up) protection device and prevents any debris not captured by the embolic filter 410 from entering the cerebral arteries and traveling to the brain. If the embolic filter 410 is proximal to the deflector 460, the deflector 460 can serve as the primary means of embolic protection and the embolic filter 410 can serve as the secondary means of embolic protection. The deflector 460 first deflects debris away from the carotid arteries, then the embolic filter 410 captures debris (e.g., including deflected debris) as blood flows through the descending aorta.

**[0086]** In some embodiments, the catheter 402 and outer sheath 412 can have lips, shoulders, nubs, and/or detents, for example similar to those shown in FIGS. 2A and 2B and described herein. For example, lips, shoulders, nubs, and/or detents can be positioned on the catheter 402 distal to the deflector 460, between the deflector 460 and embolic filter 410, and proximal to the embolic filter 410 to engage corresponding lips, shoulders, nubs, and/or detents on the outer sheath 412. The lips, shoulders, nubs, and/or detents can advantageously provide the user with information about the longitudinal position of the outer sheath 412 so that the user knows when neither, one, or both of the deflector 460 and embolic filter 410 are deployed. In some embodiments, either or both of the deflector 460 and embolic filter 410 can be movably coupled to the catheter 402 via an intermediate tube similar to that shown in FIGS. 3A – 3D and described herein.

[0087] An embodiment of an embolic protection device 500, similar to the embolic protection device 100 in FIGS. 1A – 1E, is shown in FIGS. 5A and 5B. The embolic protection device 500 comprises a catheter 502, an embolic filter 510, a movable outer sheath 512, and a handle 570. In some embodiments, the catheter 502 is a pigtail-type catheter as shown in the close up view of FIG. 5B and described herein. The catheter 502 includes a distal portion 504 configured to assume a generally arcuate shape being at least a semi-circle. In some embodiments, the distal portion 504 of the catheter 502 includes one or more radiopaque markers 506. A side wall of the catheter 502 may optionally include one or more apertures 508 in the distal portion 504 that are configured to deliver one or more fluids (e.g., imaging dye, contrast agent, oxygenated blood, saline, any combination thereof, or the like) to a body lumen.

[0088] As illustrated in FIG. 5B, the embolic filter 510 comprises a frame 524 and a filter medium 526. In its deployed configuration, the embolic filter 510 opens towards a distal end 516 of the catheter 502. The device 500 further comprises a pull wire 522 that is coupled to the frame 524 and can be retracted to deflect or bend the frame 524 and change the orientation and shape of the embolic filter 510, in manner similar to that described above with reference to FIGS. 1B – 1D.

[0089] Returning to FIG. 5A, the handle 570 has a wire-engagement mechanism 574 configured to advance or retract the pull wire 522 by movement of a first slider 572. The handle 570 also has a sheath-engagement mechanism 578 configured to advance or retract the deployment mechanism (e.g. outer sheath) 512 by movement of a second slider 576.

[0090] FIGS. 6A – 6G illustrate embodiments of an embolic protection device 600. In these embodiments, the embolic protection device 600 comprises a catheter 602 (e.g., a pigtail catheter) having a proximal end 614, a distal end 616, and a lumen 618 extending from the proximal end 614 to the distal end 616 along a longitudinal axis of catheter 602. The lumen 618 may be configured to house a guidewire 1290 (see FIG. 12A) that is longitudinally movable through this lumen to coil or straighten the distal portion 604 of the catheter depending on whether the guidewire is retracted (to coil the distal portion) or extended (to straighten the distal portion). In some embodiments, the catheter 602 includes a distal portion 604 configured to assume a generally arcuate shape being at least a semi-circle. A side wall of the catheter 602 may optionally include one or more apertures 608 in the distal portion 604 that are configured to deliver one or more fluids (e.g., imaging dye, contrast agent, oxygenated blood, saline, any combination thereof, or the like) to a body lumen 1292 (see FIG. 12A). The apertures 608 (the plural intended to include embodiments in which the distal portion 604 includes one aperture 608) are in fluid communication with the lumen 618.

In some embodiments, the distal portion 604 of the catheter 602 includes one or more radiopaque markers 606. In some embodiments, the radiopaque markers 606 are wrapped around the circumference of the distal portion 604 of the catheter 602 and can have the same or different widths. The embolic protection device 600 further comprises a self-expanding embolic filter 610 defined by a frame 624 and a filter medium 626, and a deployment mechanism 612 (e.g., a longitudinally retractable outer sheath or a longitudinally retractable ring). The embolic filter 610 is disposed around the catheter 602.

**[0091]** FIG. 6B illustrates the embolic filter 610 deployed in a self-expanded configuration by retraction of the deployment mechanism (e.g., outer sheath) 612. The embolic filter 610 includes a distal opening 640 that is defined by the frame 624, faces the distal end 616 of the catheter 602, and extends proximally from the distal opening 640 to a closed proximal end 642. The embolic protection device 600 further comprises a push wire 622 that is coupled to the frame 624. The push wire 622 can be advanced, in the distal direction, to deflect (or bend) and extend the frame 624; and, in turn, change the configuration of the embolic filter 610 between self-expanded, partially expanded, and fully expanded. In some embodiments, advancing the push wire 622 may cause the distal opening 640 of the embolic filter 610 to change orientation, shape, and/or size to engage at least a portion of the interior body lumen 1292 (see FIG. 12D) wall. FIG. 6B illustrates the push wire 622 in a retracted, i.e., un-advanced, state with the frame 624 extending in a distal, longitudinal direction, albeit angled back somewhat (e.g., less than about 45 degrees) in a lateral direction toward the proximal end 614. The catheter 602 may be partially surrounded towards its proximal end 614 by a support catheter 650 that terminates at a head 652, proximal to the distal portion 604 of the catheter 602. The support catheter 650 may be made of a thicker, stiffer material to add rigidity and provide a protective or supporting layer surrounding the catheter 602.

**[0092]** FIGS. 6C, 6E, and 6G show front-end views of the embolic filter 610, as viewed from the distal opening 640, in the self-expanded, partially expanded, and fully expanded configurations, respectively. The catheter 602 is removed from these views for clarity. The frame 624 comprises two sides (624a, 624b) that each extend generally in a first lateral direction away from the catheter 602/support catheter 650 and then loop back on opposite sides around the catheter 602/support catheter 650 and extend generally in the opposite lateral direction before converging and meeting to form a substantially elliptical (i.e., shaped like an ellipse), or alternatively, a substantially ovular (i.e. shaped like an oval), or circular shape. As shown, the embolic filter 610 is symmetrical about a plane (identified in the figure as a dotted line labeled "P"). For ease of discussion, the embolic filter 610 is referred to as having

a left side and a right side. Elements on the left side of the embolic filter 610 are mirrored by elements on the right side of the embolic filter 610.

**[0093]** FIGS. 6D and 6E illustrate the embolic filter 610 in the partially expanded configuration with the frame 624 deflected (i.e., bent) by advancement of the push wire 622 in the distal direction. The frame 624 comprises a movable portion 630 and a fixed portion 632. The movable portion 630 of the frame 624 can move, longitudinally, with respect to the catheter 602/support catheter 650. With respect to the catheter 602/support catheter 650, the movable portion 630 can move, longitudinally, while the fixed portion 632 cannot. The frame 624 is coupled to the push wire 622 at the movable portion 630. In a convenient embodiment, the push wire 622 and movable portion 630 are joined by a crimp. In other embodiments, the push wire 622 and movable portion 630 are joined by a weld, adhesive, or threads. The frame 624 is attached to the support catheter 650 (or alternatively, directly to the catheter 602) by the fixed portion 632. The fixed portion 632 of the frame 624 may be attached to the catheter 602/support catheter 650 by a weld, an adhesive, or the like.

**[0094]** Starting at the fixed portion 632, the frame 624 extends in a distal, longitudinal direction and then bends at an angle with respect to the longitudinal axis of the catheter 602/support catheter 650. When the push wire 622 is in its retracted state, the frame 624 bends at an acute angle and extends in a proximal, longitudinal direction such that the frame 624 folds onto itself (see FIG. 6B). Advantageously, in this configuration, the embolic filter 610 may more effectively retain embolic debris captured during a procedure. The curvature of the frame 624 adjacent the movable portion 630 may aid in collapsing the frame 624 in order to advance the outer sheath 612 over the embolic filter 610.

**[0095]** FIG. 6E shows the front-end view of the embolic filter 610, as viewed from the distal opening 640, when the push wire 622 is advanced and the embolic filter 610 assumes a partially expanded configuration. The advancing push wire 622 urges the movable portion 630 forward relative to the catheter 602/support catheter 650. (Shown in FIG. 6D as an arrow pointing away from the support catheter 650.) This in turn deflects or bends the frame 624 longitudinally in the distal direction and laterally outward. In a deflected configuration (i.e., when the push wire 622 is advanced), the distal opening 640 of the embolic filter 610 may be substantially perpendicular to the longitudinal axis of the catheter 602/support catheter 650 and may span laterally across the body lumen 1292 (see FIG. 12D), substantially perpendicular to the longitudinal axis of the body lumen 1292. In the deflected configuration, the width, $X_{bent}$, across the distal opening 640 is increased compared to the corresponding dimension in the non-deflected configuration. By increasing the width, $X_{bent}$, in the bent configuration, the frame 624 defining the distal opening 640 engages the body lumen 1292.

[0096] FIGS. 6F and 6G illustrate the embolic filter 610 in the fully expanded configuration with the frame 624 extended by the further advancement of the push wire 622 in the distal direction. Moving the push wire 622 further, distally, urges the movable portion 630 sideways relative to the catheter 602/support catheter 650. This in turn extends the frame 624 radially outward, away from the catheter 602/support catheter 650. (Shown in FIG. 6G as a left directional arrow and right directional arrow pointing away from the support catheter 650.) In some embodiments, in addition to extending the frame 624 in the radial direction, the advancing push wire 622 moves the movable portion 630 forward relative to the catheter 602/support catheter 650; which, in turn, bends the frame 624, further, in the longitudinal direction. In one embodiment, the movable portion 630 is formed with a curve or bend to aid in extending the frame 624 in the radial direction.

[0097] In an extended configuration, the width, $X_{extended}$, across the distal opening 640 is increased compared to the corresponding dimension ($X_{bent}$) in the partially expanded configuration of the embolic filter 610. By increasing the width, $X_{extended}$, in the extended configuration, the frame 624 defining the distal opening 640 engages the body lumen 1292. The increase in the width across the distal opening 640 between the partially expanded configuration ($X_{bent}$) and the fully expanded configuration ($X_{extended}$) of the embolic filter 610 (and intermediate configurations in between) may represent a range of filter sizes or diameters, e.g., 25 millimeters (mm) to 40 mm. The range of filter sizes accommodates variations in patient vasculature. Advantageously, instead of a one-size-fits-all device or multiple devices of different sizes, certain embodiments of the embolic protection device 600 provide a single device that can be tailored to a particular patient and/or a particular surgical procedure. For example, a surgeon can expand the embolic filter 610 to a first size and then adjust the embolic filter 610 to a second size to achieve a better fit within a patient's vasculature.

[0098] In some embodiments, the distal opening 640 of the embolic filter 610 has a diameter of from about 2 centimeters (cm) to about 6 cm (e.g., from about 2.5 cm to about 4 cm or to about 4.5 cm). The embolic filter 610 can comprise any suitable size or diameter to accommodate anatomic variability in patients' body lumens 1292 (see FIG. 12A).

[0099] FIGS. 7A – 7C illustrate another embodiment of an embolic protection device 700 comprising a catheter 702, an embolic filter 710, a movable outer sheath 712, and an actuating mechanism for operating the embolic filter 710. A portion of the catheter 702 is slidably received and supported by a fixed inner catheter 750 that terminates at a head 752. The fixed inner catheter 750 may be made of a thicker, stiffer material to add rigidity and provide a protective or supporting layer surrounding the catheter 702. The embolic filter 710

is disposed around the fixed inner catheter 750 and is configured to self-expand to a radially expanded configuration, as shown in FIG. 7A, when not confined or restrained by the outer sheath 712.

**[00100]** The embolic filter 710 includes a frame 724 and a filter medium 726. The frame 724 defines a distal opening 740 of the embolic filter 710 and includes a movable portion 730 for controlling the size or diameter of the distal opening 740. The embolic filter 710 extends proximally from the distal opening 740 to a closed proximal end 742. The frame 724 further includes a fixed portion 732 for attaching the frame 724 to the fixed inner catheter 750 at a location adjacent to the closed proximal end 742 of the embolic filter 710. In some embodiments, the embolic protection device 700 is similar to the embolic protection device 600 of FIGS. 6A – 6G with the addition of the actuating mechanism.

**[00101]** The actuating mechanism comprises an inner catheter 756 and an outer catheter 758. The inner catheter 756 slides over the fixed inner catheter 750. The outer catheter 758 slides over the inner catheter 756. The movement of the inner catheter 756 and outer catheter 758 relative to the fixed inner catheter 750 controls the size or diameter of the embolic filter 710, as will be described in greater detail below.

**[00102]** The embolic protection device 700 further includes a push wire 722 coupled to a distal portion 764 of the outer catheter 758. The push wire 722 is longitudinally movable between a fully retracted state, a partially advanced (or partially retracted) state, and a fully advanced state by the outer catheter 758. The push wire 722 is further coupled to the movable portion 730 of the frame 724. Moving the outer catheter 758, relative to the fixed inner catheter 750, translates into moving the push wire 722 between the fully retracted, partially advanced, and fully advanced states. This in turn urges the movable portion 730, causing the frame 724 to deflect (or bend) or extend.

**[00103]** In various embodiments of the embolic protection device 700, the foregoing device components may be coupled to each other, as described above, by any number of means and techniques. For example, in a convenient embodiment, sleeves made from polyether block amide (PEBAX®) or other similar biocompatible material attach the push wire 722 to the distal portion 764 of the outer catheter 758, attach the top guide 760 to the distal portion 766 of the inner catheter 756, and attach the bottom guide 762 to the fixed inner catheter 750. Additionally or alternatively, the device components may be joined together with a biocompatible adhesive(s).

**[00104]** The actuating mechanism further comprises a top guide 760 and a bottom guide 762 for directing the deflection and extension of the frame 724 so that the distal opening 740 of the embolic filter 710 faces towards a distal end (or working end) of the

device 220 as it expands. In some embodiments, the top guide 760 and the bottom guide 762 keep the movable portion 730 and the fixed portion 732 of the frame 724 straight, respectively. The top guide 760 and the bottom guide 762 are arranged at opposite points around the fixed inner catheter 750 with portions disposed along the fixed inner catheter 750. The top guide 760 is coupled at one end to a distal portion 766 of the inner catheter 756. A portion of the top guide 760, distal to the distal portion 766, is in slidable engagement with the fixed inner catheter 750 at or otherwise adjacent to the closed proximal end 742 of the embolic filter 710. For example, a portion of the top guide 760 slides under the filter medium 726 along the fixed inner catheter 750 and passes through the closed proximal end 742 of the embolic filter 710. The bottom guide 762 is fixedly attached to the fixed inner catheter 750 at or otherwise adjacent to the closed proximal end 742 of the embolic filter 710.

**[00105]** At the distal opening 740 of the embolic filter 710, the top guide 760 and the bottom guide 762 are movable away from the fixed inner catheter 750. The top guide 760 slidably receives the movable portion 730 of the frame 724 and the bottom guide 762 receives the fixed portion 732. The arrangement causes the top guide 760 and bottom guide 762 to flare or flex outward away from the fixed inner catheter 750 (as one moves from the closed proximal end 742 of the embolic filter 710 to the distal opening 740), thereby, giving the embolic filter 710 a general funnel-like appearance. The top guide 760 and the bottom guide 762 may also support the filter medium 726, in the longitudinal and lateral directions, between the distal opening 740 and the closed proximal end 742 of the embolic filter 710. In a convenient embodiment, the top guide 760 and the bottom guide 762 are hypotubes made from stainless steel, polyetheretherketone (PEEK), or other biocompatible material.

**[00106]** FIG. 7A further illustrates the outer sheath 712 fully retracted over the embolic filter 710 and the embolic filter 710 exposed. The inner catheter 756 and outer catheter 758 are in their initial positions (labeled "A" in the figure) relative to the fixed inner catheter 750. With the embolic filter 710 unsheathed, the movable portion 730 and the fixed portion 732 of the frame 724, with the top guide 760 and bottom guide 762, flex outwardly away from the fixed inner catheter 750. This causes the distal opening 740 of the embolic filter 710 to lie at an angle with respect to the fixed inner catheter 750. For example, the frame 724 and the fixed inner catheter 750 are at an angle of 45 degrees or less. At this stage in deployment, the embolic filter 710 is in a self-expanded configuration with the frame 724 unbent.

**[00107]** FIG. 7B illustrates the distal opening 740 partial expanded to a first size or diameter. The inner catheter 756 and outer catheter 758 are advanced in unison, distally, over the fixed inner catheter 750. The inner catheter 756 and outer catheter 758 are moved from their initial positions (labeled "A" in the figure) to their intermediate positons (labeled "B" in

the figure), relative to the fixed inner catheter 750. The concerted movement of the inner catheter 756 and the outer catheter 758 advances the push wire 722 and the top guide 760 together; and, in turn, urges the movable portion 730 of the frame 724, longitudinally, in the distal direction (forward direction). This rotates the distal opening 740 of the embolic filter 710 into an orientation substantially perpendicular to the longitudinal axis of the fixed inner catheter 750 and expands the distal opening 740 to the first size (e.g., a diameter of about 25 mm).

**[00108]** FIG. 7C illustrates the distal opening 740 fully expanded to a second size larger than the first size. In FIG. 7E, the outer catheter 758 is distally advanced over the inner catheter 756 and the fixed inner catheter 750. Without the inner catheter 756 moving, the outer catheter 758 moves from its intermediate positon (labeled "B" in the figure) to its final position (labeled "C" in the figure), relative to the fixed inner catheter 750. The continued distal movement of the outer catheter 758 moves the push wire 722 without moving the top guide 760. A length of the movable portion 730 of the frame 724 is radially played out from the top guide 760 (i.e., out of the plane of the page), extending the frame 724 and further expanding the distal opening 740 of the embolic filter 710 to the second size (e.g., a diameter of about 40 mm).

**[00109]** FIGS. 8A – 8F illustrate embodiments of an embolic protection device 800 comprising a catheter 802, an embolic filter 810, a movable outer sheath 812, and a handle 870 for manually operating the embolic filter 810. In FIG. 8B, the embolic protection device 800 further comprises a push wire 822, a filter frame 824, a filter media 826, a movable portion 830, a fixed portion 832, a fixed inner catheter 850, an inner catheter 856, an outer catheter 858, a top guide 860, and a bottom guide 862 arranged in a configuration similar to the configuration described above with reference to FIGS. 7A – 7C. For example, the push wire 822 is coupled to a distal portion 864 of the outer catheter 858, and the top guide 860 is coupled at one end to a distal portion 866 of the inner catheter 856. In some embodiments, the embolic protection device 800 is similar to the embolic protection device 700 of FIGS. 7A – 7C with the addition of the handle 870.

**[00110]** FIG. 8A illustrates the handle 870 having a first slider 872 operable for manually retracting the outer sheath 812 over the catheter 802 and the embolic filter 810 to deploy the embolic filter 810 in a self-expanded configuration. The first slider 872 is further used to manually advance the outer sheath 812 over the catheter 802 and the embolic filter 810, and collapse/recover the embolic filter 810. The handle 870 further includes a second slider 874 operable for manually increasing and decreasing the size or diameter of a distal opening 840

of the embolic filter 810. (The embolic filter 810 extends proximally from the distal opening 840 to a closed proximal end 842.)

**[00111]** In some embodiments, the catheter 802 is a pigtail-type catheter as shown in FIG. 8B and described herein. The catheter 802 includes a distal portion 804 configured to assume a generally arcuate shape being at least a semi-circle. In some embodiments, the distal portion 804 of the catheter 802 includes one or more radiopaque markers 806. A side wall of the catheter 802 may optionally include one or more apertures 808 in the distal portion 804 that are configured to deliver one or more fluids (e.g., imaging dye, contrast agent, oxygenated blood, saline, any combination thereof, or the like) to a body lumen.

**[00112]** The catheter 802 has a proximal end, a distal end 816, and a lumen 818 extending between the proximal end and the distal end 816. The lumen 818 may be configured to house a guidewire 1290 (see FIGS. 12A and 12B) that is longitudinally moveable through this lumen to coil or straighten the distal portion 804 of the catheter 802 depending on whether the guidewire is retracted (to coil the distal portion) or extended (to straighten the distal portion). The apertures 808 and the lumen 818 may in fluid communication with each other in order to deliver one or more fluids to a body lumen as described above.

**[00113]** As shown in the FIG. 8B, an example of the catheter 802 is partially surrounded towards its proximal end by the fixed inner catheter 850 that terminates at a head 852, proximal to the distal portion 804 of the catheter 802. The fixed inner catheter 850 may be made of a thicker, stiffer material to add rigidity and provide a protective or supporting layer surrounding the catheter 802.

**[00114]** FIG. 8C illustrates an example of the handle 870 (with the handle cover removed for clarity) including a sheath-engagement mechanism 876 configured to advance or retract the outer sheath 812 by movement of the first slider 872. The outer sheath 812 is joined to the sheath-engagement mechanism 876. Any number of suitable means, (e.g., fastener and/or adhesive) or techniques (e.g., sonic welding, solvent welding, and overmolding) can be used to join the outer sheath 812 and sheath-engagement mechanism 876.

**[00115]** The sheath-engagement mechanism 876 is movable within the handle 870 between a distal, initial position (shown in FIG. 8C) and a proximal, final position (shown in FIG. 8D). The initial position of the sheath-engagement mechanism 876 corresponds with the outer sheath 812 circumferentially disposed around at least a portion of embolic filter 810 and the embolic filter 810 housed in the collapsed configuration. The final position of the sheath-engagement mechanism 876 corresponds with the outer sheath 812 longitudinally retracted over the embolic filter 810 and the embolic filter 810 deployed in the self-expanded configuration.

[00116] The sheath-engagement mechanism 876 is selectively operable by the first slider 872. For example, an operator presses down on the first slider 872 with their thumb to unlock the sheath-engagement mechanism 876 from the handle 870 in order to move the sheath-engagement mechanism 876 from the initial position (shown in FIG. 8C) to the final position (shown in FIG. 8D). The operator moves the first slider 872, proximally, using their thumb to retract the outer sheath 812 and expose the embolic filter 810. To collapse/recover the embolic filter 810, the operator moves the first slider 872, distally, and advances the outer sheath 812 over the embolic filter 810.

[00117] The example of the handle 870 shown in FIG. 8C further includes an engagement mechanism 878 configured to change the size or diameter of the distal opening 840 of the embolic filter 810 by movement of the second slider 874. The engagement mechanism 878 comprises a top pull 880 and a bottom pull 882. The top pull 880 is coupled to a proximal portion of the outer catheter 858 and the bottom pull 882 is coupled to a proximal portion of the inner catheter 856 (shown in FIG. 8F).

[00118] The engagement mechanism 878 is movable within the handle 870 between an initial (proximal) position (shown in FIGS. 8C and 8D), an intermediate position (shown in FIG. 8E), and a final (distal) position (shown in FIG. 8F). The initial position of the engagement mechanism 878 corresponds with the embolic filter 810 in the self-expanded configuration with the filter frame 824 undeflected (or unbent). The intermediate position of the engagement mechanism 878 corresponds with the embolic filter 810 in a partially expanded configuration with the filter frame 824 deflected (or bent) in the longitudinal direction. The final position of the engagement mechanism 878 corresponds with the embolic filter 810 in a fully expanded configuration with the filter frame 824 extended in the radial direction.

[00119] The engagement mechanism 878 is selectively operable by the second slider 874. For example, with the engagement mechanism 878 at the initial position (shown in FIG. 8D), a user presses the second slider 874 down. The applied force causes a projection (not shown) extending from the second slider 874 to move downward through a hole (not shown) in the top pull 880 and into a recess (not shown) in the bottom pull 882.

[00120] In FIG. 8E, with combined reference to FIG. 8B, with the second slider 874 depressed and engaged with both the top pull 880 and the bottom pull 882, the operator moves the second slider 874, distally, using their thumb to advance the outer catheter 858 and the inner catheter (hidden from view) together. The concerted movement of the outer catheter 858 and the inner catheter moves the push wire 822 and the top guide 860 together (i.e., moved in unison). This in turn, advances the movable portion 830, longitudinally, in the

distal direction (forward direction), and expands the distal opening 840 of the embolic filter 810.

**[00121]** The distal opening 840 continues to expand with the distal movement of the second slider 874 until the engagement mechanism 878 reaches the intermediate position shown in FIG. 8E. At the intermediate position, the distal opening 840 is at a first size (e.g., a diameter of about 25 mm) and the second slider 874 partially disengages from the engagement mechanism 878. For example, a spring and ball plunger (not shown), located within the handle 870, lifts the projection out of the recess in the bottom pull 882. The second slider 874 disengages from the bottom pull 882 but remains engaged with the top pull 880. It may be convenient to refer to the engagement between the top pull 880 and the bottom pull 882 as temporary.

**[00122]** In FIG. 8F, with combined reference to FIG. 8B, the operator continues to move the second slider 874, distally, to advance the outer catheter 858 farther in the distal direction. With the bottom pull 882 disengaged, the inner catheter 856 and the top guide 860 are fixed in position, while the push wire 822 advances farther in the distal direction. As a result, a length of the movable portion 830 is radially played out from the top guide 860 (i.e., out of the plane of the page) and further expands the distal opening 840 of the embolic filter 810 to a next size (e.g., a diameter of about 30 mm). The distal opening 840 expands to its maximum size (e.g., a diameter of about 40 mm) when the engagement mechanism 878 is at the final position as shown in FIG. 8F. To recover the embolic filter 810, the process described above with reference to FIGS. 8C – 8F is carried out in reverse.

**[00123]** In some embodiments, a wire of an embolic protection device as described herein, e.g., the pull wire 122 of the embolic protection device 100 of FIG. 1B or the push wire 622 of the embolic protection device 600 of FIG. 6B, comprises a metal material, for example, stainless steel. Alternatively, the wire may comprise a plastic material or other suitable material. In some embodiments, the wire is stainless steel coated in polytetrafluoroethylene (PTFE). In the case of the wire being a pull wire, similar to the pull wire 122 of FIG. 1B, the pull wire is flexible but may have sufficient rigidity to deflect (or bend) a frame of an embolic filter in a proximal direction when the pull wire is retracted in a manner similar to that described above with reference to FIGS. 1C and 1D. In the case of the wire being a push wire, similar to the push wire 622 of FIG. 6B, the push wire is flexible but may have sufficient rigidity to deflect/bend a frame of an embolic filter in a distal direction when the pull wire is advanced; and to extend the frame in a radial direction when the pull wire is father advanced in a manner similar to that described above with reference to FIGS. 6D – 6F.

**[00124]** In some embodiments, a filter medium (e.g., the filter medium 126 of FIG. 1A or the filter medium 626 of FIG. 6B) comprises a braided mesh, for example braided nitinol mesh. In some embodiments, the filter medium comprises a porous membrane, for example a semi-permeable polyurethane membrane. In other embodiments, the filter medium has a pore size of from about 100 microns to about 150 microns (e.g., about 125 microns).

**[00125]** In some embodiments, an embolic filter (e.g., the embolic filter 110 of FIG. 1B or the embolic filter 610 of FIG. 6B) comprises an anti-thrombogenic coating (e.g., a heparin coating or other coating comprising a thrombin or platelet inhibitor) to advantageously reduce thrombogenicity.

**[00126]** The embolic filter is configured to self-expand to a radially expanded configuration illustrated in, for example FIGS. 1B and 1C, and FIGS. 6B and 6C, when not confined or restrained by an deployment device, such as the outer sheath 112 of FIG. 1A or the outer sheath 612 of FIG. 6A.

**[00127]** In some embodiments wherein the deployment mechanism comprises an outer sheath (e.g., the movable outer sheath 112 of FIG. 1A or the movable outer sheath 612 of FIG. 6A), the outer sheath is configured to be circumferentially disposed around at least a portion of a catheter and a embolic filter (e.g., the catheter 102 and the embolic filter 110 of FIG. 1A; or the catheter 602 and the embolic filter 610 of FIG. 6A). The outer sheath is configured to contain or house the embolic filter in a collapsed configuration. The outer sheath is longitudinally movable with respect to the catheter, and can be longitudinally retracted (i.e., moved longitudinally in a proximal direction) to deploy the embolic filter and longitudinally advanced (i.e., moved longitudinally in a distal direction) to recapture the embolic filter and any embolic material collected by the embolic filter. The embolic filter is configured to self-expand upon longitudinal retraction of the outer sheath.

**[00128]** In some embodiments, an embolic filter of an embolic protection device as described herein (e.g., the embolic filter 110 of FIG. 1A and the embolic filter 610 of FIG. 6A) is configured to at least partially collapse upon longitudinal extension of an outer sheath (e.g., the outer sheath 112 of FIG. 1A and the outer sheath 612 of FIG. 6A). In these embodiments, a distal opening of the embolic filter (e.g., the distal opening 140 of FIG. 1B and the distal opening 640 of FIG. 6B) assumes a substantially closed configuration thereby sequestering or substantially sequestering the filtered material.

**[00129]** In some embodiments, a catheter of an embolic protection device as described herein (e.g., the catheter 102 of FIG. 1A and the catheter 602 of FIG. 6A) may comprise a flexible material so as to be maneuverable within a body lumen (e.g., the body lumen 992 of FIG. 9A and the body lumen 1292 of FIG. 12A) as further described herein. For example, in

some embodiments, the catheter comprises a metal or metal alloy. In other embodiments, the catheter comprises a polymer (e.g., polyurethane, silicone, latex, polytetrafluoroethylene (PTFE), a plastic material, any combination thereof, or the like). In some embodiments, the catheter comprises a metal-reinforced plastic (e.g., including nitinol, stainless steel, and the like). Other materials are also possible. In some embodiments, the catheter is substantially free of latex (natural or synthetic), which may cause allergic reactions in some patients. In some embodiments, the catheter comprises braid-reinforced tubing to advantageously increase the strength of the catheter. In some embodiments, the catheter comprises a braided catheter shaft including a layer of braided wire between two layers of catheter tubing, which may increase the strength of the catheter. In some embodiments, the catheter does not include a braided layer, which may increase the flexibility of the catheter. In some embodiments, the catheter comprises a lubricious coating, for example a coating having a low friction coefficient, to advantageously allow for smoother navigation through tortuous vasculature. In some embodiments, the catheter coating has anti-thrombotic properties to advantageously inhibit thrombus formation. In some embodiments, the catheter has a size (i.e., outside diameter) between about 3 French and about 5 French (between about 2 mm and about 3 mm). Other sizes are also possible, for example depending on the size of the target body lumen of a particular patient. In some embodiments, the catheter has a length between about 65 centimeters (cm) and about 135 cm. Other lengths are also possible, for example to allow for insertion of the catheter in the femoral, radial, brachial, or subclavian artery. The catheter can be manufactured, for example, by extrusion, injection molding, or another suitable process.

**[00130]** In some embodiments, an embolic protection device as described herein may include one or more radiopaque marker bands located at a distal portion of a catheter. For example, the embolic protection device 100 of FIGS. 1A and 1B with the radiopaque markers 106 located at the distal portion 104 of the catheter 102. As another example, the embolic protection device 600 of FIGS. 6A and 6B with the radiopaque markers 606 located at the distal portion 604 of the catheter 602. When the distal portion assumes a generally arcuate shape, the circumferential radiopaque marker bands may be visualized to confirm that the distal portion is generally arcuate. In some embodiments, the radiopaque marker bands are located so that when the distal portion assumes its generally arcuate configuration, the marker bands are at the distal most point of the catheter, i.e., actually beyond a distal end of the catheter (e.g., beyond the distal end 116 of the catheter 102 shown in FIGS. 1A and 1B; or beyond the distal end 616 of the catheter 602 shown in FIGS. 6A and 6B).

[00131] The radiopaque markers comprise a radiopaque material, for example platinum, tantalum, tungsten, palladium, and/or iridium. Other radiopaque materials are also possible. In some embodiments, a material may be considered radiopaque, for example, if the average atomic number is greater than 24 or if the density is greater than about 9.9 g/cm$^3$. In some embodiments a distal portion of the catheter (e.g., the distal portion 104 of the catheter 102 of FIGS. 1A and 1B; and the distal portion 604 of the catheter 602 of FIGS. 6A and 6B) may be infused with a radiopaque material so that the entire distal portion is visible using imaging techniques.

[00132] In some embodiments, an outer sheath of an embolic protection device as described herein comprises a hollow tube configured to circumferentially surround at least a portion of the catheter. For example, the outer sheath 112 of the embolic protection device 100 of FIGS. 1A – 1F or the outer sheath 612 of the embolic protection device 600 of FIGS. 6A – 6G. The outer sheath is longitudinally movable with respect to the catheter and is configured to at least partially contain or house the embolic filter in a collapsed configuration when circumferentially surrounding the embolic filter, for example, as shown in FIG. 1A and FIG. 6A. The outer sheath is longitudinally proximally retractable to release the embolic filter to the expanded, open configuration when not contained by the outer sheath.

[00133] In some embodiments, the outer sheath extends proximally to a proximal end of the catheter (e.g., the proximal end 114 of the catheter 102 shown in FIG. 1A or the proximal end 614 of the catheter 602 shown in FIG. 6A) so that the user can grasp and manipulate the outer sheath directly. In some embodiments, the outer sheath extends proximally over only a portion of the catheter, and a secondary device (e.g., a push-rod such as found in stent deployment systems) is coupled to the outer sheath (e.g., to the proximal end of the outer sheath) to allow for indirect manipulation of the outer sheath. Manipulation of the outer sheath may be mechanical, electronic, manual, combinations thereof, and the like.

[00134] In some embodiments, an embolic protection device as described herein may have a longitudinally extending groove (not shown) along its outer surface. For example, the embolic protection device 100 of FIG. 1B includes a longitudinally extending groove along the catheter 102, along the support catheter 150, or along the deployment mechanism (e.g. outer sheath) 112. In another example, the embolic protection device 600 of FIG. 6B includes a longitudinally extending groove along the catheter 602, along the support catheter 650, or along the deployment mechanism/outer sheath 612. In some embodiments, the groove may extend substantially from the proximal end to the distal end of the embolic protection device. The groove may be useful for guiding another catheter device alongside the embolic protection device. For example, the groove may be useful for guiding a valve

delivery device alongside and beyond the distal end of the embolic protection device. Advantageously, the second device may be tracked along the groove and pass beyond the embolic protection device while the embolic filter is deployed as shown, for example, in FIG. 13A.

**[00135]** A device according to the disclosure herein can comprise some or all of the features of the embolic protection device 100, 200, 300, 400, 500, 600, 700, and 800 as shown in FIGS. 1A – 1F; FIGS. 2A and 2B; FIGS. 3A – 3D; FIGS. 4A – 4C; FIGS. 5A and 5B; FIGS. 6A – 6G; FIGS. 7A – 7C; and FIGS. 8A – 8F; and is described herein in various combinations.

**[00136]** III. METHODS OF CAPTURING EMBOLIC DEBRIS

**[00137]** Another aspect of the present invention provides a method 900 of capturing embolic debris during a closed-heart medical procedure (e.g., an aortic valve replacement procedure), as illustrated in a stepwise fashion in FIGS. 9A – 9E, using an embolic protection device of the present invention (e.g., the embolic protection device 100, 200, 300, 400, or 500 as described herein).

**[00138]** Referring to FIG. 9A, in one embodiment, a guidewire 990 is percutaneously inserted into a body lumen 992 of a patient, for example a femoral, radial, brachial, or subclavian artery, and navigated to the desired anatomical location, for example, the ascending aorta. The guidewire 990 can be a J-tipped wire having a diameter of about 0.035 in. (approx. 0.089 cm). Other types and dimensions of guidewires 990 useful for this method are also possible.

**[00139]** In some embodiments, the proximal end of the guidewire 990 is inserted into the opening at the distal end 116 of the catheter 102. When the guidewire 990 is in the lumen 118 of the catheter 102 at the distal portion 104 of the catheter 102, the distal portion 104 of the catheter is straightened or assumes the curvature of the guidewire 990. The distal end 116 of the catheter 102 is inserted into the body lumen 992 by tracking the lumen 118 of the catheter 102 over the guidewire 990, as shown in FIG. 9A. The outer diameter of the guidewire 990 is smaller than the inner diameter of the embolic protection device 100 such that the embolic protection device 100 may be tracked over the guidewire 990. The inner surface of the lumen 118 and/or the outer surface of the guidewire 990 may include a lubricious coating to reduce friction during tracking. The guidewire 990 keeps the distal portion 104 of the catheter 102 substantially straight (e.g., from being in the generally arcuate state) as the catheter 102 is inserted into and navigated within the patient's body.

**[00140]** The radiopaque marker(s) 106 are used to visualize and position the distal portion 104 of the catheter 102 during tracking. The guidewire 990 is retracted, i.e., moved

longitudinally in a proximal direction, a sufficient distance to allow the distal portion 104 of the catheter 102 to assume the generally arcuate shape, as shown in FIG. 9B. The distal portion 104 of the catheter 102 is positioned at the desired anatomical landmark, for example, the lower border of the noncoronary cusp of the aortic valve. The radiopaque marker(s) 106 are on the distal-most section of the distal portion 104 when the distal portion 104 assumes its generally arcuate shape. In some embodiments the distal portion 104 of the catheter 102 may be infused with a radiopaque material so that the entire distal portion 104 is visible using imaging techniques.

**[00141]** In some embodiments of the method, the proximal end 114 of the catheter 102 is connected to a contrast material injector, and contrast material is injected into the lumen 118 of the catheter 102, for example to visualize the anatomy around the device 100. The contrast material exits the catheter 102 lumen 118 through the opening at the distal end 116 of the catheter 102 and/or through one or more apertures 108 in the side wall of the catheter 102. Injecting contrast material can aid in visualizing and positioning the catheter 102.

**[00142]** In some embodiments, a second guidewire is percutaneously inserted into a second body lumen, for example the other femoral artery, and a second catheter is tracked over the second guidewire. The second catheter can carry a medical device or instrument, for example, a replacement valve, a valve repair system, or a radio frequency ablation system. Once the second catheter and associated device or instrument are properly positioned, the outer sheath 112 of the catheter 102 is longitudinally proximally retracted, allowing the embolic filter 110 to assume the expanded, deployed configuration, as shown in FIG. 9C.

**[00143]** Next, the pull wire 122 can be retracted to bend the frame 124 of the embolic filter 110. The pull wire 122 bends the frame 124 in a proximal longitudinal direction and laterally outward. In a fully bent configuration (i.e., with pull wire fully retracted), as shown in FIGS. 9D and 9E, the distal opening 140 of the embolic filter 110 may be substantially perpendicular to the catheter 102 and may span laterally across the body lumen 992, substantially perpendicular to the longitudinal axis of the body lumen 992. The fully bent configuration may engage the body lumen 992, thereby capturing embolic debris 994 in the embolic filter 110 without allowing embolic debris to travel around the outside of the embolic filter 110. The second guidewire and/or the second catheter can also be positioned after the embolic filter 110 is deployed. The distal opening 140 of the embolic filter 110 is located in the ascending aorta so that blood flows through the filter before flowing into the carotid arteries or descending aorta. In some embodiments, when the embolic filter 110 is deployed, the catheter 102 rests against the interior lumen wall, thereby stabilizing the catheter 102.

The procedure can then be performed, and embolic debris dislodged or otherwise in the blood stream during the procedure is captured by the embolic filter 110.

**[00144]** After the procedure, the pull wire 122 is advanced and the outer sheath 112 is longitudinally distally advanced to recapture the embolic filter 110, returning the frame to the unbent configuration and returning the embolic filter 110 to the collapsed configuration and capturing any embolic debris 994 (see FIG. 9E) contained within the embolic filter 110. The second catheter and catheter 102 can then be withdrawn from the patient's body. The catheter 102 can be retracted over the guidewire 990 or without straightening the distal portion 104 of the catheter 102 because the arcuate shape of the distal portion 104 is atraumatic to the blood vessels.

**[00145]** In some embodiments, the procedure performed is a cardiac valve replacement procedure, for example an aortic valve replacement procedure. The embolic protection device 100 is introduced into the patient and navigated to the aortic valve as described herein and shown in FIGS. 9A-9E. The radiopaque marker(s) 106 assist in delineating the lower border of the noncoronary cusp to assist in proper positioning of a percutaneously implanted replacement aortic valve. Once the catheter 102 is positioned, a second guidewire can be percutaneously inserted into a second body lumen and navigated to the level of the ascending aorta or left ventricle. A balloon can be tracked over the second guidewire to the aortic valve. The outer sheath 112 is then retracted to deploy the embolic filter 110 and the pull wire 122 is retracted to bend the frame 124 to a bent configuration. Balloon inflation of the valve can then be performed, and the embolic filter 110 captures embolic debris 994 dislodged during the procedure or otherwise in the blood stream. After balloon pre-dilation, the pull wire 122 is advanced and the outer sheath 112 is advanced to recapture the embolic filter 110 and any embolic debris 994 contained within the embolic filter 110. The balloon is removed, and a second catheter carrying a valvular prosthesis is advanced to the level of the ascending aorta by tracking the catheter over the second guidewire. The outer sheath 112 is again retracted to redeploy the embolic filter 110 and the pull wire 122 is again retracted. The radiopaque marker(s) 106 allow the user to properly position the valve prosthesis, for example about 4 mm to about 6 mm below the lower border of the noncoronary cusp. After the procedure is completed, the pull wire 122 is advanced and the outer sheath 112 is advanced to recapture the embolic filter 110 and any captured embolic debris 994, and the catheters are removed from the body. In some embodiments, the second catheter can be removed prior to recapturing the embolic filter 110 and embolic debris 994.

**[00146]** In some embodiments, the procedure is a cardiac valve repair procedure. The method described herein can also be adapted for a mitral valve repair or replacement

procedure. In some embodiments, the procedure is a radio frequency ablation procedure, for example to treat atrial fibrillation. In some embodiments, the procedure is a catheterization procedure or structural heart procedure.

**[00147]** In some embodiments, a method of capturing embolic debris as described herein may include inserting a second catheter device through the same vessel as the embolic protection device. The second catheter device may be inserted after the embolic protection device and may be tracked along a longitudinal groove in the outer surface of the embolic protection device. For example, a valve delivery catheter device may be guided alongside the embolic protection device and beyond the distal end of the embolic protection device by tracking the valve delivery device along the groove. Advantageously, the second device may be tracked along the groove and pass beyond the embolic protection device while the embolic filter is deployed as shown, for example, in FIG. 13A.

**[00148]** FIG. 10 illustrates another embodiment of a method 1000 of deflecting and capturing embolic debris during a medical procedure using an embolic protection device 1001. The embolic protection device 1001 is similar to the embolic protection device 300 that is described in FIGS. 3A – 3D, in that it has an intermediate tube 1030. The embolic protection device 1001 further comprises an embolic filter 1010 that is movably coupled to a catheter 1002 by way of a frame 1024 and is longitudinally movable with respect to the catheter 1002. As shown in the figure, the catheter 1002 is at least partially surrounded by a support catheter 1050 that terminates at a head 1052, proximal to a distal portion 1004 of the catheter 1002. The embolic filter 1010 is coupled to the intermediate tube 1030 that at least partially circumferentially surrounds the support catheter 1050. The intermediate tube 1030 is longitudinally movable with respect to the catheter 1002.

**[00149]** The embolic protection device 1001 further comprises an outer sheath (not shown) configured to at least partially circumferentially surround both the catheter 1002/support catheter 1050 and the intermediate tube 1030. The intermediate tube 1030 and the outer sheath can be moved simultaneously and independently. The longitudinal position of the embolic filter 1010 with respect to the catheter 1002 can be adjusted while the embolic filter 1010 is in the collapsed configuration or in a deployed or partially deployed, expanded configuration.

**[00150]** The method 1000 includes capturing emboli using the embolic protection device 1001 in a manner similar to the method 900 described above with reference to FIGS. 9A – 9E. For example, a distal end 1016 of the catheter 1002 is inserted into a body lumen 1080 of a patient by tracking a lumen 1018 of the catheter 1002 over a guidewire, which was previously percutaneously inserted into the body lumen 1080. The guidewire keeps a distal

portion 1004 of the catheter 1002 substantially straight (e.g., from being in the generally arcuate state) as the catheter 1002 is inserted into and navigated within the patient's body. The radiopaque marker 1006 is used to visualize and position the distal portion 1004 of the catheter 1002 during tracking. Visualization may also be accomplished by perfusing imaging dye or contrast agent through apertures 1008 in the distal portion 1004 of the catheter 1002. Once positioned at the desired anatomical landmark (e.g., the lower border of the noncoronary cusp of the aortic valve), the guidewire is retracted a sufficient distance to allow the distal portion 1004 of the catheter 1002 to assume the generally arcuate shape, as shown in FIG. 10.

**[00151]** The longitudinal position of the embolic filter 1010 within the body lumen 1080 can be adjusted by simultaneously moving the intermediate tube 1030 and the outer sheath. When the embolic filter 1010 is in the desired longitudinal position within the body lumen 1080, the intermediate tube 1030 is held stationary while the outer sheath is retracted to deploy the embolic filter 1010. Next, the pull wire 1022 is retracted to bend the frame 1024 and open the embolic filter 1010 to capture emboli.

**[00152]** The method 1000 further includes deflecting emboli. The embolic protection device 1001 also comprises a deflector 1060 similar to that shown in FIGS. 4A – C. Once the embolic protection device 1001 is in position (as described above), the deflector 1060 is deployed from the outer sheath to cover the brachiocephalic and left common carotid artery. In some patients, the deflector 1060 might also cover the left subclavian artery. During a subsequent medical procedure, the deflector 1060 can prevent emboli from entering the carotid arteries, and the embolic filter 1010 can capture emboli deflected by the deflector 1060 before it travels to other parts of the patient's body. The method 1000 can also be performed with various other embolic protection devices, for example as described herein, and deflector devices that may vary in configuration and how they are introduced into the body and navigated to the aortic arch.

**[00153]** FIG. 11 illustrates another embodiment of a method 1100 of deflecting and capturing embolic debris. An embolic protection device 1101 comprises a catheter 1102 (e.g., a pigtail catheter) with a radiopaque marker 1106 and an embolic filter 1110 disposed around the catheter 1102 similar to the embolic filter 110 illustrated in FIGS. 1A – 1F and described herein. As shown in the figure, the catheter 1102 is partially surrounded by a support catheter 1150 that terminates at a head 1152, proximal to a distal portion 1104 of the catheter 1102.

**[00154]** The method 1100 includes capturing emboli using the embolic protection device 1101 in a manner similar to the method 900 described above with reference to FIGS. 9A –

9E. For example, a distal end 1116 of the catheter 1102 is inserted into a body lumen 1180 of a patient by tracking a lumen 1118 of the catheter 1102 over a guidewire, which was previously percutaneously inserted into the body lumen 1180. The guidewire keeps a distal portion 1104 of the catheter 1102 substantially straight (e.g., from being in the generally arcuate state) as the catheter 1102 is inserted into and navigated within the patient's body. The radiopaque marker 1106 is used to visualize and position the distal portion 1104 of the catheter 1102 during tracking. Visualization may also be accomplished by perfusing imaging dye or contrast agent through apertures 1108 in the distal portion 1104 of the catheter 1102.

**[00155]** Once positioned at the desired anatomical landmark (e.g., the lower border of the noncoronary cusp of the aortic valve), the guidewire is retracted a sufficient distance to allow the distal portion 1104 of the catheter 1102 to assume the generally arcuate shape, as shown in FIG. 11. An outer sheath (not shown) of the catheter 1102 is longitudinally, proximally retracted, allowing the embolic filter 1110 to assume the expanded, deployed configuration, as shown in FIG. 11. Next, the pull wire 1122 is retracted to bend the frame 1124 and open the embolic filter 1110 to capture emboli.

**[00156]** The method 1100 further includes deflecting emboli with a deflector 1160. As shown, the deflector 1160 is mounted to a shaft 1162 and contained in an introducer 1168 during insertion. The introducer 1168 is introduced into the patient's body through the artery (e.g., right radial artery) and navigated to the aortic arch via the brachiocephalic artery. Once in position, the deflector 1160 is deployed from the introducer 1168 and pulled back to cover the brachiocephalic and left common carotid artery. In some patients, the deflector 1160 might also cover the left subclavian artery. In some embodiments, the deflector 1160 can be introduced and deployed before the catheter 1102 is navigated to the aortic arch. During a subsequent medical procedure, the deflector 1160 can prevent emboli from entering the carotid arteries, and the embolic filter 1110 can capture emboli deflected by the deflector 1160 before it travels to other parts of the patient's body. The method 1100 can also be performed with various other embolic protection devices, for example as described herein, and deflector devices that may vary in configuration and how they are introduced into the body and navigated to the aortic arch.

**[00157]** Another aspect of the present invention provides a method of capturing embolic debris during a closed-heart procedure, comprising inserting a distal end of a embolic protection device into a body lumen, the embolic protection device comprising a catheter having a proximal end, a distal end, and a lumen extending from the proximal end of the catheter to the distal end of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter that assumes a generally arcuate shape being at

least a semi-circle when the guidewire is at least partially longitudinally retracted; a self-expanding embolic filter that is disposed around the catheter proximal to the distal portion, wherein the embolic filter comprises a frame, and the frame defines an opening of the embolic filter; a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism; and a pull wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable, and when longitudinally retracted, bends the frame longitudinally toward the proximal end of the catheter and laterally outward from the catheter, such that the opening of the embolic filter generally faces the distal end of the catheter. The method further includes tracking the lumen of the catheter over the guidewire that is percutaneously inserted into the body lumen.

**[00158]** Some embodiments further comprise at least partially longitudinally retracting the guidewire from the lumen of the catheter, so that the distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle.

**[00159]** In some embodiments, the distal portion of the catheter comprises a radiopaque marker; and the method further comprises positioning the catheter by visualizing the radiopaque marker using an imaging technique.

**[00160]** Some embodiments comprise at least partially longitudinally retracting the deployment mechanism and allowing the self-expanding embolic filter to assume an expanded, deployed configuration.

**[00161]** Some embodiments comprise longitudinally retracting the wire, thereby bending the frame longitudinally toward the proximal end of the catheter and laterally outward from the catheter, wherein the opening defined by the frame substantially spans the body lumen.

**[00162]** Some embodiments comprise longitudinally retracting the wire to a proximal position, thereby bending the frame so that the opening of the filter defined by the frame is substantially perpendicular to the longitudinal direction of the catheter, wherein the opening defined by the frame substantially spans the body lumen.

**[00163]** In some embodiments, the embolic filter is movably coupled to the catheter and is longitudinally moveable with respect to the catheter, and the method comprises longitudinally moving the embolic filter with respect to the catheter.

**[00164]** In some embodiments, the embolic protection device comprises a self-expanding deflector coupled to the catheter proximal to the distal portion, and the method comprises deploying the self-expanding deflector to direct embolic debris toward the embolic filter.

**[00165]** In some embodiments, the deployment mechanism is a sheath that is circumferentially disposed around at least a portion of the catheter.

**[00166]** In some embodiments, the distal portion of the catheter comprises one or more apertures that communicate with the lumen of the catheter; the method further comprising perfusing a fluid into the body lumen through the one or more apertures.

**[00167]** In some embodiments, the embolic protection device comprises a longitudinal groove along an outer surface of the embolic protection device; the method further comprising inserting a second catheter device alongside the embolic protection device by tracking the second catheter device along the groove.

**[00168]** In some embodiments, the second catheter device is advanced past the embolic filter of the embolic protection device while the embolic filter is in a deployed configuration.

**[00169]** Another aspect of the present invention provides a method of capturing embolic debris during a closed-heart procedure, the method comprising inserting a distal end of a embolic protection device into a body lumen, the embolic protection device comprising a catheter having a proximal end, a distal end, and a lumen extending from the proximal end of the catheter to the distal end of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted; a self-expanding embolic filter that is disposed around the catheter proximal to the distal portion, wherein the embolic filter comprises a frame, and the frame defines an opening of the embolic filter; a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism; a wire coupled to the frame of the self-expanding filter, wherein the wire is longitudinally movable, and when longitudinally retracted, bends the frame longitudinally toward the proximal end of the catheter and laterally outward from the catheter, such that the opening of the embolic filter generally faces the distal end of the catheter

**[00170]** The method further includes tracking a lumen of the catheter over a guidewire that is percutaneously inserted into the body lumen and at least partially longitudinally retracting the guidewire from the lumen of the catheter, so that the distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle upon retracting the guidewire from the distal portion of the catheter. The method further includes longitudinally retracting the deployment mechanism and deploying the self-expanding embolic filter. The method further

includes longitudinally retracting the wire and bending the frame of the embolic filter longitudinally toward the proximal end of the catheter and laterally outward from the catheter.

**[00171]** Yet another aspect of the present invention provides a method 1200 of capturing embolic debris during a closed-heart medical procedure (e.g., an aortic valve replacement procedure), as illustrated in a stepwise fashion in FIGS. 12A – 12D, using an embolic protection device of the present invention (e.g., the embolic protection device 600, 700, or 800 as described herein).

**[00172]** Referring to FIG. 12A, in one embodiment, a guidewire 1290 is percutaneously inserted into a body lumen 1292 of a patient, for example a femoral, radial, brachial, or subclavian artery, and navigated to the desired anatomical location, for example, the ascending aorta. The guidewire 1290 can be a J-tipped wire having a diameter of about 0.035 in. (approx. 0.089 cm). Other types and dimensions of guidewires useful for this method are also possible.

**[00173]** In other embodiments, the proximal end of the guidewire 1290 is inserted into the opening at the distal end 616 of the catheter 602. When the guidewire 1290 is in the lumen 618 of the catheter 602 at the distal portion 604 of the catheter 602, the distal portion 604 of the catheter is straightened or assumes the curvature of the guidewire 1290. The distal end 616 of the catheter 602 is inserted into the body lumen 1292 by tracking the lumen 618 of the catheter 602 over the guidewire 1290, as shown in FIG. 12A. The outer diameter of the guidewire 1290 is smaller than the inner diameter of the embolic protection device 600 such that the embolic protection device 600 may be tracked over the guidewire 1290. The inner surface of the lumen 618 and/or the outer surface of the guidewire 1290 may include a lubricious coating to reduce friction during tracking. The guidewire 1290 keeps the distal portion 604 of the catheter 602 substantially straight (e.g., from being in the generally arcuate state) as the catheter 602 is inserted into and navigated within the patient's body.

**[00174]** The radiopaque marker(s) 606 are used to visualize and position the distal portion 604 of the catheter 602 during tracking. The guidewire 1290 is retracted, i.e., moved longitudinally in a proximal direction, a sufficient distance to allow the distal portion 604 of the catheter 602 to assume the generally arcuate shape, as shown in FIG. 12B. The distal portion 604 of the catheter 602 is positioned at the desired anatomical landmark, for example, the lower border of the noncoronary cusp of the aortic valve. The radiopaque marker(s) 606 are on the distal-most section of the distal portion 604 when the distal portion 604 assumes its generally arcuate shape. In some embodiments, the distal portion 604 of the catheter 602

may be infused with a radiopaque material so that the entire distal portion 604 is visible using imaging techniques.

**[00175]** In other embodiments of the method, the proximal end 614 of the catheter 602 is connected to a contrast material injector, and contrast material is injected into the lumen 618 of the catheter 602, for example to visualize the anatomy around the embolic protection device 600. The contrast material exits the lumen 618 through the opening at the distal end 616 of the catheter 602 and/or through one or more apertures 608 in the side wall of the catheter 602. Injecting contrast material can aid in visualizing and positioning the catheter 602.

**[00176]** In other embodiments, a second guidewire is percutaneously inserted into a second body lumen, for example the other femoral artery, and a second catheter is tracked over the second guidewire. The second catheter can carry a medical device or instrument, for example, a replacement valve, a valve repair system, or a radio frequency ablation system. Once the second catheter and associated device or instrument are properly positioned, the outer sheath 612 is longitudinally retracted in the proximal direction, allowing the embolic filter 610 to assume the self-expanded, deployed configuration, as shown in FIG. 12C.

**[00177]** Next, the push wire 622 can be advanced to bend the filter frame of the embolic filter 610. The push wire and the filter frame are not shown in FIGS. 12A – 12D, but can be seen in FIGS. 6B – 6F as the push wire 622 and the frame 624, respectively. The push wire bends the filter frame in a distal longitudinal direction and laterally outward. In the bent configuration (i.e., with the pull wire advanced in the distal direction), as shown in FIG. 12D, the distal opening 640 of the embolic filter 610 may be substantially perpendicular to the catheter 602 and may span laterally across the body lumen 1292, substantially perpendicular to the longitudinal axis of the body lumen 1292. To accommodate the size of the body lumen 1292, the push wire can be advanced farther to extend the frame in the radial direction and further expand the embolic filter 610.

**[00178]** The bent configuration may engage the body lumen 1292, thereby capturing embolic debris 1294 in the embolic filter 610 without allowing embolic debris to travel around the outside of the embolic filter 610. The second guidewire and/or the second catheter can also be positioned after the embolic filter 610 is deployed. The distal opening 640 of the embolic filter 610 is located in the ascending aorta so that blood flows through the embolic filter 610 before flowing into the carotid arteries or descending aorta. In some embodiments, when the embolic filter 610 is deployed, the catheter 602 rests against the interior lumen wall, thereby stabilizing the catheter 602. The procedure can then be

performed and embolic debris 1294 dislodged or otherwise in the blood stream during the procedure is captured by the embolic filter 610.

**[00179]** After the procedure, the push wire 622 is retracted and the outer sheath 612 is longitudinally and distally advanced to recapture the embolic filter 610, returning the filter frame to the unbent configuration and returning the embolic filter 610 to the collapsed configuration. And in turn capturing any embolic debris 1294 (see FIG. 12D) contained within the embolic filter 610. The second catheter and catheter 602 can then be withdrawn from the patient's body. The catheter 602 can be retracted over the guidewire 1290 or without straightening the distal portion 604 of the catheter 602 because the arcuate shape of the distal portion 604 is atraumatic to the blood vessels.

**[00180]** In other embodiments, the procedure performed is a cardiac valve replacement procedure, for example an aortic valve replacement procedure. The embolic protection device 600 is introduced into the patient and navigated to the aortic valve as described herein and shown in FIGS. 12A – 12D. The radiopaque marker(s) 606 assist in delineating the lower border of the noncoronary cusp to assist in proper positioning of a percutaneously implanted replacement aortic valve. Once the catheter 602 is positioned, a second guidewire can be percutaneously inserted into a second body lumen and navigated to the level of the ascending aorta or left ventricle. A balloon can be tracked over the second guidewire to the aortic valve. The outer sheath 612 is then retracted to deploy the embolic filter 610 and the push wire 622 is advanced to bend the frame 624 to a bent configuration. And if needed to engage the interior body lumen 1292, the push wire 622 may be advanced even farther to extend the frame 624 to an extended configuration. Balloon inflation of the valve can then be performed, and the embolic filter 610 captures embolic debris 1294 dislodged during the procedure or otherwise in the blood stream. After balloon pre-dilation, the push wire 622 is retracted and the outer sheath 612 is advanced to recapture the embolic filter 610 and any embolic debris 1294 contained within the embolic filter 610. The balloon is removed, and a second catheter carrying a valvular prosthesis is advanced to the level of the ascending aorta by tracking the catheter over the second guidewire. The outer sheath 612 is again retracted to redeploy the embolic filter 610 and the push wire 622 is again advanced. The radiopaque marker(s) 606 allow the user to properly position the valve prosthesis, for example about 4 mm to about 6 mm below the lower border of the noncoronary cusp. After the procedure is completed, the push wire 622 is retracted and the outer sheath 612 is advanced to recapture the embolic filter 610 and any captured embolic debris 1294, and the catheters are removed from the body. In some embodiments, the second catheter can be removed prior to recapturing the embolic filter 610 and embolic debris 1294.

[00181] In other embodiments, the procedure is a cardiac valve repair procedure. The method described herein can also be adapted for a mitral valve repair or replacement procedure. In some embodiments, the procedure is a radio frequency ablation procedure, for example to treat atrial fibrillation. In some embodiments, the procedure is a catheterization procedure or structural heart procedure.

[00182] In other embodiments, a method of capturing embolic debris as described herein may include inserting a second catheter device through the same vessel as the embolic protection device. The second catheter device may be inserted after the embolic protection device and may be tracked along a longitudinal groove in the outer surface of the embolic protection device. For example, a valve delivery catheter device may be guided alongside the embolic protection device and beyond the distal end of the embolic protection device by tracking the valve delivery device along the groove. Advantageously, the second device may be tracked along the groove and pass beyond the embolic protection device while the embolic filter is deployed as shown, for example, in FIG. 13A.

[00183] Another aspect of the present invention provides a method of capturing embolic debris during a closed-heart procedure, comprising inserting a distal end of a embolic protection device into a body lumen, the embolic protection device comprising a catheter having a proximal end, a distal end, and a lumen extending from the proximal end of the catheter to the distal end of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter that assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted; a self-expanding embolic filter that is disposed around the catheter proximal to the distal portion, wherein the embolic filter comprises a frame, and the frame defines an opening of the embolic filter; a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism; and a wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable with respect to the catheter; when the wire is longitudinally advanced, in a distal direction, to a first position, the wire is configured to bend the frame longitudinally towards the distal end of the catheter and laterally outward from the catheter, such that the opening of the embolic filter generally faces the distal end of the catheter and expands to a first diameter; and when the wire is longitudinally advanced, in the distal direction, to a second position distally farther than the first position, the wire is configured to extend the frame radially outward from the catheter, such that the opening of

the embolic filter expands to a second diameter larger than the first diameter. The method further includes tracking the lumen of the catheter over the guidewire that is percutaneously inserted into the body lumen.

**[00184]** Other embodiments further comprise at least partially longitudinally retracting the guidewire from the lumen of the catheter, so that the distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle.

**[00185]** In other embodiments, the distal portion of the catheter comprises a radiopaque marker; and the method further comprises positioning the catheter by visualizing the radiopaque marker using an imaging technique.

**[00186]** Other embodiments comprise at least partially longitudinally retracting the deployment mechanism and allowing the self-expanding embolic filter to assume an expanded, deployed configuration.

**[00187]** Other embodiments comprise longitudinally advancing the wire, thereby bending the frame longitudinally toward the proximal end of the catheter and laterally outward from the catheter, wherein the opening defined by the frame substantially spans the body lumen.

**[00188]** Other embodiments comprise longitudinally advancing the wire to the first position, thereby bending the frame longitudinally towards the distal end of the catheter and laterally outward from the catheter, and expanding the opening of the embolic filter to the first diameter, which substantially spans the body lumen.

**[00189]** Other embodiments comprise longitudinally advancing the wire to the second position distally farther than the first position, thereby extending the frame radially outward from the catheter and expanding the opening of the embolic filter to the second diameter larger than the first diameter, which substantially spans the body lumen.

**[00190]** In other embodiments, the deployment mechanism is a sheath that is circumferentially disposed around at least a portion of the catheter.

**[00191]** In other embodiments, the distal portion of the catheter comprises one or more apertures that communicate with the lumen of the catheter; the method further comprising perfusing a fluid into the body lumen through the one or more apertures.

**[00192]** In other embodiments, the embolic protection device comprises a longitudinal groove along an outer surface of the embolic protection device; the method further comprising inserting a second catheter device alongside the embolic protection device by tracking the second catheter device along the groove.

**[00193]** In other embodiments, the second catheter device is advanced past the embolic filter of the embolic protection device while the embolic filter is in a deployed configuration.

**[00194]** Another aspect of the present invention provides a method of capturing embolic debris during a closed-heart procedure, the method comprising inserting a distal end of a embolic protection device into a body lumen, the embolic protection device comprising a catheter having a proximal end, a distal end, and a lumen extending from the proximal end of the catheter to the distal end of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted; a self-expanding embolic filter that is disposed around the catheter proximal to the distal portion, wherein the embolic filter comprises a frame, and the frame defines an opening of the embolic filter; a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism; a wire coupled to the frame of the self-expanding filter, wherein the wire is longitudinally movable.

**[00195]** The method further includes tracking the lumen of the catheter over the guidewire that is percutaneously inserted into the body lumen and at least partially longitudinally retracting the guidewire from the lumen of the catheter, so that the distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle upon retracting the guidewire from the distal portion of the catheter. The method further includes longitudinally retracting the deployment mechanism and deploying the self-expanding embolic filter. The method further includes longitudinally advancing the wire, in a distal direction, to a first position, thereby bending the frame longitudinally towards the distal end of the catheter and laterally outward from the catheter, and expanding the opening of the embolic filter to a first diameter.

**[00196]** IV. EXAMPLES

**[00197]** Example 1: Cadaver Model

**[00198]** Referring to FIGS. 13A and 13B, an embolic protection device of the present invention (EPD-1) was tested in a human cadaver model to visually assess the device's ability to cover all cerebral vessels with an embolic filter while an endovascular device was passed through the aorta and alongside the EPD-1. In the photographs of FIGS. 13A and 13B, the EPD-1 is deployed and covering the opening of cerebral vessels of the cadaver while at the same time, a TAVR delivery system passes above the filter. In FIG. 13A, the TAVR delivery system is tracked along a longitudinal groove on the outer surface of the EPD-1 catheter. In FIG. 13B, the TAVR delivery system is tracked outside the groove of the EPD-1 catheter.

**[00199]** Example 2: Clinical Study

**[00200]** Referring to FIG. 14 and FIGS. 15A – 15J, the safety and performance of an embolic protection device according to the present invention ("EPD-1") was assessed during transcatheter aortic valve replacement (TAVR) procedures on human subjects. The primary objective was to evaluate the performance and the treatment of effect of the use of the EPD-1 during TAVR with respect to procedure-related cerebral embolic burden as determined by diffusion-weighted magnetic resonance imaging (DW-MRI). A secondary objective was to analyze the safety profile and type of captured debris from the EPD-1 filter after TAVR.

**[00201]** The study was designed as a multi-center non-randomized trial including up to 5 clinical sites to evaluate the performance and the treatment effect of the use of the EPD-1 during TAVR with respect to procedure-related silent ischemic damage and cerebral embolic burden, as determined by DW-MRI studies performed before and after the procedure. A secondary objective was to analyze the safety profile and the type of captured debris from the EPD-1 filter after TAVR. The potential risk of neurological compromise and stroke was assessed based on neurological evaluations pre and post procedure. The study population was comprised of up to thirty (30) subjects with severe native aortic valve stenosis who meet the commercially approved indications for TAVR and complied with the inclusion/exclusion criteria.

**[00202]** Primary Endpoints: 1) Device performance: defined as the successful insertion, placement, and removal of the EPD-1. Device performance was evaluated during and after completion of the TAVR index procedure. 2) Acute cerebral embolic burden reduction after TAVR, defined as number and volume of brain lesions detected with DW MRI at Day 2-5 post TAVR procedure compared with baseline.

**[00203]** Secondary Endpoints: 1) Rate of major adverse cardiac and cerebrovascular events at 30-days post TAVR index procedure compared to historical data. Major Adverse Cardiac and Cerebrovascular Events (MACCE) are defined as: All-cause mortality; All stroke (major, minor, TIA); Acute Kidney Injury (Class 3). 2) Clinical assessment of subject's neurological status pre- and post-index procedure using the NIH stroke scale.

**[00204]** Eleven subjects were enrolled in a multi-center, non-randomized, prospective pilot study. The performance characteristics of the EPD-1 were evaluated post-procedurally and scored on a 5-point score (1, unacceptable to 5, excellent). The average performance across all patients of all characteristics for the EPD-1 was 4.8 at clinical site 1 and 3.4 at clinical site 2. Average performance scores (at each of the clinical sites) for each assessed characteristic EPD-1 performance are illustrated in the bar graphs of FIG. 14. The characteristics scored were: vessel access, tracking, use of sheath and deployment buttons, positioning, re-

sheathing, removal, visualization during aortography, deployment, positioning, repositioning, retrieval, stability, visibility in place, ease to deploy, and ease to sheath.

**[00205]** Pre-to-post procedure aortic gradient measurements averaged 86.4% reduction in all eleven (11) subjects confirming success of TAVR treatments.

**[00206]** All subjects underwent DW-MRI pre-and-post-procedure, and evaluation of images were consistent with identification of some ischemic lesions. MRI was performed at the Baseline and Pre-Discharge (Day 2-5) visits in the eleven (11) subjects that underwent a Transcatheter Aortic Valve Replacement (TAVR) procedure at each of the two clinical sites. The MRI protocol consisted of the following sequences: Axial DWI, Axial FLAIR and 3D T1-weighted IR-GRE. DWI contrast is sensitive to water molecules and helps locate and quantify fresh lesions. Total lesions were counted, lesion location, size and volume was assessed, and total lesion volume were analyzed. FIGS. 15A – 15J show the DW-MRI images of the brains for three (3) representative human subjects (001-05, 001-06 and 002-01).

**[00207]** A median lesion count of 6 and a median lesion volume of 193.9 $mm^3$ were observed among the eleven (11) subjects. A breakdown of lesions by location is detailed in Table 1. These results indicate a lower lesion count and volume when compared to both historical controls and clinical trials involving cleared and investigational embolic protection devices.

**[00208]** Table 1: Brain lesions by location for all patients (clinical sites 1 and 2) from the clinical study.

| **Vascular Territory** | **Lesion Count** |
|---|---|
| Anterior Choroidal Artery | 2 |
| Anterior Cerebral Artery | 3 |
| Middle Cerebral Artery | 40 |
| Posterior Cerebral Artery | 22 |
| Vertebrobasilar Artery | 1 |
| Anterior Inferior Cerebellar Artery | 0 |
| Posterior Inferior Cerebellar Artery | 12 |
| **Total Lesion Count (Entire Brain)** | **80** |

**[00209]** Table 2 provides a detailed comparison of lesion count and volume between the clinical study of this Example 2 and clinical studies for comparable devices. These results demonstrate that protection using the EPD-1 could reduce the number of ischemic lesions or their volume, thus supporting the utility of the procedure.

[00210] Table 2: Comparison of EPD-1 performance to that of cleared and investigational devices.

| Study | Device | # of Subjects | Median Lesion Count | Median Lesion Volume ($mm^3$) | Time Range of Imaging |
|---|---|---|---|---|---|
| CLEAN-TAVI | None (control) | 45 | 16 | 800 | 2 D |
| **EXAMPLE 2** | **EPD-1** | **11*** | **6** | **193.9** | **<48 hours** |
| SENTINEL | Claret Medical Sentinel | 91 | 3 Protected areas only | 294 | 2 – 7D |
| PROTAVI-C | Edwards Lifesciences Embrella Embolic Deflector System (investigational) | 42 | 8 | 305 | 7D |
| DEFLECT-III | TriGuard™ HDH Embolic Deflection Device (investigational) | 46 | N/A | 46% > 150 | 2 – 6D |

[00211] The time point at which MRI was taken differs between these studies. Whereas DW-MRI was performed within 48 hours post-procedure for all patients in Example 2; for other referenced studies, imaging was performed at a longer time point. Because the appearance of hyper-intensity during DW-MRI imaging is known to evolve over time, these other referenced studies would have likely observed a higher lesion volume, had DW-MRI been taken within 48 hours post-procedure. Nonetheless, the EPD-1 outperformed the referenced, comparable devices with respect to acute cerebral embolic burden reduction. Three patients had elevated lesion counts; however, they were considered outliers as the filter was recaptured and the TAVR device post dilated. During these outlier procedures, the operators were concerned about interaction of the balloon catheter with the filter frame due to the small anatomy of the aorta. This typically results in liberation of debris.

[00212] The EPD-1 captured thrombi in all procedures. Two examples of captured thrombi are shown in the photographs of FIGS. 16A and 16B. The photograph of FIG. 16A shows a thrombi captured by the EPD-1 of Example 2. The photograph of FIG. 16B shows an actual pathologic finding of a 4.6 mm collagenous fragment captured within the EPD-1 filter during a TAVR procedure. Neurological evaluation of all patients using NIHSS at discharge and 30 days post-procedure showed that scores for all patients remained at baseline levels, except for one patient developing limb ataxia. No serious adverse events were

recorded. Debris captured by the embolic filter of the EPD-1 included collagen, fibrin, thrombi, and calcium.

**[00213]** A summary of endpoints is shown in Table 3.

**[00214]** Table 3: Summary of endpoints from the clinical studies of Example 2.

| **Endpoints** | **Result** | |
|---|---|---|
| | Success | Failure |
| Primary Endpoints | | |
| Device performance successful deployment and retrieval | 100% | 0% |
| Acute cerebral embolic burden reduction after TAVR | The EPD-1 device showed reduction in acute cerebral embolic burden when compared to both historical controls and other marketed and investigational devices. | |
| Secondary Endpoints | | |
| MACCE, 30-days post-procedure (No Events) | 100% | 0% |
| NIH stroke scale pre-and-post-procedure | 100% (Scores=0) | 0% |
| Gross histologic evaluation of embolic debris captured | 100% | 0% |

## OTHER EMBODIMENTS

**[00215]** It is to be understood that while the invention has been described in conjunction with the detailed description thereof, the foregoing description is intended to illustrate and not limit the scope of the invention, which is defined by the scope of the appended claims. Other aspects, advantages, and modifications are within the scope of the following claims.

**[00216]** It is to be understood by one having ordinary skill in the art that the specific devices and processes illustrated in the attached drawings and described in this specification are simply example embodiments of the inventive concepts defined in the appended claims. Hence, specific dimensions and other physical characteristics relating to the embodiments disclosed herein are not to be considered as limiting, unless the claims expressly state otherwise. It is also to be understood that construction of the described invention and other components is not limited to any specific material. Other example embodiments of the invention disclosed herein may be formed from a wide variety of materials, unless described otherwise herein.

**[00217]** Changes and modifications in the specifically-described embodiments may be carried out without departing from the principles of the present invention, which is intended to be limited only by the scope of the appended claims as interpreted according to the principles of patent law including the doctrine of equivalents.

What is claimed is:

1. An embolic protection device comprising:

a catheter having a proximal end, a distal end, and a lumen extending from the proximal end to the distal end along a longitudinal axis of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter that assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted;

a self-expanding embolic filter that is disposed around the catheter, proximal to the distal portion, wherein the embolic filter comprises a frame and the frame defines an opening of the embolic filter;

a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism; and

a wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable, and when longitudinally retracted, is configured to bend the frame longitudinally toward the proximal end of the catheter and laterally outward from the catheter, such that the opening of the embolic filter generally faces the distal end of the catheter.

2. The embolic protection device of claim 1, wherein the wire is coupled to the frame at a distal coupling.

3. The embolic protection device of either of claims 1 or 2, wherein the wire, when longitudinally retracted to a proximal position, is configured to bend the frame so that the opening of the embolic filter defined by the frame is substantially perpendicular to the longitudinal axis of the catheter.

4. The embolic protection device of any one of claims 1-3, wherein the wire, when longitudinally advanced to a distal position, is configured to position the frame so that the opening of the embolic filter defined by the frame is substantially parallel or angled less than 45 degrees with respect to longitudinal axis of the catheter.

5. The embolic protection device of any one of claims 1-4, wherein embolic protection device has a handle, wherein the handle comprises a mechanism configured to advance or retract the wire.

6. The embolic protection device of any one of claims 1-5, wherein embolic protection device has a handle, wherein the handle comprises a mechanism configured to advance or retract the deployment mechanism.

7. The embolic protection device of any one of claims 1-6, wherein the opening of the embolic filter defined by the frame is substantially in the shape of an ellipse.

8. The embolic protection device of any one of claims 1-7, wherein the catheter extends through the opening of the embolic filter.

9. The embolic protection device of any one of claims 1-8, wherein the distal portion of the catheter comprises a radiopaque marker.

10. The embolic protection device of claim 9, wherein the radiopaque marker comprises one or more circumferential bands.

11. The embolic protection device of any one of claims 1-10, wherein the frame comprises a shape memory material.

12. The embolic protection device of any one of claims 1-11, wherein the embolic filter comprises a filter medium, which comprises a semi-permeable polyurethane material having a pore size of from about 100 microns to about 150 microns.

13. The embolic protection device of any one of claims 1-12, wherein the embolic protection device comprises a longitudinal groove along an outer surface of the embolic protection device.

14. The embolic protection device of any one of claims 1-13, further comprising a self-expanding deflector coupled to the catheter, proximal to the distal portion, wherein the deflector has a longitudinal axis parallel to the longitudinal axis of the catheter.

15. The embolic protection device of any one of claims 1-14, wherein the deployment mechanism comprises a sheath that is circumferentially disposed around at least a portion of the catheter, wherein the sheath deploys the self-expanding embolic filter when the sheath is at least partially longitudinally retracted.

16. The embolic protection device of any one of claims 1-15, wherein the distal portion of the catheter comprises one or more apertures that communicates with the lumen of the catheter.

17. A method of capturing embolic debris during a closed-heart procedure, the method comprising:

inserting a distal end of a embolic protection device into a body lumen, the embolic protection device comprising:

a catheter having a proximal end, a distal end, and a lumen extending from the proximal end to the distal end along a longitudinal axis of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter that assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted;

a self-expanding embolic filter that is disposed around the catheter, proximal to the distal portion, wherein the embolic filter comprises a frame, and the frame defines an opening of the embolic filter;

a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism; and

a wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable, and when longitudinally retracted, bends the frame longitudinally toward the proximal end of the catheter and laterally outward from the catheter, such that the opening of the embolic filter generally faces the distal end of the catheter; and

tracking the lumen of the catheter over the guidewire that is percutaneously inserted into the body lumen.

18. The method of claim 17, further comprising at least partially longitudinally retracting the guidewire from the lumen of the catheter so that the distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle.

19. The method of either of claims 17 or 18, wherein the distal portion of the catheter comprises a radiopaque marker; the method further comprising positioning the catheter by visualizing the radiopaque marker using an imaging technique.

20. The method of any one of claims 17-19, further comprising at least partially longitudinally retracting the deployment mechanism and allowing the self-expanding embolic filter to assume an expanded, deployed configuration.

21. The method of any one of claims 17-20, further comprising longitudinally retracting the wire, thereby bending the frame longitudinally toward the proximal end of the catheter and laterally outward from the catheter, wherein the opening defined by the frame substantially spans the body lumen.

22. The method of any one of claims 17-20, further comprising longitudinally retracting the wire to a proximal position, thereby bending the frame so that the opening of the embolic filter defined by the frame is substantially perpendicular to the longitudinal axis of the catheter, wherein the opening defined by the frame substantially spans the body lumen.

23. The method of any one of claims 17-22, wherein the embolic filter is movably coupled to the catheter and is longitudinally moveable with respect to the catheter; the method further comprising longitudinally moving the embolic filter with respect to the catheter.

24. The method of any one of claims 17-23, wherein the embolic protection device further comprises a self-expanding deflector coupled to the catheter, proximal to the distal portion; the method further comprising deploying the self-expanding deflector to direct embolic debris toward the embolic filter.

25. The method of any one of claims 17-24, wherein the deployment mechanism is a sheath that is circumferentially disposed around at least a portion of the catheter.

26. The method of any one of claims 17-25, wherein the distal portion of the catheter comprises one or more apertures that communicate with the lumen of the catheter; the method further comprising perfusing a fluid into the body lumen through the one or more apertures.

27. The method of any one of claims 17-26, wherein the embolic protection device comprises a longitudinal groove along an outer surface of the embolic protection device; the method further comprising inserting a second catheter device alongside the embolic protection device by tracking the second catheter device along the groove.

28. The method of claim 27, wherein the second catheter device is advanced past the embolic filter of the embolic protection device while the embolic filter is in a deployed configuration.

29. A method of capturing embolic debris during a closed-heart procedure, the method comprising:

inserting a distal end of a embolic protection device into a body lumen, the embolic protection device comprising:

a catheter having a proximal end, a distal end, and a lumen extending from the proximal end of the catheter to the distal end of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted;

a self-expanding embolic filter that is disposed around the catheter, proximal to the distal portion, wherein the embolic filter comprises a frame, and the frame defines an opening of the embolic filter;

a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism;

a wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable, and when longitudinally retracted, bends the frame longitudinally toward the proximal end of the catheter and laterally outward from the catheter, such that the opening of the embolic filter generally faces the distal end of the catheter; and

tracking the lumen of the catheter over the guidewire that is percutaneously inserted into the body lumen;

at least partially longitudinally retracting the guidewire from the lumen of the catheter, so that the distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle upon retracting the guidewire from the distal portion of the catheter;

longitudinally retracting the deployment mechanism and deploying the self-expanding embolic filter; and

longitudinally retracting the wire and bending the frame of the embolic filter longitudinally toward the proximal end of the catheter and laterally outward from the catheter.

30. A method for capturing embolic debris during a closed-heart procedure comprising:

(i) providing an embolic protection device, wherein the embolic protection device comprises:

a catheter having a proximal end, a distal end, and a lumen extending from the proximal end of the catheter to the distal end of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter that assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted;

a self-expanding embolic filter that is disposed around the catheter, proximal to the distal portion, wherein the embolic filter comprises a frame and the frame defines an opening of the embolic filter;

a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism; and

a wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable, and when longitudinally retracted, is configured to bend the frame longitudinally toward the proximal end of the catheter and laterally outward from the catheter, such that the opening of the embolic filter generally faces the distal end of the catheter; and

(ii) inserting a distal end of the embolic protection device into a body lumen by tracking the lumen of the catheter over a guidewire that is percutaneously inserted into the body lumen; and

(iii) longitudinally retracting the deployment mechanism and deploying the a self-expanding embolic filter.

31. An embolic protection device comprising:

a catheter having a proximal end, a distal end, and a lumen extending from the proximal end to the distal end along a longitudinal axis of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter that assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted;

a self-expanding embolic filter that is disposed around the catheter, proximal to the distal portion, wherein the embolic filter comprises a frame and the frame defines an opening of the embolic filter;

a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism;

a wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable with respect to the catheter;

when the wire is longitudinally advanced, in a distal direction, to a first position, the wire is configured to bend the frame longitudinally towards the distal end of the catheter and laterally outward from the catheter, such that the opening of the embolic filter generally faces the distal end of the catheter and expands to a first diameter; and

when the wire is longitudinally advanced, in a distal direction, to a second position distally farther than the first position, the wire is configured to extend the frame radially outward from the catheter, such that the opening of the embolic filter expands to a second diameter larger than the first diameter.

32. The embolic protection device of claim 31, wherein the wire, when longitudinally advanced to the first position, is configured to bend the frame so that the opening of the embolic filter defined by the frame is substantially perpendicular to the longitudinal axis of the catheter.

33. The embolic protection device of any one of claims 31 or 32, wherein the wire, when longitudinally retracted to a proximal position, is configured to position the frame so that the

opening of the embolic filter defined by the frame is substantially parallel or angled less than 45 degrees with respect to the longitudinal axis of the catheter.

34. The embolic protection device of claim 31, wherein the frame includes two sides; and

each side of the frame extending generally in a first lateral direction away from the catheter and then looping back on an opposite side around the catheter, and extend generally in the opposite lateral direction before converging and meeting to form the opening of the embolic filter having a substantially elliptical, ovular or circular shape.

35. The embolic protection device of claim 31, wherein the frame includes

a fixed portion coupled to the catheter, proximal to the distal portion, wherein the fixed portion does not move in a longitudinal direction; and

a movable portion continuous with the fixed portion of the frame, wherein the movable portion is coupled to the wire and is urged by the wire;

when the wire is advanced to the first position, the wire urges the movable portion of the frame, in a longitudinal direction, towards the distal end of the catheter and bends the frame to expand the opening of the embolic filter to the first diameter; and

when the wire is advanced to the second position, the wire urges the movable portion of the frame, in a radial direction, away from the catheter and extends the frame to expand the opening of the embolic filter to the second diameter.

36. The embolic protection device of claim 35, further comprising an outer catheter disposed around at least a portion of the catheter and coaxial with the lumen of the catheter, wherein the outer catheter is longitudinally slidable over the catheter; and

wherein the wire is coupled to a distal portion of the outer catheter such that the wire is moved by the outer catheter sliding over the catheter.

37. The embolic protection device of claim 36, further comprising an inner catheter disposed between the outer catheter and the catheter, wherein the inner catheter is longitudinally slidable over the catheter; and

a guide attached at one end to a distal portion of the inner catheter so that the guide is moved by the inner catheter sliding over the catheter, wherein the guide slidably receives the movable portion of the frame causing the guide to flex outwardly away from the catheter.

38. The embolic protection device of claim 37, wherein the guide is a top guide and the embolic protection device further comprising a bottom guide attached at one end to the catheter, wherein the bottom guide and the top guide are arranged on opposite sides of the catheter, and wherein the bottom guide receives the fixed portion of the frame causing the bottom guide to flex outwardly away from the catheter.

39. The embolic protection device of any one of claims 31-35, wherein embolic protection device has a handle, wherein the handle comprises a mechanism configured to advance or retract the wire.

40. The embolic protection device of claim 37, further comprising:

a handle coupled to the proximal end of the catheter;

a top pull coupled to a proximal portion of the outer catheter and is longitudinally movable within the handle;

a bottom pull coupled to a proximal portion of the inner catheter and is longitudinally movable within the handle, wherein the bottom pull is in temporary engagement with the top pull;

when the top pull and the bottom pull are engaged, the top pull and the bottom pull are moved in unison by movement of a slider, which, in turn, urges the guide together with the movable portion of the frame in the longitudinal direction and expands the opening of the embolic filter to the first diameter; and

when the top pull and the bottom pull are disengaged, the top pull is moved without the bottom pull by movement of the slider, which, in turn, urges the movable portion of the frame in the radial direction and expands the opening of the embolic filter to the second diameter.

41. The embolic protection device of any one of claims 31-40, wherein the catheter extends through the opening of the embolic filter.

42. The embolic protection device of any one of claims 31-41, wherein the distal portion of the catheter comprises a radiopaque marker.

43. The embolic protection device of claim 42, wherein the radiopaque marker comprises one or more circumferential bands.

44. The embolic protection device of any one of claims 31-43, wherein the frame comprises a shape memory material.

45. The embolic protection device of any one of claims 31-44, wherein the embolic filter comprises a filter medium, which comprises a semi-permeable polyurethane material having a pore size of from about 100 microns to about 150 microns.

46. The embolic protection device of any one of claims 21-45, wherein the embolic protection device comprises a longitudinal groove along an outer surface of the embolic protection device.

47. The embolic protection device of any one of claims 31-46, wherein the deployment mechanism comprises a sheath that is circumferentially disposed around at least a portion of the catheter, wherein the sheath deploys the self-expanding embolic filter when the sheath is at least partially longitudinally retracted.

48. The embolic protection device of any one of claims 31-47, wherein the distal portion of the catheter comprises one or more apertures that communicates with the lumen of the catheter.

49. A method of capturing embolic debris during a closed-heart procedure, the method comprising:

inserting a distal end of a embolic protection device into a body lumen, the embolic protection device comprising:

a catheter having a proximal end, a distal end, and a lumen extending from the proximal end to the distal end along a longitudinal axis of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter that assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted;

a self-expanding embolic filter that is disposed around the catheter, proximal to the distal portion, wherein the embolic filter comprises a frame and the frame defines an opening of the embolic filter;

a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed

configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism;

a wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable with respect to the catheter;

when the wire is longitudinally advanced, in a distal direction, to a first position, the wire is configured to bend the frame longitudinally towards the distal end of the catheter and laterally outward from the catheter, such that the opening of the embolic filter generally faces the distal end of the catheter and expands to a first diameter; and

when the wire is longitudinally advanced, in the distal direction, to a second position distally farther than the first position, the wire is configured to extend the frame radially outward from the catheter, such that the opening of the embolic filter expands to a second diameter larger than the first diameter; and

tracking the lumen of the catheter over the guidewire that is percutaneously inserted into the body lumen.

50. The method of claim 49, further comprising at least partially longitudinally retracting the guidewire from the lumen of the catheter so that the distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle.

51. The method of either of claims 49 or 50, wherein the distal portion of the catheter comprises a radiopaque marker; the method further comprising positioning the catheter by visualizing the radiopaque marker using an imaging technique.

52. The method of any one of claims 49-51, further comprising at least partially longitudinally retracting the deployment mechanism and allowing the self-expanding embolic filter to assume an expanded, deployed configuration.

53. The method of claim 49-52, further comprising longitudinally advancing the wire to the first position, thereby bending the frame longitudinally towards the distal end of the catheter and laterally outward from the catheter, and expanding the opening of the embolic filter to the first diameter, which substantially spans the body lumen.

54. The method of claim 53, further comprising longitudinally advancing the wire to the second position distally farther than the first position, thereby extending the frame radially

outward from the catheter and expanding the opening of the embolic filter to the second diameter larger than the first diameter, which substantially spans the body lumen.

55. The method of any one of claims 49-52, further comprising longitudinally advancing the wire to the first position, thereby bending the frame so that the opening of the embolic filter defined by the frame is substantially perpendicular to the longitudinal axis of the catheter, wherein the opening defined by the frame, substantially spans the body lumen.

56. The method of any one of claims 49-55, wherein the deployment mechanism is a sheath that is circumferentially disposed around at least a portion of the catheter.

57. The method of any one of claims 49-56, wherein the distal portion of the catheter comprises one or more apertures that communicate with the lumen of the catheter; the method further comprising perfusing a fluid into the body lumen through the one or more apertures.

58. The method of any one of claims 49-57, wherein the embolic protection device comprises a longitudinal groove along an outer surface of the embolic protection device; the method further comprising inserting a second catheter device alongside the embolic protection device by tracking the second catheter device along the groove.

59. The method of claim 58, wherein the second catheter device is advanced past the embolic filter of the embolic protection device while the embolic filter is in a deployed configuration.

60. A method of capturing embolic debris during a closed-heart procedure, the method comprising:

inserting a distal end of a embolic protection device into a body lumen, the embolic protection device comprising:

a catheter having a proximal end, a distal end, and a lumen extending from the proximal end of the catheter to the distal end of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter that assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted;

a self-expanding embolic filter that is disposed around the catheter, proximal to the distal portion, wherein the embolic filter comprises a frame and the frame defines an opening of the embolic filter;

a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism; and

a wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable with respect to the catheter;

tracking the lumen of the catheter over the guidewire that is percutaneously inserted into the body lumen;

at least partially longitudinally retracting the guidewire from the lumen of the catheter, so that the distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle upon retracting the guidewire from the distal portion of the catheter;

longitudinally retracting the deployment mechanism and deploying the self-expanding embolic filter;

longitudinally advancing the wire, in a distal direction, to a first position, thereby bending the frame longitudinally towards the distal end of the catheter and laterally outward from the catheter, and expanding the opening of the embolic filter to a first diameter.

61. The method of claim 60, further comprising longitudinally advancing the wire, in the distal direction, to a second position distally farther than the first position, thereby extending the frame radially outward from the catheter and expanding the opening of the embolic filter to a second diameter larger than the first diameter.

62. A method for capturing embolic debris during a closed-heart procedure comprising:

(i) providing an embolic protection device, wherein the embolic protection device comprises:

a catheter having a proximal end, a distal end, and a lumen extending from the proximal end of the catheter to the distal end of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter that assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted;

a self-expanding embolic filter that is disposed around the catheter, proximal to the distal portion, wherein the embolic filter comprises a frame and the frame defines an opening of the embolic filter;

a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism; and

a wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable with respect to the catheter; and

(ii) inserting a distal end of the embolic protection device into a body lumen by tracking the lumen of the catheter over a guidewire that is percutaneously inserted into the body lumen;

(iii) longitudinally retracting the deployment mechanism and deploying the a self-expanding embolic filter; and

(iv) longitudinally advancing the wire, in a distal direction, to a first position, thereby bending the frame longitudinally towards the distal end of the catheter and laterally outward from the catheter, and expanding the opening of the embolic filter to a first diameter.

63. The method of claim 62, further comprising longitudinally advancing the wire, in the distal direction, to a second position distally farther than the first position, thereby extending the frame radially outward from the catheter and expanding the opening of the embolic filter to a second diameter larger than the first diameter.

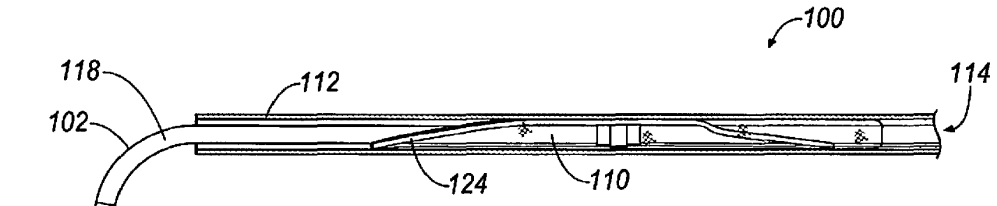

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FIG. 1A

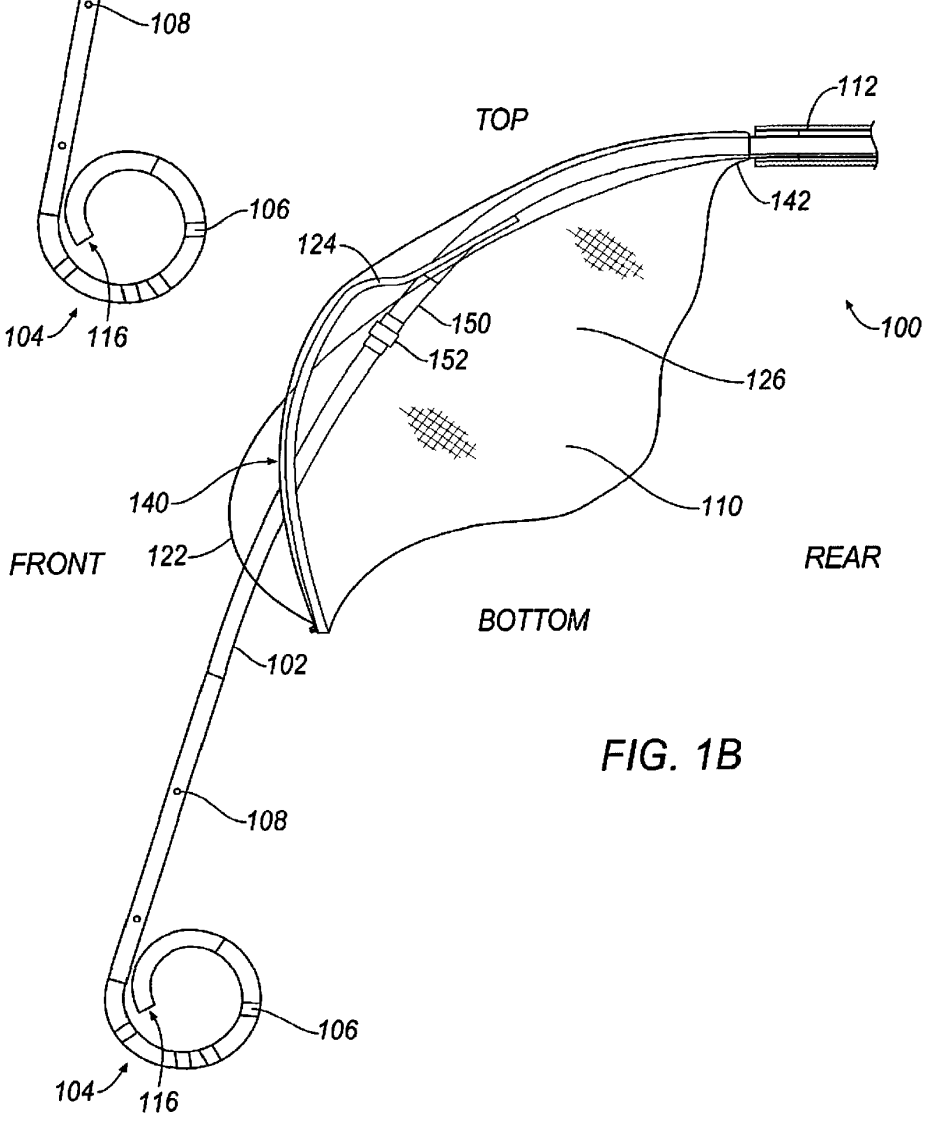

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FIG. 1B

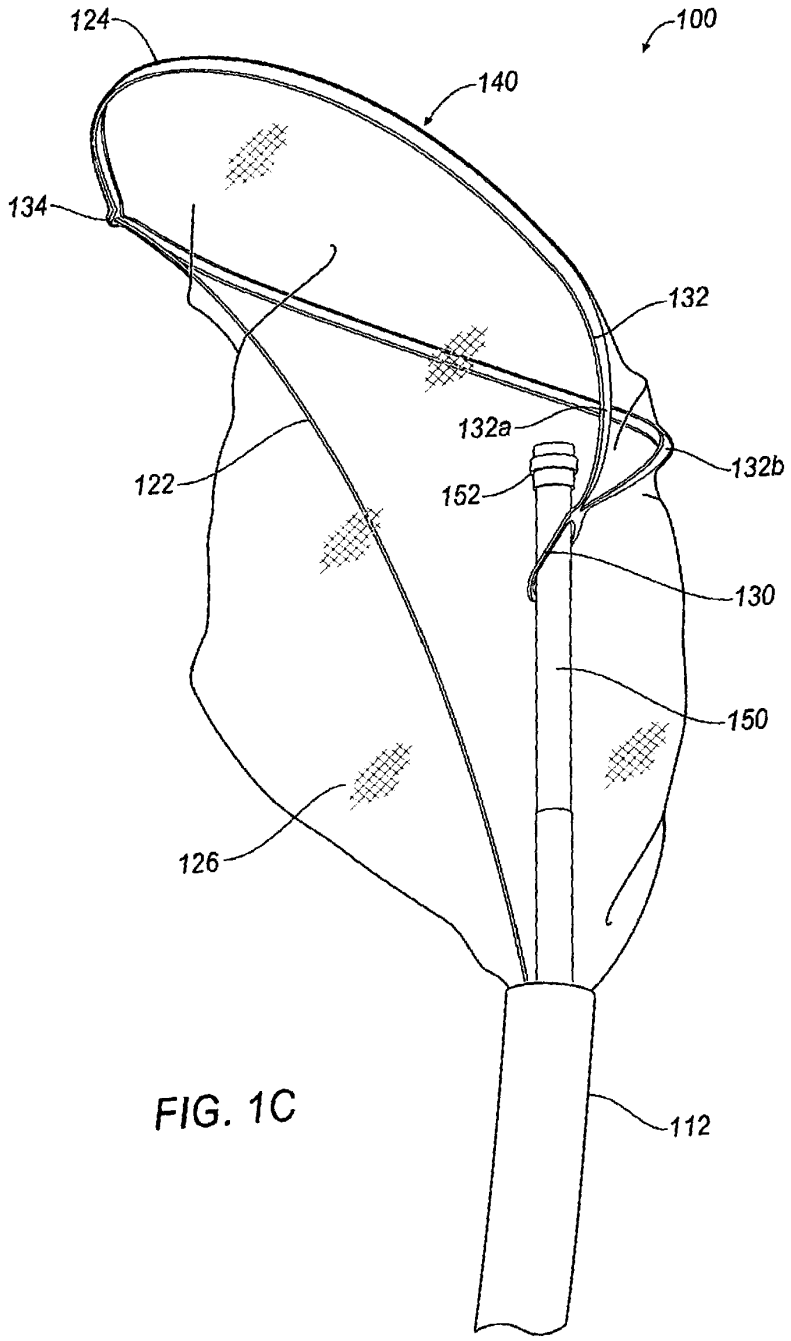



FIG. 1C

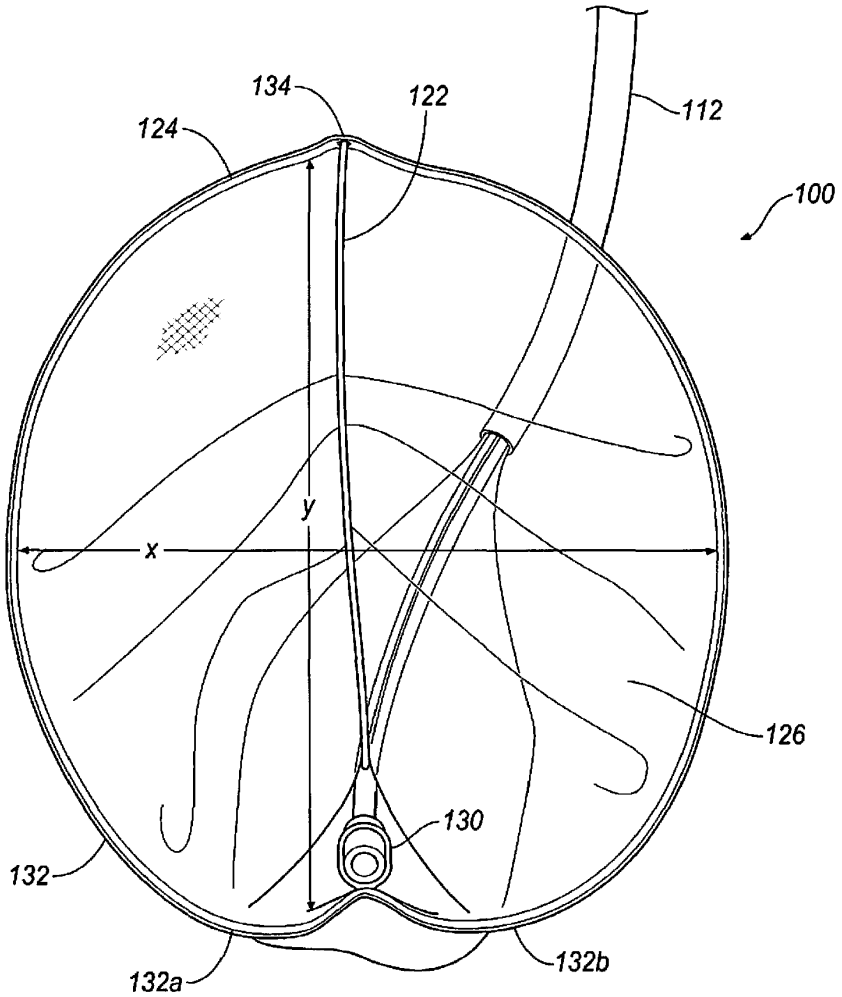



FIG. 1D

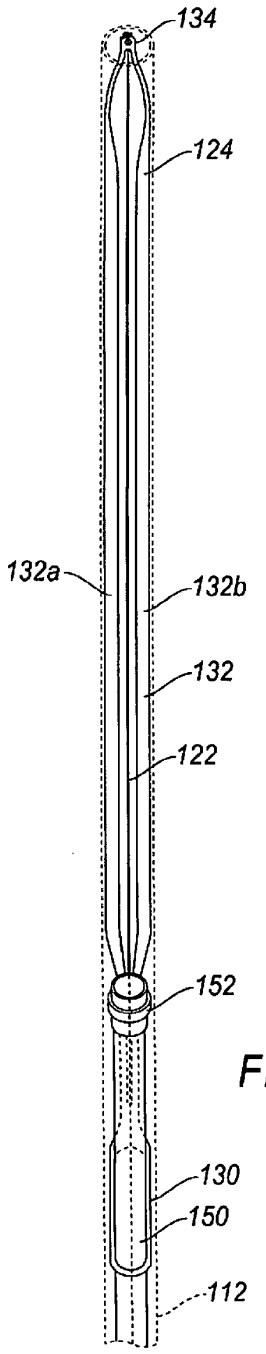

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FIG. 1E

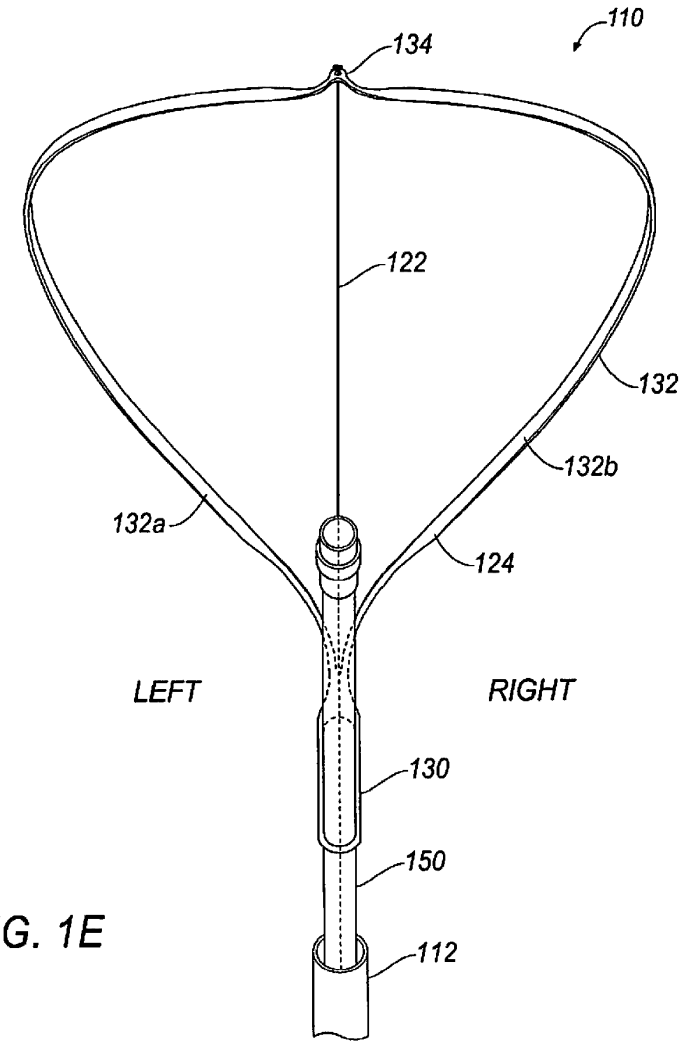

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FIG. 1F

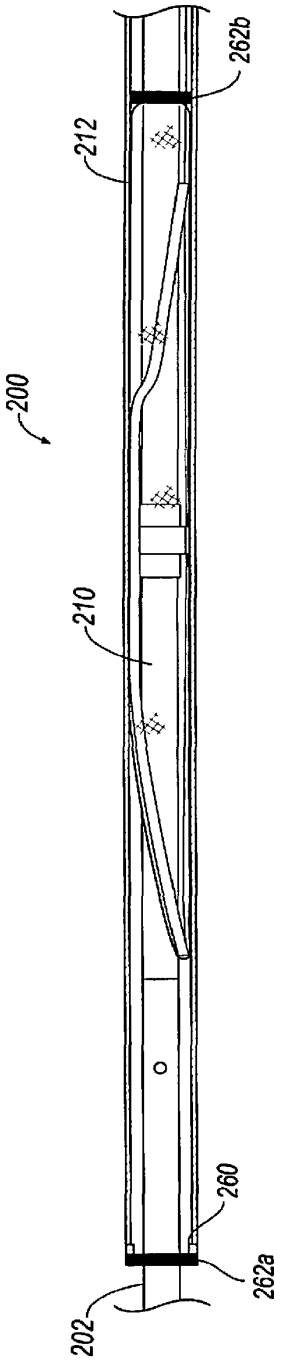

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FIG. 2A

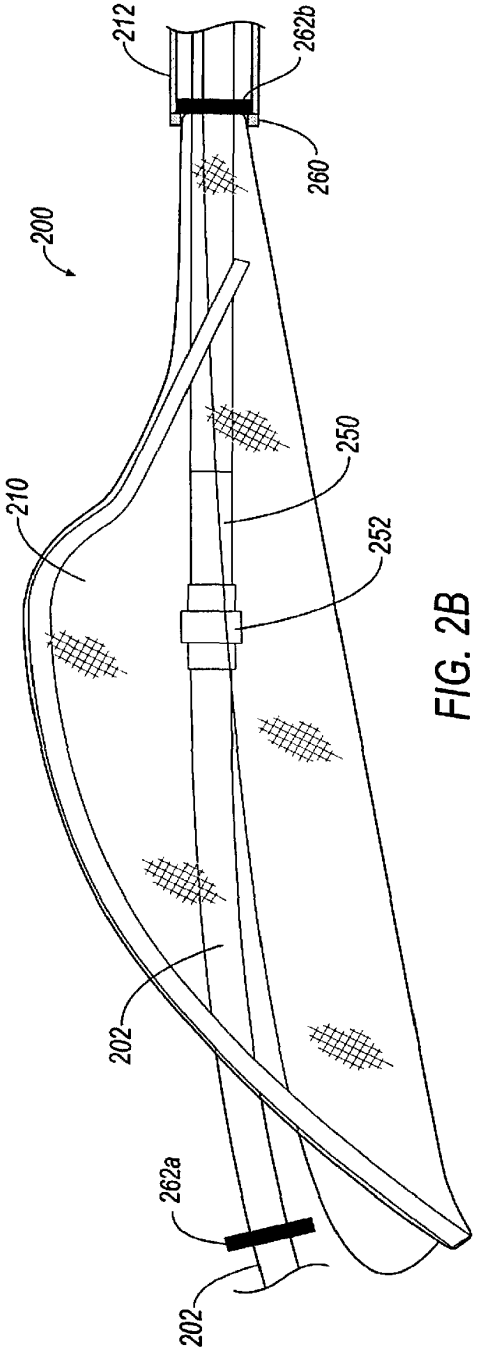

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FIG. 2B

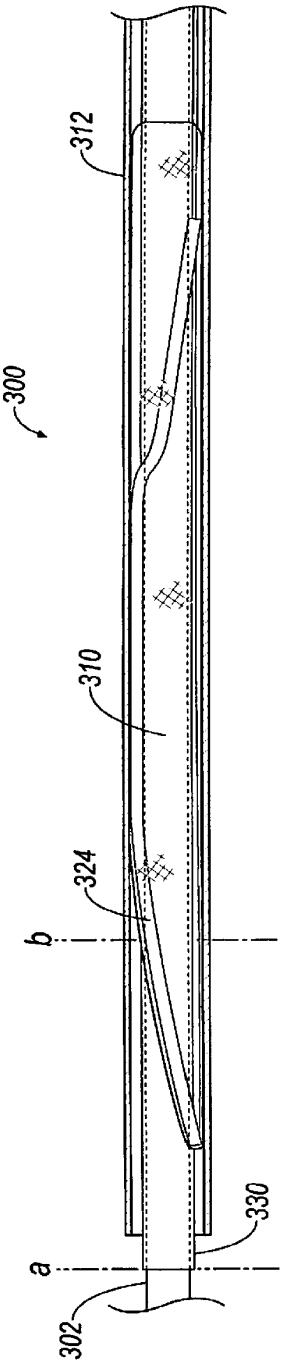



FIG. 3A

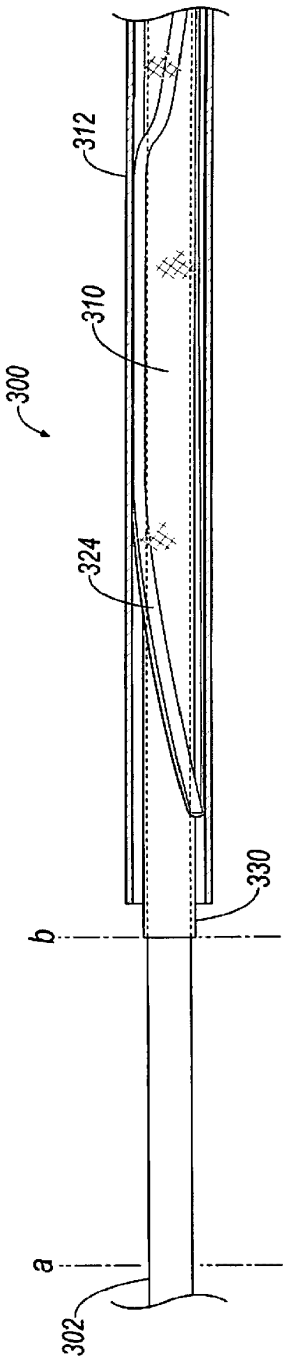



FIG. 3B

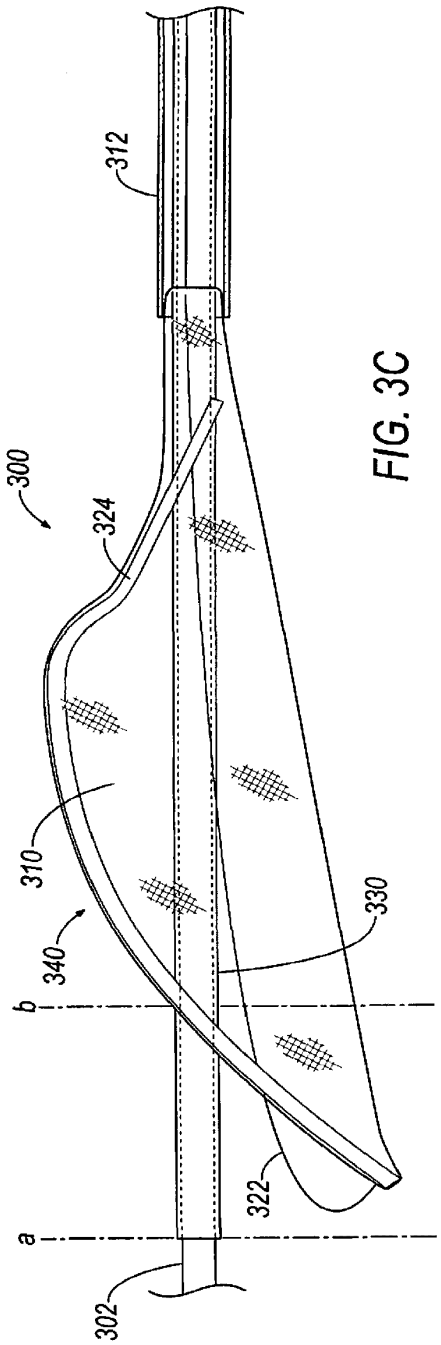



FIG. 3C

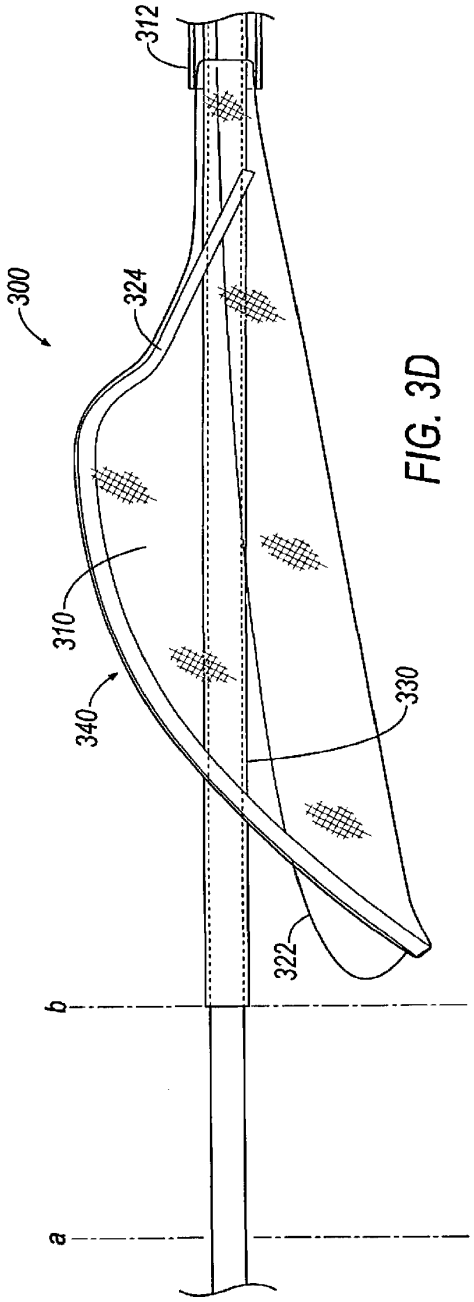



FIG. 3D

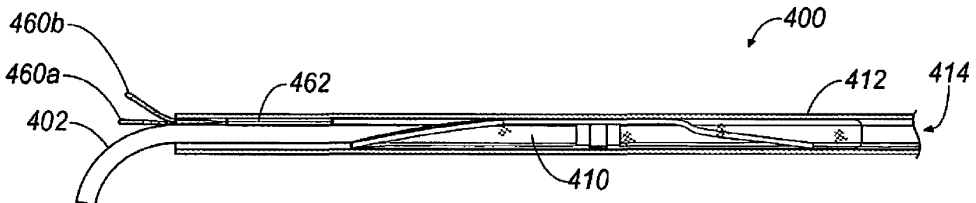

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FIG. 4A

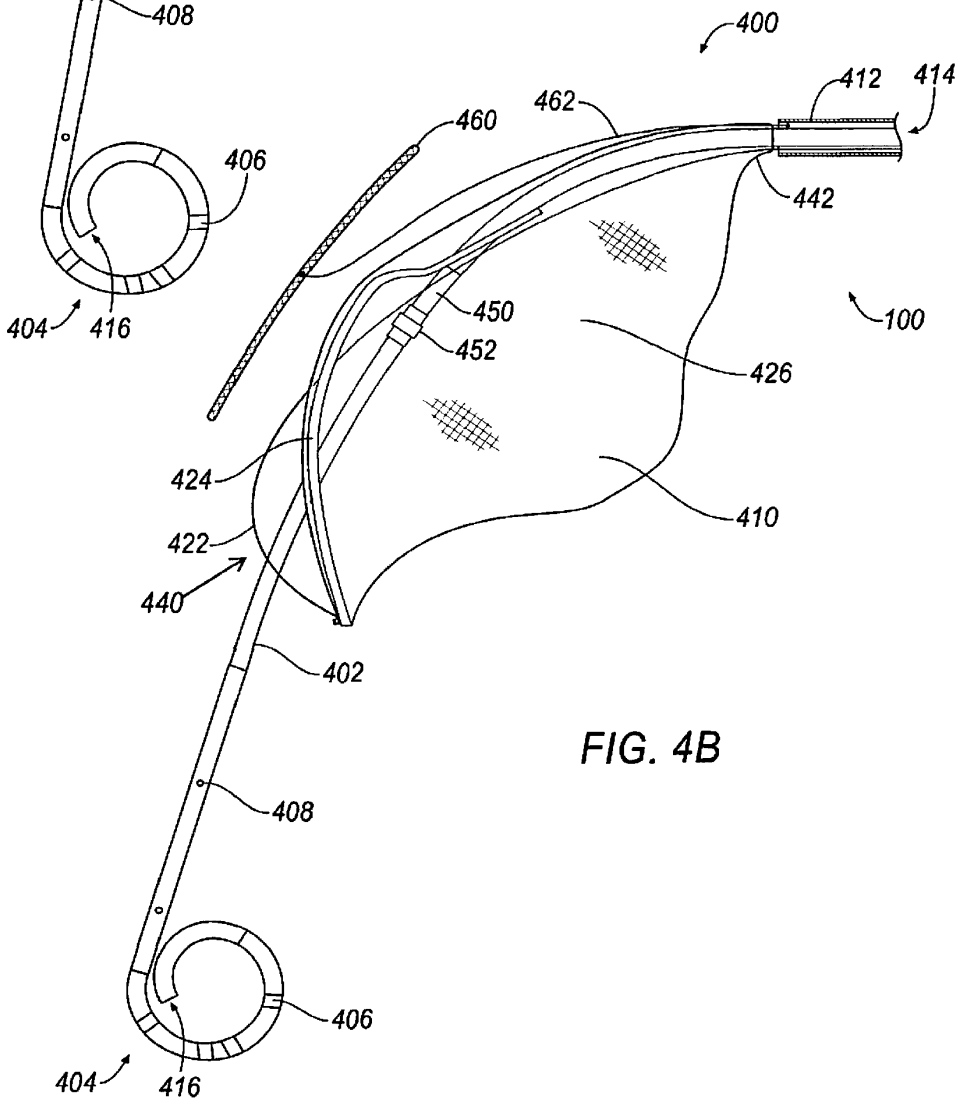

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FIG. 4B

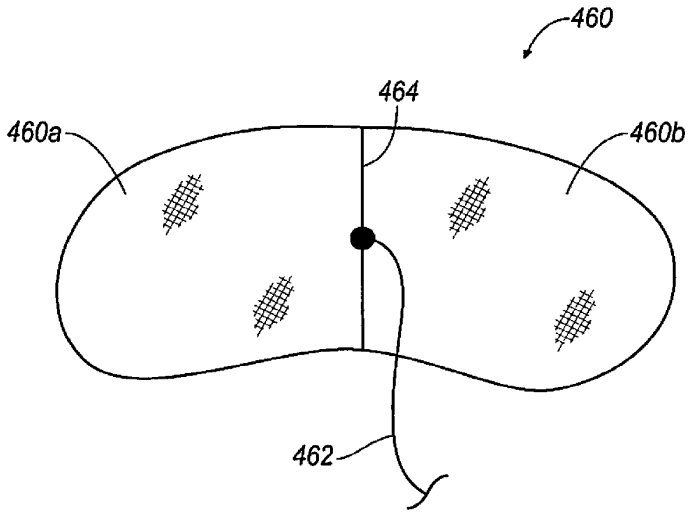



FIG. 4C

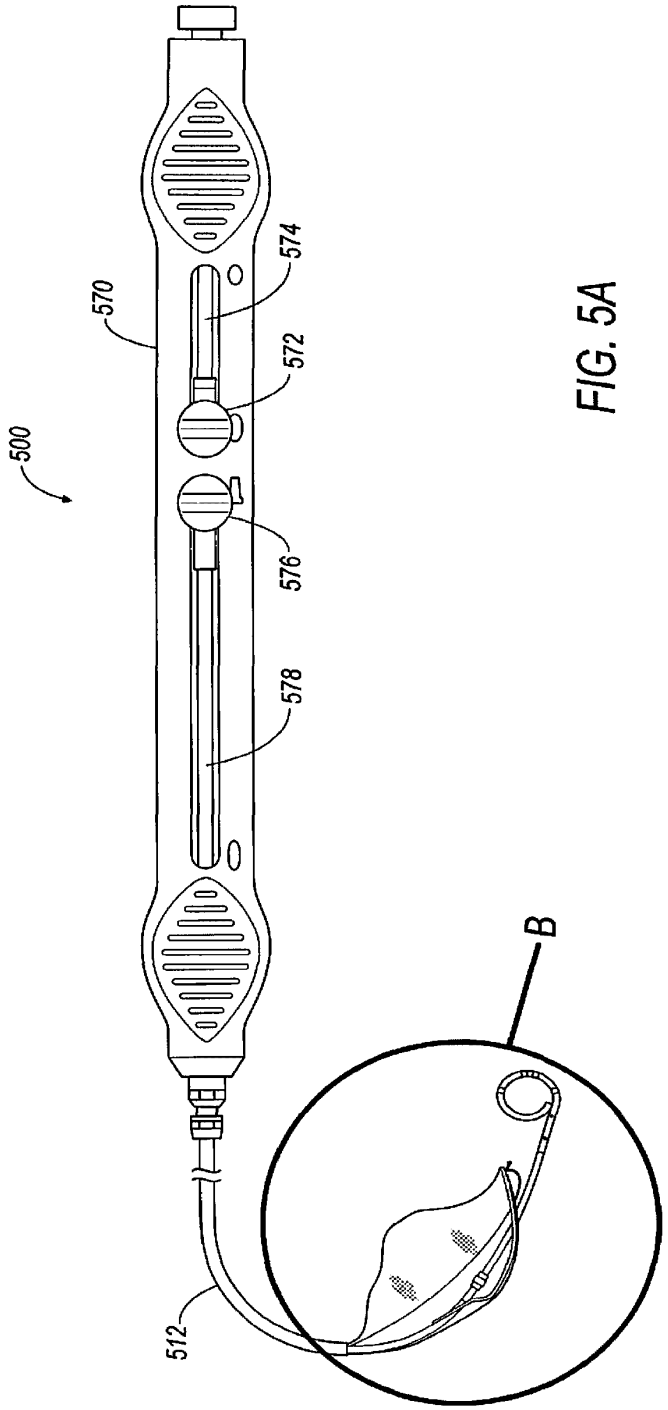



FIG. 5A

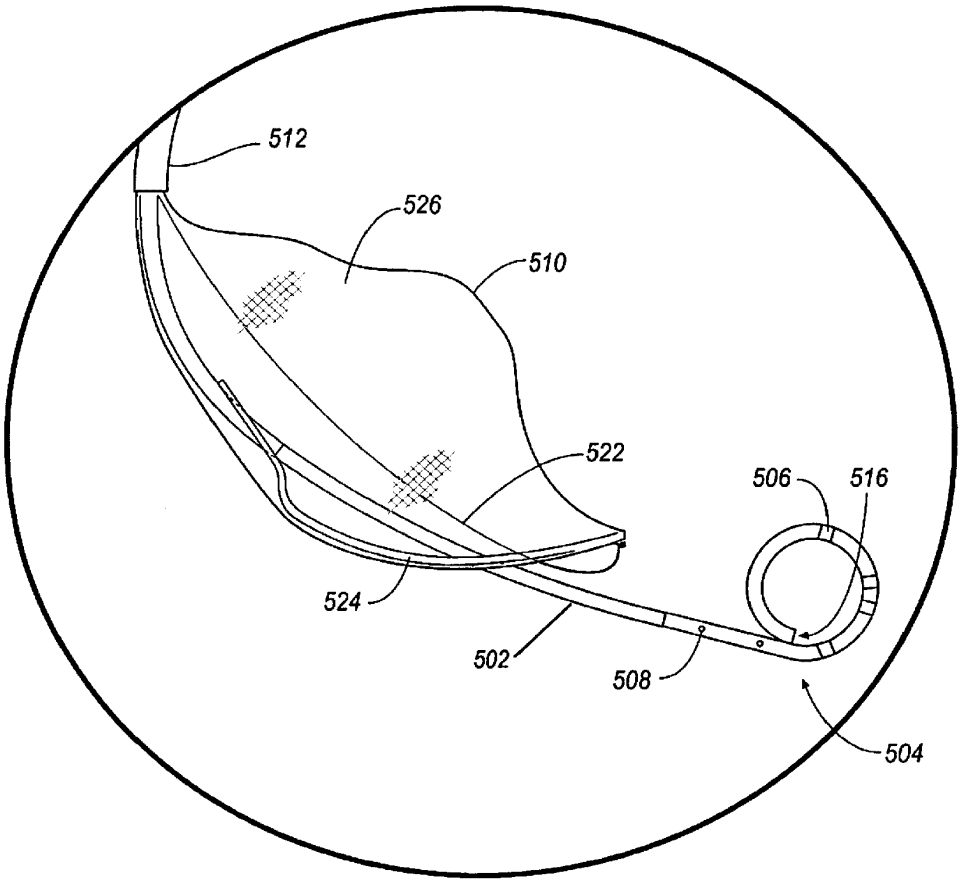



FIG. 5B

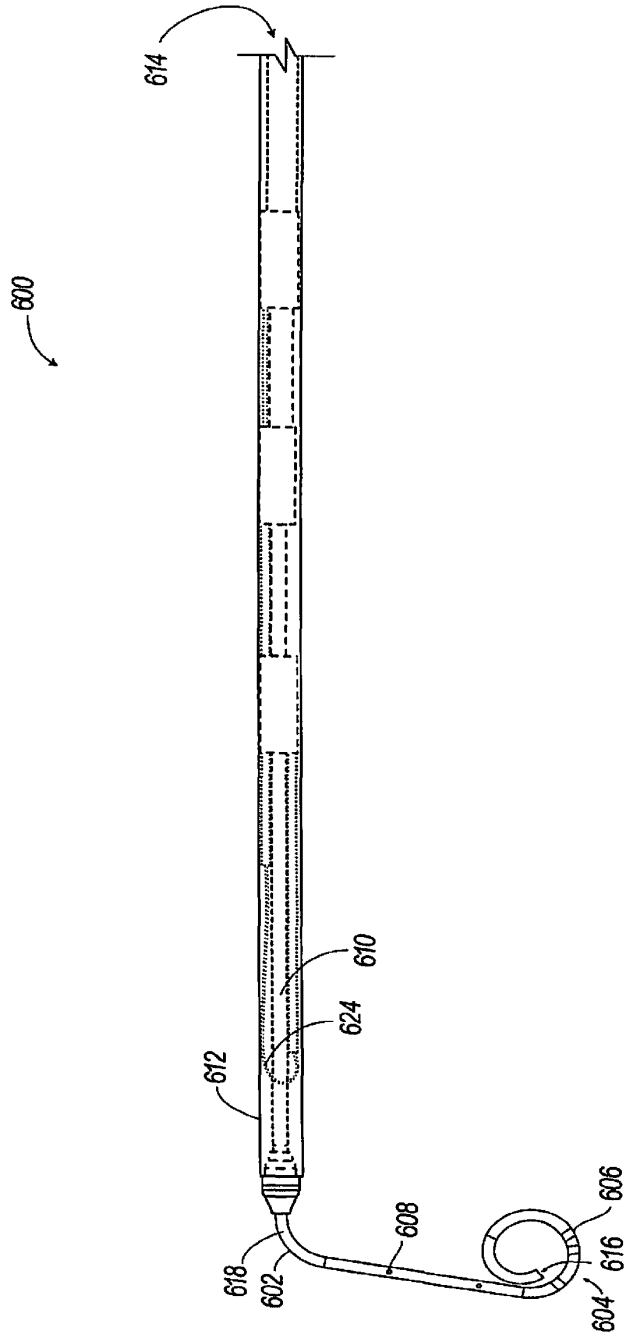



FIG. 6A

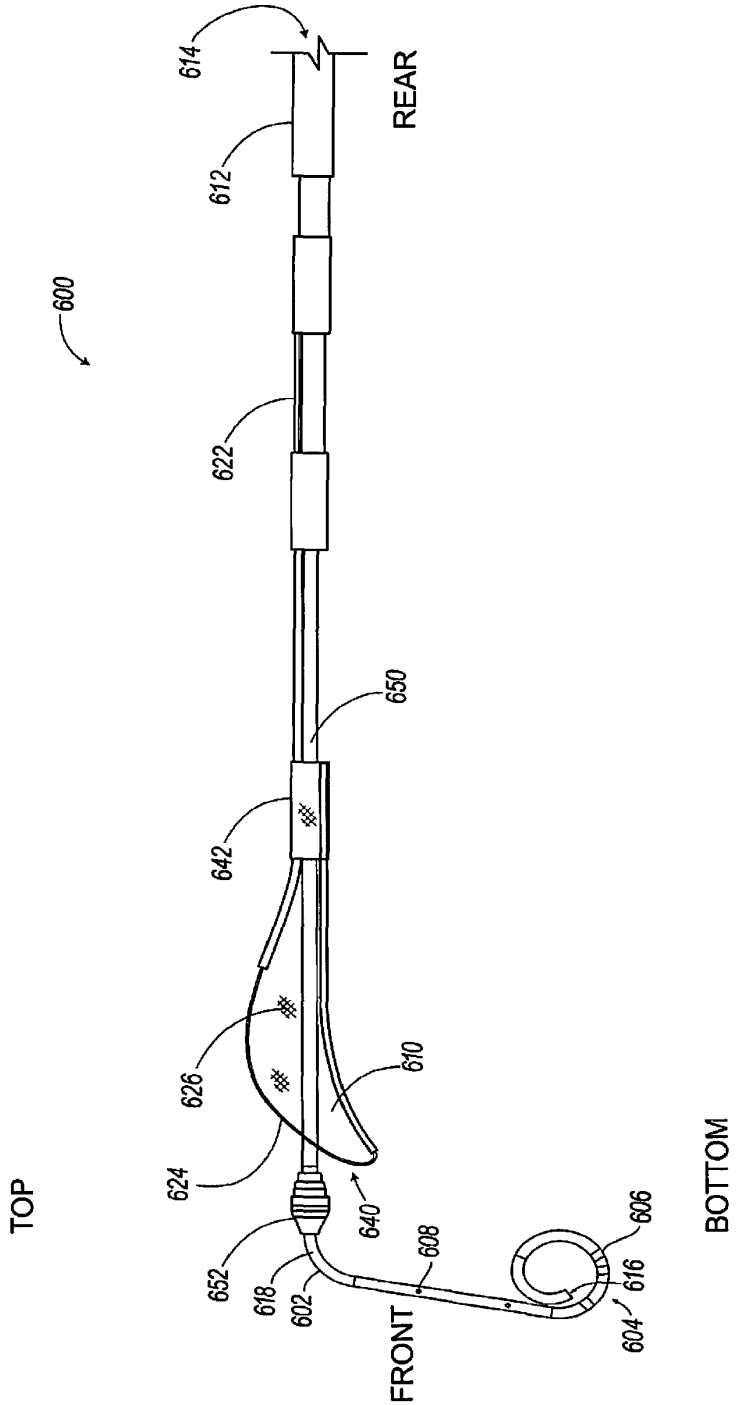

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FIG. 6B

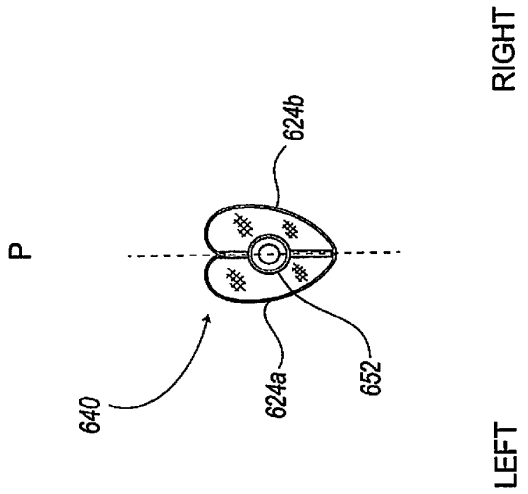



FIG. 6C

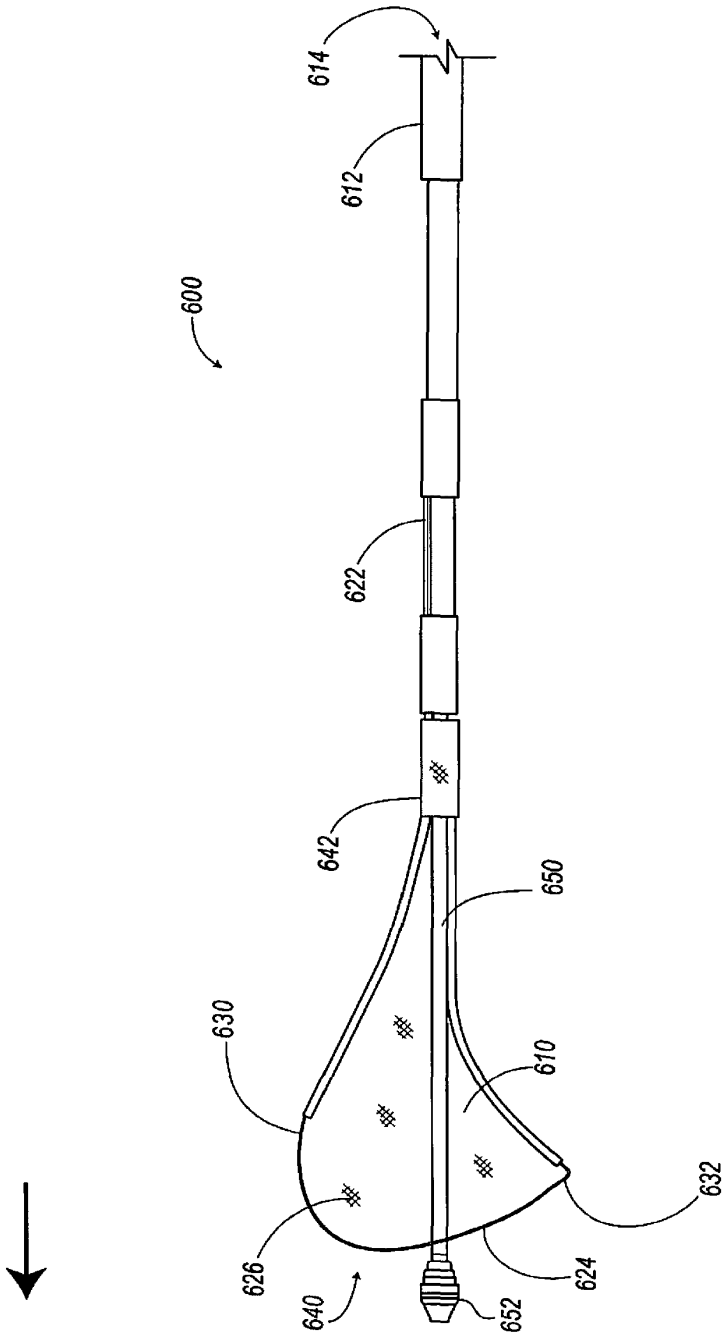



FIG. 6D

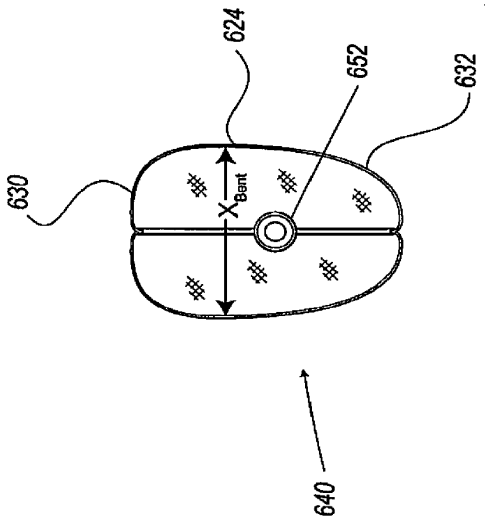



FIG. 6E

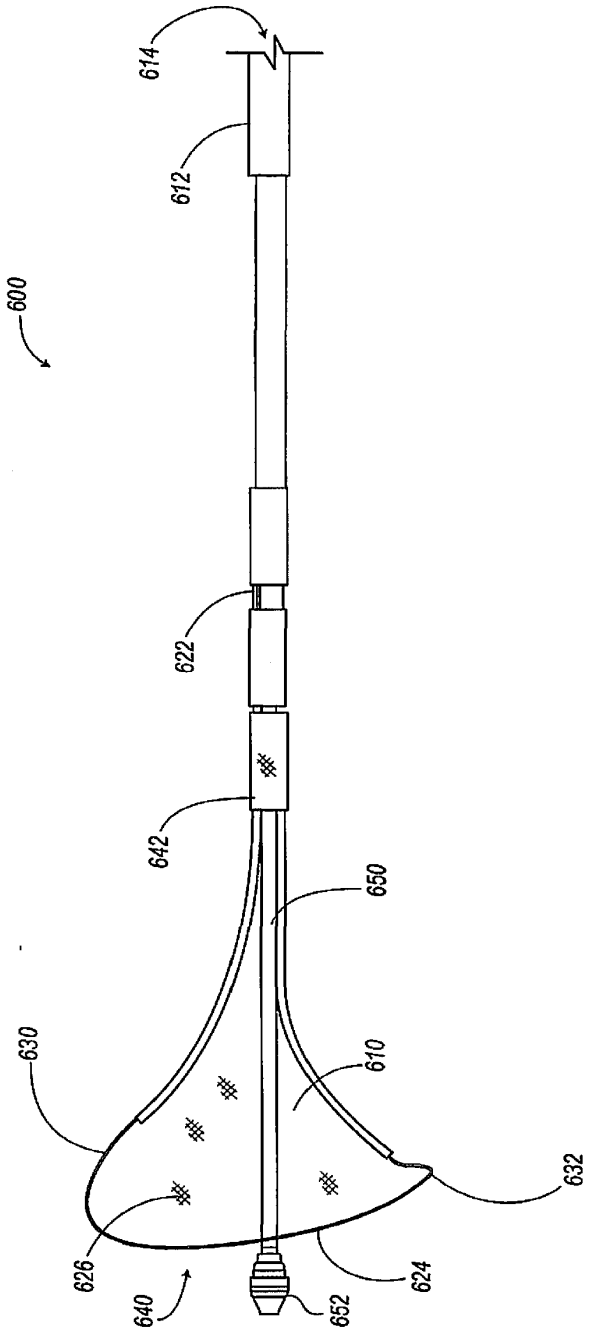



FIG. 6F

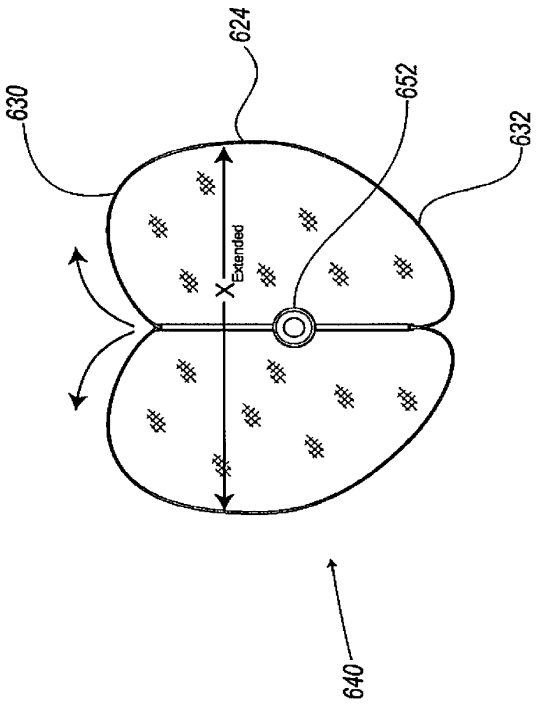



FIG. 6G

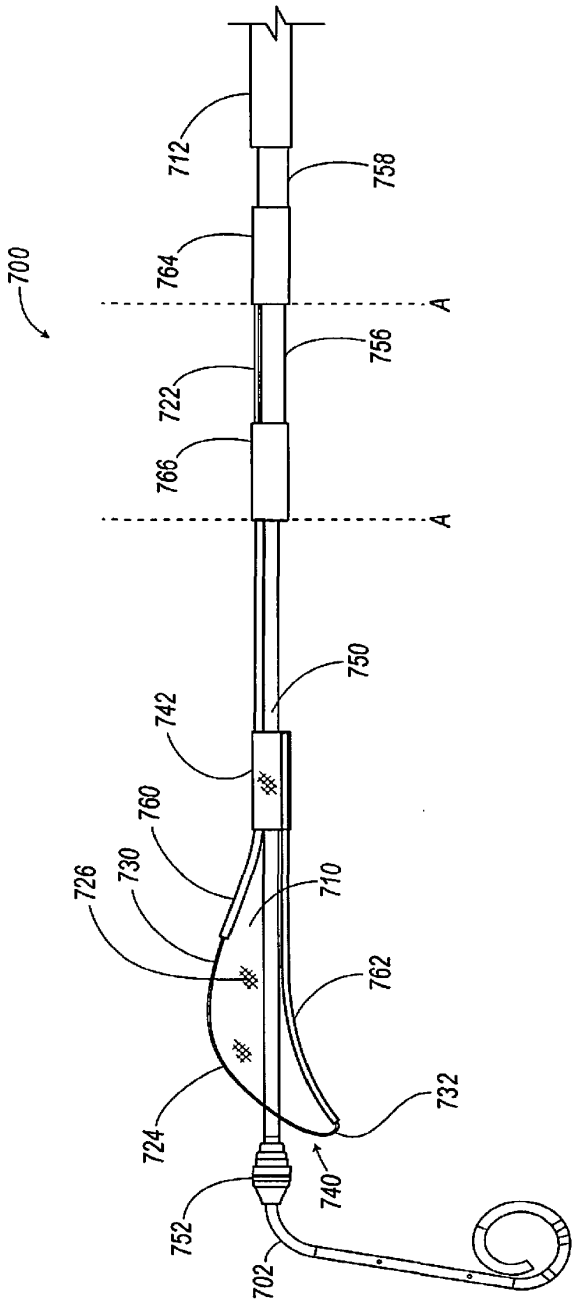

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FIG. 7A

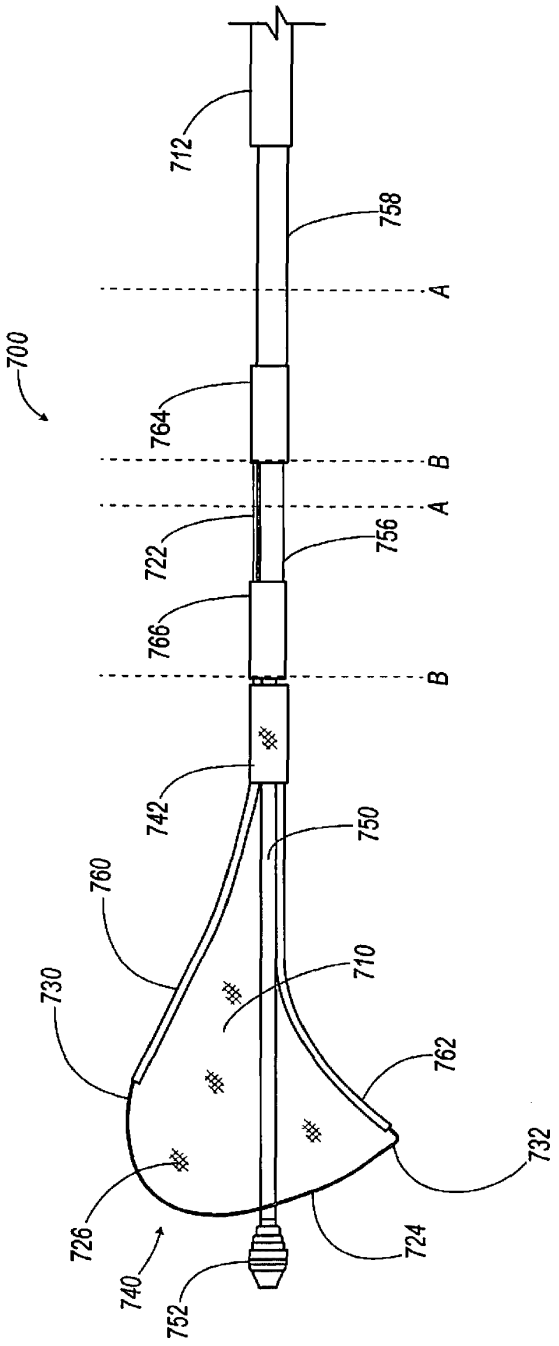

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FIG. 7B

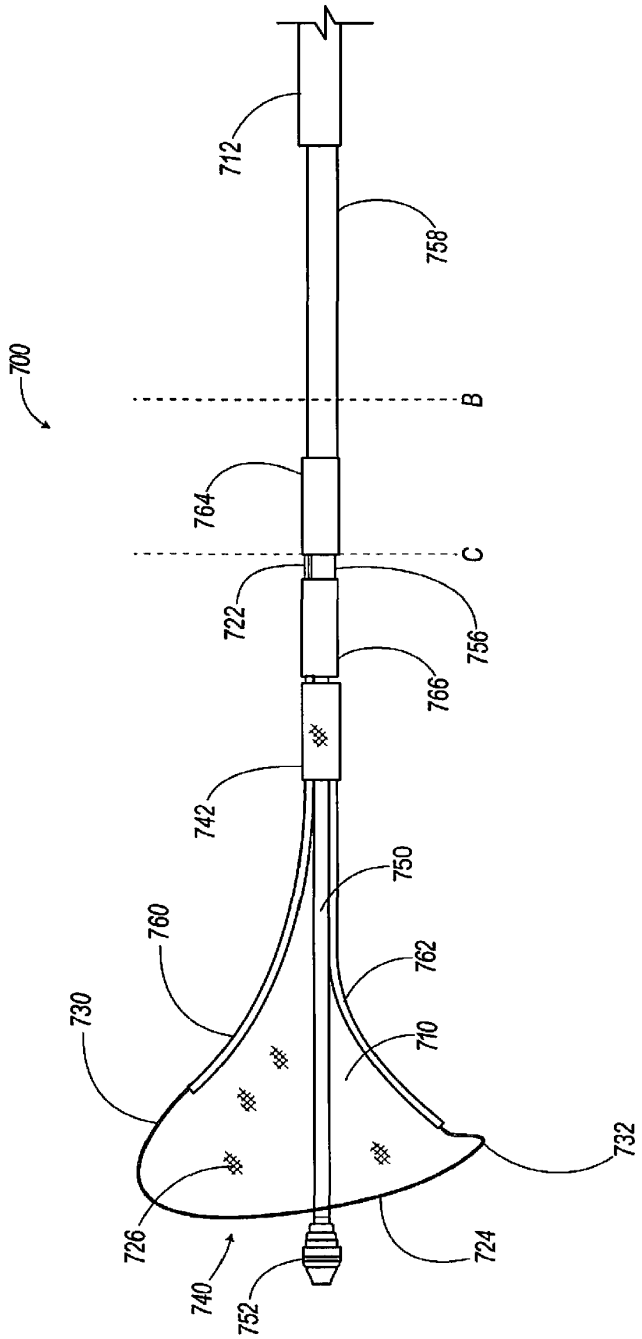

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FIG. 7C

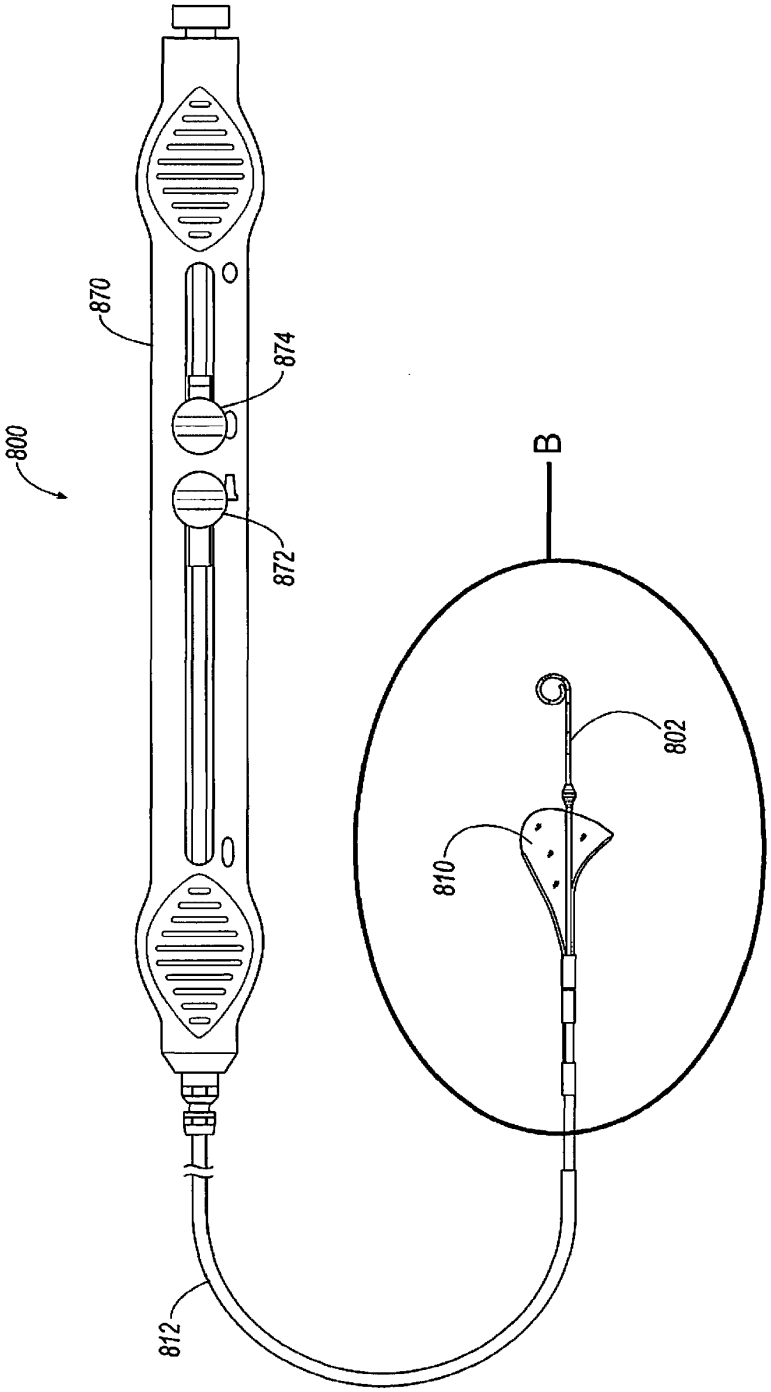



FIG. 8A

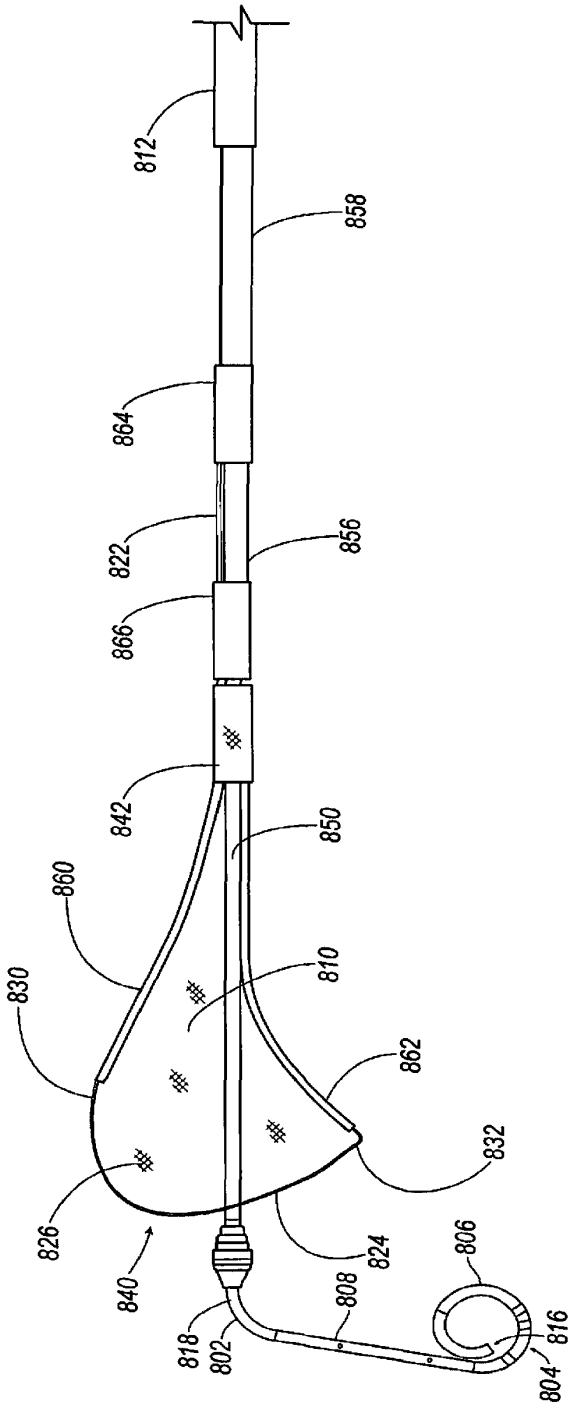

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FIG. 8B

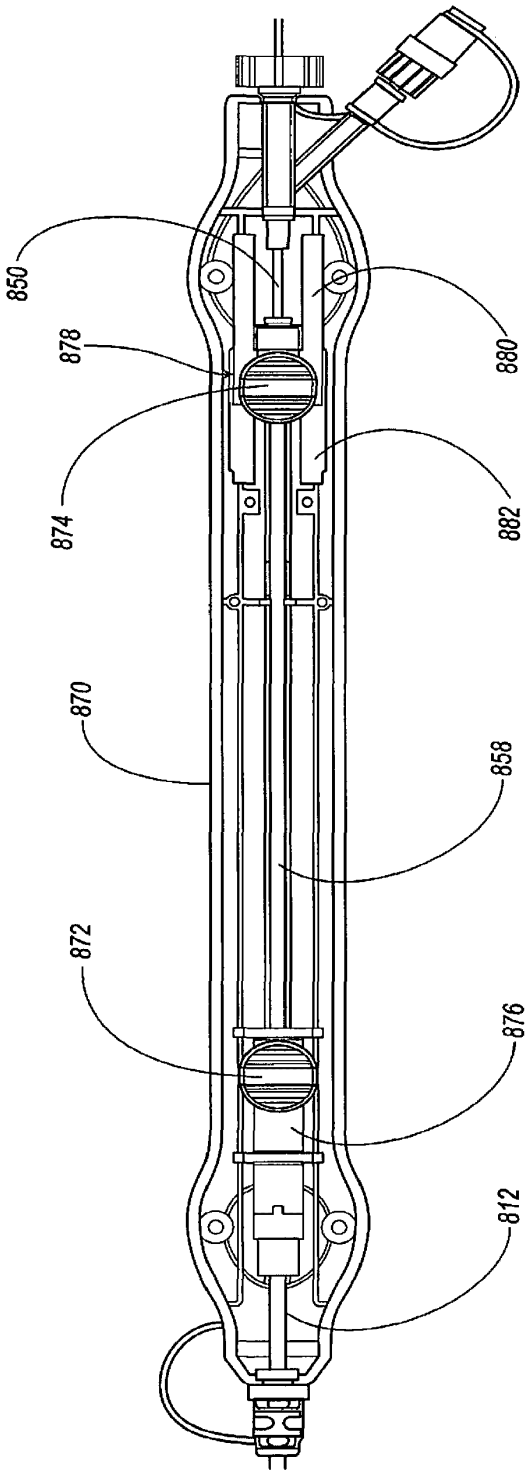



FIG. 8C

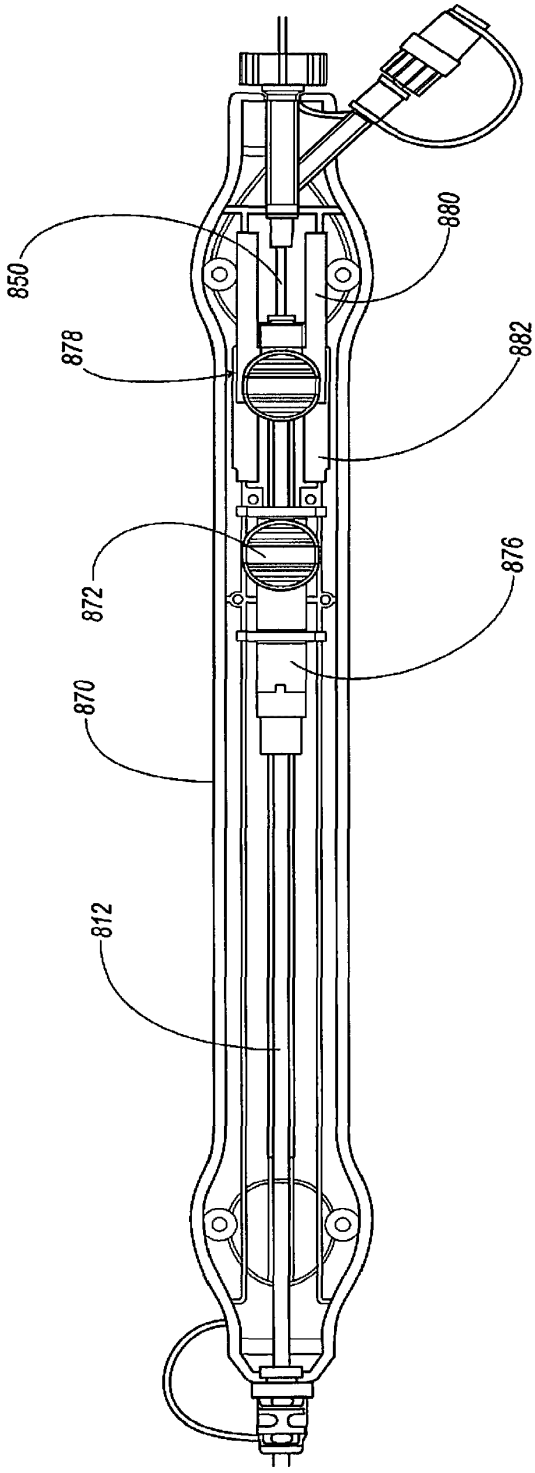



FIG. 8D

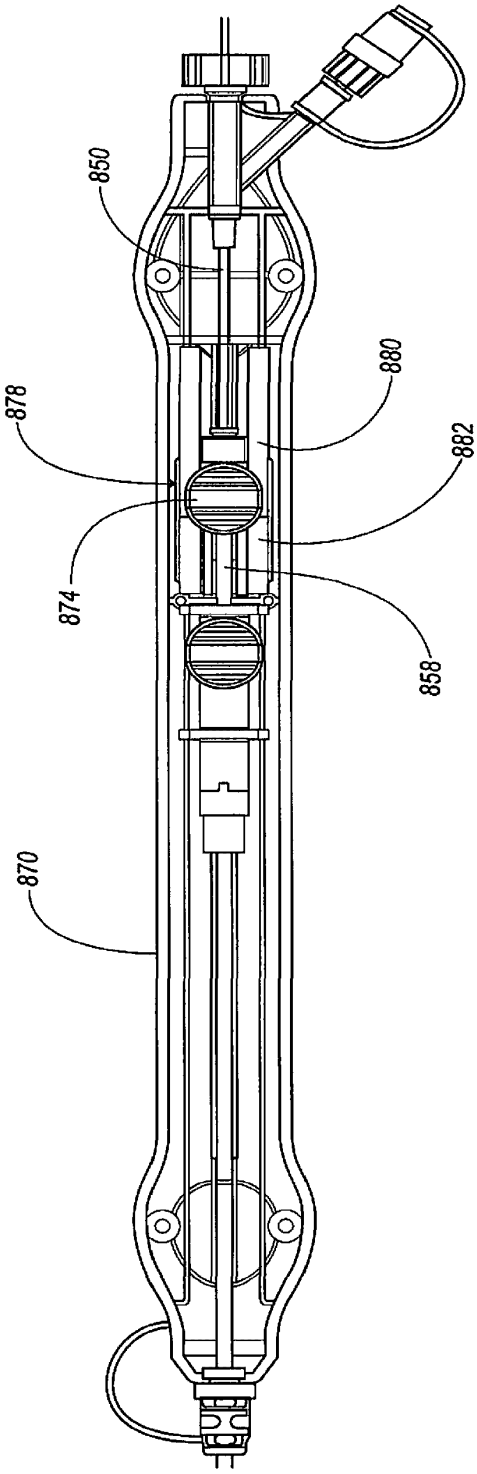



FIG. 8E

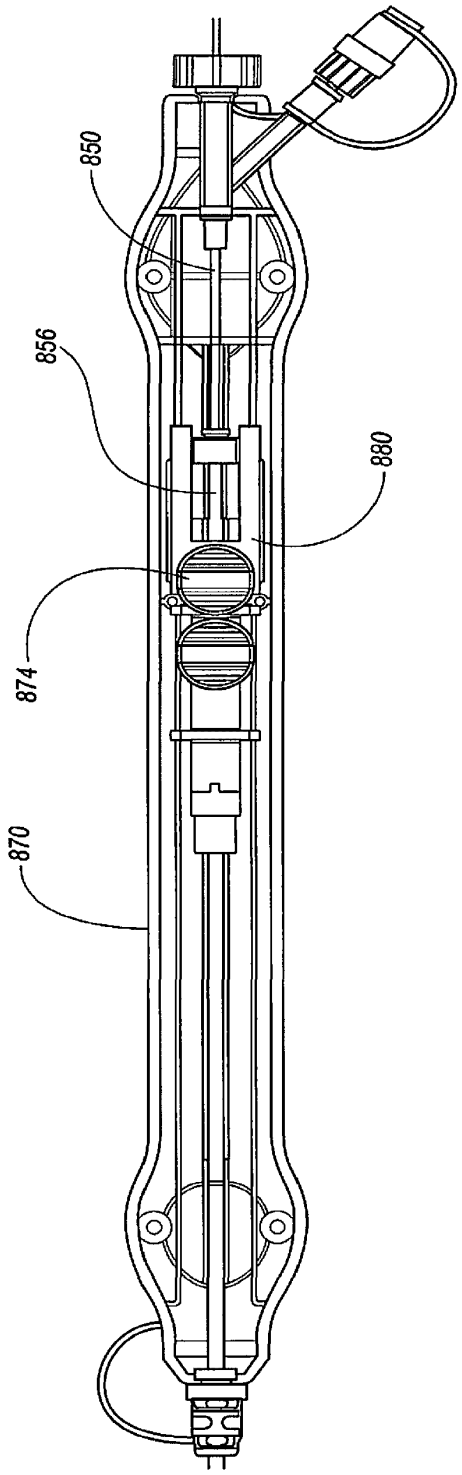



FIG. 8F

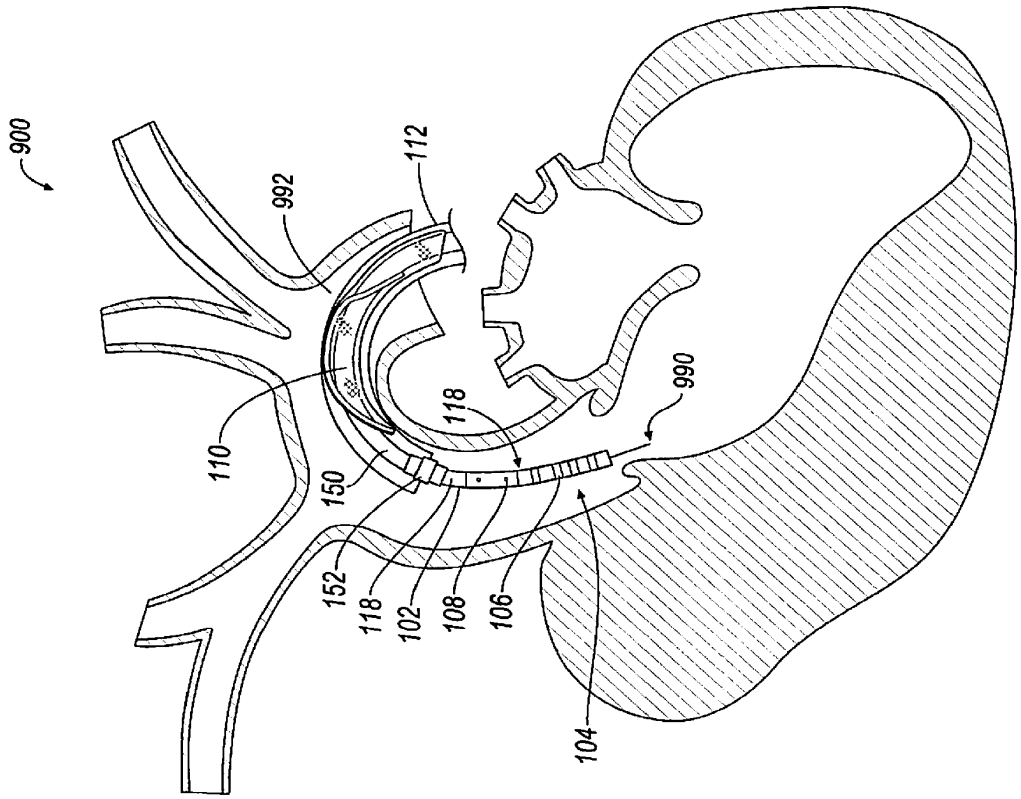



FIG. 9A

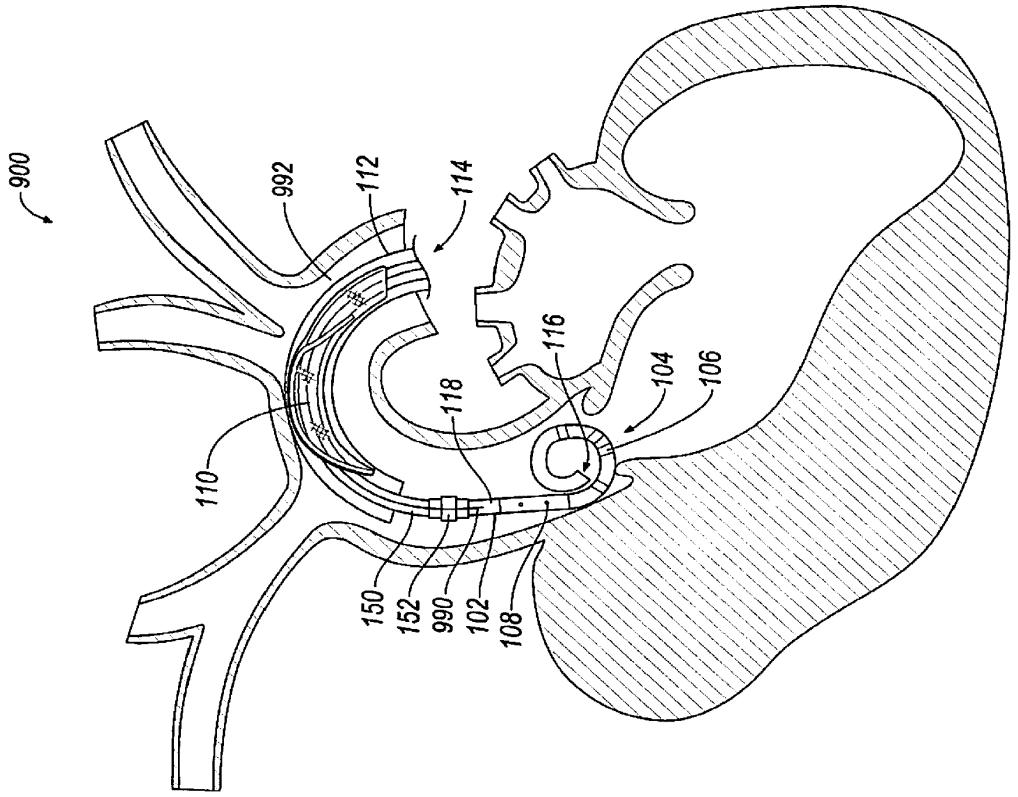



FIG. 9B

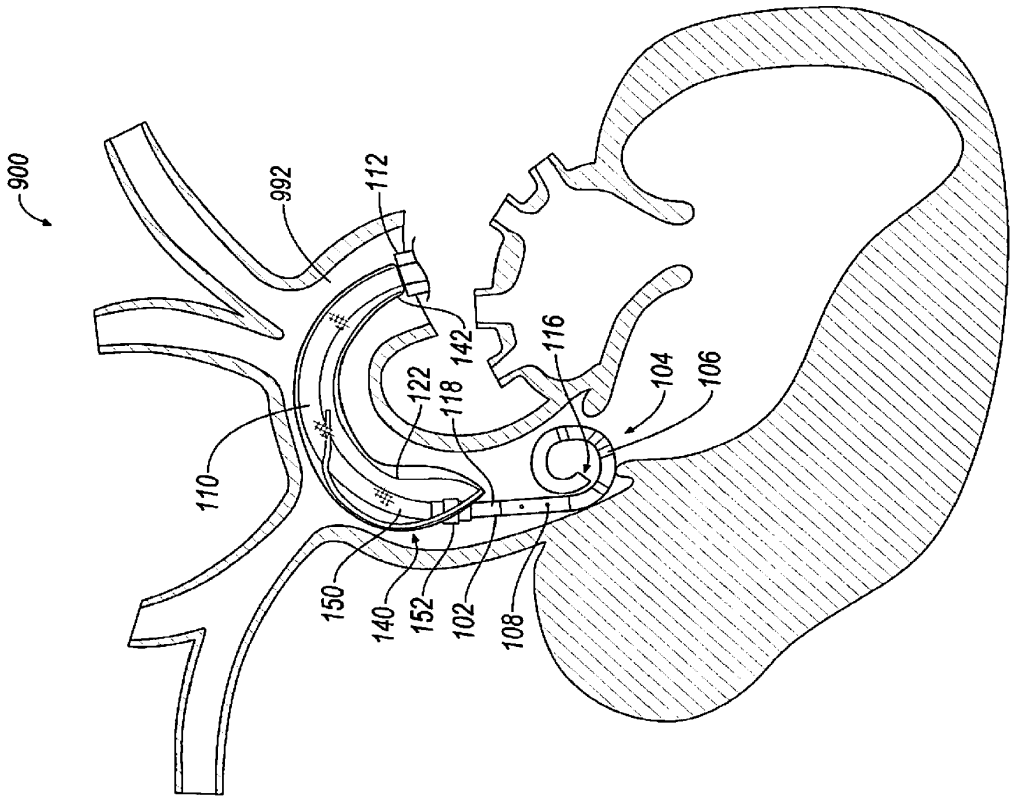



FIG. 9C

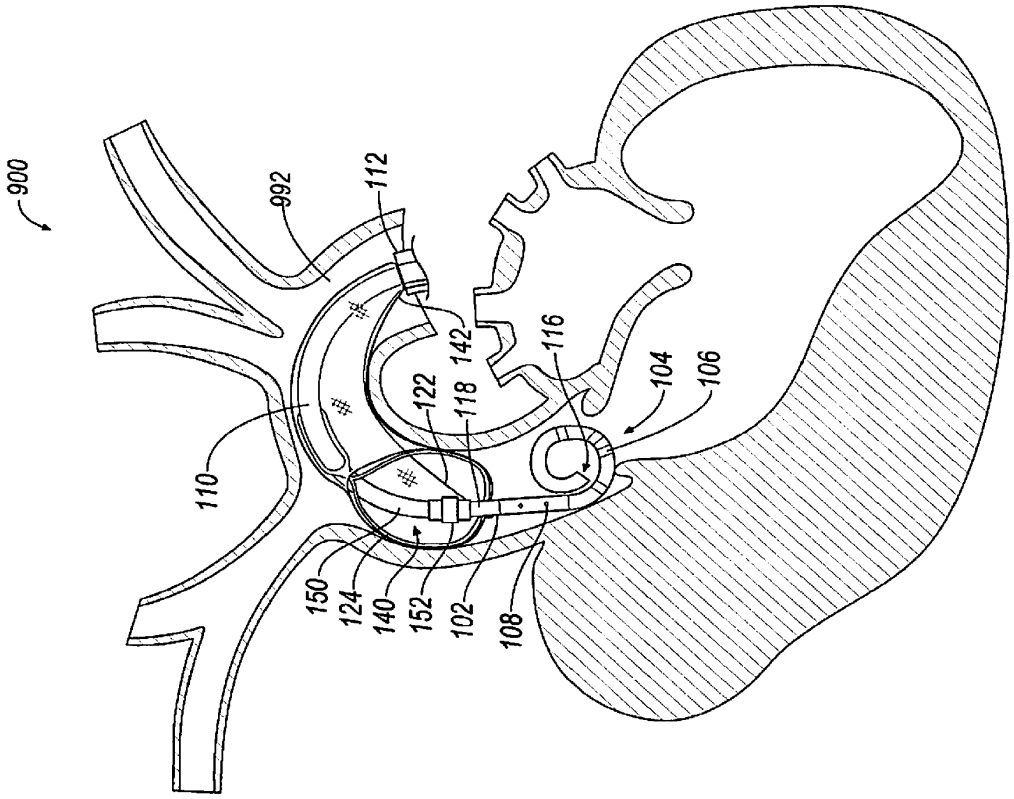



FIG. 9D

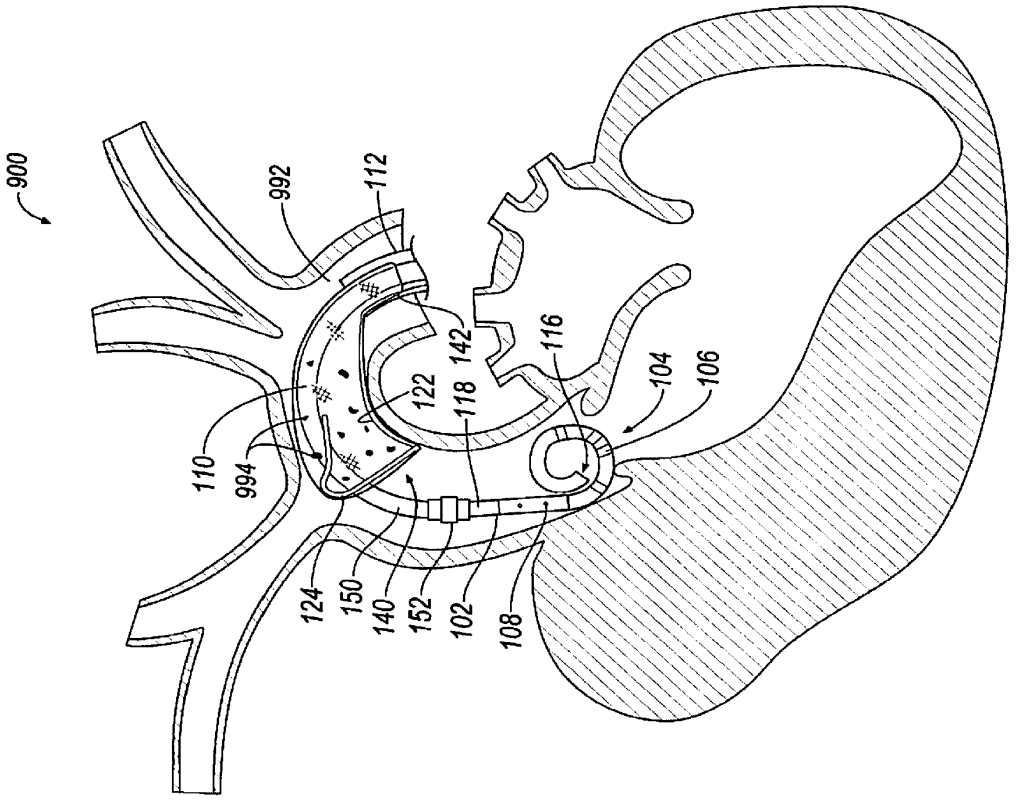

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FIG. 9E

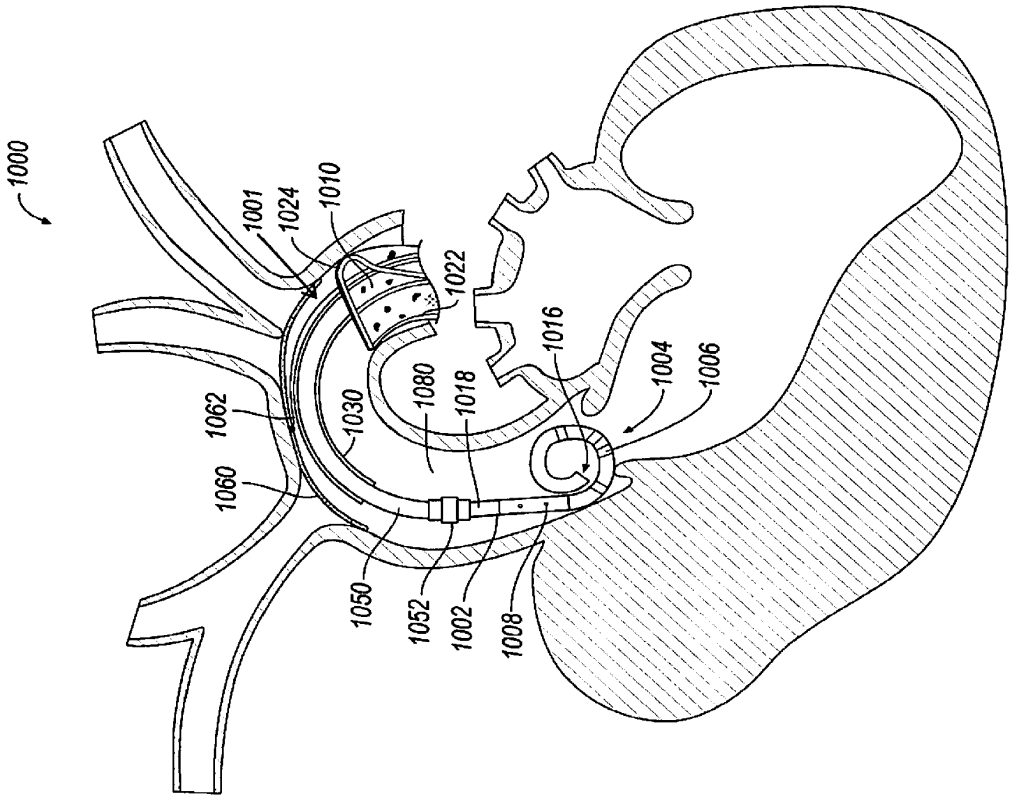

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FIG. 10

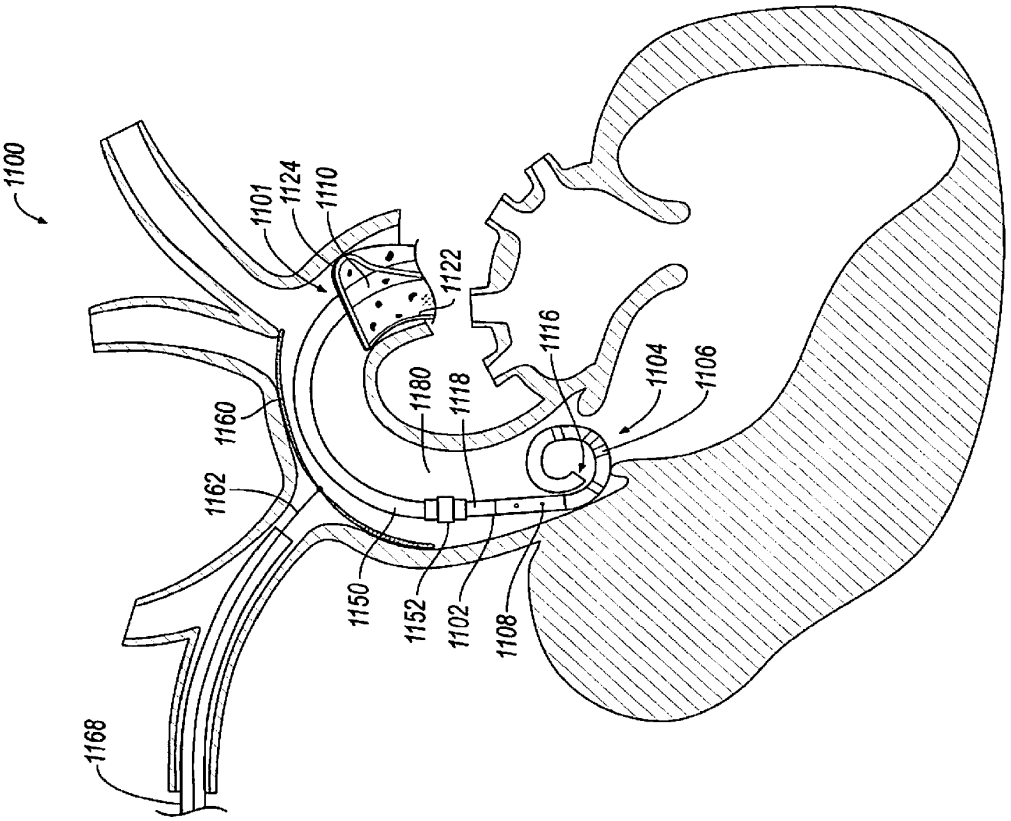

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FIG. 11

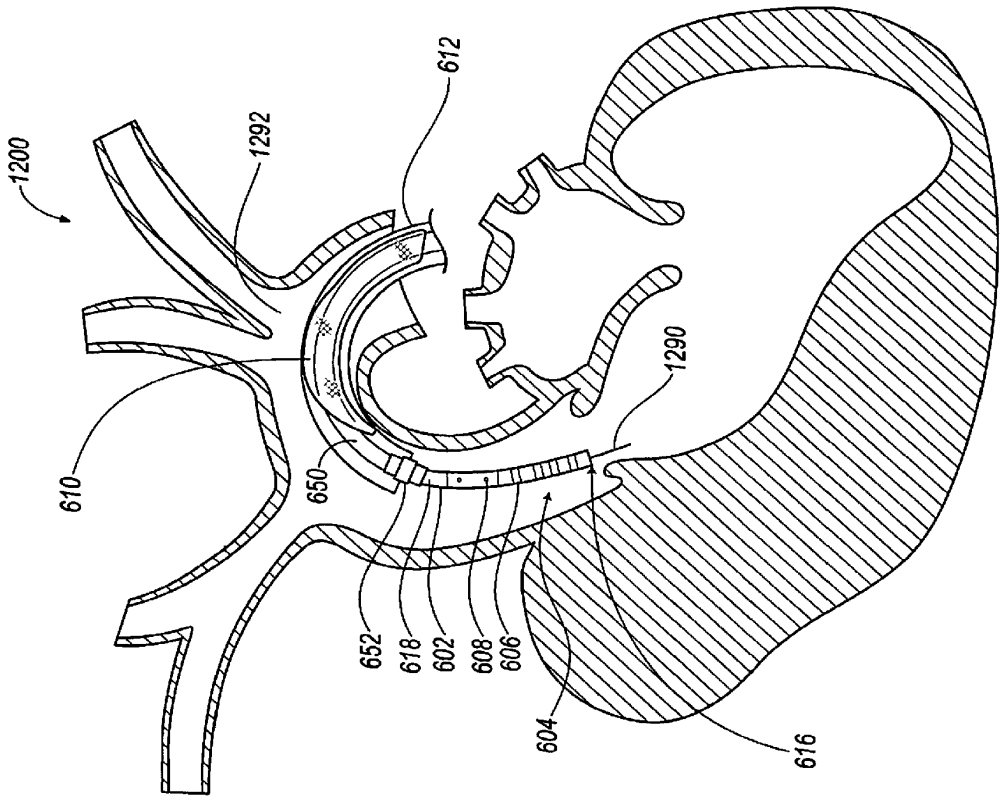



FIG. 12A

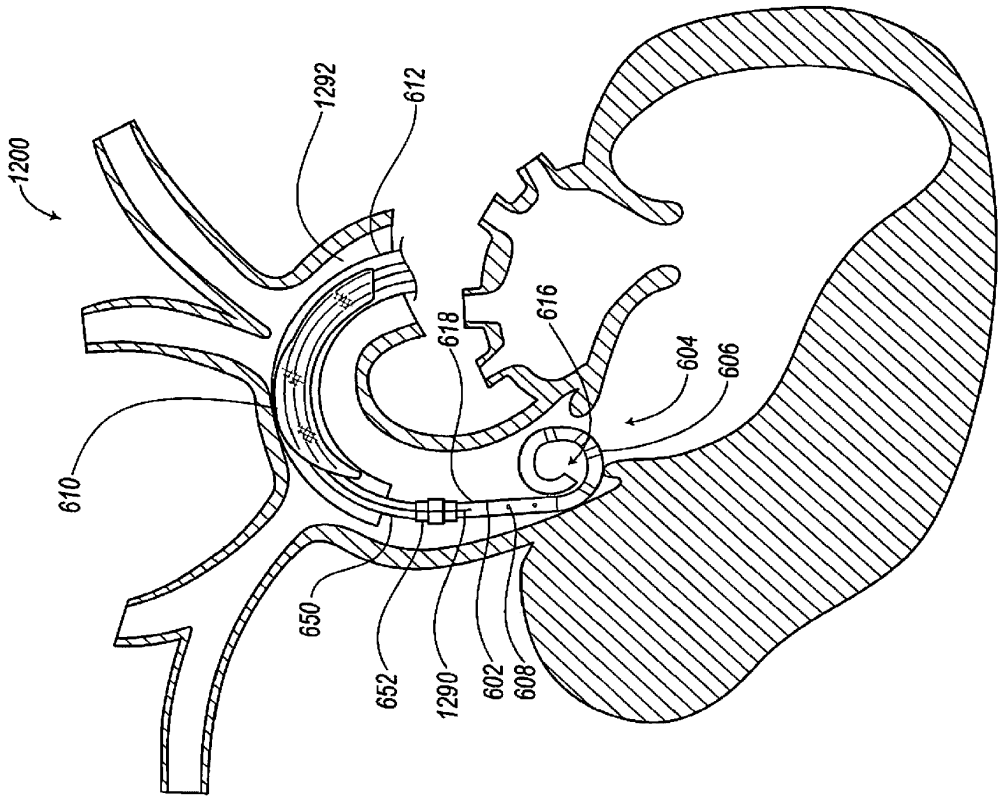



FIG. 12B

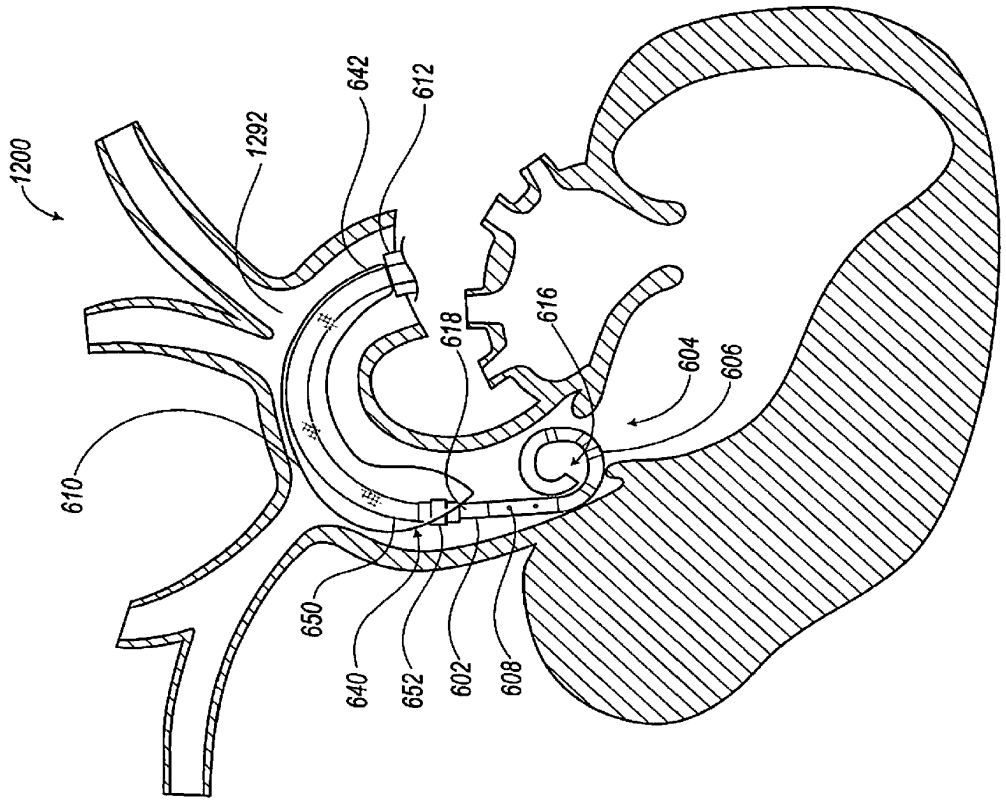



FIG. 12C

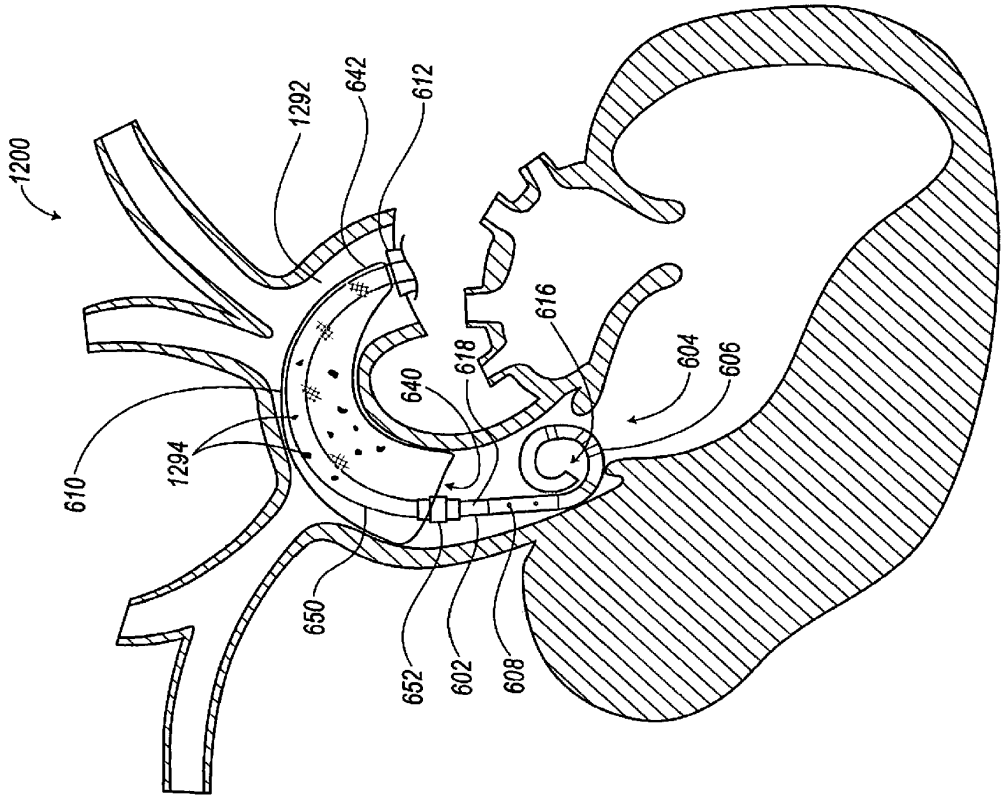



FIG. 12D

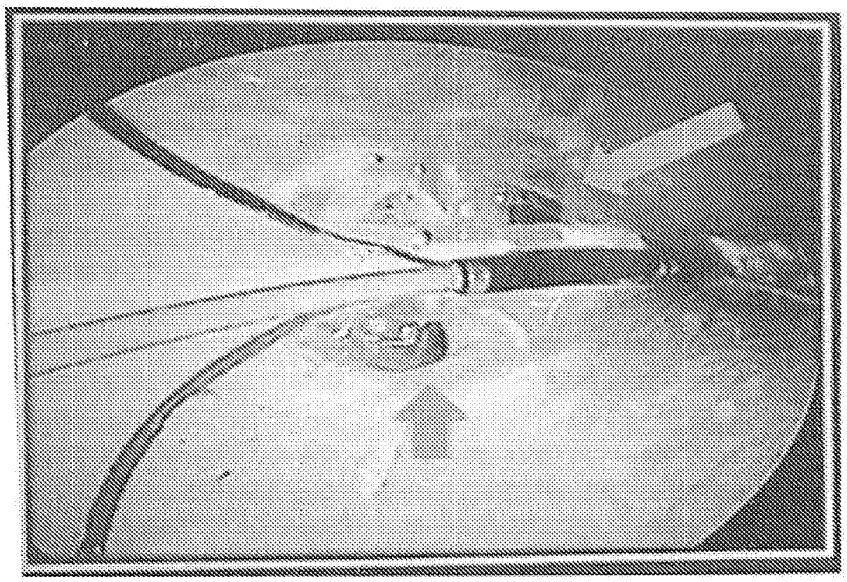


FIG. 13A

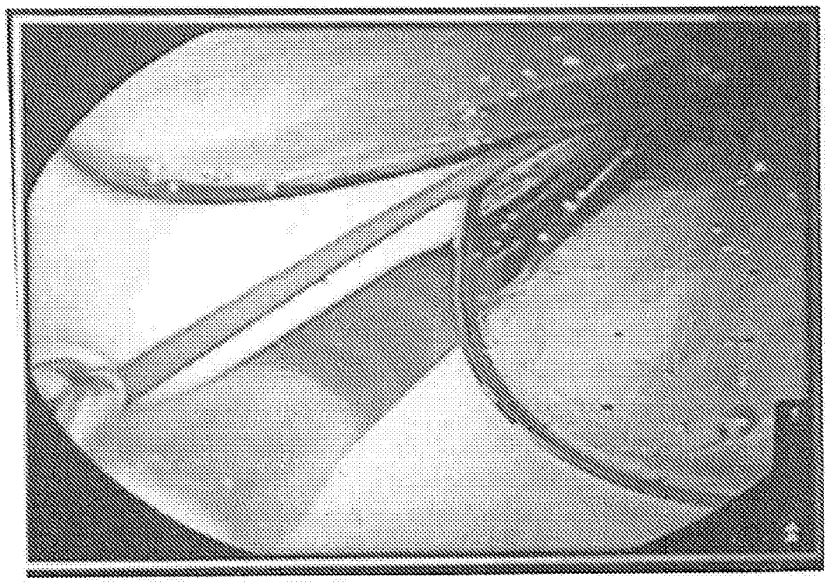


FIG. 13B

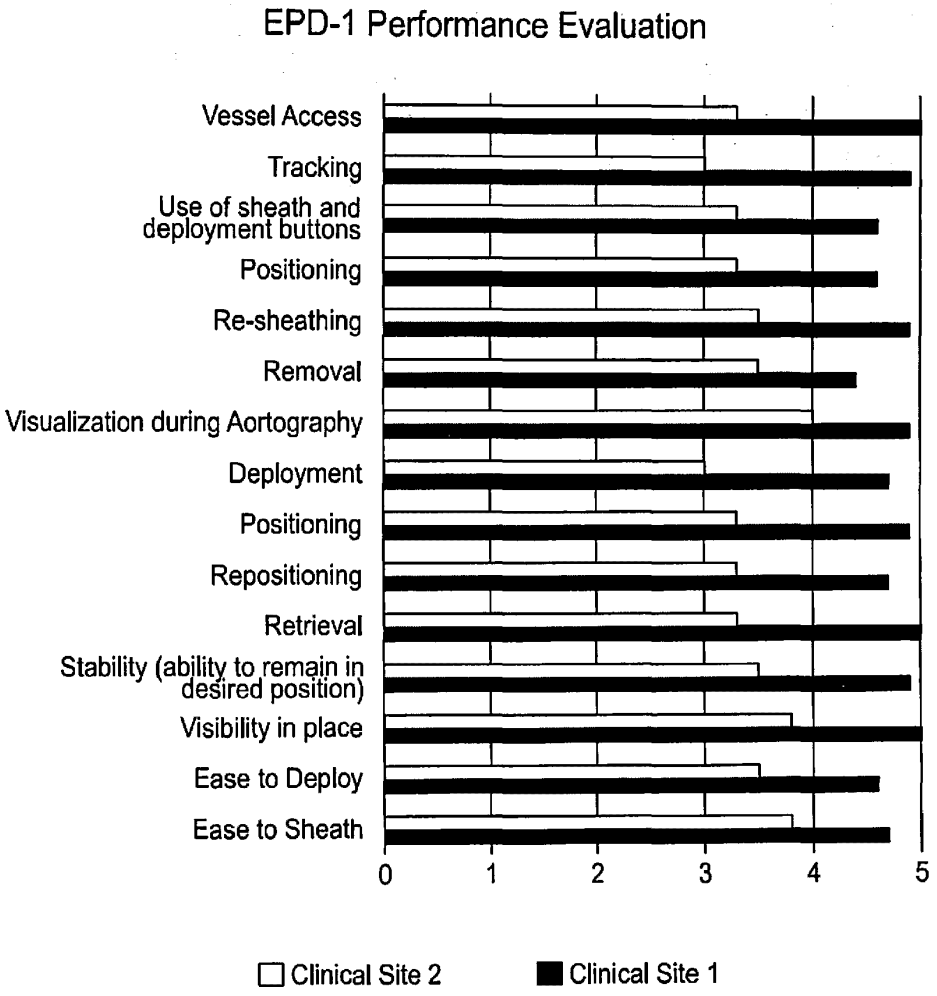

EPD-1 Performance Evaluation
Vessel Access
Tracking
Use of sheath and deployment buttons
Positioning
Re-sheathing
Removal
Visualization during Aortography
Deployment
Positioning
Repositioning
Retrieval
Stability (ability to remain in desired position)
Visibility in place
Ease to Deploy
Ease to Sheath
0
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Clinical Site 2
Clinical Site 1

*FIG. 14*

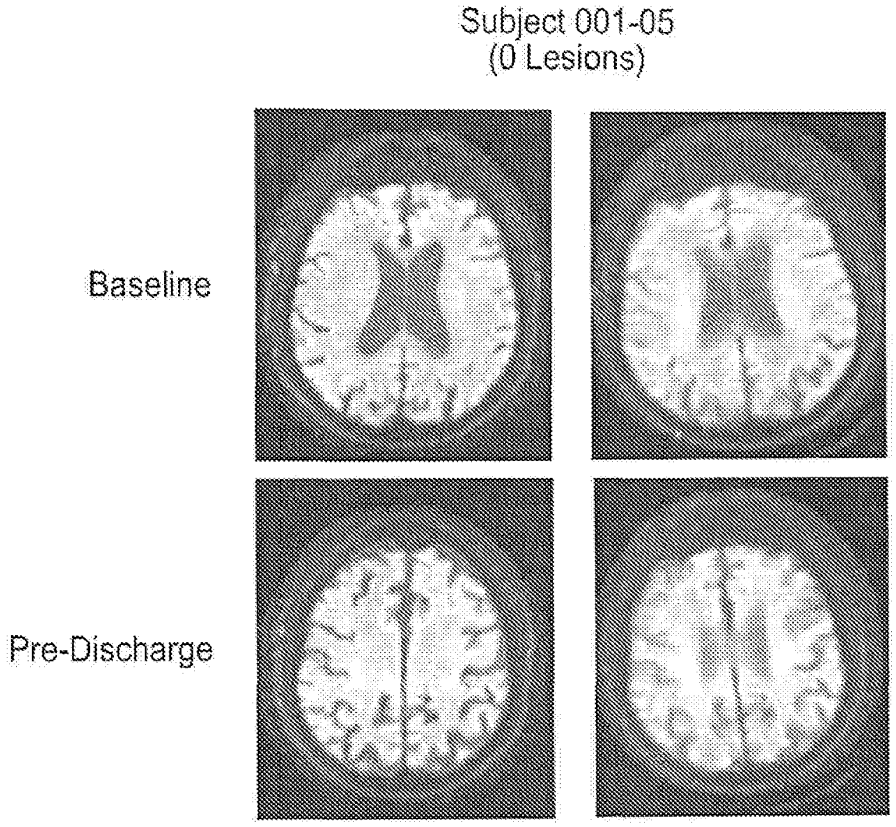



FIG.15A

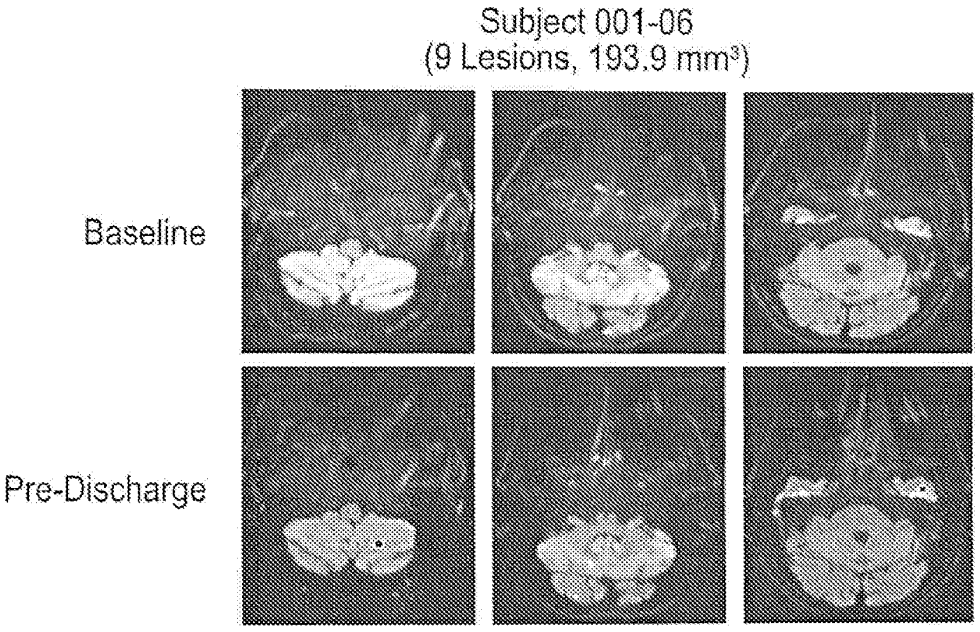



FIG. 15B

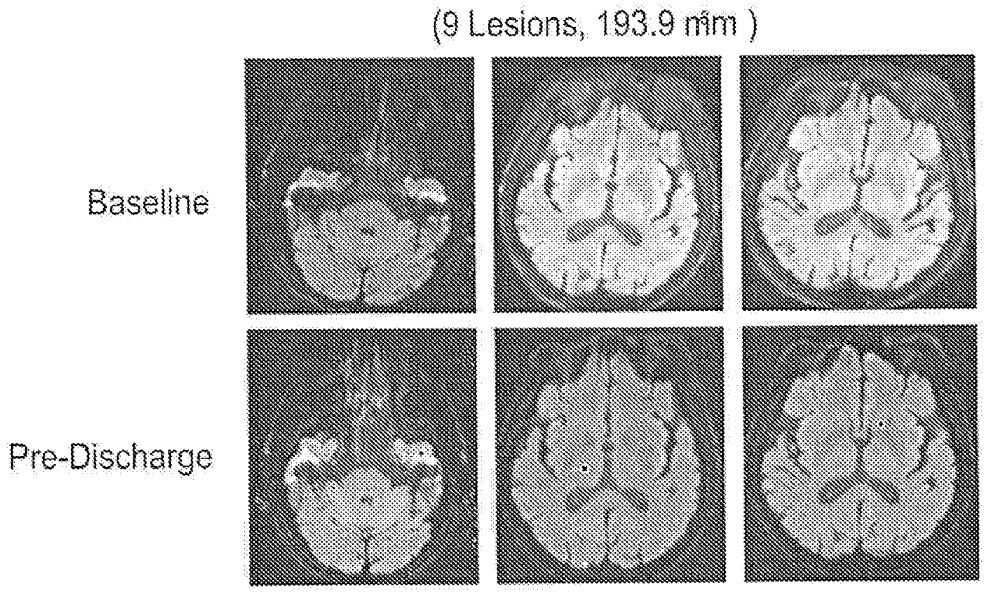



FIG. 15C

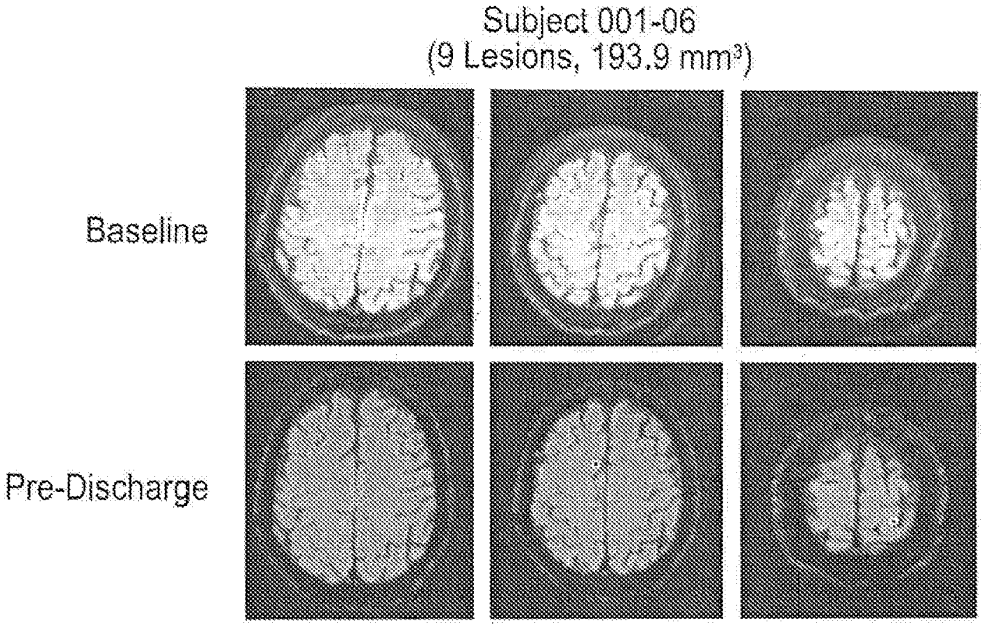



FIG. 15D

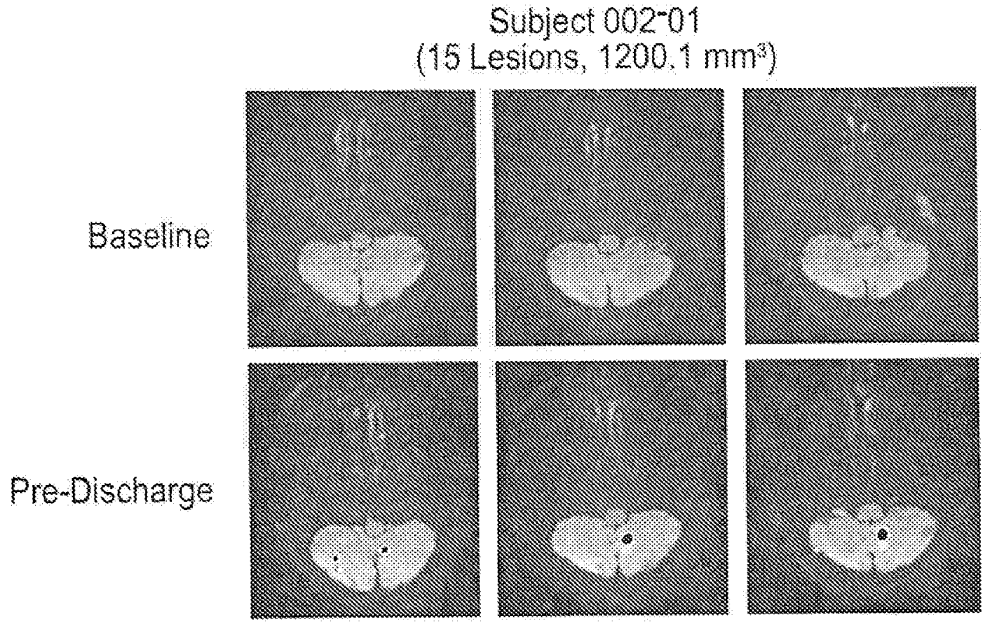



FIG. 15E

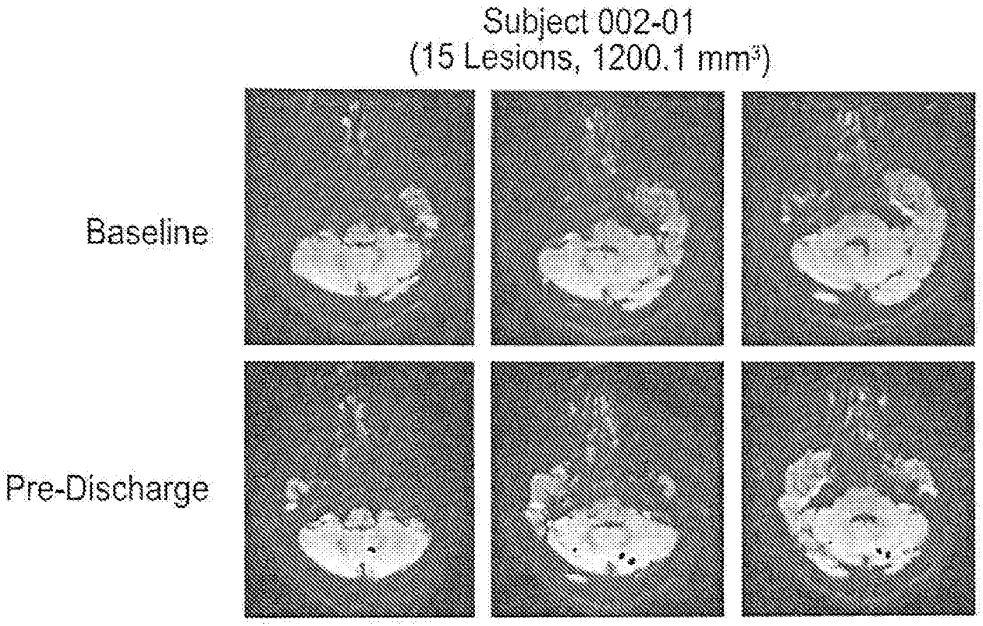



FIG. 15F

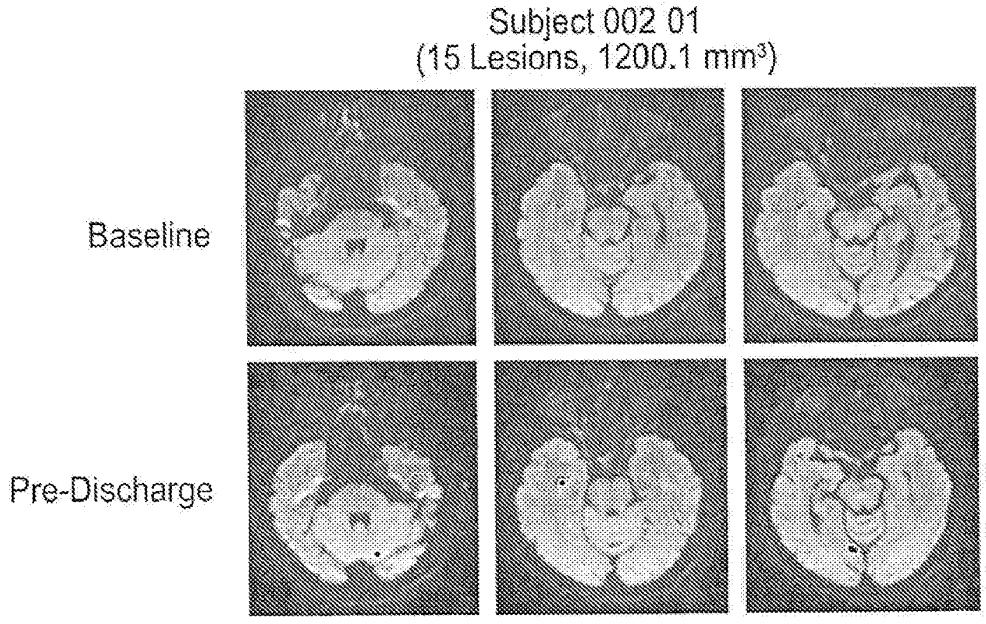



FIG. 15G

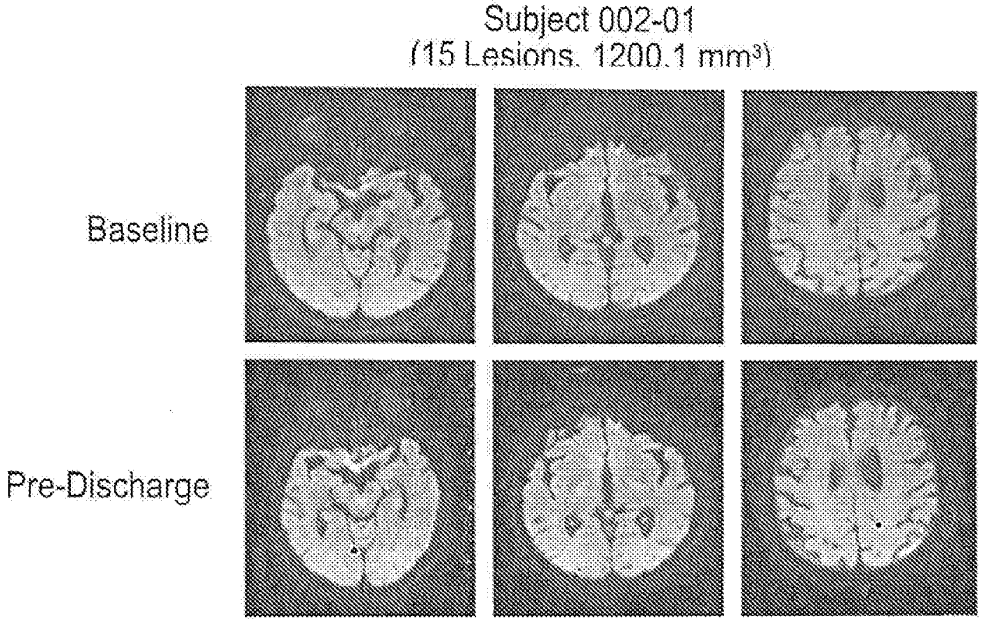



FIG. 15H

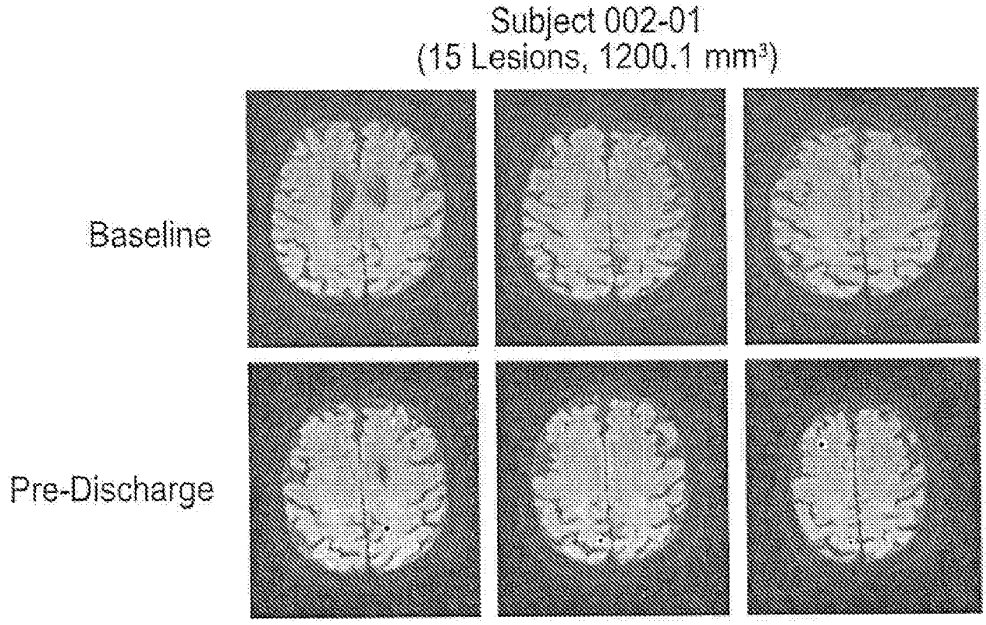



FIG. 15I

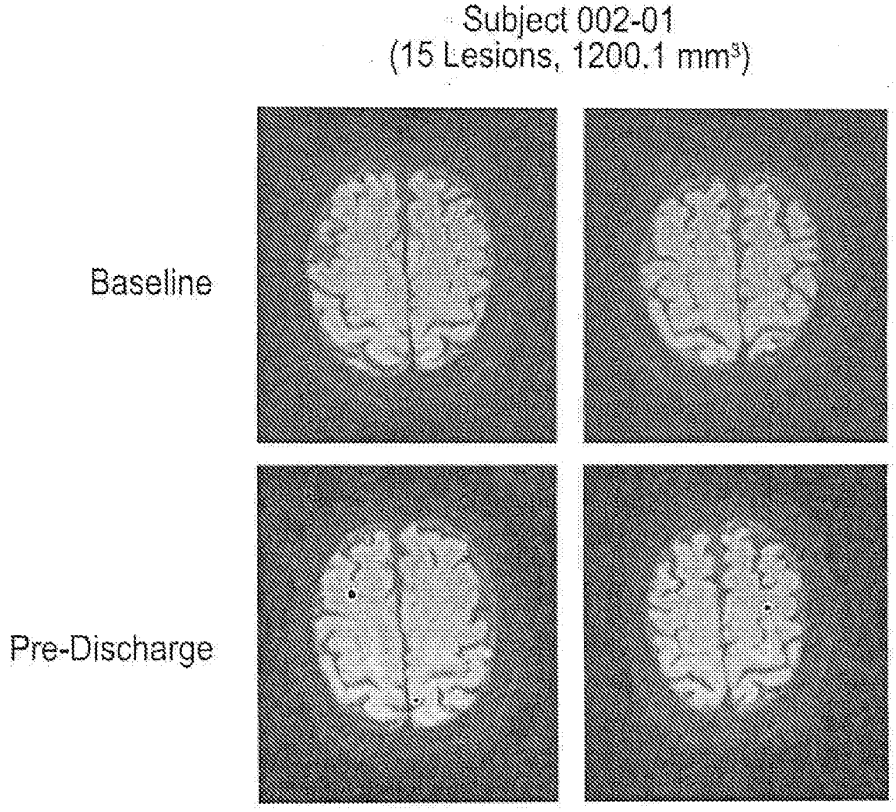



FIG. 15J

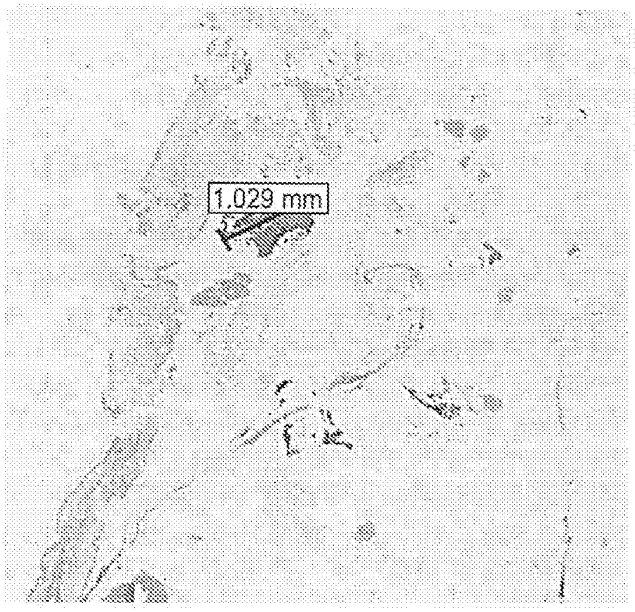



FIG. 16A

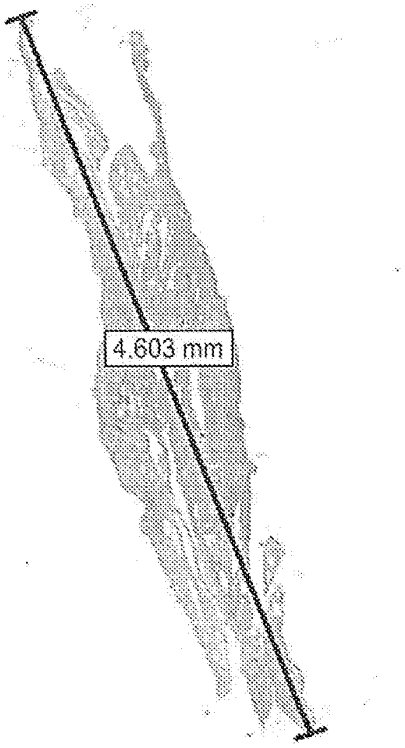



FIG. 16B

# INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/020952

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/01
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br><br>Y<br><br><br>A | US 2013/245669 A1 (BASU SHUBHAYU [US] ET AL) 19 September 2013 (2013-09-19)<br>paragraphs [0100], [0101], [0105], [0093], [0094]; claims; figures | 1-13,15,<br>16<br>14,<br>31-34,<br>39,41-48<br>35-38,40 |
| | ----- | |
| Y | US 2012/179033 A1 (MERHI WILLIAM M [US]) 12 July 2012 (2012-07-12)<br>paragraph [0094]; figure 12 | 14 |
| | ----- | |
| X<br><br>A | US 2002/026203 A1 (BATES JAMES S [US] ET AL) 28 February 2002 (2002-02-28)<br>paragraphs [0053] - [0057]; claims; figures | 1-13,15,<br>16<br>31 |
| | ----- | |
| | -/-- | |

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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

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

"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 |
|---|---|
| 10 May 2019 | 21/05/2019 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Douskas, K |

1

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## INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/020952

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US 2012/172915 A1 (FIFER DANIEL W [US] ET AL) 5 July 2012 (2012-07-05) paragraphs [0165] - [0182]; figure 36 | 1-7 |
| Y | US 2014/180329 A1 (KRAHBICHLER ERIK [SE]) 26 June 2014 (2014-06-26) paragraph [0129]; claims; figures | 31-34, 39,41-48 |

1

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

## INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2019/020952

**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. [X] Claims Nos.: 17-30, 49-63
because they relate to subject matter not required to be searched by this Authority, namely:

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

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

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

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

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

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

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

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

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

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2005)

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2019/020952

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| US 2013245669 A1 | 19-09-2013 | US 2013245669 A1 | 19-09-2013 |
| | | WO 2013116613 A1 | 08-08-2013 |
| US 2012179033 A1 | 12-07-2012 | AU 2011353593 A1 | 11-07-2013 |
| | | BR 112013017310 A2 | 04-10-2016 |
| | | CA 2823198 A1 | 12-07-2012 |
| | | DK 2661305 T3 | 03-09-2018 |
| | | EP 2661305 A1 | 13-11-2013 |
| | | ES 2686018 T3 | 16-10-2018 |
| | | IL 227099 A | 31-07-2018 |
| | | JP 5896575 B2 | 30-03-2016 |
| | | JP 2014505537 A | 06-03-2014 |
| | | KR 20140034752 A | 20-03-2014 |
| | | PL 2661305 T3 | 30-11-2018 |
| | | RU 2013136918 A | 20-02-2015 |
| | | US 2012179033 A1 | 12-07-2012 |
| | | WO 2012094195 A1 | 12-07-2012 |
| US 2002026203 A1 | 28-02-2002 | AU 740589 B2 | 08-11-2001 |
| | | CA 2304562 A1 | 08-04-1999 |
| | | CA 2501576 A1 | 08-04-1999 |
| | | DE 69824431 T2 | 09-06-2005 |
| | | EP 1018951 A1 | 19-07-2000 |
| | | JP 4199417 B2 | 17-12-2008 |
| | | JP 2001517526 A | 09-10-2001 |
| | | JP 2008100078 A | 01-05-2008 |
| | | US 6099534 A | 08-08-2000 |
| | | US 6280451 B1 | 28-08-2001 |
| | | US 2002026203 A1 | 28-02-2002 |
| | | US 2003135233 A1 | 17-07-2003 |
| | | US 2006009786 A1 | 12-01-2006 |
| | | WO 9916363 A1 | 08-04-1999 |
| US 2012172915 A1 | 05-07-2012 | US 2012172915 A1 | 05-07-2012 |
| | | US 2012172916 A1 | 05-07-2012 |
| | | US 2012172917 A1 | 05-07-2012 |
| | | US 2012172918 A1 | 05-07-2012 |
| | | US 2012172919 A1 | 05-07-2012 |
| | | US 2012172920 A1 | 05-07-2012 |
| | | US 2015209131 A1 | 30-07-2015 |
| | | US 2015335416 A1 | 26-11-2015 |
| | | US 2016193028 A1 | 07-07-2016 |
| | | US 2017181834 A1 | 29-06-2017 |
| | | US 2019091005 A1 | 28-03-2019 |
| | | WO 2012092377 A1 | 05-07-2012 |
| US 2014180329 A1 | 26-06-2014 | US 2014180329 A1 | 26-06-2014 |
| | | US 2017119518 A1 | 04-05-2017 |

Form PCT/ISA/210 (patent family annex) (April 2005)

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
05 October 2023 (05.10.2023)

WIPO | PCT

(10) International Publication Number
WO 2023/192925 A2

(51) International Patent Classification:
*A61M 5/178* (2006.01) *A61B 17/00* (2006.01)

(21) International Application Number:
PCT/US2023/065128

(22) International Filing Date:
30 March 2023 (30.03.2023)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/326,196 31 March 2022 (31.03.2022) US

(71) Applicant: **INARI MEDICAL, INC.** [US/US]; 6001 Oak Canyon, Suite #100, Irvine, California 92618 (US).

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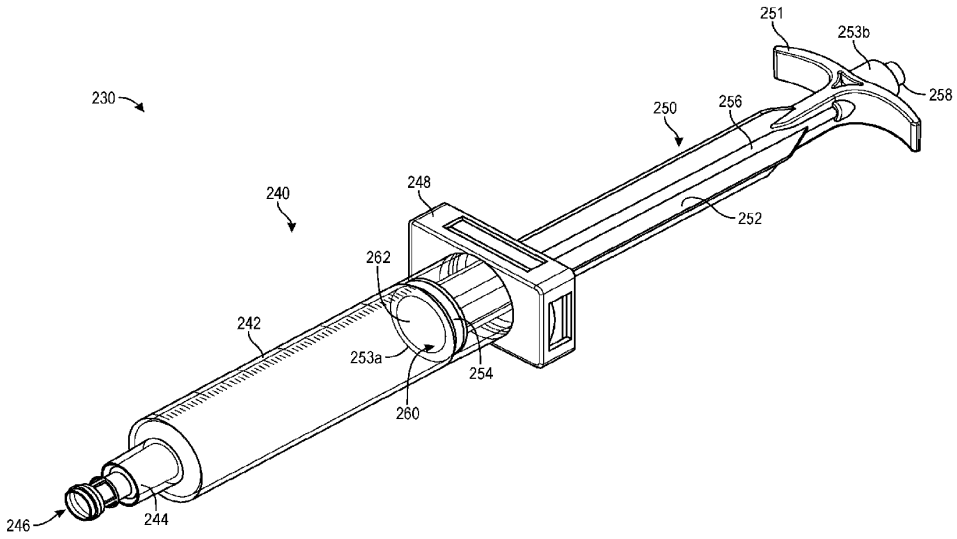



*FIG. 2A*

(57) Abstract: Disclosed herein are clot treatment systems with filtering syringes, and associated devices and methods. The filtering syringe can be coupled to a catheter subsystem insertable within a patient. The filtering syringe can aspirate material (e.g., clot material, blood, etc.) from a patient via the catheter subsystem. The filtering syringe can include a plunger assembly, and the plunger assembly can include one or more filters. Each of the filters can be configured to (i) allow at least a first portion of aspirated material (e.g., blood) to pass through at least one of the filters, and (ii) prevent at least a second portion of the aspirated material (e.g., clot material) from passing through at least one of the filters. In some embodiments, the filtering syringe is fluidly coupled to a filtered material subsystem that can fluidly couple the filtering syringe to the patient or another suitable fluid outflow location.

*[Continued on next page]*

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# BLOOD-FILTERING DEVICES FOR USE WITH CLOT TREATMENT SYSTEMS

## CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This application claims benefit of U.S. Provisional Application No. 63/326,196, filed March 31, 2022, entitled BLOOD-FILTERING DEVICES FOR USE WITH CLOT TREATMENT SYSTEMS, which is incorporated by reference herein in its entirety.

## TECHNICAL FIELD

**[0002]** The present technology generally relates to blood-filtering devices for use with clot treatment systems, and associated methods.

## BACKGROUND

**[0003]** Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

**[0004]** When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. However, infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can accordingly lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

**[0005]** In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT commonly occurs where there is a propensity for stagnated blood (e.g., long-distance air travel, immobility, etc.) and clotting (e.g., cancer; recent surgery, such as orthopedic surgery, etc.). DVT can obstruct drainage of venous blood from the legs, leading to swelling, ulcers, pain, and infection. DVT can also create a reservoir in which blood clots can collect and then travel to other parts of the body, including the heart, lungs, brain (which may cause a stroke), abdominal organs, and/or extremities.

**[0006]** Various devices exist for performing a thrombectomy or removing clot material to reestablish blood flow within a patient. Such devices can remove the target clot material and often additionally remove one or more fluids (e.g., blood) along with the clot material. These

devices are often designed to make it difficult to return removed fluids (e.g., blood) to the patient, even when doing so may be advantageous. For example, some existing devices include bypass circuits that can be cumbersome to set up and may require a specially trained user (e.g., a perfusionist) present to operate correctly.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0007]** Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

**[0008]** Figure 1 is a partially schematic side view of a clot treatment or clot removal system comprising an aspiration assembly configured in accordance with embodiments of the present technology.

**[0009]** Figure 2A is a perspective view of a pressure source comprising a vacuum-pressure locking syringe configured in accordance with embodiments of the present technology.

**[0010]** Figure 2B is a perspective view of a plunger assembly of the vacuum-pressure locking syringe of Figure 2A in accordance with embodiments of the present technology.

**[0011]** Figure 2C is an exploded perspective view of the plunger assembly of Figure 2A in accordance with embodiments of the present technology.

**[0012]** Figures 3–7B illustrate various embodiments of filtered material subsystems coupled to the syringe of Figure 2A and configured in accordance with embodiments of the present technology.

**[0013]** Figure 8A is a perspective view of another plunger assembly configured in accordance with embodiments of the present technology.

**[0014]** Figure 8B is a perspective view of a filter assembly configured in accordance with embodiments of the present technology.

**[0015]** Figures 9A and 9B are perspective views of another filtering syringe configured in accordance with embodiments of the present technology.

**[0016]** Figure 10 is a perspective view of another filtering syringe configured in accordance with embodiments of the present technology.

**[0017]** Figure 11A is a perspective view of another filtering syringe configured in accordance with embodiments of the present technology

**[0018]** Figure 11B is an enlarged perspective view of a distal portion of the filtering syringe of Figure 11A, with other portions of the filtering syringe omitted for illustrative clarity.

**[0019]** Figure 11C is a perspective view of a filter assembly of the filtering syringe of Figure 11A, configured in accordance with embodiments of the present technology.

**[0020]** Figure 11D is an enlarged side cross-sectional view of the filtering syringe of Figure 11A taken along section line 11D–11D in Figure 11B.

**[0021]** Figure 12A is a perspective view of a filter assembly of another filtering syringe configured in accordance with embodiments of the present technology.

**[0022]** Figure 12B is a cross-sectional view of the filter assembly of Figure 12A taken along section line 12B–12B in Figure 11B in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

**[0023]** The present technology is generally directed to clot treatment systems with filters, and associated devices and methods. In some of the embodiments described in detail below, the filters can be part of a filtering syringe. The filtering syringe can be coupled to a catheter subsystem insertable within a patient, such that the filtering syringe can remove (e.g., aspirate) material (e.g., clot material, blood) from a patient via the catheter subsystem. The filtering syringe can include a plunger assembly, and the plunger assembly can include one or more filters. The filters can be configured to (i) allow at least a first portion of material removed from the patient to pass through at least one of the filters, and (ii) prevent at least a second portion of the removed material from passing through at least one of the filters. In some embodiments, for example, the one or more filters are configured to (i) allow blood to pass through at least one of the filters, and (ii) prevent clot material from passing through at least one of the filters, such that the at least one filter can "filter" blood from the material removed from the patient.

**[0024]** In some embodiments, the clot treatment systems further include a filtered material subsystem. The filtered material subsystem can include one or more valves and/or tubing sections that can fluidly couple the filtering syringe and the patient. Additionally, in at least some embodiments, the filtered material subsystem includes a fluid drive element fluidly coupled to the filtering syringe and operable to draw fluid through one or more of the filters, for example,

to filter the blood from the clot material within the filtering syringe and/or to otherwise drive flow of the blood through at least part of the filtered material subsystem. In operation, the filtered material subsystem can be configured to (i) capture/receive all or part of the blood within the filtering syringe, and/or (ii) return/reintroduce all or part of the blood within the filtering syringe back to the patient.

**[0025]** In some aspects of the present technology, the filtering syringe can be used to perform multiple material removal (e.g., aspiration) cycles while remaining coupled to the filtered material subsystem and/or the catheter subsystem such that, during one or more of the material removal cycles, at least part of the aspirated material (e.g., blood) removed from the patient can be filtered and/or reintroduced into the patient without disconnecting the filtering syringe from the filtered material subsystem and/or the catheter subsystem, and/or while maintain a generally consistent (e.g., optimal) vacuum power/pressure and/or volumetric flowrate throughout the one or more material removal cycles. In some embodiments, the filtering syringe can be used to perform multiple material removal cycles while remaining fluidly coupled to the catheter system via a single fluid control device. In some aspects, having multiple fluid control devices (e.g., check-valves, Y-connectors, and the like) between a catheter system and a pressure source can reduce the pressure/aspiration power applied by the pressure source to the catheter system. In some embodiments, the filtering syringe can be used to perform one or more material removal cycles while remaining fluidly coupled to catheter and returning at least part of the filtered blood to the patient without using any fluid control devices to control/direct fluid flow between the filtering syringe and the patient. Additionally, or alternatively, at least some of the filtered material subsystems are expected to be safer and/or reduce the likelihood that clot material removed from the patient is accidentally/inadvertently reintroduced into the patient. For example, at least some of the filtered material subsystems can define one or more flow paths configured to direct the flow of the aspirated material to inhibit or prevent the filtered material (e.g., blood) from being reintroduced into the filtering syringe and/or the clot material in the filtering syringe from being driven back into the patient P. In these and other embodiments, at least some of the filtering syringes and/or filtered material subsystems can be configured such that a user can more easily perform one or more tests or other analyses on at least part of the filtered material before or instead of returning the filtered material to the patient.

**[0026]** Certain details are set forth in the following description and in Figures 1–12B to provide a thorough understanding of various embodiments of the present technology. In other instances, well-known structures, materials, operations, and/or systems often associated with

intravascular procedures, blood filtering, clot removal procedures, catheters, and the like are not shown or described in detail in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. Those of ordinary skill in the art will recognize, however, that the present technology can be practiced without one or more of the details set forth herein and/or with other structures, methods, components, and so forth. Moreover, although many of the devices and systems are described herein in the context of removing and/or treating aspirated material and/or clot material, the present technology can be used to remove and/or treat other unwanted material in addition or alternatively to clot material, such as thrombi, emboli, plaque, intimal hyperplasia, post-thrombotic scar tissue, etc. Accordingly, the terms "clot," "clot material," and "aspirated material" as used herein can refer to any of the foregoing materials and/or the like.

**[0027]** The terminology used below is to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain examples of embodiments of the technology. Indeed, certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

**[0028]** The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope unless expressly indicated. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as the position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles, and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles, and features without departing from the present technology. In addition, those of ordinary skill in the art will appreciate that further embodiments of the present technology can be practiced without several of the details described below.

**[0029]** With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to a specific orientation. It will be appreciated that such

designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

**[0030]** Figure 1 is a partially schematic side view of a clot treatment or clot removal system comprising an aspiration assembly 10 ("assembly 10") configured in accordance with embodiments of the present technology. In the illustrated embodiment, the assembly 10 includes a catheter subsystem 100, a tubing subsystem 120, a pressure source 130, and a filtered material subsystem 170. The catheter subsystem 100 includes a catheter 102 (e.g., an aspiration catheter) comprising an elongated shaft defining a lumen 104 and having a distal portion 103a and a proximal portion 103b. The catheter 102 can be intravascularly advanced to a treatment site within a blood vessel of a patient P such that, for example, the distal portion 103a is positioned in and/or proximate to clot material within the blood vessel. The catheter subsystem 100 further includes a valve 106 that can be integral with or coupled to the proximal portion 103b of the catheter 102.

**[0031]** In general, the clot removal system (i) can include features generally similar or identical to those of the clot removal systems described in detail in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety, and/or (ii) can be used to treat/remove clot material from a patient (e.g., a human patient) using any of the methods described in detail therein. In some embodiments, the catheter subsystem 100 can include some features that are at least generally similar in structure and function, or identical in structure and function, to those of the catheters disclosed in (i) U.S. Patent Application Publication No. 17/529,018, titled "CATHETERS HAVING SHAPED DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS," and filed November 17, 2021, and/or (ii) U.S. Patent Application Publication No. 17/529,064, titled "CATHETERS HAVING STEERABLE DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS," and filed November 17, 2021, each of which is incorporated herein by reference in its entirety.

**[0032]** In the illustrated embodiment, the valve 106 includes a distal portion 107a, a proximal portion 107b, and a lumen 109 extending therethrough from the distal portion 107a to the proximal portion 107b. In some embodiments, the valve 106 is a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in the proximal direction through the valve 106 as various components, such as delivery sheaths,

pull members, guidewires, interventional devices, other aspiration catheters, etc., are inserted through the valve 106 to be delivered through the catheter 102 to a treatment site in a blood vessel. The valve 106 further includes one or more branches or side ports 108 configured to fluidly couple the lumen 104 of the catheter 102 to the tubing subsystem 120. In the illustrated embodiment, the valve 106 includes buttons 101 that can be actuated (e.g., depressed) to open a conduit within the lumen 109. In some embodiments, the valve 106 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety. In some embodiments, the proximal portion 107b of the valve 106 is further configured to be detachably coupled (e.g., via a snap-fit arrangement) to a filtering device, such as one or more of the filtering syringes described in greater detail below with reference to Figures 2A-2C.

**[0033]** The tubing subsystem 120 fluidly couples the catheter subsystem 100 to the pressure source 130. More specifically, the tubing subsystem 120 can include one or more tubing sections 124 (individually labeled as a first tubing section 124a and a second tubing section 124b), at least one fluid control device 126 (e.g., a valve), and at least one connector 128 for fluidly coupling the tubing subsystem 120 to the pressure source 130 and/or other suitable components. More specifically, in the illustrated embodiment, the fluid control device 126 is a stopcock that is fluidly coupled to (i) the side port 108 of the valve 106 via the first tubing section 124a and (ii) the connector 128 via the second tubing section 124b. In at least some embodiments, the fluid control device 126 is a three-way stopcock, and includes a free port or inlet configured to allow a user to fluidly couple additional devices to the catheter subsystem 100 while the pressure source 130 is also fluidly coupled to the catheter subsystem 100, for example, to reintroduced filtered blood into a patient as described in detail below with reference to Figure 3. The fluid control device 126 is externally operable by a user to regulate the flow of fluid therethrough and, specifically, from the lumen 104 of the catheter 102 to the pressure source 130. In other embodiments, the fluid control device 126 can be a clamp that can be actuated (e.g., compressed or squeezed by the hand of a user) to partially or fully restrict fluid flow through the first tubing section 124a and/or the second tubing section 124b. In yet other embodiments, the fluid control device 126 can be omitted and its functionality incorporated into the pressure source 130.

**[0034]** The pressure source 130 is configured to generate (e.g., form, create, charge, build up) a vacuum (e.g., negative relative pressure) and store the vacuum for subsequent application

to the catheter subsystem 100. Further details of suitable pressure sources are described in detail below with reference to Figures 2A–2C and 9A–12B. In some embodiments, the pressure source 130 aspirates fluid (e.g., blood), clot material, and/or other material from the patient P during a clot removal process. In the illustrated embodiment, the pressure source 130 is fluidly coupled to the filtered material subsystem 170. The filtered material subsystem 170 can receive the aspirated fluid, clot material, and/or other material from the pressure source 130 and filter the fluid from the other material. In some embodiments, the filtered material subsystem 170 can be fluidly coupled to the patient P and configured to reintroduce the aspirated fluid (e.g., blood) into the patient. Additional details regarding suitable filtered material subsystems are described in greater detail below with reference to Figures 3-7B. Additionally, in at least some embodiments, the filtered material subsystem 170 can be omitted and the pressure source 130 can be used to transfer the aspirated fluid (e.g., blood) to the patient (e.g., intravenously, via the fluid control device 126, via one of the side ports 108, and the like) or any other suitable location.

**[0035]** During operation of the assembly 10, a user can first close the fluid control device 126 before activating the pressure source 130 to build up vacuum pressure within the pressure source 130 (e.g., a vacuum chamber of the pressure source 130). In some embodiments, the user can control or select the volume of the generated vacuum. In this manner, a vacuum is charged within the pressure source 130 before the pressure source 130 is fluidly connected to the catheter subsystem 100. To aspirate the lumen 104 of the catheter 102, the user can open the fluid control device 126 to fluidly connect the pressure source 130 to the catheter subsystem 100 and thereby apply or release the vacuum stored in the pressure source 130 to the lumen 104 of the catheter 102. Opening of the fluid control device 126 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing subsystem 120 and the catheter 102, thereby generating suction throughout the catheter 102. In particular, the suction is applied at the distal portion 103a of the catheter 102. In one aspect of the present technology, pre-charging or storing the vacuum before applying the vacuum to the lumen 104 of the catheter 102 is expected to generate greater suction forces (and corresponding fluid flow velocities) at and/or near the distal portion 103a of the catheter 102 compared to simply activating the pressure source 130 while it is fluidly connected to the catheter 102. The suction forces generated by application of the stored vacuum can be used to aspirate or otherwise remove aspirated material from within a blood vessel of a human patient. The aspirated material can be received by the pressure source 130, and at least a portion of the aspirated material can be filtered, transferred to the filtered material subsystem 170, and/or returned to/reintroduced into the patient P or another suitable outflow location.

**[0036]** Figure 2A is a perspective view of a pressure source 230 comprising a vacuum-pressure locking and/or filtering syringe ("filtering syringe 230") configured in accordance with embodiments of the present technology. In some embodiments, the filtering syringe 230 can include some features generally similar or identical to those of any one of the syringes described in detail in U.S. Patent Application No. 17/396,426, filed August 6, 2021, and titled "AUTOMATICALLY LOCKING VACUUM SYRINGES, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

**[0037]** In the illustrated embodiment, the filtering syringe 230 includes a barrel assembly 240 and a filtering plunger assembly 250 ("the plunger assembly 250"). The barrel assembly 240 includes a chamber or barrel 242, a tip 244 extending distally from the barrel 242, and a lumen or bore 246 extending through the tip 244 and the barrel 242. In some embodiments, the barrel assembly 240 includes a locking component 248. The barrel 242 is shown as transparent in Figure 2A for clarity.

**[0038]** The plunger assembly 250 can include a body or plunger 252 having a first (e.g., distal) end portion 253a defining a distal end terminus of the plunger 252, and a second (e.g., proximal) end portion 253b opposite the first end portion 253a and defining a proximal end terminus of the plunger 252. The plunger assembly 250 can further include a seal 254, a port or valve 258 (such as a Luer-activated valve or any other suitable valve), and a lumen 256 (partially obscured in Figure 2A) extending at least partially or fully through the plunger 252 between the first end portion 253a and the second end portion 253b. Additionally, the plunger assembly 250 can include a handle 251 to improve user handling of the plunger assembly 250. In the illustrated embodiment, the seal 254 is positioned proximate to the first end portion 253a, and the valve 258 and the handle 251 are positioned proximate to the second end portion 253b. The lumen 256 can be fluidly coupled to the valve 258, and the valve 258 can be fluidly coupled to the filtered material subsystem 170 and/or the patient P (Figure 1), such that fluid within the lumen 256 can flow to and/or toward the filtered material subsystem 170 and/or the patient P via the valve 258.

**[0039]** The plunger assembly 250 further includes a filter assembly 260. In the illustrated embodiment, the filter assembly 260 is positioned at the first end portion 253a of the plunger 252 and at a distal end portion of the lumen 256. In other embodiments, the filter assembly 260 can be positioned proximate to the second end portion 253b, proximally from the lumen 256, and/or at any other suitable position relative to the lumen 256 and/or within the filtering syringe 230. The filter assembly 260 can include one or more filters 262 (which can also be referred to

as "filtering elements," "filtering stages," or the like). As described in detail below, fluid (e.g., blood) can be pulled through the filters 262 into the lumen 256 and out of the valve 258.

**[0040]** At least a portion of the plunger assembly 250 is advanceable distally and proximally through the barrel 242. In the illustrated embodiment, the seal 254 sealably engages an interior surface of the barrel 242 and forms a substantially fluid impermeable seal therewith. Referring to both Figures 1 and 2A together, the tip 244 can be configured to detachably couple the filtering syringe 230 to the tubing subsystem 120. In the illustrated embodiment, the tip 244 is a Luer connector that can be coupled to the connector 128 and/or the proximal portion 107b of the valve 106 via one or more suitable adaptors. In some embodiments, the barrel 242 can be made of a transparent material that permits a user to visualize material (e.g., aspirated material) within the barrel 242.

**[0041]** With continued reference to Figures 1 and 2A together, during operation of the assembly 10, a user can first close the fluid control device 126 and then grip the plunger assembly 250 and/or the barrel assembly 240 to withdraw (e.g., retract) the plunger 252 at least partially out of the barrel 242 to thereby generate a vacuum in the barrel 242. In some embodiments, once the user has withdrawn the plunger 252 to a predetermined volume, the locking component 248 can automatically engage the plunger 252 to lock the plunger 252 relative to the barrel 242. In other embodiments, the plunger 252 can be locked by rotating the plunger 252 relative to the barrel 242 to engage the locking component 248. In some such embodiments, the user can control the volume of the vacuum—by withdrawing the plunger 252 more or less—to provide a desired amount or level of suction/aspiration upon opening of the fluid control device 126. In other embodiments, the filtering syringe 230 may not be a locking syringe, and the user can instead hold the plunger 252 in position relative to the barrel 242. In some embodiments, the syringe has a volume of about 60 cc or less than about 60 cc. With the plunger 252 withdrawn, the user can open the fluid control device 126 to aspirate material (e.g., clot material, bodily fluid(s), and the like) through the lumen 104 and into the barrel 242. The filters 262 of the filter assembly 260 can be selected to allow select material(s) and/or fluid(s) (e.g., one or more vascular fluids, blood, plasma, water, hemoglobin, white blood cells, and the like) aspirated from the patient to pass therethrough. For example, one or more of the filters 262 can (i) allow a first portion of the aspirated material (e.g., blood, blood plasma, and the like) to pass through the filter assembly 260, and (ii) prevent at least a second portion of the aspirated material (e.g., clot material, thrombi, emboli, and the like) from passing through the filter assembly 260. Accordingly, when pressure is applied to the lumen 256, the filter assembly 260 can "filter" or otherwise separate

the first portion of the aspirated material (e.g., blood) from the second portion of the aspirated material (e.g., clot material).

**[0042]** Figure 2B is a perspective view of the plunger assembly 250 of Figure 2A. Figure 2C is an exploded perspective view of the plunger assembly 250 of Figure 2A. Referring to Figures 2B and 2C together, in the illustrated embodiment, the filter assembly 260 includes a first filter 262a and a second filter 262b. Each of the filters 262a-b can be formed from a polyester, a polyamide, a hemocompatible material, a combination thereof, and/or any other suitable material. The first and second filters 262a-b can provide multiple stages of filtration to, for example, prolong the life of the filter assembly 260 and/or provide an increased filtering surface area. The first and second filters 262a-b can have the same, generally similar, or different sizes, thicknesses, porosities, and the like. In at least some embodiments, for example, the first filter 262a has a relatively large/coarse porosity of about 200 microns, and the second filter 262b has a relatively small/fine porosity of about 40 microns. In such embodiments, the first filter 262a can be configured to be relatively resilient to negative pressure, large aspirated thrombi, and/or cleaning, and the second filter 262b can be configured to filter blood, microemboli, and the like. In other embodiments, the first filter 262a and/or the second filter 262b can have any other suitable porosity, such as less than 40 microns, more than 200 microns, and/or any porosity therebetween. In these and other embodiments, the first and second filters 262a-b can have any other suitable configuration.

**[0043]** In some embodiments, one or more of the filters 262 can be detachably coupled to the plunger assembly 250 (to, e.g., form the filter assembly 260), such that one or more of the filters 262 can be removed from the plunger assembly 250, such as for cleaning, reuse, and/or disposal. Alternatively or additionally, one or more of the filters 262 can be coupled to, integrally formed with, or otherwise form a single-piece assembly with the plunger 252, such that the plunger 252 can be removed from the barrel 242 to clean, reuse, and/or dispose of the plunger 252 and/or the filter after use. Although the first and second filters 262a-b have a circular shape in the embodiment illustrated in Figure 2C, in other embodiments one or both of the filters 262a-b can have a disc, pleated, conical, cylindrical, or any other suitable shape. Although in first and second filters 262a-b are positioned adjacent to each other in the embodiment illustrated in Figure 2C, in other embodiments the first and second filters 262a-b can be spaced apart from each other. In at least some embodiments, for example, the first filter 262a can be positioned proximate the distal end portion 253a of the plunger assembly 250 and the second filter 262b can be positioned proximate the proximal end portion 253b of the plunger assembly 250 opposite

the first filter 262a. Although the filter assembly 260 includes two filters in the embodiment illustrated in Figure 2C, in other embodiments the filter assembly 260 can include more or fewer of the filters 262, such as one, more than two, or any other suitable number of filters 262.

**[0044]** Referring to Figure 2C, the lumen 256 has a first (e.g., distal) aperture or opening 257a and a second (e.g., proximal) aperture or opening 257b opposite the first opening 257a. In the illustrated embodiment, the first opening 257a is positioned to receive fluid from the barrel 242 (Figure 2A) through the filter assembly 260, and the second opening 257b is fluidly coupled to the valve 258. In some aspects of the present technology, it is expected that the lumen 256 will be unlikely to substantially clog during use because it receives fluid filtered by the filter assembly 260.

**[0045]** Figures 3–7B illustrate embodiments of filtered material subsystems 370–770, respectively, configured in accordance with embodiments of the present technology. Each of the various filtered material subsystems 370–770 can include some features that are generally similar in structure and function, or identical in structure and function, to one another and/or to the corresponding features of the filtered material subsystem 170 described in detail above with reference to Figure 1 and can operate in a generally similar or identical manner to one another and/or to the filtered material subsystem 170. Moreover, one or more of the different features of the filtered material subsystems 370–770 of the present technology can be combined or omitted.

**[0046]** Figure 3 is a perspective view of the filtering syringe 230 of Figure 2A coupled to the assembly 10 of Figure 1 in accordance with embodiments of the present technology. In the illustrated embodiment, the tip 244 of the barrel assembly 240 is fluidly coupled to the connector 128, and the valve 258 of the plunger assembly 250 is fluidly coupled to a filtered material subsystem 370 generally similar in structure and/or function to the filtered material subsystem 170 of Figure 1. In the illustrated embodiment, the filtered material subsystem 370 comprises a syringe ("the syringe 370"). In other embodiments, the filtered material subsystem 370 can include a blood bag, a container, and/or any other suitable fluid reservoir.

**[0047]** During a procedure involving the assembly 10, such as a clot treatment and/or a clot removal procedure, a user can open the fluid control device 126 after withdrawing the plunger 252 to charge a vacuum in the barrel 242 to aspirate aspirated material AM into the barrel 242, as described in detail with reference to Figures 1 and 2A. The aspirated material AM can include a first (e.g., filterable) portion FM ("the first material FM," "the filterable material FM," and the like) and a second (e.g., unfilterable) portion UFM ("the second material UFM,"

"the unfilterable material UFM," and the like). For example, the first material FM can comprise blood and the second material UFM can comprise clot material.

**[0048]** After aspirating the aspirated material AM, the user can close the fluid control device 126 to inhibit the aspirated material AM from flowing back through the fluid control device 126, into the assembly 10, and/or otherwise toward the patient P (Figure 1). When the aspirated material AM is within the barrel 242, the user can filter the aspirated material AM using the filter assembly 260 to separate all or part of the first material FM from the second material UFM. More specifically, the user can apply a force/pressure to the valve 258 with the syringe 370 to draw the aspirated material AM against the filter assembly 260 and cause at least part of the first material FM to flow through the filter assembly 260 toward the syringe 370. To apply the force/pressure to the valve 258, the user can (i) move the syringe 370 in a first (e.g., distal) direction D1 toward the plunger assembly 250 to depress the plunger 252 through the barrel 242 to drive the aspirated material AM against the filter assembly 260 and the through the lumen 256 to the syringe 370 and/or (ii) actuate the syringe 370 (e.g., by withdrawing a plunger thereof in a second direction D2) to draw the first material FM through the filter assembly 260 without depressing the plunger 252.

**[0049]** Once all or part of the first material FM is within the syringe 370, the user can (i) disconnect the syringe 370 from the valve 258, and/or (ii) return at least a portion of the first material FM (e.g., blood) to the patient. For example, the user can connect the syringe 370 to the fluid control device 126 (e.g., the free port or inlet, described above with reference to Figure 1) and actuate the syringe 370 to inject all or part of the first material FM within the syringe 370 into the catheter 102 (Figure 1) and the patient. As another example, the user can use the syringe 370 to inject all or part of the first filtered material FM into the patient intravenously, via one or more of the side ports 108 (Figure 1), and/or using any other suitable method or technique. Additionally, or alternatively, the user can (i) disconnect the filtering syringe 230 from the assembly 10, (ii) remove all or part of the remaining aspirated material AM and/or the second material UFM from the barrel 242, and/or (iii) use the filtering syringe 230 to perform one or more subsequent aspirations to remove additional material from the patient. In some embodiments, for example, the user can flush all or part of the aspirated material AM from the filtering syringe 230 via the valve 258 by, for example, fluidly coupling the valve 258 to a fluid source and flowing fluid at least partially through the filtering syringe 230 and toward and/or out of the tip 244. In other embodiments, the user can place the tip 244 of the filtering syringe 230 into a bowl containing a saline solution, or any other suitable washing/flushing solution,

withdraw the plunger 252 to pull at least a portion of the saline solution into the barrel 242 (e.g., to mix with any aspirated material AM contained therein), and then depress the plunger 252 to expel all or part of the aspirated material AM and/or the saline solution from the barrel 242. In these and other embodiments, the user can de-air the filtering syringe 230 before aspirating material from the patient. For example, the user can use the syringe 370 to (i) inject liquid (e.g., saline) into the filtering syringe 230 and/or (ii) draw fluid (e.g., air, liquid, etc.) from within the filtering syringe via, for example, the valve 258 on the filtering syringe 230. Additionally, or alternatively, the user can de-air the syringe 370 before reintroducing the first filtered material FM into the patient, for example, by actuating the plunger of the syringe 370 to remove air bubbles from the syringe's barrel.

**[0050]** Figure 4 is an enlarged side view of the filtering syringe 230 of Figure 2A coupled to a filtered material subsystem 470 in accordance with embodiments of the present technology. In the illustrated embodiment, the filtered material subsystem 470 includes a fluid control device 472 and a tubing section 474. The tubing section 474 can fluidly couple the filtering syringe 230, via the fluid control device 472, to the patient P or another suitable outflow location. The fluid control device 472 can include a one-way valve, a check valve, or any other suitable fluid control device. A first (e.g., distal) end of the fluid control device 472 is fluidly coupled to the valve 258 of the filtering syringe 230, and a second (e.g., proximal) end of the fluid control device 472 is fluidly coupled to the tubing section 474. In the illustrated embodiment, the fluid control device 472 is configured to allow fluid (e.g., the first material FM, Figure 3) to flow in the second direction D2 (e.g., through the fluid control device 472 to and/or toward the patient P), and to substantially or fully prevent fluid from flowing in the first direction D1 (e.g., opposite the second direction D2, from the patient P toward the filtering syringe 230).

**[0051]** In operation, the user can couple the filtering syringe 230 to the assembly 10 (e.g., via the connector 128, Figure 1) and actuate the assembly 10 to aspirate the aspirated material AM from the patient P, as described previously herein. Then, the user can close the fluid control device 126 (Figure 1) and move the plunger 252 in the first direction D1 to filter the aspirated material AM. Specifically, movement of the plunger 252 in the first direction D1 drives the first material FM in the second direction D2, through the filter assembly 260, the lumen 256, and the valve 258 and into the filtered material subsystem 470. In some embodiments, at least a portion of the first material FM can be returned to/reintroduced into the patient P via the tubing 474.

**[0052]** In some aspects of the present technology, the filtering syringe 230 can remain coupled to the filtered material subsystem 470 for one or more aspiration cycles, e.g., unless or until the filtering syringe 230 is filled with the second material UFM (Figure 3) and/or the user determines that the filtering syringe 230 should be cleaned/flushed. Accordingly, in at least some aspects of the present technology, the filtering syringe 230 and the filtered material subsystem 470 are expected to form a generally or substantially closed-loop system operable to remove aspirated material from the patient and return at least a portion of the aspirated material (e.g., the first material FM) to the patient P.

**[0053]** Figure 5 is a side view of the filtering syringe 230 of Figure 2A coupled to a filtered material subsystem 570 in accordance with embodiments of the present technology. In the illustrated embodiment, the filtered material subsystem 570 includes two fluid control devices 572a-b (i.e., a first fluid control device 572a and a second fluid control device 572b), two tubing sections 574a-b (i.e., a first tubing section 574a and a second tubing section 574b), and a fluid drive component 576. Each of the fluid control devices 572a-b can be generally similar or identical in structure and/or function to the fluid control device 472 of Figure 4. The fluid drive component 576 can include a syringe (e.g., "the drive syringe 576"), which can be generally similar or identical in structure and/or function to the syringe 370 of Figure 3. The first fluid control device 572a can be coupled to the valve 258 of the filtering syringe 230; the first tubing section 574a can be (i) positioned between the first fluid control device 572a and the second fluid control device 572b, and (ii) fluidly coupled to the drive syringe 576; and the second tubing section 574b can be fluidly coupled to the second fluid control device 572b opposite the first tubing section 574a. In the illustrated embodiment, the first tubing section 574a is a "T-shaped" tubing section and the drive syringe 576 has a plunger 578 that can be withdrawn/depressed to drive fluid in/out of the drive syringe 576.

**[0054]** The first and second fluid control devices 572a-b are each one-way valves positioned to allow fluid (e.g., the first material FM, Figure 3) to flow in the second direction D2 (e.g., from the filtering syringe 230 toward the patient P), and to substantially or fully prevent the fluid from flowing in a direction opposite the second direction D2 (e.g., from the patient P toward the filtering syringe 230). Accordingly, the first and second fluid control devices 572a-b can define one or more flow paths FP (i.e., a first flow path FP1 and a second flow path FP2) through the filtered material subsystem 570. The drive syringe 576 is configured to control the flow of fluid through the filtered material subsystem 570, e.g., through the first and second flow paths FP1, FP2. In the illustrated embodiment, for example, the user can withdraw the plunger

578 to drive fluid along the first flow path FP1 from the filtering syringe 230, through the first fluid control device 572a, and into the drive syringe 576. As the user withdraws the plunger 578, the second fluid control device 572b can substantially or fully prevent the drive syringe 576 from drawing fluid from the patient P, (e.g., because the force/pressure applied to the second fluid control device 572b when the plunger 578 is withdrawn in a direction opposite the second direction D2).

**[0055]** After the user has withdrawn the plunger 578, the user can depress the plunger 578 to drive fluid along the second flow path FP2 from the drive syringe 576, through the second fluid control device 572b, into the second tubing section 574b, and toward the patient P. As the user depresses the plunger 578, the first fluid control device 572a can substantially or fully prevent the drive syringe 576 from driving fluid flow into the filtering syringe 230 (e.g., because the force/pressure applied to the first fluid control device 572a when the user depresses the plunger 578 is in a direction opposite the second direction D2). In some aspects of the present technology, this can inhibit or prevent filtered material (e.g., the first material FM) from being reintroduced into the filtering syringe 230 and/or the aspirated material AM in the filtering syringe 230 from being driven back into the patient P (e.g., through the catheter 102; Figure 1).

**[0056]** In some aspects of the present technology, the user can operate the drive syringe 576 to de-air the filtered material subsystem 570 and/or the filtering syringe 230. De-airing the filtering syringe 230 can be generally similar to the filtering process described above, but with the drive syringe 576 drawing air and/or other fluid(s) from the filtering syringe 230 instead of the first material FM. In further aspects of the present technology, after the user has withdrawn the plunger 578 but before or instead of depressing the plunger 578, the user can (i) decouple the drive syringe 576 from the first tubing section 574a, (ii) perform one or more tests on the material within the drive syringe 576, (iii) transfer all or part of the material within the drive syringe 576 to another site and/or patient, (iv) take one or more images of the material within the drive syringe 576, and/or flush the filtering syringe 230 and/or the drive syringe 576.

**[0057]** Figure 6 is a side view of the filtering syringe 230 of Figure 2A coupled to a filtered material subsystem 670 in accordance with embodiments of the present technology. The filtered material subsystem 670 can include aspects generally similar in structure and/or function to the filtered material subsystem 570 of Figure 5, with like reference numbers (e.g., first tubing section 674a versus the first tubing section 574a of Figure 5) indicating like elements. Additionally, the filtered material subsystem 670 includes a second locking syringe 630 ("second

syringe 630") that can be generally similar in structure and/or function to the filtering syringe 230 ("first filtering syringe 230") of Figure 2A. In some embodiments, the second syringe 630 may not include a filtering assembly or filters.

**[0058]** In operation, a plunger 652 of the second syringe 630 can be withdrawn and then locked to generate and store vacuum within the second syringe 630. Once material is aspirated into the filtering syringe 230, the vacuum pressure in the second syringe 630 can automatically draw some of the aspirated material toward and through the filter assembly 260 along the first flow path FP1 such that some of the filtered blood can be drawn into the second syringe 630. To fully filter the material from the filtering syringe 230 into the filtered material subsystem 670, the locking component 248 can be unlocked to allow the plunger 252 to move in the first direction D1 to equalize the pressures between the filtering syringe 230 and the second syringe 630. After the filtered material FM is drawn into the second syringe 630, the second plunger 652 can be unlocked (via, e.g., locking component 648) and depressed to drive fluid from the second syringe 630 along the second flow path FP2 from the second syringe 630 to and/or toward the patient P.

**[0059]** Figure 7A is a side view of the filtering syringe 230 of Figure 2A coupled to a filtered material subsystem 770 in accordance with embodiments of the present technology. The filtered material subsystem 770 can include aspects that are generally similar in structure and/or function to the filtered material subsystem 570 of Figure 5, with like reference numbers (e.g., drive syringe 776 versus the drive syringe 576 of Figure 5) indicating like elements. Additionally, the filtered material subsystem 770 includes a fluid control device 780. The fluid control device 780 can include a three-way valve, a stopcock, or any other suitable fluid control device. Each of the filtering syringe 230, the drive syringe 776, and tubing section 774 can be fluidly coupled to the fluid control device 780. The fluid control device 780 can be configured to selectively control the flow of fluid through one or more of the flow paths FP1, FP2 within the filtered material subsystem 770. In the illustrated embodiment, for example, the fluid control device 780 includes an actuation element or lever 782 operable to transition the fluid control device 780 between (i) a first configuration (shown in Figure 7A) in which the first flow path FP1 is open (e.g., the fluid control device 780 allows fluid to flow from the filtering syringe 230 toward and/or to the drive syringe 776) and the second flow path FP2 is closed (e.g., the fluid control device 780 partially or fully prevents fluid from entering the tubing section 774), and (ii) a second configuration (not shown) in which the first flow path FP1 is closed (e.g., the fluid control device 780 partially or fully prevents fluid from entering the filtering syringe 230) and

the second flow path FP2 is open (e.g., the fluid control device 780 allows fluid to flow from the drive syringe 776 toward and/or into the tubing section 774).

**[0060]** In operation, the user can transition the fluid control device 780 to the first configuration and withdraw the plunger 778 to drive fluid along the first flow path FP1, e.g., from the filtering syringe 230, through the fluid control device 780, and into the drive syringe 776. As the user withdraws the plunger 778, the fluid control device 780 can substantially or fully prevent the drive syringe 776 from drawing fluid from the patient P when the tubing section 774 is fluidly coupled to the patient P (e.g., because the second flow path FP2 is closed when the fluid control device 780 is in the first configuration). After the user has withdrawn the plunger 778, the user can transition the fluid control device 780 from the first configuration toward and/or to the second configuration and depress the plunger 778 to drive fluid along the second flow path FP2 from the drive syringe 776, through the fluid control device 780, into the tubing section 774, and toward the patient P. As the user depresses the plunger 778, the fluid control device 780 can substantially or fully prevent the drive syringe 776 from driving fluid into the filtering syringe 230 because the first flow path FP1 is closed when the stopcock is in the second configuration. In some embodiments, after depressing the plunger 778, the user can perform one or more additional aspiration cycles with the filtered material subsystem 770 without disconnecting the filtering syringe 230 or the drive syringe 776 from the fluid control device 780.

**[0061]** Figure 7B illustrates the filtering syringe 230 of Figure 2A coupled to the filtered material subsystem 770 in accordance with additional embodiments of the present technology. In Figure 7B, the drive syringe 776 (Figure 7A) has been disconnected from the fluid control device 780 such that the fluid control device 780 has a free aperture or port 784. Additionally, the fluid control device 780 has been transitioned to a third configuration in which fluid can flow along a third flow path FP3, from the filtering syringe 230, through the fluid control device 780, and toward the patient P. Accordingly, when the fluid control device 780 is in the third configuration, the user can drive fluid through the filtered material subsystem 770 by moving the plunger 252 in the first direction D1, as described in detail above with reference to Figure 4. In some aspects of the present technology, the user can de-air/flush the filtering syringe 230 and/or the tubing section 774 via the free port 784. For example, the user can transition the fluid control device 780 to the first configuration (Figure 7A) to de-air/flush the filtering syringe 230 along the first flow path FP1 (Figure 7A) and/or transition the fluid control device 780 to the second configuration (not shown) to de-air/flush the tubing section 774 along the second flow path FP2 (Figure 7A).

**[0062]** Figure 8A is a perspective view of another plunger assembly 850 configured in accordance with embodiments of the present technology. The plunger assembly 850 can include at least some aspects that are generally similar or identical in structure and/or function to the plunger assembly 250 of Figures 2A–2C, with like reference numbers (e.g., lumen 856 versus the lumen 256 of Figures 2A–2C) indicating generally similar or identical aspects. Additionally, in the illustrated embodiment, the plunger assembly 250 further includes a pleated filter assembly 860. Referring to Figure 8B, in the illustrated embodiment the pleated filter assembly 860 includes a first filter 862a and a second filter 862b. In other embodiments, the pleated filter assembly 860 can include more or fewer filters. In these and other embodiments, the pleated filter assembly 860 can have a greater filtering surface area compared to the generally flat or planar filters/filter assemblies. Accordingly, in some aspects of the present technology, the pleated filter assembly 860 can have an increased filtering surface area compared to the filter assembly 260 of Figures 2A–2C while having a generally similar or identical cross-sectional area as the filter assembly 260.

**[0063]** Figures 9A and 9B are perspective views of another filtering syringe 930 configured in accordance with embodiments of the present technology. The filtering syringe 930 can include at least some aspects that are generally similar or identical in structure and/or function to the filtering syringe 230 of Figures 2A–2C, with like reference numbers (e.g., lumen 946 versus the lumen 246 of Figure 2A) indicating generally similar or identical aspects. In the illustrated embodiment, the filtering syringe 930 includes the plunger assembly 850 of Figure 8A. In other embodiments, the filtering syringe 930 can include the plunger assembly 250 of Figures 2A–2C, or any other suitable plunger assembly. Additionally, the filtering syringe 930 includes a detachable cap 943 (which can also be referred to as a "locking cap," a "twist cap," a "removable cap," and the like). The detachable cap 943 can be releasably coupled to the barrel 242. Referring to Figure 9B, the detachable cap 943 can be configured to matingly engage with a coupling portion 945 of the barrel 242. In the illustrated embodiment, the coupling portion 945 includes one or more coupling slots or grooves 947, the detachable cap 943 includes one or more tabs or protrusions 949 (which can extend radially from an inner surface of the cap 943, as shown in Figure 9B), and each coupling slot 947 is configured to slidably receive a corresponding tab 949 to couple the detachable cap 943 to the barrel 942. In at least some embodiments, the detachable cap 943 can include an O-ring or other sealing element (not visible in Figure 9B) that forms a substantially fluid-impermeable seal with the barrel 942 when the detachable cap 943 is coupled to the barrel 942, for example, to maintain a vacuum pressure generated/stored within

the barrel 942, and/or to inhibit or prevent fluid and/or other aspirated material within the barrel 942 from leaking out the barrel 942.

**[0064]** In operation, a user can rotate the detachable cap 943 relative to the barrel 942 (e.g., in the direction shown by the arrow R) to couple and/or uncouple the detachable cap 943 and the barrel 942. The user can uncouple the detachable cap 943 from the barrel 942 after performing one or more material removal cycles to, for example, flush or remove any fluid, clot material, or other aspirated material collected within the barrel 942. After flushing/removing material collected within the barrel 942, the user can recouple the detachable cap 943 to the barrel 942 and use the filtering syringe 930 to perform one or more additional material removal cycles, alone or in combination with any of the filtered material systems described in detail with reference to Figures 3–7B.

**[0065]** Figure 10 is a perspective view of another filtering syringe 1030 configured in accordance with embodiments of the present technology. The filtering syringe 1030 can include at least some aspects that are generally similar or identical in structure and/or function to the filtering syringe 230 of Figure 2A–2C and/or the filtering syringe 930 of Figures 9A–9B, with like numbers (e.g., barrel 1042 versus the barrel 242 of Figure 2A and/or the barrel 942 of Figures 9A and 9B) indicating generally similar or identical aspects. The filtering syringe 1030 can include a plunger assembly 1050 having a first (e.g., distal) body portion 1052a and a second (e.g., proximal) body portion 1052b. The first body portion 1052a can include the filter assembly 860 of Figures 8A and 8B, a seal or sealing element 1054, a valve 1058 (e.g., a luer-activated valve, a one-way valve, or the like), and/or a locking feature 1059 configured to engage a locking component 1048 of the filtering syringe 1030. In other embodiments, the first body portion 1052a can include the filter assembly 260 of Figures 2A–2C, or any other suitable filter and/or filter assembly. The second body portion 1052b can include a handle 1051, a plunger $1052b_1$, and/or a tip 1055. The tip 1055 can be configured to couple (e.g., fluidly coupled) to the valve 1058, such that the second body portion 1052b can be coupled/connected to the first body portion 1052a.

**[0066]** In the illustrated embodiment, the second body portion 1052b includes a syringe ("syringe 1052b"), such as a 30cc luer-lock syringe, or any other suitable syringe, including any of the filtering syringes described herein. In these and other embodiments, the syringe 1052b can have an internal volume less than, equal to, or greater than an internal volume of the barrel 1042. The tip 1055 of the syringe 1052b can be coupled to the first body portion 1052a, such that

movement of the syringe 1052b can cause corresponding movement of the first body portion 1052a. In operation, for example, the plunger assembly 1050 (e.g., the syringe 1052b) can be drawn (e.g., proximally, by a user) relative to the barrel 1042 to generate and/or store a vacuum within the filtering syringe 1030, as described previously with reference to Figures 1–2C. Continuing to move the plunger assembly 1050 can cause the locking component 1048 to engage the locking feature 1059 of the first body portion 1052a, for example, to lock the plunger assembly 1050 relative to the barrel assembly 1040 and store a vacuum within the barrel 1042, as described previously regarding Figures 2A–2C. Once a vacuum has been generated and/or stored within the filtering syringe 1030, the filtering syringe 1030 can be used to perform one or more material removal cycles, for example, as described previously with reference to Figures 1–2C, and/or alone or in combination with any of the filtered material systems described in detail with reference to Figures 3–7B. After the filtering syringe 1030 has been used to perform a material removal cycle, at least a portion of the aspirated material within the barrel 1042 can be filtered by actuating the plunger $1052b_1$ of the syringe 1052b to draw material (e.g., blood) through the filter assembly 860 and into the syringe 1052b via the valve 1058. In at least some embodiments, the syringe 1052b can be configured such that all or substantially all of the aspirated blood within the barrel 1042 can be filtered and drawn into the syringe 1052b. Additionally, or alternatively, the syringe 1052b can be advanced toward the aspirated material within the barrel 1042 to filter material within the barrel 1042. In these and other embodiments, because the first body portion 1052a sealingly engages the barrel 1042, withdrawing the plunger $1052b_1$ proximally can cause a corresponding distal movement of the syringe 1052b and the first body portion 1052a within the barrel 1042 as blood is filtered and drawn into the syringe 1052b. Similarly, moving the syringe 1052b distally can cause a corresponding proximal movement of the plunger $1052b_1$. Once at least a portion of the filtered material is drawn into the syringe 1052b, the syringe 1052b can then be disconnected from the first body portion 1052a and the filtered material (e.g., blood) within the syringe 1052b can be, for example, returned to the patient.

**[0067]** Figure 11A is a perspective view of another filtering syringe 1130 configured in accordance with embodiments of the present technology. Figure 11B is an enlarged perspective view of a distal portion 11B of the filtering syringe 1130 in accordance with embodiments of the present technology. Referring to Figures 11A and 11B together, the filtering syringe 1130 can include at least some aspects that are generally similar or identical in structure and/or function to the filtering syringe 230 of Figure 2A–2C, the filtering syringe 930 of Figures 9A–9B, and/or

the filtering syringe 1030 of Figure 10, with like numbers (e.g., barrel assembly 1140 versus the barrel assembly 240 of Figure 2A, the barrel assembly 940 of Figures 9A and 9B, and/or the barrel assembly 1040 of Figure 10) indicating generally similar or identical aspects. The filtering syringe 1130 can include the barrel assembly 1140, a plunger assembly 1150, and a filtered material subsystem 1170. The filtered material subsystem 1170 can be fluidly coupled to the plunger assembly 1150. The plunger assembly 1150 can include a plunger 1152 that can be slidably received within the barrel assembly 1140. The plunger 1152 can include a filter assembly 1160 and a seal 1154. In the illustrated embodiment, the filter assembly 1160 is seated at least partially within the plunger 1152 proximal to a first or distal end portion 1153a of the plunger 1152 and distal from the seal 1154. In other embodiments, the filter assembly 1160 can have another suitable position.

**[0068]** Figure 11C is a perspective view of the filter assembly 1160 in accordance with embodiments of the present technology. The filter assembly 1160 can include an annular filter 1162 defining a central space 1164. The annular filter 1162 can be configured to allow flow of select fluids (e.g., blood) across the annular filter 1162 toward and/or away from the central space 1164, such as radially outwardly or inwardly relative to a longitudinal axis X of the annular filter 1162. In the illustrated embodiment, the annular filter 1162 includes one or more folds or pleats 1166, each of which can increase a surface area of the annular filter 1162 while maintaining a generally compact formfactor. In some aspects of the present technology, the pleats 1166 and/or the increased surface area of the annular filter 1162 associated therewith are expected to reduce or prevent blockages, clogs, and/or other reductions of fluid flow through the annular filter 1162, which can increase the number of filtrations performed before replacement of the annular filter 1162.

**[0069]** Figure 11D is an enlarged side cross-sectional view of the filtering syringe 1130 taken along section line 11D–11D in Figure 11B in accordance with embodiments of the present technology. The first end portion 1153a of the plunger 1152 can at least partially define a first or distal chamber portion 1141a on a first (e.g., distal) side of the first end portion 1153a and a second or proximal portion chamber portion 1141b on a second (e.g., proximal) side of the first end portion 1153a opposite the first side. A lateral-most edge 1168 of the first end portion 1153a can have a dimension (e.g., a diameter) less than a corresponding dimension (e.g., a dimeter) of an inner surface 1190 of the barrel 1142, such that the lateral-most edge 1168 can be spaced apart from an inner surface 1190 of the barrel 1142 to define a gap or fluid passage 1192 that fluidly couples the first chamber portion 1141a and the second chamber portion 1141b. The

annular filter 1162 can be carried by the plunger 1152 and can be positioned at least partially within the second chamber portion 1141b, such as with the central space 1164 of the annular filter 1162 at least partially aligned with a lumen 1156 of the plunger 1152, and/or such that all or substantially all fluid within the barrel 1142 that enters the lumen 1156 must pass through the annular filter 1162. In the illustrated embodiment, the annular filter 1162 is radially inward from the lateral-most edge 1168, such that the lateral-most edge 1168 overhangs or otherwise extends radially outward relative to the annular filter 1162.

**[0070]** During a procedure, aspirated material AM including blood and/or clot material can be drawn into the first chamber portion 1141a of the barrel 1142. The plunger 1152 can be advanced in the first direction D1 and/or a vacuum can be applied to the lumen 1156 to cause at least some material (e.g., blood) within the first chamber portion 1141a to flow through the gap 1192, into the second chamber portion 1141b, at least partially through the annular filter 1162, into the central space 1164 of the annular filter 1162, and/or into the lumen 1156, such as shown by flow path arrow FP in Figure 11D. The material (e.g., blood) within the lumen 1156 can flow into the filtered material subsystem 1170 and/or be returned to the patient P, including via any of the techniques described previously herein. The first end portion 1153a and/or the gap 1192 between the first chamber portion 1141a and the second chamber portion 1141b are expected to prevent at least a portion of the aspirated material AM (e.g., at least some aspirated clot material) from entering the second chamber portion 1141b and/or otherwise reduce or prevent contact between the aspirated material AM and the annular filter 1162, without or substantially without inhibiting the flow of other material (e.g., blood) between the first chamber portion 1141a and the second chamber portion 1141b. This, in turn, is expected to reduce or prevent clogs or other obstructions to fluid flow through the annular filter 1162. Accordingly, the first end portion 1153a and/or the gap 1192 can be configured to provide a first filtering stage that inhibits or prevents relatively large material from entering the second chamber portion 1141b while the annular filter 1162 can provide a second filtering stage that inhibits or prevents relatively smaller material from entering the lumen 1156.

**[0071]** Figure 12A is a perspective view of a plunger assembly 1250 of another filtering syringe configured in accordance with embodiments of the present technology. At least some aspects of the plunger assembly 1250 can be at least generally similar or identical in structure and/or function to one or more of the plunger assemblies 250, 850, 1050, 1150 described previously herein. For example, the plunger assembly 1250 includes a plunger 1252 configured

to carry one or more filters 1162 (Figure 12B). However, a first or distal end portion 1253a of the plunger 1252 includes one or more holes or apertures 1292.

**[0072]** Figure 12B is a cross-sectional view of the plunger assembly 1250 of Figure 12A taken along section line 12B–12B in Figure 11B. In Figure 12B, the plunger assembly 1250 is shown positioned within a barrel 1242 of a filtering syringe 1230, in accordance with embodiments of the present technology. As best seen in Figure 12B, the plunger 1252 defines a filter chamber 1294 configured to receive the annular filter 1162 and a lumen 1256 that can be fluidly coupled to the filtered material subsystem 1170 and/or the patient. The holes 1292 formed in the first end portion 1253a of the plunger 1252 can be configured to allow fluid communication between the filter chamber 1294 (e.g., the central space 1164 of the annular filter 1162) and the exterior of the plunger 1252 (e.g., the interior of the barrel 1242). More specifically, when the annular filter 1162 is positioned within the filter chamber 1294, individual ones of the holes 1292 can allow at least some of the aspirated material AM within the barrel 1242 (including, e.g., blood and/or other fluids) to flow into the central space 1164 of the annular filter 1162. A proximal end portion 1263 of the filter 1162 can be sealed so that at least some of the aspirated material AM that passes through the holes 1292 is caught within the central space 1164, e.g., and does not pass through the filter 1162 into the filter chamber 1294 and/or the lumen 1256. A distal end portion 1265 of the filter 1162 can be coupled to at least part of the first end portion 1253a, e.g., to prevent, or at least partially prevent, the aspirated material AM from entering the filter chamber 1294 without passing through the central space 1164 of the annular filter 1162.

**[0073]** During a procedure, the plunger 1252 can be moved the first direction D1 relative to the barrel 1242 to force at least some of the aspirated material AM through individual ones of the holes 1292 and/or into the central space 1164. As the aspirated material AM collects within the central space 1164, the filter 1162 can separate blood and/or other fluids contained within the aspirated material AM from the aspirated material AM. Because the proximal and distal end portions 1263, 1265 of the annular filter 1162 are sealed, the blood and/or other fluids can be separated by causing the blood and/or other fluids to flow outwardly from the central space 1164 across the filter 1162. For example, moving the plunger 1252 in the first direction D1 relative to the barrel 1242 can force the blood and/or other fluids across the filter 1162, into a space between the filter 1162 and the filter chamber 1294, and into and/or through at least a portion of the lumen 1256. The blood and/or other fluids within the lumen 1256 can flow to the filtered material subsystem 1170 and/or be returned to the patient P.

**[0074]** Accordingly, in some aspects of the present technology, a filtering syringe can be coupled to a catheter subsystem insertable within a patient. The filtering syringe can aspirate material (e.g., clot material, blood, etc.) from a patient via the catheter subsystem. The filtering syringe can include a plunger assembly, and the plunger assembly can include one or more filters. Individual ones of the filters can be configured to (i) allow at least a first portion of aspirated material to pass through at least one of the filters, and (ii) prevent at least a second portion of the aspirated material from passing through at least one of the filters. In some embodiments, for example, the filters are configured to (i) allow blood to pass through the filters, and (ii) prevent clot material from passing through the filters, such that the filters can "filter" blood from the other material aspirated from the patient. In some embodiments, the filtering syringe is fluidly coupled to a filtered material subsystem. The filtered material subsystem can include one or more valves and/or tubing sections that can fluidly couple the filtering syringe to the patient or another suitable fluid (e.g., blood) outflow location. The filtered material subsystem can (i) capture/receive all or part of the first portion of the aspirated material filtered by the filtering syringe, and/or (ii) return/reintroduce all or part of the first portion of the aspirated material into the patient.

**[0075]** Several aspects of the present technology are set forth in the following examples:

1. A filtering syringe for treatment of clot material from within a blood vessel of a patient, the filtering syringe comprising:

a barrel defining a chamber configured to receive at least a portion of the clot material and blood from the human patient;

a plunger assembly having a first end portion and a second end portion opposite the first end portion, wherein the plunger assembly includes a filter proximate to the first end portion, a port proximate to the second end portion, and a lumen therebetween and fluidly coupling the filter and the port;

wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel; and

wherein the filter is configured to allow at least part of the blood received within the chamber to separate from the portion of the clot material and enter the lumen of the plunger assembly.

2. The filtering syringe of example 1, further comprising a tip configured to fluidly couple the filtering syringe to a clot treatment system.

3. The filtering syringe of example 1 or example 2 wherein the filter has a circular, annular, cylindrical, and/or pleated shape.

4. The filtering syringe of any of examples 1-3 wherein the filter has a porosity between about 40 microns and about 200 microns.

5. The filtering syringe of any of examples 1-4 wherein the filter includes at least one of a polyester, a polyamide, and/or a hemocompatible material.

6. The filtering syringe of any of examples 1-5 wherein the filter is a first filter having a first porosity, the filtering syringe further comprising a second filter having a second porosity.

7. The filtering syringe of example 6 wherein the first porosity is different than the first porosity.

8. The filtering syringe of example 6 wherein the first porosity is the same as the second porosity.

9. The filtering syringe of any of examples 6-8 wherein the second filter is positioned proximate the first end portion of the plunger assembly.

10. The filtering syringe of any of examples 6-9 wherein the second filter is spaced apart from the first filter.

11. The filtering syringe of any of examples 1-10 wherein the port includes a luer-activated valve.

12. The filtering syringe of any of examples 1-11 wherein the first end portion of the plunger assembly is a distal end portion of the plunger assembly and the second end portion is a

proximal end portion of the plunger assembly, wherein the filter is positioned proximally from the distal end portion.

13. The filtering syringe of any of examples 1-12 wherein the chamber includes an inner surface, and wherein first end portion of the plunger assembly is radially spaced apart from chamber such that the barrel assembly and the plunger assembly at least partially define (i) a first chamber portion positioned on a first side of the first end portion of the plunger assembly, (ii) a second chamber portion positioned on a second side of the first end portion of the plunger assembly, the second side opposite the first side, and (iii) a gap fluidly coupling the first chamber portion and the second chamber portion.

14. The filtering syringe of example 13 wherein the filter is positioned in the second chamber portion, wherein the first chamber portion is configured to receive at least the portion of the clot material from the patient, wherein the gap is configured to at least partially prevent the portion of the clot material from entering the second chamber portion, and wherein the filter is configured to allow blood within the second chamber portion to enter the lumen.

15. The filtering syringe of any of examples 1-14 wherein the first end portion of the plunger assembly is configured to at least partially prevent contact between the filter and the portion of the clot material.

16. The filtering syringe of any of examples 1-15 wherein the plunger assembly defines a filter chamber configured to receive the filter, and wherein the first end portion of the plunger assembly includes one or more holes in fluid communication with the filter chamber.

17. The filtering syringe of example 16 wherein the filter is an annular filter defining a central space, and wherein individual ones of the one or more holes are positioned to direct at least a portion of the clot material and/or the blood received from the patient into the central space.

18. A system for intravascular treatment of clot material from within a blood vessel of a human patient, the system comprising:

a catheter configured to be intravascularly positioned at a treatment site proximate to the clot material within the blood vessel;

a filtering syringe configured to generate negative pressure, wherein the filtering syringe includes—

a tip configured to be fluidly coupled to the catheter to receive at least a portion of the clot material and blood from within the blood vessel via the catheter, and

a filter assembly including one or more filters configured to filter the blood from the portion of the clot material.

19. The system of example 18, further comprising a filtered material system fluidly coupled to the filtering syringe and configured to receive at least a portion of the filtered blood.

20. The system of example 19, wherein the filtered material system includes a fluid drive component operable to drive flow of the filtered blood through at least part of the filtered material system.

21. The system of example 20 wherein the filtered material system includes at least one flow path, and wherein fluid drive component is operable to drive the flow of the filtered blood through the at least one flow path.

22. The system of example 21 wherein the at least one flow path is configured to direct fluid flow away from the filtering syringe.

23. The system of any of examples 19-22 wherein the filtering syringe further includes a valve opposite the tip, wherein the filtered material system includes (i) a fluid control device fluidly coupled to the valve and (ii) tubing fluidly coupled to the fluid control device, and wherein the fluid control device is configured to at least partially prevent filtered blood within the tubing from entering the filtering syringe.

24. A method for removing clot material from within a blood vessel of a human patient, the method comprising:

positioning a distal portion of a catheter proximate to the clot material within the blood vessel;

coupling a filtering and pressure-generating syringe to the catheter via a fluid control device, wherein (i) opening of the fluid control device fluidly connects the filtering and pressure-generating syringe to the catheter, and (ii) closing the fluid control device fluidly disconnects the filtering and pressure-generating syringe from the catheter;

activating the syringe to generate a vacuum while the fluid control device is closed;

opening the fluid control device to apply the vacuum to the catheter to thereby aspirate at least a portion of the clot material into the catheter; and

filtering blood from the portion of the clot material via a filter of the syringe.

25. The method of example 24 wherein filtering the blood includes moving a plunger of the syringe to cause the filter to move toward the portion of the clot material.

26. The method of example 24 or example 25 wherein filtering the blood includes actuating a fluid drive component of a filtered material system to cause the blood to flow through the filter proximally toward the fluid drive component.

27. A filtering syringe for removing target material from within a human patient, the filtering syringe comprising:

a barrel defining a chamber configured to receive at least a portion of the target material and fluid from the human patient;

a plunger assembly having a first end portion and a second end portion opposite the first end portion, wherein the plunger assembly includes a filter proximate to the first end portion, a valve proximate to the second end portion, and a lumen therebetween and fluidly coupling the filter and the valve;

wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel; and

wherein the filter is configured to allow at least part of the fluid received within the chamber to pass through the filter and enter the lumen of the plunger assembly.

28. The filtering syringe of example 27 wherein the fluid includes blood.

29. The filtering syringe of example 27 or example 28 wherein the target material includes clot material.

30. A filtering syringe for treating a human patient, comprising:

a barrel defining a chamber configured to receive first material and second material from within the human patient;

a plunger assembly having a first end portion and a second end portion opposite the first end portion, wherein the plunger assembly includes a filter proximate to the first end portion, a valve proximate to the second end portion, and a lumen therebetween and fluidly coupling the filter and the valve;

wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel; and

wherein the filter is configured to (i) allow at least part of the first material received within the chamber to pass through the filter and enter the lumen of the plunger assembly, and (ii) prevent at least part of the second material received within the chamber from passing through the filter.

31. The filtering syringe of example 30 wherein the first material includes blood.

32. The filtering syringe of example 30 or example 31 wherein the second material includes clot material.

33. A filtering syringe for treating a human patient, comprising:

a barrel defining a chamber configured to receive first material and second material from within the human patient; and

a plunger assembly including a first body portion and a second body portion, wherein the first body portion includes a filter and a valve, and wherein the second body portion defines an interior chamber and is detachably couplable to the first body portion via the valve;

wherein at least part of the first body portion and the second body portion are insertable within the chamber and slidable relative to the barrel; and

wherein the filter is configured to allow at least part of the first material received within the chamber to pass through the filter and into the interior chamber of the second body portion.

34. The filtering syringe of example 33 wherein the second body portion comprises a syringe including a plunger operable to draw at least part of the first material within the chamber through the filter and into the interior chamber of the syringe.

35. The filtering syringe of example 34 wherein the syringe includes a tip, and wherein the valve of the first body portion is configured to matingly engage the tip of the syringe to fluidly couple the chamber of the barrel to the interior chamber of the syringe.

36. The filtering syringe of any of examples 33-35 wherein the first material includes blood.

37. The filtering syringe of any of examples 33-36 wherein the second material includes clot material.

**[0076]** The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology, as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

**[0077]** From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

**[0078]** Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in

the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A filtering syringe for treatment of clot material from within a blood vessel of a patient, the filtering syringe comprising:

a barrel defining a chamber configured to receive at least a portion of the clot material and blood from the patient; and

a plunger assembly having a first end portion and a second end portion opposite the first end portion, wherein the plunger assembly includes a filter proximate to the first end portion, a port proximate to the second end portion, and a lumen therebetween and fluidly coupling the filter and the port;

wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel; and

wherein the filter is configured to allow at least part of the blood received within the chamber to separate from the portion of the clot material and enter the lumen of the plunger assembly.

2. The filtering syringe of claim 1, further comprising a tip configured to fluidly couple the filtering syringe to a clot treatment system.

3. The filtering syringe of claim 1 wherein the filter has a circular, annular, cylindrical, and/or pleated shape.

4. The filtering syringe of claim 1 wherein the filter has a porosity between about 40 microns and about 200 microns.

5. The filtering syringe of claim 1 wherein the filter includes at least one of a polyester, a polyamide, and/or a hemocompatible material.

6. The filtering syringe of claim 1 wherein the filter is a first filter having a first porosity, the filtering syringe further comprising a second filter having a second porosity.

7. The filtering syringe of claim 6 wherein the first porosity is different than the first porosity.

8. The filtering syringe of claim 6 wherein the first porosity is the same as the second porosity.

9. The filtering syringe of claim 6 wherein the second filter is positioned proximate the first end portion of the plunger assembly.

10. The filtering syringe of claim 6 wherein the second filter is spaced apart from the first filter.

11. The filtering syringe of claim 1 wherein the port includes a luer-activated valve.

12. The filtering syringe of claim 1 wherein the first end portion of the plunger assembly is a distal end portion of the plunger assembly and the second end portion is a proximal end portion of the plunger assembly, wherein the filter is positioned proximally from the distal end portion.

13. The filtering syringe of claim 1 wherein the chamber includes an inner surface, and wherein first end portion of the plunger assembly is radially spaced apart from chamber such that the barrel assembly and the plunger assembly at least partially define (i) a first chamber portion positioned on a first side of the first end portion of the plunger assembly, (ii) a second chamber portion positioned on a second side of the first end portion of the plunger assembly, the second side opposite the first side, and (iii) a gap fluidly coupling the first chamber portion and the second chamber portion.

14. The filtering syringe of claim 13 wherein the filter is positioned in the second chamber portion, wherein the first chamber portion is configured to receive at least the portion of the clot material from the patient, wherein the gap is configured to at least partially prevent the portion of the clot material from entering the second chamber portion, and wherein the filter is configured to allow blood within the second chamber portion to enter the lumen.

15. The filtering syringe of claim 1 wherein the first end portion of the plunger assembly is configured to at least partially prevent contact between the filter and the portion of the clot material.

16. The filtering syringe of claim 1 wherein the plunger assembly defines a filter chamber configured to receive the filter, and wherein the first end portion of the plunger assembly includes one or more holes in fluid communication with the filter chamber.

17. The filtering syringe of claim 16 wherein the filter is an annular filter defining a central space, and wherein individual ones of the one or more holes are positioned to direct at least a portion of the clot material and/or the blood received from the patient into the central space.

18. A system for intravascular treatment of clot material from within a blood vessel of a human patient, the system comprising:

a catheter configured to be intravascularly positioned at a treatment site proximate to the clot material within the blood vessel; and

a filtering syringe configured to generate negative pressure, wherein the filtering syringe includes—

a tip configured to be fluidly coupled to the catheter to receive at least a portion of the clot material and blood from within the blood vessel via the catheter, and

a filter assembly including one or more filters configured to filter the blood from the portion of the clot material.

19. The system of claim 18, further comprising a filtered material system fluidly coupled to the filtering syringe and configured to receive at least a portion of the filtered blood.

20. The system of claim 19, wherein the filtered material system includes a fluid drive component operable to drive flow of the filtered blood through at least part of the filtered material system.

21. The system of claim 20 wherein the filtered material system includes at least one flow path, and wherein fluid drive component is operable to drive the flow of the filtered blood through the at least one flow path.

22. The system of claim 21 wherein the at least one flow path is configured to direct fluid flow away from the filtering syringe.

23. The system of claim 19 wherein the filtering syringe further includes a valve opposite the tip, wherein the filtered material system includes (i) a fluid control device fluidly coupled to the valve and (ii) tubing fluidly coupled to the fluid control device, and wherein the fluid control device is configured to at least partially prevent filtered blood within the tubing from entering the filtering syringe.

24. A method for removing clot material from within a blood vessel of a human patient, the method comprising:

positioning a distal portion of a catheter proximate to the clot material within the blood vessel;

coupling a filtering and pressure-generating syringe to the catheter via a fluid control device, wherein (i) opening of the fluid control device fluidly connects the filtering and pressure-generating syringe to the catheter, and (ii) closing the fluid control device fluidly disconnects the filtering and pressure-generating syringe from the catheter;

activating the syringe to generate a vacuum while the fluid control device is closed;

opening the fluid control device to apply the vacuum to the catheter to thereby aspirate at least a portion of the clot material into the catheter; and

filtering blood from the portion of the clot material via a filter of the syringe.

25. The method of claim 24 wherein filtering the blood includes moving a plunger of the syringe to cause the filter to move toward the portion of the clot material.

26. The method of claim 24 wherein filtering the blood includes actuating a fluid drive component of a filtered material system to cause the blood to flow through the filter proximally toward the fluid drive component.

27. A filtering syringe for removing target material from within a human patient, the filtering syringe comprising:

a barrel defining a chamber configured to receive at least a portion of the target material and fluid from the human patient; and

a plunger assembly having a first end portion and a second end portion opposite the first end portion, wherein the plunger assembly includes a filter proximate to the first end portion, a valve proximate to the second end portion, and a lumen therebetween and fluidly coupling the filter and the valve;

wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel; and

wherein the filter is configured to allow at least part of the fluid received within the chamber to pass through the filter and enter the lumen of the plunger assembly.

28. The filtering syringe of claim 27 wherein the fluid includes blood.

29. The filtering syringe of claim 27 wherein the target material includes clot material.

30. A filtering syringe for treating a human patient, comprising:

a barrel defining a chamber configured to receive first material and second material from within the human patient; and

a plunger assembly having a first end portion and a second end portion opposite the first end portion, wherein the plunger assembly includes a filter proximate to the first end portion, a valve proximate to the second end portion, and a lumen therebetween and fluidly coupling the filter and the valve;

wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel; and

wherein the filter is configured to (i) allow at least part of the first material received within the chamber to pass through the filter and enter the lumen of the plunger

assembly, and (ii) prevent at least part of the second material received within the chamber from passing through the filter.

31. The filtering syringe of claim 30 wherein the first material includes blood.

32. The filtering syringe of claim 30 wherein the second material includes clot material.

33. A filtering syringe for treating a human patient, comprising:

a barrel defining a chamber configured to receive first material and second material from within the human patient; and

a plunger assembly including a first body portion and a second body portion, wherein the first body portion includes a filter and a valve, and wherein the second body portion defines an interior chamber and is detachably couplable to the first body portion via the valve;

wherein at least part of the first body portion and the second body portion are insertable within the chamber and slidable relative to the barrel; and

wherein the filter is configured to allow at least part of the first material received within the chamber to pass through the filter and into the interior chamber of the second body portion.

34. The filtering syringe of claim 33 wherein the second body portion comprises a syringe including a plunger operable to draw at least part of the first material within the chamber through the filter and into the interior chamber of the syringe.

35. The filtering syringe of claim 34 wherein the syringe includes a tip, and wherein the valve of the first body portion is configured to matingly engage the tip of the syringe to fluidly couple the chamber of the barrel to the interior chamber of the syringe.

36. The filtering syringe of claim 33 wherein the first material includes blood.

37. The filtering syringe of claim 33 wherein the second material includes clot.

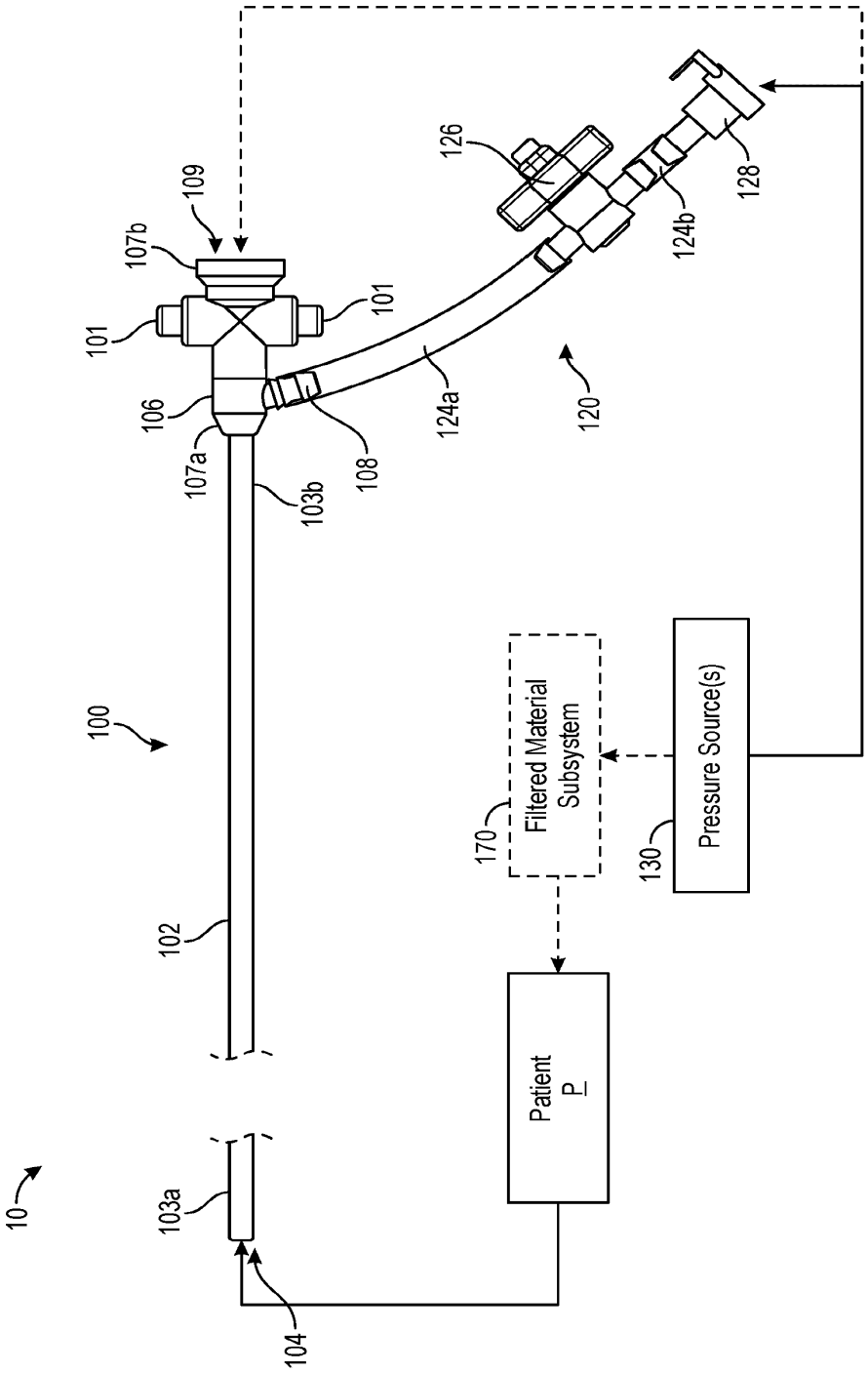

10
100
101
101
102
103a
103b
104
106
107a
107b
108
109
120
124a
124b
126
128
130
170
Filtered Material Subsystem
Pressure Source(s)
Patient P

*FIG. 1*

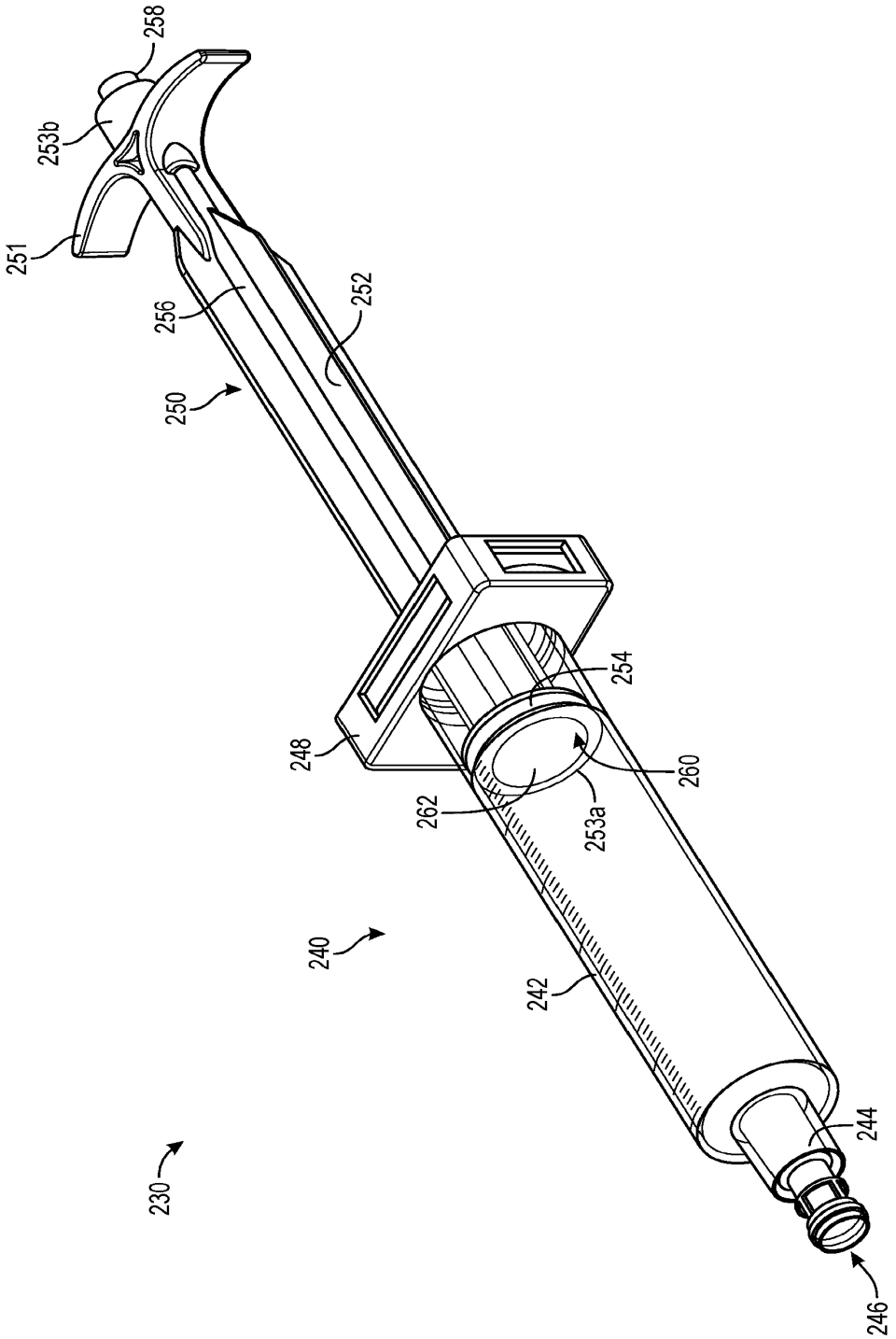

258
253b
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256
252
250
254
248
260
262
253a
240
242
244
230
246

*FIG. 2A*

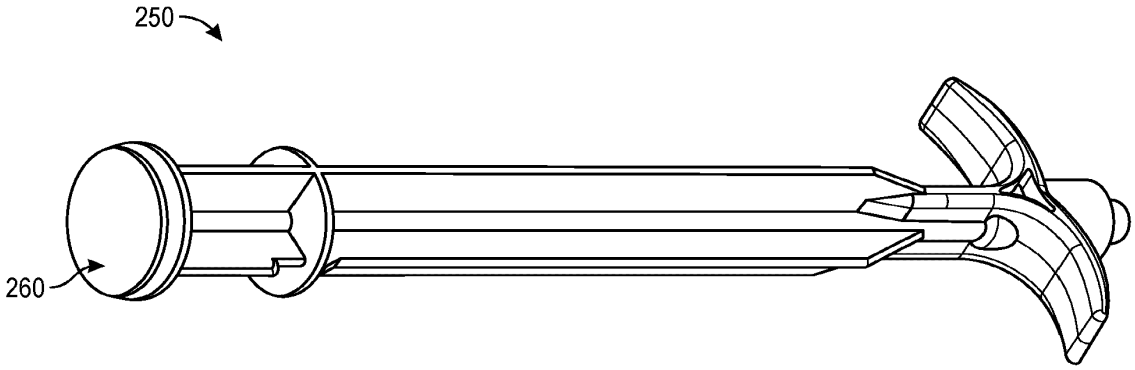



*FIG. 2B*

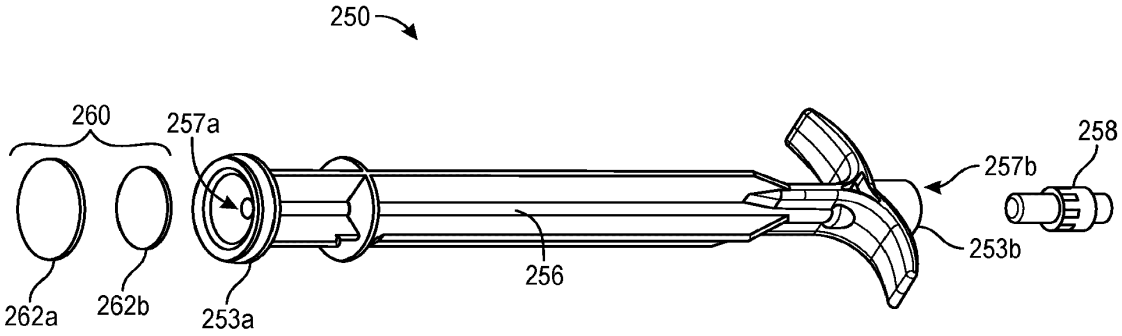



*FIG. 2C*

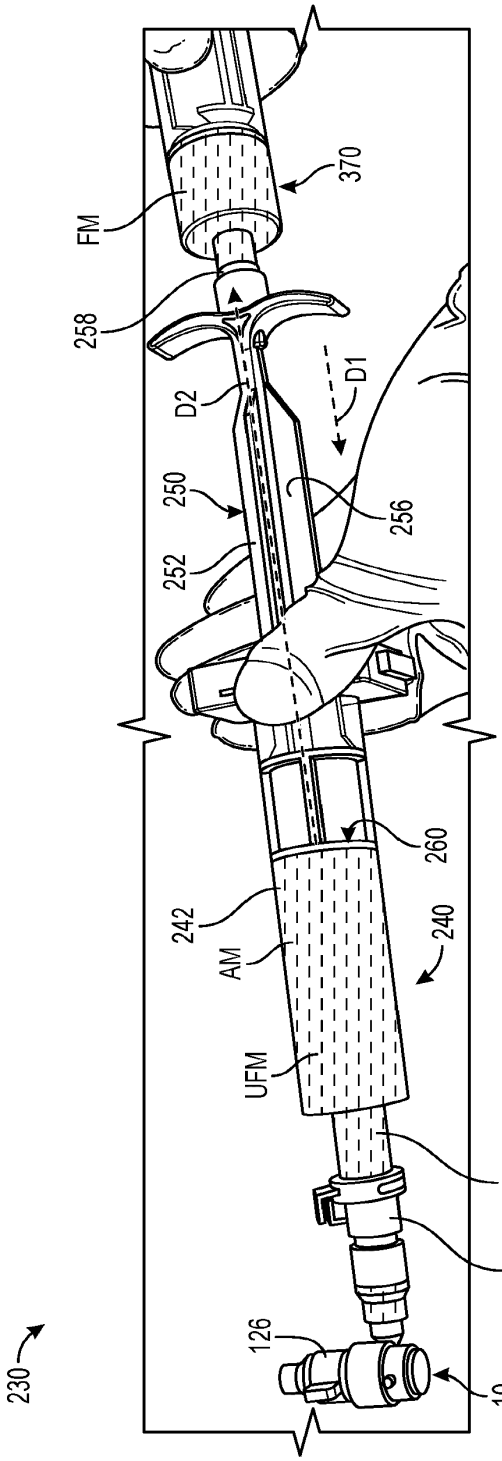



*FIG. 3*

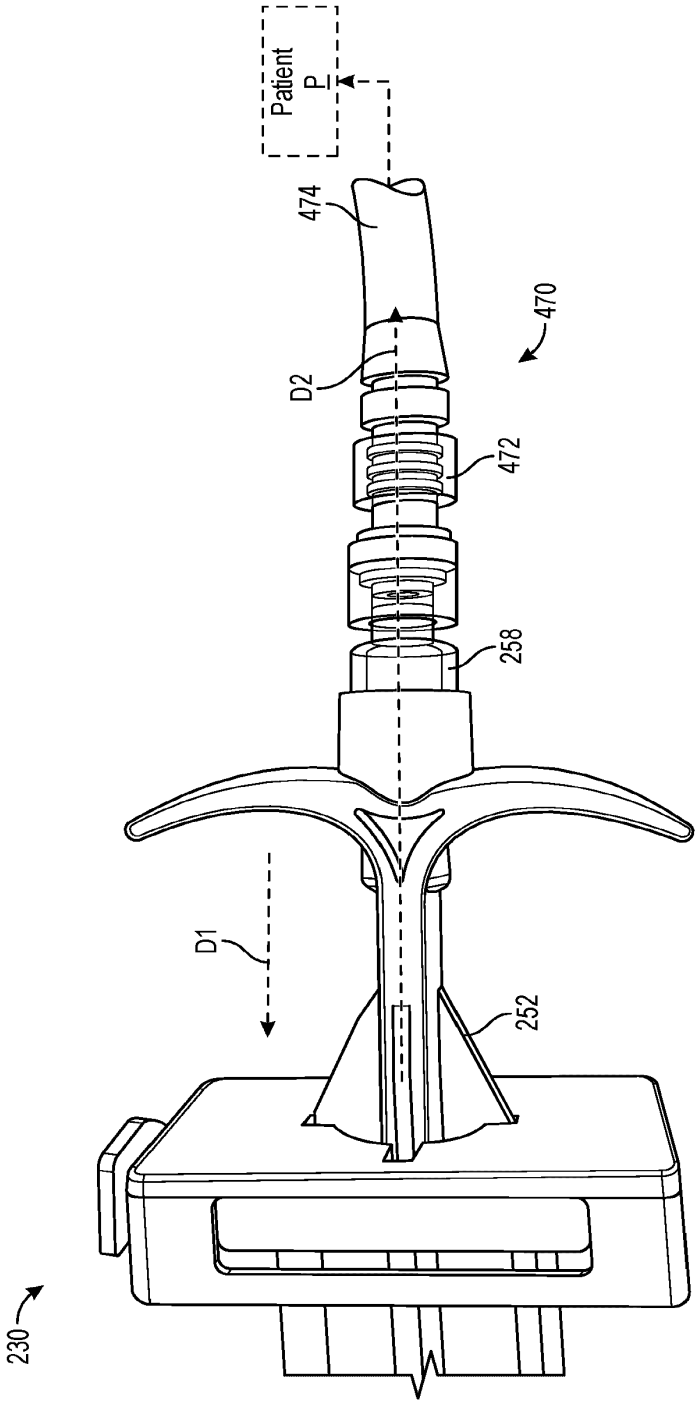



*FIG. 4*

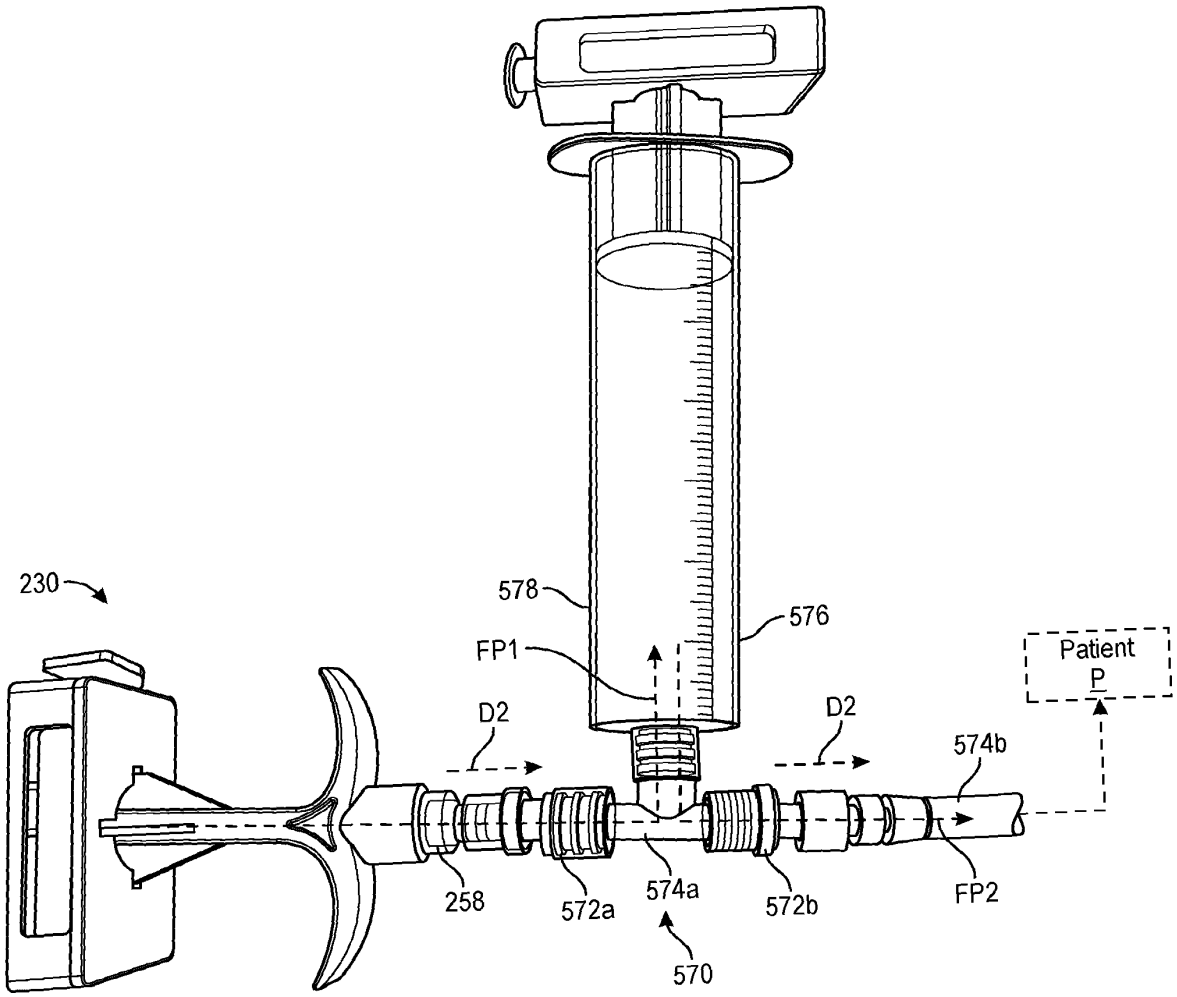



*FIG. 5*

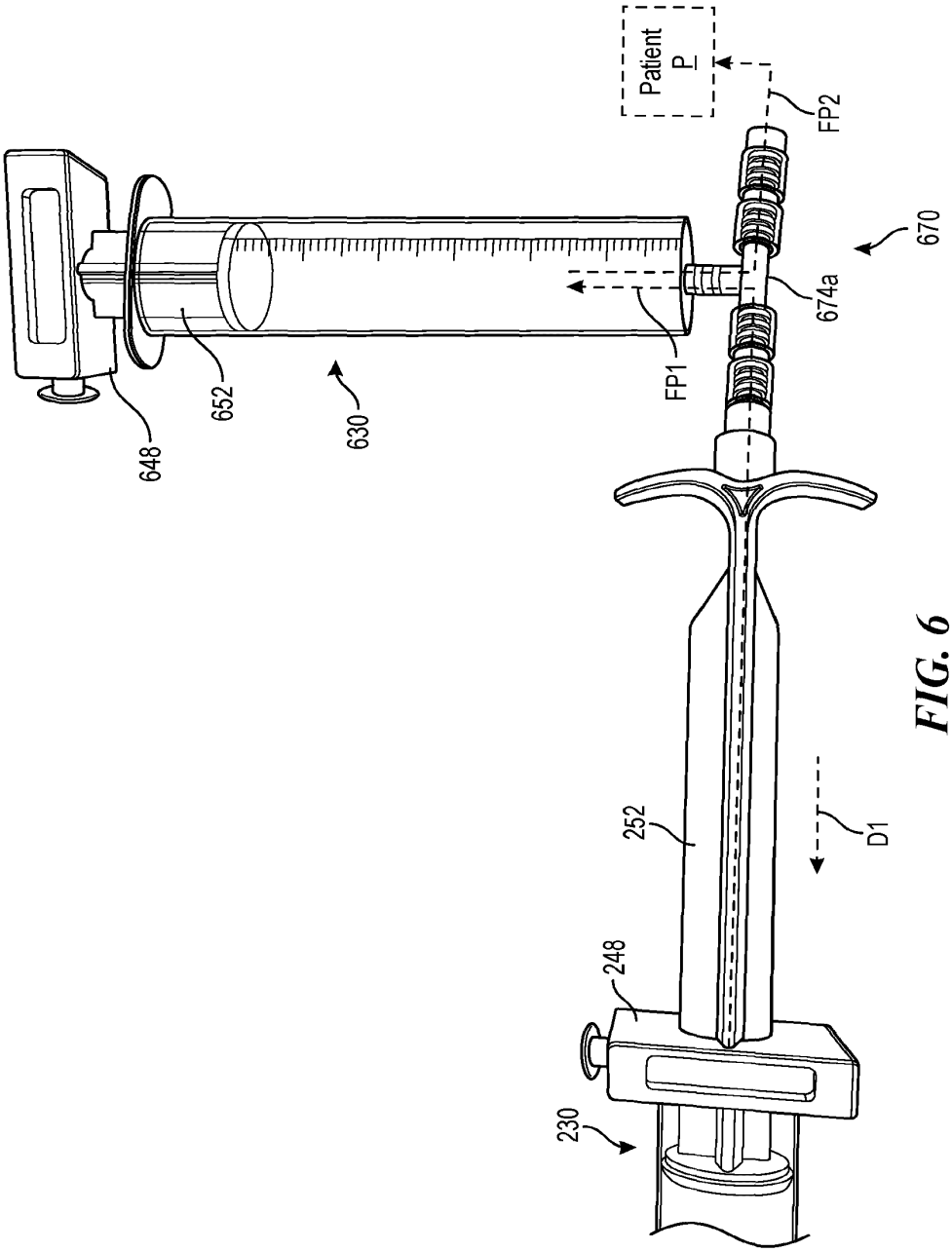



*FIG. 6*

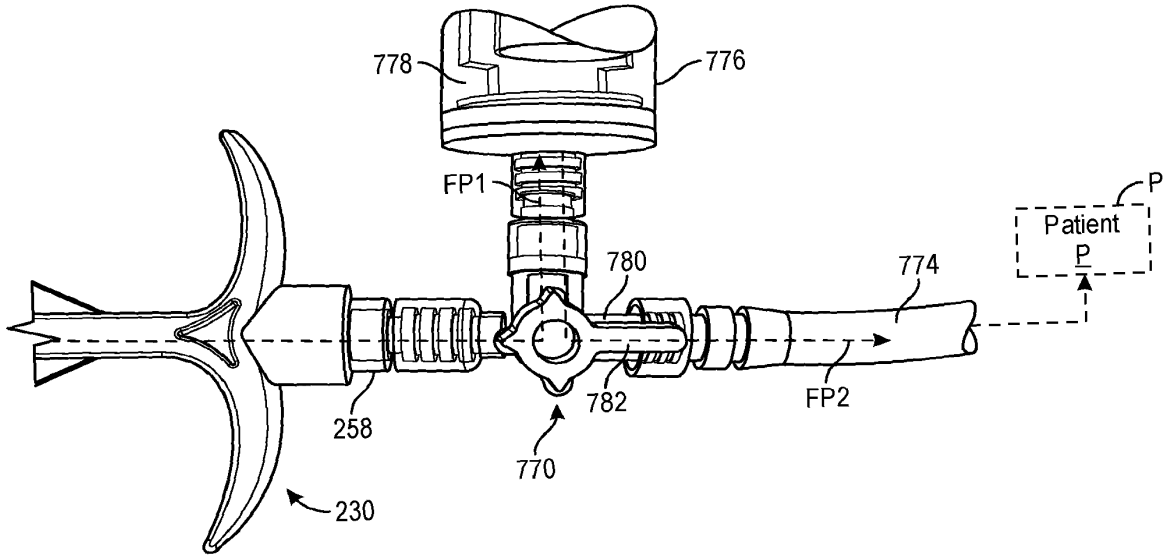

778
776
FP1
P
Patient
P
780
774
258
782
FP2
770
230

*FIG. 7A*

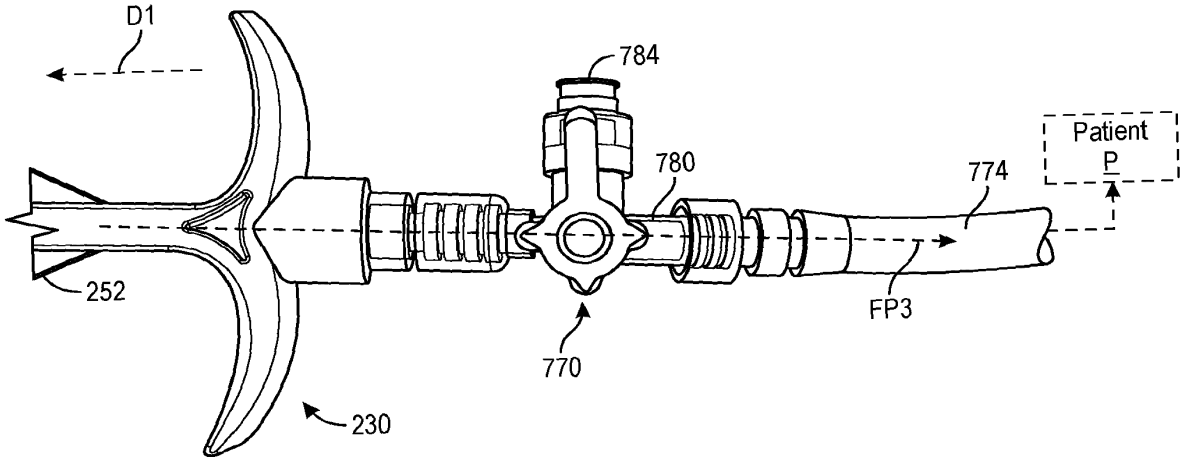

D1
784
Patient
P
780
774
252
FP3
770
230

*FIG. 7B*

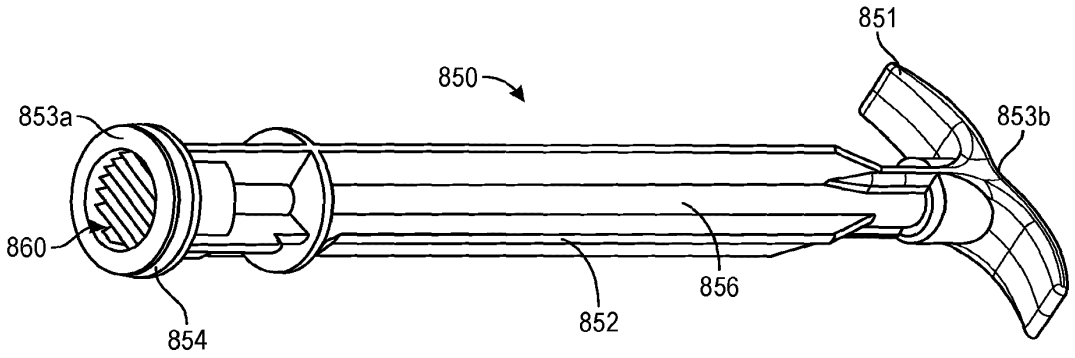



*FIG. 8A*

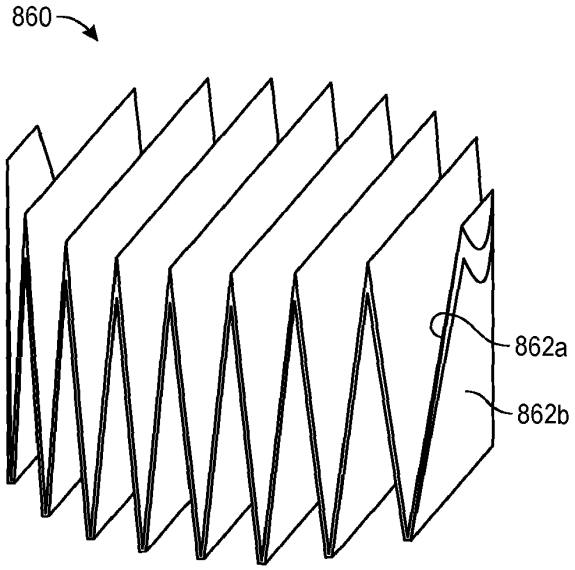



*FIG. 8B*

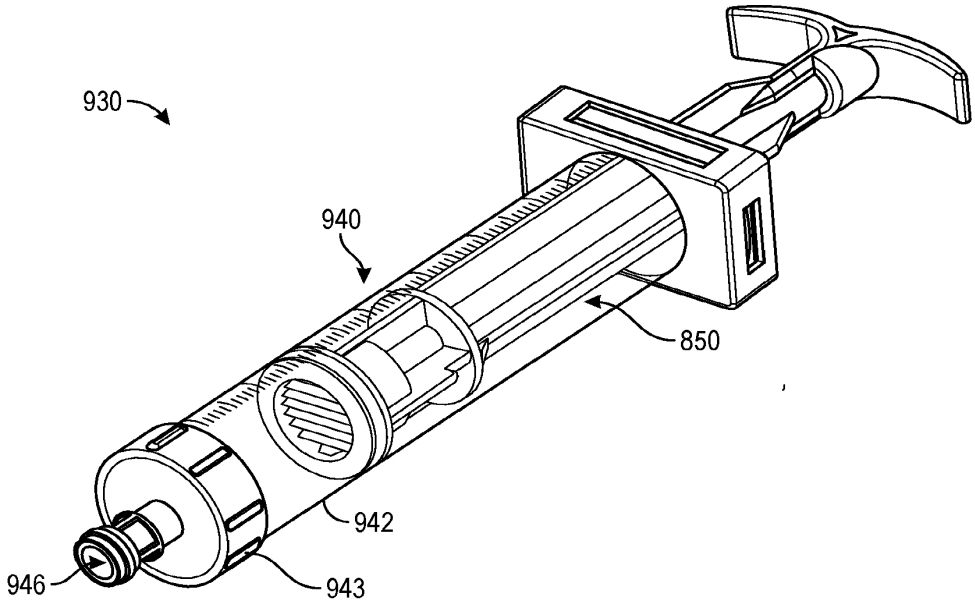



*FIG. 9A*

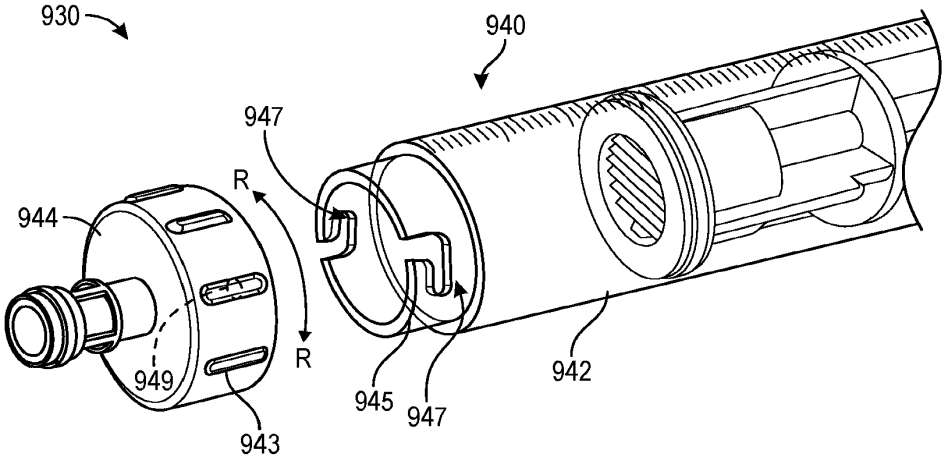



*FIG. 9B*

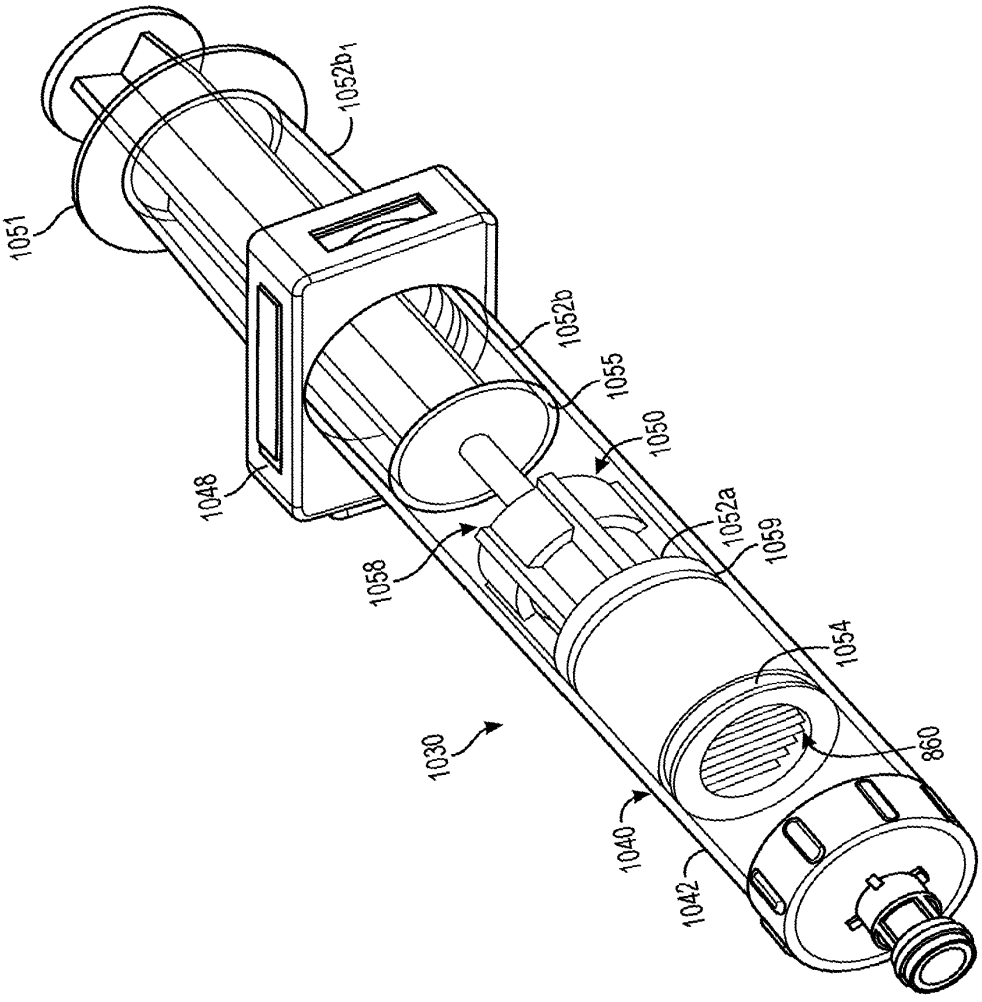

1052b1
1051
1052b
1055
1050
1048
1052a
1059
1058
1054
860
1030
1040
1042

FIG. 10

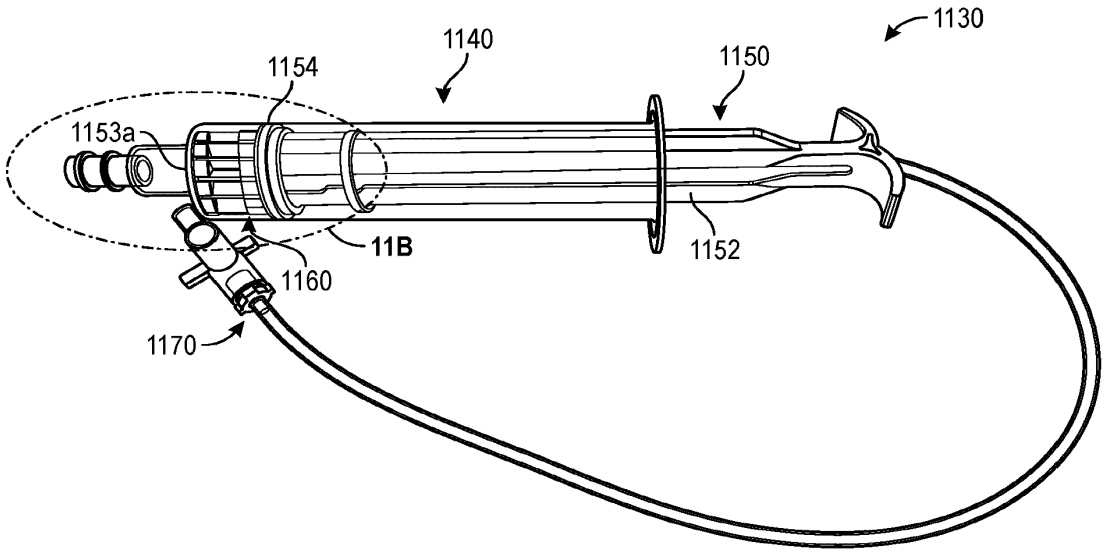



*FIG. 11A*

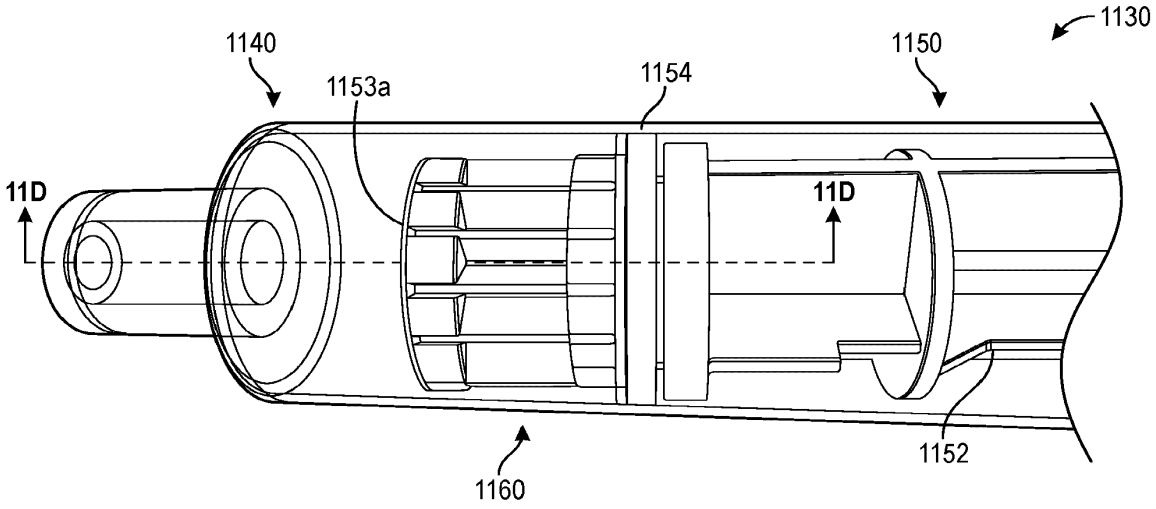



*FIG. 11B*

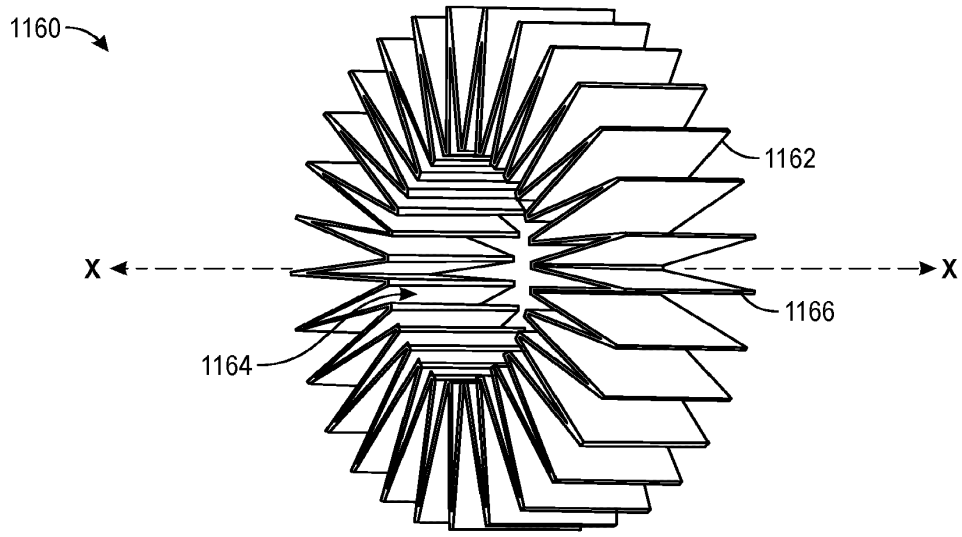



*FIG. 11C*

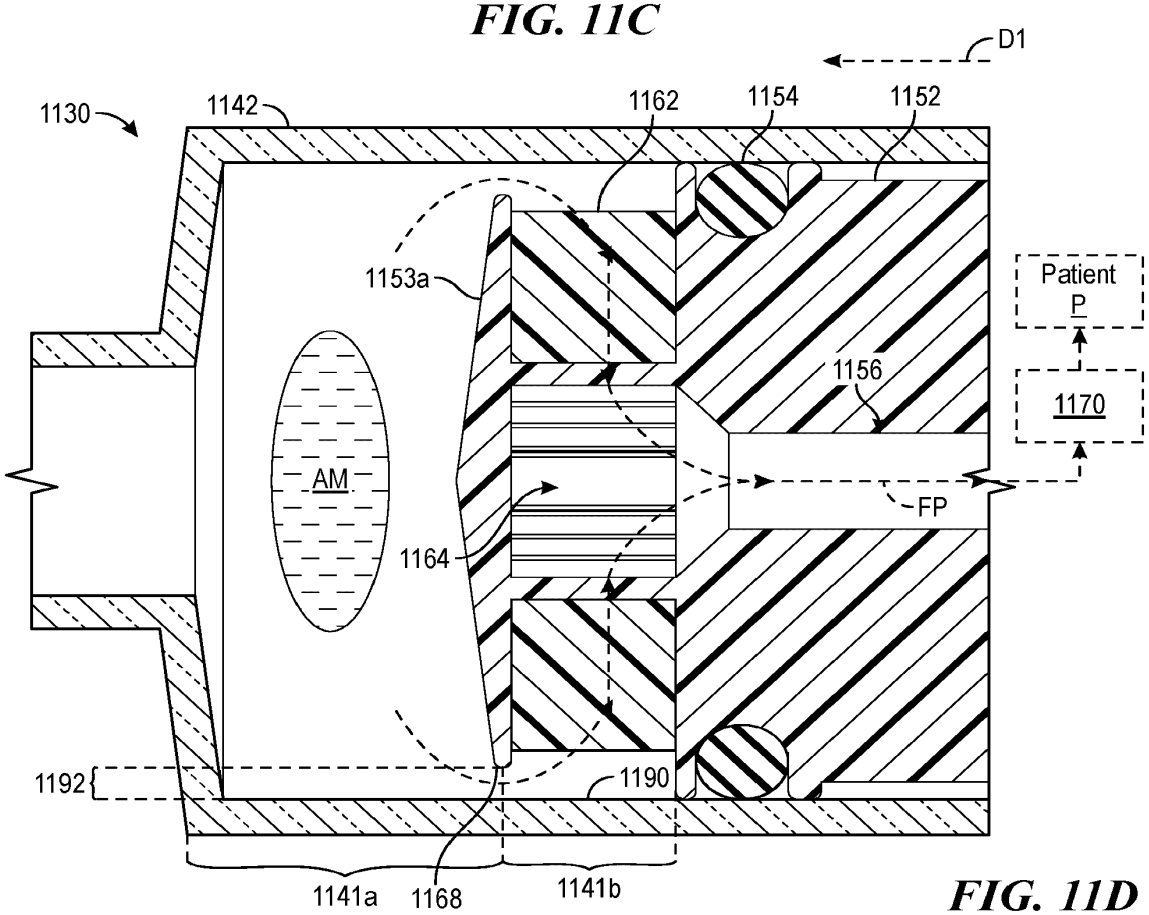



*FIG. 11D*

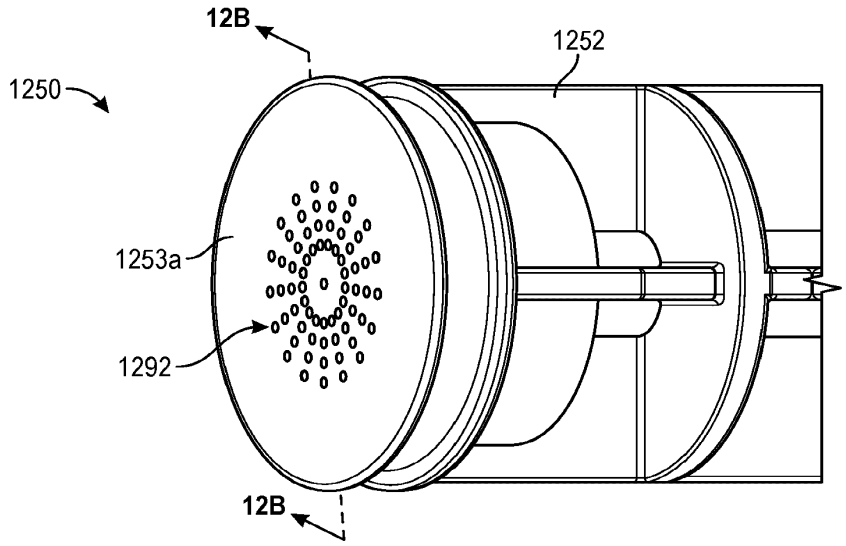



*FIG. 12A*

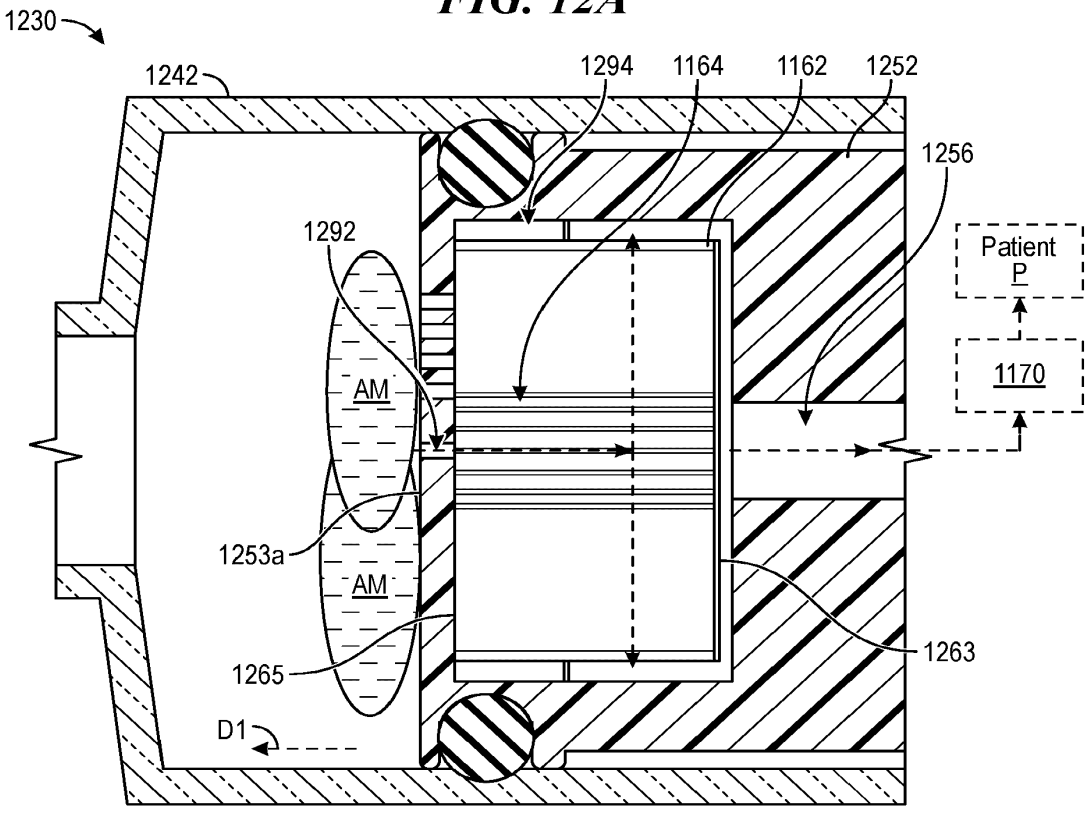



*FIG. 12B*

Espacenet

CN106178227A Device for locking catheter sheath and dilator

Applicants: SHANGHAI MICROPORT MEDICAL (GROUP) CO LTD

Inventors: LIU ZHIYONG,ZHANG JIULI,HE JIAN,YI KEJING

Classifications:
IPC ***A61M25/01; A61M29/00;***

Priorities: CN201510218753A 2015-04-30

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Device for locking catheter sheath and dilator

Abstract

The invention provides a device for locking and unlocking a catheter sheath and a dilator. With the adoption of the device, the catheter sheath and the dilator are convenient and fast to lock and unlock, and vascular injury is reduced. The catheter sheath comprises a sheath base and a sheath tube connected to the sheath base; the dilator comprises a dilator base and a dilator tube connected onto the dilator base; the dilator tube penetrates through the sheath base and is inserted into the sheath tube; the device is used for locking and unlocking the sheath base and the dilator base and comprises a fastening mechanism and a releasing mechanism which are arranged between the sheath base and the dilator base, wherein the fastening mechanism is suitable for fastening the dilator and the sheath base when the dilator tube is pushed into the sheath tube, the releasing mechanism is suitable for enabling the dilator to produce moving force of the dilator relative to the sheath tube in a rotating process of the dilator base relative to the sheath base, and then the sheath base is forced to be released from the dilator.

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(51)Int.Cl.
*A61M 25/01*(2006.01)
*A61M 29/00*(2006.01)

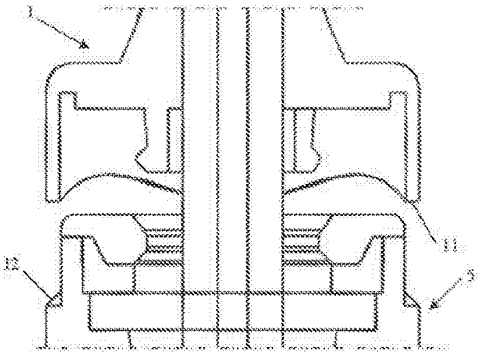
权利要求书1页 说明书4页 附图7页

(54)发明名称

锁定导管鞘和扩张器的装置

(57)摘要

一种锁定和解锁导管鞘和扩张器的装置，导管鞘和扩张器的锁定和解锁方便便捷，并减少血管损伤。其中，导管鞘包括鞘座以及连接在鞘座上的鞘管，扩张器包括扩张器座和连接在扩张器座上的扩张器管，扩张器管穿过所述鞘座插入到所述鞘管，所述装置用于将所述鞘座和所述扩张器座锁定解锁，其中，所述装置包括在所述鞘座与所述扩张器座之间配置的扣接机构以及脱扣机构，所述扣接机构适合于在所述扩张器管推入到所述鞘管的过程中，使得所述扩张器与所述鞘座扣接，所述脱扣机构适合于在所述扩张器座相对所述鞘座转动的过程中，使得所述扩张器产生所述扩张器相对所述鞘座的移动力，进而迫使所述鞘座和所述扩张器脱扣。




CN 106178227 A

1. 用于锁定和解锁导管鞘和扩张器的装置，所述导管鞘包括鞘座以及连接在所述鞘座上的鞘管，所述扩张器包括扩张器座和连接在所述扩张器座上的扩张器管，所述扩张器管穿过所述鞘座插入到所述鞘管，其特征在于，所述装置用于将所述鞘座和所述扩张器座锁定和解锁，并包括在所述鞘座与所述扩张器座之间配置的扣接机构以及脱扣机构，所述扣接机构适合于在所述扩张器管推入到所述鞘管的过程中，使得所述扩张器座与所述鞘座扣接；所述脱扣机构适合于在所述扩张器座相对所述鞘座转动的过程中，使得所述扩张器产生相对所述鞘座的移动力，进而迫使所述鞘座和所述扩张器座脱扣。

2. 如权利要求 1 所述的装置，其特征在于，所述脱扣机构配置成使所述扩张器座能以任意旋动方向相对所述鞘座转动，并进而使得所述扩张器产生相对所述鞘座的所述移动力。

3. 如权利要求 1 所述的装置，其特征在于，所述脱扣机构包括所述鞘座与所述扩张器座中的至少一方提供的脱扣斜面，以及另一方提供的抵接所述脱扣斜面的抵接部，所述扩张器座能转动以借助于所述抵接部沿所述脱扣斜面的相对运动来使所述鞘座与所述扩张器座相对分离，进而使所述鞘座和所述扩张器脱扣。

4. 如权利要求 3 所述的装置，其特征在于，所述脱扣斜面为波浪形结构的波峰和波谷之间的光滑斜面。

5. 如权利要求 4 所述的装置，其特征在于，所述波浪形结构的任意波峰两侧都有波谷。

6. 如权利要求 4 所述的装置，其特征在于，所述波浪形结构包括第一波浪形结构和第二波浪形结构，所述扩张器座具有第一波浪形结构，所述鞘座具有第二波浪形结构，其中所述第一波浪形结构和所述第二波浪形结构中的一方提供所述脱扣斜面，另一方提供所述抵接部。

7. 如权利要求 6 所述的装置，其特征在于，所述第一波浪形结构和所述第二波浪形结构之间呈几何相似并且彼此互补地嵌合。

8. 如权利要求 1 所述的装置，其特征在于，所述扣接机构包括所述扩张器座上轴向伸出的爪扣以及位于所述鞘座上的倒扣，所述鞘座和所述扩张器座通过所述爪扣和所述倒扣扣接。

9. 如权利要求 8 所述的装置，其特征在于，所述倒扣形成于所述鞘座的内周侧壁上，所述爪扣能相对所述鞘座轴向推动而于所述内周侧壁处径向向内弹性形变，并且所述爪扣能随所述扩张器座的推动，发生回弹并与所述倒扣相卡，以实现所述锁定。

10. 如权利要求 8 所述的装置，其特征在于，所述鞘座包括鞘帽，所述鞘帽包括上帽和下帽，所述上帽的外周侧为渐缩结构，所述下帽的内周侧为渐缩结构，所述上帽坐落于所述下模，所述上帽的外周侧和所述下帽的内周侧彼此结合，所述上帽相对所述下帽径向向内突出，形成所述倒扣。



INARI_017795

# 锁定导管鞘和扩张器的装置

## 技术领域

[0001] 本发明涉及一次性使用医疗器械领域，具体地说是一种用于经皮介入手术，将导丝、手术器具、医疗器械等引入病人血管系统（特别是动脉）的具有止血功能的辅助器材。

## 背景技术

[0002] 现代医疗技术发展迅速，产生了许多经皮介入手术的方法，在这些方法中，经皮冠脉腔内血管成形术（PTCA）、X-射线造影术以及其它类似的手术是经常使用的。有许多技术可将相关的医疗器械引入到人体血管系统中，其中得到广泛运用的是Seldinger技术（经皮血管穿刺技术）。在Seldinger技术中，首先用穿刺针在动脉或静脉上开一个小口，再将导丝通过穿刺针的内腔引入动脉或静脉，取出穿刺针。将扩张器穿过导管鞘止血阀进入导管鞘内腔，两者锁定后一起通过导丝的引导进入动脉或静脉。待导管鞘的鞘管位置固定后，撤出扩张器，最终导管鞘可提供进出或更换各种介入器材的通道。

[0003] 导管鞘和扩张器通过卡扣连接而锁定，锁定完成后，鞘管与扩张器管一起进入动脉或静脉。待鞘管位置固定后，需使导管鞘和扩张器分离，后撤出扩张器。对于卡扣式结构，导管鞘和扩张器分离需施加一轴向分离力，此时鞘管与扩张器管均处于人体血管当中，在分离的瞬间鞘管极易发生抖动而触及血管壁，导致血管痉挛或损伤。对于初学Seldinger技术的术者，该情况发生的概率更高，显著增加手术时间及术者的痛苦。

## 发明内容

[0004] 本发明的目的在于提供一种锁定导管鞘和扩张器的装置，使得导管鞘和扩张器的锁定和解锁方便便捷，并减少血管损伤。

[0005] 根据本发明的用于锁定和解锁导管鞘和扩张器的装置，所述导管鞘包括鞘座以及连接在所述鞘座上的鞘管，所述扩张器包括扩张器座和连接在所述扩张器座上的扩张器管，所述扩张器管穿过所述鞘座插入到所述鞘管，其中，所述装置用于将所述鞘座和所述扩张器座锁定和解锁，并包括在所述鞘座与所述扩张器座之间配置的扣接机构以及脱扣机构，所述扣接机构适合于在所述扩张器管推入到所述鞘管的过程中，使得所述扩张器座与所述鞘座扣接；所述脱扣机构适合于在所述扩张器座相对所述鞘座转动的过程中，使得所述扩张器产生相对所述鞘座的移动力，进而迫使所述鞘座和所述扩张器座脱扣。

[0006] 根据本发明的较佳实施例中，所述的装置的所述脱扣机构配置成使所述扩张器座能以任意旋动方向相对所述鞘座转动，并进而使得所述扩张器产生相对所述鞘座的所述移动力。

[0007] 根据本发明的较佳实施例中，所述的装置的所述脱扣机构包括所述鞘座与所述扩张器座中的至少一方提供的脱扣斜面，以及另一方提供的抵接所述脱扣斜面的抵接部，所述扩张器座能转动以借助于所述抵接部沿所述脱扣斜面的相对运动来使所述鞘座与所述扩张器座相对分离，进而使所述鞘座和所述扩张器脱扣。

[0008] 根据本发明的较佳实施例中，所述脱扣斜面为波浪形结构的波峰和波谷之间的光



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滑斜面。

[0009] 根据本发明的较佳实施例中，所述波浪形结构的任意波峰两侧都有波谷。

[0010] 根据本发明的较佳实施例中，所述波浪形结构包括第一波浪形结构和第二波浪形结构，所述扩张器座具有第一波浪形结构，所述鞘座具有第二波浪形结构，其中所述第一波浪形结构和所述第二波浪形结构中的一方提供所述脱扣斜面，另一方提供所述抵接部。

[0011] 根据本发明的较佳实施例中，所述第一波浪形结构和所述第二波浪形结构之间呈几何相似并且彼此互补地嵌合。

[0012] 根据本发明的较佳实施例中，所述扣接机构包括所述扩张器座上轴向伸出的爪扣以及位于所述鞘座上的倒扣，所述鞘座和所述扩张器座通过所述爪扣和所述倒扣扣接。

[0013] 根据本发明的较佳实施例中，所述倒扣形成于所述鞘座的内周侧壁上，所述爪扣能相对所述鞘座轴向推动而于所述内周侧壁处径向向内弹性形变，并且所述爪扣能随所述扩张器座的推动，发生回弹并与所述倒扣相卡，以实现所述锁定。

[0014] 根据本发明的较佳实施例中，所述鞘座包括鞘帽，所述鞘帽包括上帽和下帽，所述上帽的外周侧为渐缩结构，所述下帽的内周侧为渐缩结构，所述上帽坐落于所述下模，所述上帽的外周侧和所述下帽的内周侧彼此结合，所述上帽相对所述下帽径向向内突出，形成所述倒扣。

[0015] 借助于扣接机构，在推入时可实现导管鞘与扩张器锁定，借助于旋转机构，通过旋转可实现导管鞘与扩张器的脱扣，因此本发明提供了一种能够在介入手术过程中提供一种良好的导管鞘与扩张器锁定及分离方案，使两者可有效且便捷的锁定且避免分离时鞘管抖动，有效减少血管损伤。

## 附图说明

[0016] 本发明的上述的以及其他的特征、性质和优势将通过下面结合附图和实施例的描述而变得更加明显，其中：

[0017] 图 1 为本发明一实施例中配套的导管鞘和扩张器的部分分解视图；

[0018] 图 2 为图 1 中导管鞘的鞘帽的分解视图；

[0019] 图 3 为图 2 中鞘帽的剖视图；

[0020] 图 4 为图 1 中将扩张器座推入到鞘座的示意图，其显示了内部构造；

[0021] 图 5 为图 1 中将扩张器座推入到鞘座的示意图，其显示了外部构造；

[0022] 图 6 为图 1 中扩张器座与鞘座相扣合的示意图，其显示了内部构造；

[0023] 图 7 为图 1 中扩张器座与鞘座相扣合的示意图，其显示了外部构造；

[0024] 图 8 为图 1 中导管鞘和扩张器装配后的立体图；

[0025] 图 9 为图 8 中导管鞘和扩张器旋转分离瞬间的示意图，其显示了内部构造；

[0026] 图 10 为图 8 中导管鞘和扩张器旋转分离瞬间的示意图，其显示了外部构造；

[0027] 图 11 为图 9 中导管鞘和扩张器旋转分离后的示意图；

[0028] 图 12 为图 10 中导管鞘和扩张器旋转分离后的示意图；

[0029] 图 13 为图 8 中导管鞘和扩张器旋转分离后的示意图。

## 具体实施方式



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[0030] 下面结合具体实施例和附图对本发明作进一步说明，在以下的描述中阐述了更多的细节以便于充分理解本发明，但是本发明显然能够以多种不同于此描述的其它方式来实施，本领域技术人员可以在不违背本发明内涵的情况下根据实际应用情况作类似推广、演绎，因此不应以此具体实施例的内容限制本发明的保护范围。

[0031] 需要注意的是，这些以及后续其他的附图均仅作为示例，其并非是按照等比例的条件绘制的，并且不应该以此作为对本发明实际要求的保护范围构成限制。

[0032] 如图1所示，导管鞘A包括鞘座5以及连接在鞘座5上的鞘管7，扩张器B包括扩张器座1和连接在扩张器座1上的扩张器管8，扩张器管8穿过鞘座5插入到鞘管7中。根据本发明的锁定导管鞘A和扩张器B的装置用于将鞘座5和扩张器座1锁定，其包括鞘座5与扩张器座1之间配置的扣接机构以及脱扣机构，扣接机构适合于在扩张器管推入到鞘管的过程中使得鞘座5与扩张器座1扣接，脱扣机构适合于在扩张器座相对鞘座转动的过程中产生扩张器座相对鞘座的移动力，进而迫使鞘座和扩张器座脱扣。扣接机构和脱扣机构的实现方式较多，后面将结合附图例举一较佳实施例，值得一提的是，本发明的扣接机构和脱扣机构不限于此。导管鞘A还包括鞘座5内设置的止血阀4和套在鞘管7外周侧上的扩散应力管6，这些与已有的导管鞘一样，不赘述其详情。

[0033] 如图2和图3所示，鞘座5包括鞘帽，鞘帽包括上帽2和下帽3，上帽2的外周侧为渐缩结构，类似于碗状，下帽3的内周侧为渐缩结构，也类似于碗状，上帽2坐落于下模3，上帽2的外周侧和下帽3的内周侧彼此结合，上帽2相对下帽3径向向内突出，形成倒扣10。鞘帽由上帽2和下帽3分体成形，这主要为了便于制造的角度考虑。在其他实施例中，鞘帽也可以是一体成型件。

[0034] 如图4和图6所示，扩张器座1具有环形的裙边11A以及轴向伸出的多个爪扣9，多个爪扣9形成的圆的外径大于上帽2的最小内径。在将扩张器B推入到导管鞘A中时，爪扣9能相对鞘座5轴向移动而于上帽2的内周侧壁处径向向内弹性变形，并能随扩张器座1的推动，爪扣9回弹与倒扣10相卡合，以实现锁定。爪扣9的数量不限，可以多于三个或少于三个。爪扣9和倒扣10构成所述扣接机构。扣接机构的实现不限于此，例如可以在鞘帽和扩张器座的一方形成凸环，另一方形成环形槽，凸块卡入到环形槽中也可以使得鞍座5和扩张器座1扣接。扣接机构还可以通过其他方式实现。

[0035] 如图5和图7所示，扩张器座1具有第一波浪形结构11，鞘座5具有第二波浪形结构12，二者结构呈几何意义上的相似，这样第一波浪形结构11与第二波浪形结构12就能彼此互补，呈嵌合状态。更为重要的是，第一波浪形结构11和第二波浪形结构12容许彼此相对转动，这样在转动的过程中，由于波峰和波谷之间的斜面会产生一个迫使彼此分离的力。本领域的技术人员将可以理解到第一波浪形结构11与第二波浪形结构12构成所述脱扣机构，不过脱扣机构的实现不限于此，例如可以在鞘座5与扩张器座1中一方提供的脱扣斜面，另一方提供抵接脱扣斜面的抵接部，抵接部也可以是斜面，例如斜面在转动过程中产生的升力来迫使二者分离，进一步可以使得前述扣接机构分离。脱扣机构主要是将旋转转换为直线运动，从而产生一个直线分离的力。

[0036] 在前述的实施例中，波浪形结构可以沿鞘座5和扩张器座1的部分外周或者整个外周形成。波峰或波谷数量不限。可以在一个波谷的一侧设置波峰，或者两侧都设置波峰。

[0037] 如图4和图5所示，第一波浪形结构11为扩张器座1的外周侧的裙边11A的端面，



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第二波浪形结构 12 为鞘座 5 的外周侧壁的轴肩面。

[0038] 如图 9 至图 11 所示，分离过程中，只需手持导管鞘 A 及扩展器 B，顺时针或逆时针轴向转动扩张器座 1，此时无需顾及转动方向，使其与鞘座 5 相对分离直至爪扣 9 从倒扣 10 中脱离，然后向导管鞘 A 及扩张器 B 施加轴向分离力即可实现无抖动分离。

[0039] 相对于前述实施例，卡扣式锁定结构在导管鞘和扩张器分离过程中，因术者施加轴向分离力而使得鞘座及扩张器座在分离的瞬间，两者间束缚力显著下降。而此时术者来不及调整分离力，导致滞留在血管中的鞘管显著抖动，造成血管痉挛或损伤。另外，若鞍座 5 和扩张器座 1 通过螺纹等旋转式锁定结构来连接，无论是锁定还是解除锁定过程都需要进行旋转，且只有固定某一方向旋转才能实现锁定或解除锁定，增加操作繁琐程度。前述实施例通过其结构设计可通过任意方向的旋转，例如顺时针旋转或逆时针旋转，使扩张器座 1 与鞘座 5 平缓分离，避免鞘座 5 在分离时的抖动，从而减小血管痉挛及损伤。在本发明的一实施例中，脱扣机构也可以配置成在一个方向旋转可以使得扣接机构脱扣。

[0040] 值得注意的是，除非另有定义，否则前述描述中所使用的所有技术术语具有与本领域的普通技术人员通常所理解的相同的含义。本申请案中描述了特定方法、装置，但与前述内容中所述的方法和装置类似或等价的任何方法和材料可在本技术的实践中使用。尽管已相当详细地且通过说明来描述技术的实施方式，但所述说明仅用于清楚地理解，且并非意在限制。已在描述中使用各种术语来传达对本技术的理解，应理解，所述各种术语的含义延伸到各种术语的常见语言或语法变化或形式。也应理解，当术语是指装置或设备时，所述术语或名称作为当代的实例而提供，且本技术步骤不受所述文字范围的限制。前述的术语将被理解为已由现今当代术语描述，所述前述的术语可合理地理解为当代术语或当代术语所包含的体系子集命名的衍生物。此外，在不脱离所公开技术的范围的情况下，技术的任何实施方式的任何一个或多个特征可与技术的任一实施方式的任何一个或多个其他特征组合。更进一步地，应理解，本技术不限于已为了例证而阐述的实施方式，但本技术仅由对本专利申请案所附权利要求书的公平解读来定义，包括将本技术的每一元件有权享有的整个范围的同等效力。因此，本发明虽然以较佳实施例公开如上，但其并不是用来限定本发明，任何本领域技术人员在不脱离本发明的精神和范围内，都可以做出可能的变动和修改。因此，凡是未脱离本发明技术方案的内容，依据本发明的技术实质对以上实施例所作的任何修改、等同变化及修饰，均落入本发明权利要求所界定的保护范围之内。



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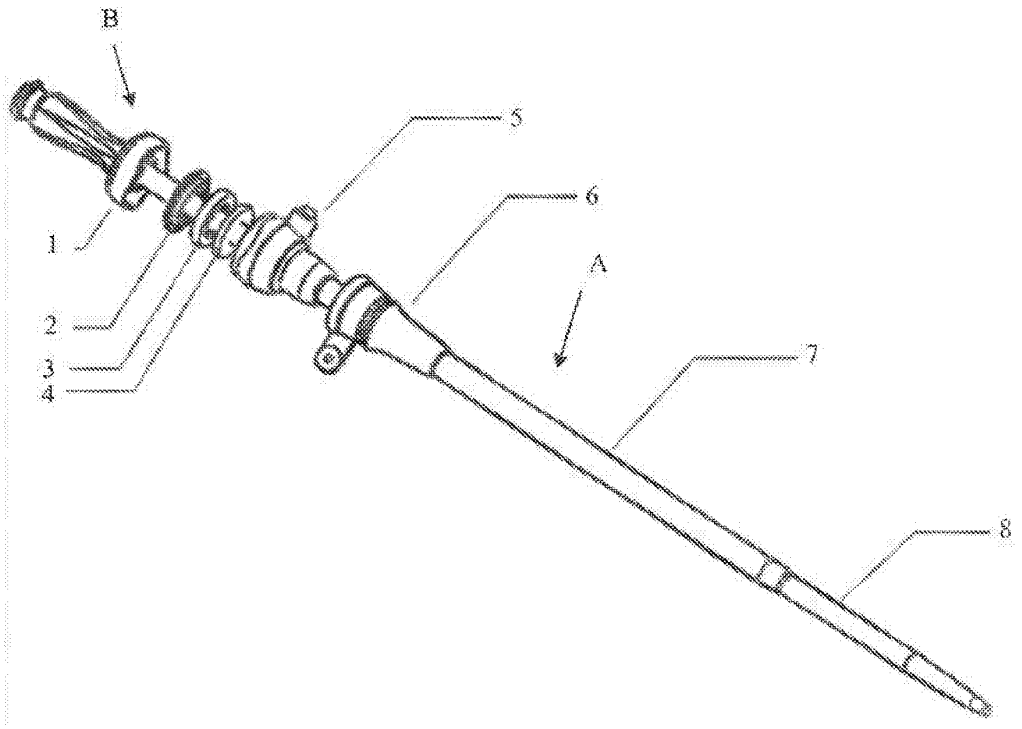



图 1

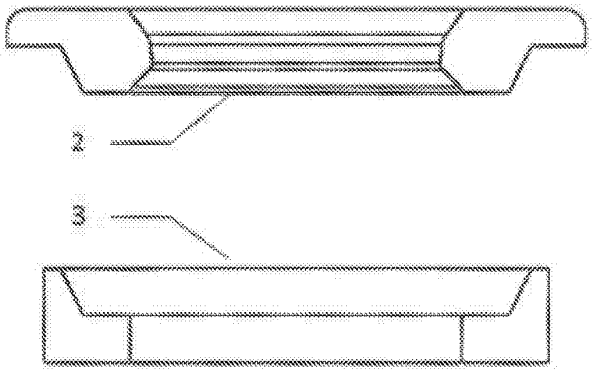



图 2



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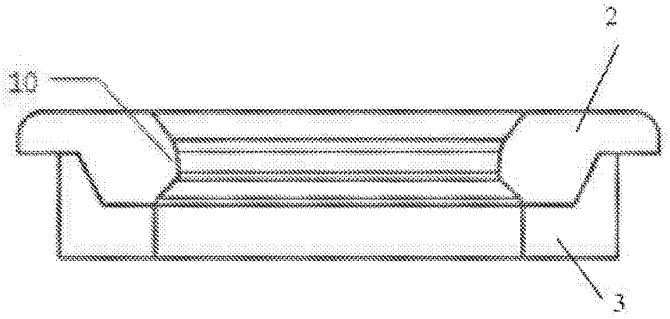



图 3

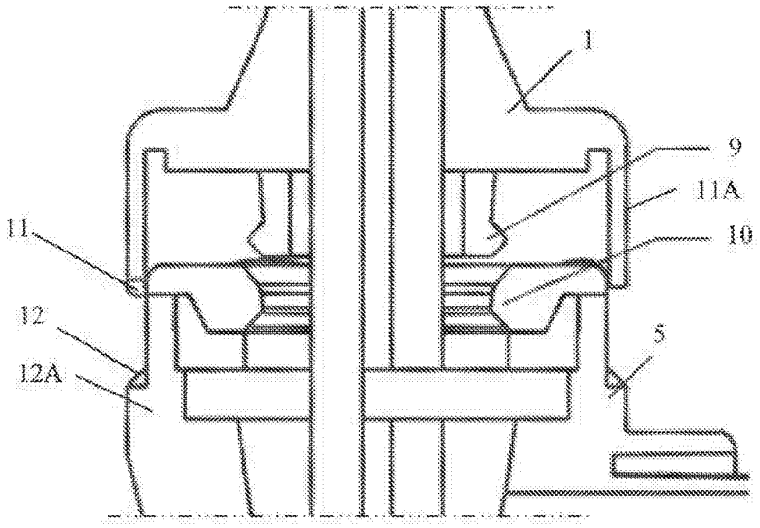



图 4

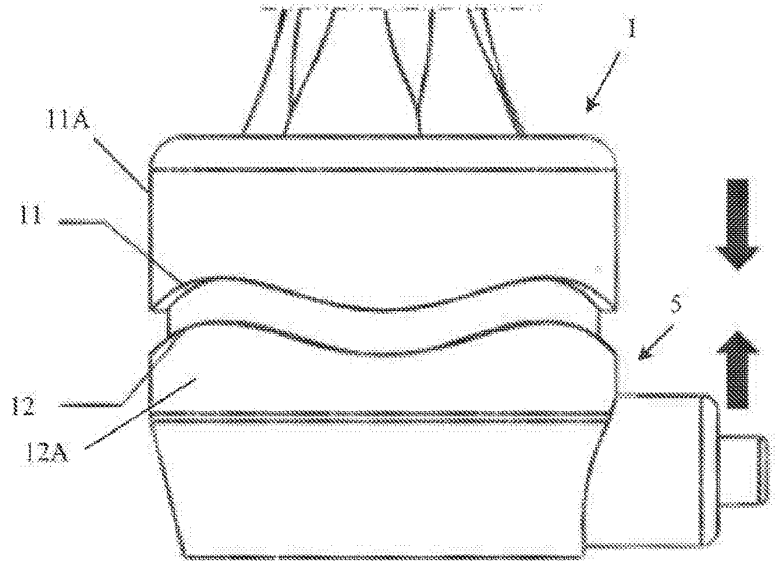



图 5

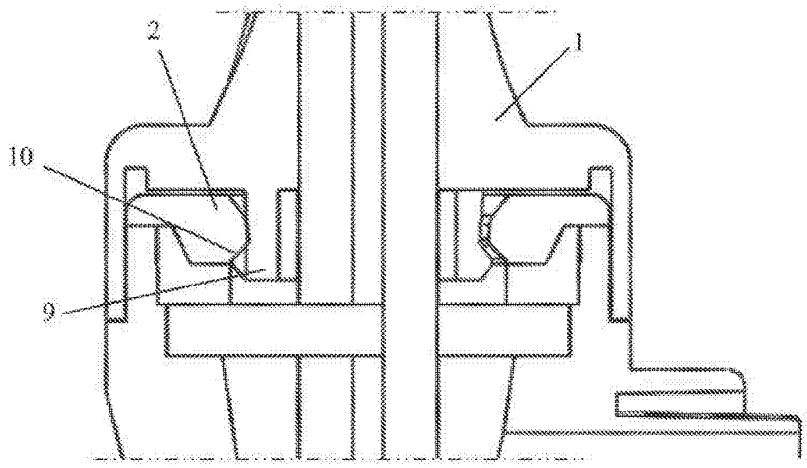



图 6



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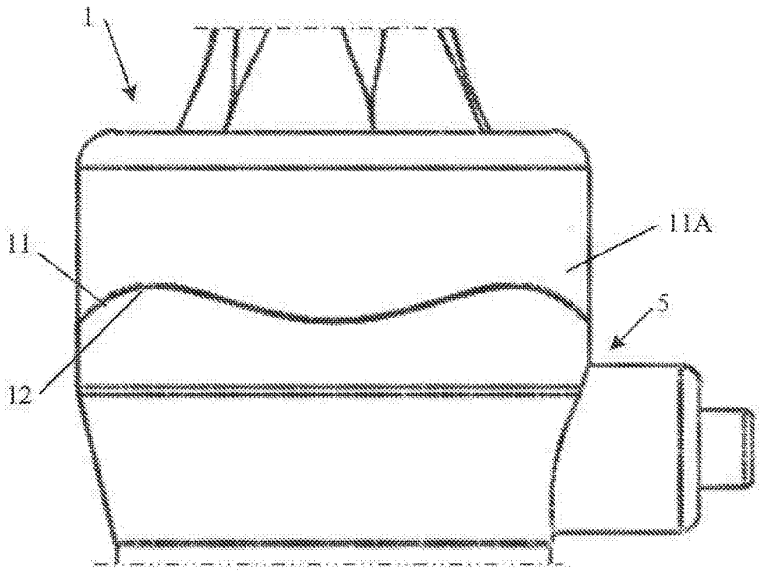



图 7

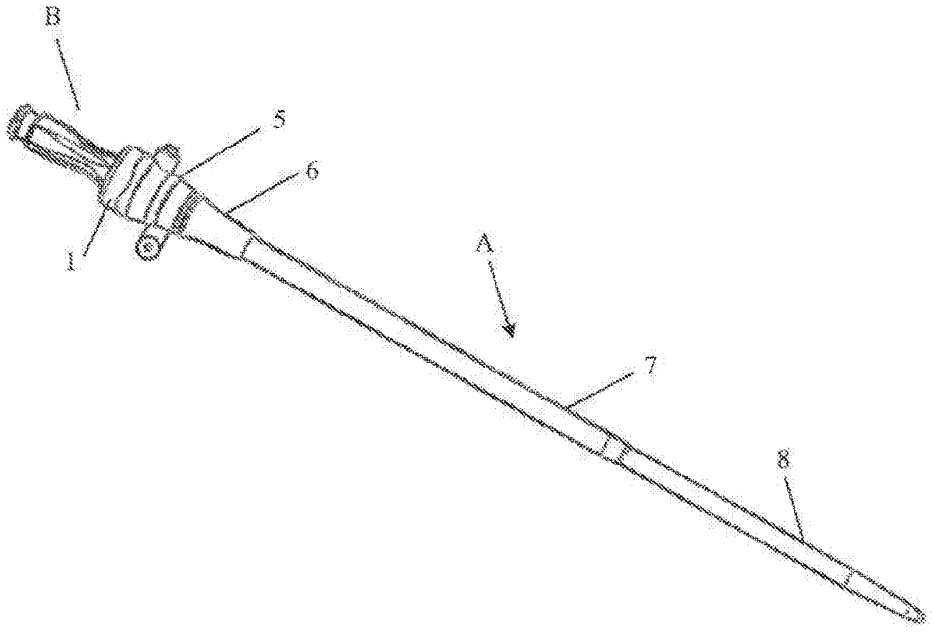



图 8

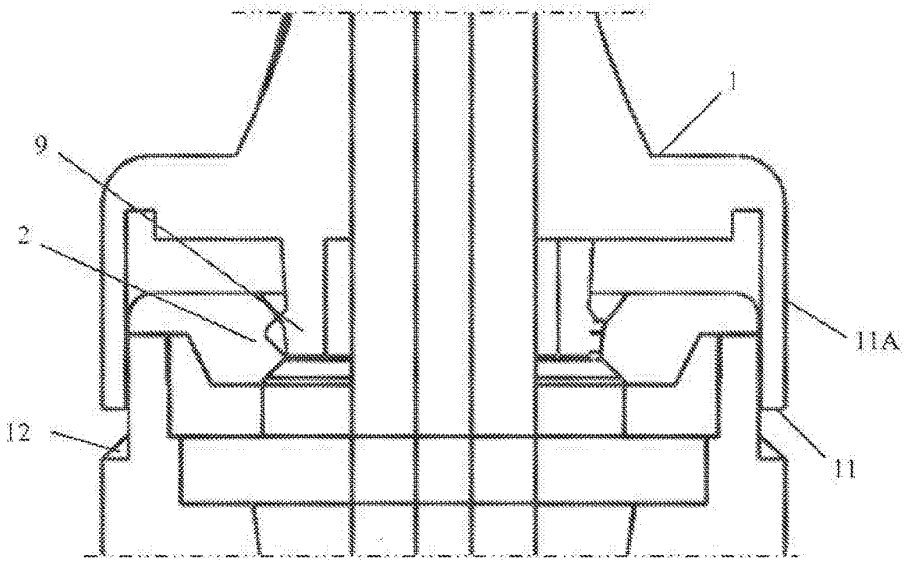



图 9

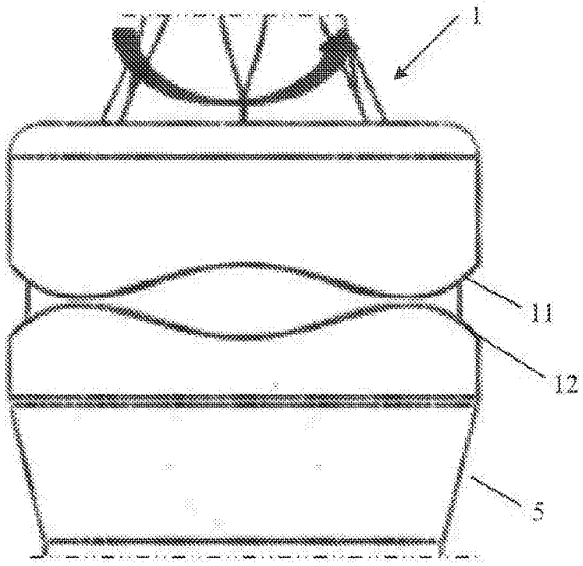



图 10



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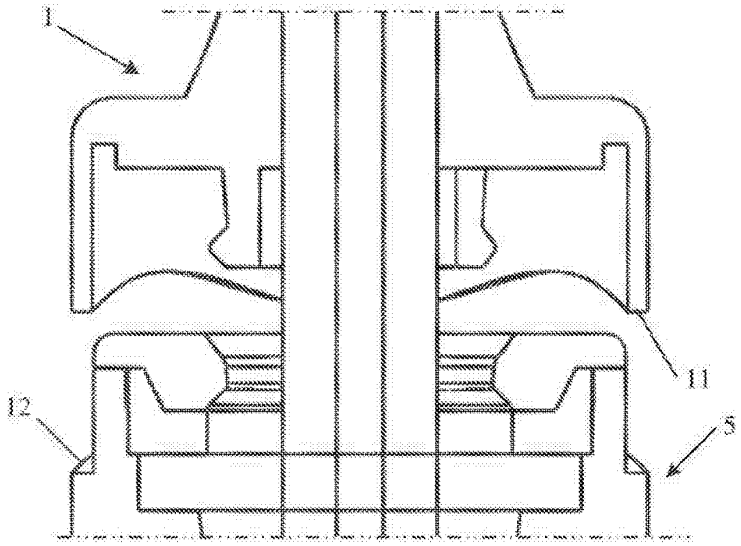



图 11

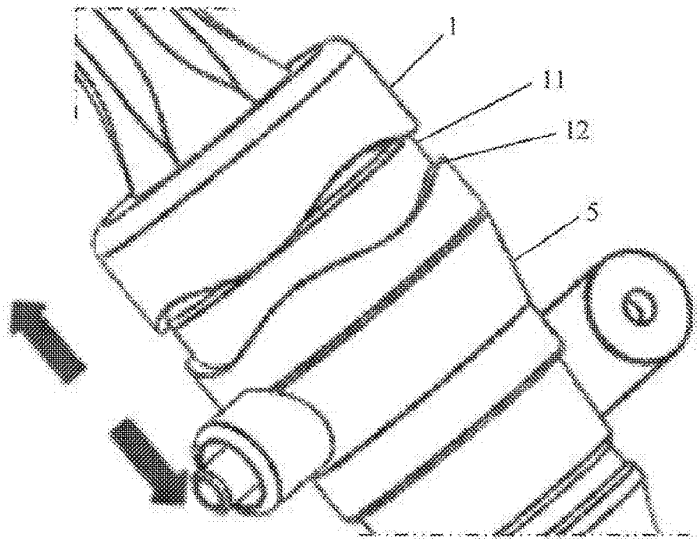



图 12

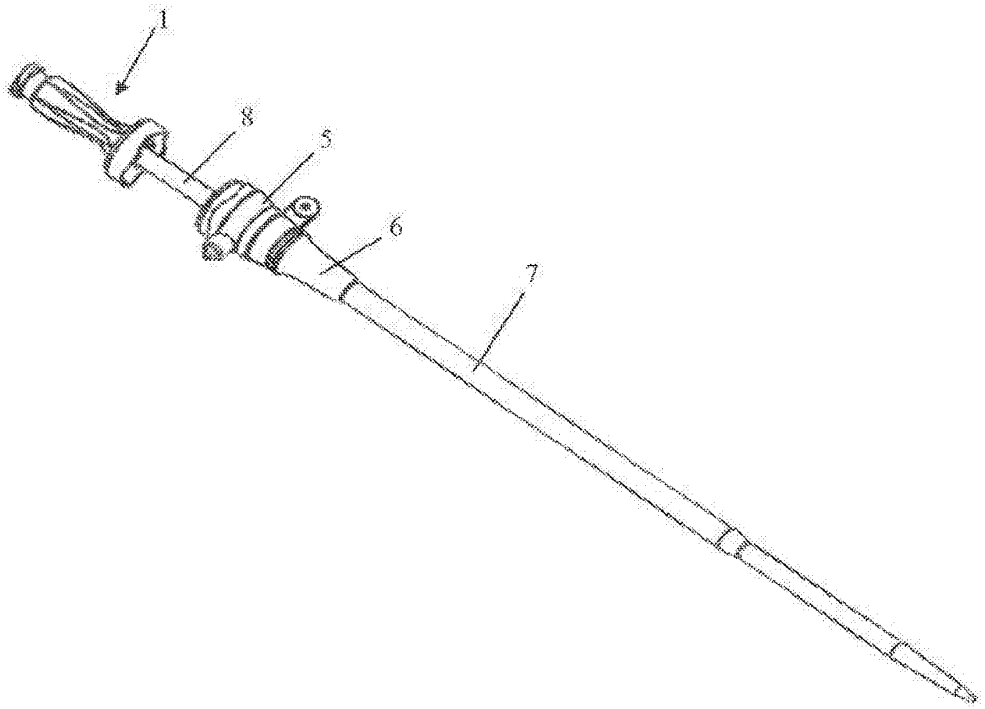



图 13

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A61B 2017/22038; A61B 2017/22079; A61B 2217/005; A61M 25/0074; A61M 25/0097; A61M 2025/0019; A61M 2025/0042; A61M 2025/0175; A61M 2025/0681; (Cont.)

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Remarks:
This application was filed on 06-09-2022 as a divisional application to the application mentioned under INID code 62.

## (54) RAPID ASPIRATION THROMBECTOMY SYSTEM

(57) There is provided a dilator (340) for facilitation of intraluminal medical procedures within the neurovasculature. The dilator (1340) comprises a flexible elongate body having a tubular body extending along a length between a proximal end region and a distal end region having a tapered distal tip (1346) tapering distally from a first outer diameter to a second outer diameter that is smaller than the first outer diameter. A single lumen extends longitudinally through the flexible elongate body to a distal opening at the tapered distal tip (1346). The tapered distal tip (1346) has a first radiopaque marker (343) disposed at a proximal end of the tapered distal tip (1346) and a second radiopaque marker (344) disposed at a distal end of the tapered distal tip (1346). The first and second radiopaque markers identify the tapered distal tip (1346). The dilator further comprises a proximal spine (1362) extending from the proximal end region of the flexible elongate body.

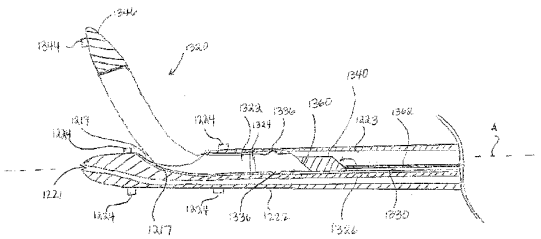


Fig. 12C

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(52) Cooperative Patent Classification (CPC): (Cont.)
A61M 2210/0693

## Description

### CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This application claims priority to U.S. Provisional Application Serial No. 62/111,481, filed February 4, 2015, and U.S. Provisional Application Serial No. 62/142,637, filed April 3, 2015.

**[0002]** This application is also related to the following U.S. Patent Applications: (1) US Patent Application Serial Number 14/576,953, filed December 19, 2014; and (2) US Patent Application Serial Number 14/569,365, filed December 12, 2014; (3) US Patent Application Serial Number 14/537,316, filed November 10, 2014; (4) US Patent Application Serial Number 14/221,917, filed March 21, 2014.

### BACKGROUND

**[0003]** The present disclosure relates generally to medical methods and devices for the treatment of acute ischemic stroke. More particularly, the present disclosure relates to methods and systems for navigating complex anatomy to perform rapid and safe aspiration and removal of cerebral occlusions.

**[0004]** Acute ischemic stroke is the sudden blockage of adequate blood flow to a section of the brain, usually caused by thrombus or other emboli lodging or forming in one of the blood vessels supplying the brain. If this blockage is not quickly resolved, the ischemia may lead to permanent neurologic deficit or death. The timeframe for effective treatment of stroke is within 3 hours for intravenous (IV) thrombolytic therapy and 6 hours for site-directed intra-arterial thrombolytic therapy or up to 8 hours for interventional recanalization of a blocked cerebral artery. Re-perfusing the ischemic brain after this time period has no overall benefit to the patient, and may in fact cause harm due to the increased risk of intracranial hemorrhage from fibrinolytic use. Even within this time period, there is strong evidence that the shorter the time period between onset of symptoms and treatment, the better the results. Unfortunately, the ability to recognize symptoms, deliver patients to stroke treatment sites, and finally to treat these patients within this timeframe is rare. Despite treatment advances, stroke remains the third leading cause of death and the leading cause of serious, long-term disability in the United States.

**[0005]** Endovascular treatment of acute stroke is comprised of either the intra-arterial administration of thrombolytic drugs such as recombinant tissue plasminogen activator (rtPA), mechanical removal of the blockage, or a combination of the two. As mentioned above, these interventional treatments must occur within hours of the onset of symptoms. Both intra-arterial (IA) thrombolytic therapy and interventional thrombectomy involve accessing the blocked cerebral artery via endovascular techniques and devices.

**[0006]** Like IV thrombolytic therapy, IA thrombolytic therapy alone has the limitation in that it may take several hours of infusion to effectively dissolve the clot. Interventional thrombectomy therapies have involved capturing and removing the clot using snares, coils or temporary stents (also known as retrievable stent devices), and suctioning the clot with or without adjunct disruption of the clot. Retrievable stent devices are also utilized to restore flow quickly to the vessel during the intervention. Hybrid procedures are also utilized, combining retrievable stent devices and aspiration via the guide catheter or via intermediate catheters to aid in the removal of the clot and reduce the risk of distal emboli. Finally, balloons or stents have been used to create a patent lumen through the clot when clot removal or dissolution was not possible.

**[0007]** To access the cerebral anatomy, guide catheters or guide sheaths are used to guide interventional devices to the target anatomy from an arterial access site, typically the femoral artery. Balloon guide catheters are often used to enable proximal carotid artery occlusion during periods of the procedure which may potentially liberate a high level of emboli. The proximal occlusion has the effect of arresting forward flow and increasing aspiration efficiency through the lumen of the guide catheter. The length of the guide is determined by the distance between the access site and the desired location of the guide distal tip. Interventional devices such as guidewires, microcatheters, and intermediate catheters used for sub-selective guides and aspiration, are inserted through the guide and advanced to the target site. Often, devices are used in a co-axial fashion, namely, a guidewire inside a microcatheter inside an intermediate catheter is advanced as an assembly to the target site in a stepwise fashion with the inner, most atraumatic elements, advancing distally first and providing support for advancement of the outer elements. The length of each element of the coaxial assemblage takes into account the length of the guide, the length of proximal connectors on the catheters, and the length needed to extend from the distal end. Thus, for example, the working length of an intermediate catheter is typically 20-40 cm longer than the working length of a guide, and the working length of a microcatheter is typically 10-30 cm longer than the working length of the intermediate catheter. The guidewire is typically longer than the microcatheter by another 20-50 cm.

**[0008]** Some exemplary issues with current technology include the time required or even the ability to access the site of the occlusion, the time required to restore flow or the inability to fully, or even partially, restore flow to the vessel, the occurrence of distal emboli during the procedure, which has potentially negative neurologic effect and procedural complications such as perforation and intracerebral hemorrhage. There is a need for a system of devices and methods that enable rapid access, optimized aspiration of the clot, distal protection throughout all stages of the procedure, which potentially liberate emboli, and safe and rapid exchange of devices as needed to fully restore flow to the blocked cerebral vessel.

## SUMMARY

**[0009]** In one aspect, there is disclosed an intravascular access system for facilitation of intraluminal medical procedures within the neurovasculature through an access sheath. The system includes an aspiration or support catheter having a flexible, distal luminal portion having an inner diameter defining a lumen extending between a proximal opening at a proximal end of the luminal portion and a distal opening at a distal end of the luminal portion. The catheter has a rigid spine coupled to at least the proximal end of the luminal portion and extending proximally therefrom. The system includes a dilator having a flexible, distal dilator portion sized to be received within the lumen of the luminal portion; and a rigid, dilator spine extending proximally from the dilator portion.

**[0010]** The dilator spine can align side-by-side with the spine of the catheter. The distal dilator portion can have a tapered distal tip. The dilator can have a length at least as long as a length of the catheter such that a distal tip of the dilator protrudes from the distal opening of the luminal portion. The dilator can be generally tubular along at least a portion of the length. A proximal end of the catheter spine can include a gripping feature configured for a user to grasp in order to move the catheter through an access sheath. A proximal end of the dilator spine can include a tab configured to be locked with the gripping feature on the catheter spine. When the catheter and the dilator are in a locked configuration they can be advanced as a single unit through the access sheath. The gripping feature and the dilator tab can be removably coupled such that in a locked configuration the dilator tab engages the gripping feature and in an unlocked configuration the dilator tab disengages from the gripping feature. The dilator tab can be affixed to the dilator or can be slideable on the dilator to accommodate different relative positions between the dilator and the catheter. The distal dilator portion can include one or more detents on an outer surface configured to lock with correspondingly-shaped surface features on an inner surface of the luminal portion lumen through which the dilator portion extends. The dilator spine and the catheter spine can have a similar stiffness and kink-resistance. The dilator can have a visual marker on a distal end and/or a proximal end of the distal tip. A distal end region of the dilator can be more flexible and increasingly stiffen towards a proximal end region of the dilator. The catheter spine and dilator spine can be configured to cause bi-directional sliding movement of the luminal portion through a lumen of an access sheath and navigate the luminal portion into a cerebral vessel to reach a treatment site.

**[0011]** In an interrelated aspect, disclosed is an intravascular access system for facilitation of intraluminal medical procedures within the neurovasculature having an access sheath and an aspiration or support catheter. The access sheath has a sheath body having an inner diameter defining a lumen between a proximal end and a distal end of the sheath body. The sheath body has at least one opening from the lumen near a distal end region of the sheath body. The aspiration or support catheter includes a flexible, distal luminal portion having an outer diameter sized for insertion through the lumen of the access sheath, an inner diameter defining a lumen extending between a proximal opening at a proximal end of the luminal portion and a distal opening at a distal end of the luminal portion, and a length between the proximal opening and the distal opening. The aspiration or support catheter includes a rigid spine coupled to at least the proximal end of the luminal portion and extending proximally therefrom. The rigid spine is configured to cause bi-directional sliding movement of the luminal portion through the lumen of the access sheath and out the at least one opening to navigate the luminal portion into a cerebral vessel to reach a treatment site. A portion of the outer diameter of the luminal portion fluidly seals with the inner diameter of the access sheath when the distal end of the luminal portion extends into the cerebral vessel to reach the treatment site.

**[0012]** The luminal portion and the sheath body can be concentrically aligned and the lumen of the luminal portion and the lumen of the sheath body form a contiguous aspiration lumen from the distal end of the luminal portion to the proximal end of the sheath body. The contiguous aspiration lumen can be used to aspirate fluid and debris from the distal opening of the luminal portion. The contiguous aspiration lumen can be to deliver materials through the distal opening of the luminal portion. The contiguous aspiration lumen can form a step-up in diameter where the lumen of the luminal portion empties into the lumen of the sheath body. The lumen of the luminal portion can be shorter than the lumen of the sheath body. The luminal portion and the sheath body can form an overlap region when the luminal portion extends distally beyond the at least one opening of the sheath body. The outer diameter of the luminal portion can approach the inner diameter of the lumen of the sheath body such that a seal is formed by the overlap region. The seal can be configured to enable sealing against a vacuum of up to 25 inHg, or up to 28 inHg. The seal within the overlap region can be configured to enable sealing against a pressure of up to 300 mmHg or up to 600 or up to 700 mmHg. The seal can be located distal a proximal end of the luminal portion and proximal to the at least one opening of the sheath body.

**[0013]** The system can further include a sealing element positioned on an external surface of the luminal portion. The sealing element can include a stepped up diameter or protruding feature in the overlap region. The sealing element can include one or more external ridge features. The one or more ridge features can be compressible when the luminal portion is inserted into the lumen of the sheath body. The sealing element can include one or more inclined surfaces biased against an inner surface of the sheath body lumen. The sealing element can include one or more expandable members actuated to seal. The sheath body can have an outer

diameter suitable for insertion into the carotid artery. The outer diameter of the sheath body can be between 5Fr and 7Fr.

**[0014]** The sheath body can have a length between the proximal end and the distal end suitable for locating the distal end of the sheath body at the petrous portion of an internal carotid artery from a transfemoral approach. The length of the sheath body can be between 80 cm and 105 cm. The length of the luminal portion can be between 10 cm and 25 cm. The length of the luminal portion can be less than a length of the sheath body such that as the catheter is retracted into the sheath body a seal remains between an overlap region of the luminal portion and the inner diameter of the sheath body.

**[0015]** The spine can be longer than an entire length of the sheath body. The luminal portion can include three or more layers including an inner lubricious liner, a reinforcement layer, and an outer jacket layer. The outer jacket layer can be composed of discreet sections of polymer with different durometers, compositions, and/or thicknesses to vary the flexibility along the length of the distal luminal portion. The outer diameter of the distal luminal portion can be sized for navigation into cerebral arteries. The inner diameter of the distal luminal portion can be between 0.040" and 0.088". The outer diameter of the luminal portion can approach the inner diameter of the sheath body creating a sealed area at an overlap region while still allowing the catheter to move through the sheath body. The catheter can be tapered towards the distal opening such that a distal-most end of the luminal portion has a smaller outer diameter compared to a more proximal region of the luminal portion near where the luminal portion seals with the sheath body. The distal end region of the sheath body can include an occlusion element. The distal end region of the sheath body can include an expanding distal tip. The at least one opening from the lumen can include a side opening located a distance away from a distal tip of the sheath body. The distal tip of the sheath body further can include a ramp feature configured to direct at an angulation the catheter away from a longitudinal axis of the sheath body lumen out through the at least one opening.

**[0016]** The spine can be longer than an entire length of the sheath body. The spine can be a wire having an outer dimension from 0.014" to 0.018". The spine can be a hypotube having a guide-wire passageway extending therethrough. The spine can be a ribbon having an outer dimension from 0.010" to 0.025" thick. The ribbon can be curved along at least a portion of an arc. The spine can be configured to rotate the luminal portion around a longitudinal axis of the access sheath. The spine can be eccentrically coupled to the luminal portion and the spine extend proximally from the luminal portion to outside the proximal end of the sheath body. The proximal end of the luminal portion can have an angled cut. The angled cut can be generally planar or curved. The sheath body can have one or more visual markers on the distal end region of the sheath body. The distal luminal portion can have one or more visual markers at a distal end region of the luminal portion, a proximal end region of the luminal portion or both. The one or more visual markers on the sheath body and the one or more visual markers on the luminal portion can be visually distinct. The spine can have one or more visual markers. The one or more visual markers of the spine can indicate overlap between the distal luminal portion and the sheath body. The one or more visual markers of the spine can be positioned so that when the visual marker of the spine is aligned with a portion of the access sheath, the catheter is positioned at a distal-most position with minimal overlap length needed to create a seal between the catheter and the sheath body.

**[0017]** The system can further include a dilator having a flexible, distal dilator portion having a distal tip and sized to be received within the luminal portion of the catheter. The dilator can be a tubular element along at least a portion of its length. The dilator can be a solid rod formed of malleable material configured to be shaped by a user. The dilator can further include a rigid, dilator spine extending proximally from the dilator portion. The dilator spine can be coaxial and can have a lumen extending through it. The dilator spine can be eccentric. When in use, the dilator spine can align side-by-side with the spine of the catheter. The distal tip of the dilator can be tapered. The dilator can have a length at least as long as a length of the catheter such that the distal tip protrudes from the distal opening of the luminal portion. A proximal end of the spine can include a gripping feature configured for a user to grasp in order to move the catheter through the access sheath. A proximal end of the dilator spine can include a tab configured to be locked with the gripping feature on the catheter spine. When the catheter and dilator are in a locked configuration they can be advanced as a single unit through the sheath body. The gripping feature and the dilator tab can be removably coupled such that in a locked configuration the dilator tab engages the gripping feature and in an unlocked configuration the dilator tab disengages from the gripping feature. The dilator tab can be affixed to the dilator and/or can be slideable on the dilator to accommodate different relative positions between the dilator and the catheter.

**[0018]** The distal dilator portion can include one or more detents on an outer surface configured to lock with correspondingly-shaped surface features on an inner surface of the luminal portion lumen through which the dilator portion extends. The dilator spine and the catheter spine can have a similar stiffness and kink-resistance. The dilator can have a visual marker on a distal end and/or a proximal end of the distal tip. A distal end region of the dilator can be more flexible and increasingly stiffens towards the proximal end region of the dilator.

**[0019]** The access sheath can further include a connector that connects the proximal end of the sheath body to a proximal hemostasis valve. The proximal hemostasis valve can have an adjustable opening sized large enough to allow removal of the catheter without dislodging any

clots thereon. When in use with the access sheath, the rigid spine of the catheter can extend proximally from the luminal portion through the access sheath lumen and out the proximal hemostasis valve of the access sheath. The connector can provide a connection of the proximal end of the sheath body to an aspiration line. The connector can have a large bore inner lumen and connects to a large-bore aspiration line. The aspiration line can connect to an aspiration source. The aspiration source can be an active aspiration source. The aspiration line can connect to a forward drip or flush line. The access sheath can further include a proximal extension portion such that when the distal luminal portion of the catheter is withdrawn from the sheath body lumen it remains within the proximal extension portion. The inner diameter of the luminal portion can be sized to permit placement of an interventional device through the luminal portion.

**[0020]** Other features and advantages should be apparent from the following description of various implementations, which illustrate, by way of example, the principles of the invention.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0021]**

FIG. 1 is an exploded view of a system of devices for accessing and removing a cerebral occlusion to treat acute ischemic stroke from a femoral artery access site;

FIG. 2A shows components of the system of FIG. 1 in position in a patient from the transfemoral approach to treat the occlusion;

FIG. 2B is a detailed view of a portion of the system of FIG. 2A taken along circle BB;

FIG. 3 shows components of the system of FIG. 1 being used via a transcarotid access site;

FIG. 4 shows an implementation of an access sheath;

FIG. 5 shows an implementation of a proximal portion of the access sheath of FIG. 4 provided as a separate, removable component;

FIG. 6 shows an implementation of a connector to minimize flow resistance through the access sheath of FIG. 4 into the proximal portion;

FIG. 7 shows an implementation of an access sheath having an occlusion balloon;

FIGs. 8A-8B show implementations of sealing elements between the access sheath body and luminal portion of a catheter extending therethrough;

FIG. 9 shows an implementation of a microcatheter and retrievable stent device positioned through a spined catheter;

FIGs. 10A-10C show implementations of expandable portions on retrievable stent devices;

FIG. 11 shows an implementation of an aspiration system for use with the systems described herein;

FIG. 12A shows an implementation of a spined catheter system for use with the systems described herein;

FIG. 12B shows the spined catheter system of FIG. 12A having a spined dilator extending through a lumen of a spined catheter;

FIG. 12C shows the spined catheter system of FIG. 12A extended through a side opening of an implementation of an access sheath;

FIG. 13 is a cross-sectional view taken about line A-A of FIG. 12B;

FIG. 14 is a cross-sectional view taken about line B-B of FIG. 12B;

FIG. 15A shows an implementation of a spined aspiration catheter-dilator system having a spined catheter and a spined dilator in a locked configuration;

FIG. 15B shows the spined aspiration catheter-dilator system having the spined catheter and the spined dilator in an unlocked configuration;

FIG. 16 shows an implementation of a spined catheter system extending distally to an access sheath to treat an embolus in a cerebral vessel.

## DETAILED DESCRIPTION

**[0022]** One of the major drawbacks to current acute stroke intervention procedures is the amount of time required to restore blood perfusion to the brain. This time includes the time it takes to access the occlusive site or sites in the cerebral artery, and the time it takes to completely remove the occlusion in the artery. Because it is often the case that more than one attempt must be made to completely remove the occlusion, reducing the number of attempts as well as reducing the time required to exchange devices for additional attempts is an important factor in minimizing the overall time. Additionally, each attempt is associated with potential procedural risk due to device advancement in the delicate cerebral vasculature.

**[0023]** Disclosed herein are methods and devices that

enable safe and rapid access to the complex neurovascular anatomies of the cerebral and intracranial arteries and removal of the occlusion. The methods and devices include one or more access devices, catheters, and thrombectomy devices to remove the occlusion. Methods and devices are also disclosed to provide active aspiration and/or passive flow reversal for the purpose of facilitating removal of the occlusion as well as minimizing distal emboli. The system offers the user a degree of flow control so as to address the specific hemodynamic requirements of the cerebral vasculature. The systems described herein provide superior ease of use in that a single operator may operate the disclosed systems using single-point continuous aspiration for rapid and safe exchange without switching. The higher efficiency of aspiration force through the systems described herein reduces distal embolic debris and increases the rate of "one-pass" thrombectomy.

**[0024]** It should be appreciated that while some embodiments are described with specific regard to aspirating a neurovascular anatomy, the embodiments are not so limited and may also be applicable to other uses. For example, the spined aspiration catheter and one or more components of the access systems described herein may be used to deliver working devices to a target vessel of a coronary anatomy, or other vasculature anatomy. It should be appreciated that where the phrase "aspiration catheter" is used herein that such a catheter may be used for other purposes besides or in addition to aspiration, such as the delivery of fluids to a treatment site or as a support catheter providing a conduit that facilitates and guides the delivery or exchange of other devices such as a guidewire or interventional devices. Alternatively, the access systems need not be limited only to the vasculature can be useful for access of other parts of the body outside the vasculature. It should also be appreciated that reference throughout this specification to a particular feature, structure, configuration, characteristic or implementation or embodiment may be combined in any suitable manner. The use of relative terms throughout the description may denote a relative position or direction. For example, "distal" may indicate a first direction away from a reference point. Similarly, "proximal" may indicate a location in a second direction opposite to the first direction. However, such terms are provided to establish relative frames of reference, and are not intended to limit the use or orientation of an anchoring delivery system to a specific configuration described in the various embodiments below.

**[0025]** FIG. 1 shows a system of devices for accessing and removing a cerebral occlusion to treat acute ischemic stroke from a femoral artery access site. The system 100 includes an access sheath 220, sheath dilator 250, guidewire 270, one or more spined aspiration or support catheters 320, dilator 340, microcatheter 400, and a retrievable stent device 500, each of which will be described in more detail below. Further, the system 100 can include one or more arterial access sheath system 200 that includes an access sheath 220, one or more sheath dilators 250 and a sheath guidewire 270. The system 100 can include one or more spined catheter systems 300 including a spined aspiration or support catheter 320, a tapered dilator 340, and alternatively a catheter clearing tool 350. The spine catheter system 300 can incorporate nested spined catheters to provide for extended reach into distal sites. The system 100 can include an access sheath system 200, a tapered catheter system 300, a microcatheter 400, and a retrievable stent device 500.

**[0026]** FIG. 2A shows some elements of the system in position in the patient from the transfemoral approach to treat the occlusion. The access sheath 220 can be inserted through a femoral artery insertion site positioned with the distal tip of the access sheath 220 at or near the petrous portion of the internal carotid artery ICA. The spined aspiration catheter 320 can be positioned with the distal tip at the face of the occlusion in the artery. In some implementations, the access sheath 220 can be inserted through a direct puncture in the wall of the common carotid artery and advanced into the internal carotid artery rather than via a transfemoral approach (see FIG. 3).

**[0027]** As seen more clearly in detailed FIG. 2B, the access sheath 220 can have a sheath body 222 and an inner lumen 223 extending between a proximal end and a distal end region of the sheath body 222. The spined aspiration catheter 320 is sized to extend through the inner lumen 223 of the access sheath 220 such that a distal end region of the catheter 320 extends beyond a distal end region of the access sheath 220. The catheter 320 is shown in FIG. 2B exiting the lumen 223 of the sheath body 222 through a distal opening 221. It should be appreciated, however, that the sheath body 222 may have one or more side openings near a distal end region of the body 222 through which the catheter 320 can extend (see FIG. 12C) as will be described in more detail below.

**[0028]** Still with respect to FIG. 2B, the spined aspiration catheter 320 can include a relatively flexible, distal luminal portion 322 coupled to a stiff and kink-resistant proximal spine 330. The distal luminal portion 322 can have an inner lumen 323 extending between a proximal end and a distal end of the luminal portion 322. The lumen 323 of the catheter 320 can have a first inner diameter and the lumen 223 of the access sheath 220 can have a second, larger inner diameter. The lumens 223, 323 are fluidly connected and contiguous such that fluid flow into and/or out of the system is possible, such as by applying suction from an aspiration source coupled to the system via a connector 226 on the access sheath 220. An overlap region 120 between the distal section of the sheath body 222 and the luminal portion 322 of the catheter 320 is sized and configured to create a seal that enables a continuous aspiration lumen from the distal tip region of the spined catheter 320 to the proximal sheath connector 226. If the sheath body 222 has a side opening through which the distal luminal portion 322 of the catheter 320 extends, the seal created at the overlap region 120 be-

tween the sheath body 222 and the luminal portion 322 is located proximal to the side opening.

**[0029]** Key dimensions that affect aspiration force through a tube include radius (r), pressure (P), viscosity (n) and length (L) where Flow = $Q = \pi r^4(\Delta P)/8nL$. Changes in radius increase flow to the $4^{th}$ power and length is inversely proportional to flow. As will be described in more detail below, the aspiration catheter has an over-the-wire portion that is a fraction of the overall distance required to reach the target site. This configuration greatly speeds up the time required to retract and re-advance the catheter. Further, the systems described herein can provide for a markedly increased radius and luminal area for aspiration of the clot and markedly shorter length, particularly compared to prior systems where the aspiration lumen runs along the entire inner diameter of the aspiration catheter. In the systems described herein, the majority of the aspiration lumen has a radius of the procedural sheath. The catheter 320 is smaller in diameter than the guide, but steps up in luminal diameter upon reaching the lumen of the access sheath 220 allowing for a greater aspiration force to be applied to a majority of the length of the luminal system. Further, the overall length of this narrow diameter region of the catheter 320 is much shorter compared to the overall length of the access sheath. The proximal spine 330 of the catheter 320 has a length and structure that extends through the lumen 223 of the access sheath 220 to a proximal end of the system such that it can be used to advance and retract the catheter 320 through the lumen 223 of the sheath 220. The spine 330 of the aspiration catheter 320, however, takes up only a fraction of the luminal space the system resulting in increased luminal area for aspiration. Increased luminal area for aspiration increases the time it takes to aspirate the occlusion and increases the possibility of removing the occlusion in a single aspiration attempt. The stepped up luminal diameter also increases the annular area available for forward flushing of contrast, saline, or other solutions while devices such as microcatheters or tapered dilators are coaxially positioned in the spined catheter 320 and access sheath 220. This can increase the ease and ability to perform angiograms during device navigation.

**[0030]** Current stroke interventions pose a risk of distal emboli being released. During the effort to remove or dissolve clot blockages in the cerebral artery, for example, there is a significant risk of thrombus fragmentation creating embolic particles that can migrate downstream into either the occluded vessel or other vessels and compromise cerebral perfusion. In carotid artery stenting procedures (CAS), embolic protection devices and systems are commonly used to reduce the risk of embolic material from entering the cerebral vasculature. The types of devices include intravascular distal filters, and reverse flow or static flow systems. Unfortunately, because of the delicate anatomy and access challenges as well as the need for rapid intervention, these types of embolic protection systems are not used in interventional treatment of acute ischemic stroke. The period of a stroke intervention when flow is restored is normally considered an important time as the brain is now being perfused by blood. However, it is also a period of embolic risk. While there is blockage in the artery, there is no flow. Therefore any embolic debris created by crossing the occlusion with guidewire and/or microcatheter, or deployment of a retrievable stent device across the occlusion, remains stagnant. However, when flow is restored to the artery, the emboli can now flow antegrade to distal vascular territories.

**[0031]** A second period of embolic risk occurs when the retrievable stent device is being pulled back into the guide or catheter. In prior methods and devices, aspiration is applied to the intermediate catheter during retrievable stent device retraction into the catheter, or the catheter and retrievable stent device are pulled back together into the guide, while simultaneously applying aspiration to the guide catheter. Two points of aspiration, through the catheter and through the guide, may both be utilized to reduce risk of distal emboli during the critical step of drawing the occlusion through the guide and out of the patient. Often, two people are required to enable two points of aspiration, or aspiration is performed sequentially from first the catheter and then the guide, which may lead to interruption in aspiration or sub-optimal aspiration. In the disclosed systems and methods, reverse flow may be applied to the target site during device advancement, at the critical time of flow restoration, and during the entire time that the occlusion is being removed, with a single point of aspiration.

**[0032]** In an aspect of the disclosure, the level of aspiration may be modified from a low level to achieve adequate protection from distal emboli, to a higher level to provide effective aspiration removal of the occlusion. This aspect allows distal protection without high levels of blood loss, yet allows a strong aspiration force as needed to remove the occlusion.

**[0033]** In another aspect, there are disclosed methods and devices for additionally providing active aspiration or passive retrograde flow during the procedure to remove thrombus and to minimize distal emboli. The system offers the user a degree of blood flow control so as to address the specific hemodynamic requirements of the cerebral vasculature. The system may include a flow controller, which allows the user to control the timing and mode of aspiration.

**[0034]** In another aspect, there are disclosed methods and devices for additionally providing flushing steps to minimize emboli entrapment in the system and increased visibility of particulates in the system during use.

**[0035]** The following descriptions provide detailed implementations and benefits of each aspect of the disclosed invention.

**[0036]** Referring again to FIG. 1 illustrating an implementation of an access sheath 220. The sheath 220 can include a sheath body 222 that is the insertable portion of the sheath 220 (i.e. the portion that inserts into the patient), a proximal connector 226, an aspiration line 230,

a proximal hemostasis valve 234 and a flush line 236. The sheath 220 may also include a proximal extension portion 240, and may also include a valve on the connector 226 to fluidly isolate the sheath body 222 from the proximal portion 240 of the access sheath 220. The access sheath 220 may come in a kit with one or more dilators 250, and a sheath guidewire 270.

**[0037]** The diameter of the sheath body 222 is suitable for insertion into the carotid artery, with an inner lumen 223 that is suitably sized for providing a passageway for catheters to treat the occlusion. In an implementation, the sheath body 222 can have an inner diameter of about 0.074" and an outer diameter of about 0.090", corresponding to a 5 French sheath size, an inner diameter of about 0.087" and an outer diameter of about 0.104", corresponding to a 6 French sheath size, or an inner diameter of about 0.100" and an outer diameter of about 0.177", corresponding to a 7 French sheath size. The length of the sheath body 222 is configured to enable the distal tip of the sheath body 222 to be positioned as far distal as the petrous portion of the internal carotid artery. In an implementation, the sheath body 222 length is suitable for a transfemoral approach, in the range 80 to 90 cm or up to about 100 cm or up to about 105 cm. In an implementation, the sheath body 222 length is suitable for a transcarotid approach to the petrous ICA, in the range 20 to 25 cm. In an implementation, the sheath body 222 length is suitable for a transcarotid approach to the CCA or proximal ICA, in the range 10-15 cm. The sheath body 222 is configured to assume and navigate the bends of the vasculature and be subject to high aspiration forces without kinking, collapsing, or causing vascular trauma.

**[0038]** The sheath body 222 can be constructed in two or more layers. An inner liner can be constructed from a low friction polymer such as PTFE (polytetrafluoroethylene) or FEP (fluorinated ethylene propylene) to provide a smooth surface for the advancement of devices through the inner lumen. An outer jacket material can provide mechanical integrity to the inner liner and may be constructed from materials such as PEBAX, thermoplastic polyurethane, polyethylene, nylon, or the like. A third layer can be incorporated that can provide reinforcement between the inner liner and the outer jacket. The reinforcement layer can prevent flattening or kinking of the inner lumen of the sheath body 222 to allow unimpeded device navigation through bends in the vasculature as well as aspiration or reverse flow. The sheath body 222 can be circumferentially reinforced. The reinforcement layer can be made from metal such as stainless steel, Nitinol, Nitinol braid, helical ribbon, helical wire, cut stainless steel, or the like, or stiff polymer such as PEEK. The reinforcement layer can be a structure such as a coil or braid, or tubing that has been laser-cut or machine-cut so as to be flexible. In another implementation, the reinforcement layer can be a cut hypotube such as a Nitinol hypotube or cut rigid polymer, or the like.

**[0039]** The flexibility of the sheath body 222 can vary over its length, with increasing flexibility towards the distal portion of the sheath body 222. The variability in flexibility may be achieved in various ways. For example, the outer jacket may change in durometer and/or material at various sections. A lower durometer outer jacket material can be used in a distal section of the sheath compared to other sections of the sheath. Alternately, the wall thickness of the jacket material may be reduced, and/or the density of the reinforcement layer may be varied to increase the flexibility. For example, the pitch of the coil or braid may be stretched out, or the cut pattern in the tubing may be varied to be more flexible. Alternately, the reinforcement structure or the materials may change over the length of the sheath body 222. In an implementation, the distal-most section has a flexural stiffness (E*I) in the range 50 to 300 N-mm2 and the remaining portion of the sheath body 222 has a flexural stiffness in the range 500 to 1500 N-mm2 , where E is the elastic modulus and I is the area moment of inertia of the device. In another implementation, there is a transition section between the distal-most flexible section and the proximal section, with one or more sections of varying flexibilities between the distal-most section and the remainder of the sheath body 222. In this implementation, the distal-most section is about 2 cm to about 5 cm, the transition section is about 2 cm to about 10 cm and the proximal section takes up the remainder of the sheath length.

**[0040]** The tip of the sheath body 222 may include one or more distal radiopaque markers 224 (see FIG. 1). In an implementation, the radiopaque tip marker 224 is a metal band, for example platinum iridium alloy, embedded near the distal end of the sheath body 222. Alternately, the access sheath tip material may be a separate radiopaque material, for example a barium polymer or tungsten polymer blend. The distal region of the sheath body 222 is also the area of the overlap region 120 that allows a seal between the catheter 320 and the sheath body 222, creating a continuous aspiration lumen. Thus, the outer diameter of the luminal portion 322 of the aspiration catheter 320 approaches the inner diameter of the distal region of the sheath body 222 lumen 223 such that a seal is formed. The relative location of the seal formed may vary depending on where the aspiration catheter 320 exits the lumen 223 of the sheath body 222 and the location of the openings from the sheath body 222, as described in more detail below. For example, if the sheath body 222 has an opening at the distal tip the location of the seal may be closer to the distal end of the sheath body 222 compared to if the sheath body 222 has one or more side openings in the distal end region of the sheath body 222 through which the catheter 320 exits the lumen 223.

**[0041]** Referring again to FIG. 1, the access sheath 220 also can include a connector 226 that connects a proximal end of the sheath body 222 to the proximal hemostasis valve 234, and also provides a connection to the aspiration line 230. This connector 226 can have a large bore inner lumen, and connects to a large-bore aspiration line 230. In an implementation, the inner lumen

of the connector 226 is at least .080". In an implementation, the inner lumen of the aspiration line 230 is at least .080". The aspiration line 230 can terminate in a stopcock, female Luer connector, or other connector 232 that allows connection to an aspiration source. In an implementation, the aspiration source is an active aspiration source such as a syringe or a pump. In another implementation, the aspiration source is a reverse flow shunt line such as that described in US Patent Number 8,157,760 and US Patent Publication Number 2010/0217276, which are both incorporated by reference. The large bore aspiration line 230 can be constructed to be resistant to collapse. For example, the aspiration line 230 can be a thick-walled polymer tubing or a reinforced polymer tubing. The aspiration line valve 232 enables the line 230 to be opened or closed. In one implementation, the valve 232 also allows connection of one or more additional fluid lines, for connecting a forward drip or a flush line for contrast or saline injections. As an example, the valve 232 may be a stopcock manifold commonly used in interventional procedures to allow multiple connections. The connector 226 may also include means to secure the access sheath 220 to the patient to reduce the risk of sheath dislodgement during the case. For example, the connector 226 may include one or more suture eyelets 233.

**[0042]** With reference still to FIG. 1, the proximal end of the access sheath 220 can terminate in a proximal hemostasis valve 234. This valve 234 allows the introduction of devices through the sheath 220 into the vasculature, while preventing or minimizing blood loss and preventing air introduction into the access sheath 220. The hemostasis valve 234 can include a flush line 236 or a connection to a flush line 236 so that the sheath 220 can be flushed with saline or radiopaque contrast during the procedure as desired. The flush line 236 can also be used as a second point of aspiration during portions of the procedure as described more fully below. The hemostasis valve 234 can be a static seal-type passive valve, or an adjustable-opening valve such as a Tuohy-Borst valve or rotating hemostasis valve (RHV). The hemostasis valve 234 can be integral to the access sheath 220, or the access sheath 220 can terminate on the proximal end in a female Luer adaptor to which a separate hemostasis valve 234 component, such as a passive seal valve, a Tuohy-Borst valve or rotating hemostasis valve may be attached. In an implementation, the valve 234 has an adjustable opening that is open large enough to allow removal of devices that have adherent clot on the tip without causing the clot to dislodge at the valve 234 during removal. Alternately, the valve 234 is removable and is removed when the catheter tip is being removed from the sheath 220 to prevent clot dislodgement at the valve 234.

**[0043]** Referring again to FIG. 1, the arterial sheath system 200 can include one or more sheath dilators 250 and a sheath guidewire 270. The sheath guidewire 270 can be inserted first into the artery using standard vascular access techniques such as a micropuncture technique or Modified Seldinger technique. The sheath dilator 250 allows for smooth insertion of the access sheath 220 through a puncture site in the arterial wall. The dilator 250 can be inserted into the access sheath 220 and then the two components can be inserted together over the sheath guidewire 270 into the artery The distal end 256 of the dilator 250 can be generally tapered to allow the dilator 250 to dilate the needle puncture site as it is being inserted through the arterial wall into the artery. The tapered distal end 256 can be generally between 6 and 12 degrees total included angle (relative to a longitudinal axis of the dilator), with a radiused leading edge.

**[0044]** An inner lumen of the dilator 250 can accommodate the sheath guidewire 270, and can have an inner diameter of between .037" to .041" to correspond to a sheath guidewire 270 of between .035" to .038". Alternately, the inner lumen of the dilator 250 can be between .020" to .022" to accommodate a sheath guidewire 270 of between .014" to .018". Alternately, the dilator 250 can be a two part dilator with an inner dilator and an outer dilator. The outer dilator can have an inner diameter of between .037" to .041", and the inner dilator can have an inner diameter of between .020" to .022". In use, the sheath 220 can be inserted into the artery with the outer dilator with a sheath guidewire 270 between .035" and .038". The sheath guidewire 270 may then be removed and replaced with the inner dilator and a smaller guidewire of between .014" and .018", and the access sheath 220 can then be advanced further distally to the desired site in the carotid artery.

**[0045]** To insert the arterial sheath 220 initially over the sheath guidewire 270 into the artery, the dilator taper 256 can have a certain stiffness and taper angle to provide the adequate dilating force on the arterial puncture site. However, to safely reach the petrous portion of the ICA, it may be desirable to have a sheath dilator 250 with a softer and/or longer taper at a distal end than that used for initial arterial access. In an implementation, the access sheath system 200 can include two or more tapered dilators. The first tapered dilator can be used with the arterial access device to gain entry into the artery, and is thus sized and constructed in a manner similar to standard introducer sheath dilators. Example materials that may be used for the tapered dilator include, for example, high density polyethylene, 72D PEBAX, 90D PEBAX, or equivalent stiffness and lubricity material. A second tapered dilator may be supplied with a softer distal section or a distal section that has a lower bending stiffness relative to the distal section of the first tapered dilator, and/or a longer taper length. That is, the second dilator has a distal region that is softer, more flexible, or articulates or bends more easily than a corresponding distal region of the first dilator. The distal region of the second dilator thus bends more easily than the corresponding distal region of the first dilator. In an implementation, the distal section of the first dilator has a bending stiffness in the range of 50 to 100 N-mm2 and the distal section of the

second dilator has a bending stiffness in the range of 5 to 15 N-mm2. The second dilator (which has a distal section with a lower bending stiffness) may be exchanged with the initial, first dilator such that the access sheath 220 may be advanced into the internal carotid artery and around curvature in the artery without undue force or trauma on the vessel due to the softer distal section of the second dilator.

**[0046]** The distal section of the soft, second dilator may be, for example, 35 or 40D PEBAX, with a proximal portion made of, for example 72D PEBAX. An intermediate mid portion or portions may be included on the second dilator to provide a smooth transition between the soft distal section and the stiffer proximal section. In an implementation, both dilators have an inner diameter of between .037" to .041". In an alternate implementation, the first dilator has an inner diameter of between .037" to .041" and the second dilator has an inner diameter of between .020" to .022". In yet another implementation, the second dilator is a two part dilator with an inner dilator and an outer dilator, as described above. In an implementation, one or both dilators may have radiopaque tip markers 224 so that the dilator tip position is visible on fluoroscopy. In one variation, the radiopaque marker 224 is a section of tungsten loaded PEBAX or polyurethane that is heat welded to the distal tip of the dilator. Other radiopaque materials may similarly be used to create a radiopaque marker 224 at the distal tip.

**[0047]** In an implementation, the access sheath 220 includes a proximal extension 240 that extends between the connector 226 and the proximal hemostasis valve 234. In the transcarotid configuration of the system, it may be desirable to move the proximal hemostasis valve 234 away from the distal tip of the access sheath 220, effectively elongating or lengthening the proximal portion of the access sheath that is outside the body while maintaining the length of the insertable sheath body portion 222. This allows the user to insert devices into the proximal hemostasis valve 234 of the access sheath 220 from a point further away from the target site and therefore away from the x-ray source and/or image intensifier used to image the target site fluoroscopically, thereby minimizing radiation exposure of the user's hands and also his or her entire body. In this implementation, the proximal extension 240 can be in the range between 10 and 25 cm, or between 15 and 20 cm. In either the transcarotid or transfemoral configuration, it may also be desirable to provide a section of the access sheath 220 that is fluidly connected to the access sheath aspiration line, but which may extend proximally from the aspiration line connection. This will allow users to pull devices out of the flow of blood from the sheath tip to the aspiration line, without completely removing the device from the access sheath 220.

**[0048]** In an alternate implementation, it may also be desirable to intermittently isolate this proximal portion 240 from the sheath body 222. In an implementation, as shown in FIG. 4, the connector 226 includes a valve 242 that can close off the fluid connection between the sheath body 222 and the proximal portion 240 of the access sheath 220, including the aspiration line 230, proximal extension 240 and proximal hemostasis valve 234. This can allow the distal portion of a catheter, retrievable stent device, or other thrombectomy device to be pulled into this proximal extension portion 240, the valve 242 closed to fluidly isolate the sheath body 222 from the proximal portion of the sheath, and then the proximal hemostasis valve 234 to be widely opened or removed, or the entire proximal extension portion 240 of the sheath 220 removed, without arterial bleeding from the sheath 220. The proximal extension 240 can be at least as long as the distal luminal portion 222 of the spined catheter 320 so that the distal luminal portion 322 may be pulled entirely into the proximal extension 240 and the valve 242 closed off before the proximal hemostasis valve 234 is widely opened to remove the catheter 320 entirely from the sheath 220.

**[0049]** Alternately, after the thrombectomy device or other interventional device is pulled into this proximal extension portion 240 and the sheath body 222 closed off via the valve 242, a portion of the thrombectomy device, such as the distal luminal portion 322 of the aspiration catheter 320, may remain in the proximal extension 240 and be flushed or otherwise cleared by creating flow from the flush line to the aspiration lines to dislodge clot without fully removing the device 320 from the access sheath 220. This ability to flush and clear the thrombectomy device without fully removing the thrombectomy device may reduce bleeding, time, and risk of air emboli during the steps between thrombectomy attempts. Also, withdrawing the thrombectomy device into the proximal extension 240 without fully removing it from the sheath body 222 while flushing and clearing also minimizes operator and staff exposure to blood and debris associated with device cleansing. In any of these implementations, the proximal extension tubing is clear so that the flush solution and presence/absence of embolic debris or air is clearly visible through the tubing.

**[0050]** The proximal extension portion 240 of the access sheath 220 can be provided as a separate, removable component that can be attached to any sheath with a standard connection on the proximal end. As shown in FIG. 5, a proximal component 280 includes a connector 285 that can attach to a proximal hub 15 of a standard sheath 10. The coupled components can create an assembly with the configuration and features of access sheath 220. In this implementation, the user can select from any of several already available sheaths of appropriate length, shape, and mechanical characteristics for the procedure, and perform the steps of the procedure described in this disclosure. The removable proximal component 280 can include the Y-arm connector 226, aspiration line 230, proximal extension 240, proximal hemostasis valve 234 and flush line 236, along with the valve connectors 232 and 238 terminating the aspiration

line 230 and flush line 236 respectively. A connector 285 can couple to the proximal connector 226 on the sheath 220. In an implementation as shown in FIG. 6, the connector 285 is configured to minimize the flow resistance through the sheath 10 and into the proximal portion 280. For example, instead of a standard male-female Luer connection, the connector 285 can include an adaptor 60 with an inner lumen and surface that matches a standard female Luer connector 62 typically found on sheaths, a seal element 64 that seals between the adaptor 60 and the sheath female Luer 62, and a rotating nut 66 that engages the thread elements of the female Luer 62 and couples the adaptor 60 and Luer 62 together such that the seal 64 is compressed and can seal against fluid and air vacuum and pressure. Again with respect to FIG.5, the proximal component 280 may also include a valve 242 on the Y-arm connector 226, so that when the proximal component 280 is attached to a sheath 10, the proximal section may be selectively open or closed to fluid connection with the sheath 10. A similar type of connection can be made for connector 232 connecting the sheath aspiration line 230 to an aspiration source.

**[0051]** In a preferred implementation, the proximal connection has a proximal extension length of about 22 cm, a Y-arm connector of about 7 cm, and a proximal hemostasis valve of length about 5 cm for a total length of about 34 cm.

**[0052]** It may be desirable to transiently occlude the carotid artery during the intervention to arrest antegrade flow of emboli during portions of the procedure. In an implementation, as shown in FIG. 7, the access sheath 220 includes an occlusion balloon 246 on the distal tip of the sheath body 222. An additional lumen in sheath body 222 can be connected to an inflation line 248 and fluidly connects the balloon 246 to the inflation line 248. An inflation device is attached to inflation line 248 to inflate the occlusion balloon 246. In this implementation, the balloon 246 is inflated when carotid artery occlusion is desired.

**[0053]** In some instances it is desirable to keep the sheath tip as small as possible during sheath insertion to minimize the diameter of the arterial puncture, but to expand the opening of the sheath 220 after it has been inserted into the vessel. At least one purpose of this feature is to minimize the effect or creation of distal emboli during pull back of an aspiration catheter 320 or other thrombectomy device into the sheath 220. During a thrombectomy procedure, the thrombus may be "pulled back" into a distal opening 221 of the sheath 220 on a device that has captured the thrombus. If the distal tip of the sheath 220 is enlarged relative to its initial size, or flared into a funnel shape, the chance of pieces of the thrombus breaking off and causing emboli is minimized because the larger size or funnel shape of the sheath tip is more likely to accommodate the emboli being drawn into it without being split into multiple pieces. This creates a better clinical outcome for the patient. In an implementation of the access sheath, the distal portion of the sheath body 222 is a material and/or construction such that the tip can be expanded after the sheath 220 is inserted into the artery and positioned in its desired location. In an implementation, the distal region of the sheath has an ID of about 0.087" can be enlarged to a diameter of about 0.100" to 0.120" although the size may vary and/or be flared.

**[0054]** Examples of expanding distal tip constructions include covered braided tips that can be shortened to expand. Another example of an expanding distal tip construction is an umbrella or similar construction that can open up with mechanical actuation or elastic spring force when unconstrained. Other mechanisms of expandable diameter tubes are well known in the art. One particular implementation is a sheath made of material that is deformable when expanded using a high pressure balloon. Co-pending U. S. Patent Publication number 2015/0173782, filed on December 19, 2014, describes exemplary devices and is incorporated herein by reference in its entirety. Construction of such features are described in co-pending Publication number 2015/0173782.

**[0055]** The distal end region of the sheath body 222 also may vary in the location, size and number of openings. The sheath body 222 may incorporate one or more openings near the distal end region of the sheath 220 that allow for fluid flow between the lumen 223 of the sheath body 222 and the vasculature within which the sheath 220 is positioned. The one or more openings can be sized to allow at least the luminal portion 322 of the aspiration catheter 320 to extend therethrough. The one or more openings may be sized larger than the outer diameter of the luminal portion 322 such that the one or more openings form an elongate mouth, slot or notch in a distal end region of the sheath body 222. The one or more openings may be formed within a region of the side wall of the sheath body 222 just proximal to the distal end, such that the opening is located at least 0.25 mm, 0.5 mm, 1.0 mm, 1.5 mm, 2.0 mm, 2.5 mm, 3.0 mm, 3.5 mm, or 4.0 mm or greater from the distal end of the sheath body 222. The one or more openings may be a plurality of openings forming a porous region near the distal end region of the sheath body 222 wherein at least one of the pluralities of openings is sized large enough to allow one or more components of the system to exit the lumen 223 of the sheath body 222. In some implementations, the one or more openings includes a distal opening 221 from the lumen 223 of the sheath body 222 (see FIGs. 4 and 12C). In some implementations, the one or more openings includes an elongate, distal mouth forming a side opening 1219 on a first side of the sheath body 222 located near a distal end region (see FIG. 12C). The side opening 1219 may be located at least 0.25 mm or more from the distal end of the sheath body 222. The side opening 1219 may having a diameter that is at least as large as the outer diameter of the distal luminal portion 322 of the spined catheter 320. Preferably, the side opening 1219 has a diameter that is at least 1.5x, 2x, 2.5x, or

3x as large as the outer diameter of the distal luminal portion 322. In another implementation, the sheath body 222 includes a pair of side openings 1219 on opposing and/or adjacent sides of the sheath body 222 near the distal end region. In another implementation, the sheath body 222 includes a distal opening 221 from the lumen 223 and one or more elongate side openings 1219 from the lumen 223. It should be appreciated that the sheath body 222 can be rotated around the longitudinal axis A such that the one or more side openings 1219 are positioned to allow for distal extension of the catheter 320 from the side openings 1219 in a desired direction relative to the longitudinal axis A of the sheath 220. Inclusion of a wide-mouthed side opening 1219 can allow for a range of exit angles for the catheter 320 from a position substantially (i.e. very nearly) parallel to the sheath body 222 to a position that is at an angle to the sheath body 222, for example substantially perpendicular or at a right angle to the sheath body 222, as well as greater than 90° angle. This arrangement can be critically important in situations where there is severe angulation within the vessel being traversed or where a bifurcation is present. Often, tortuous segments in vessels and bifurcations have severe angulations to 90° or greater angle up to 180°. Classic severe angulation points in the vasculature can include the aorto-iliac junction, the left subclavian artery takeoff from the aorta, the brachiocephalic (innominate) artery takeoff from the ascending aorta as well as many other peripheral locations.

**[0056]** Referring again to FIG. 1, as mentioned above the catheter system 300 can include a spined aspiration catheter 320 having a flexible, distal luminal portion 322 and a rigid, proximal spine 330. The outer diameter of the distal luminal portion 322 as well as the flexibility and lubricity of the luminal portion 322 paired with the rigid spine 330 allow for the spined aspiration catheter 320 to navigate to the site of occlusions in the cerebral vasculature compared to other systems configured to navigate the cardiac vasculature. The systems described herein can reach occlusions in a region of the anatomy that has a long, tortuous access route. The route may contain stenosis plaque material in the aortic arch and carotid and brachiocephalic vessel origins, presenting a risk of embolic complications. Further, cerebral vessels are usually more delicate and prone to perforation than coronary or other peripheral vasculature. The catheter systems described herein can provide for neurovascular interventional procedures more easily due to its ability to overcome these access challenges. The catheter systems described herein are designed for navigating tortuosity rather than pushing through it. U.S. Patent Publication Number 2015/0174368, filed on December 12, 2014, and U.S. Patent Publication Number 2015/0173782, filed on December 19, 2014, describe features of catheter devices that can navigate the tortuous anatomy of the cerebral arteries.

**[0057]** The length of the distal luminal portion 322 can vary. In some implementations, the length of the distal luminal portion 322 extends from a region near the distal tip of the access sheath body 222 to the site of the occlusion in the carotid artery, forming a proximal overlap region 120 with the distal end of the access sheath 220 (see FIG. 2B). Taking into account the variation in occlusion sites and sites where the access sheath distal tip may be positioned, the length of the distal luminal portion 322 may range from about 10 cm to about 25 cm. The length of the distal luminal portion 322 is less than the length of the sheath body 222 of the access sheath 220, such that as the spined aspiration catheter 320 is retracted into the sheath body 222 there remains a seal between the overlap region 328 of the spined aspiration catheter 320, and the inner diameter of the sheath body 222.

**[0058]** The catheter systems described herein can incorporate multiple spined catheters that are nested inside one another to allow for an extended reach into the tortuous anatomy. For example, a first spined catheter 320 having an outer diameter sized to be received within the lumen of the sheath body 222 may have a second spined catheter 320 extending through the inner lumen of the first spined catheter 320. The second spined catheter 320 can be extended using its proximal spine beyond a distal end of the first spined catheter 320 such that the smaller diameter second spined catheter 320 can reach a more distal region of the vasculature, particularly one having a narrower dimension. In this implementation, the first spined catheter 320 can act as a support catheter for the second spined catheter 320. The second spined catheter 320 can have an inner lumen that fluidly communicates with the inner lumen of the first spined catheter 320 that fluidly communicates with an inner lumen of the sheath body 222 forming a contiguous aspiration lumen.

**[0059]** In an implementation, the distal luminal portion 322 of the catheter 320 is constructed to be flexible and lubricious, so as to be able to be safely navigated to the target site, and kink resistant and collapse resistant when subjected to high aspiration forces, so as to be able to effectively aspirate the clot, with sections of increasing flexibility towards the distal end. In an implementation, the distal luminal portion 322 includes three or more layers, including an inner lubricious liner, a reinforcement layer, and an outer jacket layer. The outer jacket layer may be composed of discreet sections of polymer with different durometers, composition, and/or thickness to vary the flexibility along the length of the distal luminal portion 322. In an implementation the lubricious inner liner is a PTFE liner, with one or more thicknesses along variable sections of flexibility. In an implementation, the reinforcement layer is a generally tubular structure formed of, for example, a wound ribbon or wire coil or braid. The material for the reinforcement structure may be stainless steel, for example 304 stainless steel, nitinol, cobalt chromium alloy, or other metal alloy that provides the desired combination of strengths, flexibility, and resistance to crush. In an implementation, the reinforcement structure includes multiple materials and/or designs, again to vary the flexibility along the length of the

distal luminal portion 322. In an implementation, the outer surface of the catheter 320 is coated with a lubricious coating such as a hydrophilic coating. In some implementations the coating may be on an inner surface and/or an outer surface to reduce friction during tracking. The coating may include a variety of materials as is known in the art. The spine portion 330 may also be coated to improve tracking through the access sheath 220. Suitable lubricious polymers are well known in the art and may include silicone and the like, hydrophilic polymers such as high-density polyethylene (HDPE), polytetrafluoroethylene (PTFE), polyarylene oxides, polyvinylpyrolidones, polyvinylalcohols, hydroxy alkyl cellulosics, algins, saccharides, caprolactones, and the like, and mixtures and combinations thereof. Hydrophilic polymers may be blended among themselves or with formulated amounts of water insoluble compounds (including some polymers) to yield coatings with suitable lubricity, bonding, and solubility.

**[0060]** The outer diameter of the distal luminal portion 322 can be sized for navigation into cerebral arteries. It is desirable to have a catheter having an inner diameter that is as large as possible that can be navigated safely to the site of the occlusion, in order to optimize the aspiration force. A suitable size for the inner diameter may range between .040" and .075" or may range between 0.040" and 0.088", depending on the patient anatomy and the clot size and composition. The outer diameter should be as small as possible while still maintaining the mechanical integrity of the catheter 320. However, at the overlap region 120, the outer diameter (OD) of the catheter 320 approaches the inner diameter (ID) of the access sheath 220, so as to create a sealed area at the overlap region 120 whilst still enabling the catheter 320 to be inserted easily through the sheath 220 and positioned at the desired site. In an implementation, the catheter 320 and access sheath 220 are sized to match at the overlap region 120 with no change in catheter 320 outer diameter (see FIG. 2B). In an implementation, the difference between the catheter OD and the access sheath ID at the overlap region is .002" or less. In another implementation, the difference is .003" or less. In an implementation, the catheter 320 is tapered towards the distal tip of the distal luminal portion 322 such that the distal-most end of the catheter has a smaller outer diameter compared to a more proximal region of the catheter near where it seals with the access sheath. In another implementation, the catheter OD steps up at an overlap portion 328 to more closely match the sheath inner diameter (see FIG. 1). This implementation is especially useful in a system with more than one catheter suitable for use with a single access sheath size. It should be appreciated where the catheter OD of the spined catheter 320 matches the sheath inner diameter or the difference is 0.002" or less, a seal to fluid being injected or aspirated can be achieved by the overlap portion 328 such that no increase in catheter OD is necessary. A seal to fluid being injected or aspirated between the catheter and the sheath can be achieved by the overlap between their substantially similar dimensions without incorporating any separate sealing structure or seal feature.

**[0061]** In another implementation as shown in Figure 8A and 8B, there is a sealing element 336 positioned on the external surface of the proximal end of the distal luminal portion 322. The sealing element 336 can be one or more external ridge features, and can be compressed when the catheter 320 is inserted into the lumen of the access sheath 220. The ridge geometry can be such that the sealing element 336 behaves as an O-ring, quad ring, or other piston seal design. Figure 8B shows a similar configuration, with the sealing element 336 having a wiper seal configuration such as an inclined surface that is biased against an inner surface of access sheath body 222. Alternately, the seal element 336 may be an inflatable or expandable member such as a balloon or covered braid structure that can be inflated or expanded and provide sealing between the two devices at any time, including after the catheter 320 is positioned at the desired site. An advantage to this implementation is that there is no sealing force being exerted on the catheter 320 during catheter positioning, but rather is applied or actuated to seal after the catheter 320 is positioned.

**[0062]** It should be appreciated that the shape of the proximal end region of the distal luminal portion 322 may have an angled cut compared to the straight cut shown in the FIGs. 8A-8B. It should also be appreciated that the spine 330 may be coupled to a proximal end region of the catheter 320 and/or may extend along at least a portion of the distal luminal portion 322 such that the spine 330 couples to the distal luminal portion 322 a distance away from the proximal end. The spine 330 can be coupled to the portion 322 by a variety of mechanisms including bonding, welding, gluing, sandwiching, stringing, tethering, or tying one or more components making up the spine 330 and/or portion 322. In some implementations, the spine 330 and luminal portion 322 are coupled together by sandwiching the spine 330 between layers of the distal luminal portion 322. For example, the spine 330 can be a hypotube or rod having a distal end that is skived, ground or cut such that the distal end can be laminated or otherwise attached to the layers of the catheter portion 322 near a proximal end region. The region of overlap between the distal end of the spine 330 and the portion 322 can be at least about 1 cm. This type of coupling allows for a smooth and even transition from the spine 330 to the luminal portion 322.

**[0063]** In an implementation, the overlap region is configured to enable sealing against a vacuum of up to 25 inHg, or up to 28 inHg. In an implementation, the overlap region 120 is configured to enable sealing against a pressure of up to 300 mmHg or up to 600 mmHg or up to 700 mmHg with minimal to no leakage. In addition, there may be features that prevent excessive advancement of the spined aspiration catheter 320 beyond the distal end of the access sheath 220. In any implementation that involves a stepped up diameter or protruding feature at the overlap region 328 of the spined aspiration catheter 320,

the access sheath body 222 may include an undercut at the tip that prevents the proximal overlap portion of the spined aspiration catheter 320 to exit the sheath body 222.

**[0064]** The distal luminal portion 322 of the catheter 320 can have a radiopaque marker 324 at the distal tip to aid in navigation and proper positioning of the tip under fluoroscopy (see FIG. 1). Additionally, the proximal overlap region 328 of the catheter 320 may have one or more proximal radiopaque markers 1324 (see FIG. 12C) so that the overlap region 120 can be visualized as the relationship between the access sheath distal marker 224 and the catheter proximal marker 1324. In an implementation, the two markers (marker 324 at distal tip and a more proximal marker 1324) are distinct so as to minimize confusion of the fluoroscopic image, for example the catheter proximal marker 1324 may be a single band and the sheath tip marker 224 may be a double band.

**[0065]** The spine 330 of the spined aspiration catheter 320 is coupled to a proximal end region of the distal luminal portion 322. The spine 330 is configured to allow distal advancement and proximal retraction of the catheter 320 through the lumen 223 of the access sheath 220. In an implementation, the length of the spine 330 is longer than the entire length of the access sheath 220 (from distal tip to proximal valve), such as by about 5 cm to 15 cm. As shown in FIG. 1, the spine 330 can include a mark 332 to indicate the overlap between the distal luminal portion 322 of the catheter 320 and the sheath body 222. The mark 332 can be positioned so that when the mark 332 is aligned with the sheath proximal valve 234 during insertion of the catheter 320 through the sheath 220, the spined aspiration catheter 320 is positioned at the distal-most position with the minimal overlap length needed to create the seal between the spined aspiration catheter 320 and the access sheath 220. The spine 330 can include a gripping feature such as a tab 334 on the proximal end to make the spine easy to grasp and advance or retract. The tab 334 can coupled with one or more other components of the system 300, such as a dilator configured to extend through the lumen 323 of the distal luminal portion 322 as will be described in more detail below. The proximal tab 334 can be designed to be easily identifiable amongst the other devices existing in the sheath proximal valve 234, such as guidewires 270 or retrievable stent device wires 500. In an implementation, the spine 330 is colored a bright color, or marked with a bright color, to make it easily distinguishable from guidewire, retrievable stent tethers, or the like.

**[0066]** The spine 330 can be configured with sufficient stiffness to allow advancement and retraction of the distal luminal portion 322 of the spined aspiration catheter 320, yet also be flexible enough to navigate through the cerebral anatomy as needed. Further, the outer diameter of the spine 330 is sized to avoid taking up too much luminal area in the lumen 223 of the access sheath 220 and sheath body 222. In an implementation, the spine 330 is a round wire, with dimensions from .014" to .018". In another implementation, the spine 330 is a ribbon with dimensions ranging from .010" to .015" thick, and .015" thick to .025" thick. The ribbon can have a variety of cross-sectional shapes such as a flat ribbon or curved ribbon forming a c-shape or other shape along an arc. In another implementation, the spine 330 is a hypotube. In an implementation, the spine 330 material is a metal such as a stainless steel or nitinol as well as a plastic such as any of a variety of polymers.

**[0067]** One or more components of the systems described herein may be made from a metal, metal alloy, polymer, a metal-polymer composite, ceramics, combinations thereof, and the like, or other suitable materials. Some examples of suitable metals and metal alloys include stainless steel, such as 304V, 304L, and 316LV stainless steel; mild steel; nickel-titanium alloy such as linear-elastic and/or super-elastic nitinol; other nickel alloys such as nickel-chromium-molybdenum alloys (e.g., UNS: N06625 such as INCONEL® 625, UNS: N06022 such as HASTELLOY® C-22®, UNS: N10276 such as HASTELLOY® C276®, other HASTELLOY® alloys, and the like), nickel-copper alloys (e.g., UNS: N04400 such as MONEL® 400, NICKELVAC® 400, NICORROS® 400, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nickel-molybdenum alloys (e.g., UNS: N10665 such as HASTELLOY® ALLOY B2®), other nickel-chromium alloys, other nickel-molybdenum alloys, other nickel-cobalt alloys, other nickel-iron alloys, other nickel-copper alloys, other nickel-tungsten or tungsten alloys, and the like; cobalt-chromium alloys; cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like); platinum enriched stainless steel; titanium; combinations thereof; and the like; or any other suitable material.

**[0068]** The junction between the distal luminal portion 322 of the catheter 320 and the proximal spine 330 can be configured to allow a smooth transition of flexibility between the two portions so as not to create a kink or weak point, and also allow smooth passage of devices such as guidewires and microcatheters through the continuous inner lumen created by the lumen 223 of the access sheath 220 and the lumen 323 of the luminal portion 322 of the catheter 320. In an implementation, the distal luminal portion 322 has a transition section 326 (see FIG. 1) near where the portion 322 couples to the spine 330 that has an angled cut such that there is no abrupt step transition from the sheath 220 inner lumen 223 to the catheter 320 inner lumen 323. The angled cut can be generally planer. In an alternate implementation, the angled cut is curved or stepped to provide a more gradual transition zone. The distal luminal portion 322 and the spine 330 may be joined by a weld bond, a mechanical bond, an adhesive bond, or some combination thereof. The distal end of the spine 330 may have features that facilitate a mechanical joint during a weld, such as a textured surface, protruding features, or cut-out features. During a heat weld process, the features would facilitate

a mechanical bond between the polymer distal luminal portion 322 and the spine 330. In another implementation, such as the catheter system 1300 shown in FIGs. 12A-12B having a spined catheter 1320 and a dilator 1340 extending therethrough, a smooth transition of flexibility between the two portions is formed so as not to kink or create a weak point during advancement of the system 1300. Loss of this smooth flexibility transition can occur upon removal of the dilator 1340 from the spined catheter 1320. The spine 1330 can be intended primarily to withdraw the spined catheter 1320 where risk of kink or weak spot formation is markedly lower.

**[0069]** Because the spined aspiration catheter 320 does not have a lumen that runs its entire length 320 due to the presence of the spine 330 on its proximal end region, traditional flushing and preparation steps, either before use or during the procedure should the lumen of the catheter become clogged, are ineffective. In a traditional single lumen catheter, a syringe is attached to the proximal adaptor of the catheter and the inner lumen may be forcefully flushed with solution. The spined catheter 320 can be supplied with an accessory catheter flushing and clearing device 350 (see FIG. 1). This device 350 may be a tube with a rounded or tapered tip on a distal end and a female Luer connection on the proximal end. The Luer connector allows a syringe to be connected to the device 350. The blunt or tapered tip enables the device 350 to be inserted into either the distal or proximal end of the luminal portion 322 of the catheter 320, without risk of damaging the catheter 320, and the syringe actuated to flush the device. The OD of the clearing device 350 is closely matched with the ID of the luminal portion 322 of the spined catheter 320, such that the spined aspiration catheter 320 may be flushed with enough force to clear out the catheter of debris and aspirated occlusive material. The device 350 may also be used to mechanically clear out any entrapped thrombus in a plunger-type action, the working length of the device 350 can be at least as long as the distal luminal portion 322 of the catheter 320, so that it may be inserted through the entire lumen 323 of the distal luminal portion 322. Flushing may occur in conjunction with plunging the device 350, to more effectively clear the catheter 320 of entrapped thrombus or other embolic material.

**[0070]** In an alternate implementation, the aspiration catheter 320 is a single lumen catheter, for example, the type of catheter described in co-pending application U.S. Patent Publication Number 2015/0174368, filed December 12, 2014. In such an implementation, the catheter may be supplied with or coupled with a tapered co-axial dilator 340 that is generally tubular and has a tapered distal portion that provides a smooth transition between the catheter and a guidewire positioned within the catheter.

**[0071]** The spined aspiration catheter 320 can be navigated through the vasculature over an appropriately-sized microcatheter and guidewire. Alternately, the spined catheter 320 can be supplied with a co-axial dilator 340 (see FIG. 1). The dilator 340 is sized and shaped to be inserted through the internal lumen 323 of the distal luminal portion 322 of the catheter 320 in a coaxial fashion, such that a proximal end region of the dilator 340 aligns side-by-side with the spine 330 of the catheter 320 when in use. The dilator 340 can have a tapered distal tip 346. The length of the dilator 340 can be at least as long as the spined aspiration catheter 320 allowing for the distal tapered tip 346 as a minimum to protrude from the distal end of the luminal portion 322 of the spined catheter 320. The dilator 340 can have an outer diameter that forms a smooth transition to the distal tip of the catheter, and the distal tapered tip 346 that provides a smooth transition down to the guidewire that extends out the inner lumen of the dilator 340. The dilator 340 can be generally tubular along at least a portion of its length. In an implementation, the tapered dilator 340 is designed to accommodate a guidewire that may be in the range of 0.014" and 0.018" diameter for example. In this implementation, the inner luminal diameter may be between .020" and .024". The tapered distal tip 346 may be in range from 1.5 cm to 3 cm.

**[0072]** It should be appreciated that the dilators described herein for use with the spined catheters can vary in their configuration. For example, as described above the dilator 340 can be a co-axial dilator 340 that is generally tubular and has a tapered distal portion that provides a smooth transition between the catheter 320 and a guidewire positioned within the catheter 320. The tubular body of the dilator 340 can extend along the entire length of the catheter 320. Alternatively, the dilator 340 can incorporate a proximal spine that aligns side-by-side with the spine of the catheter 320. The proximal spine can be positioned co-axial or eccentric to a distal end region of the dilator 340. The co-axial proximal spine of the dilator 340 can have a lumen extending through it. Alternatively, the dilator 340 can be a solid rod having no lumen. The solid rod dilator can be formed of a malleable material that skives down to have a narrow outer diameter (e.g. 0.010" - 0.014") such that the dilator can be shaped to whatever angle or shape is desired by the user, similar to how a guidewire may be used. In this configuration, the catheter system does not include a guidewire or microcatheter. Such a dilator has a benefit over a microcatheter in that it can have an outer diameter that is 0.003" - 0.010" smaller than the inner diameter of the spined catheter 320.

**[0073]** The dilator 340 may have a proximal female Luer adaptor 348 at a proximal end to allow the dilator 340 to be flushed with a syringe. The dilator 340 may also incorporate a clip feature at a proximal end allowing the dilator 340 to be the material of the dilator 340 can be flexible enough and the taper distal tip 346 can be long enough to create a smooth transition between the flexibility of the guidewire and the flexibility of the catheter. This configuration can facilitate advancement of the catheter 320 through the curved anatomy and into the target cerebral vasculature. In an implementation, the distal end

of the dilator 340 has a radiopaque marker 344 and/or a marker 343 at the proximal end of the taper distal tip 346. The marker material may be a platinum/iridium band, a tungsten, platinum, or tantalum-impregnated polymer, or other radiopaque marker.

**[0074]** The dilator 340 can be constructed to have variable stiffness between the distal and proximal ends of the dilator 340. For example, the distal most section that extends beyond the distal end of the luminal portion 322 of the catheter 320 can be made from a more flexible material, with increasingly stiffer materials towards the more proximal sections. In some implementations, the dilator 340 can be a spined dilator having a proximal spine as will be described in more detail below. The proximal end of the dilator 340 can include a tab 1364 that allows the dilator 340 to lock with the tab 334 on the proximal end of the spine 330 of the catheter 320, such that the two components (the spined catheter 320 and the dilator 340) may be advanced as a single unit over the guidewire (see FIG. 12A). In some implementations, the tab 334 of the catheter 320 can form a ring having a central opening extending therethrough. The tab 1364 of the dilator 340 can have an annular detent with a central post. The central post of the tab 1364 can be sized to insert through the central opening of the tab 334 such that the ring of the tab 334 is received within the annular detent of tab 1364 forming a singular grasping element for a user to advance and/or withdraw the catheter system through the access sheath. The tab 1364 may be affixed to the dilator 340, or may be slideable on the dilator 340 to accommodate different relative positions between the dilator 340 and the spined catheter 320.

**[0075]** FIGs. 12A-16 provide additional views of a spined aspiration catheter and dilator system 1300 as described elsewhere herein. FIGs. 12A-12B show the spined aspiration catheter 1320 having a dilator 1340 extending through an aspiration lumen 1323 of the distal luminal portion 1322. As described elsewhere herein, the catheter 1320 can have a proximal spine 1330 having a tab 1334 and a distal luminal portion 1322 having an aspiration lumen 1323. The spine 1330 can extend between the distal luminal portion 1322 and the tab 1334. The dilator 1340 can be received within the aspiration lumen 1323 of the spined catheter 1320. The dilator 1340 can include a distal dilator portion 1360 and a proximal spine 1362. The dilator portion 1360 can extend between a distal tip 1346 of the dilator 1340 to the start of the proximal spine 1362. When engaged with the catheter 1320, the dilator portion 1360 of the dilator 1340 may extend through an entire length of the distal luminal portion 1322 of the catheter 1320 such that the dilator tip 1346 extends a fixed distance beyond a distal end of the distal luminal portion 1322 of the catheter 1320 providing a smooth transition for improved tracking. The dilator tip 1346 can be tapered as described elsewhere herein and can be soft, atraumatic and flexible to the vessel wall to facilitate endovascular navigation to an embolus in a tortuous anatomy compared to dilators typically used for percutaneous arterial access, which are meant to bluntly dissect through tissue and artery wall.

**[0076]** The dilator 1340 is shown in a locked configuration with the catheter 1320 configured for improved tracking through a tortuous and often diseased vasculature in acute ischemic stroke. The dilator portion 1360 can include one or more detents on an outer surface of the dilator portion 1360. The detents can be located near a proximal end region and/or a distal end region of the dilator portion 1360. The detents are configured to lock with correspondingly-shaped surface features on the inner surface of the lumen 1323 through which the dilator portion 1360 extends. The dilator 1340 can include a dilator tab 1364 on a proximal end of the proximal spine 1362 of the dilator 1340, which as discussed above can be configured to connect and lock with a corresponding feature on the proximal end region of the catheter spine 1330, for example via one or more detents or other surface features. Thus, the dilator 1340 and the catheter 1320 can have more than a single point of locking connection between them. The proximal spine 1362 of the dilator 1340 can extend between the dilator portion 1360 and the tab 1364 of the dilator 1340. The dilator portion 1360 can be a tubular element as described elsewhere herein that forms a guidewire lumen running a length of the dilator portion 1360 (and an entire length of the distal luminal portion 1322 of the spined catheter 1320). It should be appreciated that the entire dilator 1340 can be tubular element configured to receive a guidewire through the spine 1362 as well as the dilator portion 1360. The proximal end of the dilator portion 1360, i.e., the transition section 1326 between the dilator portion 1360 and the proximal spine 1362, may include a "step up" to smooth the transition between the distal luminal portion 1322 of the catheter 1320 and the dilator portion 1360 of the dilator 1340. The transition section 1326 can incorporate an angled cut such that there is no abrupt step transition from the sheath 1220 inner lumen 1223 to the catheter 1320 inner lumen 1323. Accordingly, the spined aspiration catheter-dilator 1300 may be smooth to the vascular wall it interfaces with.

**[0077]** The proximal spine 1362 of the dilator 1340 may have a similar stiffness and character as the spine 1330 of catheter 1320. More particularly, one or both of the spines 1362, 1330 may be stiff and/or kink resistant. Furthermore, one or both of the spines 1362, 1330 may have a stiffness to allow pushing the distal portions, i.e., the combined distal luminal portion 1322 and dilator portion 1360, through an access sheath or a guide-sheath while producing a very low profile. In an embodiment, one or both of the spines 1362, 1330 includes a stiff wire.

**[0078]** The catheter tab 1334 and the dilator tab 1364 can be removably connected with one another. More particularly, the tabs 1334, 1364 may have a locked configuration and an unlocked configuration. In the locked configuration, the dilator tab 1364 can be engaged with the catheter tab 1334. In the unlocked configuration, the dilator tab 1364 may be disengaged from the catheter tab

1334. The dilator tab 1364 may attach, e.g., click or lock into, the catheter tab 1334 in a fashion as to maintain the relationships of corresponding section of the spined dilator 1340 and the spined catheter 1320 in the locked configuration. Such locking may be achieved by, e.g., using a detent on the dilator tab 1364 that snaps into place within a recess formed in the catheter tab 1334, or vice versa. In some implementations, the spine 1330 of the spined catheter 1320 can run alongside or within a specialized channel of the dilator spine 1362. The channel can be located along a length of the dilator spine 1362 and have a cross-sectional shape that matches a cross-sectional shape of the catheter spine 1330 such that the spine 1330 of the catheter 1320 can be received within the channel and slide smoothly along the channel bi-directionally. Once the spined catheter 1320 and spined dilator 1340 are fixed, the combined system, i.e., the spined aspiration catheter-dilator 1300 may be delivered to a target site, for example through the lumen 223 of the access sheath 220 described elsewhere herein.

**[0079]** Referring to FIG. 12B, a spined aspiration catheter-dilator 1300 having a spined catheter 1320 and a spined dilator 1340 in an unlocked configuration is illustrated in accordance with an embodiment. When the spined aspiration catheter-dilator 1300 is positioned at the target site, as discussed herein, the dilator tab 1364 can be unlocked from the catheter tab 1334. The spined dilator 1340 may be withdrawn and the spined catheter 1320 may be used, e.g., for aspiration or for wire or balloon delivery.

**[0080]** Referring to FIG. 13, a cross-sectional view, taken about line A-A of FIG. 12B, of a spined catheter 1320 coaxially aligned with a spined dilator 1340 is illustrated in accordance with an embodiment. The cross-section illustrates a portion of the catheter-dilator having the dilator portion 1360 received within the aspiration lumen 1323 of distal luminal portion 1322. The lumen 1323 may have an inner diameter in a range up to 0.072 inches, although a larger or smaller inner diameter is possible (larger or smaller possible). The wall of the distal luminal portion 1322 may resist kinking or ovalizing to provide maximum diameter for aspiration. The dilator portion 1360 may be received in the distal luminal portion 1322 in a slip fit. Thus, in an embodiment, an outer dimension of the dilator portion 1360 may be less than the inner diameter of the distal luminal portion 1322. For example, the lumen 1323 may have a diameter of 0.072 inches and the dilator portion 1360 may have an outer dimension of 0.070 inches.

**[0081]** Referring to FIG. 14, a cross-sectional view, taken about line B-B of FIG. 12B, of a spined catheter 1320 after removal of a spined dilator 1340 is illustrated in accordance with an embodiment. The cross-section illustrates the distal luminal portion 1322 after the dilator portion 1360 has been retracted and/or removed. The distal luminal portion 1322 has an inner wall 1321 defining the lumen 1323. The lumen 1323 may be circular, as shown, or may have any other shape. In an embodiment, the effective diameter of the lumen 1323 ranges up to 0.072 inches.

**[0082]** Referring to FIG. 15A, a spined aspiration catheter-dilator system 1300 having a spined catheter 1320 and a spined dilator 1340 in a locked configuration is illustrated in accordance with an embodiment. In an embodiment, the spine 1330 and dilator 1340 may have an outer dimension that is substantially similar over an entire length. For example, rather than converging to a smaller dimension between the dilator portion 1360 and the dilator spine 1362, the dilator spine 1362 may have a same dimension as the dilator portion 1360. Thus, a catheter-dilator having a substantially same cross-sectional area over at least a majority of its length may be provided. As discussed above, the spine dilator 1340 and the spine catheter 1320 may have corresponding tabs 1334, 1364 that engage in a locked configuration and disengage in an unlocked configuration.

**[0083]** Referring to FIG. 15B, a spined aspiration catheter-dilator having a spined catheter 1320 and a spined dilator 1340 in an unlocked configuration is illustrated in accordance with an embodiment. The spined dilator 1340 may be removed from the spined catheter 1320 in a manner similar to that described above. In an embodiment, the spined aspiration catheter-dilator may have a similar cross-sectional area over a majority of its length, and thus, the shapes of the spined catheter 1320 and the spined dilator 1340 may be complimentary. For example, the spine 1330 may have a cross-sectional area along an arc, such as a quarter circle, and thus, a cross-sectional area of the dilator spine 1362 may be three quarters of a circle. As such, the spine 1330 may conform to the dilator spine 1362 to provide an overall cross-sectional area of a full circle.

**[0084]** Referring to FIG. 16, a schematic view of a spined catheter 1320 having a distal luminal portion 1322 having an inner lumen 1323 located in a neurovascular anatomy is illustrated in accordance with an embodiment. Used in conjunction with an access sheath 1220 having a sheath body 1222 and an inner lumen 1232, in an embodiment where the spined catheter 1320 reaches the ICA and the distance to embolus E is consistently felt to be less than 20 cm, one would see that the distal luminal portion 1322 having a length of 25 cm would allow for an overlap region 1120 with the access sheath 1220 to create a seal. The overlap region 1120 may have a length of a few centimeters, and the may vary depending on the distance from the embolus E to the distal end of the distal luminal portion 1322, e.g., depending on how far the spined catheter 1320 is advanced relative to the access sheath 1220.

**[0085]** As described elsewhere herein, the luminal area available for aspiration of the embolus is greater using the spined catheter 1320 as compared to an aspiration system having a conventional large bore catheter in an access sheath. More particularly, the combined volume of the luminal area of the spined catheter 1320 and the luminal area of the access sheath 1220 proximal to the

distal luminal portion 1322 is greater than the luminal area of the large bore catheter along the entire length of the system. Thus, the likelihood of removing the embolus in a single aspiration attempt may be increased. More particularly, the stepped up luminal diameter along the spine 1330 may enable a greater aspiration force to be achieved resulting in improved aspiration of the embolus. The stepped up luminal diameter may also increase the annular area available for forward flushing of contrast, saline, or other solutions while devices such as microcatheters or tapered inner members are coaxially positioned in the spined catheter and access sheath. Thus, the ease and ability to perform angiograms during device navigation may be improved.

**[0086]** The disclosed systems may be supplied with ancillary devices that are particularly configured to be used with the system. It should be appreciated that reference to one implementation of an access sheath system or aspiration catheter system is not intended to be limited and that the ancillary devices described herein can be used with any of the systems having any of a variety or combination of features described herein. For example, where an access sheath is described below it should be appreciated that one or more features of any of the access sheaths or access sheath systems described herein can be incorporated. Similarly, where a spined catheter is described below one or more featured of any of the spined catheters or spined catheter systems described herein can be incorporated.

**[0087]** In an implementation, the system includes a microcatheter 400 (see FIG. 1). The microcatheter 400 can be configured to be particularly suited for navigation in the cerebral vasculature. The microcatheter 400 may be used in place of the tapered dilator 340 to help navigate the spined catheter 320 to the desired site. As such, it may include means at the proximal end to lock the spine 330 to the microcatheter 400, so that so that the two components (the spined catheter 320 and the microcatheter 400) may be advanced as a single unit over the guidewire. In some instances the microcatheter 400 is advanced ahead of the catheter 320, to provide support as the catheter 320 is advanced, or to cross the occlusion and perform an angiogram distal to the occlusion. In this case, the length of the microcatheter 400 can be longer than the spined catheter 320 by about 10 to 20 cm. The microcatheter 400 may also be used to deliver a retrievable stent device 500 to the occlusion. In this case, the microcatheter 400 can have an inner diameter suitable for delivery of the retrievable stent device 500, for example, in the range .021" to .027" and with a PTFE inner liner. The microcatheter 400 can be at least about 5-10 cm longer or at least about 5 - 20 cm longer than the overall length of the spined catheter 320 to allow the microcatheter 400 to extend beyond the distal end of the aspiration catheter 320 during navigation.

**[0088]** In an implementation, the system includes a retrievable stent device 500 with a distal expandable section 510, which is sized and configured to be delivered through the microcatheter 400, as shown in FIG. 9. The retrievable stent device 500 may be used in conjunction with the other components of the system to aid in removal of the occlusion. The retrievable stent device 500 may also be used to quickly restore flow to the occluded artery during the thrombectomy procedure. Examples of retrievable stent devices include the Solitaire Revascularization Device (Medtronic) or the Trevo Stentriever (Stryker).

**[0089]** In a method of use, the retrievable stent device 500 is used to assist in bringing thrombus into the catheter 320 during an aspiration step, or clearing the catheter 320 that may become clogged during the aspiration step. In an implementation, the retrievable stent device 500 is configured to be particularly suited for performing these functions. For example, as shown in FIG. 10A, the distal end of the expandable portion 510 of the device 500 has multiple struts or elements 520 that come together at the distal tip to close off the distalmost end, such that the device allows blood flow across the device, but captures the thrombus pieces as the device 500 is pulled into the catheter 320, and subsequently through the catheter 320 and out the distal end. Alternately, the distal end 520 is a filter element or a balloon element.

**[0090]** In another example, in FIG. 10B, the retrievable stent device 500 includes two or more segments with one or more proximal segments 510a configured to be expanded in the catheter distal inner lumen while one or more distal segments 510b are expanded across the occlusion as is done with prior retrievable stent devices. Alternately, as seen in FIG. 10C, the retrievable stent device 500 has a very long expandable portion 510, such that a proximal portion of the expandable portion may be expanded in the catheter distal inner lumen while the distal portion is expanded across the occlusion. In all these implementations, the proximal end of expandable section 510 has minimal structural elements that will allow the expandable section to be pulled easily into the lumen of the catheter 320, and out of the access sheath 320, so as minimize impediment of thrombus aspiration through the device. In these examples, the expandable portion 510 is still engaged with the clot even when the clot is aspirated into the catheter 320, and if the catheter 320 becomes corked, the device 500 is well-positioned to clear the clot when it is pulled back. Once the retrievable stent device 500 has been removed from the luminal portion 322 of the catheter 320, additional aspiration can be applied to the site through the catheter 320 if it is still partially or fully occluded. This step would not be possible if the catheter 320 remained clogged; the catheter would have to be removed and cleared outside the patient before being reinserted for additional aspiration. This configuration of retrievable stent device 500 can be used with either a conventional single lumen aspiration catheter, or a spined aspiration catheter 320.

**[0091]** The implementations of device 500 as shown in FIGs. 10A-10C may be used with known thrombectomy devices and methods to address the issue of cathe-

ters clogging during thrombus aspiration.

**[0092]** In an implementation, the system includes an aspiration source 600, as shown in FIG. 2A or FIG. 3. The aspiration source 600 can be attached to the aspiration line 230 on the access sheath 220. Examples of aspiration source 600 include a syringe or an active aspiration pump. The aspiration source 600 may be connected to a delivery location, such as a receptacle. The receptacle and source of aspiration 600 may be separate, such as a mechanical or electromechanical fluid pump whose outlet is connected to a blood collection reservoir or may be combined into a single device such as a syringe or syringe pump. Alternately, the blood collection reservoir is connected to a source of vacuum such as a hospital vacuum line or an air vacuum pump, and is thus the receptacle as well as the source of aspiration. A filter and/or a check valve may be coupled with the aspiration source. The pump may be a positive displacement pump such as a diaphragm or piston pump, a peristaltic pump, centrifugal pump, or other fluid pump mechanism known in the art.

**[0093]** In an implementation, the aspiration source is a variable state or multi-state aspiration source, and includes a mechanism to control the level of aspiration, for example by modifying the vacuum level in the vacuum pump, by modifying the power to the motor of a positive displacement, peristaltic or centrifugal pump, or modifying the syringe pull back speed in the syringe or syringe pump. Alternately, the aspiration rate may be varied by providing an element with variable resistance to flow, for example parallel flow paths that can switch between a high and low flow resistance path, flow orifices or lumens that can be variably opened, or other means to vary flow resistance. In an example, the aspiration source is configured to have two levels of aspiration: a high level of aspiration to be used when the catheter is in contact with the thrombotic material, to aspirate the thrombotic occlusion, and a low level of aspiration to be used during steps in the procedure that are high risk of causing distal emboli, for example crossing the lesion or when flow is restored to the vessel when a retrievable stent device is expanded.

**[0094]** In another example, as shown in FIG. 11, the aspiration source 600 further includes a flow sensor 275 that senses flow in the aspiration line 230, coupled to a controller that controls the level of aspiration. The aspiration source 600 can increase in aspiration level when the flow rate is slow and decrease when the flow rate is increased. In this manner, the force is greatest when the catheter is clogged or partially clogged, but decreases to a minimal level when there is free flow to ensure protection from distal emboli but limit the volume of aspirated blood. In this manner, the system optimizes the thrombus aspiration while limiting the amount of blood aspirated. Alternately, the aspiration source 600 can include a vacuum gauge. When the flow in the catheter 320 is blocked or restricted the pump creates a higher level of vacuum. In this example the aspiration force may be configured to rise when higher vacuum is detected.

**[0095]** In yet another aspiration source implementation, the aspiration source 600 provides a cyclic level of aspiration force, for example, an aspiration force that cycles between a high level of vacuum to a lower level of vacuum at a set frequency, or from a high level of vacuum to no vacuum, or from a high level of vacuum to a pressure source. A cyclic aspiration mode may provide a jackhammer type force on the thrombus and increase the ability to aspirate the thrombus through the catheter. The cyclic aspiration force may be enabled through solenoid valves, a programmable pump motor, or the like. In an implementation, cyclic aspiration is applied only when clogged or restricted flow is detected in the aspiration line, either through low flow or high vacuum, as discussed above, and at other times, the aspiration source reverts to a low level of flow, or be turned off. This configuration may be controlled by the user, or controlled automatically via a feedback loop to the aspiration source.

**[0096]** In an implementation, the system includes a mechanism for passive reverse flow that is configured to be connected to the aspiration line on the access sheath. For example, the aspiration line is connected to a lower pressure site such as a central vein, or an external receptacle set to zero or negative pressure.

**[0097]** In an implementation as shown in FIG. 11, the flush line 236 may be connected via stopcock 238 to a syringe 286 that may hold saline fluid or radiopaque contrast. Additionally the flush line 236 may be connected to a flush source 288, for example, a pressurized bag of saline. A valve 292 can control flow from the flush source 288 to the flush line 236. When the valve 292 is opened to the flush line 236 a pressurized source of fluid is provided. In an implementation, the valve 292 is coupled via a mechanical or electromechanical coupler 295 to the aspiration source 600 such that the valve 292 is only open when the aspiration source 600 is on. Alternately, the valve 292 is coupled to a flow sensor 275 in the aspiration line 230, such that the valve 292 is only on when there is flow in the direction towards the aspiration source 600. In these implementations, the flow rate of the flush source 288 is configured to flow just enough to keep the proximal extension 240 clear of blood but not so high as to cause flow to work against the aspiration flow and limit aspiration of thrombus. An advantage of this implementation is that the proximal extension 240 remains clear of blood and any emboli or air that is in the proximal extension 240 is clearly visible. This provides a feedback to the user on when and if to flush the catheter with saline or contrast via syringe 286.

**[0098]** In another implementation, the valve 292 is coupled either mechanically or electromechanically to the valve 242 that connects the sheath body 222 to the proximal portion 240 of the sheath 220. The coupling 290 can be configured such that the valve 292 can only be opened when the valve 242 is closed. This feature allows the proximal extension 240 to be cleared of blood via a flush step, without risk of flushing emboli back through the

catheter into the vasculature. The coupling 290 may be configured in one of several ways For example, the coupling 290 may always open the valve 238 when the valve 242 is closed, or the coupling may prevent the valve 238 from opening unless valve 242 is closed but that does not automatically open.

**[0099]** In an implementation, the valve 292 is a variable state valve that allows different levels of flush flow rate. In this example, the valve 292 is configured to allow a slow flush when the aspiration source is on a low setting, a higher level of flush when the aspiration source is on a high setting. In an implementation, the valve allows yet a higher level of flush when the valve 242 is closed. These configurations allow a continuous removal of debris and/or clear visibility of the proximal portion of the access sheath and minimizes the risk of distal emboli or air entering the vasculature during the steps of the procedure. For example, during the step when the distal tip of catheter is being removed from the proximal hemostasis valve 234, any clot that was captured on the tip of the catheter may be liberated when the catheter is pulled through the valve, but with the continuous flush the liberated emboli would be flushed into the aspiration line and not remain in the sheath where it might be re-injected into the vasculature, for example during a contrast injection after the catheter is removed.

**[0100]** Again with respect to FIG. 1, the system 100 may include a kit of multiple devices. In an implementation, the kit includes an access sheath system 200 wherein the access sheath system includes an access sheath, one or more tapered sheath dilators, and one or more sheath guidewires. In another implementation, the system 100 includes an access sheath system 200 and one or more spined catheter systems 300 with one or more inner diameters. In an implementation, the spined catheter system 300 includes a spined aspiration catheter 320 and a tapered dilator 340. In an implementation, the spined catheter system 300 also includes a catheter clearing tool 350. In yet another implementation, the system 100 includes an access sheath system 200, a tapered catheter system 300, a microcatheter 400, and a retrievable stent device 500.

**[0101]** In an implementation configured for transcarotid access, the kit includes an access sheath 220, wherein the insertable sheath body 222 length is about 23 cm, the proximal extension 240 is about 22 cm, the connector 226 is about 7 cm and the proximal hemostasis valve 234 is about 5 cm, for an overall access sheath length of about 57 cm. In an implementation, the kit also includes a spined aspiration catheter 320 wherein the catheter distal luminal portion 322 is about 20 cm, the transition section 326 is about 2-4 cm, and the spine section 330 is about 65 cm, for an overall spined catheter length of about 88 cm. In another implementation, the kit also includes a tapered dilator 340 with a working length of 93 cm. In another implementation, the kit also includes a microcatheter 400 with a working length of about 198 cm and a retrievable stent device 500 with an overall length of 128 cm.

**[0102]** In an implementation configured for transfemoral access, the kit includes an access sheath system 220, wherein the insertable sheath body 222 length is about 90 cm, the proximal extension 240 is about 22 cm, the connector 226 is about 7 cm and the proximal hemostasis valve 234 is about 5 cm, for an overall access sheath length of about 124 cm. The proximal portion of the access sheath may be a removable proximal portion 280. In an implementation, the kit also includes a spined aspiration catheter 320, wherein the catheter distal luminal portion 322 is about 20 cm, the transition section 326 is about 2-4 cm, the spine section 330 is about 132 cm, for an overall spined catheter length of about 155 cm. In another implementation, the kit also includes a tapered dilator 340 with a working length of 160 cm. In another implementation, the kit also includes a microcatheter 400 with a working length of about 165 cm and a retrievable stent device 500 with an overall length of 195 cm.

**[0103]** In another implementation, the kit includes an access sheath 220 with a removable proximal portion 280, and a single lumen aspiration catheter. In another implementation, the kit includes only the proximal portion 280 that can be attached to any introducer sheath suitable for the procedure. In this implementation, the kit may also include a spined aspiration catheter 320 or a single lumen aspiration catheter.

**[0104]** In any of these implementations, the kit may also include an aspiration source, for example a pump, an attachment to a vacuum pump, a syringe, a syringe that is attachable to a syringe pump, or the like. The kit may also include means for automatic flushing, for example coupling means 290 or 292.

**[0105]** As described elsewhere herein, it should be appreciated that reference to one implementation of an access sheath system or catheter system is not intended to be limited and that the kits described herein can incorporate any of the systems and/or ancillary devices described herein as having any of a variety of features. For example, where an access sheath is described as being a part of a kit it should be appreciated that one or more features of any of the access sheaths or access sheath systems described herein can be incorporated. Similarly, where a spined catheter is described as being part of a kit one or more featured of any of the spined catheters or spined catheter systems described herein can be incorporated.

**[0106]** FIGs. 2A and 3 illustrates methods of use. As shown in FIG. 2A, an access sheath 220 is inserted using standard vascular access sheath into the femoral artery, and advanced until the sheath tip is positioned at a site as distal as safely possible in the internal or common carotid artery. In FIG. 3, the access sheath 220 is inserted directly into the common carotid artery, and advanced until the sheath tip is positioned at a site as distal as safely possible in the internal carotid artery. In either scenario, the sheath may be advanced initially to the common carotid artery or proximal internal carotid artery, and

then the dilator and is exchanged for a softer dilator before advancing the sheath more distally into the internal carotid artery. The sheath is then secured to the patient using a suture through the eyelet on the sheath connector. The sheath aspiration line 230 is connected to an aspiration source 600 such as a syringe or aspiration pump. The sheath aspiration line may also be connected via a stopcock or stopcock manifold to a forward flush line (such as a pressurized saline bag).

**[0107]** Once the sheath tip is positioned at the desired location, it is secured to the patient. A spined catheter, tapered dilator, and guidewire are pre-assembled in a co-axial configuration and introduced through the sheath proximal hemostasis valve into the carotid artery. The spined aspiration catheter 320 is advanced through access sheath and positioned until the distal tip is at the treatment site. The devices are advanced using standard interventional techniques until the distal catheter tip is at the proximal face of the occlusion. A mark 332 on the spine 330 ensures that there is still an overlap region 120 between the distal luminal portion 322 of the catheter and the access sheath body 222. At this point, the tapered dilator 340 and guidewire can be removed. In an alternate implementation, a microcatheter 400 is used in place of the tapered dilator 340 to help navigate the catheter 320 to the occlusion. During the procedure, the forward flush is opened to the aspiration lumen to keep the lumen clear before or between periods of aspiration. At any point during device navigation, aspiration may be initiated from the aspiration source 600 at a level suitable for distal embolic protection, for example when the guidewire or microcatheter 400 is crossing the occlusion.

**[0108]** Once the distal tip of the spined aspiration catheter 320 is at the face of the clot, aspiration is initiated at a level suitable for aspiration thrombectomy, which is a higher level than for distal embolic protection. The catheter 320 may remain in aspiration mode against the clot for some period of time, as deemed suitable by the user. Depending on the results of the aspiration thrombectomy maneuver (as observed by flow though the aspiration line and/or resistance to backwards force on the spine of the catheter), the user may determine that the clot has been completely aspirated, or if not, the user may choose to move the catheter 320 back and forth to aspirate the clot in situ, or to slowly retract the catheter 320 into the sheath 220. If flow is restored to the artery via aspiration of the clot through the catheter 320 and sheath 220, a final angiogram may be performed and the catheter 320 can be retracted. If however, thrombus occludes the catheter tip and cannot be removed, the catheter 320 is pulled back, with some or all of the occlusion attached through suction force to the tip of the catheter 320.

**[0109]** In the latter scenario, aspiration is maintained at the tip of the catheter 320 the entire time the catheter 320 is being pulled into the access sheath 220. Once the catheter 320 has been completely retracted into the access sheath 220, the catheter 320 can be quickly removed from the sheath body 222 while aspiration is maintained on the sheath 220. It should be appreciated that the catheter 320 may be withdrawn into the sheath body 222 after extending through the distal opening 219 at the distal tip of the sheath body 222. Alternatively, the catheter 320 may be extending through a side opening 219 near a distal end region of the sheath body 222 such that withdrawal of the catheter 320 into the sheath body 220 occurs through this side opening 219. At some time during catheter retraction, depending on if the catheter 320 is clogged with occlusive material, the aspiration level may be changed from a high level desirable for aspiration thrombectomy to a lower level desirable for distal embolic protection. By providing the ability to maintain aspiration continuously from either the catheter tip or the sheath tip or the sheath distal region, and providing the means to change aspiration levels and maintain asp, the procedure optimizes the ability to aspiration clot while minimizing distal emboli and minimizing blood loss from aspiration. If desired, aspiration may also be initiated at the flush line 236 of the proximal valve 234, to reduce chance of distal embolization during removal of the catheter tip with possibly adhered clot through the proximal valve 234.

**[0110]** The spined aspiration catheter 320 may be removed completely from the proximal hemostasis valve 234 of the sheath 220. Alternately, if the access sheath 220 has a proximal extension 240, the distal luminal portion 322 may be pulled into the proximal extension portion 240. In the latter scenario, once pulled in, the catheter 320 and sheath 220 may be flushed to remove potential embolic material without removing the catheter 320 completely from the sheath 220. A vigorous flush from the proximal valve flush line 236 simultaneous with aspiration from the aspiration line 230 creates a flush environment for the catheter 320 and sheath 220. If desired, a catheter clearing tool 350 may be inserted into the sheath proximal valve 234 and used at this time to clear the inner lumen 323 of the catheter 320. If the access sheath 220 has a connector valve 242, the proximal portion 240 may be closed off from the sheath body 222 during this stage, so that there is no risk of flushing embolic material into the sheath body 222 and thence into the artery.

**[0111]** Alternately, the valve 242 may be closed off and aspiration paused while the proximal valve 242 is opened or removed and the catheter 320 is completely removed from the sheath 220. Closing the valve 242 limits the blood loss from the sheath 220 as the catheter 320 is removed. The catheter 320 may then be flushed onto the table or into a bowl or other receptacle, using the cleaning tool 350. The proximal extension portion 240 may also be flushed by providing a flush source 288 from the proximal valve flush line 236 simultaneous with aspiration from the aspiration line 230, or by opening a side port on the aspiration line 230 to flush to the table or into a bowl or other receptacle. If desired, an angiogram may be performed to assess flow through the treated artery. If the procedure dictates, the catheter 320 or another catheter may be re-advanced as above over a guidewire and tapered dilator 340 or microcatheter 400 to the site of the

occlusion to attempt another aspiration thrombectomy step. The flushing of the catheters and proximal extension portion 240 of the access sheath 220 minimizing the risk of distal emboli during these subsequent steps.

**[0112]** In another exemplary method, a retrievable stent device 500 can be used in conjunction with aspiration to remove the thrombotic occlusion. FIG. 9 illustrates this method of use through either a transcarotid or transfemoral access site. In this scenario, the access sheath 220 can be positioned as above and advanced until the sheath tip is positioned at a site as distal as safely possible in the internal carotid artery. The spined aspiration catheter 320 can be then pre-loaded onto a microcatheter 400 and guidewire, and the co-axial assembly can be introduced via the access sheath 220 into the carotid artery and advanced into the cerebral vasculature. The microcatheter 400 and guidewire can be advanced across occlusion. The tip of the spined aspiration catheter 320 can be advanced as distal as possible but proximal to the clot.

**[0113]** At this point, the guidewire can be removed and the retrievable stent device 500 inserted through the microcatheter 400 until it too is positioned across the occlusion. The microcatheter 400 can be pulled back to deploy the stent. At any point during device navigation, aspiration may be initiated from the aspiration source at a level suitable for distal embolic protection, for example when the guidewire or microcatheter 400 is crossing the occlusion, or prior to stent deployment. By having aspiration initiated before stent deployment, any emboli that was liberated while crossing the lesion is not carried downstream on restoration of flow in the artery, but is rather captured into the catheter tip. While the retrievable stent device 500 is deployed, aspiration may be maintained. It is typically deployed for several minutes before retraction of the stent is attempted, to maximize the engagement of the stent struts to the occlusion. Then, the retrievable stent device 500 can be pulled into the spined catheter 320 and continued to be retracted until it has been completely removed from the proximal valve of the access sheath 220.

**[0114]** Alternately, the stent device 500 can be pulled into the distal portion of the spined catheter 320, and the stent device 500 and spined catheter 320 can be pulled back together out of the access sheath 220. Aspiration may be increased to a higher level during stent and/or catheter retraction steps, to optimize aspiration of clot and minimize distal emboli. If the access sheath 220 has a proximal extension 240 with a valve on the connector, the device 500 can be pulled into the proximal extension 240 and the valve closed, and then the proximal hemostasis valve 234 may be opened widely and the stent device 500 or the stent device/spined catheter combination may be pulled out. The proximal extension section 240 may then be flushed via the valve flush line 236 and the aspiration line 230 before the same or alternate devices are reinserted for another thrombectomy attempt, if the procedure dictates.

**[0115]** Alternately after placement of an aspiration catheter 320, a long or segmented stent retriever 500 can be positioned as above with a microcatheter 400 such that part of the expandable portion 510 is across the thrombus and part is in the distal segment 322 of the catheter 320, and then expanded. After the expandable portion 510 is expanded aspiration can be initiated so that thrombus either is suctioned completely out of the vessel and catheter 320 into the aspiration source 600, or is suctioned into the distal tip and/or distal lumen 323 of the catheter 320. At that point, the long or segmented stent retriever 500 can be carefully pulled into the catheter 320, while maintaining aspiration. During this time clot that has been clogging the catheter 320 and/or debris that is liberated during this step should be aspirated into the catheter 320. Complete removal of the stent retrieval device 500 from the working channel 323 of the catheter 320 should free up the lumen 323 from occlusive material.

**[0116]** In any of these scenarios, the aspiration source may be a variable or multi-state aspiration source that is configured to maximize the aspiration force on the thrombotic occlusion while minimizing blood loss during periods of free flow in the catheter.

**[0117]** In another exemplary method, the access sheath 220 has an occlusion balloon 246. As seen in FIG. 7, the balloon 246 may be inflated during steps of the procedure that are high risk for distal emboli, for example retraction of the stent device 500 or the spined catheter 320 with adhered clot. The balloon 246 has the effect of stopping antegrade flow and increasing the force of aspiration in the carotid artery, thus increasing the aspiration of clot and reducing the risk of distal emboli.

**[0118]** In another exemplary method, the access sheath 220 has an expandable distal tip. In this method, the distal tip may be expanded sometime after the access sheath tip has been positioned at the desired site, but before retraction of the spined catheter 320 into the access sheath 220. This method would reduce the chance of distal emboli caused by the release of clot that was adhered to the distal tip of the spined catheter 320, as the distal tip is pulled into the tip of the sheath 220. Instead, the access sheath tip that is expanded or flared out acts as a funnel to capture the entire clot.

**[0119]** In another exemplary method and as discussed briefly above, the access sheath 1220 has a side opening 1219 (best shown in FIG. 12C). In this method, the spined catheter 1320 having a spined dilator 1340 extending through lumen 1323 of the distal luminal portion 1322 of the catheter 1320 can be advanced distally through the lumen 1223 of the access sheath 1220 towards the distal end region of the sheath body 1222. The distal tip of the distal luminal portion 1322 of the spined catheter 1320 (which may having the spined dilator extending through the distal luminal portion 1322 and forming a distal-most end to the catheter system) may exit the lumen 1223 via the side opening 1219 and then be further advanced distally beyond the distal tip of the access sheath 1220. A ramp feature 1217 or other internal feature can be incor-

porated at a distal end region of the lumen 1223 to provide a surface against which the tip of the dilator can be deflected to guide the catheter 1320 away from a longitudinal axis A of the lumen 1223 of the sheath body 1222 towards the side opening 1219 to achieve a smooth transition or exit from the lumen 1223. The distal tip 1346 of the dilator 1340 can abut against the ramp feature 1217 and be directed at a slight angulation away from the longitudinal axis of the sheath body 1222 towards the side opening 1219. As described elsewhere herein, the sheath body 1222 and thus the side opening 1219 can be rotated around the longitudinal axis A such that the one or more side openings 1219 are positioned to allow for distal extension of the catheter 1320 from the side openings 1219 in a desired direction relative to the longitudinal axis A of the sheath 1220. This will often be dictated by the anatomy encountered by the operator. Also as mentioned elsewhere herein, an overlap region 1120 is formed between the distal luminal portion 1322 of the catheter and the access sheath body 1222. A sealing element 1336 can be positioned on the external surface of the distal luminal portion 1322, for example, near a proximal end region of the distal luminal portion 1322 and may be located within the overlap region 1120. The seal formed can allow for full transmission of aspiration force through the contiguous lumen formed by the lumen 1323 of the luminal portion 1322 and the lumen 1223 of the access sheath body 1222 upon withdrawal of the dilator 1340 from the lumen 1323 of the luminal portion 1322.

**[0120]** In another exemplary method, the aspiration source 600 is connected to a blood collection reservoir that maintains the integrity of the blood in such a way that the blood can be safely returned to the patient at the conclusion of the thrombectomy portion of the procedure, either directly or through subsequent treatment of the blood such as cell washing and/or blood filtration. In another exemplary method, the aspiration source is connected to a blood shunt that is connected in turn to a device such as a venous sheath or a venous return catheter that enables blood to be returned to the patient during the procedure and not requiring a blood reservoir. In another exemplary method, the blood is collected in a reservoir and subsequently discarded at the end of the procedure.

**[0121]** In another exemplary method, the access sheath 1220 is delivered as described elsewhere herein from a femoral insertion site to a right or left subclavian artery or an external carotid artery. The access sheath 1220 may be delivered to a carina of a bifurcation between a target vessel having the embolus, such as the internal carotid artery (ICA), and another vessel, such as the external carotid artery (ECA). Once the access sheath 1220 is in position a working device such as a splined aspiration catheter 1320 can be delivered through the lumen 1223 of the access sheath 1220 into the target vessel. The lumen 1223 of the access sheath 1220 and the lumen 1323 of the catheter 1320 are contiguous and form a stepped up diameter for aspiration as described elsewhere herein. An overlap region 1120 is maintained between the catheter 1320 extending distally from the lumen 1223 of the access sheath 1220. It should be appreciated that the catheter 1320 can extend distally from the lumen 1223 of the access sheath 1220 through an opening 1221 at the distal tip of the access sheath 1220 or a side opening 1119 near the distal region of the access sheath 1220. The body 1222 of the access sheath 1220 may be oriented to provide optimum placement of the side opening 1119 relative to the anatomy. The overlap region 1120 between the distal luminal portion 1322 of the catheter 1320 and the access sheath body 1222 can create a seal and allow for full transmission of aspirating force through the contiguous lumen formed by the lumen 1323 of the luminal portion 1322 and the lumen 1223 of the access sheath body 1222, as well as providing a seal for delivery of fluids to the target vessel such as angiographic contrast injection, saline, one or more drugs or other materials directly into the neurovascular anatomy. The spined aspiration catheter 1320 can create a more powerful aspiration force by allowing for the working lumen 1223 of the access sheath 1220 to provide a majority of the aspiration column. As described elsewhere herein, the dimension of the lumen 1323 of the distal luminal portion 1322 of the aspiration catheter 1320 may be less than the diameter of the lumen 1223 of the access sheath 1220, which is reduced only by a diameter of the spine 1330 extending therethrough. The increased diameter of the lumen can create a larger aspiration column than, e.g., an aspiration column of a large bore catheter having a similar overall length. The spined aspiration catheter 1320 may also be used as a supportive delivery catheter, for example, where the operator wants to reach the petrous carotid or other hard to reach landmarks within the cerebral vasculature. More particularly, after delivering the spined aspiration catheter 1320 into the target vessel through the working lumen 1223 of the access sheath 1220, a secondary working device such as a guidewire, microcatheter, stent retriever, etc. may be delivered through the lumen 1323 into a more distal anatomy to perform other procedural operations as described elsewhere herein.

**[0122]** While this specification contains many specifics, these should be construed as descriptions of features specific to particular implementations. Certain features that are described in this specification in the context of separate implementations can also be implemented in combination in a single implementation. Conversely, various features that are described in the context of a single implementation can also be implemented in multiple implementations separately or in any suitable sub-combination. Moreover, although features may be described above as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination may be directed to a sub-combination or a variation of a sub-combination.

Similarly, while operations are depicted in the drawings in a particular order, this should not be understood as requiring that such operations be performed in the particular order shown or in sequential order, or that all illustrated operations be performed, to achieve desirable results.

## STATEMENTS

**[0123]**

1. An intravascular access system for facilitation of intraluminal medical procedures within the neurovasculature through an access sheath, the system comprising:
an aspiration or support catheter comprising:

a flexible, distal luminal portion having an inner diameter defining a lumen extending between a proximal opening at a proximal end of the luminal portion and a distal opening at a distal end of the luminal portion; and
a rigid spine coupled to at least the proximal end of the luminal portion and extending proximally therefrom; and
a dilator comprising:

a flexible, distal dilator portion sized to be received within the lumen of the luminal portion; and
a rigid, dilator spine extending proximally from the dilator portion.

2. The system of statement 1, wherein, when in use, the dilator spine aligns side-by-side with the spine of the catheter.
3. The system of statements 1 or 2, wherein the distal dilator portion has a tapered distal tip.
4. The system of any of statements 1-3, wherein the dilator has a length at least as long as a length of the catheter such that a distal tip of the dilator protrudes from the distal opening of the luminal portion.
5. The system of any of statements 1-4, wherein the dilator is generally tubular along at least a portion of the length.
6. The system of any of statements 1-5, wherein a proximal end of the catheter spine includes a gripping feature configured for a user to grasp in order to move the catheter through an access sheath.
7. The system of statement 6, wherein a proximal end of the dilator spine includes a tab configured to be locked with the gripping feature on the catheter spine.
8. The system of statement 7, wherein when the catheter and the dilator are in a locked configuration they are advanced as a single unit through the access sheath.
9. The system of statements 7 or 8, wherein the gripping feature and the dilator tab are removably coupled such that in a locked configuration the dilator tab engages the gripping feature and in an unlocked configuration the dilator tab disengages from the gripping feature.
10. The system of any of statements 7-9, wherein the dilator tab is affixed to the dilator.
11. The system of any of statements 7-9, wherein the dilator tab is slideable on the dilator to accommodate different relative positions between the dilator and the catheter.
12. The system of any of the preceding statements, wherein the distal dilator portion comprises one or more detents on an outer surface configured to lock with correspondingly-shaped surface features on an inner surface of the luminal portion lumen through which the dilator portion extends.
13. The system of any of the preceding statements, wherein the dilator spine and the catheter spine have a similar stiffness and kink-resistance.
14. The system of any of the preceding statements, wherein the dilator has a visual marker on a distal end and/or a proximal end of the distal tip.
15. The system of any of the preceding statements, wherein a distal end region of the dilator is more flexible and increasingly stiffens towards a proximal end region of the dilator.
16. The system of any of the preceding statements, wherein the catheter spine and dilator spine are configured to cause bi-directional sliding movement of the luminal portion through a lumen of an access sheath and navigate the luminal portion into a cerebral vessel to reach a treatment site.
17. An intravascular access system for facilitation of intraluminal medical procedures within the neurovasculature, the system comprising:

an access sheath having a sheath body comprising an inner diameter defining a lumen between a proximal end and a distal end of the sheath body, and at least one opening from the lumen near a distal end region of the sheath body; and
an aspiration or support catheter comprising:

a flexible, distal luminal portion having an outer diameter sized for insertion through the lumen of the access sheath, an inner diameter defining a lumen extending between a proximal opening at a proximal end of the luminal portion and a distal opening at a distal end of the luminal portion, and a length between the proximal opening and the distal opening; and
a rigid spine coupled to at least the proximal end of the luminal portion and extending proximally therefrom,
wherein the rigid spine is configured to

cause bi-directional sliding movement of the luminal portion through the lumen of the access sheath and out the at least one opening to navigate the luminal portion into a cerebral vessel to reach a treatment site, and wherein a portion of the outer diameter of the luminal portion fluidly seals with the inner diameter of the access sheath when the distal end of the luminal portion extends into the cerebral vessel to reach the treatment site.

18. The system of statement 17, wherein the luminal portion and the sheath body are concentrically aligned and the lumen of the luminal portion and the lumen of the sheath body form a contiguous aspiration lumen from the distal end of the luminal portion to the proximal end of the sheath body.
19. The system of statement 18, wherein the contiguous aspiration lumen is usable to aspirate fluid and debris from the distal opening of the luminal portion.
20. The system of statements 18 or 19, wherein the contiguous aspiration lumen is usable to deliver materials through the distal opening of the luminal portion.
21. The system of any of statements 17-20, wherein the contiguous aspiration lumen forms a step-up in diameter where the lumen of the luminal portion empties into the lumen of the sheath body.
22. The system of any of statements 17-21, wherein the lumen of the luminal portion is shorter than the lumen of the sheath body.
23. The system of any of statements 17-22, wherein the luminal portion and the sheath body form an overlap region when the luminal portion extends distally beyond the at least one opening of the sheath body.
24. The system of statement 23, wherein the outer diameter of the luminal portion approaches the inner diameter of the lumen of the sheath body such that a seal is formed by the overlap region.
25. The system of statement 24, wherein the seal is configured to enable sealing against a vacuum of up to 25 inHg, or up to 28 inHg.
26. The system of statement 24, wherein the seal within the overlap region is configured to enable sealing against a pressure of up to 300 mmHg.
27. The system of any of statements 24-26, wherein the seal is located distal a proximal end of the luminal portion and proximal to the at least one opening of the sheath body.
28. The system of any of statements 24-27, further comprising a sealing element positioned on an external surface of the luminal portion.
29. The system of statement 28, wherein the sealing element includes a stepped up diameter or protruding feature in the overlap region.
30. The system of statement 28, wherein the sealing element comprises one or more external ridge features.
31. The system of statement 30, wherein the one or more ridge features are compressible when the luminal portion is inserted into the lumen of the sheath body.
32. The system of statement 28, wherein the sealing element comprises one or more inclined surfaces biased against an inner surface of the sheath body lumen.
33. The system of statement 28, wherein the sealing element comprises one or more expandable members actuated to seal.
34. The system of any statements 17-33, wherein the sheath body has an outer diameter suitable for insertion into the carotid artery.
35. The system of statement 34, wherein the outer diameter of the sheath body is between 5Fr and 7Fr.
36. The system of any of statements 17-35, wherein the sheath body has a length between the proximal end and the distal end suitable for locating the distal end of the sheath body at the petrous portion of an internal carotid artery from a transfemoral approach.
37. The system of statement 36, wherein the length of the sheath body is between 80 cm and 105 cm.
38. The system of any of statements 17-37, wherein the length of the luminal portion is between 10 cm and 25 cm.
39. The system of any of statements 17-38, wherein the length of the luminal portion is less than a length of the sheath body such that as the catheter is retracted into the sheath body a seal remains between an overlap region of the luminal portion and the inner diameter of the sheath body.
40. The system of any of statements 17-39, wherein the spine is longer than an entire length of the sheath body.
41. The system of any of statements 17-40, wherein the luminal portion includes three or more layers including an inner lubricious liner, a reinforcement layer, and an outer jacket layer.
42. The system of statement 41, wherein the outer jacket layer is composed of discreet sections of polymer with different durometers, compositions, and/or thicknesses to vary the flexibility along the length of the distal luminal portion.
43. The system of any of statements 17-42, wherein the outer diameter of the distal luminal portion is sized for navigation into cerebral arteries.
44. The system of any of statements 17-43, wherein the inner diameter of the distal luminal portion is between 0.040" and 0.088".
45. The system of any of statements 17-44, wherein the outer diameter of the luminal portion approaches the inner diameter of the sheath body creating a sealed area at an overlap region while still allowing the catheter to move through the sheath body.
46. The system of any of statements 17-45, wherein the catheter is tapered towards the distal opening

such that a distal-most end of the luminal portion has a smaller outer diameter compared to a more proximal region of the luminal portion near where the luminal portion seals with the sheath body.

47. The system of any of statements 17-46, wherein the distal end region of the sheath body comprises an occlusion element.

48. The system of any of statements 17-47, wherein the distal end region of the sheath body comprises an expanding distal tip.

49. The system of any of statements 17-48, wherein the at least one opening from the lumen comprises a side opening located a distance away from a distal tip of the sheath body.

50. The system of any of statements 17-49, wherein a distal tip of the sheath body further comprises a ramp feature configured to direct at an angulation the catheter away from a longitudinal axis of the sheath body lumen out through the at least one opening.

51. The system of any of statements 17-50, wherein the spine is longer than an entire length of the sheath body.

52. The system of any of statements 17-51, wherein the spine is a wire having an outer dimension from 0.014" to 0.018".

53. The system of any of statements 17-52, wherein the spine is a hypotube having a guide-wire passageway extending therethrough.

54. The system of any of statements 17-53, wherein the spine is a ribbon having an outer dimension from 0.010" to 0.025" thick.

55. The system of statement 54, wherein the ribbon is curved along at least a portion of an arc.

56. The system of any of statements 17-55, wherein the spine is configured to rotate the luminal portion around a longitudinal axis of the access sheath.

57. The system of any of statements 17-56, wherein the spine is eccentrically coupled to the luminal portion and the spine extends proximally from the luminal portion to outside the proximal end of the sheath body.

58. The system of any of statements 17-57, wherein the proximal end of the luminal portion has an angled cut.

59. The system of statement 58, wherein the angled cut is generally planar or is curved.

60. The system of any of statements 17-59, wherein the sheath body has one or more visual markers on the distal end region of the sheath body.

61. The system of any of statements 17-60, wherein the distal luminal portion has one or more visual markers at a distal end region of the luminal portion, a proximal end region of the luminal portion or both.

62. The system of statements 60 or 61, wherein the one or more visual markers on the sheath body and the one or more visual markers on the luminal portion are visually distinct.

63. The system of any of statements 60-62, wherein the spine has one or more visual markers.

64. The system of statement 63, wherein the one or more visual markers of the spine indicates overlap between the distal luminal portion and the sheath body.

65. The system of statements 63 or 64, wherein the one or more visual markers of the spine is positioned so that when the visual marker of the spine is aligned with a portion of the access sheath, the catheter is positioned at a distal-most position with minimal overlap length needed to create a seal between the catheter and the sheath body.

66. The system of any of statements 17-65, further comprising a dilator comprising a flexible, distal dilator portion having a distal tip and sized to be received within the luminal portion of the catheter.

67. The system of statement 66, wherein the dilator is a tubular element along at least a portion of its length.

68. The system of statement 66, wherein the dilator is a solid rod formed of malleable material configured to be shaped by a user.

69. The system of statement 66, wherein the dilator further comprises a rigid, dilator spine extending proximally from the dilator portion.

70. The system of statement 69, wherein the dilator spine is coaxial.

71. The system of statement 70, wherein the coaxial dilator spine has a lumen extending through it.

72. The system of statement 69, wherein the dilator spine is eccentric.

73. The system of any of statements 69-72, wherein when in use the dilator spine aligns side-by-side with the spine of the catheter.

74. The system of any of statements 66-73, wherein the distal tip is tapered.

75. The system of statement 74, wherein the dilator has a length at least as long as a length of the catheter such that the distal tip protrudes from the distal opening of the luminal portion.

76. The system of any of statements 69-75, wherein a proximal end of the spine includes a gripping feature configured for a user to grasp in order to move the catheter through the access sheath.

77. The system of statement 76, wherein a proximal end of the dilator spine includes a tab configured to be locked with the gripping feature on the catheter spine.

78. The system of statement 77, wherein when the catheter and dilator are in a locked configuration they are advanced as a single unit through the sheath body.

79. The system of statements 77 or 78, wherein the gripping feature and the dilator tab are removably coupled such that in a locked configuration the dilator tab engages the gripping feature and in an unlocked configuration the dilator tab disengages from the

gripping feature.
80. The system of any of statements 77-79, wherein the dilator tab is affixed to the dilator.
81. The system of any of statements 77-79, wherein the dilator tab is slideable on the dilator to accommodate different relative positions between the dilator and the catheter.
82. The system of any of statements 66-81, wherein the distal dilator portion comprises one or more detents on an outer surface configured to lock with correspondingly-shaped surface features on an inner surface of the luminal portion lumen through which the dilator portion extends.
83. The system of any of statements 69-82, wherein the dilator spine and the catheter spine have a similar stiffness and kink-resistance.
84. The system of any of statements 66-83, wherein the dilator has a visual marker on a distal end and/or a proximal end of the distal tip.
85. The system of any of statements 66-84, wherein a distal end region of the dilator is more flexible and increasingly stiffens towards the proximal end region of the dilator.
86. The system of any of statements 17-85, wherein the access sheath further comprises a connector that connects the proximal end of the sheath body to a proximal hemostasis valve.
87. The system of statement 86, wherein the proximal hemostasis valve has an adjustable opening sized large enough to allow removal of the catheter without dislodging any clots thereon.
88. The system of statement 86 or 87, wherein, when in use with the access sheath, the rigid spine of the catheter extends proximally from the luminal portion through the access sheath lumen and out the proximal hemostasis valve of the access sheath.
89. The system of any of statements 86-88, wherein the connector provides a connection of the proximal end of the sheath body to an aspiration line.
90. The system of any of statements 86-89, wherein the connector has a large bore inner lumen and connects to a large-bore aspiration line.
91. The system of statement 89 or 90, wherein the aspiration line connects to an aspiration source.
92. The system of statement 91, wherein the aspiration source is an active aspiration source.
93. The system of any of statements 89-92, wherein the aspiration line connects to a forward drip or flush line.
94. The system of any of statements 17-93, wherein the access sheath further comprises a proximal extension portion such that when the distal luminal portion of the catheter is withdrawn from the sheath body lumen it remains within the proximal extension portion.
95. The system of any of statements 17-94, wherein the inner diameter of the luminal portion is sized to permit placement of an interventional device through the luminal portion.

## Claims

1. A dilator for facilitation of intraluminal medical procedures within the neurovasculature, the dilator comprising:

   a flexible elongate body having a tubular body extending along a length between a proximal end region and a distal end region having a tapered distal tip tapering distally from a first outer diameter to a second outer diameter that is smaller than the first outer diameter, a single lumen extending longitudinally through the flexible elongate body to a distal opening at the tapered distal tip, wherein the tapered distal tip has a first radiopaque marker disposed at a proximal end of the tapered distal tip and a second radiopaque marker disposed at a distal end of the tapered distal tip, the first and second radiopaque markers identifying the tapered distal tip; and
   a proximal spine extending from the proximal end region of the flexible elongate body.

2. The dilator of claim 1, wherein the proximal spine has a single lumen extending through an entire length of the proximal spine and that communicates with the single lumen of the flexible elongate body.

3. The dilator of claim 1 or 2, wherein the distal end region is more flexible than the proximal end region of the flexible elongate body.

4. The dilator of any preceding claim, wherein the distal opening of the flexible elongate body is sized to accommodate a guidewire having an outer diameter of between 0.014" and 0.018".

5. The dilator of any preceding claim, wherein the inner diameter of the flexible elongate body is between 0.020" and 0.022".

6. The dilator of any preceding claim, wherein the tapered distal tip of the flexible elongate body extends over a length between 1.5 cm and 3 cm.

7. The dilator of any preceding claim, wherein the proximal spine has an outer diameter that is smaller than an outer diameter of the flexible elongate body.

8. The dilator of any of claims 1 to 6, wherein the proximal spine and the flexible elongate body are substantially similar in outer diameter.

9. The dilator of any preceding claim, wherein a section

of the proximal spine is configured to be advanced into a blood vessel of a patient, wherein at least a portion of the section comprises a different material than a portion of the flexible elongate body.

**10.** The dilator of any preceding claim, wherein the flexible distal dilator portion is made of polymer.

**11.** The dilator of claim 10, wherein the distal tip portion is made of 35D or 40D PEBAX

**12.** The dilator of claim 10, wherein the proximal spine comprises metal.

**13.** The dilator of any preceding claim, wherein the proximal spine has a lumen with an extracorporeal, proximal opening.

**14.** The dilator of any preceding claim, wherein one or both radiopaque markers are made of polymer impregnated with tungsten, platinum, or tantalum.

**15.** A system including the dilator of claim 1, the system further comprising a catheter comprising a flexible distal luminal portion having a proximal end, a proximal opening, a distal end, and a lumen extending between the proximal end and the distal end, wherein the flexible elongate body has an outer diameter that is 0.003" to 0.010" smaller than the lumen of the catheter.

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FIG. 1

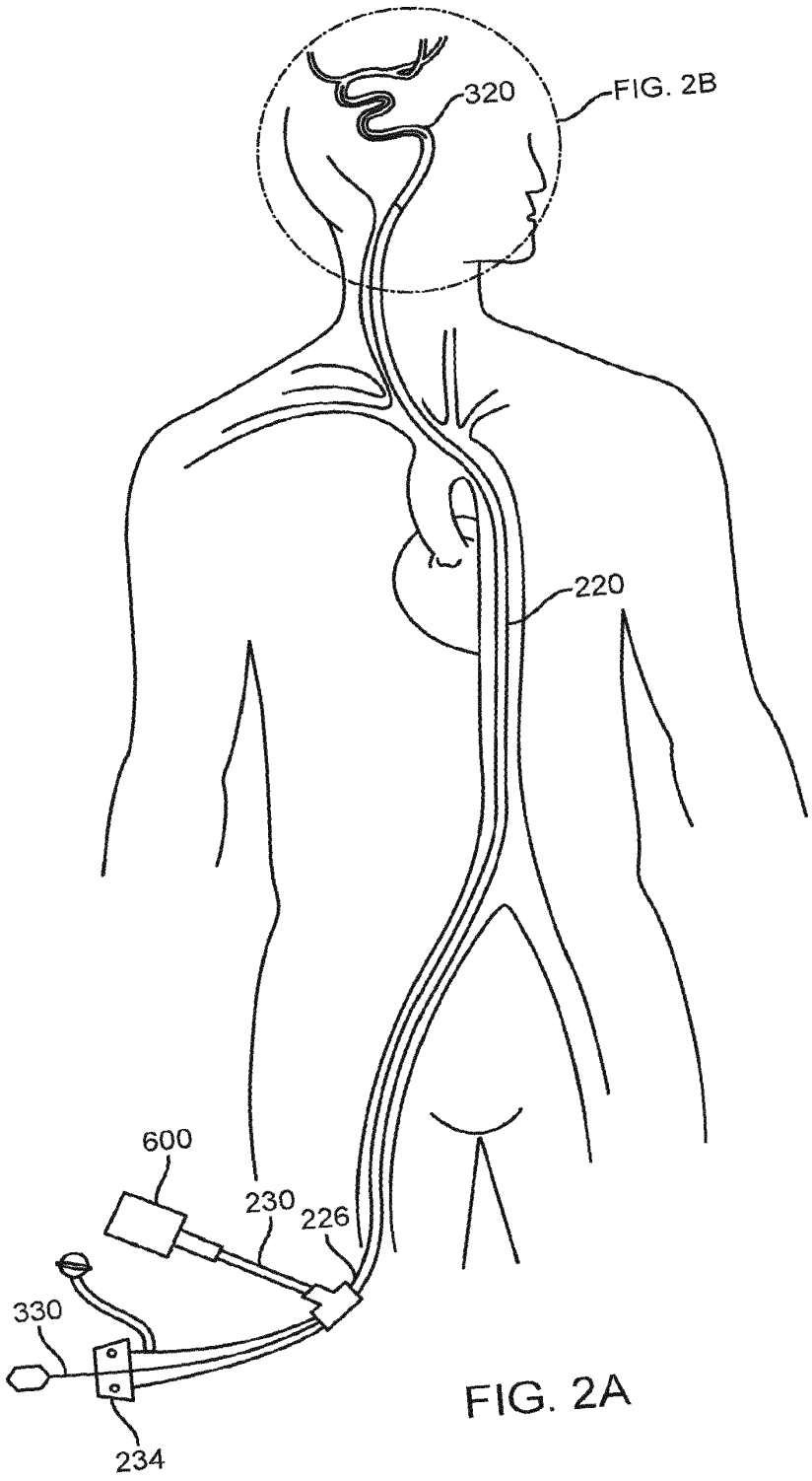



FIG. 2A



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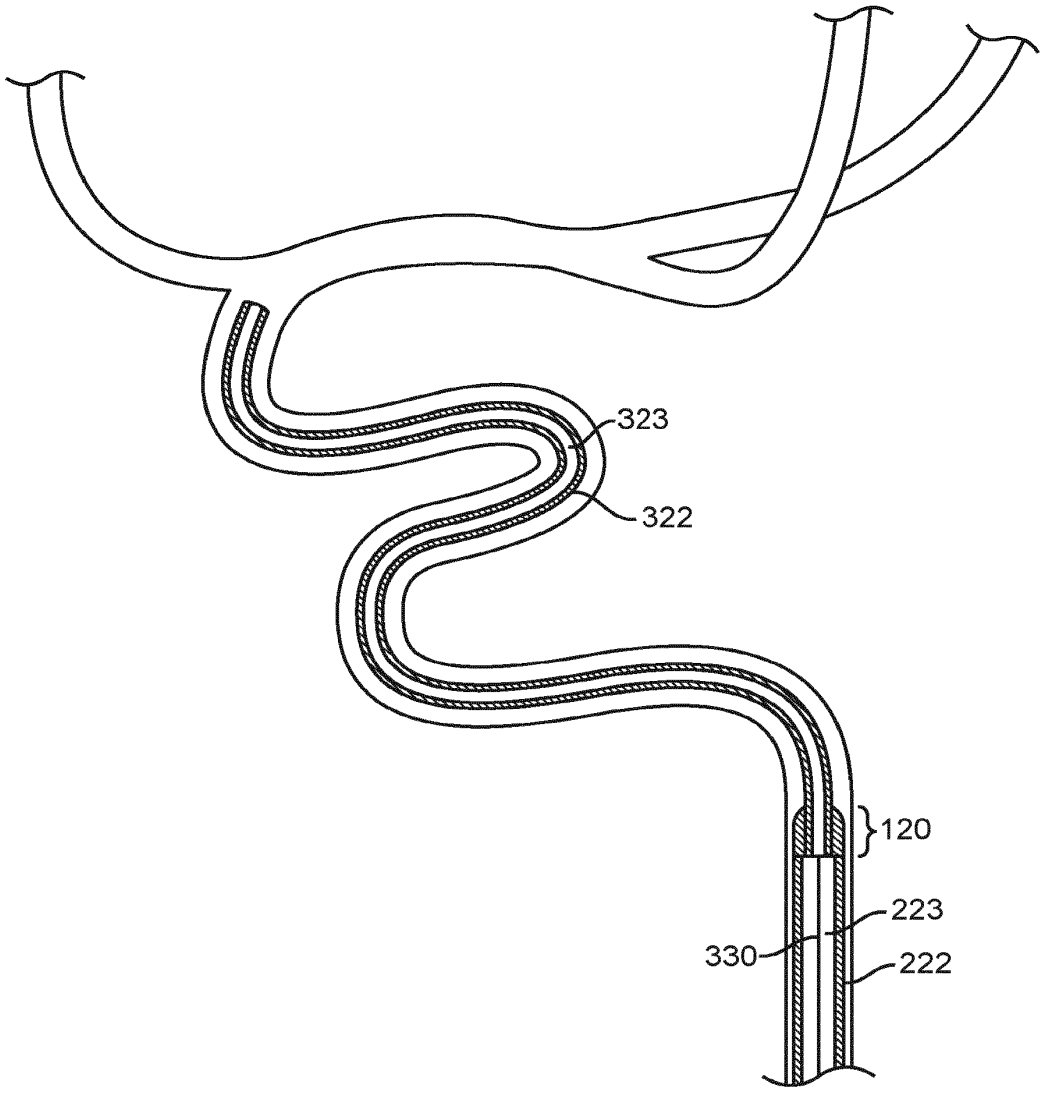



FIG. 2B

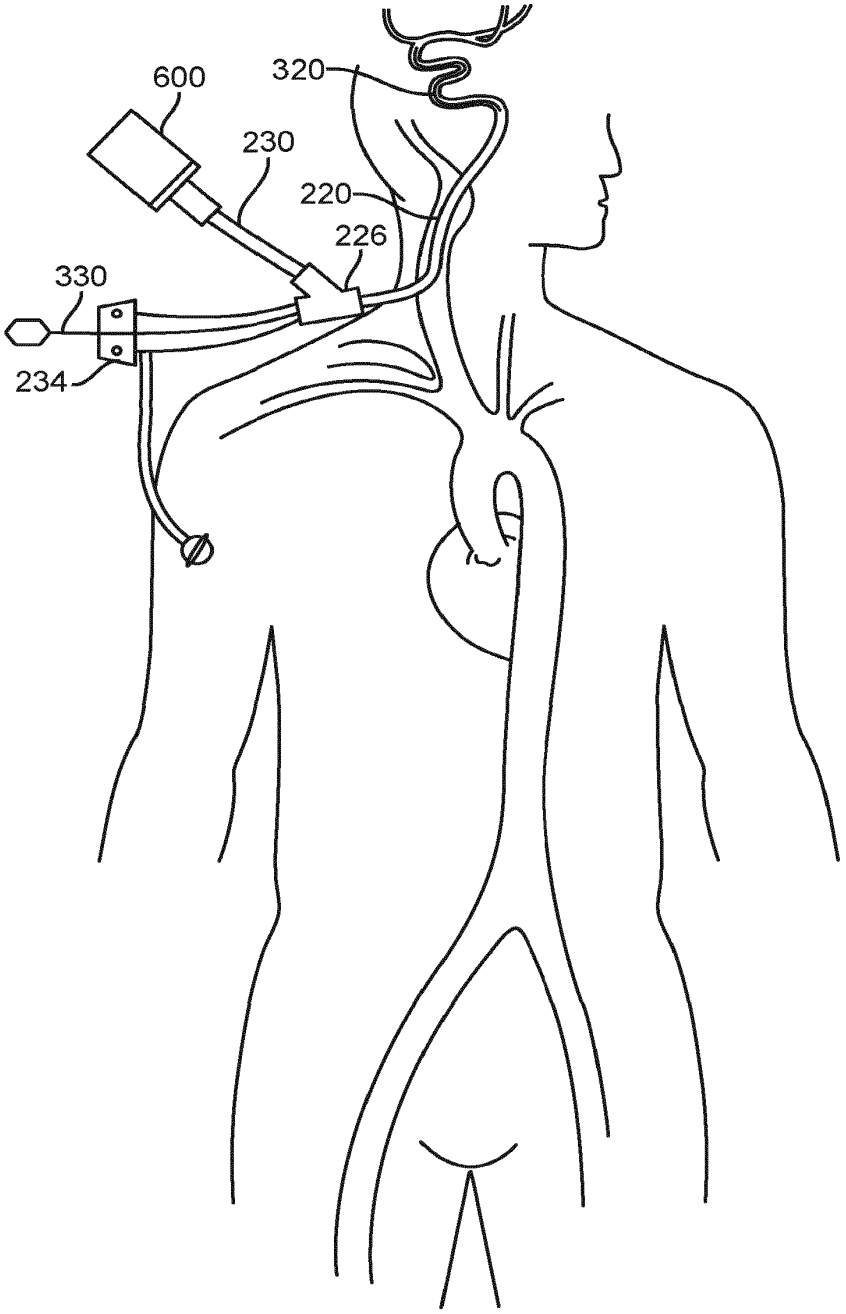



FIG. 3

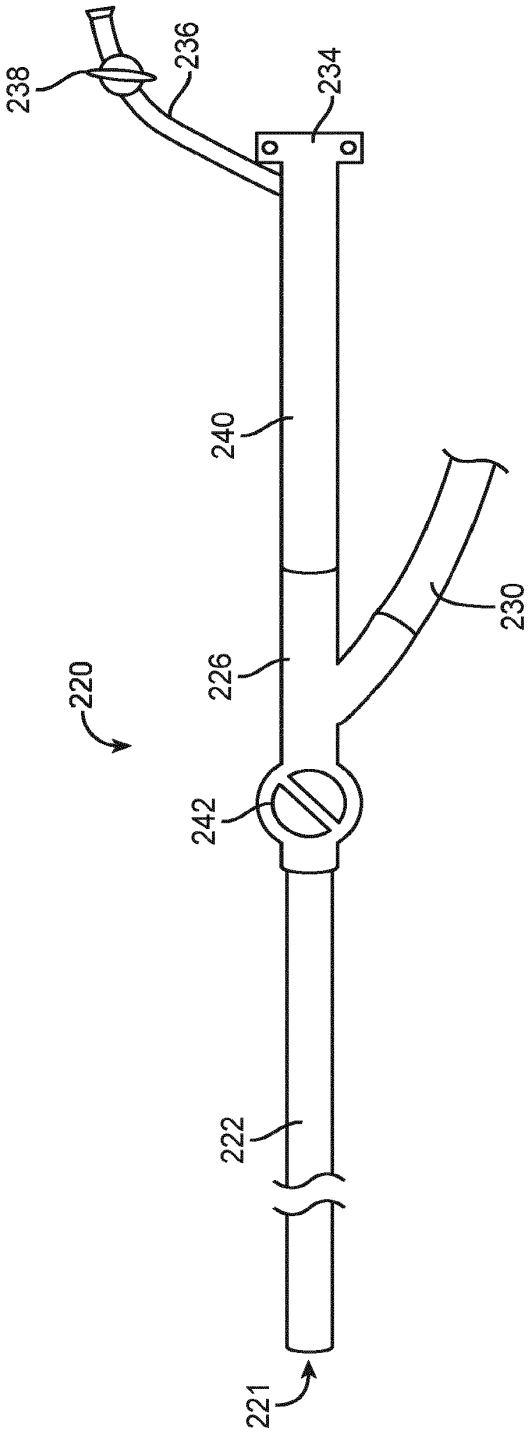



FIG. 4

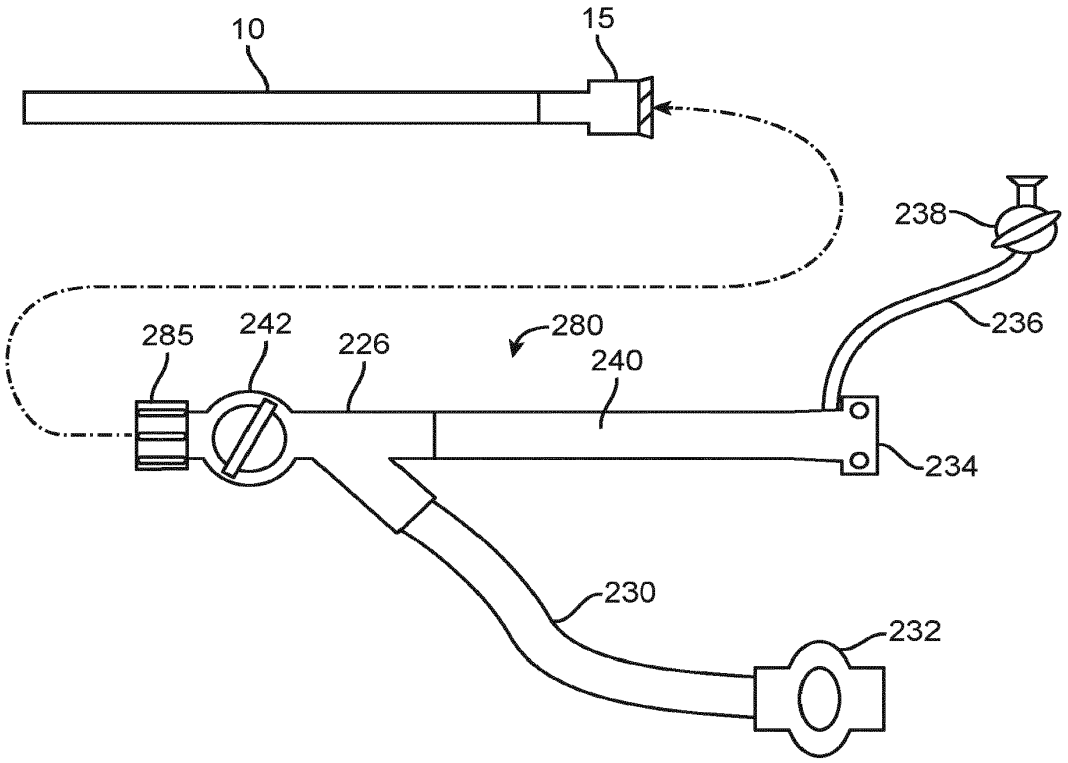



FIG. 5

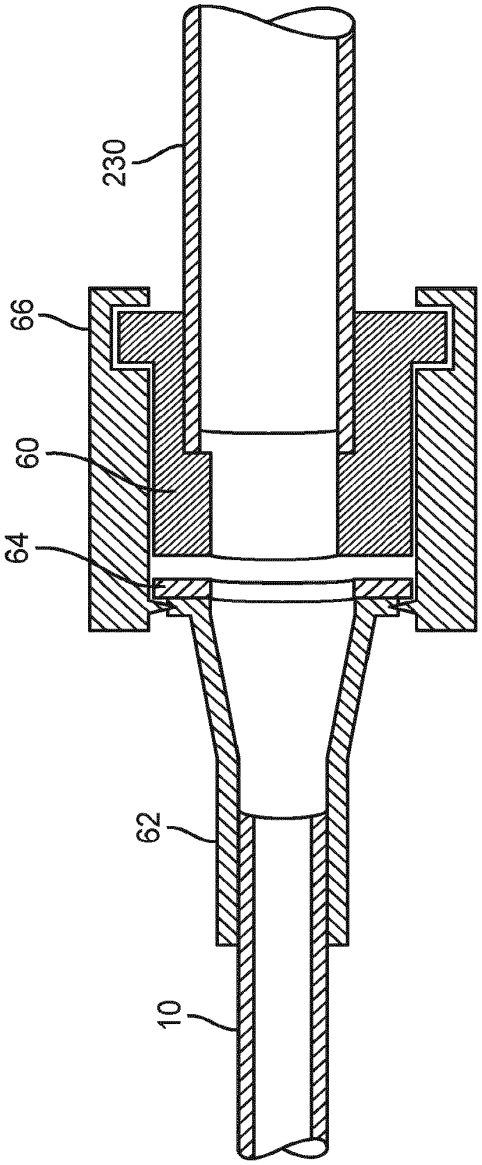



FIG. 6

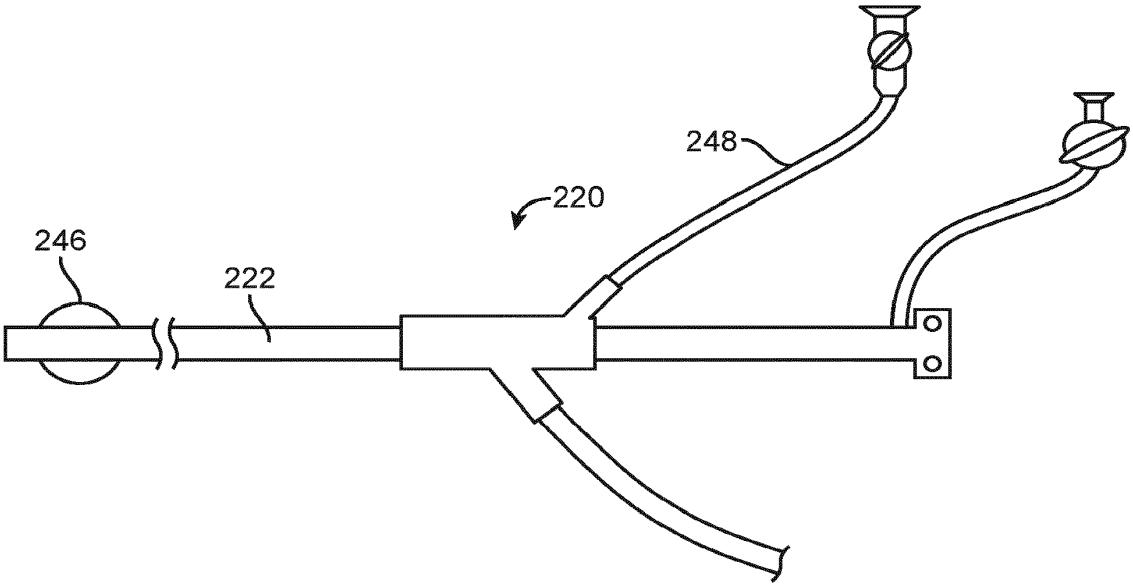



FIG. 7

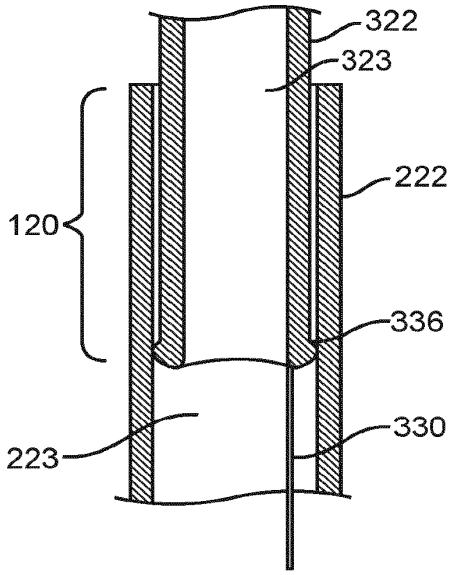



FIG. 8A

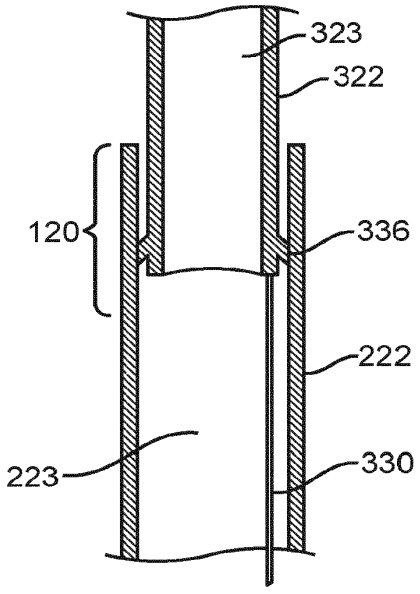



FIG. 8B

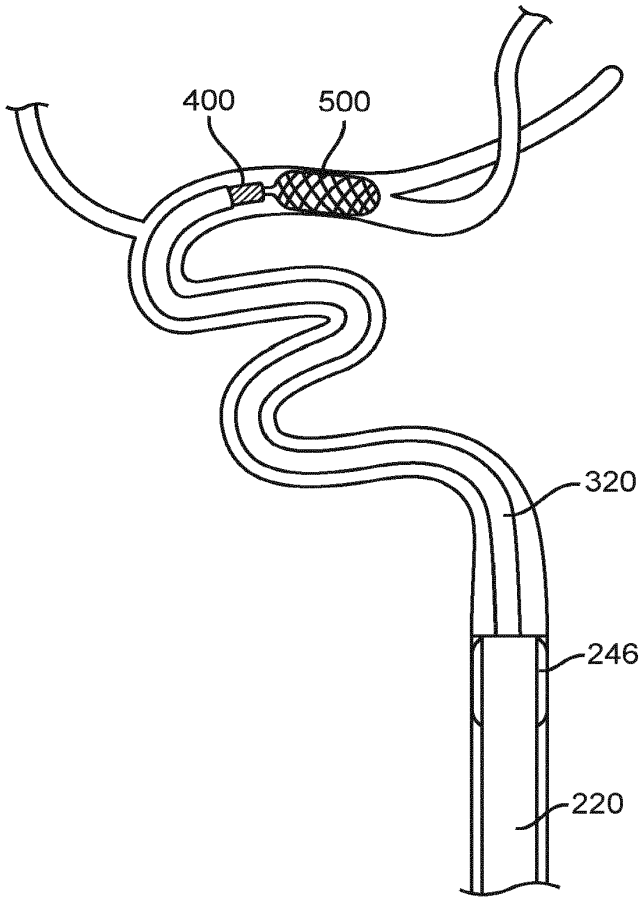



FIG. 9

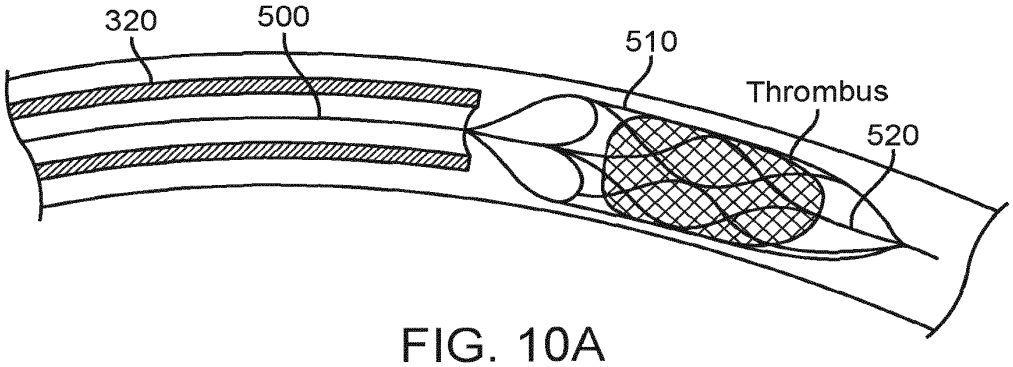



FIG. 10A

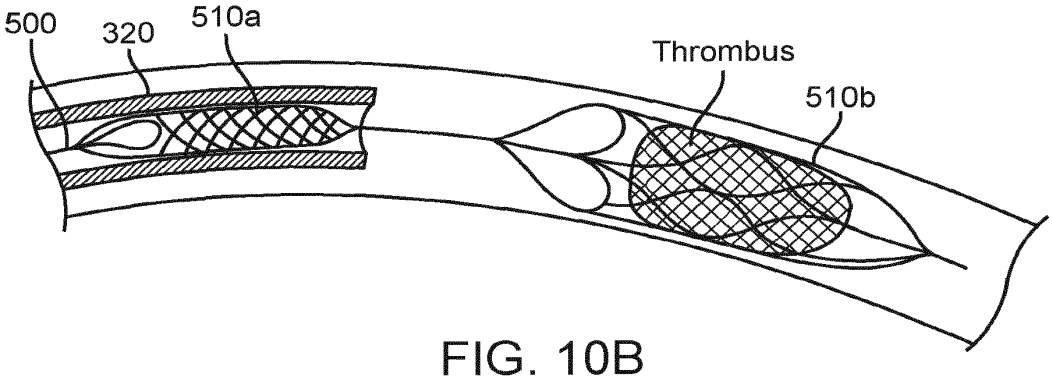



FIG. 10B

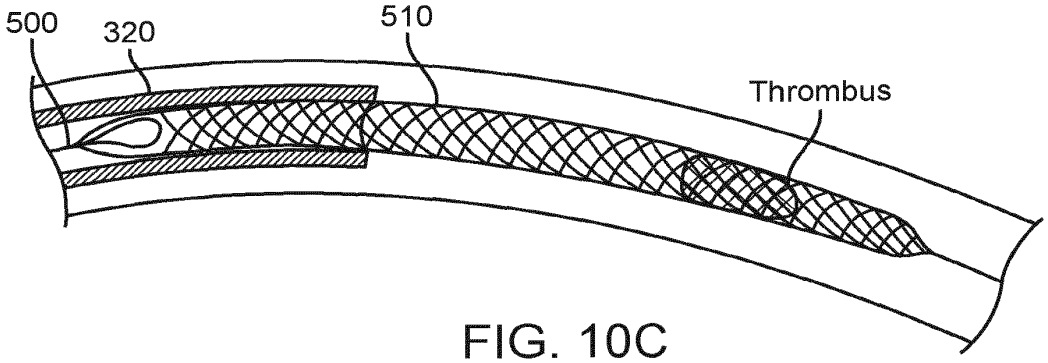



FIG. 10C

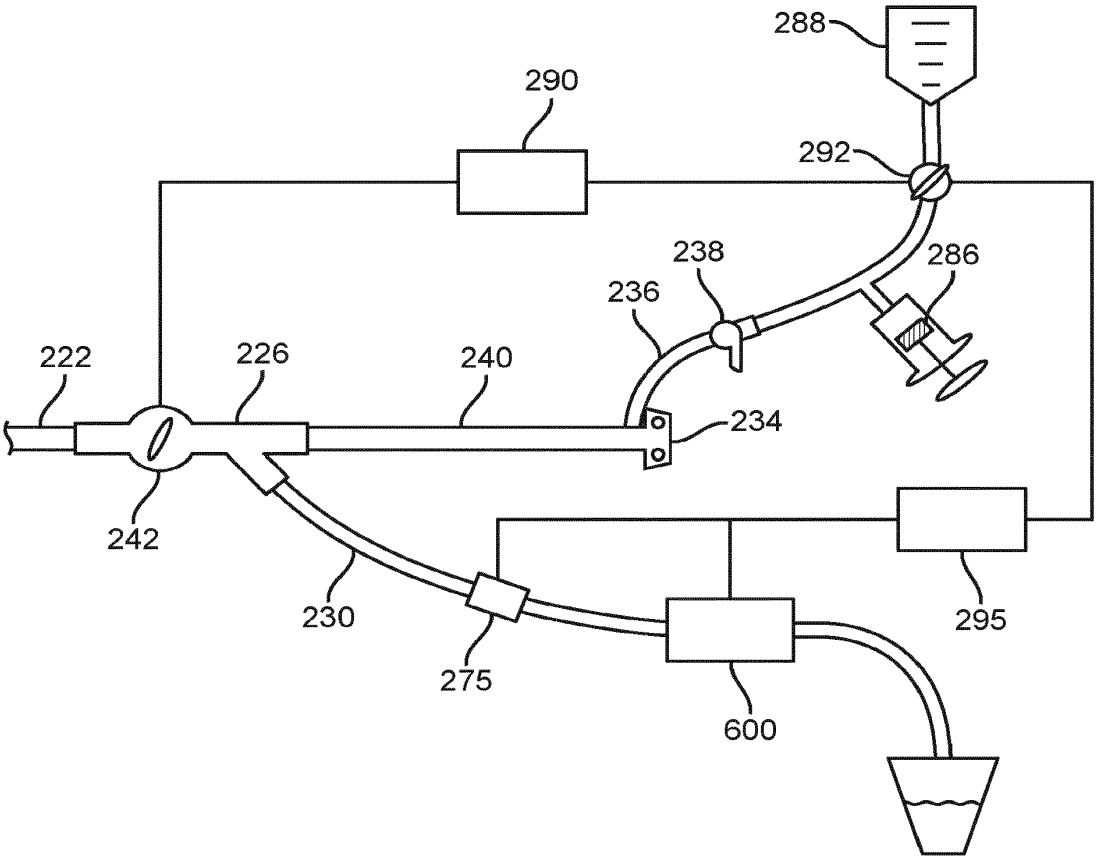



FIG. 11

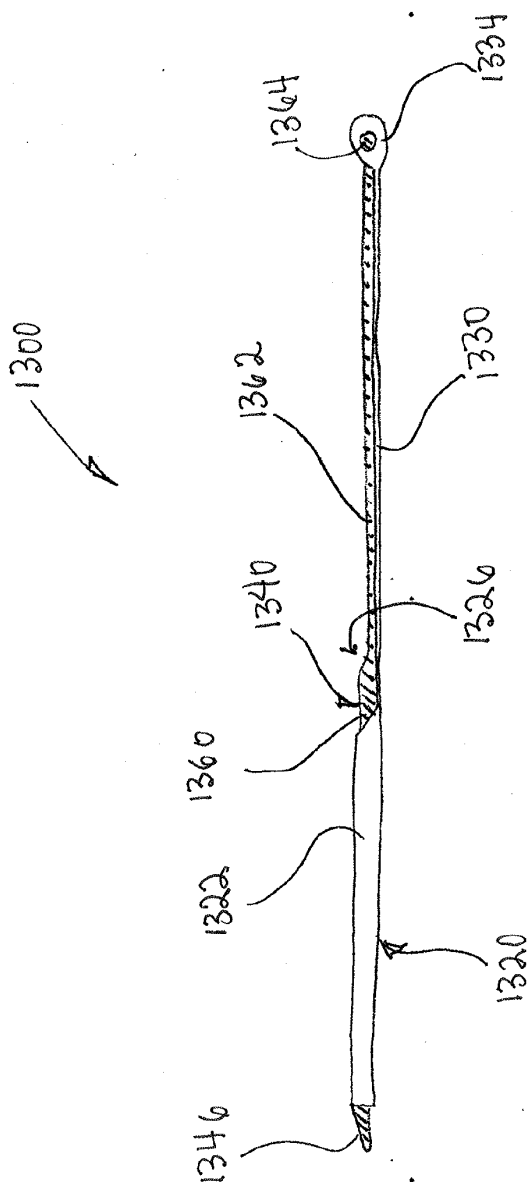



FIG. 12A

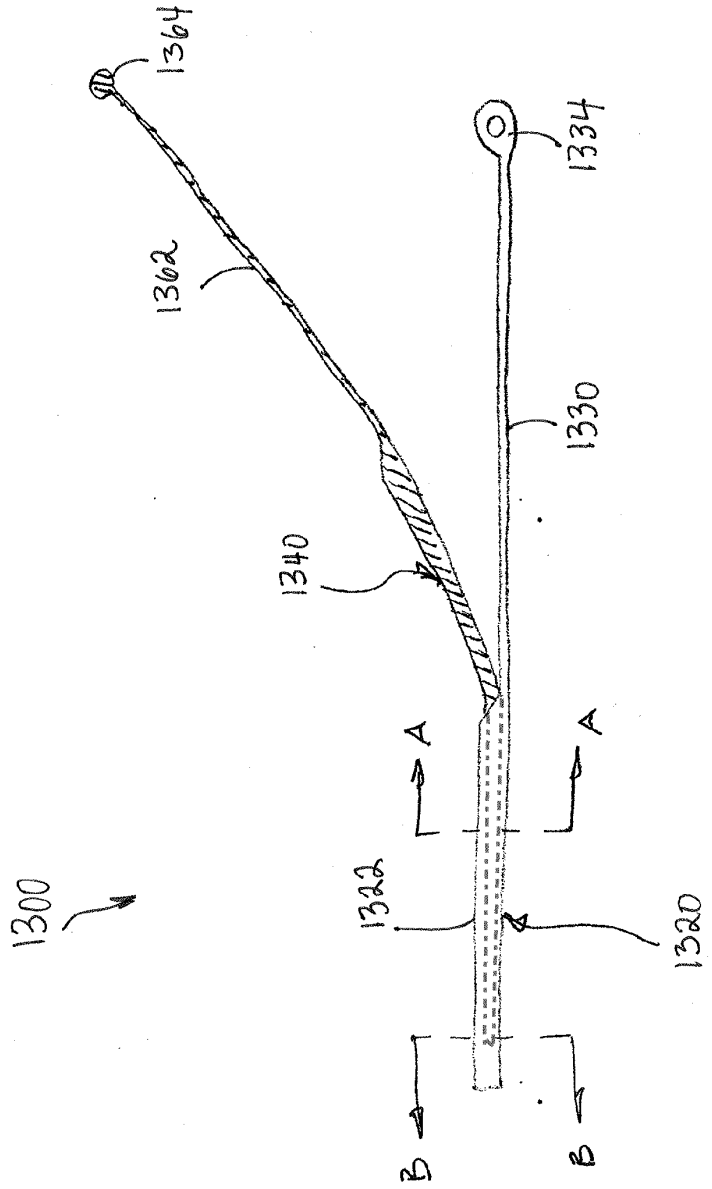



FIG. 12B

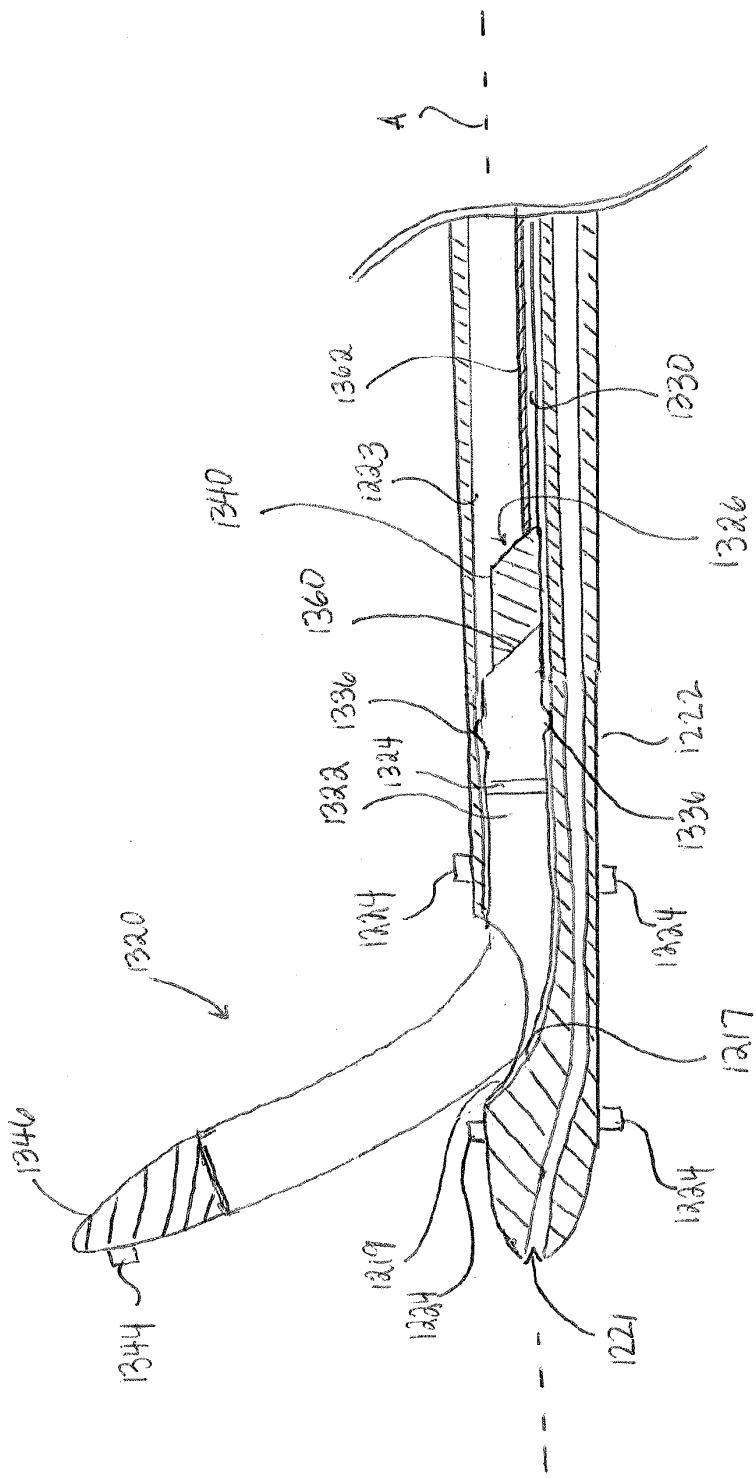
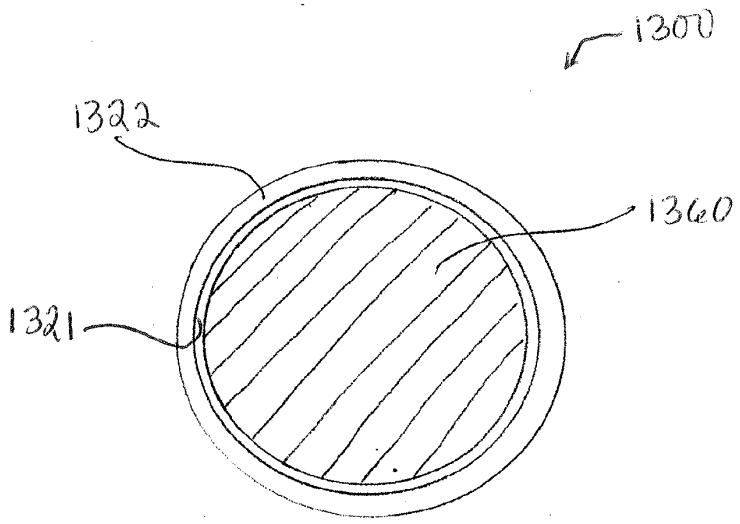
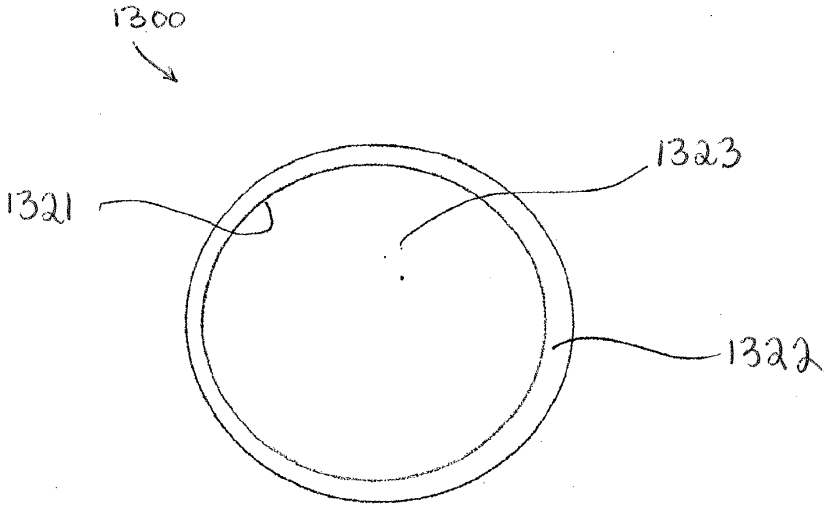

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FIG. 12C




A - A
FIG. 13




B - B
FIG. 14

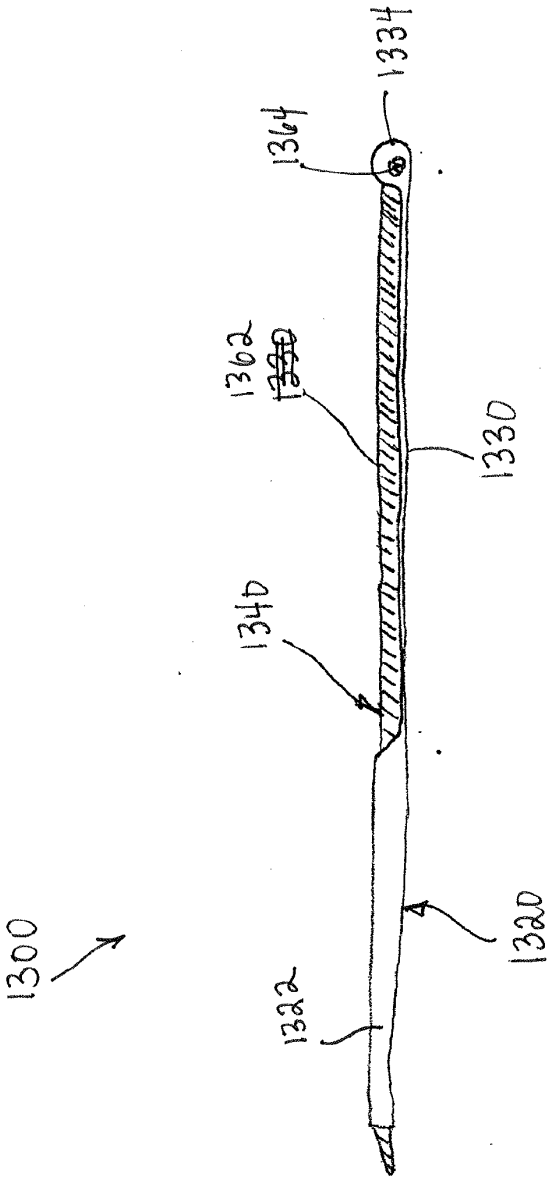



FIG. 15A

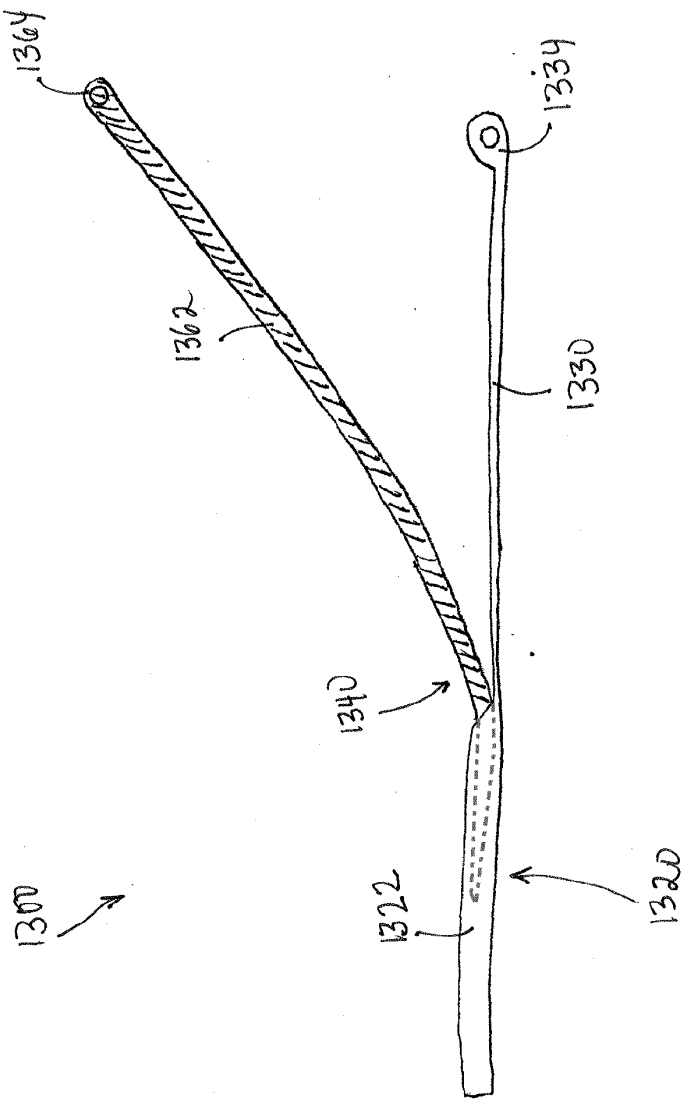



FIG. 15B

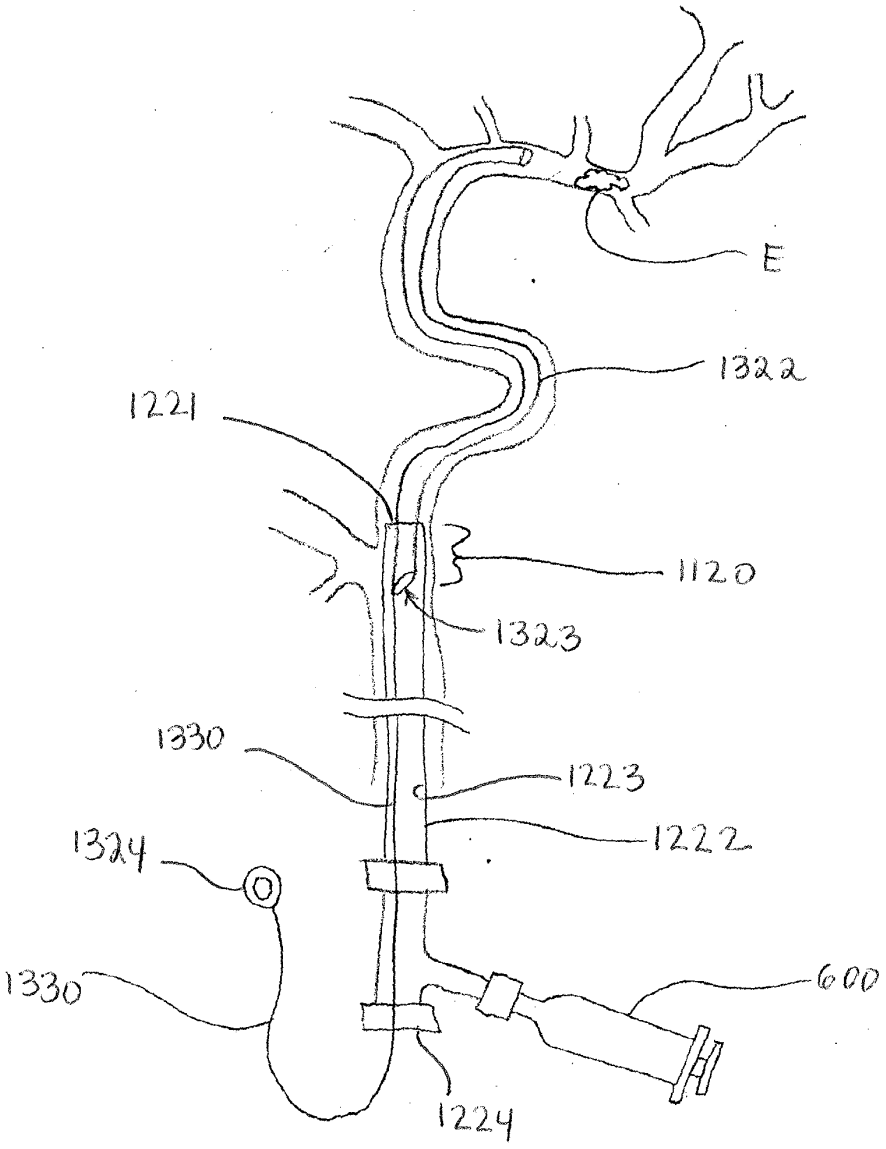



FIG. 16

Europäisches Patentamt
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# EUROPEAN SEARCH REPORT

Application Number
EP 22 19 4205

## DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document with indication, where appropriate, of relevant passages | Relevant to claim | CLASSIFICATION OF THE APPLICATION (IPC) |
|---|---|---|---|
| X | WO 2012/035633 A1 (GOODMAN CO LTD [JP]; FUJIWARA TATSUMICHI [JP]; IZAWA KEI [JP]) 22 March 2012 (2012-03-22)<br>* figures 1, 2, 3, 7 *<br>* paragraph [0028] - paragraph [0076] * | 1-15 | INV.<br>A61B17/221<br>A61M29/00<br>A61M25/01<br>A61M25/06 |
| A | US 2008/243222 A1 (SCHAFERSMAN JESSICA A [US] ET AL) 2 October 2008 (2008-10-02)<br>* figures 1, 4 *<br>* paragraphs [0033], [0034] * | 1-15 | ADD.<br>A61B17/22<br>A61M25/00 |
| A | US 2003/050600 A1 (RESSEMANN THOMAS V [US] ET AL) 13 March 2003 (2003-03-13)<br>* figures 1A, 6A-I, 11E, 11G *<br>* paragraphs [0086] - [0089] *<br>* paragraphs [0095] - [0125] *<br>* paragraphs [0208] - [0209] * | 1-15 | |

TECHNICAL FIELDS SEARCHED (IPC)

A61B
A61M

The present search report has been drawn up for all claims

| Place of search | Date of completion of the search | Examiner |
|---|---|---|
| The Hague | 3 January 2023 | Emirdag, Eda |

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
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E : earlier patent document, but published on, or after the filing date
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EPO FORM 1503 03.82 (P04C01)

## ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 22 19 4205

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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03-01-2023

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| WO 2012035633 A1 | 22-03-2012 | JP WO2012035633 A1 | 20-01-2014 |
| | | WO 2012035633 A1 | 22-03-2012 |
| US 2008243222 A1 | 02-10-2008 | NONE | |
| US 2003050600 A1 | 13-03-2003 | AU 2002327606 A1 | 25-02-2004 |
| | | EP 1531740 A1 | 25-05-2005 |
| | | JP 2005535380 A | 24-11-2005 |
| | | US 2003050600 A1 | 13-03-2003 |
| | | WO 2004014240 A1 | 19-02-2004 |

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

## REFERENCES CITED IN THE DESCRIPTION

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### Patent documents cited in the description


- US 62111481 **[0001]**
- US 62142637 **[0001]**
- US 57695314 **[0002]**
- US 56936514 **[0002]**
- US 53731614 **[0002]**
- US 22191714 **[0002]**
- US 8157760 B **[0041]**
- US 20100217276 A **[0041]**
- US 20150173782 A **[0054] [0056]**
- US 20150174368 A **[0056] [0070]**

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# ELECTRONIC PAYMENT RECEIPT

| APPLICATION # | RECEIPT DATE / TIME | ATTORNEY DOCKET # |
|---|---|---|
| **17/498,642** | **11/21/2023 02:03:34 PM Z ET** | **111552-8023.US02** |

## Title of Invention

SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

## Application Information

| | | | |
|---|---|---|---|
| APPLICATION TYPE | Utility - Nonprovisional Application under 35 USC 111(a) | PATENT # | - |
| CONFIRMATION # | 1040 | FILED BY | JiYoung Anderson |
| PATENT CENTER # | 63340019 | AUTHORIZED BY | Matthew Williams |
| CUSTOMER # | 25096 | FILING DATE | 10/11/2021 |
| CORRESPONDENCE ADDRESS | - | FIRST NAMED INVENTOR | Richard Quick |

## Payment Information

| PAYMENT METHOD | PAYMENT TRANSACTION ID | PAYMENT AUTHORIZED BY |
|---|---|---|
| **CARD / 3369** | **E2023AKE04025935** | **JiYoung Anderson** |

| FEE CODE | DESCRIPTION | ITEM PRICE($) | QUANTITY | ITEM TOTAL($) |
|---|---|---|---|---|
| 1801 | REQUEST FOR CONTINUED EXAMINATION (RCE) - 1ST REQUEST (SEE 37 CFR 1.114) | 1360.00 | 1 | 1360.00 |
| | | | **TOTAL AMOUNT:** | **$1,360.00** |

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

**New Applications Under 35 U.S.C. 111**

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

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

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

**New International Application Filed with the USPTO as a Receiving Office**

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

# CORRECTED APPLICATION DATA SHEET

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

| Application Data Sheet 37 CFR 1.76 | Attorney Docket Number | 111552-8023.US02 |
|---|---|---|
| | Application Number | |
| Title of Invention | SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS | |

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

## Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

## Inventor Information:

**Inventor 1** Remove

**Legal Name**

| Prefix | Given Name | Middle Name | Family Name | Suffix |
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| | Richard | | Quick | |

**Residence Information (Select One)** ◉ US Residency ○ Non US Residency ○ Active US Military Service

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**Mailing Address of Inventor:**

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| Address 1 | c/o Inari Medical, Inc. |
| Address 2 | ~~9 Parker, Suite #100~~ 6001 Oak Canyon, Suite #100 |

| City | Irvine | State/Province | CA |
|---|---|---|---|
| Postal Code | 92618 | Country | US |

**Inventor 2** Remove

**Legal Name**

| Prefix | Given Name | Middle Name | Family Name | Suffix |
|---|---|---|---|---|
| | Benjamin | Edward | Merritt | |

**Residence Information (Select One)** ◉ US Residency ○ Non US Residency ○ Active US Military Service

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|---|---|---|---|---|---|

**Mailing Address of Inventor:**

| | |
|---|---|
| Address 1 | c/o Inari Medical, Inc. |
| Address 2 | 6001 Oak Canyon, Suite #100 |

| City | Irvine | State/Province | CA |
|---|---|---|---|
| Postal Code | 92618 | Country | US |

**Inventor 3** Remove

**Legal Name**

| Prefix | Given Name | Middle Name | Family Name | Suffix |
|---|---|---|---|---|
| | John | Coleman | Thress | |

**Residence Information (Select One)** ◉ US Residency ○ Non US Residency ○ Active US Military Service

| Application Data Sheet 37 CFR 1.76 | Attorney Docket Number | 111552-8023.US02 |
|---|---|---|
| | Application Number | |
| Title of Invention | SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS | |

| City | Capistrano Beach | State/Province | CA | Country of Residence | US |
|---|---|---|---|---|---|

Mailing Address of Inventor:

| Address 1 | c/o Inari Medical, Inc. | | |
|---|---|---|---|
| Address 2 | 6001 Oak Canyon, Suite #100 | | |
| City | Irvine | State/Province | CA |
| Postal Code | 92618 | Country i | US |

Inventor 4 — Remove

Legal Name

| Prefix | Given Name | Middle Name | Family Name | Suffix |
|---|---|---|---|---|
| | Paul | | Lubock | |

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

| City | Monarch Beach | State/Province | CA | Country of Residence | US |
|---|---|---|---|---|---|

Mailing Address of Inventor:

| Address 1 | c/o Inari Medical, Inc. | | |
|---|---|---|---|
| Address 2 | 6001 Oak Canyon, Suite #100 | | |
| City | Irvine | State/Province | CA |
| Postal Code | 92618 | Country i | US |

Inventor 5 — Remove

Legal Name

| Prefix | Given Name | Middle Name | Family Name | Suffix |
|---|---|---|---|---|
| | Thomas | M. | Tu | |

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

| City | Louisville | State/Province | KY | Country of Residence | US |
|---|---|---|---|---|---|

Mailing Address of Inventor:

| Address 1 | c/o Inari Medical, Inc. | | |
|---|---|---|---|
| Address 2 | 6001 Oak Canyon, Suite #100 | | |
| City | Irvine | State/Province | CA |
| Postal Code | 92618 | Country i | US |

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. — Add

## Correspondence Information:

**Enter either Customer Number or complete the Correspondence Information section below.**
**For further information see 37 CFR 1.33(a).**

☐ **An Address is being provided for the correspondence Information of this application.**

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Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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| Application Data Sheet 37 CFR 1.76 | Attorney Docket Number | 111552-8023.US02 |
|---|---|---|
| | Application Number | |
| Title of Invention | SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS | |

| | | | |
|---|---|---|---|
| **Customer Number** | 25096 | | |
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## Application Information:

| | | | |
|---|---|---|---|
| **Title of the Invention** | SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS | | |
| **Attorney Docket Number** | 111552-8023.US02 | **Small Entity Status Claimed** | ☐ |
| **Application Type** | Nonprovisional | | |
| **Subject Matter** | Utility | | |
| **Total Number of Drawing Sheets (if any)** | 20 | **Suggested Figure for Publication (if any)** | 1A |

## Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

| Application number of the previously filed application | Filing date (YYYY-MM-DD) | Intellectual Property Authority or Country |
|---|---|---|
| | | |

## Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

## Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

| | | | |
|---|---|---|---|
| Please Select One: | ◉ Customer Number | ○ US Patent Practitioner | ○ Limited Recognition (37 CFR 11.9) |
| Customer Number | 25096 | | |

PTO/AIA/14 (11-15)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| Application Data Sheet 37 CFR 1.76 | Attorney Docket Number | 111552-8023.US02 |
|---|---|---|
| | Application Number | |
| Title of Invention | SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS | |

## Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

| Prior Application Status | Pending | | Remove |
|---|---|---|---|
| Application Number | Continuity Type | Prior Application Number | Filing or 371(c) Date (YYYY-MM-DD) |
| | Continuation of | 16/258344 | 2019-01-25 |
| Prior Application Status | Expired | | Remove |
| Application Number | Continuity Type | Prior Application Number | Filing or 371(c) Date (YYYY-MM-DD) |
| 16/258344 | Claims benefit of provisional | 62/622691 | 2018-01-26 |

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

## Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

| | | | Remove |
|---|---|---|---|
| Application Number | Country[i] | Filing Date (YYYY-MM-DD) | Access Code[i] (if applicable) |
| | | | |

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

## Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

| Application Data Sheet 37 CFR 1.76 | Attorney Docket Number | 111552-8023.US02 |
|---|---|---|
| | Application Number | |
| Title of Invention | SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS | |

## Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

**NOTE**: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

**1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)**

**A. Priority Document Exchange (PDX)** - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

**B. Search Results from U.S. Application to EPO** - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

**2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)**

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

**NOTE:** Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

PTO/AIA/14 (11-15)
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|---|---|---|
| | Application Number | |
| Title of Invention | SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS | |

## Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

**Applicant 1**

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

| | | |
|---|---|---|
| ◉ Assignee | ○ Legal Representative under 35 U.S.C. 117 | ○ Joint Inventor |
| ○ Person to whom the inventor is obligated to assign. | ○ Person who shows sufficient proprietary interest | |

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

| | |
|---|---|
| Name of the Deceased or Legally Incapacitated Inventor: | |
| If the Applicant is an Organization check here. | ☒ |
| Organization Name | Inari Medical, Inc. |

**Mailing Address Information For Applicant:**

| | | | |
|---|---|---|---|
| **Address 1** | ~~9 Parker, Suite #100~~ 6001 Oak Canyon, Suite #100 | | |
| Address 2 | | | |
| **City** | Irvine | **State/Province** | CA |
| **Country** | US | Postal Code | 92618 |
| Phone Number | | Fax Number | |
| Email Address | | | |

Additional Applicant Data may be generated within this form by selecting the Add button.

## Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
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| Application Data Sheet 37 CFR 1.76 | Attorney Docket Number | 111552-8023.US02 |
|---|---|---|
| | Application Number | |
| Title of Invention | SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS | |

**Assignee 1**

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

| Prefix | **Given Name** | Middle Name | **Family Name** | Suffix |
|---|---|---|---|---|
| | | | | |

**Mailing Address Information For Assignee including Non-Applicant Assignee:**

| | | | |
|---|---|---|---|
| **Address 1** | | | |
| Address 2 | | | |
| **City** | | **State/Province** | |
| **Country**[i] | | Postal Code | |
| Phone Number | | Fax Number | |
| Email Address | | | |

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

## Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

| **Signature** | /Matthew S. Williams/ | | | Date (YYYY-MM-DD) | 2023-11-21 |
|---|---|---|---|---|---|
| First Name | Matthew S. | Last Name | Williams | Registration Number | 77,516 |

Additional Signature may be generated within this form by selecting the Add button.

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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| | Application Number | |
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This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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.**

# 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 records.

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 CooperationTreaty.

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.

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Docket No.: 111552.8023.US02

## DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

| Title of Invention | SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS |
|---|---|

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 17/498,642

filed on 2021-10-11.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any wilful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

### WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms
PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Benjamin Edward Merritt Date: 11/13/23

Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 1 minute 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.**
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

164443986.1

Based on USPTO form PTO/AIA/01

Docket No.: 111552.8023.US02

## DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

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|---|---|

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This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 17/498,642

filed on 2021-10-11.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any wilful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

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LEGAL NAME OF INVENTOR

Inventor: John Coleman Thress Date: 11/13/2023

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 1 minute 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

164443986.1

Based on USPTO form PTO/AIA/01

Docket No.: 111552.8023.US02

**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)**

| | |
|---|---|
| Title of Invention | SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS |

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 17/498,642

filed on 2021-10-11

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

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**WARNING:**

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PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Paul Lubock Date: November 16, 2023

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 1 minute 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2

164443986.1

Based on USPTO form PTO/AIA/01

Docket No.: 111552.8023.US02

**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)**

| Title of Invention | SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS |
|---|---|

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 17/498,642

filed on 2021-10-11.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any wilful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

## WARNING:

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LEGAL NAME OF INVENTOR

Inventor: Thomas M. Tu Date : 11/17/23

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 1 minute 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2

164443986.1

UNITED STATES
PATENT AND TRADEMARK OFFICE

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

# ELECTRONIC PAYMENT RECEIPT

| APPLICATION # | RECEIPT DATE / TIME | ATTORNEY DOCKET # |
|---|---|---|
| **17/498,642** | **11/21/2023 11:10:38 AM Z ET** | **111552-8023.US02** |

## Title of Invention

SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

## Application Information

| | | | |
|---|---|---|---|
| APPLICATION TYPE | Utility - Nonprovisional Application under 35 USC 111(a) | PATENT # | - |
| CONFIRMATION # | 1040 | FILED BY | JiYoung Anderson |
| PATENT CENTER # | 63335316 | AUTHORIZED BY | Matthew Williams |
| CUSTOMER # | 25096 | FILING DATE | 10/11/2021 |
| CORRESPONDENCE ADDRESS | - | FIRST NAMED INVENTOR | Richard Quick |

## Payment Information

| PAYMENT METHOD | PAYMENT TRANSACTION ID | PAYMENT AUTHORIZED BY |
|---|---|---|
| **CARD / 3369** | **E2023AKB11339137** | **JiYoung Anderson** |

| FEE CODE | DESCRIPTION | ITEM PRICE($) | QUANTITY | ITEM TOTAL($) |
|---|---|---|---|---|
| 1830 | PROCESSING FEE, EXCEPT IN PROVISIONAL APPLICATIONS | 140.00 | 1 | 140.00 |
| 1819 | CORRECTION OF INVENTORSHIP AFTER FIRST ACTION ON MERITS | 640.00 | 1 | 640.00 |
| | | | **TOTAL AMOUNT:** | **$780.00** |

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

**New Applications Under 35 U.S.C. 111**

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

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

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

**New International Application Filed with the USPTO as a Receiving Office**

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

Doc Code: R48.REQ
Document Description: Request under Rule 48 correcting inventorship

PTO/AIA/40 (04-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**REQUEST FOR CORRECTION IN A PATENT APPLICATION RELATING TO INVENTORSHIP OR AN INVENTOR NAME, OR ORDER OF NAMES, OTHER THAN IN A REISSUE APPLICATION (37 CFR 1.48)**

| | |
|---|---|
| Application Number | 17/498,642 - Conf. 1040 |
| Filing Date | 2021-10-11 |
| First Named Inventor | Richard Quick |
| Art Unit | 3771 |
| Examiner Name | Tuan Van Nguyen |
| Practitioner Docket Number | 111552.8023.US02 |

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

Applicant hereby **requests that the inventorship be corrected or changed, or that the name of the inventor or a joint inventor, or the order of the names of joint inventors, be changed,** in the above-identified application. **Note:** 37 CFR 1.48 applies to any request to correct inventorship filed on or after September 16, 2012, regardless of the application filing date. **Do not submit this form after payment of the issue fee or if the application has been patented.** See 37 CFR 1.324 for correction of inventorship in a patent.

Please check the applicable box(es) below.

For a nonprovisional application:

☑ 1. This request is to correct or change the inventorship in a **nonprovisional** application (**under 37 CFR 1.48(a)**) and includes:

☑ An application data sheet (ADS) in accordance with 37 CFR 1.76(c) with the corrected or updated information shown with markings (*e.g.*, underlining for insertions, strikethrough for deletions). See the Manual of Patent Examining Procedure (MPEP) section 601.05(a) for information about filing an ADS in an application filed on/after September 16, 2012. For information about filing a Supplemental ADS in an application filed before September 16, 2012, see MPEP 601.05(b).

☑ The processing fee set forth in 37 CFR 1.17(i). $ 140

☑ An inventor is being added. An inventor's oath or declaration by any actual inventor who has not yet executed an oath or declaration is required (see 37 CFR 1.48(b)). See MPEP 602.01(a) for information about an inventor's oath or declaration for an application filed on/after September 16, 2012 (*e.g.*, form **PTO/AIA/01**). For information about an inventor's oath or declaration for an application filed before September 16, 2012 (*e.g.*, form **PTO/SB/01**), see MPEP 602.01(b).

☑ This request is being filed after the first Office action on the merits has been given or mailed (see 37 CFR 1.48(c) and 1.17(d)). Check one of the following:

☐ This request to correct or change the inventorship is due solely to the cancellation of claims in the application.

OR

☑ The fee set forth in 37 CFR 1.17(d) is due (in addition to the fee set forth in 37 CFR 1.17(i)). $ 640.00



This collection of information is required by 37 CFR 1.48. 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 1.11 and 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.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

PTO/AIA/40 (04-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# REQUEST FOR CORRECTION IN A PATENT APPLICATION RELATING TO INVENTORSHIP OR AN INVENTOR NAME, OR ORDER OF NAMES, OTHER THAN IN A REISSUE APPLICATION (37 CFR 1.48)

☐ 2. This request is to correct or update the name of the inventor or a joint inventor, or the order of names of joint inventors, in a **nonprovisional** application (**under 37 CFR 1.48(f)**) and includes:

☐ An application data sheet in accordance with 37 CFR 1.76(c) identifying the complete inventive entity, including the corrected or updated name of the inventor, or the new order of names shown with markings (*e.g.*, underlining for insertions, strikethrough for deletions). See the MPEP 601.05(a) for information about filing an ADS in an application filed on/after September 16, 2012. For information about filing a Supplemental ADS in an application filed before September 16, 2012, see MPEP 601.05(b).

☐ The processing fee set forth in 37 CFR 1.17(i). $ _____

**For a provisional application:**

☐ This request is to change or correct the inventorship, or correct or update the name of the inventor or a joint inventor, in a **provisional** application (**under 37 CFR 1.48(d)**) and includes:

☐ **Attached hereto** is a document that is signed by a party set forth in 37 CFR 1.33(b) and identifies each inventor by his or her legal name, in the preferred order. Note: the document may be an application data sheet in accordance with 37 CFR 1.76(c) that identifies the changes with markings (underlining for insertions, strikethrough for deletions).

☐ The processing fee set forth in 37 CFR 1.17(q). $ _____

**Fee Payment Information:**

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously

☐ A check in the amount of the fee is enclosed.

☑ Payment by credit card. Form PTO-2038 is attached.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 50-0665.

☑ Payment made via EFS-Web.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

I am the

☐ Applicant*

☑ attorney or agent of record Registration number 77,516

☐ attorney or agent acting under 37 CFR 1.34 Registration number _____

Signature /Matthew S. Williams/

Typed or printed name Matthew S. Williams

Date 2023-11-21

**NOTE:** This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. *Juristic entities must be represented by a patent practitioner (See 37 CFR 1.31, applicable to any paper filed on or after September 16, 2012 that is presented on behalf of a juristic entity, regardless of application filing date). Submit multiple forms if more than one signature is required, see below**.

☒ ** Total of 1 forms are submitted.

## 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.

UNITED STATES
PATENT AND TRADEMARK OFFICE

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

# ELECTRONIC ACKNOWLEDGEMENT RECEIPT

| APPLICATION # | RECEIPT DATE / TIME | ATTORNEY DOCKET # |
|---|---|---|
| **17/498,642** | **11/21/2023 11:10:38 AM Z ET** | **111552-8023.US02** |

## Title of Invention

SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

## Application Information

| | | | |
|---|---|---|---|
| APPLICATION TYPE | Utility - Nonprovisional Application under 35 USC 111(a) | PATENT # | - |
| CONFIRMATION # | 1040 | FILED BY | JiYoung Anderson |
| PATENT CENTER # | 63335316 | FILING DATE | 10/11/2021 |
| CUSTOMER # | 25096 | FIRST NAMED INVENTOR | Richard Quick |
| CORRESPONDENCE ADDRESS | - | AUTHORIZED BY | Matthew Williams |

## Documents

**TOTAL DOCUMENTS: 3**

| DOCUMENT | PAGES | DESCRIPTION | SIZE (KB) |
|---|---|---|---|
| Corrected Application Data Sheet - 111552-8023US2.pdf | 9 | Application Data Sheet | 328 KB |
| Warning: This is not a USPTO supplied ADS fillable form. Data in the form cannot be automatically loaded to other USPTO systems. | | | |
| Declaration additional - 111552.8023.US02.pdf | 4 | Oath or Declaration filed | 2265 KB |
| 2023-11-21 Request for Correction - 111552.8023.US02.pdf | 3 | Request under Rule 48 correcting inventorship | 228 KB |

## Digest

| DOCUMENT | MESSAGE DIGEST(SHA-512) |
|---|---|
| Corrected Application Data Sheet - 111552-8023US2.pdf | 4EAC300060BCD28F21718E31EF04104B16FE70D7E076288BD CD2895C92DBFE98B5AD70557DE4887AAC4358E140CF49FD0 E2D696752323D2FB884726CA372F503 |
| Declaration additional - 111552.8023.US02.pdf | 11F885ECB238DA539C64F3DB1AE20CB78BFB069AD3AC27A4 BAAA7094CC84C4BD75C77C9EBA62794DFA92D19D9582146D 7567576FCBEB4EABA1EAB1BC9C1F88AE |
| 2023-11-21 Request for Correction - 111552.8023.US02.pdf | 1C74E1E6D2A3BD22AFBE63F1F03A77899191527F0309D2F6A 6CA5F9423C48DD855B5A6F52ED6483E17F3951619CE0D87C3 0DFF92BB5AB443A423927F9A41B2F8 |

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**

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

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

**New International Application Filed with the USPTO as a Receiving Office**

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

# NOTICE OF ALLOWANCE AND FEE(S) DUE

25096 7590 11/08/2023

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

| EXAMINER | |
|---|---|
| NGUYEN, TUAN VAN | |
| **ART UNIT** | **PAPER NUMBER** |
| 3771 | |

DATE MAILED: 11/08/2023

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 17/498,642 | 10/11/2021 | Richard Quick | 111552-8023.US02 | 1040 |

TITLE OF INVENTION: SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

| APPLN. TYPE | ENTITY STATUS | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|---|---|---|---|---|---|---|
| nonprovisional | UNDISCOUNTED | $1200 | $0.00 | $0.00 | $1200 | 02/08/2024 |

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

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

**HOW TO REPLY TO THIS NOTICE:**

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

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

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

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

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

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

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

## PART B - FEE(S) TRANSMITTAL

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

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

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

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence 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. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

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

25096 7590 11/08/2023
PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

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. |
|---|---|---|---|---|
| 17/498,642 | 10/11/2021 | Richard Quick | 111552-8023.US02 | 1040 |

TITLE OF INVENTION: SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

| APPLN. TYPE | ENTITY STATUS | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|---|---|---|---|---|---|---|
| nonprovisional | UNDISCOUNTED | $1200 | $0.00 | $0.00 | $1200 | 02/08/2024 |

| EXAMINER | ART UNIT | CLASS-SUBCLASS |
|---|---|---|
| NGUYEN, TUAN VAN | 3771 | 606-200000 |

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

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

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

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(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)

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

❑ Electronic Payment via Patent Center or 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

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.

❑ Applicant asserting small entity status. See 37 CFR 1.27

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.

❑ Applicant changing to regular undiscounted fee status.

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

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

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

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 17/498,642 | 10/11/2021 | Richard Quick | 111552-8023.US02 | 1040 |

25096 7590 11/08/2023

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

| EXAMINER | |
|---|---|
| NGUYEN, TUAN VAN | |
| **ART UNIT** | **PAPER NUMBER** |
| 3771 | |

DATE MAILED: 11/08/2023

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

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

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

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

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

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

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

## Privacy Act Statement

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

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

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

| *Notice of Allowability* | **Application No.** 17/498,642 | **Applicant(s)** Quick, Richard | |
|---|---|---|---|
| | **Examiner** TUAN V NGUYEN | **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 amendment filed on September 14, 2023.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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

3. ☑ The allowed claim(s) is/are 21-31 and 41-63 . 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 _____.

/TUAN V NGUYEN/
Primary Examiner, Art Unit 3771

***Notice of Pre-AIA or AIA Status***

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

***Allowable Subject Matter***

Claims 21-31 and 41-63 allowed.

Please see Office action dated June 26, 2023 for examiner's statement of reasons for allowance.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached Monday - Friday 8:30 AM - 5:30 PM.

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 published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is

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

/TUAN V NGUYEN/
Primary Examiner, Art Unit 3771

| Search Notes | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 17/498,642 | Quick, Richard |
| | Examiner | Art Unit |
| | TUAN V NGUYEN | 3771 |

| CPC - Searched* | | |
|---|---|---|
| **Symbol** | **Date** | **Examiner** |
| A61M1/60,0001,0003 | 06/17/2023 | TN |
| A61M39/0613 | 06/17/2023 | TN |
| A61B2017/22035,22079,22042,22094,22034 | 06/17/2023 | TN |
| A61B17/221,22031 | 06/17/2023 | TN |
| A61M25/01,0122,0082 | 06/17/2023 | TN |
| A61F2/95 | 06/17/2023 | TN |
| A61M2210/12 | 06/17/2023 | TN |

| 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** |
| Reviewed references cited in parent case | 06/17/2023 | TN |
| Group/subgroups combined with text (see search history printout) | 06/17/2023 | TN |
| Search update (see search history printout) | 11/01/2023 | TN |

| /TUAN V NGUYEN/<br>Primary Examiner, Art Unit 3771 | |
|---|---|

| Search Notes | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 17/498,642 | Quick, Richard |
| | Examiner | Art Unit |
| | TUAN V NGUYEN | 3771 |

| Interference Search | | | |
|---|---|---|---|
| **US Class/CPC Symbol** | **US Subclass/CPC Group** | **Date** | **Examiner** |
| Text search | USPAT; US_PGPUB | 11/01/2023 | TN |

| | |
|---|---|
| /TUAN V NGUYEN/<br>Primary Examiner, Art Unit 3771 | |

| Issue Classification | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 17/498,642 | Quick, Richard |
| | Examiner | Art Unit |
| | TUAN V NGUYEN | 3771 |

| CPC | | | | | | |
|---|---|---|---|---|---|---|
| Symbol | | | | | Type | Version |
| A61B | / | 17 | / | 22031 | F | 2013-01-01 |
| A61M | / | 25 | / | 0082 | I | 2013-01-01 |
| A61B | / | 17 | / | 22 | I | 2013-01-01 |
| A61M | / | 39 | / | 06 | I | 2013-01-01 |
| A61B | / | 17 | / | 221 | I | 2013-01-01 |
| A61B | / | 2017 | / | 22042 | A | 2013-01-01 |
| A61M | / | 2210 | / | 12 | A | 2013-01-01 |
| A61B | / | 2017 | / | 22079 | A | 2013-01-01 |
| A61B | / | 2017 | / | 22094 | A | 2013-01-01 |
| A61B | / | 2017 | / | 22034 | A | 2013-01-01 |
| A61B | / | 2017 | / | 00907 | A | 2013-01-01 |
| A61B | / | 2217 | / | 005 | A | 2013-01-01 |

| CPC Combination Sets | | | | | | | |
|---|---|---|---|---|---|---|---|
| Symbol | | | | | Type | Set | Ranking | Version |
| | / | | / | | | | | |

| NONE | | Total Claims Allowed: | |
|---|---|---|---|
| (Assistant Examiner) | (Date) | 34 | |
| /TUAN V NGUYEN/<br>Primary Examiner, Art Unit 3771 | 01 November 2023 | O.G. Print Claim(s) | O.G. Print Figure |
| (Primary Examiner) | (Date) | 1 | 1 |

U.S. Patent and Trademark Office — Part of Paper No.: 20231101

| Issue Classification | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 17/498,642 | Quick, Richard |
| | Examiner | Art Unit |
| | TUAN V NGUYEN | 3771 |

| INTERNATIONAL CLASSIFICATION | | | | |
|---|---|---|---|---|
| CLAIMED | | | | |
| A61B | / | 17 | / | 22 |
| A61M | / | 25 | / | 00 |
| A61M | / | 39 | / | 06 |
| A61B | / | 17 | / | 221 |

| NON-CLAIMED | | | | |
|---|---|---|---|---|
| | / | | / | |

| US ORIGINAL CLASSIFICATION | |
|---|---|
| CLASS | SUBCLASS |
| | |

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

| NONE<br>(Assistant Examiner) (Date) | Total Claims Allowed: 34 | |
|---|---|---|
| /TUAN V NGUYEN/<br>Primary Examiner, Art Unit 3771<br>(Primary Examiner) 01 November 2023 (Date) | O.G. Print Claim(s)<br>1 | O.G. Print Figure<br>1 |

U.S. Patent and Trademark Office Part of Paper No.: 20231101

| Issue Classification | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 17/498,642 | Quick, Richard |
| | Examiner | Art Unit |
| | TUAN V NGUYEN | 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 | | 10 | | 19 | 8 | 28 | | 37 | 17 | 46 | 29 | 55 | | |
| | 2 | | 11 | | 20 | 12 | 29 | | 38 | 18 | 47 | 21 | 56 | | |
| | 3 | | 12 | 1 | 21 | 9 | 30 | | 39 | 19 | 48 | 22 | 57 | | |
| | 4 | | 13 | 2 | 22 | 10 | 31 | | 40 | 20 | 49 | 23 | 58 | | |
| | 5 | | 14 | 3 | 23 | | 32 | 11 | 41 | 24 | 50 | 30 | 59 | | |
| | 6 | | 15 | 4 | 24 | | 33 | 13 | 42 | 25 | 51 | 31 | 60 | | |
| | 7 | | 16 | 5 | 25 | | 34 | 14 | 43 | 26 | 52 | 32 | 61 | | |
| | 8 | | 17 | 6 | 26 | | 35 | 15 | 44 | 27 | 53 | 33 | 62 | | |
| | 9 | | 18 | 7 | 27 | | 36 | 16 | 45 | 28 | 54 | 34 | 63 | | |

| NONE | | Total Claims Allowed: | |
|---|---|---|---|
| (Assistant Examiner) | (Date) | 34 | |
| /TUAN V NGUYEN/<br>Primary Examiner, Art Unit 3771 | 01 November 2023 | O.G. Print Claim(s) | O.G. Print Figure |
| (Primary Examiner) | (Date) | 1 | 1 |

U.S. Patent and Trademark Office — Part of Paper No.: 20231101

## PE2E SEARCH - Search History (Prior Art)

| Ref # | Hits | Search Query | DBs | Default Operator | Plurals | British Equivalents | Time Stamp |
|---|---|---|---|---|---|---|---|
| L183 | 7 | ("20150352325" "20070038225" "20150025555" "20220240959" "5911710" "8057497" "20150173782").pn. | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/19 12:06 PM |
| L184 | 8 | ("20150352325" "20070038225" "20150025555" "20220240959" "5911710" "8057497" "20150173782" "5197485").pn. | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/19 12:06 PM |
| L185 | 166 | A61B2017/22034,22042,22079,22094.cpc. AND (reservoir container collect$4) WITH (debris thromb$5 embol$5) AND filter SAME valve | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/19 03:18 PM |
| L186 | 13 | A61B17/220758,320725.cpc. AND (reservoir container collect$4) SAME filter SAME valve | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/19 03:18 PM |
| L187 | 139 | A61B17/22031,22,221.cpc. AND (reservoir container collect$4) SAME filter SAME valve | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/19 03:18 PM |
| L188 | 487 | A61M39/0613.cpc. | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/19 09:55 PM |
| L189 | 27 | ("10772636"\|"11166703"\|"20050203605"\|"20160192912"\|"20210038385"\|"20210393278"\|"5256150"\|"5330436"\|"6152144"\|"6540722"\|"7128073"\|"7152605"\|"7678131"\|"7713282"\|"7722641"\|"8080032"\|"8480708"\|"8523897"\|"8535343"\|"8647367"\|"8784469"\|"8834519"\|"9011551"\|"9168043"\|"9301769"\|"9566073"\|"9717488").PN. | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/24 08:28 AM |
| L190 | 14 | ("10531883"\|"10960114"\|"20050004534"\|"20060264905"\|"20100094201"\|"20100106081"\|"20160030708"\|"20160106353"\|"20160135829"\|"20170021130"\|"20190365 | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/24 08:28 AM |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | 395"\|"5234403"\|"5244619"\|"9581942").PN. | | | | | |
| L191 | 18 | ("11697011"\|"11697012"\|"20130030460"\|"20130144326"\|"20130204297"\|"20140005715"\|"20140180397"\|"20140222070"\|"20140324091"\|"20150018859"\|"20150150672"\|"20150196744"\|"20160038267"\|"20160367285"\|"20230200970"\|"20230218310"\|"20230218313"\|"20230218383").PN. | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/24 08:29 AM |
| L192 | 8 | ("10183159"\|"20070233043"\|"20230233311"\|"20230240705"\|"20230240706"\|"20230241302"\|"8343167"\|"8568465").PN. | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/24 08:29 AM |
| L193 | 55 | ("10058339"\|"10384034"\|"10456555"\|"10485952"\|"10926060"\|"10953195"\|"1101890"\|"11065019"\|"11185664"\|"11224450"\|"11224721"\|"11305094"\|"11383064"\|"11395903"\|"11576691"\|"11596768"\|"11744691"\|"20040019310"\|"20080312681"\|"20110071503"\|"20120109109"\|"20130150793"\|"20170143359"\|"20170143938"\|"20170281204"\|"20180055999"\|"20180250498"\|"20190015298"\|"20190366036"\|"20200046940"\|"20200121334"\|"20210138194"\|"20210205577"\|"20210404464"\|"20220033888"\|"20220370761"\|"20230059721"\|"20230122587"\|"20230248380"\|"20230270991"\|"3416531"\|"3860006"\|"4981478"\|"5391152"\|"5639276"\|"5971958"\|"7122034"\|"7481805"\|"7815608"\|"8021351"\|"8070694"\|"9241669"\|"9265512"\|"9532792"\|"9662129").PN. | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/24 08:29 AM |
| L194 | 10 | ("20030023263"\|"20030135151"\|"20040039351"\|"20110152889"\|"20140180055"\|"2020002271 | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/24 08:30 AM |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | 1"\|"20230310137"\|"20230310138"\|"20230310751"\|"6017335").PN. | | | | | |
| L195 | 1 | ("10799331").pn. | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/24 08:55 AM |

## PE2E SEARCH - Search History (Interference)

| Ref # | Hits | Search Query | DBs | Default Operator | Plurals | British Equivalents | Time Stamp |
|---|---|---|---|---|---|---|---|
| N75 | 1 | (method SAME clot SAME vessel AND positioning SAME distal SAME elongated WITH shaft SAME clot AND pre NEAR charging SAME vacuum SAME pressure WITH source AND fluidly SAME connecting SAME pressure WITH source SAME shaft AND unsealing SAME attach$5 WITH member SAME shaft AND advancing SAME device SAME through SAME attach$5 WITH member SAME shaft AND engaging SAME device SAME second WITH portion SAME clot).clm. | (US-PGPUB; USPAT) | OR | ON | ON | 2023/11/01 09:12 AM |

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

| U.S. PATENTS AND PUBLICATIONS | | | | | |
|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | 1. | 20230233311 | 07-27-2023 | Merritt et al. | |
| | 2. | 20070233043 | 10-04-2007 | Dayton et al. | |
| | 3. | 8343167 | 01-01-2023 | Henson | |
| | 4. | 8568465 | 10-29-2013 | Freudenthal et al. | |
| | 5. | 20230241302 | 08-03-2023 | Merritt et al. | |
| | 6. | 20230240705 | 08-03-2023 | Rosenbluth et al. | |
| | 7. | 20230240706 | 08-03-2023 | Rosenbluth et al. | |
| | 8. | 10183159 | 01-22-2019 | Nobles et al. | |
| | 9. | 20190366036 | 12-05-2019 | Jalgaonkar et al. | |
| | 10. | 20110071503 | 03-24-2011 | TAKAGI et al. | |
| | 11. | 20120109109 | 05-03-2012 | KAJII | |
| | 12. | 20100016837 | 01-21-2010 | HOWAT | |
| | 13. | 20180250498 | 09-06-2018 | Stern et al. | |
| | 14. | 11744691 | 09-05-2023 | Merritt et al. | |
| | 15. | 20230248380 | 08-10-2023 | Long et al. | |
| | 16. | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Foreign Document Number[3] | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[5] |
| | 1. | WO2023137341 | 07-20-2023 | Inari Medical, Inc. | | |
| | 2. | WO2015179329 | 11-26-2015 | WALK VASCULAR, LLC | | |
| | 3. | WO2023147353 | 08-03-2023 | Inari Medical, Inc. | | |



ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.V.N/

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

| NON-PATENT LITERATURE DOCUMENTS | | | |
|---|---|---|---|
| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T[5] |
| | | | |
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| EXAMINER SIGNATURE | | | |
|---|---|---|---|
| Examiner Signature | /TUAN V NGUYEN/ | Date Considered | 11/01/2023 |

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

## CERTIFICATION STATEMENT

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

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

**OR**

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

☐ See attached certification statement.

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

☐ None

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information that may be material to the examination of this

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

PTO/SB/08a (01-10)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, Applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

**COPIES OF REFERENCES**

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

## SIGNATURE

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

| | | | |
|---|---|---|---|
| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2023-08-29 |
| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

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



ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.V.N/

# Bibliographic Data

Application No: 17/498,642

Foreign Priority claimed: ○ Yes ◉ No

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

Verified and Acknowledged: /TUAN V NGUYEN/ (Examiner's Signature) | (Initials)

Title: SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

| FILING or 371(c) DATE | CLASS | GROUP ART UNIT | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 10/11/2021 | 606 | 3771 | 111552-8023.US02 |
| RULE | | | |

**APPLICANTS**

Inari Medical, Inc., Irvine, CA,

**INVENTORS**

Richard Quick, Mission Viejo, CA, UNITED STATES

**CONTINUING DATA**

This application is a CON of 16258344 01/25/2019 PAT 11154314

16258344 has PRO of 62622691 01/26/2018

**FOREIGN APPLICATIONS**

**IF REQUIRED, FOREIGN LICENSE GRANTED****

10/20/2021

**STATE OR COUNTRY**

UNITED STATES

**ADDRESS**

PERKINS COIE LLP - SEA General

PATENT-SEA

P.O. BOX 1247

SEATTLE, WA 98111-1247

UNITED STATES

**FILING FEE RECEIVED**

$4,300

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

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

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| | **Attorney Docket Number** | 111552-8023.US02 |

| U.S. PATENTS AND PUBLICATIONS | | | | | |
|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | 1. | 11648028 | 05-16-2023 | Rosenbluth et al. | |
| | 2. | 5030201 | 07-09-1991 | Palestrant | |
| | 3. | 11642209 | 05-09-2023 | Merritt et al. | |
| | 4. | 6540722 | 04-01-2003 | Boyle et al. | |
| | 5. | 7678131 | 03-16-2010 | Muller | |
| | 6. | 9301769 | 04-05-2016 | Brady et al. | |
| | 7. | 20210393278 | 12-23-2021 | O'MALLEY et al. | |
| | 8. | 20210038385 | 02-11-2021 | Popp et al. | |
| | 9. | 20050203605 | 09-15-2005 | Dolan | |
| | 10. | 6152144 | 11-28-2000 | Lesh et al. | |
| | 11. | 9011551 | 04-21-2015 | Oral et al. | |
| | 12. | 8647367 | 02-11-2014 | Kassab et al. | |
| | 13. | 11166703 | 11-09-2021 | Kassab et al. | |
| | 14. | 8834519 | 09-16-2014 | van der Burg et al. | |
| | 15. | 7713282 | 05-11-2010 | Frazier et al. | |
| | 16. | 8080032 | 12-20-2011 | van der Burg et al. | |
| | 17. | 7722641 | 05-25-2010 | van der Burg et al. | |
| | 18. | 8523897 | 09-03-2013 | van der Burg et al. | |
| | 19. | 8535343 | 09-17-2013 | van der Burg et al. | |
| | 20. | 7152605 | 12-26-2006 | Khairkhahan et al. | |
| | 21. | 9168043 | 10-27-2015 | van der Burg et al. | |
| | 22. | 7128073 | 10-31-2006 | van der Burg et al. | |
| | 23. | 10772636 | 09-15-2020 | Kassab et al. | |
| | 24. | 8480708 | 07-09-2013 | Kassab et al. | |
| | 25. | 9717488 | 08-01-2017 | Kassab et al. | |
| | 26. | 8784469 | 07-22-2014 | Kassab | |
| | 27. | 9566073 | 02-14-2017 | Kassab et al. | |
| | 28. | 20160192912 | 07-07-2016 | Kassab et al. | |
| | 29. | 20160030708 | 02-04-2016 | Casiello et al. | |
| | 30. | 20160135829 | 05-19-2016 | Holoehwost et ah | |
| | 31. | 20060264905 | 11-23-2006 | Eskridge et al. | |





ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.V.N/

Doc code: IDS
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| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

| U.S. PATENTS AND PUBLICATIONS | | | | | |
|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | 32. | 5244619 | 09-14-1993 | Burnham | |
| | 33. | 20170021130 | 01-26-2017 | Dye | |
| | 34. | 20160106353 | 04-21-2016 | Schuetz et al. | |
| | 35. | 10960114 | 03-30-2021 | Goisis | |
| | 36. | 10531883 | 01-14-2020 | Deville et al. | |
| | 37. | 9581942 | 02-28-2017 | Shippert | |
| | 38. | 5234403 | 08-10-1993 | Yoda et al. | |
| | 39. | 20100106081 | 04-29-2010 | Brandeis | |
| | 40. | 20100094201 | 04-15-2010 | Mallaby | |
| | 41. | 20050004534 | 01-06-2005 | Lockwood et al. | |
| | 42. | 20190365395 | 12-05-2019 | Tran et al. | |
| | 43. | 20160038267 | 02-11-2016 | ALLEN et al. | |
| | 44. | 20140222070 | 08-07-2014 | BELSON et al. | |
| | 45. | 20130204297 | 08-08-2013 | Melsheimer et al. | |
| | 46. | 11697012 | 07-11-2023 | Merritt et al. | |
| | 47. | 11697011 | 07-11-2023 | Merritt et al. | |
| | 48. | 20230218310 | 07-13-2023 | Scheinblum et al. | |
| | 49. | 20230218383 | 07-13-2023 | Merritt et al. | |
| | 50. | 20230218313 | 07-13-2023 | Rosenbluth et al. | |
| | 51. | 20230200970 | 06-29-2023 | Merritt et al. | |
| | 52. | 20140324091 | 10-30-2014 | Rosenbluth et al. | |
| | 53. | 20150018859 | 01-15-2015 | Quick et al. | |
| | 54. | 20150196744 | 07-16-2015 | Aboytes | |
| | 55. | 20160367285 | 12-22-2016 | Sos | |
| | 56. | 20130144326 | 06-06-2013 | Brady et al. | |
| | 57. | 20140005715 | 01-02-2014 | Castella et al. | |
| | 58. | 20140180397 | 06-26-2014 | Gerberding et al. | |
| | 59. | 20150150672 | 06-04-2015 | Ma | |
| | 60. | 20130030460 | 01-31-2013 | Marks et al. | |
| | 61. | | | | |
| | 62. | | | | |



ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.V.N/

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

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| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Foreign Document Number[3] | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[5] |
| | 1. | WO2016014955 | 01-28-2016 | OSTEOMEDIX, INC. | | |
| | 2. | EP2942624 | 11-11-2015 | Kim, Hong | | |
| | 3. | WO2006029270 | 03-16-2006 | SMITH & NEPHEW, INC. | | |

| NON-PATENT LITERATURE DOCUMENTS | | | |
|---|---|---|---|
| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T[5] |
| | | International Search Report and Written Opinion for International App. No. PCT/US23/60502; Date of Filing: January 11, 2023, Applicant: Inari Medical, Inc., Date of Mailing: May 25, 2023, 9 pages. | |
| | | International Search Report and Written Opinion for International App. No. PCT/US23/61256; Date of Filing: January 25, 2023, Applicant: Inari Medical, Inc., Date of Mailing: June 7, 2023, 8 pages. | |
| | | Gross et al., "Dump the pump: manual aspiration thrombectomy (MAT) with a syringe is technically effective, expeditious, and cost-efficient," J NeuroIntervent Surg, 2018, 4 pages. | |
| | | | |

| EXAMINER SIGNATURE | | | |
|---|---|---|---|
| Examiner Signature | /TUAN V NGUYEN/ | Date Considered | 11/01/2023 |

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.



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| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

## CERTIFICATION STATEMENT

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

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

**OR**

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

☐ See attached certification statement.

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

☐ None

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

### COPIES OF REFERENCES

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

## SIGNATURE

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

| | | | |
|---|---|---|---|
| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2023-07-18 |
| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

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



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UNITED STATES
PATENT AND TRADEMARK OFFICE

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

# ELECTRONIC ACKNOWLEDGEMENT RECEIPT

| APPLICATION # | RECEIPT DATE / TIME | ATTORNEY DOCKET # |
|---|---|---|
| **17/498,642** | **09/14/2023 12:41:38 PM ET** | **111552-8023.US02** |

## Title of Invention

SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

## Application Information

| | | | |
|---|---|---|---|
| APPLICATION TYPE | Utility - Nonprovisional Application under 35 USC 111(a) | PATENT # | - |
| CONFIRMATION # | 1040 | FILED BY | JiYoung Anderson |
| PATENT CENTER # | 62796725 | FILING DATE | 10/11/2021 |
| CUSTOMER # | 25096 | FIRST NAMED INVENTOR | Richard Quick |
| CORRESPONDENCE ADDRESS | - | AUTHORIZED BY | Matthew Williams |

## Documents

**TOTAL DOCUMENTS: 3**

| DOCUMENT | | PAGES | DESCRIPTION | SIZE (KB) |
|---|---|---|---|---|
| 2023-9-14 Response to 2023-09-06 Notice of Non-compliant Amendment - 111552.8023.US02.pdf | | 9 | - | 60 KB |
| 2023-9-14 Response to 2023-09-06 Notice of Non-compliant Amendment - 111552.8023.US02-SA...pdf | (1-1) | 1 | Supplemental Response or Supplemental Amendment | 16 KB |
| 2023-9-14 Response to 2023-09-06 Notice of Non-compliant Amendment - 111552.8023.US02- | (2-6) | 5 | Amendment Copy Claims/Response to Suggested Claims | 30 KB |

| | | | | |
|---|---|---|---|---|
| IACS.pdf | | | | |
| 2023-9-14 Response to 2023-09-06 Notice of Non-compliant Amendment - 111552.8023.US02-REM.pdf | (7-9) | 3 | Applicant Arguments/Remarks Made in an Amendment | 36 KB |

## Digest

| DOCUMENT | MESSAGE DIGEST(SHA-512) |
|---|---|
| 2023-9-14 Response to 2023-09-06 Notice of Non-compliant Amendment - 111552.8023.US02.pdf | C5135EB862DCF51F3A0EE5C9D48F6DF9980B11F96656E5D47264B1D7EBB0B9F24D8D4C761A73729CD1A8AFFDE50146A615712DE2320445119C4BF6B335546D3E |
| 2023-9-14 Response to 2023-09-06 Notice of Non-compliant Amendment - 111552.8023.US02-SA...pdf | 0919DCA69D6BD2DF175DDA29A9B83DDCB1DF6415BD89B418916E37FE31B72C5427F49D9F92A1EF125FDB35D67CA2294F94B8310CB042DC29218EC06A63D4497F |
| 2023-9-14 Response to 2023-09-06 Notice of Non-compliant Amendment - 111552.8023.US02-IACS.pdf | 5029C2891AFF9FB1422960A848513A03A20CD8DD9B03B74C398C5EE550D8A7879C9A4B732E1EB18D28028A3DD97540A7EC89ABF1C0BF75D5BE6FD8CA94C36ED3 |
| 2023-9-14 Response to 2023-09-06 Notice of Non-compliant Amendment - 111552.8023.US02-REM.pdf | 80033228BD15C283D8DC01440D9EAAE9AFF978D74CB8FA219C4037DE9B937283280BF480F0BDDF242ED9D527BB8F009056495F39BF757357AAC8FBDF6720EF06 |

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

**New Applications Under 35 U.S.C. 111**

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

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

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

**New International Application Filed with the USPTO as a Receiving Office**

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

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

In re Application of:

Richard Quick

Application No.: 17/498,642

Filed: October 11, 2021

For: SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

Conf. No.: 1040

Art Unit: 3771

Examiner: Tuan Van Nguyen

Customer No. 25096

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

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

Dear Commissioner:

In response to the Non-Compliant Amendment mailed on September 6, 2023 and Office Action mailed on June 26, 2023, please amend and consider the above-identified application as follows:

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

**Remarks** begin on page 7.

## AMENDMENTS TO THE CLAIMS

Please amend claim 29, cancel claims 28[1] and 32–40, and add new claims 41–63. Following is a complete listing of the claims pending in the application, as amended:

1–20. (Canceled)

21. (Previously Presented) A method for the intravascular treatment of clot material within a blood vessel, the method comprising:

positioning a distal portion of an elongated shaft proximate to the clot material within the blood vessel;

pre-charging a vacuum in a pressure source;

fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft;

unsealing an attachment member coupled to a proximal portion of the elongated shaft;

advancing an interventional device distally through the attachment member and the elongated shaft; and

engaging the interventional device with a second portion of the clot material remaining within the blood vessel.

22. (Previously Presented) The method of claim 21 wherein the method further comprises withdrawing the interventional device and the second portion of the clot material into the elongated shaft.

23. (Previously Presented) The method of claim 22 wherein the method further comprises withdrawing the interventional device and the second portion of the clot material through the attachment member.

[1] The Applicant notes that two claims were erroneously labeled as "claim 28." The Applicant cancels the second of the two listed claims 28 herein and re-presents this claim as new claim 41.

24. (Previously Presented) The method of claim 23 wherein the method further comprises unsealing the attachment member before withdrawing the interventional device and the second portion of the clot material through the attachment member.

25. (Previously Presented) The method of claim 21 wherein unsealing the attachment member includes exercising a valve of the attachment member such that a lumen of the attachment member has a diameter that is about equal to an inner diameter of the elongated shaft.

26. (Previously Presented) The method of claim 21 wherein unsealing the attachment member includes pressing one or more buttons on the attachment member.

27. (Previously Presented) The method of claim 21 wherein the pressure source is a syringe.

28. (Previously Presented) The method of claim 27 wherein pre-charging the vacuum includes withdrawing a plunger of the syringe.

29. (Currently Amended) The method of claim ~~28–~~41 wherein pre-charging the vacuum in the pressure source includes activating the pressure source while the fluid control device is closed, and wherein fluidly connecting the pressure source to the elongated shaft includes opening the fluid control device.

30. (Previously Presented) The method of claim 21 wherein fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum generates suction at the distal portion of the elongated shaft.

31. (Previously Presented) The method of claim 21 wherein the blood vessel is a pulmonary blood vessel.

32–40. (Canceled)

41. (New) The method of claim 21 wherein the pressure source is fluidly coupled to the elongated shaft via a fluid control device, and wherein (a) opening of the fluid control device fluidly connects the pressure source to the elongated shaft and (b) closing of the fluid control device fluidly disconnects the pressure source from the elongated shaft.

42. (New) The method of claim 41 wherein the fluid control device comprises a user-actuatable valve.

43. (New) The method of claim 21 wherein the attachment member comprises a hemostasis valve.

44. (New) The method of claim 43 wherein the hemostasis valve includes a tubular member, a button, and a filament coupled to the button and the tubular member, and wherein unsealing the hemostasis valve includes pressing the button to loosen the filament to allow the tubular member to expand.

45. (New) The method of claim 44 wherein the method further comprises, after at least partially advancing the interventional device distally through the hemostasis valve, releasing the button to tighten the filament to allow the tubular member to collapse and seal about a portion of the interventional device.

46. (New) The method of claim 45 wherein the hemostasis valve further includes a spring, and wherein releasing the button to tighten the filament includes driving the button with the spring to tighten the filament.

47. (New) The method of claim 21 wherein the method further comprises collecting at least some of the first portion of the clot material within a filter chamber fluidly coupled between the pressure source and the elongated shaft.

48. (New) The method of claim 47 wherein the method further comprises removing a filter from within the filter chamber to provide access to the at least some of the first portion of the clot material.

49. (New) The method of claim 48 wherein the filter includes a plurality of pores sized to inhibit the clot material from flowing therethrough and to permit blood to flow therethrough.

50. (New) The method of claim 47 wherein the filter chamber is spaced apart from the pressure source and connected to the pressure source via at least one tube.

51. (New) The method of claim 47 wherein the filter chamber comprises a housing and a filter within the housing, and wherein the housing includes—

a port configured to be fluidly coupled to the elongated shaft via at least one first tube; and

a fluid connector configured to be coupled to the pressure source via at least one second tube, wherein the filter is in the housing and fluidly coupled between the port and the fluid connector, and wherein the elongated shaft is fluidly coupled to the pressure source via the filter chamber.

52. (New) The method of claim 51 wherein the elongated shaft is fluidly coupled to the pressure source via the filter chamber along a first fluid path.

53. (New) The method of claim 52 wherein the attachment member is fluidly coupled to the elongated shaft along a second fluid path at least partially different than the first fluid path.

54. (New) The method of claim 53 wherein the attachment member comprises a hemostasis valve.

55. (New) The method of claim 54 wherein unsealing the hemostasis valve includes actuating at least one button of the hemostasis valve.

56. (New) The method of claim 47 wherein the filter chamber is fluidly coupled to the elongated shaft via a first fluid path, wherein the attachment member is fluidly coupled to the elongated shaft along a second fluid path, and wherein the first fluid path branches from the second fluid path.

57. (New) The method of claim 56 wherein the attachment member is a hemostasis valve.

58. (New) The method of claim 57 wherein unsealing the hemostasis valve includes actuating at least one button of the hemostasis valve.

59. (New) The method of claim 21 wherein engaging the interventional device with the second portion of the clot material remaining within the blood vessel includes translating the interventional device relative to the elongated shaft.

60. (New) The method of claim 21 wherein the method further comprises flushing the clot container with a fluid after aspirating the first portion of the clot material into the elongated shaft and/or after engaging the interventional device with the second portion of the clot material.

61. (New) The method of claim 60 wherein the fluid is saline.

62. (New) The method of claim 21 wherein the pressure source is coupled to the elongated shaft via at least one tube, and wherein the method further comprises flushing the at least one tube with a fluid after aspirating the first portion of the clot material into the elongated shaft and/or after engaging the interventional device with the second portion of the clot material.

63. (New) The method of claim 62 wherein the fluid is saline.

## REMARKS

Claims 21–40 were pending when the present Office Action was mailed on June 26, 2023. In this response, claims 32–40 have been canceled without commenting on or conceding the merits of the rejections of these claims and without prejudice to or disclaimer of pursuing the subject matter of these claims in a continuation or other related application. Further, the Applicant notes that two claims were erroneously labeled as "claim 28." The second of the two listed claims 28 has been canceled herein and re-presented as new claim 41. Further, new claims 42–63 have been added in this response. Accordingly, claims 21–31 and 41–63 are currently pending.

The status of the application in light of this Office Action is as follows:

(A) Claims 32 and 37–39 were rejected under 35 U.S.C. § 102(a)(1) over U.S. Patent Application Publication No. 2015/0352325 to Quick ("Quick"); and claims 33–36 and 40 were rejected under 35 U.S.C. § 103 over a combination of Quick and U.S. Patent No. 5,256,150 to Quiachon et al. ("Quiachon"); and

(B) Claims 21–31 were allowed.

A. Response to the Section 102/103 Rejections of Claims 32–40

Claims 32 and 37–39 were rejected under 35 U.S.C. § 102(a)(1) over Quick. Claims 22–36 and 40 were rejected under 35 U.S.C. § 103 over the combination of Quick and Quiachon. Without commenting on or conceding the merits of the rejections of these claims, claims 32–40 have been canceled in this response to expedite prosecution of this application. Accordingly, the rejection of these claims is now moot.

B. Indication of Allowable Subject Matter

Claims 21–31 were allowed. The Applicant thanks the Examiner for indicating that claims 21–31 are allowable. Although the undersigned attorney agrees with the Examiner's conclusion that claims 21–31 are allowable, the undersigned attorney notes that these claims may be allowable for reasons other than those identified by the Examiner and does not concede that the Examiner's characterization of the terms of these claims and the prior art are correct.

C. New Claims 41–63

New claims 41–63 depend from independent claim 21. Accordingly, new claims 41–63 are patentable for at least the same reasons as allowable claim 21, and for the additional features of these dependent claims.

Conclusion

In view of the foregoing, the pending claims comply with 35 U.S.C. § 112 and are patentable over the applied references. The Applicant accordingly requests reconsideration of the application and respectfully submits that the application be allowed. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to contact the undersigned practitioner at 206.359.3343.

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or applied references, the Applicant is not conceding that previously pending claims are not patentable over the cited references; instead, any alteration or characterizations are made to expedite prosecution of this application. Silence regarding a position taken, or argument made, in the Office Action does not indicate Applicant acquiesces to that position or argument. Furthermore, arguments made with respect to a particular claim or claims apply only to those claim or claims, and not to other claims or patents/applications, unless specifically noted herein.

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

Please charge any underpayment or credit any overpayment to Deposit Account No. 50-0665, under Order No. 111552-8023.US02 from which the undersigned is authorized to draw.

Respectfully submitted,

Dated: _____September 14, 2023_____ By: /Matthew S. Williams/

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| **PATENT APPLICATION FEE DETERMINATION RECORD**<br>Substitute for Form PTO-875 | Application or Docket Number<br>17/498,642 | Filing Date<br>10/11/2021 | ☐ To be Mailed |
|---|---|---|---|

**ENTITY:** ☑ LARGE ☐ SMALL ☐ MICRO

**APPLICATION AS FILED - PART I**

| FOR | (Column 1)<br>NUMBER FILED | (Column 2)<br>NUMBER EXTRA | | RATE ($) | FEE ($) |
|---|---|---|---|---|---|
| ☐ BASIC FEE<br>(37 CFR 1.16(a), (b), or (c)) | N/A | N/A | | N/A | |
| ☐ SEARCH FEE<br>(37 CFR 1.16(k), (i), or (m)) | N/A | N/A | | N/A | |
| ☐ EXAMINATION FEE<br>(37 CFR 1.16(o), (p), or (q)) | N/A | N/A | | N/A | |
| TOTAL CLAIMS<br>(37 CFR 1.16(i)) | minus 20 = | * | | x $100 = | |
| INDEPENDENT CLAIMS<br>(37 CFR 1.16(h)) | minus 3 = | * | | x $480 = | |
| ☐ APPLICATION SIZE FEE (37 CFR 1.16(s)) | If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). | | | | |
| ☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j)) | | | | | |
| * If the difference in column 1 is less than zero, enter "0" in column 2. | | | | TOTAL | |

**APPLICATION AS AMENDED - PART II**

| AMENDMENT | 09/14/2023 | (Column 1)<br>CLAIMS REMAINING AFTER AMENDMENT | | (Column 2)<br>HIGHEST NUMBER PREVIOUSLY PAID FOR | (Column 3)<br>PRESENT EXTRA | | RATE ($) | ADDITIONAL FEE ($) |
|---|---|---|---|---|---|---|---|---|
| | Total<br>(37 CFR 1.16(i)) | * 34 | Minus | ** 34 | = 0 | | x $100 = | 0 |
| | Independent<br>(37 CFR 1.16(h)) | * 1 | Minus | *** 3 | = 0 | | x $480 = | 0 |
| | ☐ Application Size Fee (37 CFR 1.16(s)) | | | | | | | |
| | ☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) | | | | | | | |
| | | | | | | | TOTAL ADD'L FEE | 0 |

| AMENDMENT | | (Column 1)<br>CLAIMS REMAINING AFTER AMENDMENT | | (Column 2)<br>HIGHEST NUMBER PREVIOUSLY PAID FOR | (Column 3)<br>PRESENT EXTRA | | RATE ($) | ADDITIONAL FEE ($) |
|---|---|---|---|---|---|---|---|---|
| | Total<br>(37 CFR 1.16(i)) | * | Minus | ** | = | | x $0 = | |
| | Independent<br>(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. | PSS |
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| *** 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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| EXAMINER |
|---|
| NGUYEN, TUAN VAN |

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

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

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

patentprocurement@perkinscoie.com

| Notice of Non-Compliant Amendment (37 CFR 1.121) | Application No. 17/498,642 | Applicant(s) Quick, Richard |
|---|---|---|
| | Art Unit OMBL | AIA (FITF) Status Yes |

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

The amendment document filed on 08/29/2023 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
  - ☐ A. Amended paragraph(s) do not include markings.
  - ☐ B. New paragraph(s) should not be underlined.
  - ☐ C. Other _____ .
- ☐ 2. Abstract:
  - ☐ A.Not presented on a separate sheet. 37 CFR 1.72.
  - ☐ B.Other _____ .
- ☐ 3. Amendments to the drawings:
  - ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet", "New Sheet", or "Annotated Sheet" as required by 37 CFR 1.121(d).
  - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required .
  - ☐ C. Other _____ .
- ☑ 4. Amendments to the claims:
  - ☐ A. A complete listing of all of the claims is not present.
  - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
  - ☑ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
  - ☑ D. The claims of this amendment paper have not been presented in ascending numerical order.
  - ☑ E. Other: Claim number 28 status identifier is improper, listed twice as "previously presented" and " canceled" .
- ☐ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4): For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance, or a drawing submission (only) If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.
2. Applicant is given **two months** from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a Quayle action. If any of above boxes 1 to 4 are checked, the correction required is only the corrected section of the non-compliant amendment in compliance with 37 CFR 1.121.

**Extensions of time** are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

**Failure to timely respond** to this notice will result in:

**Abandonment** of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

**Non-entry** of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

Legal Instruments Examiner (LIE), if applicable /FIKIRTE A GEREMEW/ Telephone No: (703)756-1930

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(54) **Title**: SYSTEMS AND METHODS FOR REMOVAL OF BLOOD AND THROMBOTIC MATERIAL

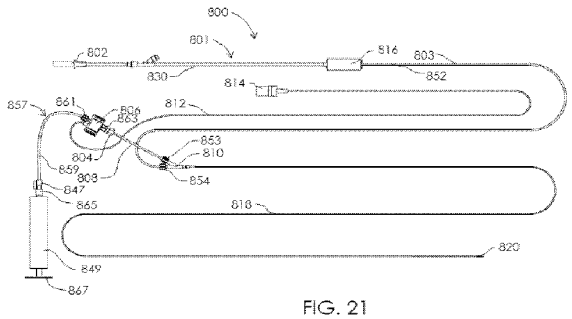



FIG. 21

(57) **Abstract**: A system for aspirating thrombus includes a catheter having a supply lumen having a distal end and an aspiration lumen configured to couple to a vacuum source and having an interior wall surface and an open distal end, an orifice at or near the distal end of the supply lumen, in fluid communication with the interior of the aspiration lumen, the orifice located proximally of the open distal end of the aspiration lumen, wherein the orifice is configured to create a spray pattern that impinges on the interior wall surface of the aspiration lumen when a distal end of the aspiration catheter is immersed within an aqueous environment, and a disposable tubing set having a first conduit configured to couple the supply lumen of the aspiration catheter to a fluid source, and a pump component associated with the first conduit and configured to detachably couple to a drive unit.

WO 2015/179329 A1

# SYSTEMS AND METHODS FOR REMOVAL OF BLOOD AND THROMBOTIC MATERIAL

## BACKGROUND OF THE INVENTION

### Field of the Invention

**[0001]** The present disclosure pertains generally to medical devices and methods of their use. More particularly, the present invention pertains to aspiration and thrombectomy devices and methods of use thereof.

### Description of the Related Art

**[0002]** Several devices and systems already exist to aid in the removal of thrombotic material. These include simple aspiration tube type devices using vacuum syringes to extract thrombus into the syringe, simple flush-and-aspirate devices, more complex devices with rotating components the pull in, macerate and transport thrombotic material away from the distal tip using a mechanical auger, systems that use very high pressure to macerate the thrombus and create a venturi effect to flush the macerated material away.

**[0003]** All of the devices described above have limitations as a result of individual design characteristics. For example, simple aspiration catheters offer ease of use and rapid deployment but may become blocked or otherwise inoperable when faced with older, more organized thrombotic material. Such devices must be removed and cleared outside the body and then re-inserted into the vasculature, which lengthens the time needed for the procedure and increases the opportunity to kink the catheter shaft. Such kinks may reduce performance by decreasing the cross-sectional area of the catheter or may render the device inoperable.

**[0004]** Mechanical rotary devices use an auger to grab and carry the thrombus away from the target area. Some create transport force via vacuum bottles while others create differential pressure at the distal tip of the device with the auger acting as a low pressure pump. These devices typically work slowly and offer the physician no feedback as to when the device should be advanced further into the lesion.

**[0005]** Flushing type devices include manual flush type devices in which the physician manipulates a hand-driven pump to provide flowing saline at the tip of the device to break up and aspirate the thrombus material, which may introduce performance variations based on the ability of the physician to consistently pump the device over the duration of the procedure. Flushing devices also include high pressure flushing devices that macerate the thrombus and then, using a vortex created by the high pressure fluid, transport the emulsified thrombotic material to a collection bag. These devices are effective at removing all levels of thrombotic material, but the pressure created by the device is so great that its action against certain vessel walls may interrupt the heart muscle stimulation mechanism and create a bradycardia event in certain patients, sometimes requiring that a pacing lead be placed in the patient prior to use. Further, interacting with the thrombotic material outside of the catheter may allow loose material to escape the capture mechanism.

## SUMMARY OF THE INVENTION

**[0006]** In one embodiment of the present invention, a system for aspirating thrombus includes an aspiration catheter having a supply lumen and an aspiration lumen, the supply lumen having a wall and a closed distal end, the aspiration lumen configured to couple to a vacuum source and having an interior wall surface, and an open distal end, an orifice in the wall of the supply lumen, in fluid communication with the interior of the aspiration lumen, the orifice located proximally of the open distal end of the aspiration lumen and adjacent the closed distal end of the supply lumen, wherein the orifice is configured to create a spray pattern when pressurized fluid is pumped through the supply lumen such that the spray pattern impinges on the interior wall surface of the aspiration lumen when a distal end of the aspiration catheter is immersed within an aqueous environment, and a disposable tubing set having a first conduit configured to couple to the supply lumen of the aspiration catheter to a fluid source, and a pump component associated with the first conduit and configured to detachably couple to a drive unit, such that motion from the drive unit is transferred to the pump component such that resultant motion of the pump component causes fluid from the fluid source to be injected through the supply lumen of the aspiration catheter, and through the orifice into the aspiration lumen.

**[0007]** In another embodiment of the present invention, a system for aspirating thrombus includes an aspiration catheter having a supply lumen and an aspiration lumen, the supply lumen having a distal end, the aspiration lumen configured to couple to a vacuum source and having an interior wall surface, and an open distal end, an orifice at or near the distal end of the supply lumen, in fluid communication with the interior of the aspiration lumen, the orifice located proximally of the open distal end of the aspiration lumen, wherein the orifice is configured to create a spray pattern when pressurized fluid is pumped through the supply lumen such that the spray pattern impinges on the interior wall surface of the aspiration lumen when a distal end of the aspiration catheter is immersed within an aqueous environment, and a disposable tubing set having a first conduit configured to couple the supply lumen of the aspiration catheter to a fluid source, and a pump component associated with the first conduit and configured to detachably couple to a drive unit, such that motion from the drive unit is transferred to the pump component such that resultant motion of the pump component causes fluid from the fluid source to be injected through the supply lumen of the aspiration catheter, and through the orifice into the aspiration lumen.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0008]** FIG. 1 is a diagrammatic view of a system for aspirating thrombus according to an embodiment of the present invention.

**[0009]** FIG. 2 is a diagrammatic view showing more detail of the proximal portion of the system for aspirating thrombus of FIG. 1.

**[0010]** FIG. 3 is a diagrammatic view of the distal end portion of the system for aspirating thrombus of FIG. 1.

**[0011]** FIG. 4 is a plan view of disposable components of a system for aspirating thrombus according to an embodiment of the present invention.

**[0012]** FIG. 5 is a detailed view of detail 5 of FIG. 4.

**[0013]** FIG. 6 is a detailed view of detail 6 of FIG. 4.

**[0014]** FIG. 7 is a detailed view of detail 7 of FIG. 4.

**[0015]** FIG. 8 is a detailed view of detail 8 of FIG. 4.

**[0016]** FIG. 9 is a plan view of a distal end of an aspiration catheter of the system for aspirating thrombus of FIG. 4.

**[0017]** FIG. 10 is a sectional view of FIG. 9 taken through line 10-10, as viewed within a blood vessel.

**[0018]** FIG. 11 is a detailed view of detail 11 of FIG. 10.

**[0019]** FIG. 12 is elevation perspective view of a pump base according to an embodiment of the present invention.

**[0020]** FIG. 13 illustrates a piston of the system for aspirating thrombus being coupled to a saddle of a piston pump.

**[0021]** FIG. 14 is a cross-sectional view of the distal tip of the aspiration catheter of FIG. 9.

**[0022]** FIG 15 is a view a cassette for coupling to a pump base.

**[0023]** FIG. 16 is a sectional view of the cassette of FIG. 15.

**[0024]** FIG. 17 is a partially exploded view of the pump base of FIG. 12.

**[0025]** FIG. 18 is a graph of a pressure vs. time relationship of a piston pump.

**[0026]** FIG. 19 is an elevation view of a piston and a cassette of a piston pump according to an embodiment of the present invention.

**[0027]** FIG. 20 is a graph of a pressure vs. time relationship of a piston pump.

**[0028]** FIG. 21 is a plan view of disposable components of a system for aspirating thrombus according to an embodiment of the present invention.

**[0029]** FIG. 22 is a detailed view of a catheter of the system for aspirating thrombus of FIG. 21.

**[0030]** FIG. 23 is a detailed view of a tubing set of the system for aspirating thrombus of FIG. 21.

**[0031]** FIG. 24 is an exploded view of a saline pump drive unit according to an embodiment of the present invention.

**[0032]** FIG. 25 is an exploded view of a disposable piston pump head of the saline pump unit of FIG. 24.

**[0033]** FIG. 26 is a sectional view of an aspiration catheter of a system for aspirating thrombus within a blood vessel according to an embodiment of the present invention.

**[0034]** FIG. 27 is a sectional view of a catheter within a blood vessel delivering a drug to a target site.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

**[0035]** For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

**[0036]** All numeric values are herein assumed to be modified by the term "about," whether or not explicitly indicated. The term "about" generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In many instances, the terms "about" may include numbers that are rounded to the nearest significant figure.

**[0037]** The recitation of numerical ranges by endpoints includes all numbers within that range (e.g. 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

**[0038]** As used in this specification and the appended claims, the singular forms "a", "an", and "the" include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

**[0039]** The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

**[0040]** FIG. 1 is a diagrammatic figure depicting an assisted aspiration system 10. The aspiration system 10 includes a remote hand piece 12 that contains a fluid pump 26 and an operator control interface 6. In one contemplated embodiment, the system 10 is a single use disposable unit. The aspiration system 10 may also include extension tubing 14, which contains a fluid irrigation lumen 2(or high pressure injection lumen) and an aspiration lumen 4, and which allows independent manipulation of a catheter 16 without requiring repositioning of the hand piece 12 during a procedure performed with the aspiration system 10. Extension tubing 14 may also act as a pressure accumulator. High pressure fluid flow from the pump 26, which may comprise a displacement pump, pulses with each stroke of the pump 26, creating a sinusoidal pressure map with distinct variations between the peaks and valleys of each sine wave. Extension tubing 14 may be matched to the pump 26 to expand and contract in unison with each pump pulse to reduce the variation in pressure caused by the pump pulses to produce a smooth or smoother fluid flow at tip of catheter 16. Any tubing having suitable compliance characteristics may be used. The extension tubing 14 may be permanently attached to the pump 26 or it may be attached to the pump 26 by a connector 44. The connector 44 is preferably configured to ensure that the extension tubing 14 cannot be attached to the pump 26 incorrectly.

**[0041]** An interface connector 18 joins the extension tubing 14 and the catheter 16 together. In one contemplated embodiment, the interface connector 18 may contain a filter assembly 8 between high pressure fluid injection lumen 2 of the extension tubing 14 and a high pressure injection lumen 36 of the catheter 16 (FIG. 3). The catheter 16 and the extension tubing 14 may be permanently joined by the interface connector 18. Alternatively, the interface connector 18 may contain a standardized connection so that a selected catheter 16 may be attached to the extension tubing 14.

**[0042]** Attached to the hand piece 12 are a fluid source 20 and a vacuum source 22. A standard hospital saline bag may be used as fluid source 20; such bags are readily available to the physician and provide the necessary volume to perform the procedure. Vacuum bottles may provide the vacuum source 22, or the vacuum source 22 may be provided by a syringe, a vacuum pump or other suitable vacuum sources.

**[0043]** In one contemplated embodiment, the catheter 16 has a variable stiffness ranging from stiffer at the proximal end to more flexible at the distal end. The variation in the stiffness of the catheter 16 may be achieved with a single tube with no radial bonds between two adjacent tubing pieces. For example, the shaft of the catheter 16 may be made from a single length of metal tube that has a spiral cut down the length of the tube to provide shaft flexibility. Variable stiffness may be created by varying the pitch of the spiral cut through different lengths of the metal tube. For example, the pitch of the spiral cut may be greater (where the turns of the spiral cut are closer together) at the distal end of the device to provide greater flexibility. Conversely, the pitch of the spiral cut at the proximal end may be lower (where the turns of the spiral cut are further apart) to provide increased stiffness. In some embodiments, a single jacket may cover the length of the metal tube to provide for a vacuum tight catheter shaft. Other features of catheter 16 are described with reference to FIG. 3, below.

**[0044]** FIG. 2 is a diagrammatic view showing more detail of the hand piece 12 and the proximal portion of assisted catheter aspiration system 10. The hand piece 12 includes a control box 24 where the power and control systems are disposed. The pump 26 may in some embodiments be a motor driven displacement pump that has a constant output. The pump displacement relationship to the catheter volume, along with the location of the orifice 42 (exit) of the catheter high pressure lumen 36 within the

aspiration lumen 38 (FIG. 3), ensures that no energy is transferred to the patient from the saline pump as substantially all pressurized fluid is evacuated by the aspiration lumen. A prime button 28 is mechanically connected to a prime valve 30. When preparing the device for use, it is advantageous to evacuate all air from the pressurized fluid system to reduce the possibility of air embolization. By depressing the prime button 28, the user connects the fluid source 20 to the vacuum source 22 via the pump 26. This forcefully pulls fluid (for example 0.9 % NaCl solution, or "saline", or "normal saline", or heparinized saline) through the entire pump system, removing all air and positively priming the system for safe operation. A pressure/vacuum valve 32 is used to turn the vacuum on and off synchronously with the fluid pressure system. One contemplated valve 32 is a ported one way valve. Such a valve is advantageous with respect to manual or electronic valve systems because it acts as a tamper proof safety feature by mechanically and automatically combining the operations of the two primary systems. By having pressure/vacuum valve 32, the possibility of turning the vacuum on without also activating the fluid system is eliminated.

**[0045]** The operator control interface 6 is powered by a power system 48 (such as a battery or an electrical line), and may comprise an electronic control board 50, which may be operated by a user by use of one or more switches 52 and one or more indicator lamps 54. The control board 50 also monitors and controls several device safety functions, which include over pressure detection, air bubble detection, and vacuum charge. A pressure sensor 64 monitors pressure (i.e. injection pressure), and senses the presence of air bubbles. Alternatively, or in conjunction, an optical device 66 may be used to sense air bubbles. In one contemplated embodiment, the pump pressure is proportional to the electric current needed to produce that pressure. Consequently, if the electric current required by pump 26 exceeds a preset limit, the control board 50 will disable the pump 26 by cutting power to it. Air bubble detection may also be monitored by monitoring the electrical current required to drive the pump 26 at any particular moment. In order for a displacement pump 26 to reach high fluid pressures, there should be little or no air (which is highly compressible) present in the pump 26 or connecting system (including the catheter 16 and the extension tubing 14). The fluid volume is small enough that any air in the system will result in no pressure being generated at the pump head. The control board monitors the pump current for any abrupt downward change that may indicate that air has entered the system. If the rate of drop is faster than a preset limit,

the control board 50 will disable the pump 26 by cutting power to it until the problem is corrected. Likewise, a block in the high pressure lumen 36 (FIG. 3), which may be due to the entry of organized or fibrous thrombus, or a solid embolus, may be detected by monitoring the electrical current running the pump 26. In normal use, the current fluxuations of the pump 26 are relatively high. For example, the pump 26 may be configured so that there is a variation of 200 milliAmps or greater in the current during normal operation, so that when current fluxuations drop below 200 milliAmps, air is identified, and the system shuts down. Alternatively, current fluxuations in the range of, for example, 50 milliAmps to 75 milliAmps may be used to identify that air is in the system. Additionally, an increase in the current or current fluxuations may indicate the presence of clot or thrombus within the high pressure lumen 36. For example, a current of greater than 600 milliAmps may indicate that thrombus it partially or completely blocking the high pressure lumen 36, or even the aspiration lumen 38 (FIG. 3).

**[0046]** A vacuum line 56, connected to the vacuum source 22, may be connected to a pressure sensor 58. If the vacuum of the vacuum source 22 is low (i.e. the absolute value pressure has decreased) or if a leak is detected in the vacuum line 56, the control board 50 disables the pump 26 until the problem is corrected. The pressure sensor 58 may also be part of a safety circuit 60 that will not allow the pump 26 to run if a vacuum is not present. Thereby, a comprehensive safety system 62, including the safety circuit 60, the pressure sensor 64 and/or the optical device 66, and the pressure sensor 58, requires both pump pressure and vacuum pressure for the system to run. If a problem exists (for example, if there is either a unacceptably low pump pressure or an absence of significant vacuum), the control board 50 will not allow the user to operate the aspiration system 10 until all problems are corrected. This will keep air from being injected into a patient, and will assure that the aspiration system 10 is not operated at incorrect parameters. Alternatively, in lieu of a direct connection (e.g., electrical, optical), the pressure sensor 58 can be configured to send a wireless signal to the control board 50, or any other component (e.g., antenna) coupled to or in communication with the control board 50, to remotely control operation of the pump 26. The removte control may be possible, whetehr the pump is within the sterile filed or outside the sterile field.

**[0047]** FIG. 3 is a diagrammatic view of the distal end portion 68 of the assisted catheter aspiration system 10, showing more details of the catheter 16. The

catheter 16 in some embodiments is a single-operator exchange catheter and includes a short guidewire lumen 34 attached to the distal end of the device. The guidewire lumen 34 can be between about 1 and about 30 cm in length, or between about 5 and about 25 cm in length, or between about 5 and about 20 cm in length, or approximately 13.5 cm in length. In other embodiments, a full-length guidewire lumen (extending the length of the catheter 16) may be used. For example, a catheter 16 sized to be used on peripheral blood vessels, including peripheral arteries, may incorporate a full-length guidewire lumen. In some embodiments, the aspiration itself may also serve as a guidewire lumen. An aspiration lumen 38 includes a distal opening 40 which allows a vacuum (for example, from vacuum source 22) to draw thrombotic material into the aspiration lumen 38. A high pressure lumen 36 includes a distal orifice 42 that is set proximally of distal opening 40 by a set amount. For example, distal orifice 42 can be set proximally of distal opening 40 by about 0.508 mm (0.020 inches), or by 0.508 mm ± 0.076 mm (0.020 inches ± 0.003inches) or by another desired amount. The orifice 42 is configured to spray across the aspiration lumen to macerate and/or dilute the thrombotic material for transport to vacuum source 22, for example, by lowering the effective viscosity of the thrombotic material. The axial placement of the fluid orifice 42 is such that the spray pattern interaction with the opposing lumen wall preferably produces a spray mist and not a swirl pattern that could force embolic material out from the distal opening 40. The spray pattern may be present at least when a distal end of the catheter 16 is within an aqueous environment, such as a body lumen, including a blood vessel. The aqueous environment may be at body temperature, for example between about 35.0°C and about 40.0°C, or between about 36.0°C and about 38.0°C. The system may be configured so that the irrigation fluid leaves the pump at a pressure of between about 3.447 megapascal (500 pounds per square inch) and about 10.342 megapascal (1500 pounds per square inch). In some embodiments, after a pressure head loss along the high pressure lumen 36, the irrigation fluid leaves orifice 42 at between about 4.137 megapascal (600 pounds per square inch) and about 8.274 megapascal (1200 pounds per square inch), or between about 4.816 megapascal (650 pounds per square inch) and about 5.861 megapascal (850 pounds per square inch).

**[0048]** FIG. 4 illustrates a system for aspirating thrombus 100 according to an embodiment of the present invention. The system for aspirating thrombus 100 depicted in FIG. 4 represents disposable components 101, comprising a tubing set 103 and an

aspiration catheter 118, which are configured to attach to a vacuum source 22, a fluid source 20 (FIGS. 1 and 2), a pressure monitor (not shown), and a pump base 200 (FIG. 12). The system for aspirating thrombus 100 is also configured to be used with a guidewire. Beginning with the components of the tubing set 103, a spike 102 (shown in more detail in FIG. 5) is configured to couple to a fluid source 20 such as a saline bag. The saline bag may have a volume of saline equal to about 1000 ml or about 500 ml. The saline may be heparinized, or may contain one or more therapeutic agents. The saline may be at room temperature, or may be warmed or cooled. A connector 104 (shown in more detail in FIG. 7), for example a luer connector, is configured to couple to a vacuum source 22. The vacuum source 22 may be a vacuum bottle having a volume of between 20 ml and 500 ml. The vacuum source 22 may instead be a 60 ml syringe whose plunger is pulled back after coupling to the connector 104. This may be a lockable plunger, which is locked in order to maintain the evacuated plunger position. In some cases, the vacuum source 22 may be a 20 ml syringe or a 30 ml syringe. An exemplary syringe with a lockable plunger is the VacLok® syringe sold by Merit Medical Systems, Inc. of South Jordan, UT, USA. The vacuum source 22 may also be a vacuum pump, with or without a collection container. A pressure transducer106 capable of measuring vacuum (including positive pressure sensors that are configured to measure positive pressure, but are capable of measuring negative pressure) is coupled to a vacuum line 108 via a y-connector 110. Signals from the pressure transducer 106 travel along a cable 112 (FIG. 7), which also supplies voltage to the pressure transducer 106. A connector 114 (also shown in FIG. 6) couples the cable 112 to a pressure monitor or to the pump base 200. A cassette 116 is a disposable component attachable to the pump base 200 (FIG. 12) for allowing pressurized injection of a liquid injectate (such as saline). The cassette 116 is described in more detail in relation to FIG. 6. The aspiration catheter 118 having a distal end 120 is shown in more detail in FIG. 8.

**[0049]** Turning to FIG. 5, the spike 102 communicates with extension tubing 122. Liquid injectate is pumped downstream at the piston pump, which pulls more liquid injectate (for example from a saline bag) through a check valve 126 and through a supply tube 130. An injection port 128 may be used for injecting other materials into the system, or for removing air or priming the system. The spike 102 may be packaged with a removable protective spike cover 124.

**[0050]** The cassette 116, as seen in FIG. 6, pulls liquid injectate from the supply tube 130, and pressurizes (in conjunction with the pump base 200) an injection tube 152. More detail of the cassette 116 will be described along with the description of the entire piston pump. FIG. 7 shows more detail of the pressure transducer 106 for measuring the vacuum. The pressure transducer 106 connects to the y-connector 110 with a luer fitting 154. The injection tube 152 and the vacuum line 108 communicate to lumens of a catheter shaft 142. For example, the injection tube 152 may be fluidly connected to a distal supply tube 168 (FIGS. 9-11), for example a polyimide or stainless steel or nitinol tube having high strength thin walls. This distal supply tube 168 may reside within the catheter shaft 142, with the annulus between forming an aspiration lumen 160 (FIGS. 9-11). A strain relief 156 protects the catheter shaft 142 from kinking and other damage. In any cases in which luer fittings 154 are used (at any of the connections), a custom luer with an added o-ring may be used in order to allow the connection to withstand elevated pressures. In some embodiments, a bespoke connector may be utilized, to increase high pressure endurance. In some embodiments, pressures as high as 6.89 megapascal (1,200 pounds per square inch) or greater may be achieved without leakage or without causing decoupling of the catheter.

**[0051]** Turning to FIG. 8, the aspiration catheter 118 is illustrated as a single-operator exchange catheter and includes a guidewire tube 132 attached to the distal end 120 on one side of the aspiration catheter 118. The guidewire tube 132 can be between about 1 and about 30 cm in length, or between about 5 and about 25 cm in length, or between about 5 and about 20 cm in length, or approximately 13.5 cm in length. The guidewire tube 132 has a distal end 136 and a proximal end 138, and a single guidewire lumen 134 passing between the two ends 136, 138. The guidewire lumen 134 may be configured to be compatible with a 0.014" guidewire, a 0.018" guidewire, or a number of other guidewire diameters. A lumen inner diameter may be about 0.406 mm (0.016 inches) for compatibility with a 0.014" guidewire. The guidewire tube 132 may be constructed of a number of materials, including nylon, polyethylene, PEBAX®, polyester, PET, or may be constructed from composite or coextruded materials. For example an inner layer may comprise high density polyethylene or FEP, PTFE, ETFE, or other materials for high lubricity, and an outer layer may include PEBAX, nylon or other materials, for combination mechanical strength and flexibility. A tie layer may be used between the inner and outer layers, for example linear low density polyethylene. The

catheter 118 may include a composite catheter shaft 142 having an inner support structure 144 covered with a polymer jacket 146. The inner support structure 144 may be a tubular braid or one or more helical coils, for example, made with stainless steel flat or round wires. The inner support structure 144 may also be spiral cut hypodermic tubing, for example made from 304 stainless steel or nickel-titanium. The spiral cut hypodermic tubing may have a pitch measuring about 4 to 6 millimeters, or about 5 millimeters at the proximal end for increased stiffness, transitioning to a pitch of about 0.75 to 1 mm or about 0.87 mm, at the distal end 150 of the inner support structure 144. In between the these two different pitch sections, may be intermediate pitch sections, for example, a section having a pitch of between about 2 mm and about 5 mm, and another section having a pitch of about 1 mm to about 2.5 mm. The inner support structure 144 may end at a transition zone 148, so that the polymer jacket 146 alone extends to the distal end 136 of the aspiration catheter 118. A catheter tip portion 140 is described in more detail in relation to FIGS. 9-11.

**[0052]** FIGS. 9-11 show an open distal end 158 of an aspiration lumen 160 for aspirating thrombus. A skive 162 may be formed in the polymer jacket 146, to aid entry of thrombus 164 that is aspirated into the aspiration lumen 160 (in the direction of arrow 180) by the combination of the vacuum created by the vacuum source 22. The skive 162 also minimizes the chances of the open distal end 158 being sucked against a blood vessel wall 166. A distal supply tube 168 has a closed distal end 170, for example, it may occluded during manufacture using adhesive, epoxy, hot melt adhesive or an interference member. Alternatively, the distal supply tube 168 may be closed off by melting a portion of it. The distal supply tube 168 has a lumen 176 extending its length and an orifice 172 formed through its wall 174 at a location adjacent and proximal to the closed distal end 170. The orifice 172 may have a diameter between about 0.0508 mm (0.002 inches) and about 0.1016 mm (0.004 inches), or about 0.0787 mm (0.0031 inches). The inner diameter of the distal supply tube 168 may be between about 0.3048 mm (0.012 inches) and about 0.4826 mm (0.019 inches), or between about 0.3556 mm (0.014 inches and about 0.4318 mm (0.017 inches) or about 0.3937 mm (0.0155 inches). The lumen 176 of the distal supply tube 168 is a continuation of an overall flow path emanating from the fluid source 20 including the extension tubing 122, the supply tube 130, the interior of the cassette 116, and the injection tube 152. In some embodiments, the lumen 176 of the distal supply tube 168 may taper, for example, from an inner diameter of about 0.3937

mm (0.0155 inches) at a proximal portion to an inner diameter of about 0.2974 mm (0.011 inches) at a distal portion. In some embodiments, the equivalent of a taper may be achieved by bonding different diameter tubing to each other, resulting in a stepped-down tubing inner diameter. In some embodiments, different diameter tapered tubing may be bonded to each other, for a combination of tapering and step-down of diameter. As described in conjunction with the piston pump, a pump output pressure wave of about 4.137 megapascal (600 pounds per square inch) to about 5.516 megapascal (800 pounds per square inch) causes a liquid injectate to flow through the flow path, including a the distal supply tube 168 (arrows 182), and causes a fluid jet 178 to exit the orifice 172 at a high velocity. The fluid jet 178, in absence of flow through the aspiration lumen 160 (for example if there is no vacuum), would impinge upon an inner wall 181 of the aspiration lumen 160 directly adjacent the orifice 172. Depending on the amount of vacuum present, the fluid jet, may curve as shown. The fluid jet 178 serves to macerate thrombus 164 that enters the aspiration lumen 160, and dilutes it. The flow rate of the liquid injectate (e.g. saline) and the amount of vacuum are controlled so that about 50% to about 70% of the volume of the mixture of the saline and blood flowing through the proximal aspiration lumen 160 is blood. Or about 60% of the volume is blood. This maceration and dilution assures that there is continuous flow through the aspiration lumen 160 so that it will not clog. The fluid jet 178 is configured to be contained within the aspiration lumen 160, and to not exit into a blood vessel or other body lumen.

**[0053]** The axial center of the orifice 172 is about 0.3302 mm (0.013 inches) to about 0.4826 mm (0.019 inches) proximal to the most proximal portion of the open distal end 158, as illustrated by distance D in FIG. 11. FIG. 14 is a cross-section of the catheter tip portion 140 at the axial center of the orifice 172. The orifice 172 it is oriented approximately along a vertical midline 184 of the aspiration lumen 160, or within a range of ± a, there where angle a is about 20°. The angle a, may be varied in different embodiments between about 1° and about 45°, or between about 20° and about 35°. The guidewire tube 132 may be secured to the polymer jacket 146 with attachment materials 186, such as adhesive, epoxy, hot melt or other materials. The guidewire tube 132 may be secured along its entire length, or at discrete locations along its length, in order to maximize flexibility. The distal supply tube 168 may be secured within the aspiration lumen 160 with attachment materials 188, such as adhesive, epoxy, hot melt or other materials. The polymer jacket 146 may comprise a number of different materials,

including PEBAX, nylon, or polyurethane. In some embodiments, the polymer jacket may be partially melt bonded to the distal supply tube 162 and/or the guidewire tube 132, in order to minimize the wall thickness of the assembly.

**[0054]** FIG. 12 illustrates a pump base 200 for coupling the cassette 116 of the system for aspiration of thrombus 100. A housing 202 is attached to an IV pole clamp 204, and contains the control circuitry and the motor for operating a piston pump system 300 (FIG. 13) which comprises the combined pump base 200 and the cassette 116. By action of a motor and cam within the pump base 200, a saddle 206 is cyclically actuated (up and down) within a window 208 to move a piston 210 within the cassette 116 (FIG. 13). Pegs 212 of the cassette 116 insert into cavities 216 in the pump base 200. Biased snaps 214 lock into one or more grooves 218 in the pump base 200. Either the cavities 216 or the grooves 218, may have one or more switches which sense the presence of the cassette 116. For example, the cassette for one particular model may have a first number (or combination) of pegs 212 or biased snaps 214, which another particular model may have a different number (or combination) of pegs 212 or biased snaps 214, which is recognized by the system. A smooth surface 224 of an elastomeric frame 222 engages edges 220 of the cassette 116, for enhanced protection. An upper space 226 is configured to engage, or closely match the supply tube 130 and a lower space 228 is configured to engage, or closely match the injection tube 152. The saddle 206 has a semi-cylindrical cavity 236 which snaps over a cylindrical engagement surface 238 on the piston 210. The saddle also has an upper edge 240 and a lower edge 242 for axially engaging a first abutment 244 and a second abutment 246, respectively, of the piston 210. A user interface 230 on the pump base 200 has one or more buttons 232 and one or more indicators 234, which allow the user to operate and assess the operation of the system 100. For example, the buttons may include a start button to begin pumping, a stop button to stop pumping, a prime button to prime the system with a fluid injectate and purge out air, or a temporary pause button. Other data entry keys are also possible. The cassette 116 may include one or more interface components 248. For example, a resistor, whose value the pump base 200 is able to measure via contacts 247, 249 when the cassette 116 is attached to the pump base. This allows the pump base to determine the appropriate parameter for operating a specific model of the system 100. For example, a first resistor having a first resistance may be used with a first model and a second resistor having a second resistance may be used with another model. Alternatively, the interface component 248 may

incorporate an RFID chip, such as a read RFID chip or a read/write RFID chip. This may allow specific data (pump operating pressures, RPM of motor output, etc.) to be recorded within the pump base or to connected hardware and identified for each patient.

**[0055]** FIG. 15 and 16 illustrate the cassette 116 with most of its internal components visible. FIG. 16 is a sectional view of the cassette 116. The cassette 116 comprises an internal supply cylinder 252 and an internal injection cylinder 254, which are cylindrical cavities extending within the cassette 116. The piston 210 includes a supply side shaft 256 and an injection side shaft 258, the supply side shaft 256 including an o-ring 266 for sealably interfacing with the supply cylinder 252 and the injection side shaft 258 including an o-ring 268 for sealably interfacing with the injection cylinder 254. Each of the o-rings 266, 268 are within a cylindrical groove 290, 292 around each respective shaft portion 256, 258. An internal ball valve 272 (FIG. 16) stops injectate (saline) from flowing through an internal channel 274 in the supply side shaft 256 of the piston 210 when the piston 210 moves in a first direction 276, but the internal ball valve 272 allows injectate to flow through the internal channel 274 and through an internal channel 282 in the injection side shaft 258 when the piston 210 moves in a second direction 278. The ball valve 272 is axially held between a spherical annular recess 284 in the interior of the supply side shaft 256 and a recess having thru channels 286 in the injection side shaft 258. The supply side shaft 256 and the injection side shaft 258 may be held together with a threaded connection 288. When the piston 210 moves in the first direction 276, the injection side shaft 258 of the piston 210 and o-ring 268 force injectate through the injection tube 152. A protective tube 280 is shown over the injection tube 152. In FIG. 15, the injection side shaft 258 is shown at the bottom of an injection pulse. Injectate is filtered through an in-line filter 262, which may be a 40 to 50 micron filter, having an approximate thickness of 0.762 mm (0.030 inches). The in-line filter 262 is configured to keep particulate out of the injectate. Even though injectate is circulated through the aspiration catheter 118, and not into the blood vessel, the filtering provided by the in-line filter 262 is an extra safety step. However, this step helps assure that particulate does not block the small orifice 172 (FIG. 11). When the piston 210 moves in the second direction 278, the supply side shaft 256 of the piston 210 and the o-ring 266 sealably move together within the supply cylinder 252, but the ball valve 272 allows the injectate to pass through the internal channels 274, 282 of the piston 210 and fill the injection cylinder 254. The injectate is able to enter from the supply tube 130 through a

check valve assembly 270 comprising an o-ring 264 and a check valve 250. The check valve 250 allows injectate to enter the interior of the cassette 116 from the supply tube 130, but not to move from the cassette 116 to the supply tube 130. The check valve 250 may be configured so that air, due at least in part to its low viscosity, will not be able to cause the check valve 250 to move (open), thus not allowing air to progress through the system. In some embodiments, the piston 210 may be a single piece (monolithic) design with a bore into which a check-valve is press-fit or bonded. A check valve compatible with this assembly may be supplied by the Lee Company of Westbrook, CT, USA.

**[0056]** The volume of injectate injected per cycle may range from about 0.02 ml to about 41 ml, or from about 0.04 ml to about 2.0 ml, or about 0.06 ml to about 0.08 ml, or about 0.07 ml. The usable volume (volume that can be injected) of the injection cylinder 254 may be configured to be less than the usable volume (volume that can be filled from) of the supply cylinder 252, in order to assure sufficient filling of the injection cylinder 254. For example, the usable volume of the injection cylinder 254 may be about 0.05 ml to about 0.12 ml, and the usable volume of the supply cylinder 252 may be about 0.07 ml to about 0.16 ml. A usable volume ratio $R_U$ of between about 1.15 and about 2.00, or between about 1.25 and about 1.85, or about 1.40 is contemplated, where:

$R_U = V_{SCU}/V_{ICU}$, wherein:
$V_{SCU}$ = Usable volume of the supply cylinder 252, and
$V_{ICU}$ = Usable volume of the injection cylinder 254.

**[0057]** A mean flow rate of between about 5 ml/minute and about 100 ml/minute. In some embodiments for use in coronary applications, 20 ml/minute may be desired. In some embodiments for use in peripheral applications, 50 ml/minute may be desired.

**[0058]** FIG. 18 illustrates a graph 600 of a pressure (P) vs. time (T) curve 602 of a piston pump. Peaks 604 and valley 606 of the curve 602 can be dependent upon the design of the piston and cylinders of the piston pump, particularly of the usable volume ratio $R_U$. Turning to FIG. 19, a piston 608 is illustrated having a first diameter $D_1$ and a second diameter $D_2$ measured at the compressed o-rings 601, 603 (when placed within cylinders 605 and 607 of a cassette 609). The diameters of the cylinders 605, 607 are thus

also defined as diameters $D_1$ and $D_2$. When the diameters $D_1$, $D_2$, and the lengths of the cylinders 605, 607 are adjusted such that the the usable volume ratio $R_U$ is optimized as previously described, a curve 610 as illustrated in FIG. 20 may be produced. The curve 610 has less-defined peaks 614 and valleys 616, and thus produces less variation of flow amplitude, and a more balanced injection.

**[0059]** The partially exploded pump base 200 in FIG. 17 illustrates the internal mechanisms for linear (up and down) actuation of the saddle 206, which is attached to a saddle stage 310. A motor 302 is controlled by a circuit board 304 and operated by the user interface 230 (FIG. 12), whose indicators 234 are lit by LEDs 306. The motor 302 turns a cam 316, in which includes a path 330. The saddle stage 310 has a pin 318 extending from its back side. The pin 318 may be press fit, bonded or screwed in place within the saddle stage 310. The saddle stage 310 is secured with screws to two slides 312, 314 through holes 326, 328, such that rotary motion of the cam 316 causes the pin 318 to track along the path 330 of the cam 316, thus causing the saddle stage 310 attached to the slides 312, 314 to slide upward and downward in cyclic motion. The shape of the cam determines the amount of acceleration and deceleration in the motion. Upper posts 322 and lower posts 324 serve as guides and/or stops of the saddle stage 310. The connector 114 of the pressure transducer 106 for measuring vacuum may be plugged into socket 308 (also shown in FIG. 12), and pressure related signals may be processed by the circuit board 304. The entire pump base 200 is reusable.

**[0060]** The inner contour diameter of the cam 316 may be sized and/or shaped to control the stroke length of the piston 210 and the amount of pulsatility (i.e., the difference between the high and low pressure). In some cases, decreasing the stroke length decreases the amount of pulsatiliy. In applications within the heart, such as coronary artery applications, lowering the amount of pulsatility can reduce the incidence of bradycardia. To compensate for a lower stroke length, and to maintain a sufficient total flow rate, the speed of the rotation of the cam (i.e. rotations per minute), can be increased, for example by increasing motor output speed, either by gearing or by increased applied voltage.

**[0061]** Another embodiment of a system for aspirating thrombus 800 is illustrated in FIG.21. The system for aspirating thrombus 800 includes, three major

components: the pump base 200 of FIG. 12, an aspiration catheter 818, and a tubing set 803. The aspiration catheter 818 and the tubing set 803 represent disposable components 801, and the pump base 200 is a reusable component. It is not necessary to sterilize the pump base 200 as it is kept in a non-sterile field or area during use. The aspiration catheter 818 and the tubing set 803 may each be supplied sterile, after sterilization by ethylene oxide gas, electron beam, gamma, or other sterilization methods. The aspiration catheter 818 may be packaged and supplied separately from the tubing set 803, or the aspiration catheter 818 and the tubing set 803 may be package together and supplied together. Alternatively, the aspiration catheter 818 and tubing set may be packaged separately, but supplied together (i.e., bundled). As shown in FIGS. 21 and 22. The aspiration catheter 818 and tubing set 803 share many of the same features as the aspiration catheter 118 and tubing set 103 of FIG. 4, but are configured to allow easier separation from each other, and additional procedural adaptability. The aspiration catheter 818 has a distal end 820 comprising a guidewire tube 832 having a distal tip 836, and a proximal end 819 comprising a y-connector 810. The catheter shaft 842 of the aspiration catheter 818 is connected to the y-connector 810 via a protective strain relief 856. In other embodiments, the catheter shaft 842 may be attached to the y-connector 810 with a luer fitting. The y-connector 810 may comprise a first female luer 851 which communicates with a catheter supply lumen (as in the catheter 118 of FIGS. 4, 8-11), and a second female luer 855 which communicates with a catheter aspiration lumen (as in catheter 118 of FIGS. 4, 8-11).

**[0062]** Turning to FIG. 23, the tubing set 803 is shown in more detail. A spike 802 for coupling to a fluid source 20 (FIG. 1) allows fluid to enter through extension tubing 822 and a check valve 826, and into supply tube 830. An optional injection port 828 allows injection of materials or removal of air, as described in relation to previous embodiments. A cassette 816 is used in conjunction with the pump base 200, and is similar in structure and function to the cassette 116 in FIGS. 15-16. Fluid is pumped into injection tube 852 from cassette 816. A male luer 854 is configured to attach to the female luer 851 of the y-connector 810.

**[0063]** Returning to FIG. 21, accessories 857 are illustrated that are intended for applying a vacuum source 22, including a syringe 849 having a plunger 867, to the catheter 818. The syringe 849 is attached to syringe extension tubing 859 via the luer 865

of the syringe 849. A stopcock 847 may be used to hold maintain the vacuum, or the plunger 867 may be a locking variety of plunger. A luer 861 of the syringe extension tubing 859 is connected to an pressure transducer 806, the pressure transducer 806 having a male luer 863 for connection to a connector (e.g., female luer) 804 of vacuum line 808. A male luer 853 at the end of the vacuum line 808 may be detachably secured to the female luer 855 of the y-connector 810 of the aspiration catheter 818. Signals from the pressure transducer 806 are carried through cable 812 to a connector 814. The connector 814 is plugged into the socket 308 (FIG. 12) of the pump base 200. Pressure related signals may be processed by the circuit board 304 of the pump base 200. The pressure transducer 806 may be power from the pump base 200, via cable 812. The accessories 857 may also be supplied sterile to the user.

**[0064]** In use, the pump base 200 resides outside the sterile field. Because operation of the pump base 200 may be controlled by the presence or absence of a pressure, a user who is working in the sterile field may turn the pump on or off without touching the non-sterile pump base 200. For example, the pump may be started by placing a vacuum on the system (e.g., pulling the plunger 867 of the syringe 849). The pump may in turn be stopped by removing the vacuum on the system (unlocking the plunger 867 of the syringe 849 and allowing to to release, or opening the stopcock 847). The syringe 849 or the combination syringe 849 and stopcock 847 may act as a sterile on/off button of the pump vase 200. Alternatively, the aspiration catheter 818 may be initially used without the pump base 200, with only aspiration being applied to the aspiration lumen. If in certain cases, if the aspiration lumen becomes clogged, the distal end 820 of the aspiration catheter 818 may be backed off of the thrombus, and the pump base 200 and tubing set 803 may be coupled to the aspiration catheter 818, to then operate with forced saline injection, for increased aspiration, and clear the aspiration lumen. This will also help stop any thrombus that is blocking the aspiration lumen from being inadvertently delivered into the blood vessel of the patient.

**[0065]** FIGS. 24 and 25 illustrate a saline pump drive unit 400 having a completely disposable pump head 500. The saline pump drive unit 400 is configured to be usable with the catheters 16, 118 described herein, or other embodiments of aspiration systems comprising fluid injection. In FIG. 24, a bottom case 402 and a top case 404 having a label 406 are secured together with screws 408. Contained within the bottom

case 402 and top case 404 are a battery pack 410 and an electronic control module 412. A battery cover 416 holds the battery pack 410 in place. In some embodiments, the battery pack 410 may supply a voltage of 18 Volts DC, but systems utilizing other voltages are possible. A user interface 414 enables operation of the saline pump drive unit. A vacuum bottle sleeve 418 may be used when a vacuum bottle is incorporated as the vacuum source 22. A spike 420 is connectable to a fluid source 20, and fluid injectate passes from the fluid source 20 through extension tubing 422 to a disposable piston pump head 500. Saline may be primed through the system by an automatic priming ("self-priming") system described herein in relation to prior embodiments, or may be primed by gravity from a saline bag that is located (for example on an IV pole) above the rest of the system. A valve on the lowest portion of the system may be opened in order to prime the entire system.

**[0066]** As illustrated in FIG. 25, the disposable piston pump head 500 is configured to couple to a motor shaft 504 of a motor 502, that is powered by the battery pack 410 of the saline pump drive unit 400. A motor plate 506 and a main body 508 of the disposable piston pump head 500 are secured to each other with screws 510, and hold the internal components of the disposable piston pump head 500. First and second follower plates 512, 514 are held together with screws 516 and bosses 518 extending from the first follower plate 512. The first and second follower plates 512, 514 rotatably hold a cam 520. The cam may be assymetric (as illustrated) or alternatively may be symmetric. The asymmetry may be incorporated in order to control the amount of noise in the pump, the contours serving to customize the shape of the pressure wave, and of the function of the pump. First and second bushings 522, 524 are rotatably held on first and second pins 526, 528. The pins 526, 528 insert into cylindrical cavities 530, 532 in each of the follower plates 512, 514.

**[0067]** In use, a user attaches the disposable piston pump head 500 to the motor 502 of the saline pump drive unit 400 by bringing the motor plate 506 close to the motor shaft 504 so that a d-shaped hole 534 in the cam 520 can be pressed over the d-shaped motor shaft 504. Alternatively, the d-shapes may be other non-circular shapes, including, but not limited to elliptical, oval, or rectangular. In operation the motor 502 turns the motor shaft 504, which in turn turns the cam 520. The cam 520 turns, forcing the bushings 522, 524 to push the first and second follower plates 512, 514 back and forth in

a first direction 536 and a second direction 538. A saddle 544 is carried on the second follower plate 514, and a piston 210 may be coupled to the saddle 544 in the same manner as described herein with other embodiments. A supply cylinder 552 and an injection cylinder 554 in the main body 508 are analogous to the supply cylinder 252 and injection cylinder 254 of the cassette 116 of the system 100. The piston 210 of the cassette 116 may be used in the disposable piston pump head 500. The labelled components related to the piston 210 in FIG. 25 are similar to those described in relation to the piston 210 in FIGS. 15 and 16. The outer diameter of the cam 520 may be sized and/or shaped to control the stroke length of the piston 210 and the amount of pulsatility (i.e., the difference between the high and low pressure). In some cases, decreasing the stroke length decreases the amount of pulsatiliy. In applications within the heart, such as coronary artery applications, lowering the amount of pulsatility can reduce the incidence of bradycardia. To compensate for a lower stroke length, and to maintain a sufficient total flow rate, the speed of the rotation of the cam (i.e. rotations per minute), can be increased, for example by increasing motor output speed, either by gearing or by increased applied voltage. A vacuum spike 546 is used for coupling to the vacuum source 22, for example a vacuum bottle held within the vacuum bottle sleeve 418. A vacuum switch valve 540, which is activated against the bias of a spring 542, may be used to allow pump activation. For example, the electronic control module 412 may be configured to initiate the operation of the motor 502 automatically when the vacuum switch valve 540 sends a signal corresponding to movement of the vacuum switch valve 540,which occurs when a significant vacuum is achieved. This control may be instead of or in addition to control from a vacuum pressure transducer, such as pressure transducer 106. The turning on of the vacuum may thus be used to simultaneously turn on the motor 502, so that a single input begins the operation of the saline pump drive unit 400. Additionally, a vacuum source 22 may be controlled by the electronic control module 412 (for example, by opening or closing a solenoid), when a minimum injectate pressure is measured by an additional pressure transducer. For example, when a pressure of about 0.62 megapascal (90 pounds per square inch) or greater is measured, the vacuum may be activated or communicated to the system. An advantage of the saline pump drive unit 400 is that the user is required only to assemble a single component onto the shaft 504 of the motor 502.

**[0068]** As previously described, the systems according to any of the embodiments of the present invention may be configured such that active flow of saline

(or other) injectate is not possible without concurrent vacuum being applied for aspiration. Also, the systems may be configured such aspiration is not possible without saline (or other) injectate flow. The systems according to any of the embodiments of the present invention may be configured such that current driving the pump (for example the current driving the motor 302, 502) is monitored, or by any alternative monitoring method, such that when a change in condition occurs, for example, air in the injection system, or clogs in any of the catheter lumens or extension tubes, or leaks within the system, the system shuts down, in order to avoid events such as injection of air into the blood vessels, or catheter or system failure.

**[0069]** FIG. 26 illustrates an aspiration catheter 700 inserted within a blood vessel 165. The aspiration catheter 700 includes a guidewire lumen 702 secured to the distal end 704 of the aspiration catheter 700 which allows the aspiration catheter 700 to be tracked over a guidewire 706. A supply lumen 708 is secured within an aspiration lumen 710. The supply lumen 708 extends through a tapering tube 712. In some embodiments, the tapering tube 712 may be constructed of polyimide. In some embodiments, the tapering tube 712 may have a luminal inner diameter that tapers from its proximal end to its distal end. For example, in some embodiments, the luminal inner diameter may taper from about 0.3937 mm (0.0155 inches) to about 0.2794 mm (0.011 inches). The supply lumen 708 extends generally parallel to the aspiration lumen 710, however a distal end 714 of the tapering tube 712 curves towards an interior wall surface 716 of the aspiration lumen 710, thus allowing an open end 718 of the supply lumen 708 to act as an orifice for applying a spray pattern 720. The open end 718 of the supply lumen 708 may further promote a jet or spray effect by having an internal diameter that is less than about 0.203 mm (0.008 inches). In some embodiments, the open end 718 of the supply lumen 708 may have an internal diameter that is between about 0.076 mm (0.003 inches) and about 0.102 mm (0.004 inches). The center of the open end 718 orifice may in some embodiments be about 0.3302 mm (0.013 inches) to about 0.4826 mm (0.019 inches) proximal to the most proximal portion 724 of the open distal end 722 of the aspiration lumen 710, as illustrated by distance D in FIG. 26. The most distal portion 726 of the open distal end 722 of the aspiration lumen 710 is slightly distal of the most proximal portion 724 in the embodiment illustrated, and thus has an angled skive, but the skive angle $A_s$ is not severe. A skive angle $A_s$ of between about 75° and about 89°, or between about 80° and about 85° may be used, in order to allow a large portion of

thrombus being pulled into the open distal end 722 of the aspiration lumen 710 to be struck by high velocity exiting jet (e.g. saline) flow, as illustrated with the spray pattern 720.

**[0070]** FIG. 27 illustrates the catheter 700 of FIG. 26 being utilized to deliver a drug 730 to a target site 732 within a blood vessel 165. The target site 732 may include an atherosclerotic lesion 728 and/or a thrombus 734. Whereas the aspiration of thrombus, as in FIG. 26, involves actively applying a vacuum (e.g., from a vacuum source) on the aspiration lumen 710, the drug delivery illustrated in FIG. 27, though utilizing the same catheter 700, allows the metering of a fine, precision volume flow rate of drug 730 to be delivered into the vessel. This is achieved by having significantly less vacuum applied to the aspiration lumen 710, or no vacuum applied to the aspiration lumen. The precision metering in small, controlled volumes, provides efficient use of typically expensive drugs, with minimal wasted drug. In some embodiments, the drug 730 may be delivered at body temperature. In other embodiments, the drug 730 may be warmed, and delivered at an elevated temperature, for example, to increase the activity and effectiveness of a drug. This may be done, for example, to get a more effective dose, with a smaller volume of drug. In other embodiments, the drug 730 may be cooled and delivered at a reduced temperature (i.e., in relation to the body temperature). The drug 730 may be cooled to control the activity level, or to delay the activity of the drug (e.g., so that it is active downstream, at a location that is not reachable by the catheter 700). In some cases, the drug 730 may be cooled in order to apply a conjunctive therapeutic cooling effect on the tissue being treated. In some cases, the therapeutic cooling effect may be achieved from cooled saline or other aqueous non-drug media alone.

**[0071]** Some of the drugs 730 which may be delivered include thrombolytic agents (clot busting drugs), such as streptokinase, tissue plasminogen activator (t-PA), recombinant or genetically-engineered tissue plasminogen activator, tenecteplase (TNK), urokinase, staphylokinase, and reteplase. Alternatively, stem cells or "cocktails" containing stem cells may be delivered. In some cases, glycoprotein inhibitos (GPI's) may be injected through the supply lumen 708 of the aspiration catheter 700. Saline or other aqueous solutions may be delivered alone for selective dilution of blood at the target site 732. In some applications, a solution may be used which is capable of exhibiting a phase change, for example, when its pressure or temperature is changed. In these

applications, a liquid may be injected that becomes a gas when exiting from a small orifice, for example at the open end 718 of the supply lumen 708. Alternatively, a gas may be injected that becomes a liquid when being force through a small orifice, such as the open end 718 of the supply lumen 708. In any of the applications in which drugs 730 or other materials are injected intravascularly through the catheter 700, the injection of the drugs 730 or other materials may occur before, during, after, or instead of an aspiration procedure. Returning to the aspiration catheter 818 of FIGS 21-22, if, during an aspiration procedure, it is desired to deliver drugs down the supply lumen and into the vessel, the tubing set 803 may be removed from the aspiration catheter 818 by disconnecting the male luer 854 of the tubing set 803 from the female luer 851 of the aspiration catheter 818, and the drug may be injected directly into the supply lumen at the female luer 851, for example, by a syringe or metering system, including a syringe/syringe pump combination. By also removing the vacuum source from the female luer 855 of the aspiration catheter 818, when aspiration lumen now serves as an overflow, so that the fluid being delivered into the patient (e.g., intravascularly) is maintained at a controlled rate. The volume of the supply lumen is relatively very small, so only a small volume of drug is needed to fill the supply lumen, and thus reach the distal top of the aspiration catheter 818. This, at the end of the procedure, very little drug is wasted, or needs to be disposed, allowing for a very cost-effective procedure.

**[0072]** In the embodiments described herein, a sterile fluid path is provided extending all the way from the fluid source 20 to the distal opening 40/open distal end 158 of the catheter 16, 118. In both the embodiments of the system 100 of FIGS. 4-17, the system 800 of FIGs. 21-23, and the embodiments of FIGS. 24-25, a disposable catheter and disposable pump set are configured to be supplied sterile, and coupled to a non-sterile (reusable) pump base 200 or pump motor 502. These combinations allow for reusability of the more expensive components, and for reusability (and maximized sterility) of the less expensive components, thus maximizing cost containment and patient safety at the same time.

**[0073]** In some cases, parts or all of the devices described herein may be doped with, made of, coated with, or otherwise include a radiopaque material. Radiopaque materials are understood to be materials capable of producing a relatively bright image on a fluoroscopy screen or another imaging technique during a medical procedure. Some

examples of radiopaque materials can include, but are not limited to, gold, platinum, palladium, tantalum, tungsten alloy, polymer material loaded with a radiopaque filler, and the like. One or more hydrophilic or hydrophobic lubricious coatings may be used in order to improve trackability of the aspiration catheter 118 through the blood vessels.

**[0074]** In some instances, a degree of MRI compatibility may be imparted into parts of the devices described herein. For example, to enhance compatibility with Magnetic Resonance Imaging (MRI) machines, it may be desirable to make various portions of the devices described herein from materials that do not substantially distort MRI images or cause substantial artifacts (gaps in the images). Some ferromagnetic materials, for example, may not be suitable as they may create artifacts in an MRI image. In some cases, the devices described herein may include materials that the MRI machine can image. Some materials that exhibit these characteristics include, for example, tungsten, cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nitinol, and the like, and others.

**[0075]** In some instances, some of the devices described herein may include a coating such as a lubricious coating or a hydrophilic coating. Hydrophobic coatings such as fluoropolymers provide a dry lubricity. Lubricious coatings improve steerability and improve lesion crossing capability. Suitable lubricious polymers are well known in the art and may include silicone and the like, hydrophilic polymers such as high-density polyethylene (HDPE), polytetrafluoroethylene (PTFE), polyarylene oxides, polyvinylpyrrolidones, polyvinylalcohols, hydroxy alkyl cellulosics, algins, saccharides, caprolactones, and the like, and mixtures and combinations thereof. Hydrophilic polymers may be blended among themselves or with formulated amounts of water insoluble compounds (including some polymers) to yield coatings with suitable lubricity, bonding, and solubility.

**[0076]** In one embodiment of the present invention, a system for aspirating thrombus includes an aspiration catheter having a high pressure supply lumen and an aspiration lumen, the supply lumen having a proximal end configured to attach to a piston pump and a closed distal end, the aspiration lumen having a proximal end configured to attach to a vacuum source and an open distal end; a first orifice in a side wall of the

supply lumen which communicates directly with the interior of the aspiration lumen, the first orifice located proximal to the open distal end of the aspiration lumen and adjacent the closed distal end of the supply lumen; the piston pump configured to generate a cyclic pressure cycle when attached to the supply lumen, wherein the first orifice creates a spray pattern at least in conjunction with a peak of the piston pump pressure cycle such that the spray pattern impinges on an interior wall of the aspiration lumen when a distal end of the aspiration catheter is immersed within an environment having a temperature of between about 36°C and 38°C, such that the spray is at an angle of between about 20° in each direction of the vertical midline of the aspiration lumen.

**[0077]** In another embodiment of the present invention, a system for aspirating thrombus includes an aspiration catheter having a high pressure supply lumen and an aspiration lumen, the supply lumen having a proximal end configured to attach to a piston pump and a closed distal end, the aspiration lumen having a proximal end configured to attach to a vacuum source and an open distal end; a first orifice in a side wall of the supply lumen which communicates directly with the interior of the aspiration lumen, the first orifice located proximal to the open distal end of the aspiration lumen and adjacent the closed distal end of the supply lumen; the piston pump configured to generate a cyclic pressure cycle when attached to the supply lumen, wherein the first orifice creates a spray pattern at least in conjunction with a peak of the piston pump pressure cycle such that the spray pattern impinges on an interior wall of the aspiration lumen when a distal end of the aspiration catheter is immersed within an environment having a temperature of between about 36°C and 38°C; a disposable cassette having a supply cylinder, an injection cylinder and a piston, the disposable cassette configured to releasably couple to at least a motor of the piston pump, the piston configured to actuate into the supply cylinder while actuating out of the injection cylinder, causing the injection cylinder to increase its volume of a liquid injectate, the piston further configured to actuate into the injection cylinder while actuating out of the supply cylinder, causing the injection cylinder to decrease its volume by injecting the liquid injectate, and causing the liquid injectate to travel through the supply lumen of the aspiration catheter.

**[0078]** In another embodiment of the present invention, a system for aspirating thrombus includes an aspiration catheter having a high pressure supply lumen and an aspiration lumen, the supply lumen having a proximal end configured to attach to a piston

pump and a closed distal end, the aspiration lumen having a proximal end configured to attach to a vacuum source and an open distal end; a first orifice in a side wall of the supply lumen which communicates directly with the interior of the aspiration lumen, the first orifice located proximal to the open distal end of the aspiration lumen and adjacent the closed distal end of the supply lumen; the piston pump configured to generate a cyclic pressure cycle when attached to the supply lumen, wherein the first orifice creates a spray pattern at least in conjunction with a peak of the piston pump pressure cycle such that the spray pattern impinges on an interior wall of the aspiration lumen when a distal end of the aspiration catheter is immersed within an environment having a temperature of between about 36°C and 38°C; wherein the piston pump includes a supply cylinder, an injection cylinder and a piston, the piston configured to actuate into the supply cylinder while actuating out of the injection cylinder, causing the injection cylinder to increase its volume of a liquid injectate, the piston further configured to actuate into the injection cylinder while actuating out of the supply cylinder, causing the injection cylinder to decrease its volume by injecting the liquid injectate, and causing the liquid injectate to travel through the supply lumen of the aspiration catheter; wherein the piston is configured to engage with a saddle associated with the piston pump, the saddle configured for cyclic linear motion, wherein motion of the saddle in a first direction actuates the piston out of the supply cylinder and motion of the saddle in a second direction actuates the piston into the supply cylinder.

**[0079]** In another embodiment of the present invention, a system for aspirating thrombus includes an aspiration catheter having a high pressure supply lumen and an aspiration lumen, the supply lumen having a proximal end configured to attach to a piston pump and a closed distal end, the aspiration lumen having a proximal end configured to attach to a vacuum source and an open distal end; a first orifice in a side wall of the supply lumen which communicates directly with the interior of the aspiration lumen, the first orifice located proximal to the open distal end of the aspiration lumen and adjacent the closed distal end of the supply lumen; the piston pump configured to generate a cyclic pressure cycle when attached to the supply lumen, wherein the first orifice creates a spray pattern at least in conjunction with a peak of the piston pump pressure cycle such that the spray pattern includes a jet; wherein the piston pump includes a supply cylinder, an injection cylinder and a piston, the piston configured to actuate into the supply cylinder while actuating out of the injection cylinder, causing the injection cylinder to increase its

volume of a liquid injectate, the piston further configured to actuate into the injection cylinder while actuating out of the supply cylinder, causing the injection cylinder to decrease its volume by injecting the liquid injectate, and causing the liquid injectate to travel through the supply lumen of the aspiration catheter; wherein a usable volume ratio $R_U$ between the supply cylinder and the invention cylinder is between about 1.15 and about 2.00. Additionally, the usable volume ratio $R_U$ may be between about 1.25 and about 1.85. Additionally, the usable volume ratio $R_U$ may be about 1.40.

**[0080]** In another embodiment of the present invention a method for delivery of a drug includes providing a catheter including a supply lumen and an aspiration lumen, the supply lumen having a distal end, the aspiration lumen configured to couple to a vacuum source and having an interior wall surface, and an open distal end, an orifice at or near the distal end of the supply lumen, in fluid communication with the interior of the aspiration lumen, the orifice located proximally of the open distal end of the aspiration lumen, wherein the orifice is configured to create a spray pattern when pressurized fluid is pumped through the supply lumen such that the spray pattern impinges on the interior wall surface of the aspiration lumen when a distal end of the aspiration catheter is immersed within an aqueous environment, providing a disposable tubing set having a first conduit configured to couple the supply lumen of the catheter to a fluid source, and a pump component associated with the first conduit and configured to detachably couple to a drive unit, such that motion from the drive unit is transferred to the pump component such that resultant motion of the pump component causes fluid from the fluid source to be injected through the supply lumen of the catheter, and through the orifice into the aspiration lumen, coupling the supply lumen of the catheter to a fluid source, wherein the fluid source contains at least a first drug for intravascular delivery, inserting the catheter within a blood vessel of a patient and advancing the catheter to a target site, coupling the pump component to a drive unit, and operating the drive unit to cause the pump component to inject at least some of the first drug in the region of the target site.

**[0081]** It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the invention. The scope of the invention is, of course, defined in the language in which the appended claims are expressed.

**[0082]** While embodiments of the present invention have been shown and described, various modifications may be made without departing from the scope of the present invention. The invention, therefore, should not be limited, except to the following claims, and their equivalents. Embodiments of the present invention are contemplated to have utility in a variety of blood vessels, including but not limited to coronary arteries, carotid arteries, intracranial/cerebral arteries, inferior and superior vena cavae and other veins (for example, in cases of deep venous thrombosis), peripheral arteries, shunts, grafts, vascular defects, and chambers of the heart. This includes, but is not limited to, any vessel having a diameter of bout two mm or greater. An aspiration catheter 118 outer diameter of about seven French or less is contemplated for many of the applications, though in certain applications, it may be larger. In some embodiments, an aspiration catheter 118 diameter of about six French or less is contemplated. Embodiments of the present invention may even be used in non-vascular applications, for example body lumens or cavities having material accumulations that need to be macerated and/or removed.

**[0083]** It is contemplated that various combinations or subcombinations of the specific features and aspects of the embodiments disclosed above may be made and still fall within one or more of the inventions. Further, the disclosure herein of any particular feature, aspect, method, property, characteristic, quality, attribute, element, or the like in connection with an embodiment can be used in all other embodiments set forth herein. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the disclosed inventions. Thus, it is intended that the scope of the present inventions herein disclosed should not be limited by the particular disclosed embodiments described above. Moreover, while the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the various embodiments described and the appended claims. Any methods disclosed herein need not be performed in the order recited. The methods disclosed herein include certain actions taken by a practitioner; however, they

can also include any third-party instruction of those actions, either expressly or by implication.

WHAT IS CLAIMED IS:

1. A system for aspirating thrombus comprising:

an aspiration catheter having a supply lumen and an aspiration lumen, the supply lumen having a wall and a closed distal end, the aspiration lumen configured to couple to a vacuum source and having an interior wall surface, and an open distal end;

an orifice in the wall of the supply lumen, in fluid communication with the interior of the aspiration lumen, the orifice located proximally of the open distal end of the aspiration lumen and adjacent the closed distal end of the supply lumen, wherein the orifice is configured to create a spray pattern when pressurized fluid is pumped through the supply lumen such that the spray pattern impinges on the interior wall surface of the aspiration lumen when a distal end of the aspiration catheter is immersed within an aqueous environment; and

a tubing set having a first conduit configured to couple to the supply lumen of the aspiration catheter to a fluid source, and a pump component associated with the first conduit and configured to detachably couple to a drive unit, such that motion from the drive unit is transferred to the pump component such that resultant motion of the pump component causes fluid from the fluid source to be injected through the supply lumen of the aspiration catheter, and through the orifice into the aspiration lumen.

2. The system of claim 1, wherein the aqueous environment has a temperature of between about 36°C and 38°C.

3. The system of claim 1, wherein the pump component comprises a piston.

4. The system of claim 3, wherein the piston is slidably contained within a supply cylinder and an injection cylinder, the piston configured to actuate into the supply cylinder while actuating out of the injection cylinder, thus causing the injection cylinder to increase its volume of fluid supplied from the fluid source, and wherein the piston is further configured to actuate into the injection cylinder while actuating out of the supply cylinder, thus causing the injection cylinder to decrease its volume by injecting fluid supplied from the fluid source into the supply lumen of the aspiration catheter.

5. The system of claim 4, wherein the piston includes an inner bore having a one-way valve.

6. The system of claim 1, wherein the spray pattern is defined by an angle of between about 1° to about 45° in each direction of the vertical midline of the aspiration lumen.

7. The system of claim 6, wherein the spray pattern is defined by an angle of between about 20° to about 35° in each direction of the vertical midline of the aspiration lumen.

8. The system of claim 1, wherein a usable volume ratio $R_U$ between the supply cylinder and the injection cylinder is between about 1.15 and about 2.00.

9. The system of claim 8, wherein the usable volume ratio $R_U$ between the supply cylinder and the injection cylinder is between about 1.25 and about 1.85.

10. The system of claim 1, wherein the open distal end of the aspiration lumen has a most distal portion and a most proximal portion, and wherein an axial center of the orifice is about 0.3302 mm to about 0.4826 mm proximal to the most proximal portion of the open distal end of the aspiration lumen.

11. The system of claim 1, further comprising a vacuum-activated interface configured to cause the drive unit to start to operate or to remain in an operating condition when a vacuum pressure at the vacuum-activated interface is less than a threshold value, and configured to cause the drive unit to stop or to remain in a non-operating condition when the vacuum pressure at the vacuum-activated interface is greater than the threshold value.

12. The system of claim 11, wherein the vacuum-activated interface comprises a vacuum switch valve.

13. The system of claim 11, wherein the vacuum-activated interface comprises a pressure transducer.

14. The system of claim 1, wherein the open distal end of the aspiration lumen is angled in relation to the longitudinal axis of the aspiration lumen.

15. A system for aspirating thrombus comprising:

an aspiration catheter having a supply lumen and an aspiration lumen, the supply lumen having a distal end, the aspiration lumen configured to couple to a vacuum source and having an interior wall surface, and an open distal end;

an orifice at or near the distal end of the supply lumen, in fluid communication with the interior of the aspiration lumen, the orifice located proximally of the open distal end of the aspiration lumen, wherein the orifice is configured to create a spray pattern when pressurized fluid is pumped through the supply lumen such that the spray pattern impinges on the interior wall surface of the aspiration lumen when a distal end of the aspiration catheter is immersed within an aqueous environment; and

a tubing set having a first conduit configured to couple the supply lumen of the aspiration catheter to a fluid source, and a pump component associated with the first conduit and configured to detachably couple to a drive unit, such that motion from the drive unit is transferred to the pump component such that resultant motion of the pump component causes fluid from the fluid source to be injected through the supply lumen of the aspiration catheter, and through the orifice into the aspiration lumen.

16. The system of claim 15, wherein the supply lumen of the aspiration catheter extends generally parallel to the aspiration lumen, and wherein the distal end of the supply lumen curves towards the interior wall surface of the aspiration lumen.

17. The system of claim 16, wherein the distal end of the supply lumen has an internal diameter that is less than about 0.203 mm.

18. The system of claim 17, wherein the distal end of the supply lumen has an internal diameter that is between about 0.076 mm and about 0.102 mm.

19. The system of claim 16, wherein the open distal end of the aspiration lumen has a most distal portion and a most proximal portion, and wherein an axial center of the orifice is about 0.3302 mm to about 0.4826 mm proximal to the most proximal portion of the open distal end of the aspiration lumen.

20. The system of claim 16, wherein the aqueous environment has a temperature of between about 36°C and 38°C.

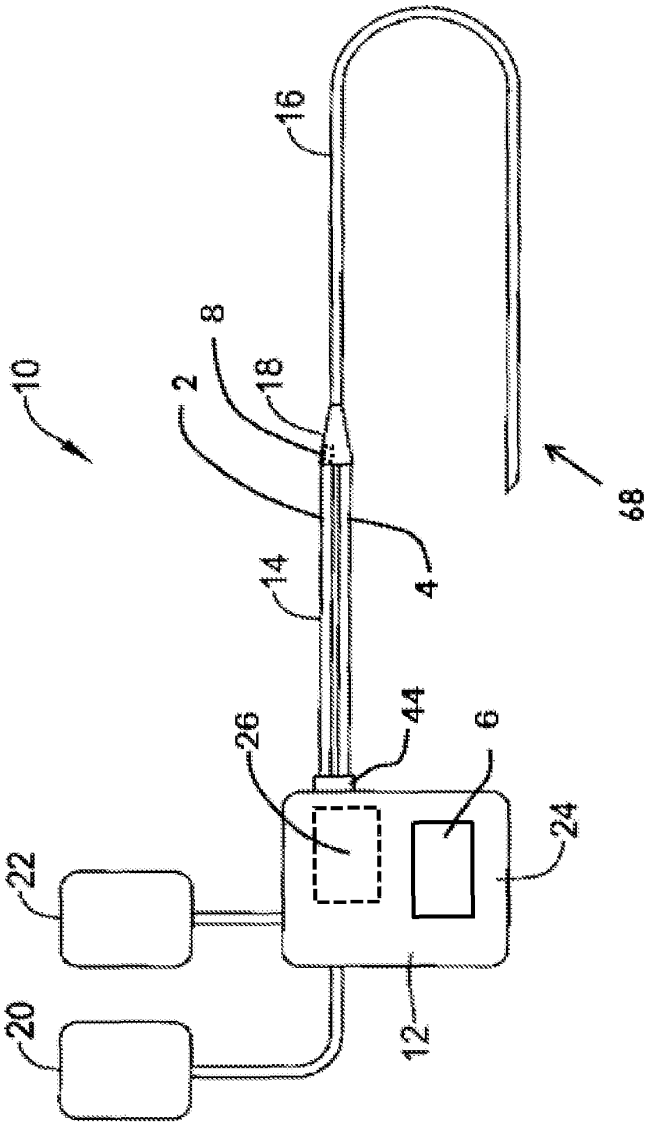



FIG. 1

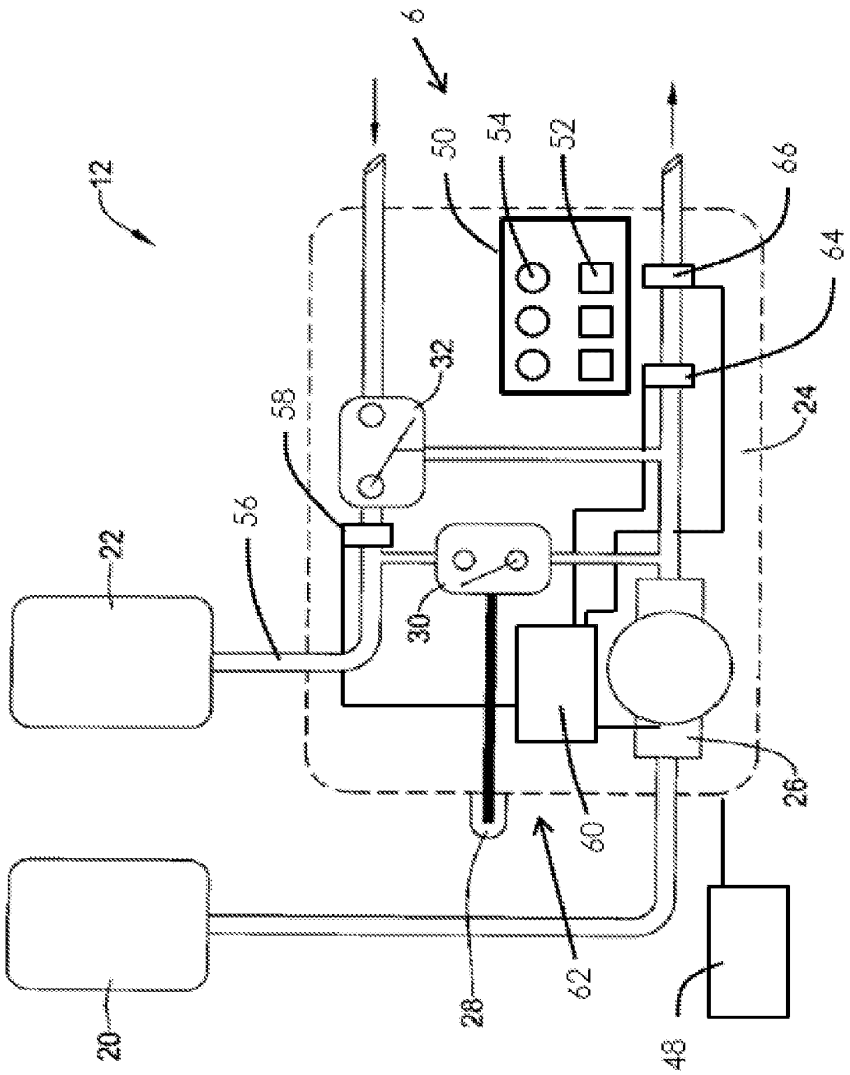



FIG. 2

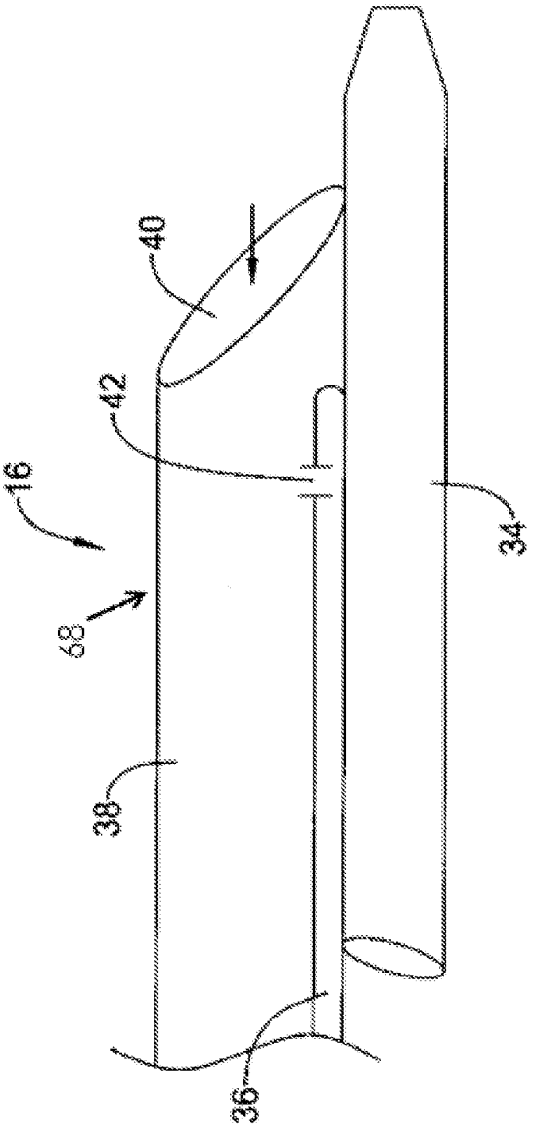



FIG. 3

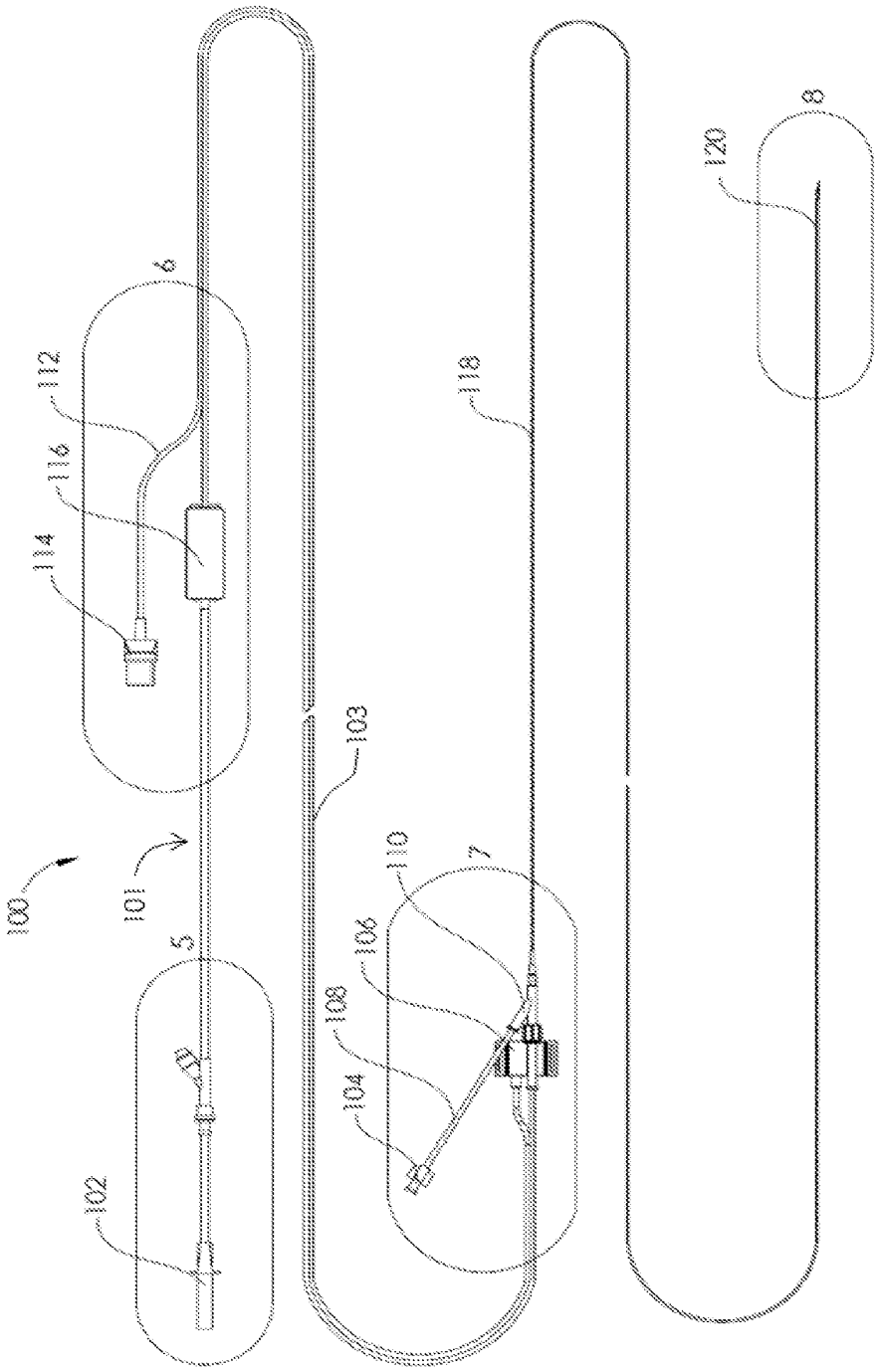



FIG. 4

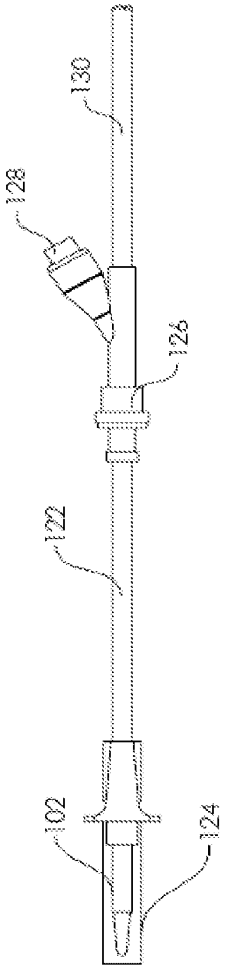

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FIG. 5

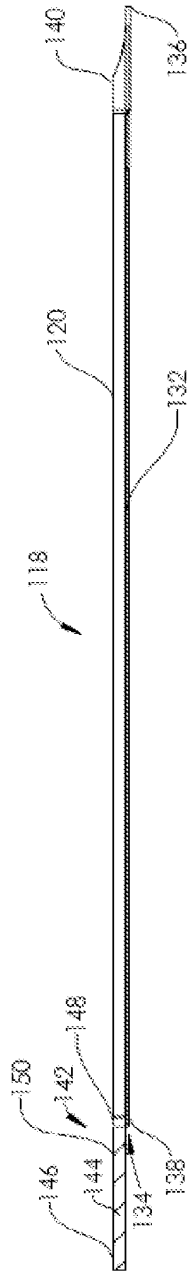

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FIG. 8

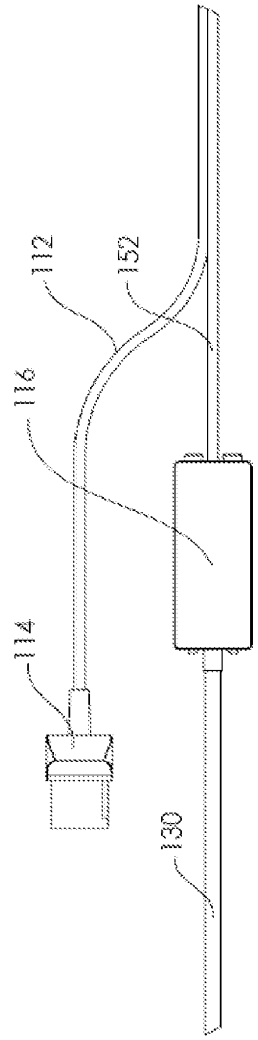



FIG. 6

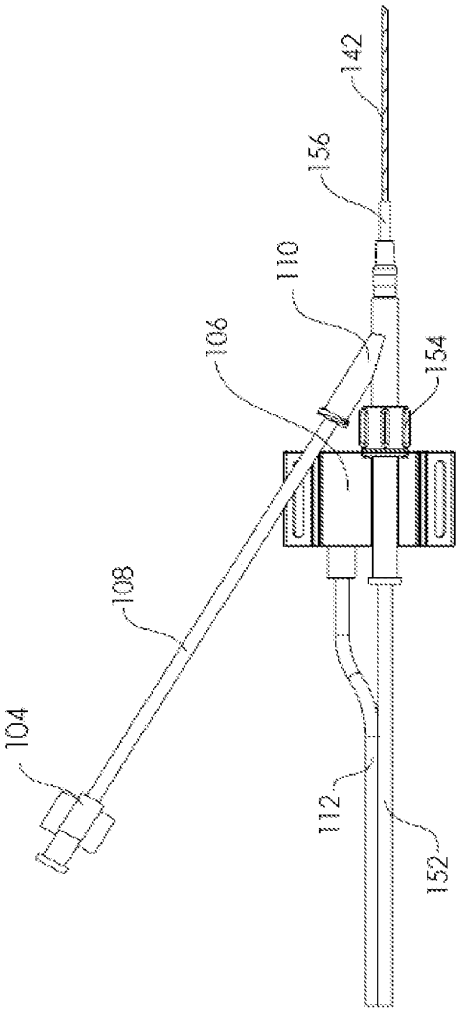



FIG. 7

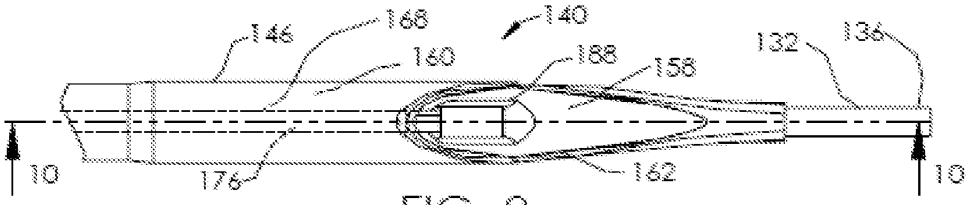



FIG. 9

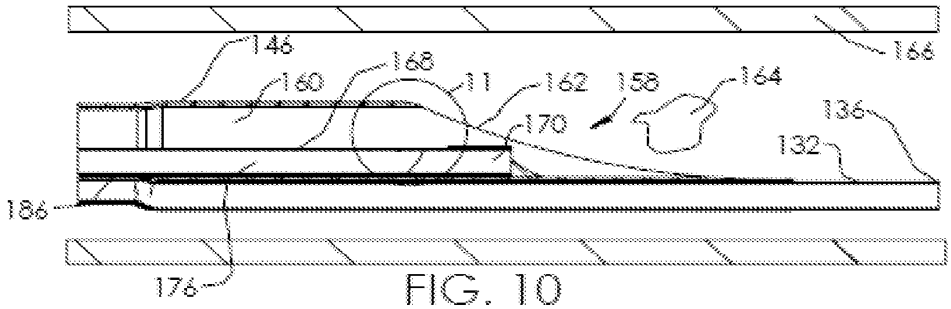



FIG. 10

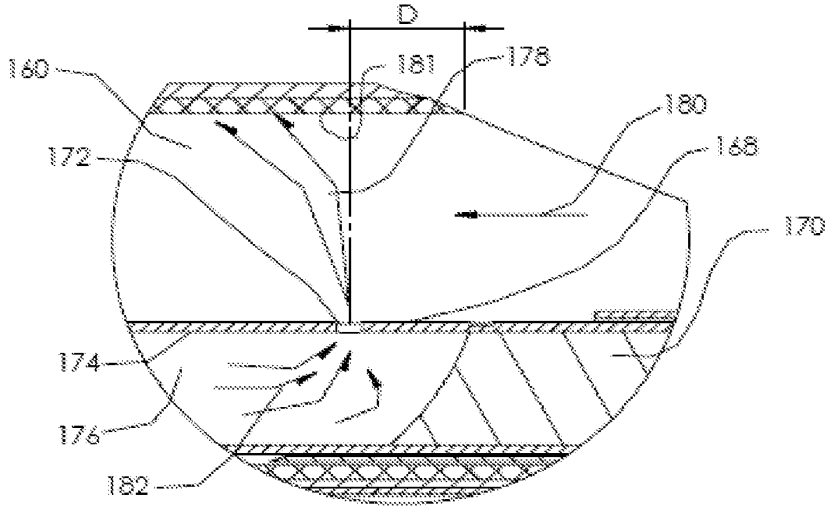



FIG. 11

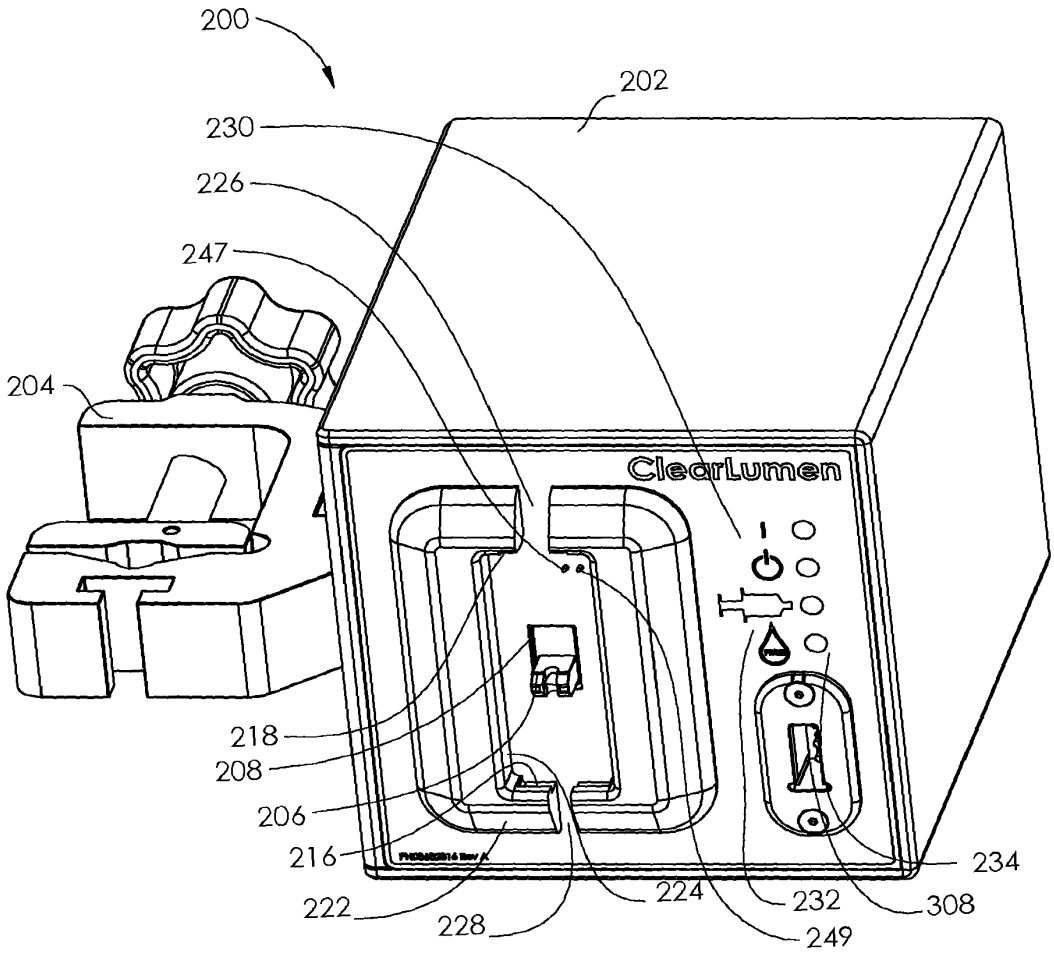

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FIG. 12

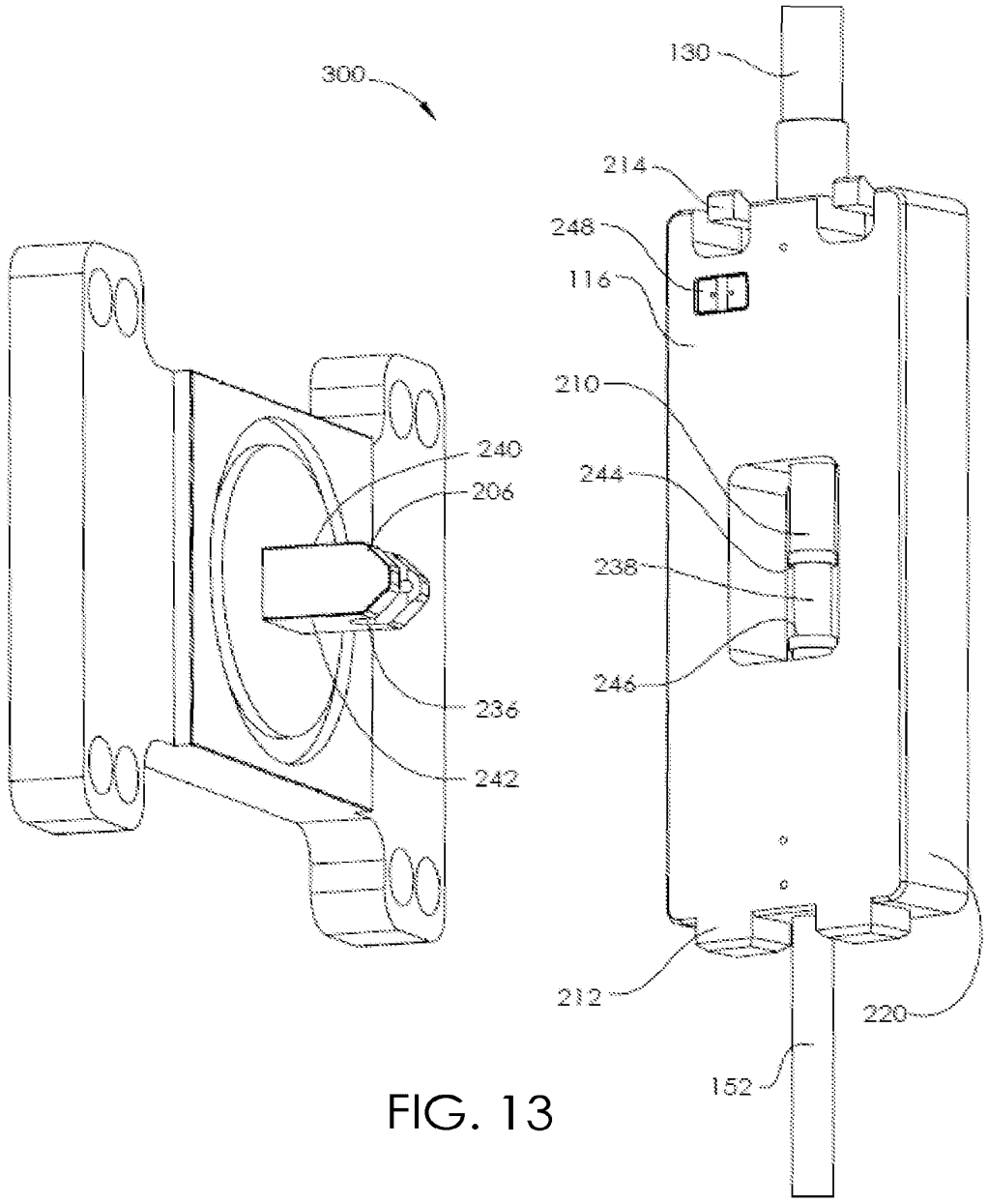



FIG. 13

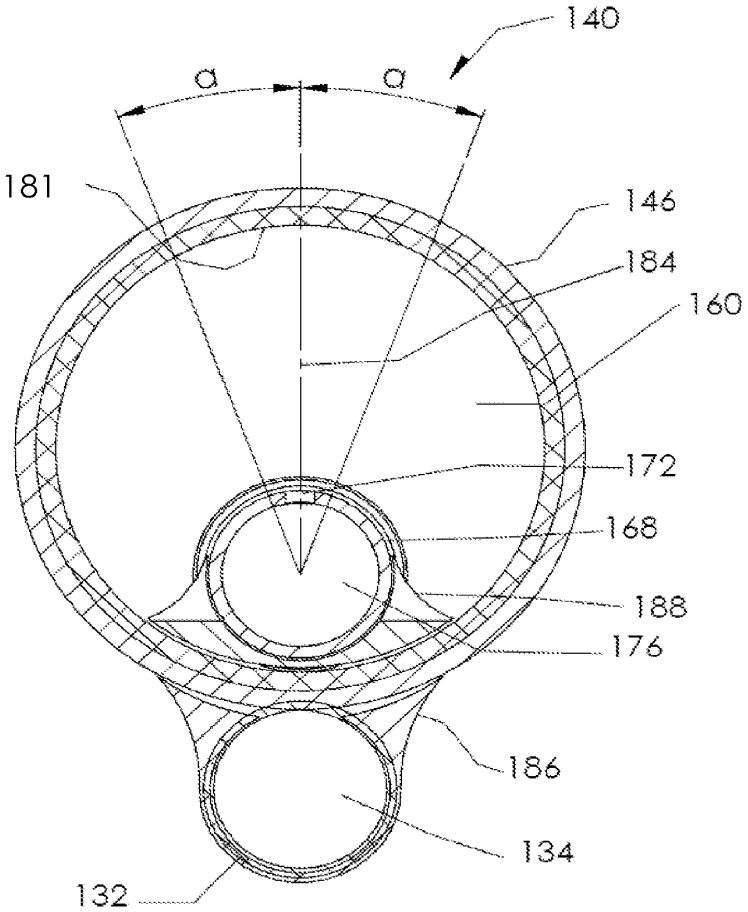



FIG. 14

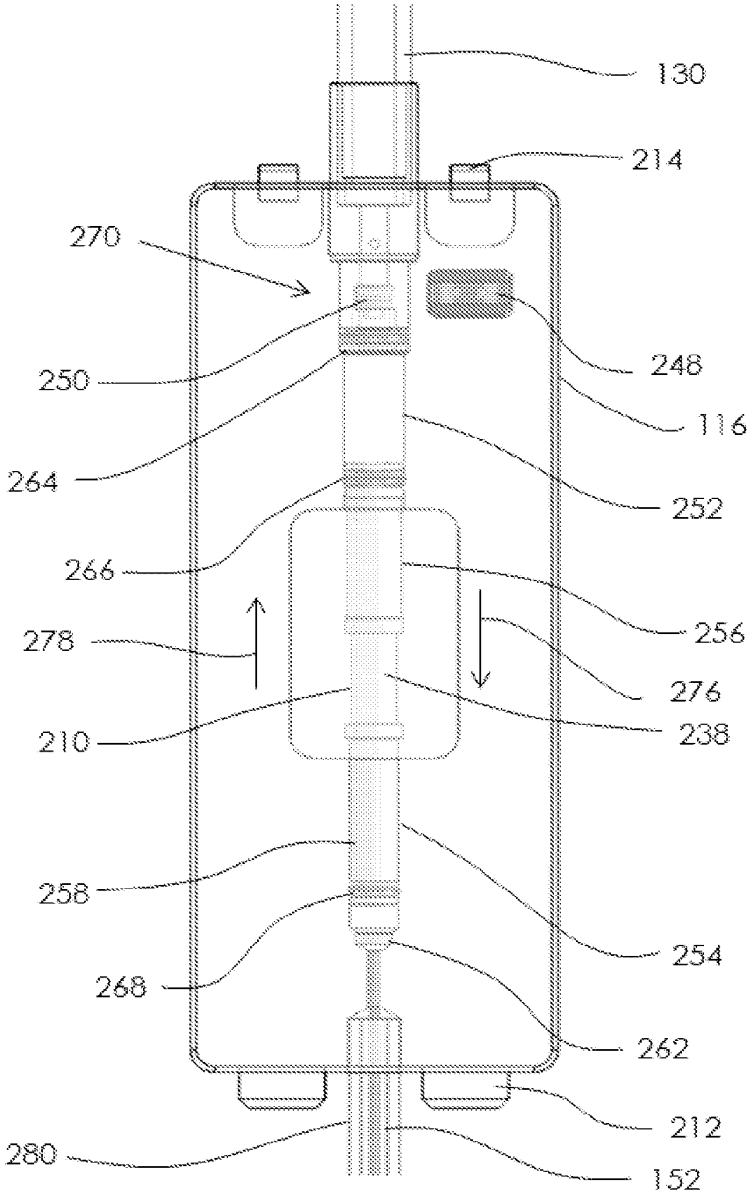

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FIG. 15

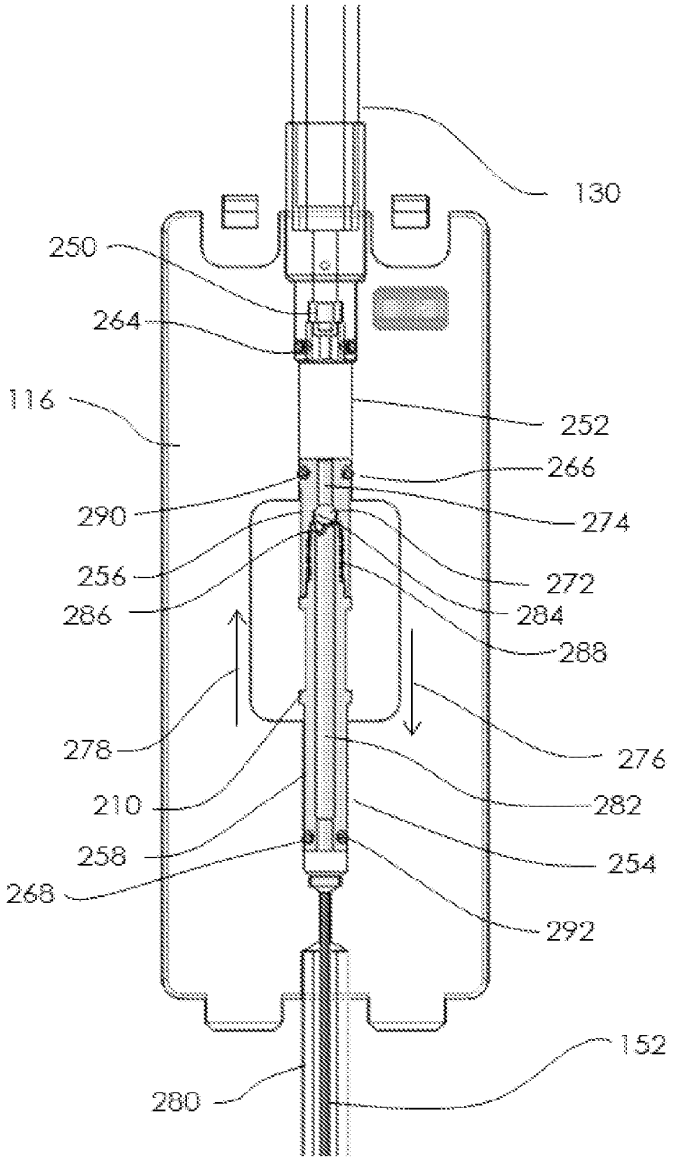

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FIG. 16

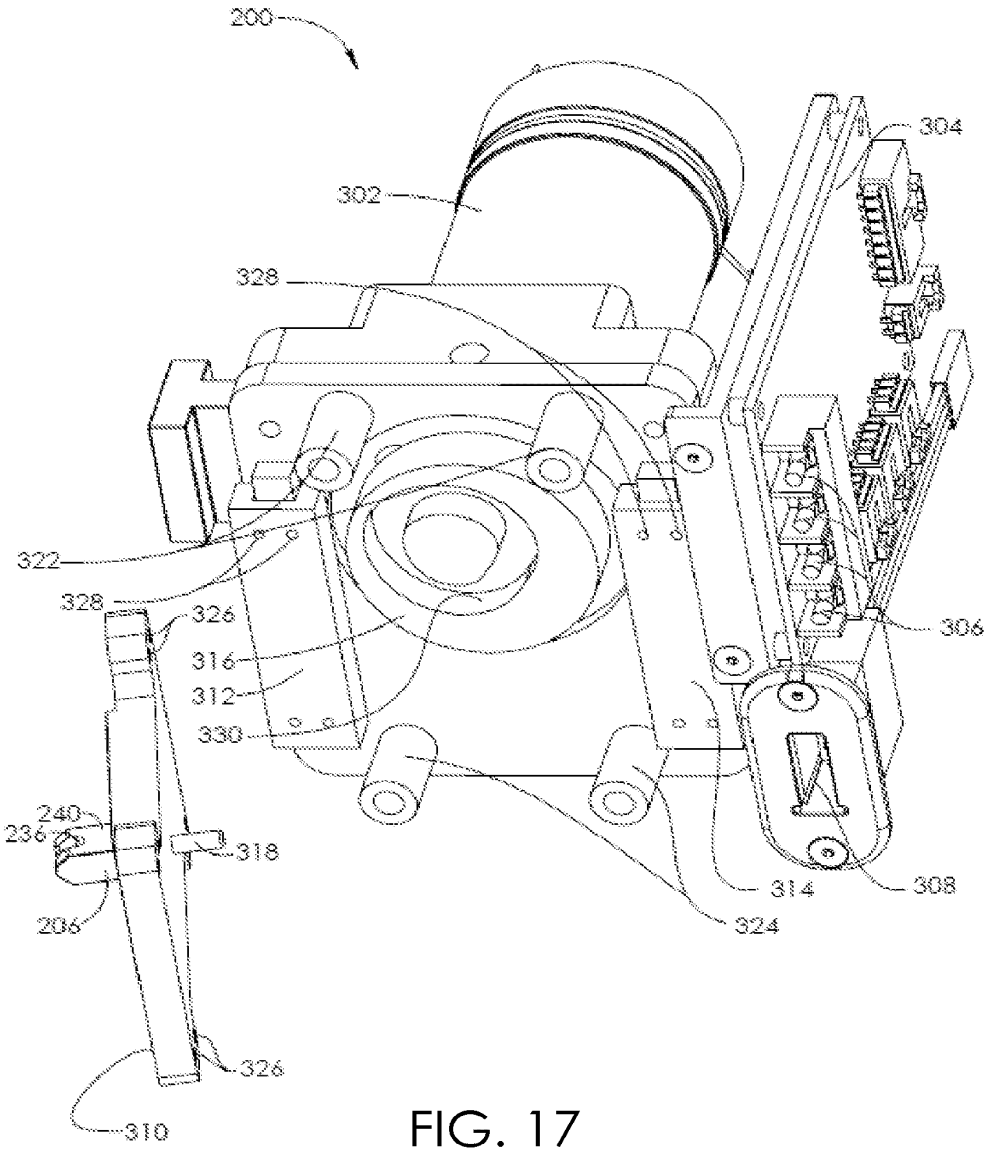

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FIG. 17

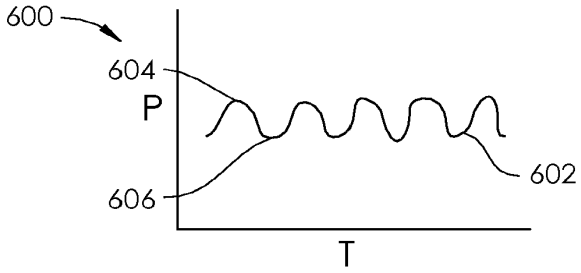



FIG. 18

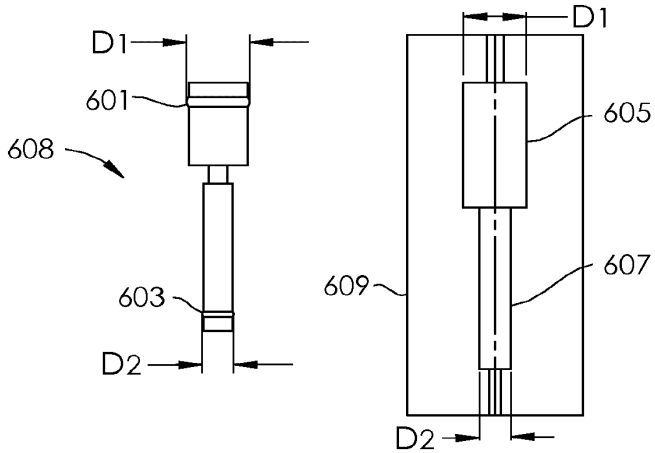



FIG. 19

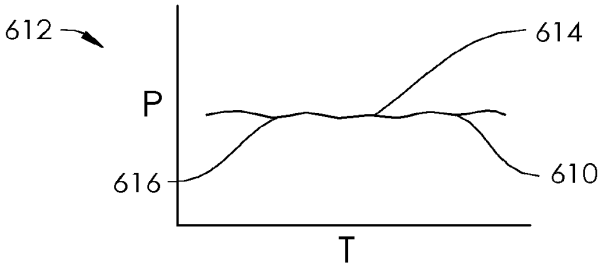



FIG. 20

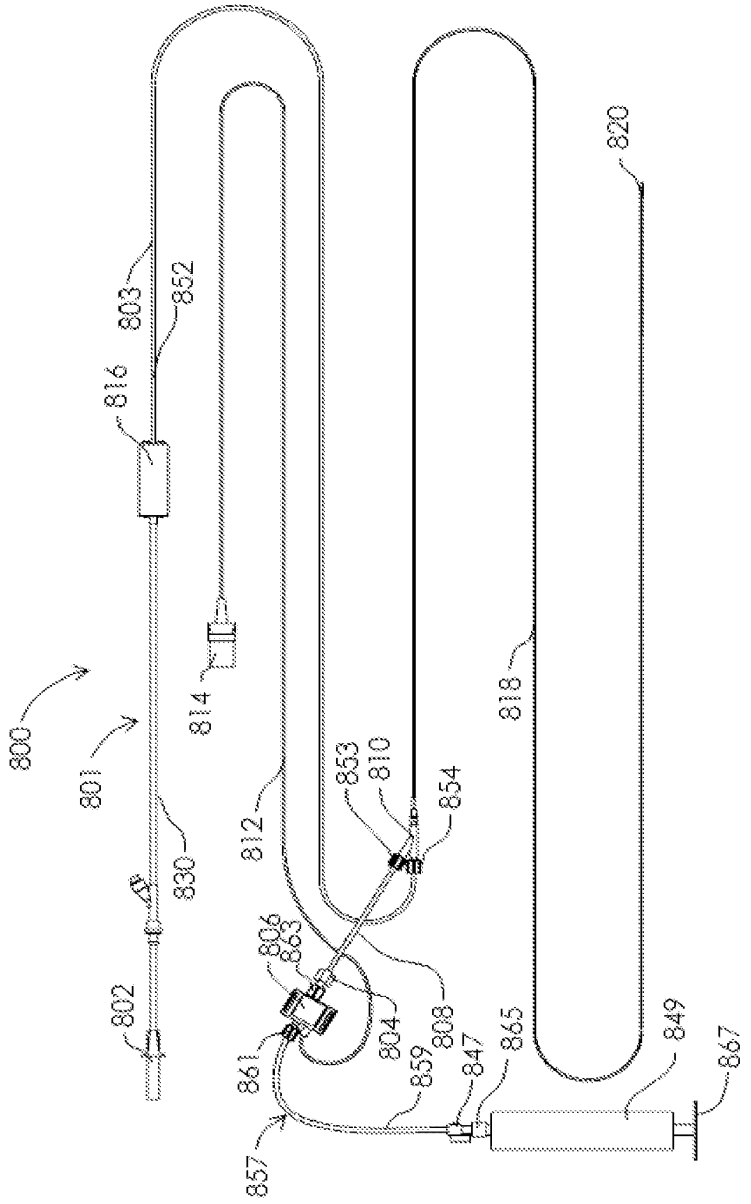

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FIG. 21

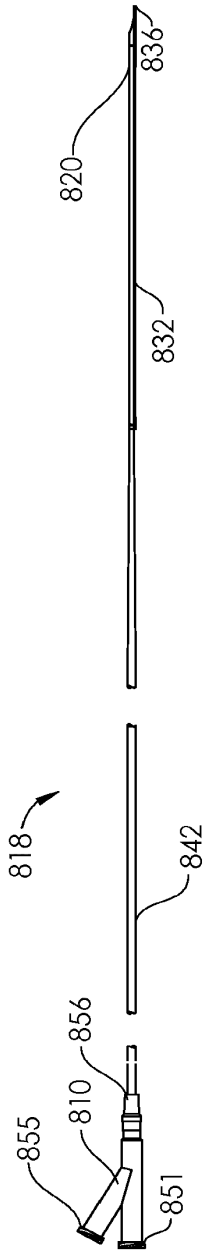



FIG. 22

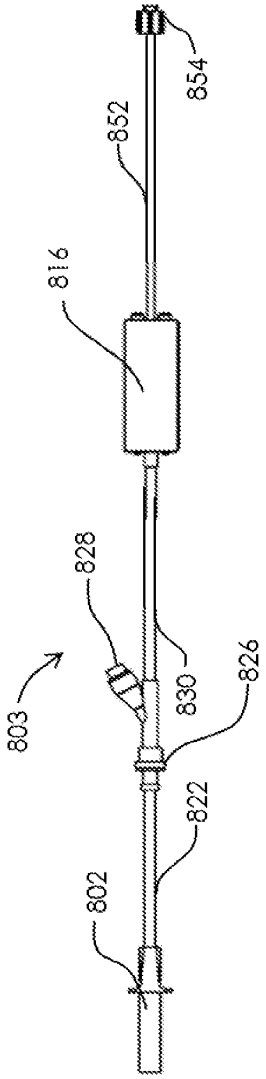



FIG. 23

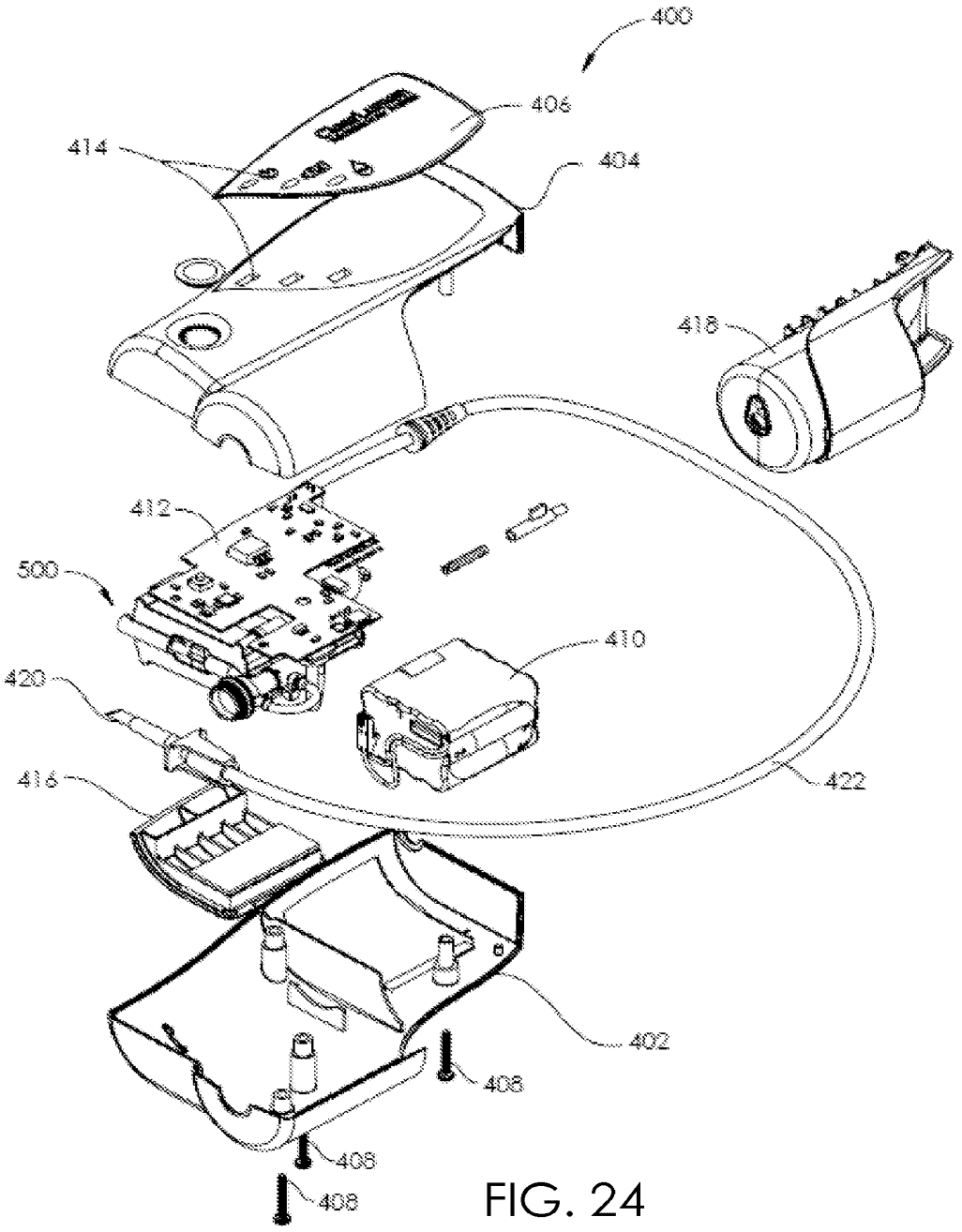



FIG. 24

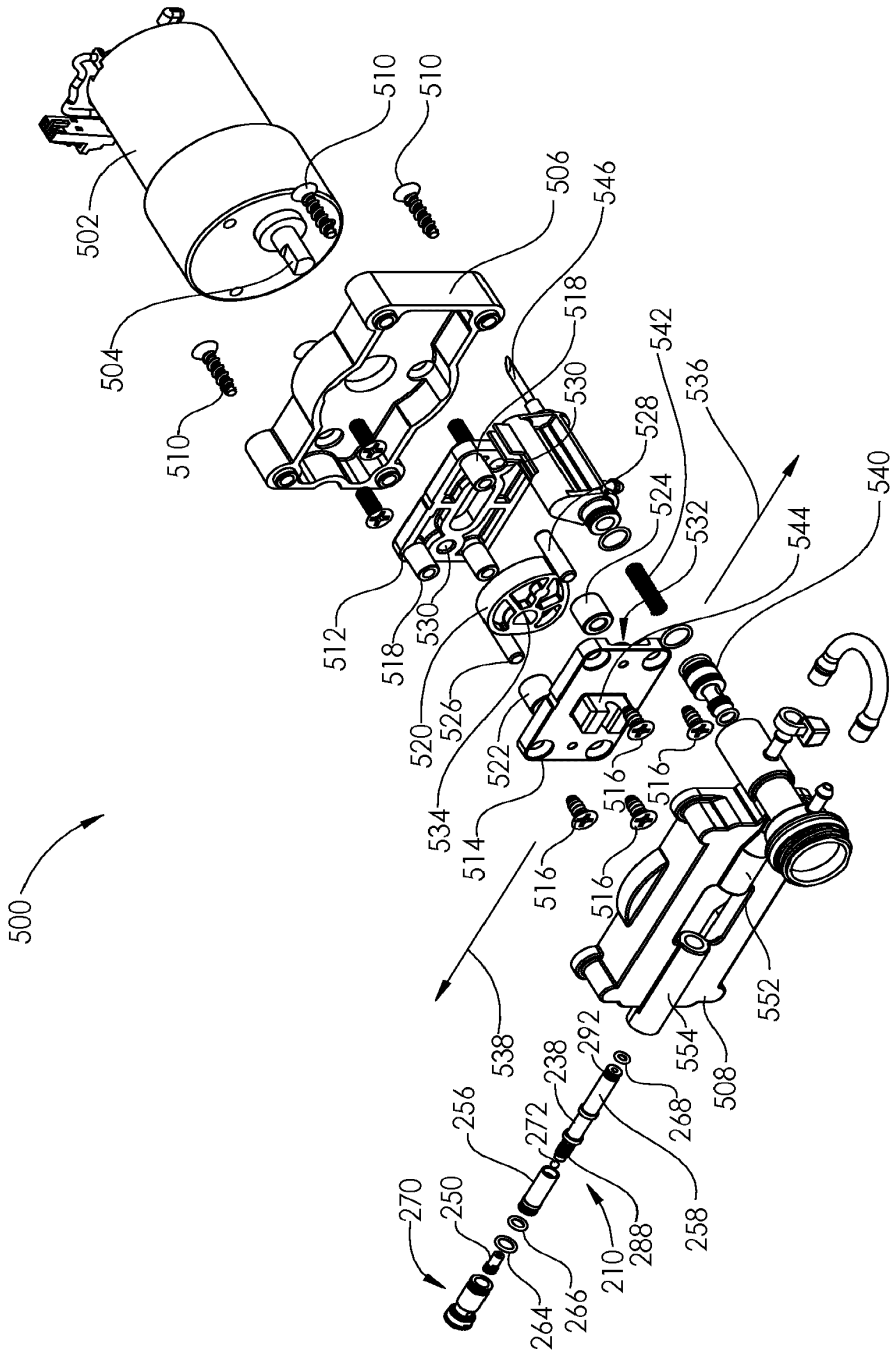

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FIG. 25

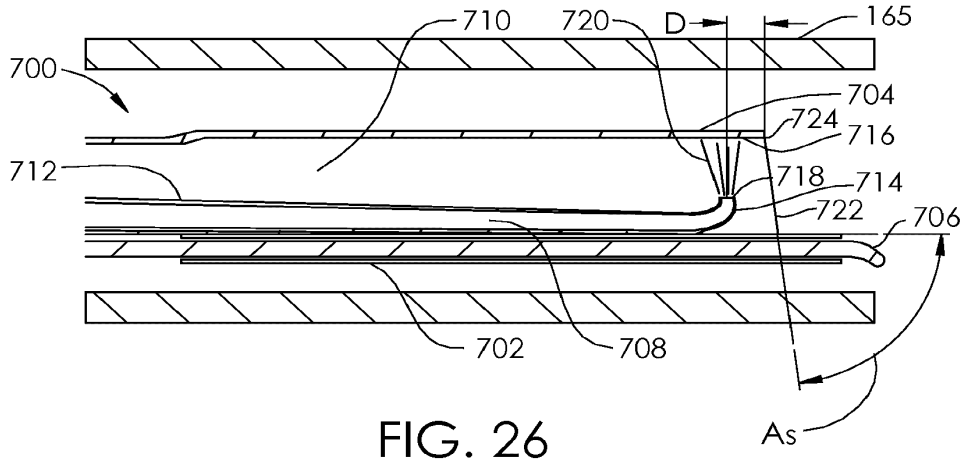

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FIG. 26

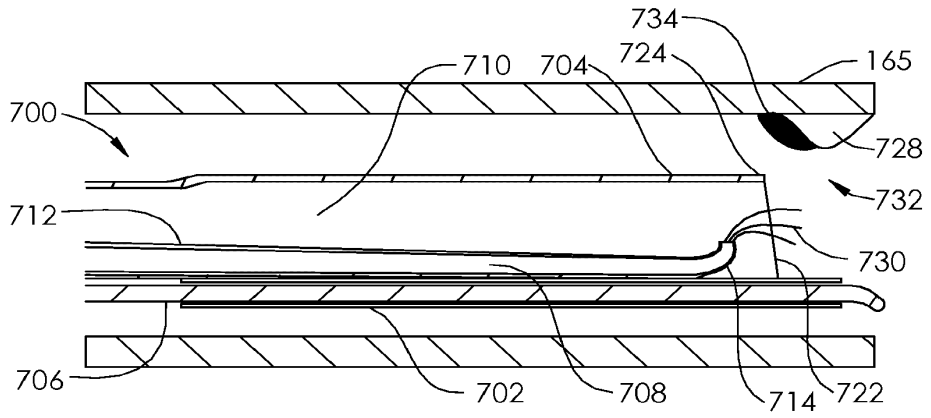

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FIG. 27

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/31460

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 1/00 (2015.01)
CPC - A61M 1/0084, A61M 25/003, A61M 1/0023, A61M 2039/082
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61M 1/00 (2015.01)
CPC - A61M 1/0084, A61M 25/003, A61M 1/0023, A61M 2039/082

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
604/508, 266-269 (UPC)
(Search term limited; see below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest (PGPB, USPT, EPAB, JPAB); Google; PatBase (All);
Search Terms: Aspirat*, suction*, vacuum*, drain*, catheter*, conduit, lumen, tube, jet, nozzle, spray, clog*, unclog*, declog*, obstruct*, anticlog*, antiobstr*, rinse, flush*, clean*, clear*, pump*, motor*, driv*, piston*, valve, one way, thromb*, blood

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | WO 1990/05493 A1 (SVEDMAN) 31 May 1990 (31.05.1990) Entire document, especially p3, ln 10 - p4, ln 27, p5, ln 11-30 and FIGS. 1, 4. | 1-20 |
| Y | US 3,429,313 A (ROMANELLI) 25 February 1969 (25.02.1969) Entire document, especially col 3, ln 10- col 4, ln 5, col 6, ln 67- col 7, ln 4 and FIG. 1. | 1-3, 6-7, 10-20 |
| Y | US 3,707,967 A (KITRILAKIS et al.) 02 January 1973 (02.01.1973) Entire document, especially Abstract, col 3, ln 44- col 4, ln 34 and FIGS. 1, 4. | 1, 4-5, 8-9 |
| A | US 2012/0289910 A1 (SHTUL et al.) 15 November 2012 (15.11.2012) Entire document. | 1-20 |
| A | US 5,713,849 A (BOSMA et al.) 03 February 1988 (03.02.1988) Entire document. | 1-20 |
| A | US 4,690,672 A (VELTRUP) 01 September 1987 (01.09.1987) Entire document. | 1-20 |
| A | US 3,916,892 A (HANSEN et al.) 11 May 1976 (11.05.1976) Entire document. | 1-20 |
| A | US 2,804,075 A (BORDEN) 27 August 1957 (27.08.1957) Entire document. | 1-20 |

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

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"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 16 July 2015 (16.07.2015) | 07 AUG 2015 |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | Authorized officer:<br>Lee W. Young<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |

Form PCT/ISA/210 (second sheet) (January 2015)

UNITED STATES
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# ELECTRONIC PAYMENT RECEIPT

| APPLICATION # | RECEIPT DATE / TIME | ATTORNEY DOCKET # |
|---|---|---|
| **17/498,642** | **08/29/2023 02:05:28 PM ET** | **111552-8023.US02** |

## Title of Invention

SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

## Application Information

| | | | |
|---|---|---|---|
| APPLICATION TYPE | Utility - Nonprovisional Application under 35 USC 111(a) | PATENT # | - |
| CONFIRMATION # | 1040 | FILED BY | JiYoung Anderson |
| PATENT CENTER # | 62698540 | AUTHORIZED BY | Matthew Williams |
| CUSTOMER # | 25096 | FILING DATE | 10/11/2021 |
| CORRESPONDENCE ADDRESS | - | FIRST NAMED INVENTOR | Richard Quick |

## Payment Information

| PAYMENT METHOD | PAYMENT TRANSACTION ID | PAYMENT AUTHORIZED BY |
|---|---|---|
| **CARD / 3369** | **E20238SE05529232** | **JiYoung Anderson** |

| FEE CODE | DESCRIPTION | ITEM PRICE($) | QUANTITY | ITEM TOTAL($) |
|---|---|---|---|---|
| 1251 | EXTENSION FOR RESPONSE WITHIN FIRST MONTH | 220.00 | 1 | 220.00 |
| 1806 | SUBMISSION OF AN INFORMATION DISCLOSURE STATEMENT | 260.00 | 1 | 260.00 |
| 1202 | EACH CLAIM IN EXCESS OF 20 | 100.00 | 13 | 1300.00 |
| | | | **TOTAL AMOUNT:** | **$1,780.00** |

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

described in MPEP 503.

**New Applications Under 35 U.S.C. 111**

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

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

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

**New International Application Filed with the USPTO as a Receiving Office**

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

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
03 August 2023 (03.08.2023)

WIPO | PCT

(10) International Publication Number
WO 2023/147353 A1

(51) International Patent Classification:
*A61M 1/00* (2006.01) *A61M 25/00* (2006.01)
*A61B 17/22* (2006.01)

(21) International Application Number:
PCT/US2023/061256

(22) International Filing Date:
25 January 2023 (25.01.2023)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/304,748 31 January 2022 (31.01.2022) US
63/395,586 05 August 2022 (05.08.2022) US

(71) Applicant: **INARI MEDICAL, INC.** [US/US]; 6001 Oak Canyon, Suite #100, Irvine, California 92618 (US).

(72) Inventors: **MERRITT, Benjamin Edward**; 6001 Oak Canyon, Suite #100, Irvine, California 92618 (US). **OFFERMAN, Garrett Thomas**; 6001 Oak Canyon, Suite #100, Irvine, California 92618 (US). **SLAUGHTER, Kali Wen-Tseng**; 6001 Oak Canyon, Suite #100, Irvine, California 92618 (US). **THRESS, John Coleman**; 6001 Oak Canyon, Suite #100, Irvine, California 92618 (US). **STRAUSS, Brian Michael**; 6001 Oak Canyon, Suite #100, Irvine, California 92618 (US). **FULLER, Donald Joseph**; 6001 Oak Canyon, Suite #100, Irvine, California 92618 (US). **SHIMIZU, Jared**; 6001 Oak Canyon, Suite #100, Irvine, California 92618 (US).

(74) Agent: **WILLIAMS, Matthew S.** et al.; PERKINS COIE LLP, P.O. Box 1247, Seattle, Washington 98111-1247 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU,

(54) Title: ASPIRATION CATHETERS HAVING GROOVED INNER SURFACES, AND ASSOCIATED SYSTEMS AND METHODS

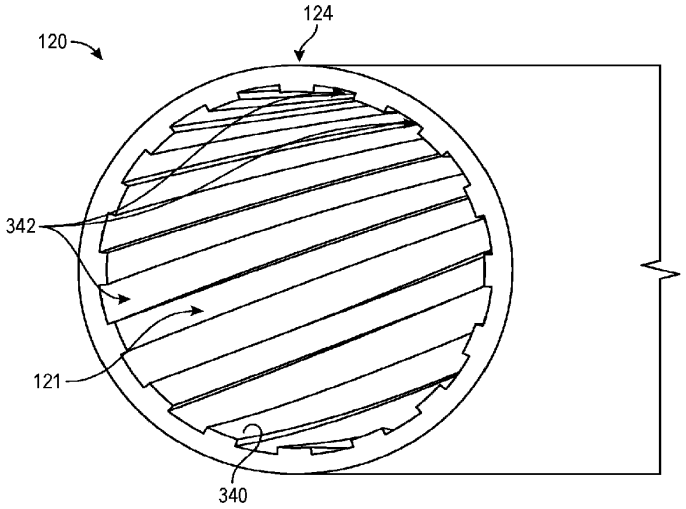



*FIG. 3A*

(57) Abstract: Disclosed herein are aspiration catheters having grooved inner surfaces for removing clot material from the vasculature of a patient, and associated systems and methods. In some embodiments, an aspiration catheter can include a proximal terminus, a distal terminus, and an inner surface defining a lumen. The inner surface includes at least one groove formed therein and that extends from the distal terminus at least partially toward the proximal terminus. When clot material is aspirated through the aspiration catheter, the at least one groove can provide a leak path past the clot material to improve the ingestion of the clot material through the catheter and inhibit clogging.

*[Continued on next page]*

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# ASPIRATION CATHETERS HAVING GROOVED INNER SURFACES, AND ASSOCIATED SYSTEMS AND METHODS

## CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This application claims the benefit of U.S. Provisional Patent Application No. 63/304,748, filed January 31, 2022, and titled "ASPIRATION CATHETERS HAVING GROOVED INNER SURFACES, AND ASSOCIATED SYSTEMS AND METHODS," and U.S. Provisional Patent Application No. 63/395,586, filed August 5, 2022, and titled "ASPIRATION CATHETERS HAVING GROOVED INNER SURFACES, AND ASSOCIATED SYSTEMS AND METHODS," each of which is incorporated by reference herein in its entirety.

## TECHNICAL FIELD

**[0002]** The present technology generally relates to clot treatment systems including aspiration catheters having grooved or rifled inner surfaces to facilitate increased clot ingestion into the aspiration catheter, reduce clogging of the aspiration catheter, increase/optimize flowrate within the aspiration catheter, and/or enhance clot removal through the aspiration catheter.

## BACKGROUND

**[0003]** Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

**[0004]** When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. Infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

**[0005]** In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT arises most commonly when there is a propensity for stagnated blood (e.g., long distance air travel, immobility, etc.) and clotting (e.g., cancer, recent surgery, such as orthopedic surgery, etc.). DVT causes harm by: (1) obstructing drainage of venous blood

from the legs leading to swelling, ulcers, pain, and infection, and (2) serving as a reservoir for blood clots to travel to other parts of the body including the heart, lungs, brain (stroke), abdominal organs, and/or extremities.

**[0006]** In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs, and therefore the entire body, and result in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting in low blood oxygen and buildup of blood carbon dioxide.

**[0007]** There are many existing techniques to reestablish blood flow through an occluded vessel. One common surgical technique, an embolectomy, involves incising a blood vessel and introducing a balloon-tipped device (such as the Fogarty catheter) to the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to translate the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Although such surgical techniques have been useful, exposing a patient to surgery may be traumatic and best avoided when possible. Additionally, the use of a Fogarty catheter may be problematic due to the possible risk of damaging the interior lining of the vessel as the catheter is being withdrawn.

**[0008]** Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating vessel stenosis, but it is generally not effective for treating acute thromboembolisms as none of the occlusive material is removed and the vessel will re-stenos after dilation. Another percutaneous technique involves placing a catheter near the clot and infusing streptokinase, urokinase, or other thrombolytic agents to dissolve the clot. Unfortunately, thrombolysis typically takes hours to days to be successful. Additionally, thrombolytic agents can cause hemorrhage and in many patients the agents cannot be used at all.

**[0009]** Various devices exist for performing a thrombectomy or removing other foreign material. However, such devices have been found to have structures which are either highly complex, cause trauma to the treatment vessel, or lack sufficient retaining structure and thus

cannot be appropriately fixed against the vessel to perform adequately. Furthermore, many of the devices have highly complex structures that lead to manufacturing and quality control difficulties as well as delivery issues when passing through tortuous or small diameter catheters. Less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all the clot material.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0010]** Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

**[0011]** Figure 1 is a partially schematic side view of a clot treatment system including a catheter in accordance with embodiments of the present technology.

**[0012]** Figures 2A and 2B are an enlarged partial cut-away side and an isometric view, respectively, of a portion of the catheter of the system of Figure 1 in accordance with embodiments of the present technology.

**[0013]** Figures 3A and 3B are an enlarged isometric view and a proximally-facing longitudinal view, respectively, of a distal portion of the catheter of Figure 1 in accordance with embodiments of the present technology. Figure 3C is an interior view of the catheter from within a lumen of the catheter in accordance with embodiments of the present technology. Figure 3D is a partially-transparent isometric view of the catheter in accordance with embodiments of the present technology.

**[0014]** Figure 4 is a partially-transparent isometric view of the catheter of Figure 1 in accordance with additional embodiments of the present technology.

**[0015]** Figure 5 is an interior view of the catheter of Figure 1 from within a lumen of the catheter in accordance with additional embodiments of the present technology.

**[0016]** Figures 6A and 6B are an enlarged isometric view and an enlarged cross-sectional side view, respectively, of a distal portion of the catheter of Figure 1 in accordance with additional embodiments of the present technology.

**[0017]** Figures 7A and 7B are side views of a distal portion of the clot treatment system of Figure 1 during a procedure for removing clot material from within a blood vessel of a patient in accordance with embodiments of the present technology.

**[0018]** Figures 8A and 8B are a proximally-facing longitudinal view and an enlarged partially-transparent side view, respectively, of a distal portion of the catheter of Figure 1 with clot material ingested therein in accordance with embodiments of the present technology.

**[0019]** Figures 9A and 9B are perspective views of the clot treatment system of Figure 1 traversing a simulated pathway to the right pulmonary artery and the left pulmonary artery, respectively, in accordance with embodiments of the present technology. Figures 9C and 9D are distally-facing longitudinal views of a proximal portion of the catheter of Figure 1 illustrating a flow pattern during aspiration without any interior grooves and with an arrangement of grooves shown in Figures 3A–3D, respectively, when the catheter traverses the simulated pathway to the right pulmonary artery shown in Figure 9A in accordance with embodiments of the present technology.

**[0020]** Figure 10A is a graph of a measured flow rate through the catheter of Figure 1 versus a number of revolutions of interior grooves along the length of the catheter for the simulated pathway to the right pulmonary artery shown in Figure 9A in accordance with embodiments of the present technology. Figure 10B is a graph of a corresponding measured time to aspirate an occlusive synthetic clot through the catheter in accordance with embodiments of the present technology.

**[0021]** Figure 11A is a graph of a measured distance traveled of an occlusive synthetic clot versus the number of revolutions of interior grooves along the length of the catheter when the clot was aspirated through the catheter of Figure 1 for the simulated pathway to the right pulmonary artery shown in Figure 9A in accordance with embodiments of the present technology. Figure 11B is a graph of a corresponding measured clot velocity in accordance with embodiments of the present technology.

**[0022]** Figure 12 is a graph of a measured maximum force required to move an occlusive synthetic clot through the catheter of Figure 1 versus the number of revolutions of interior grooves along the length of the catheter when the clot was aspirated through the catheter for the simulated pathway to the right pulmonary artery shown in Figure 9A in accordance with embodiments of the present technology.

**[0023]** Figure 13 is a longitudinal view of a mandrel over which the catheter of Figure 1 can be formed in accordance with embodiments of the present technology.

**[0024]** Figures 14A and 14B are a cross-sectional longitudinal view and an enlarged isometric view, respectively, of a mandrel over which the catheter of Figure 1 can be formed in accordance with additional embodiments of the present technology.

DETAILED DESCRIPTION

**[0025]** The present technology is generally directed to aspiration catheters having grooved inner surfaces for removing unwanted material from a patient, such as clot material from the vasculature of the patient, and associated systems and methods. In some embodiments, an aspiration catheter can include a proximal terminus, a distal terminus, and an inner surface defining a lumen. The inner surface includes at least one groove formed therein that extends at least partially between the distal terminus and the proximal terminus. When clot material is aspirated through the aspiration catheter, the at least one groove can provide a leak path past the clot material to improve the ingestion of the clot material through the catheter and inhibit clogging.

**[0026]** In some embodiments, the lumen extends about a longitudinal axis and the at least one groove can revolve circumferentially about the longitudinal axis between the proximal terminus and the distal terminus. Accordingly, the at least one groove can have a spiral/helical shape along the length of the aspiration catheter. In some aspects of the present technology, the spiral/helical shape of the at least one groove can generate a helical flow pattern within the lumen when clot material is aspirated through the aspiration catheter. The helical flow pattern can act to elongate and/or break apart the clot material and can increase the speed at which the clot material is ingested.

**[0027]** Certain details are set forth in the following description and in Figures 1–14B to provide a thorough understanding of various embodiments of the present technology. In other instances, well-known structures, materials, operations, and/or systems often associated with intravascular procedures, clot removal procedures, clot aspiration, catheters, and the like are not shown or described in detail in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. Those of ordinary skill in the art will recognize, however, that the present technology can be practiced without one or more of the details set forth herein, and/or with other structures, methods, components, and so forth. Moreover, although many of the devices and systems are described herein in the context of removing and/or treating clot material, the present technology can be used to remove and/or treat other unwanted material in addition or alternatively to clot material, such as thrombi, emboli,

plaque, intimal hyperplasia, post-thrombotic scar tissue, etc. Accordingly, the terms "clot" and "clot material" as used herein can refer to any of the foregoing materials and/or the like.

**[0028]** The terminology used below is to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain examples of embodiments of the technology. Indeed, certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

**[0029]** The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope unless expressly indicated. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles and features without departing from the present technology. In addition, those of ordinary skill in the art will appreciate that further embodiments of the present technology can be practiced without several of the details described below.

**[0030]** With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

**[0031]** The headings provided herein are for convenience only and should not be construed as limiting the subject matter disclosed.

## I. Selected Embodiments of Clot Treatment Systems

**[0032]** Figure 1 is a partially schematic side view of a clot treatment system 100 in accordance with embodiments of the present technology. The clot treatment system 100 can

also be referred to as an aspiration assembly, a clot removal system, a thrombectomy system, and/or the like. Although referred to as a clot treatment system and generally described in the context of removing clot material from the vasculature of the patient, the system 100 can be used to treat and/or remove other unwanted matter from the vasculature, body ducts, and/or other lumens of a patient. For example, the system 100 can be used to treat and/or remove emboli, foreign bodies, vegetation, and other materials from within the vasculature of a patient, gall stones from the gallbladder, and/or other materials from other body lumens.

**[0033]** In the illustrated embodiment, the clot treatment system 100 includes a tubing assembly 110 fluidly coupled to a catheter 120 via a valve 102. The catheter 120 can be referred to as an aspiration catheter, a guide catheter, an aspiration guide catheter, and/or the like. In general, the clot treatment system 100 (i) can include features generally similar or identical to those of the clot treatment systems described in detail in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety, and/or (ii) can be used to treat/remove clot material from a patient (e.g., a human patient) using any of the methods described in detail therein.

**[0034]** In the illustrated embodiment, the catheter 120 includes a proximal region or portion 122 and a distal region or portion 124 adjacent to and distal of the proximal portion 122. The catheter 120 further defines a lumen 121 extending entirely therethrough from the proximal portion 122 to the distal portion 124. The proximal portion 122 defines a proximal terminus 123 of the catheter 120, and the distal portion 124 defines a distal tip or terminus 125 of the catheter 120. In the illustrated embodiment, the distal portion 124 includes a marker band 126, such as a radiopaque marker configured to facilitate visualization of the position of the catheter 120 during a medical procedure (e.g., a clot removal procedure) using the catheter 120. In some embodiments, the catheter 120 can have a length L of between about 20–50 inches, between about 30–40 inches, about 35 inches, and so on.

**[0035]** The valve 102 is fluidly coupled to the lumen 121 of the catheter 120 and can be integral with or coupled to the proximal portion 122 of the catheter 120. In some embodiments, the valve 102 is a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by inhibiting or even preventing fluid flow in the proximal direction through the valve 102 as various components such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and the like are inserted through the valve 102

to be delivered through the catheter 120 to a treatment site in a blood vessel. The valve 102 includes a branch or side port 104 configured to fluidly couple the lumen 121 of the catheter 120 to the tubing assembly 110. In some embodiments, the valve 102 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety.

**[0036]** In the illustrated embodiment, the tubing assembly 110 fluidly couples the catheter 120 to a pressure source 106, such as a syringe (e.g., an auto-pressure locking syringe). The tubing assembly 110 can include (i) one or more tubing sections 112 (individually identified as a first tubing section 112a and a second tubing section 112b), (ii) at least one fluid control device 114 (e.g., a valve), and (iii) at least one connector 116 (e.g., a Toomey tip connector) for fluidly coupling the tubing assembly 110 to the pressure source 106 and/or other suitable components. In some embodiments, the fluid control device 114 is a stopcock that is fluidly coupled to (i) the side port 104 of the valve 102 via the first tubing section 112a and (ii) the connector 116 via the second tubing section 112b. The fluid control device 114 is externally operable by a user to regulate the flow of fluid therethrough and, specifically, from the lumen 121 of the catheter 120 to the pressure source 106. For example, the fluid control device 114 can be actuated to fluidly connect and fluidly disconnect the pressure source 106 from the lumen 121 of the catheter 120. In some embodiments, the connector 116 is a quick-release connector (e.g., a quick disconnect fitting) that enables rapid coupling/decoupling of the catheter 120 and the fluid control device 114 to/from the pressure source 106.

**[0037]** Figures 2A and 2B are an enlarged partial cut-away side and an isometric view, respectively, of a portion of the catheter 120 of Figure 1 in accordance with embodiments of the present technology. Referring to Figures 2A and 2B together, the catheter 120 includes an outer sheath 230 and an inner liner 232. The outer sheath 230 is positioned over (e.g., radially outside of) the inner liner 232. The outer sheath 230 can also be referred to as an outer jacket, an outer shaft, or an outer layer, and the inner liner 232 can also be referred to as an inner layer, an inner sheath, or an inner shaft. In the illustrated embodiment, the catheter 120 further includes (i) a braid 234 extending between the outer sheath 230 and the inner liner 232 and (ii) a coil 236 extending between the outer sheath 230 and the braid 234. In some embodiments, the braid 234 and the coil 236 extend along the entire length L (Figure 1) of the catheter 120. In some embodiments, the inner liner 232 can be omitted and the outer sheath 230 and/or another component of the catheter 120 can define an inner surface of the catheter 120.

**[0038]** In some embodiments, the outer sheath 230 is formed from a plastic material, elastomeric material, and/or thermoplastic elastomer (TPE) material. For example, the outer sheath 230 can be formed from a TPE manufactured by Arkema S.A., of Colombes, France, such as the TPEs manufactured under the trademark "Pebax." The inner liner 232 defines the lumen 121 and can be formed of a lubricious material that facilitates the movement (e.g., distal advancement, proximal retraction) of various components through the lumen 121, such as clot material, delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and the like. In some embodiments, the inner liner 232 is formed from a polymer material, a fluoropolymer material (e.g., polytetrafluoroethylene (PTFE)), and/or another material having a high degree of lubricity. In some embodiments, the inner liner 232 has an inner diameter D (Figure 2) of between about 0.2–0.5 inch (e.g., about 0.270 inch), greater than about 10 French, greater than about 16 French, greater than about 20 French, greater than about 24 French, or greater. In some embodiments, the diameter D is about 20 French or about 24 French.

**[0039]** The braid 234 can include wires, filaments, threads, sutures, fibers, or the like (collectively "wires 238") that have been woven or otherwise coupled, attached, formed, and/or joined together at a plurality of interstices 239. Accordingly, the braid 234 can also be referred to as a braided structure, a braided filament structure, a braided filament mesh structure, a mesh structure, a mesh filament structure, and the like. The wires 238 can be formed from metals, polymers, and/or composite materials. In some embodiments, individual ones of the wires 238 are rolled flat wires having a cross-sectional dimension of between about 0.001–0.005 inch (e.g., about 0.002 inch) by about 0.002–0.005 inch (e.g., about 0.0033 inch).

**[0040]** The coil 236 can include a single wire wound around the braid 234 and the inner liner 232. In other embodiments, the coil 236 includes more than one wire wound about the braid 234 and/or the inner liner 232. For example, the coil 236 can include multiple wires wound over one another and/or multiple wires wound to at least partially overlap one another to form a braided or overlapping coil structure on the braid 234 and/or the inner liner 232. The coil 236 can be formed from a metallic or other suitably strong material, such as nickel-titanium alloys (e.g., nitinol), platinum, cobalt-chrome alloys, stainless steel, tungsten, and/or titanium.

**[0041]** In some embodiments, the construction of the catheter 120 can be selected/varied to provide a desired flexibility, strength, steerability, torque response, pushability, hoop strength, and/or other property. For example, in some embodiments the braid 234 and the coil 236 can

extend through different regions of the catheter 120 (e.g., the proximal portion 122, the distal portion 124, an intermediate region therebetween, etc.) and/or only partially overlap. For example, the coil 236 can extend only through a distal region of the catheter 120 and can inhibit or even prevent kinking or other unwanted movement of the catheter 120 when the lumen 121 is aspirated during a clot removal procedure. Likewise, the hardness, thickness, and/or the like of the outer sheath 230 and the inner liner 232 can be varied in different regions of the catheter 120. For example, the outer sheath 230 and/or the inner liner 232 can be (i) relatively harder and/or thicker in the proximal portion 122 (Figure 1) of the catheter 120 to provide the catheter 120 with good torque response, pushability, and/or steerability and (ii) relatively softer and/or thinner in the distal portion 124 (Figure 1) such that the catheter 120 be steered to and positioned in difficult-to-reach regions of the anatomy (e.g., venous anatomy) of a patient while still having a relatively large size (e.g., 20 French, 24 French, greater than 24 French). In some embodiments, the catheter 120 can include some features that are at least generally similar in structure and function, or identical in structure and function, to those of the catheters disclosed in (i) U.S. Patent Application Publication No. 17/529,018, titled "CATHETERS HAVING SHAPED DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS," and filed November 17, 2021, and/or (ii) U.S. Patent Application Publication No. 17/529,064, titled "CATHETERS HAVING STEERABLE DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS," and filed November 17, 2021, each of which is incorporated herein by reference in its entirety.

## II. Selected Embodiments of Grooved Aspiration Catheters

**[0042]** In some embodiments, the catheter 120 can include grooves on an inner surface thereof that are configured (e.g., sized and shaped) to improve the efficiency/effectiveness of clot aspiration with the catheter 120 during a clot treatment procedure. Figures 3A and 3B, for example, are an enlarged isometric view and a proximally-facing longitudinal view, respectively, of the distal portion 124 (e.g., the inlet) of the catheter 120 in accordance with embodiments of the present technology. Figure 3C is an interior view of the catheter 120 from within the lumen 121 in accordance with embodiments of the present technology. And, Figure 3D is a partially-transparent isometric view of the catheter 120 in accordance with embodiments of the present technology.

**[0043]** Referring to Figures 3A–3C together, the catheter 120 includes an inner surface 340 defining the lumen 121, and a plurality of grooves 342 (which can also be referred to as

microchannels, microgrooves, channels, trenches, cuts, gutters, slits, and/or the like) formed along/in the inner surface 340. In some embodiments, the grooves 342 are formed in the inner liner 232 (Figures 2A and 2B). In the illustrated embodiment, the grooves 342 are identical and the catheter 120 includes sixteen of the grooves 342 equally spaced about a circumference of the inner surface 340—that is, equally spaced circumferentially about a longitudinal axis X of the catheter 120 (Figure 3D) that extends through the lumen 121. The grooves 342 can each have a rectangular cross-sectional shape as shown in Figures 3A and 3B or the grooves 342 can each have a curved (e.g., semicircular) shape as shown in Figure 3C. In other embodiments, the grooves 342 can have other cross-sectional shapes (e.g., rectilinear, polygonal, irregular) and/or different ones of the grooves 342 can have different cross-sectional shapes. In some embodiments, the grooves 342 have a thickness or depth D (Figure 3B) of between about 0.003–0.100 inch (e.g., between about 0.005–0.050 inch, between about 0.005–0.0010 inch) and a width W (Figure 3B) of between about 0.005–0.20 inch (e.g., between about 0.010–0.015 inch).

**[0044]** Referring to Figure 3D, in the illustrated embodiment the grooves 342 each extend (i) along the entire length L of the catheter 120 between the proximal terminus 123 and the distal terminus 125 and (ii) extend circumferentially about the longitudinal axis X along the length L of the catheter 120. That is, the grooves 342 can revolve around the longitudinal axis L to form a spiral or helix pattern. In the illustrated embodiment, each of the grooves 342 traverses four complete revolutions about the longitudinal axis X along the length L of the catheter 120. Accordingly, in some aspects of the present technology the grooves 342 form a rifling pattern on the inner surface 340 (Figures 3A–3C) of the catheter 120. In some embodiments, the length L can be about 36 inches such that catheter 120 has about 0.14 revolutions per inch (e.g., 0.1380 revolutions per inch, between about 0.10–0.20 revolutions per inch, between about 0.13–0.16 revolutions per inch).

**[0045]** Referring to Figures 3A–3D together, in other embodiments the arrangement of the grooves 342 can be varied based on for example, a particular application of the catheter 120 (e.g., a particular clot removal procedure to be carried out with the catheter 120) and/or a desired aspiration flow pattern. For example, (i) the number of the grooves 342, (ii) the number of revolutions the grooves 342 traverse along the length L of the catheter 120, (iii) the cross-sectional shape of the grooves 342, (iv) the width W and/or depth D of the grooves 342, (v) the extent of the grooves 342 along the longitudinal axis X, and so on can be varied. In some embodiments, the catheter 120 can include between 1–20 or more of the grooves 342, and the grooves 342 can traverse between 0–20 revolutions along the length L of the catheter 120.

**[0046]** For example, Figure 4 is a partially-transparent isometric view of the catheter 120 in accordance with additional embodiments of the present technology. In the illustrated embodiment, the catheter 120 includes eight of the grooves 342 equally spaced circumferentially about the longitudinal axis X and extending along the entire length L of the catheter 120 between the proximal terminus 123 and the distal terminus 125. Further, the grooves 342 each traverse two full revolutions about the longitudinal axis X along the length L of the catheter 120. In some embodiments, the length L can be about 36 inches such that catheter 120 has about 0.053 revolutions per inch (e.g., 0.0526 revolutions per inch, between about 0.02–0.09 revolutions per inch, between about 0.04–0.07 revolutions per inch).

**[0047]** For example, Figure 5 is an interior view of the catheter 120 from within the lumen 121 in accordance with additional embodiments of the present technology. In the illustrated embodiment, the catheter 120 includes sixteen of the grooves 342 and the grooves 342 extend generally parallel to the longitudinal axis X (figure 3D; extending into the page in Figure 5). That is, the grooves 342 do not revolve circumferentially around the axis X along the length of the catheter 120 (e.g., the grooves 342 traverse zero revolutions per inch).

**[0048]** For example, Figures 6A and 6B are an enlarged isometric view and an enlarged cross-sectional side view, respectively, of the distal portion 124 of the catheter 120 in accordance with additional embodiments of the present technology. Referring to Figures 6A and 6B together, in the illustrated embodiment the catheter 120 includes a single one of the grooves 342 that extends from the distal terminus 125 only partially toward the proximal terminus 123 (Figure 1) of the catheter 120. That is, the groove 342 does not extend along the full length L (Figure 1) of the catheter 120 but only partially through the distal portion 124. Moreover, in the illustrated embodiment the groove 342 extends circumferentially (e.g., spirals) about the longitudinal axis X (Figure 6A) six times before terminating at a proximal end portion. In other embodiments, the groove 342 can revolve more or fewer times about the longitudinal axis X. In some embodiments, the depth D (Figure 3B) of the groove 342 is between about 0.010–0.015 inch and the width W (Figure 3B) is between about 0.120–0.145 inch. As described in greater detail below with reference to Figure 8B, the groove 342 can be configured (e.g., shaped and/or sized) to generate a helical flow pattern within the lumen 121 when the catheter 120 is aspirated as indicated by arrow H (which spirals/revolves about the lumen 121) in Figure 6A.

**[0049]** Referring to Figures 3A–6B together, in other embodiments the grooves 342 need not extend from the distal terminus of 124 of the catheter 120 and can instead start along a middle

portion of the catheter 120 between the proximal terminus 123 and the distal terminus 125. That is, the grooves 342 can be spaced apart from the distal terminus 125 and need not extend along the full length L (Figure 1) of the catheter 120. Moreover, the grooves 342 can be equally spaced relative to one another or can be spaced at varying distances relative to one another.

III. Selected Embodiments of Clot Treatment Methods

**[0050]** Figures 7A and 7B are side views of the distal portion 124 of the catheter 120 of the clot treatment system 100 of Figure 1 during a procedure for removing clot material C (e.g., a pulmonary embolism) from within a blood vessel BV (e.g., a pulmonary blood vessel) of a patient (e.g., a human patient) in accordance with embodiments of the present technology. As noted above, in some embodiments the clot removal procedure illustrated in Figures 7A and 7B can be generally similar or identical to any of the clot removal procedures disclosed in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety.

**[0051]** With reference to Figures 1 and 7A together, the catheter 120 can be advanced through the patient to proximate the clot material C with the blood vessel BV (e.g., advanced to a treatment site within the blood vessel BV). In some embodiments, the catheter 120 can be advanced through the blood vessel BV until the distal terminus 125 of the catheter 120 is positioned proximate to a proximal portion of the clot material C. In some embodiments, the position of the distal terminus 125 can be confirmed or located via visualization of the marker band 126 using fluoroscopy or another imaging procedure (e.g., a radiographic procedure). In other embodiments, the distal terminus 125 can be positioned at least partially within the clot material C or distal of the clot material C.

**[0052]** Access to the pulmonary vessels can be achieved through the patient's vasculature, for example, via the femoral vein. In some embodiments, the clot treatment system 100 can include an introducer (e.g., a Y-connector with a hemostasis valve; not shown) that can be partially inserted into the femoral vein. A guidewire (not shown) can be guided into the femoral vein through the introducer and navigated through the right atrium, the tricuspid valve, the right ventricle, the pulmonary valve, and into the main pulmonary artery. Depending on the location of the clot material C, the guidewire can be guided to one or more of the branches of the right pulmonary artery and/or the left pulmonary artery. In some embodiments, the guidewire can be extended entirely or partially through the clot material C. In other embodiments, the guidewire

can be extended to a location just proximal of the clot material C. After positioning the guidewire, a dilator and the catheter 120 can be placed over the guidewire and advanced to the position proximate to the clot material C as illustrated in Figure 7A. The dilator can then be withdrawn proximally through the lumen 121 of the catheter 120. In some embodiments, the guidewire can then be withdrawn while, in other embodiments, the guidewire can remain and can be used to guide other catheters (e.g., delivery catheters, additional aspiration guide catheters), interventional devices, and the like to the treatment site. It will be understood, however, that other access locations into the venous circulatory system of a patient are possible and consistent with the present technology. For example, the user can gain access through the jugular vein, the subclavian vein, the brachial vein, or any other vein that connects or eventually leads to the superior vena cava. Use of other vessels that are closer to the right atrium of the patient's heart can also be advantageous as it reduces the length of the instruments needed to reach the clot material C.

**[0053]** With reference to Figures 1 and 7B together, the pressure source 106 is configured to generate (e.g., form, create, charge, build-up) a vacuum (e.g., negative relative pressure) and store the vacuum for subsequent application to the catheter 120. For example, after positioning the catheter 120 proximate the clot material C, a user can first close the fluid control device 114 before generating the vacuum in the pressure source 106 by, for example, withdrawing the plunger of a syringe coupled to the connector 116. In this manner, a vacuum is charged within the pressure source 106 (e.g., a negative pressure is maintained) before the pressure source 106 is fluidly connected to the lumen 121 of the catheter 120. To aspirate the lumen 121 of the catheter 120, the user can open the fluid control device 114 to fluidly connect the pressure source 106 to the catheter 120 and thereby apply or release the vacuum stored in the pressure source 106 to the lumen 121 of the catheter 120.

**[0054]** Opening of the fluid control device 114 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing assembly 110 and the catheter 120, thereby generating a suction pulse throughout the catheter 120. In particular, the suction is applied at the distal portion 124 of the catheter 120 to suck/aspirate/ingest at least a portion of the clot material C into the lumen 121 of the catheter 120, as shown in Figure 7B. In one aspect of the present technology, pre-charging or storing the vacuum in the pressure source 106 before applying the vacuum to the lumen 121 of the catheter 120 is expected to generate greater suction forces and corresponding fluid flow velocities at and/or near the distal terminus 125 of the catheter 120 compared to simply activating the pressure source 106 while it is fluidly connected

to the catheter 120. The vacuum pressure can act to draw the clot material C down the entire length of the catheter 120, through the side port 104, through the tubing assembly 110, and into the pressure source 106.

**[0055]** Sometimes, as shown in Figure 7B, discharging the vacuum stored in the pressure source to aspirate the lumen 121 of the catheter 120 may remove substantially all (e.g., a desired amount) of the clot material C from the blood vessel BV. That is, a single aspiration pulse may adequately remove the clot material C from the blood vessel BV. In other embodiments, a portion of the clot material C may remain in the blood vessel BV. In such instances, the user may wish to again apply vacuum pressure (conduct another "aspiration pass") to remove all or a portion of the remaining clot material C in the blood vessel BV. In such instances, the pressure source 106 can be disconnected from the tubing assembly 110 and drained (e.g., aspirated clot removal removed) before the pressure source 106 is reconnected to the tubing assembly 110 and activated once again. After removing a desired amount of the clot material C, the catheter 120 can be withdrawn from the patient.

**[0056]** Sometimes, however, the clot material C can clog and become stuck within the lumen 121 of the catheter 120 and/or around the distal terminus 125 of the catheter 120 (e.g., forming a "lollipop" around the distal terminus 125). Clearing such clogs can require (i) performing additional aspiration passes, (ii) removing the entire catheter 120 from the patient and then reinserting the same or a different catheter 120 for another aspiration pass, (iii) and/or inserting an additional clot removal element through the catheter 120 to mechanically disrupt and dislodge the clog. Such techniques to clear the clog can increase the complexity and time of the clot removal procedure.

**[0057]** In some aspects of the present technology, the grooves 342 (Figures 3A–6B) of the catheter 120 can facilitate improved ingestion/aspiration of the clot material C into and through the catheter 120—thereby inhibiting clogging—as compared to, for example, conventional catheters having a non-grooved inner surface. Figures 8A and 8B, for example, are a proximally-facing longitudinal view and an enlarged partially-transparent side view, respectively, of the distal portion 124 (e.g., inlet) of the catheter 120 with the clot material C positioned therein in accordance with embodiments of the present technology. In the illustrated embodiment, the catheter 120 includes the arrangement of the grooves 342 shown in Figures 3A–3D.

**[0058]** Referring to Figure 8A, some or all of the grooves 342 can create fluid paths (e.g., leak paths, microfluid paths, microleak paths) around the clot material C. These fluid paths can

inhibit or prevent the clot material C from clogging the lumen 121 and causing a cavitation within the pressure source 106 by keeping blood flowing generally proximally through the catheter 120 through the grooves 342 during aspiration. This movement of the blood through the grooves 342 can help pull the clot material C farther proximally into and through the lumen 121 of the catheter 120. Similarly, the grooves 342 can also reduce the area of the inner surface 340 that contacts the clot material C—thereby reducing friction between the clot material C and the catheter 120, and ultimately the aspiration force required to move the clot material C proximally through the entire length of the catheter 120.

**[0059]** Referring to Figure 8B, the rifling pattern on the grooves 342 (e.g., revolving circumferentially about the longitudinal axis of the catheter 120) can create a helical flow pattern inside the lumen 121 of the catheter 120 during aspiration as indicated by the arrow H. In some aspects of the present technology, the helical flow pattern can help keep faster moving blood travelling proximally through the lumen 121 near the inner surface 340 while maintaining the slower moving clot material C toward the center of the lumen 121. The outer "layer" of blood near the inner surface 340 can create a fluid buffer between the clot material C and the inner surface 340 of the catheter 120 that facilitates a more efficient and reliable transport of the clot material C down the entire length of the catheter 120 and into the pressure source 106 (Figure 1). More specifically, the helical flow of the blood can (i) exert an axial force against the clot material C that pulls the clot material C in a proximal direction indicated by arrow P via suction on the clot and (ii) exert a torsional force against the clot material C as indicated by the arrow H. These forces can apply shear and torsional stresses against the clot material C that act to deform (e.g., lengthen) and/or break apart the clot material C within the lumen 121 in a manner in which laminar and/or non-helical flow would not. This can further reduce the area of the inner surface 340 that contacts the clot material C—thereby reducing friction between the clot material C and the catheter 120. The decrease in friction and/or deformation of the clot material C can help the clot material C travel through the lumen 121 without clogging the lumen 121.

## IV. Selected Examples of the Performance of Embodiments of the Present Technology and Associated Optimizations

**[0060]** Referring to Figures 3A–6B together, as described above, the arrangement of the grooves 342 can be varied to provide different aspiration flow patterns, flow rates, and/or the like. In general, for example, it is expected that increasing the number of the grooves 342 will improve/strengthen the axial flow path past an ingested clot up to a point at which the grooves

342 are too small to provide an efficient leak path past the ingested clot material. Likewise, it is expected that increasing the depth D of the grooves 342 will improve the helical flow pattern at the cost of increasing the wall thickness of the catheter 120 (e.g., the thickness of the inner liner 232 shown in Figures 2A and 2B) that the grooves 342 are formed in. For example, significant increases in the depth D are expected to require a corresponding increase in the overall thickness of the inner liner 232 (e.g., an increase in the thickness of the inner liner 232 radially outside the grooves 342—i.e., on the outer side or back side of the grooves 342) to maintain the integrity of the inner liner 232. Increasing the wall thickness of the catheter 120 can decrease the flexibility of the catheter 120. Therefore, for example, the grooves 342 can be relatively deeper for applications in which the catheter 120 does not need to be made very flexible (e.g., for clot removal procedures in non-tortuous anatomies), while the grooves 342 can be made shallower for applications in which it is advantageous for the catheter 120 to be made very flexible (e.g., for clot removal procedures in tortuous anatomies such as the pulmonary arteries).

**[0061]** Similarly, it is expected that increasing the number of revolutions of the grooves 342 (where the grooves 342 are rifled along the length L of the catheter 120) will (i) improve the helical flow pattern within the catheter 120 thereby increasing the torsional forces acting to lengthen and break apart the ingested clot material while also (ii) decreasing the volumetric flow rate within the catheter 120 by increasing the length the blood must travel through the catheter 120. However, where the catheter 120 traverses a tortuous path, the linear/laminar flow provided by a catheter without grooves or with linear (e.g., non-revolving) grooves can impede flow as the flow must change its trajectory down the length of the catheter. In some aspects of the present technology, the rifled arrangement of the grooves 342 can improve the flow pattern and/or volumetric flow rate of the catheter 120 in tortuous anatomies as the blood flow need not change its trajectory through the tortuous path of the catheter 120 as much.

**[0062]** More specifically, for example, Figures 9A and 9B are perspective views of the clot treatment system 100 traversing a simulated pathway to a right pulmonary artery RPA and a left pulmonary artery LPA, respectively, in accordance with embodiments of the present technology. Referring to Figures 9A and 9B together, the pathway to the right pulmonary artery RPA can be more tortuous than the pathway to left pulmonary artery LPA. More specifically, in the illustrated embodiment the pathway to the right pulmonary artery RPA has a tortuosity defined as the amount of curvature of the catheter 120 divided by the length L (Figure 1) of the catheter 120 of about 1.40, while the pathway to the left pulmonary artery LPA has a tortuosity of about 1.06.

**[0063]** Figures 9C and 9D are distally-facing longitudinal views of the proximal portion 122 (e.g., the outlet) of the catheter 120 illustrating a flow pattern during aspiration without any of the grooves 342 and with the arrangement of the grooves 342 shown in Figures 3A–3D, respectively, when the catheter 120 traverses the simulated pathway to the right pulmonary artery RPA shown in Figure 9A in accordance with embodiments of the present technology. Referring to Figures 9C and 9D together, in both embodiments the fastest flow is toward the center of the lumen 121. However, the flow pattern generated by the catheter 120 without the grooves 342 is much less uniform than the flow pattern generated by the catheter 120 with the grooves 342. In some aspects of the present technology, the nonuniform flow pattern shown in Figure 9C traverses the lumen 121 of the catheter more slowly than the more uniform flow pattern shown in Figure 9D—reducing the volumetric flow rate of the catheter 120 and the efficiency at which the catheter 120 can ingest clot material.

**[0064]** In some aspects of the present technology, the number of rotations that the grooves 342 traverse down the length L of the catheter 120 (and/or the number of rotations per unit length) can impact the flow rate and efficiency of clot aspiration through the catheter 120. For example, Figure 10A is a graph of a measured flow rate through the catheter 120 versus the number of revolutions of the grooves 342 along the length of the catheter 120 for the simulated pathway to the right pulmonary artery shown in Figure 9A in accordance with embodiments of the present technology. The graph illustrates the plot for the average flow rate when the catheter 120 had a size of 24 French and a length of about 36 inches. Figure 10B is a graph of a corresponding measured time to aspirate an occlusive synthetic clot through the catheter 120 in accordance with embodiments of the present technology. The graph in Figure 10B illustrates the plot for a synthetic clot that was formed of silicone 27A mold and had a spherical shape with diameter greater than the diameter of the catheter 120 of 0.28 inch. Referring to Figure 10A and 10B together, the flow rate was maximized, and the corresponding aspiration time was minimized, when the catheter 120 was tested with five revolutions (e.g., about 0.14 revolutions per inch) as opposed to having no grooves (e.g., 0 revolutions per inch), or grooves with one or ten revolutions (e.g., about 0.03 or 0.28 revolutions per inch).

**[0065]** Similarly, Figure 11A is a graph of a measured distance traveled of an occlusive synthetic clot through the catheter 120 versus the number of revolutions of the grooves 342 along the length of the catheter 120 when the clot was aspirated through the catheter 120 for the simulated pathway to the right pulmonary artery shown in Figure 9A in accordance with embodiments of the present technology. The graph illustrates the plot for the average clot

distance when the catheter 120 had a size of 24 French and a length of about 36 inches, and when the synthetic clot was formed of silicone 27A mold and had a cylindrical shape with a length of 0.63 inch and a diameter of 0.28 inch. Figure 11B is a graph of a corresponding measured clot velocity in accordance with embodiments of the present technology. Figure 11B further illustrates a plot for the average clot velocity for a synthetic clot having a cylindrical shape with a smaller length of 0.37 inch. Referring to Figure 11A and 11B together, again the distance the clot traveled and the velocity of the clot during aspiration was maximized when the catheter 120 was tested with five revolutions as opposed to having no grooves, or grooves with one or ten revolutions.

**[0066]** Similarly, Figure 12 is a graph of a measured maximum force required to move an occlusive synthetic clot through the catheter 120 versus the number of revolutions of the grooves 342 along the length of the catheter 120 when the clot was aspirated through the catheter 120 for the simulated pathway to the right pulmonary artery shown in Figure 9A in accordance with embodiments of the present technology. The graph illustrates the plot for the maximum force when the catheter 120 had a size of 24 French and a length of about 36 inches, and when the synthetic clot was formed of silicone 27A mold and had a cylindrical shape with a length of 0.50 inch. As shown, the maximum force was again minimized when the catheter 120 was tested with five revolutions as opposed to having no grooves, or grooves with one or ten revolutions. That is, five revolutions of the grooves 342 minimized the friction between the clot and the catheter 120 during aspiration.

**[0067]** Accordingly, in some aspects of the present technology five revolutions of the grooves 342—or about five revolutions—can maximize the efficiency of clot removal via aspiration through the catheter 120 by (i) increasing the flow rate through the catheter 120, (ii) reducing clot aspiration time through the catheter 120, (iii) increasing the distance the clot travels through the catheter 120, (iv) increasing the velocity at which the clot travels through the catheter 120, (v) decreasing the friction between the clot and the catheter 120, and/or (vi) decreasing the force needed to pull the clot through the catheter 120. It is expected that the optimum number of revolutions (among other parameters) can vary depending on the path traversed by the catheter 120 through a patient.

**[0068]** Moreover, in some aspects of the present technology it is expected that the optimum number of revolutions is dependent on the length of the catheter 120. Accordingly, the optimum number of revolutions per unit length of the catheter 120 can remain constant for

catheters of different lengths. As set forth above, for example, the catheter 120 can include between about 0.01–0.40 revolutions per inch (e.g., about 0.028 revolutions per inch, about 0.056 revolutions per inch, about 0.139 revolutions per inch, about 0.278 revolutions per inch, between about 0.10–0.20 revolutions per inch, between about 0.12–0.16 revolutions per inch, etc.). That is, the catheter 120 can include between about 0.005–0.15 revolutions per centimeter (e.g., about 0.011 revolutions per centimeter, about 0.022 revolutions per centimeter, about 0.055 revolutions per centimeter, about 0.109 revolutions per centimeter, between about 0.03–0.08 revolutions per centimeter, between about 0.04–0.07 revolutions per centimeter, etc.).

## V. Selected Embodiments of Devices, Systems, and Methods for Manufacturing Grooved Aspiration Catheters

**[0069]** Referring to Figures 1–6B together, in some embodiments the catheter 120 can be formed about a mandrel, hypotube, or other elongate member. For example, the inner liner 232 can first be positioned about the mandrel and, in some embodiments, stretched along the mandrel to a desired thickness. Then, the braid 234 can be formed (e.g., wound, braided) about the inner liner 232 around the mandrel. Next, the coil 236 can be wound around the mandrel about the braid 234 and the inner liner 232. In some embodiments, the marker band 126 can be positioned about the mandrel in the distal portion 124. Next, the outer sheath 230 can be positioned over the inner liner 232, the braid 234, and the coil 236, and then some or all of these components can be heat shrunk, fused, laminated, or otherwise secured together.

**[0070]** To form the grooves 342, the mandrel can be formed with corresponding features that shape the inner liner 232. Figure 13, for example, is a longitudinal view of a mandrel 1350 over which the catheter 120 can be formed in accordance with embodiments of the present technology. In the illustrated embodiment, the mandrel 1350 includes a body 1352 (e.g., a cylindrical body) and positive features 1354 (e.g., extrusions, ridges, projections) projecting radially outward from the body 1352 and separated by grooves or trenches 1356. Referring to Figures 1–6B and 13 together, the positive features 1354 can correspond to the desired pattern of the grooves 342. For example, the features 1354 can have dimensions corresponding to the desired depth D and width W of the grooves 342, and can spiral about the body 1352 any number of revolutions to provide the desired rifling pattern of the grooves 342. The number of the features 1354, the spacing between the features 1354, the size (e.g., height, width) of the features 1354, the pitch or helical pattern of the features 1354, and/or other parameters of the features 1354 can be selected to produce a pattern of the grooves 342 having a desired number, depth D,

and width W. For example, the features 1354 have a rectangular cross-sectional shape in Figure 13 to produce grooves 342 having a rectangular cross-sectional shape while, in other embodiments, the features 1354 can have other cross-sectional shapes (e.g., circular, polygonal, irregular, etc.) to produce grooves 342 of corresponding shape. As a further example, in Figure 13 the mandrel 1350 includes 16 of the features 1354 such that the catheter 120 has a corresponding 16 of the grooves 342. The mandrel 1350 can have any number of the features 1354.

**[0071]** When the catheter 120 is formed (e.g., laminated) over the mandrel 1350, the catheter 120 can shrink radially about the mandrel 1350 and against/between the features 1354 to from the grooves 342. Specifically, the inner liner 232 can melt and flow into the trenches 1356 between the features 1354 before solidifying to form the grooves 342 (e.g., when the inner liner 232 comprises a Pebax material). Alternatively or additionally, the inner liner 232 can be pressed and/or formed into the trenches 1356 without melting (e.g., when the inner liner 232 comprises a PTFE material). In some embodiments, to facilitate removal of the catheter 120 from the mandrel 1350 after manufacturing, a lubricant (e.g., a silicone spray lubricant) can be applied to the mandrel 1350 prior to manufacturing of the catheter 120 (e.g., in a mold release process). Similarly, the mandrel 1350 can include a more permanent thin layer of PTFE coating over the outer surface thereof to facilitate removal and release of the catheter 120. In some embodiments, the manufacturing process can include a destructive process step that stretches and necks down the mandrel 1350 to a smaller outer diameter to facilitate removal and release of the catheter 120.

**[0072]** In some embodiments, the features 1354 can extend linearly along the length of the body 1352, and the mandrel 1350 can be fixed at one end and then rotated to provide the rifling pattern of the grooves 342. For example, the mandrel 1350 can be rotated a desired number of times during manufacturing (e.g., with the inner liner 232 in a molten state) such that the grooves 342 traverse a corresponding number of revolutions along the length L of the catheter 120. In some embodiments, the features 1354 can revolve at least partially about the body 1352, and the mandrel 1350 can be rotated during manufacturing of the catheter 120 to introduce further revolutions into the grooves 342.

**[0073]** The features 1354 of the mandrel 1350 can be formed by machining the body 1352 (e.g., a hyptotube or solid tube) to cut-out or etch the trenches 1356. In some embodiments, the machining is performed by a multi-axis machine that can rotate the mandrel 1350 during

machining such that the trenches 1356 (and the corresponding features 1354) revolve about the body 1352. In other embodiments, the mandrel 1350 can be formed by extruding the body 1352 to form the positive features 1354 and the trenches 1356.

**[0074]** Figures 14A and 14B are a cross-sectional longitudinal view and an enlarged isometric view, respectively, of a mandrel 1450 over which the catheter 120 can be formed in accordance with additional embodiments of the present technology. Referring to Figures 14A and 14B together, in the illustrated embodiment the mandrel 1450 includes a body 1452 and filaments or wires 1454 (e.g., positive features) positioned about the body 1452 that correspond to the desired pattern of the grooves 342 (Figures 1–6B). The wires 1454 can be welded to the body 1452, tightly wound about the body 1452 (e.g., and secured at both ends of the wires 1454), or otherwise secured about/to the body 1452. Referring to Figures 1–6B, 14A, and 14B together, when the catheter 120 is formed about the mandrel 1450, the inner liner 232 can melt and flow into the spaces between the wires 1454 before solidifying to form the grooves 342, and/or can be pressed/formed into the spaces between the wires 1454 to form the grooves 342. The number of the wires 1454, the spacing between the wires 1454, the size (e.g., diameter) of the wires 1454, the pitch or helical pattern of the wires 1454, and/or other parameters of the wires 1454 can be selected to produce a pattern of the grooves 342 having a desired number, depth D, and width W. For example, in the illustrated embodiment the wires 1454 are evenly spaced circumferentially about the body 1452 and in contact with each other to form a more uniform pattern of the grooves 1454. Likewise, in Figures 14A and 14B, the mandrel 1450 includes 24 of the wires 1454 such that the catheter 120 has a corresponding 24 of the grooves 342. For example, reducing the number of the wires 1454 will produce a pattern having fewer of the grooves 342, and spacing the wires 1454 apart from one another will produce a pattern having a greater depth D and width W of the grooves. Similar to the positive features 1354 of Figure 13, the wires 1454 can wrap helically about the body 1452 to correspond to the desired number of revolutions of the grooves 342, or the wires 1454 can extend linearly (or at least partially helically) along the body 1452 and the mandrel 1450 can be rotated during manufacturing to produce a revolving (e.g., helical) pattern of the grooves 342.

## VI. Additional Examples

**[0075]** Several aspects of the present technology are set forth in the following examples:

1. An aspiration catheter, comprising:

a proximal terminus;

a distal terminus; and

an inner surface defining a lumen, wherein the inner surface includes at least one groove formed therein and that extends from the distal terminus at least partially toward the proximal terminus.

2. The aspiration catheter of example 1 wherein the at least one groove extends from the distal terminus to the proximal terminus.

3. The aspiration catheter of example 1 or example 2 wherein the lumen extends along a longitudinal axis, and wherein the at least one groove revolves circumferentially about the longitudinal axis between the proximal terminus and the distal terminus.

4. The aspiration catheter of example 3 wherein the at least one groove revolves about 0.05 times or more per inch about the longitudinal axis between the proximal terminus and the distal terminus.

5. The aspiration catheter of example 3 wherein the at least one groove revolves between about 0.13–0.15 times per inch about the longitudinal axis between the proximal terminus and the distal terminus.

6. The aspiration catheter of example 3 wherein the at least one groove revolves more than about 0.13 times per inch about the longitudinal axis between the proximal terminus and the distal terminus.

7. The aspiration catheter of any one of examples 1–6 wherein the at least one groove has a spiral shape.

8. The aspiration catheter of any one of examples 1–7 wherein the at least one groove comprises a plurality of grooves.

9. The aspiration catheter of example 8 wherein the plurality of grooves are equally spaced apart about a circumference of the inner surface.

10. The aspiration catheter of example 8 or example 9 wherein the lumen extends along a longitudinal axis, and wherein the plurality of grooves revolves circumferentially about the longitudinal axis between the proximal terminus and the distal terminus.

11. The aspiration catheter of example 10 wherein the plurality of grooves revolves about 0.05 times or more per inch about the longitudinal axis between the proximal terminus and the distal terminus.

12. The aspiration catheter of example 10 wherein the plurality of grooves revolves between about 0.13–0.15 times per inch about the longitudinal axis between the proximal terminus and the distal terminus.

13. The aspiration catheter of example 10 wherein the plurality of grooves revolves more than about 0.13 times per inch about the longitudinal axis between the proximal terminus and the distal terminus.

14. The aspiration catheter of any one of examples 1–13 wherein the catheter further comprises:

an inner liner having the inner surface, wherein the at least one groove is formed in the inner liner;

a braid of wires over the inner liner;

a wire coiled over the inner liner; and

an outer sheath over the braid, the wire, and the inner liner.

15. An aspiration catheter, comprising:

a proximal terminus;

a distal terminus; and

an inner surface defining a lumen extending along a longitudinal axis, wherein the inner surface includes a plurality of grooves formed therein, wherein the grooves extend at least partially between the distal terminus and the proximal terminus,

and wherein the grooves revolve circumferentially about the longitudinal axis between the distal terminus and the proximal terminus.

16. The aspiration catheter of example 15 wherein the grooves revolve between about 0.13–0.15 times per inch about the longitudinal axis between the proximal terminus and the distal terminus.

17. The aspiration catheter of example 15 or example 16 wherein the grooves are equally spaced about a circumference of the inner surface.

18. The aspiration catheter of any one of examples 15–17 wherein the grooves extend to the distal terminus.

19. The aspiration catheter of any one of examples 15–18 wherein the grooves extend entirely between the distal terminus and proximal terminus.

20. A system for removing material from within a lumen of a human patient, the system comprising:

an aspiration catheter configured to be positioned at a treatment site proximate to the material within the lumen, wherein the aspiration catheter comprises—

a proximal terminus;

a distal terminus; and

an inner surface defining a lumen, wherein the inner surface includes at least one groove formed therein and that extends from the distal terminus at least partially toward the proximal terminus;

a tubing assembly fluidly coupled to the catheter and including a fluid control device; and

a pressure source fluidly coupled to the tubing assembly and configured to generate negative pressure, wherein the fluid control device is movable between (a) a first position in which the pressure source is fluidly connected to the aspiration catheter via the tubing assembly and (b) a second position in which the pressure source is fluidly disconnected from the aspiration catheter.

21. The system of example 20 wherein the lumen extends along a longitudinal axis, wherein the at least one groove includes a plurality of grooves, wherein the grooves are equally spaced about a circumference of the inner surface, wherein the grooves extend at least partially from the distal terminus to the proximal terminus, and wherein the grooves revolve circumferentially about the longitudinal axis between the proximal terminus and the distal terminus.

22. A method for removing material from within a lumen of a human patient, the method comprising:

positioning a distal portion of an aspiration catheter proximate to the material within the lumen, wherein the aspiration catheter includes an inner surface having at least one groove formed therein, and wherein the at least one groove extends from a distal terminus of the aspiration catheter at least partially toward a proximal terminus of the aspiration catheter;

coupling a pressure source to the aspiration catheter via a fluid control device, wherein (a) opening of the fluid control device fluidly connects the pressure source to the aspiration catheter and (b) closing of the fluid control device fluidly disconnects the pressure source from the aspiration catheter;

activating the pressure source to generate a vacuum while the fluid control device is closed; and

opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the material into the aspiration catheter.

23. The method of example 22 wherein the at least one groove defines a leak path past the clot material when the clot material is aspirated into the aspiration catheter.

24. The method of example 22 or example 23 wherein the at least one groove generates a helical flow pattern in the lumen when the clot material is aspirated into the aspiration catheter.

25. A mandrel for use in forming a catheter, comprising:

a cylindrical body; and

a plurality of features extending radially outward from the body, wherein the catheter is configured to be formed over the body and the features such that the catheter has a plurality of grooves corresponding to an arrangement of the features.

26. The mandrel of example 25 wherein the features are integrally formed with the body.

27. The mandrel of example 25 wherein the features are wires.

28. The mandrel of any one of examples 25–27 wherein the features extend helically about the body.

29. A method of forming a catheter, the method comprising:

positioning an inner liner of the catheter about a mandrel, wherein the mandrel includes a cylindrical body and a plurality of features extending radially outward from the body;

positioning an outer liner of the catheter over the inner liner about the mandrel; and

heating the inner liner and the outer liner such that the inner liner includes a plurality of grooves corresponding to the features of the mandrel.

30. The method of example 29 wherein the method further comprises cooling the inner liner and the outer liner such that the outer liner fuses to the inner liner.

31. The method of example 29 or example 30 wherein the method further comprises rotating the mandrel after heating the inner liner and the outer liner to revolve the features and the corresponding grooves in the inner liner.

32. The method of any one of examples 29–31 wherein the features are integrally formed with the body.

33. The method of any one of examples 29–31 wherein the features are wires.

34. The method of any one of examples 29–33 wherein the features extend helically about the body.

## VII. Conclusion

**[0076]** The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

**[0077]** From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

**[0078]** Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. An aspiration catheter, comprising:

a proximal terminus;

a distal terminus; and

an inner surface defining a lumen, wherein the inner surface includes at least one groove formed therein and that extends from the distal terminus at least partially toward the proximal terminus.

2. The aspiration catheter of claim 1 wherein the at least one groove extends from the distal terminus to the proximal terminus.

3. The aspiration catheter of claim 1 wherein the lumen extends along a longitudinal axis, and wherein the at least one groove revolves circumferentially about the longitudinal axis between the proximal terminus and the distal terminus.

4. The aspiration catheter of claim 3 wherein the at least one groove revolves about 0.05 times or more per inch about the longitudinal axis between the proximal terminus and the distal terminus.

5. The aspiration catheter of claim 3 wherein the at least one groove revolves between about 0.13–0.15 times per inch about the longitudinal axis between the proximal terminus and the distal terminus.

6. The aspiration catheter of claim 3 wherein the at least one groove revolves more than about 0.13 times per inch about the longitudinal axis between the proximal terminus and the distal terminus.

7. The aspiration catheter of claim 1 wherein the at least one groove has a spiral shape.

8. The aspiration catheter of claim 1 wherein the at least one groove comprises a plurality of grooves.

9. The aspiration catheter of claim 8 wherein the plurality of grooves are equally spaced apart about a circumference of the inner surface.

10. The aspiration catheter of claim 8 wherein the lumen extends along a longitudinal axis, and wherein the plurality of grooves revolves circumferentially about the longitudinal axis between the proximal terminus and the distal terminus.

11. The aspiration catheter of claim 10 wherein the plurality of grooves revolves about 0.05 times or more per inch about the longitudinal axis between the proximal terminus and the distal terminus.

12. The aspiration catheter of claim 10 wherein the plurality of grooves revolves between about 0.13–0.15 times per inch about the longitudinal axis between the proximal terminus and the distal terminus.

13. The aspiration catheter of claim 10 wherein the plurality of grooves revolves more than about 0.13 times per inch about the longitudinal axis between the proximal terminus and the distal terminus.

14. The aspiration catheter of claim 1 wherein the catheter further comprises:

an inner liner having the inner surface, wherein the at least one groove is formed in the inner liner;

a braid of wires over the inner liner;

a wire coiled over the inner liner; and

an outer sheath over the braid, the wire, and the inner liner.

15. An aspiration catheter, comprising:

a proximal terminus;

a distal terminus; and

an inner surface defining a lumen extending along a longitudinal axis, wherein the inner surface includes a plurality of grooves formed therein, wherein the grooves extend at least partially between the distal terminus and the proximal terminus, and wherein the grooves revolve circumferentially about the longitudinal axis between the distal terminus and the proximal terminus.

16. The aspiration catheter of claim 15 wherein the grooves revolve between about 0.13–0.15 times per inch about the longitudinal axis between the proximal terminus and the distal terminus.

17. The aspiration catheter of claim 15 wherein the grooves are equally spaced about a circumference of the inner surface.

18. The aspiration catheter of claim 15 wherein the grooves extend to the distal terminus.

19. The aspiration catheter of claim 15 wherein the grooves extend entirely between the distal terminus and proximal terminus.

20. A system for removing material from within a lumen of a human patient, the system comprising:

an aspiration catheter configured to be positioned at a treatment site proximate to the material within the lumen, wherein the aspiration catheter comprises—

a proximal terminus;

a distal terminus; and

an inner surface defining a lumen, wherein the inner surface includes at least one groove formed therein and that extends from the distal terminus at least partially toward the proximal terminus;

a tubing assembly fluidly coupled to the catheter and including a fluid control device; and

a pressure source fluidly coupled to the tubing assembly and configured to generate negative pressure, wherein the fluid control device is movable between (a) a first position in which the pressure source is fluidly connected to the aspiration

catheter via the tubing assembly and (b) a second position in which the pressure source is fluidly disconnected from the aspiration catheter.

21. The system of claim 20 wherein the lumen extends along a longitudinal axis, wherein the at least one groove includes a plurality of grooves, wherein the grooves are equally spaced about a circumference of the inner surface, wherein the grooves extend at least partially from the distal terminus to the proximal terminus, and wherein the grooves revolve circumferentially about the longitudinal axis between the proximal terminus and the distal terminus.

22. A method for removing material from within a lumen of a human patient, the method comprising:

positioning a distal portion of an aspiration catheter proximate to the material within the lumen, wherein the aspiration catheter includes an inner surface having at least one groove formed therein, and wherein the at least one groove extends from a distal terminus of the aspiration catheter at least partially toward a proximal terminus of the aspiration catheter;

coupling a pressure source to the aspiration catheter via a fluid control device, wherein (a) opening of the fluid control device fluidly connects the pressure source to the aspiration catheter and (b) closing of the fluid control device fluidly disconnects the pressure source from the aspiration catheter;

activating the pressure source to generate a vacuum while the fluid control device is closed; and

opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the material into the aspiration catheter.

23. The method of claim 22 wherein the at least one groove defines a leak path past the clot material when the clot material is aspirated into the aspiration catheter.

24. The method of claim 22 wherein the at least one groove generates a helical flow pattern in the lumen when the clot material is aspirated into the aspiration catheter.

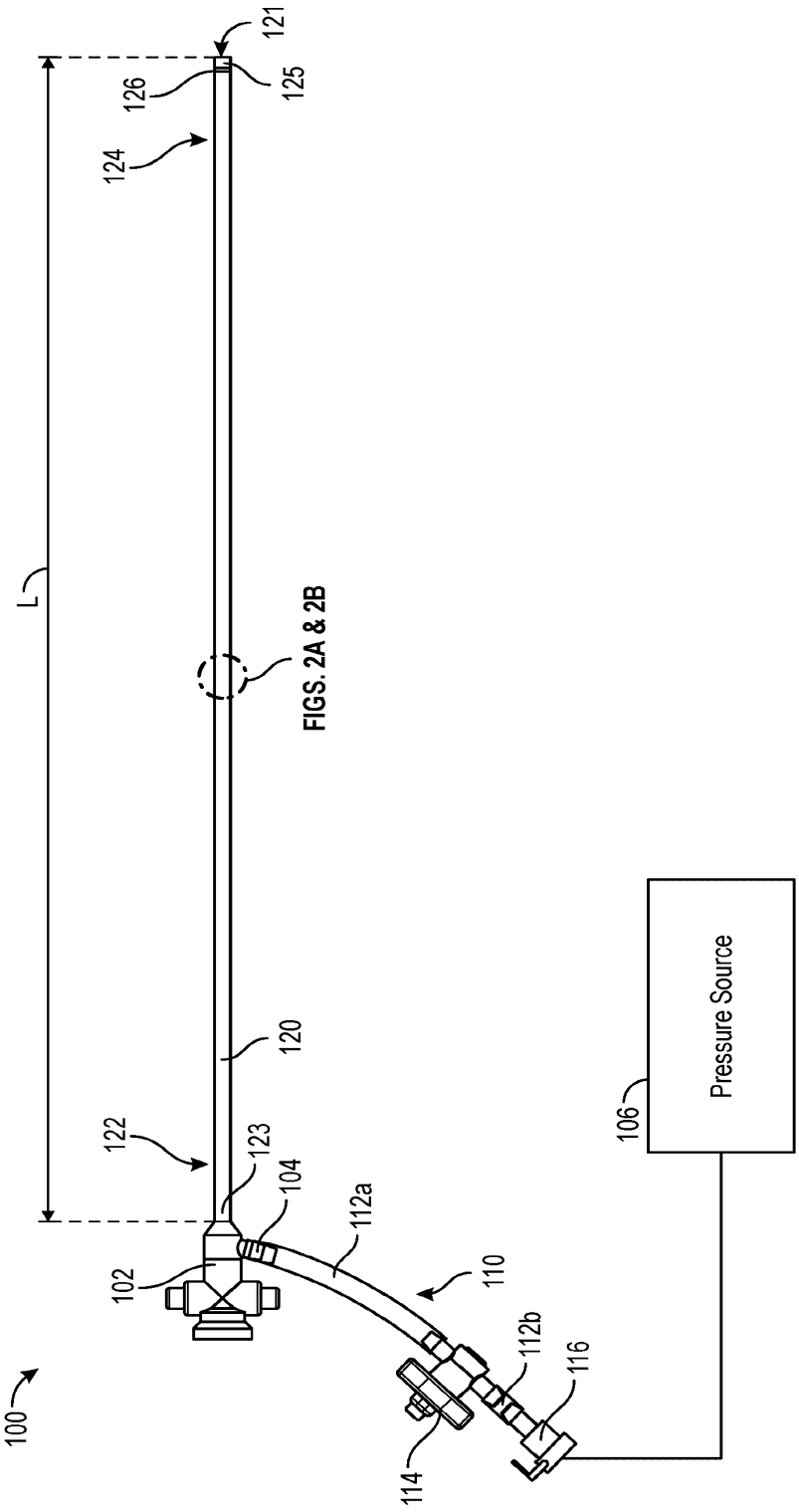

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L
FIGS. 2A & 2B
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112a
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110
112b
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114
100
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Pressure Source

*FIG. 1*

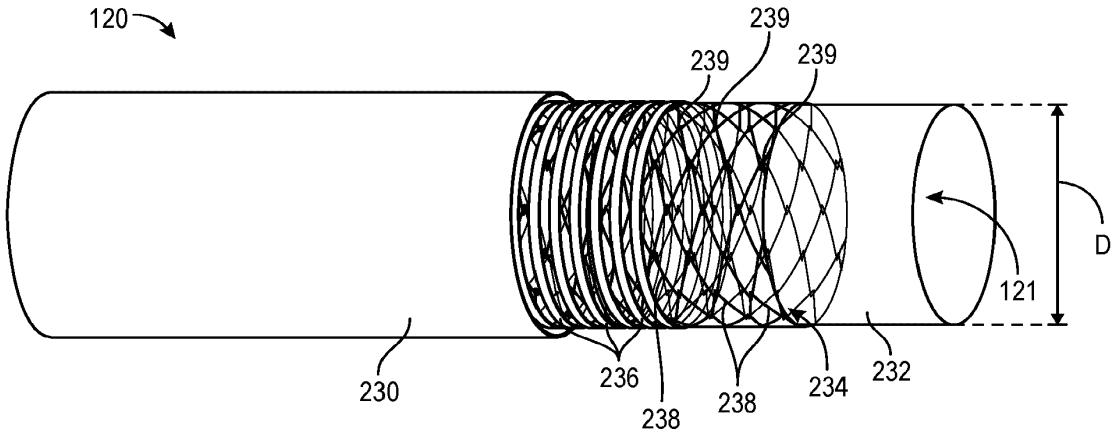

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*FIG. 2A*

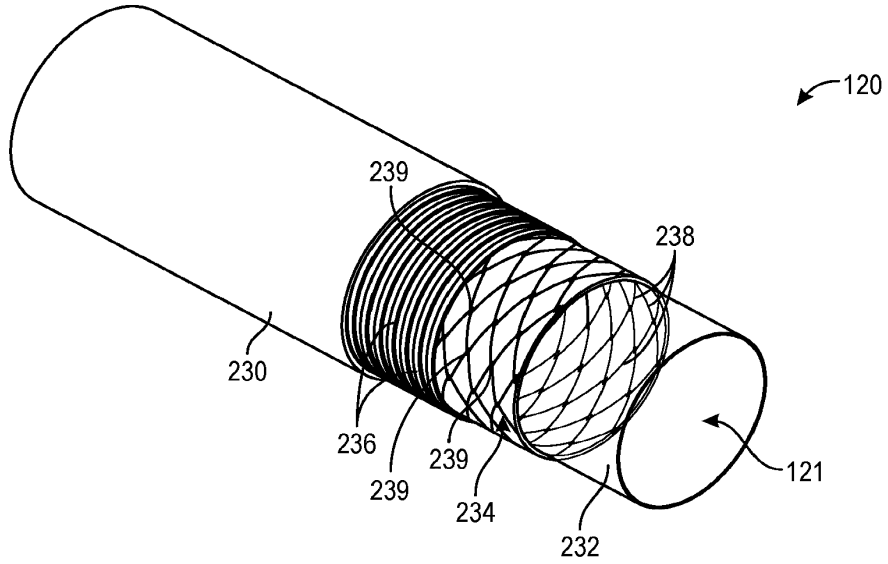

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232
121

*FIG. 2B*

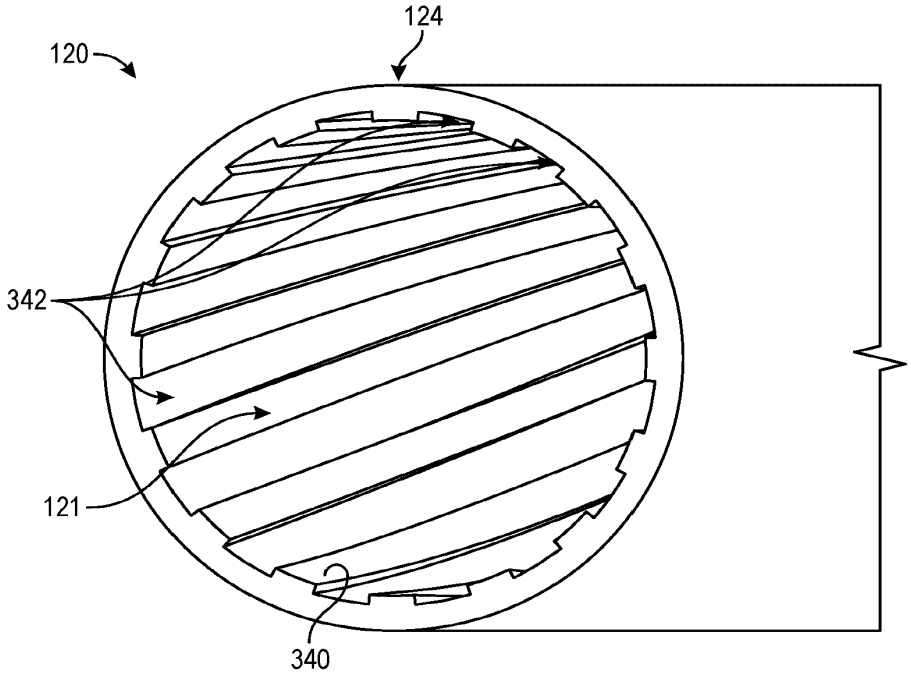



*FIG. 3A*

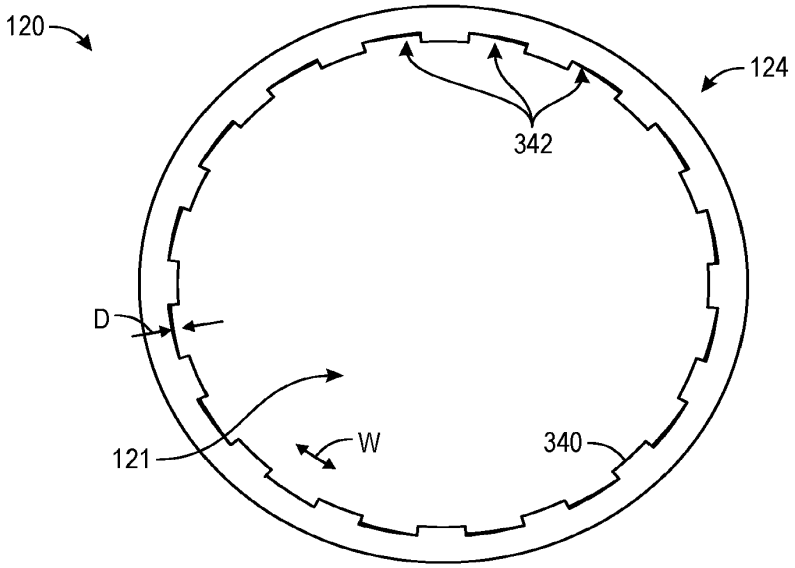



*FIG. 3B*

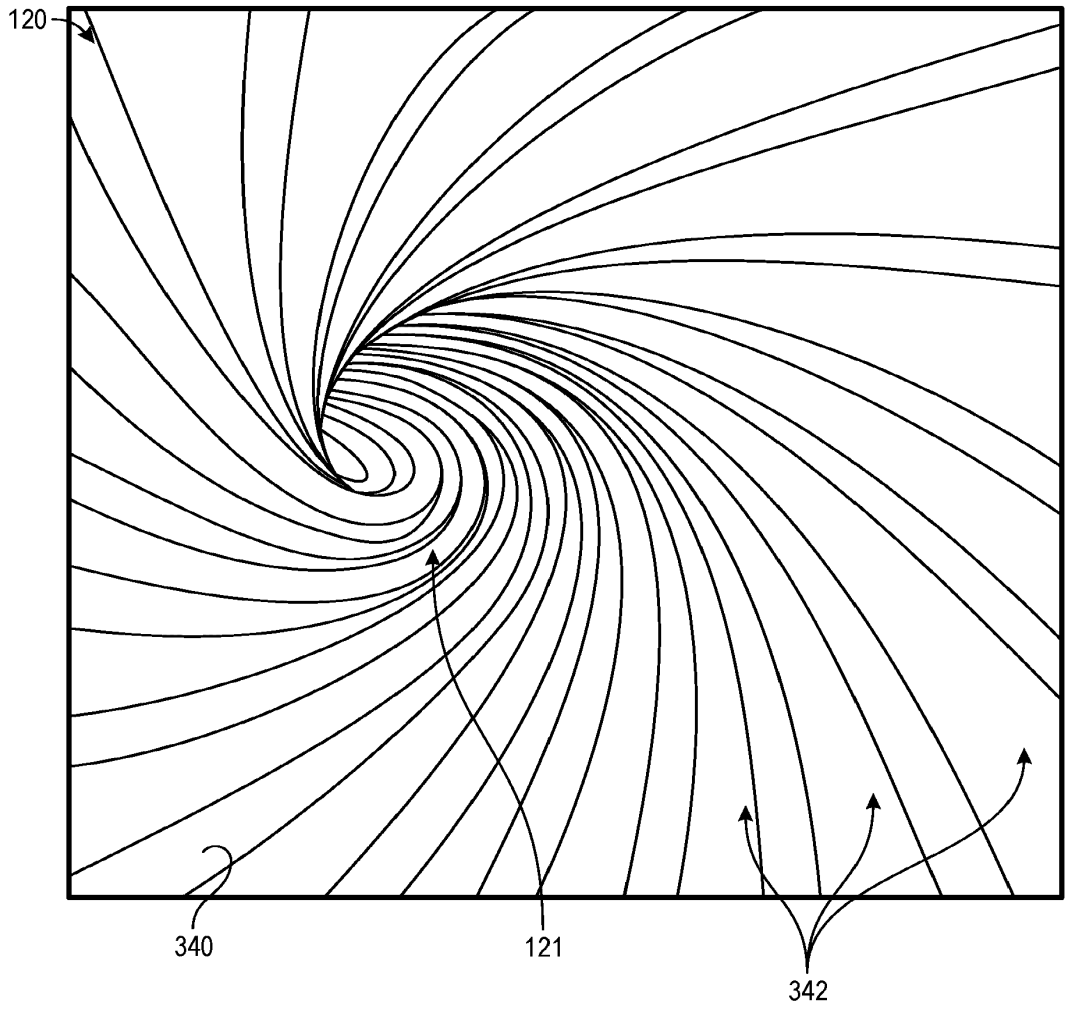



*FIG. 3C*

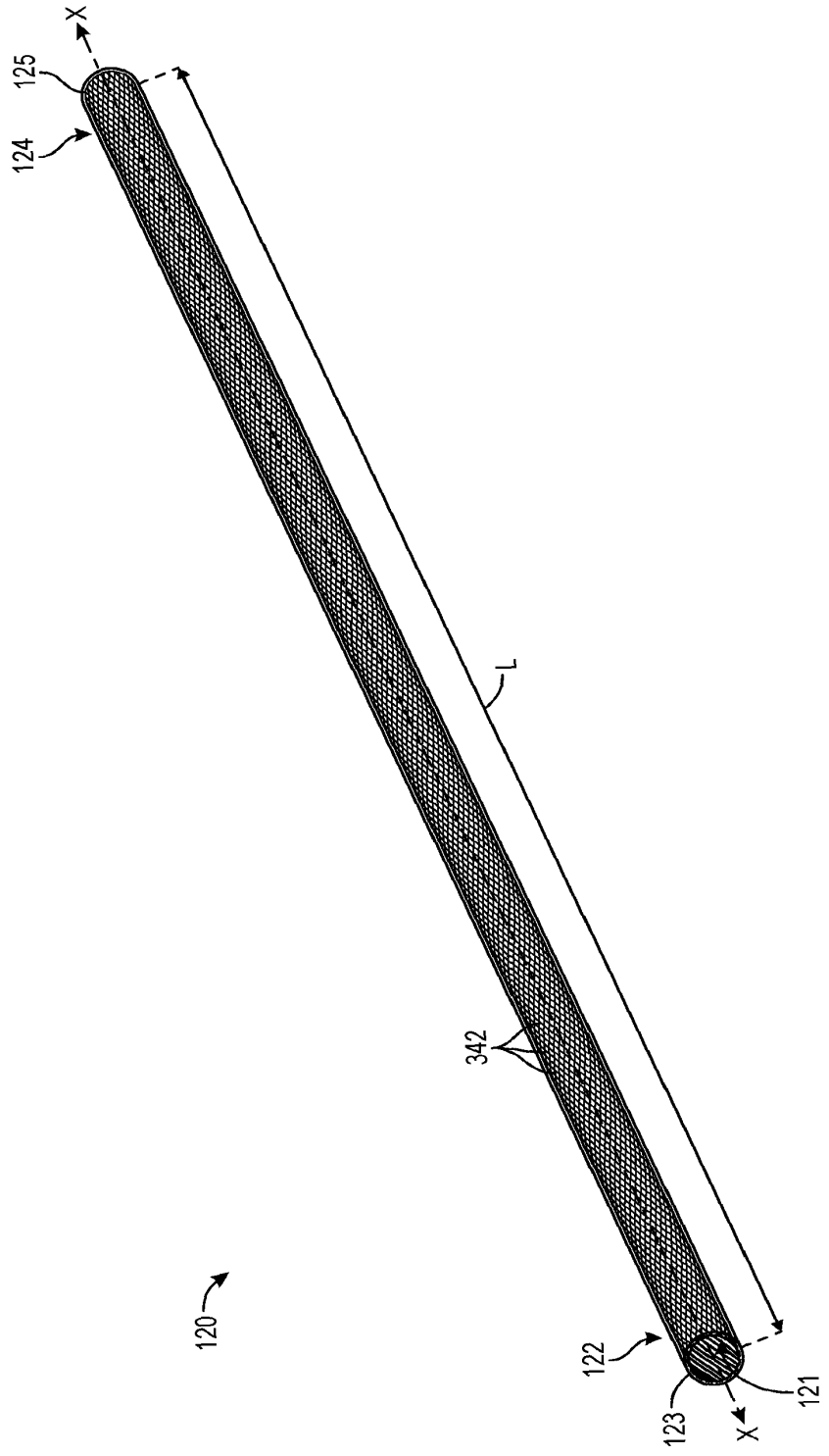



*FIG. 3D*

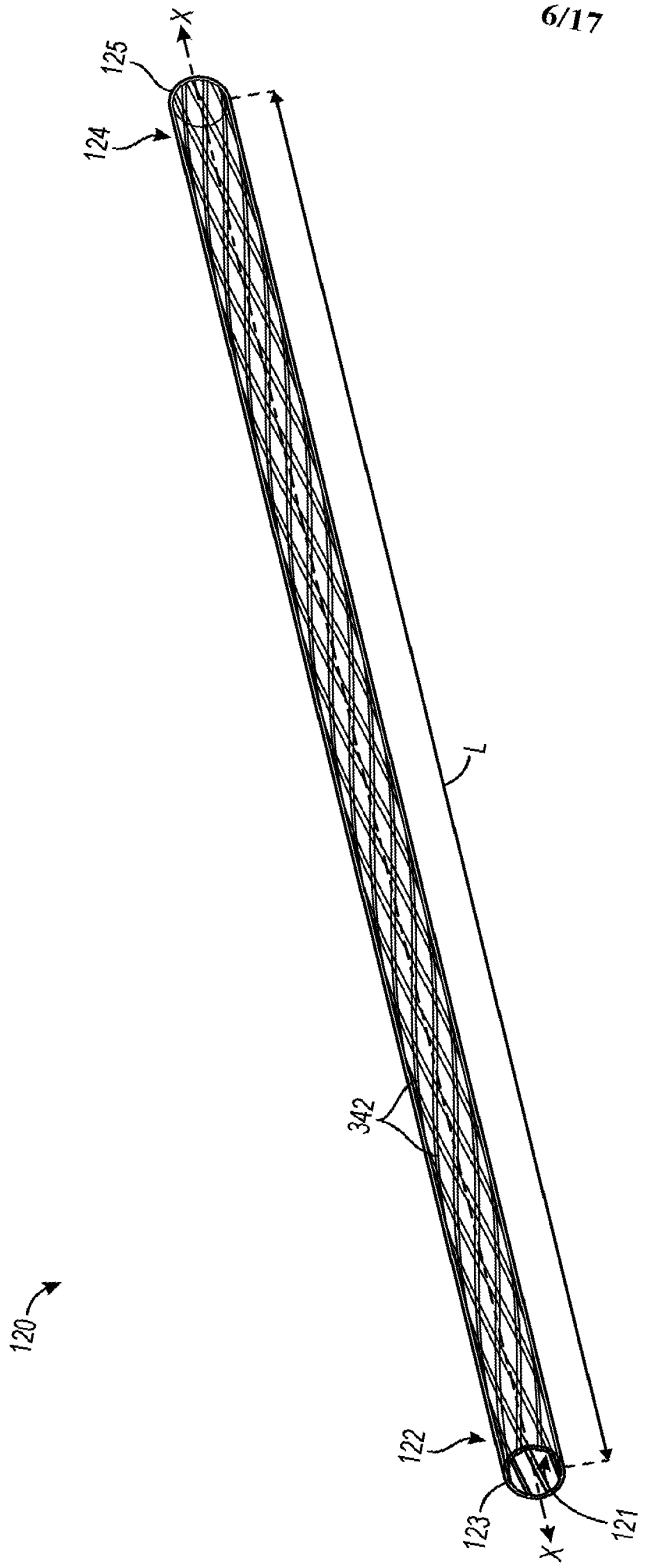



FIG. 4

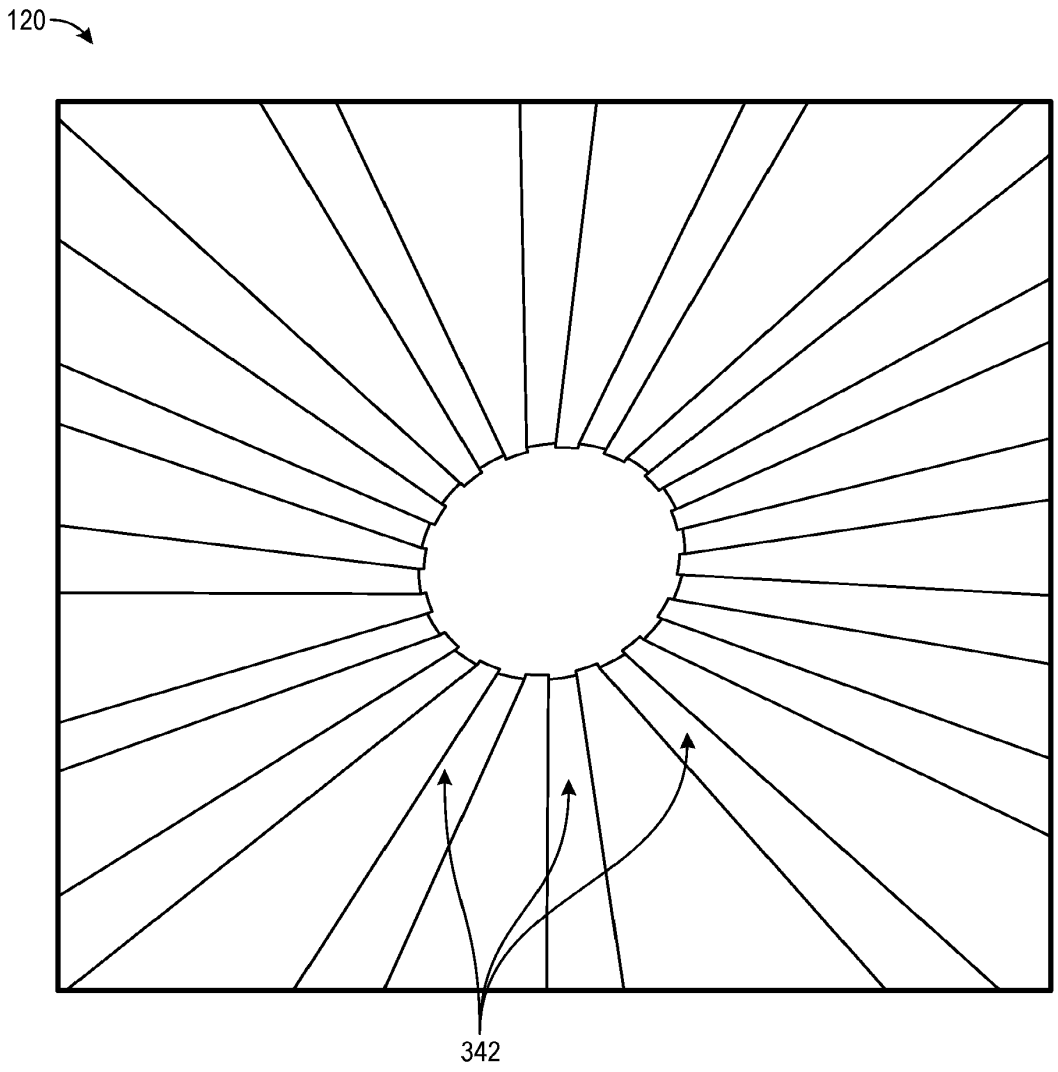



*FIG. 5*

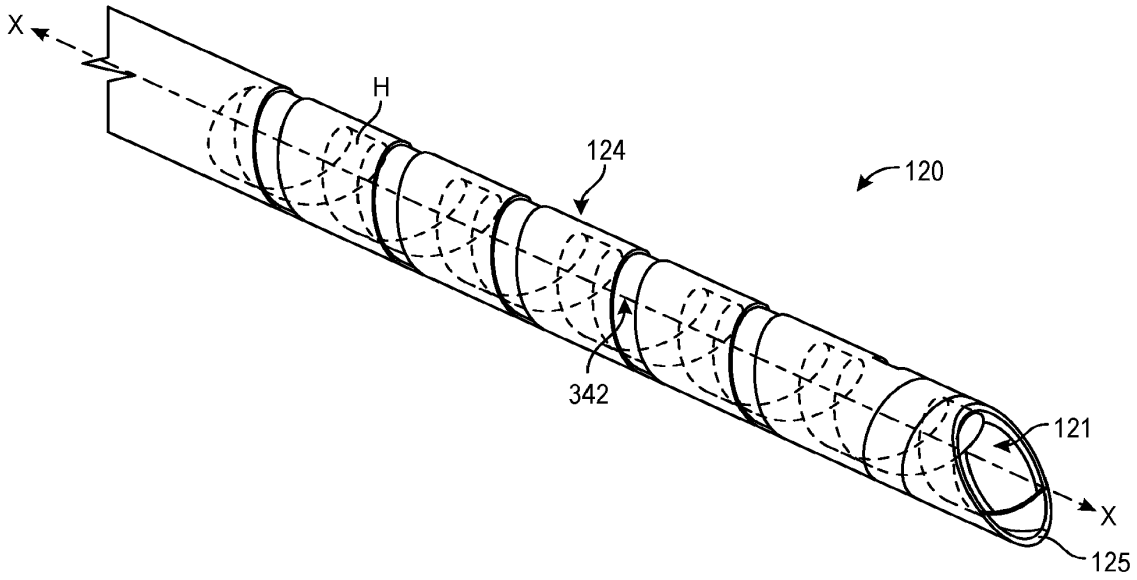



*FIG. 6A*

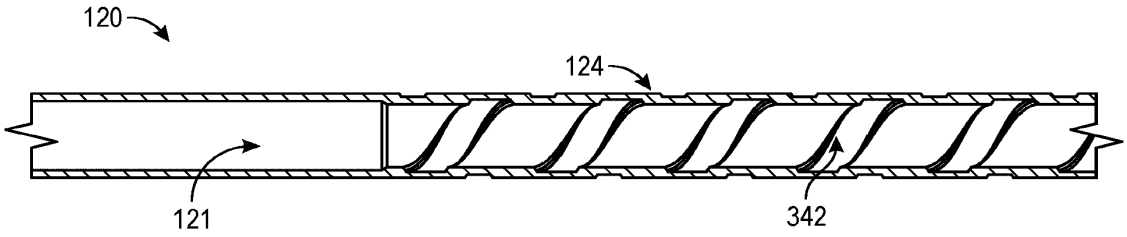



*FIG. 6B*

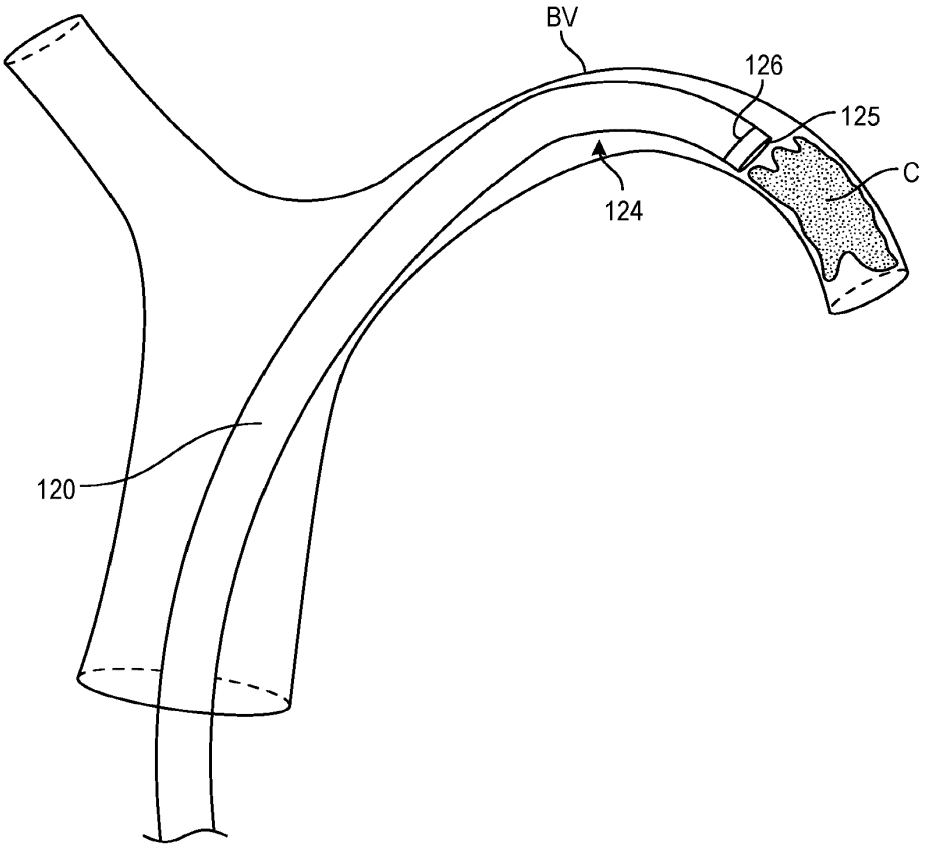



*FIG. 7A*

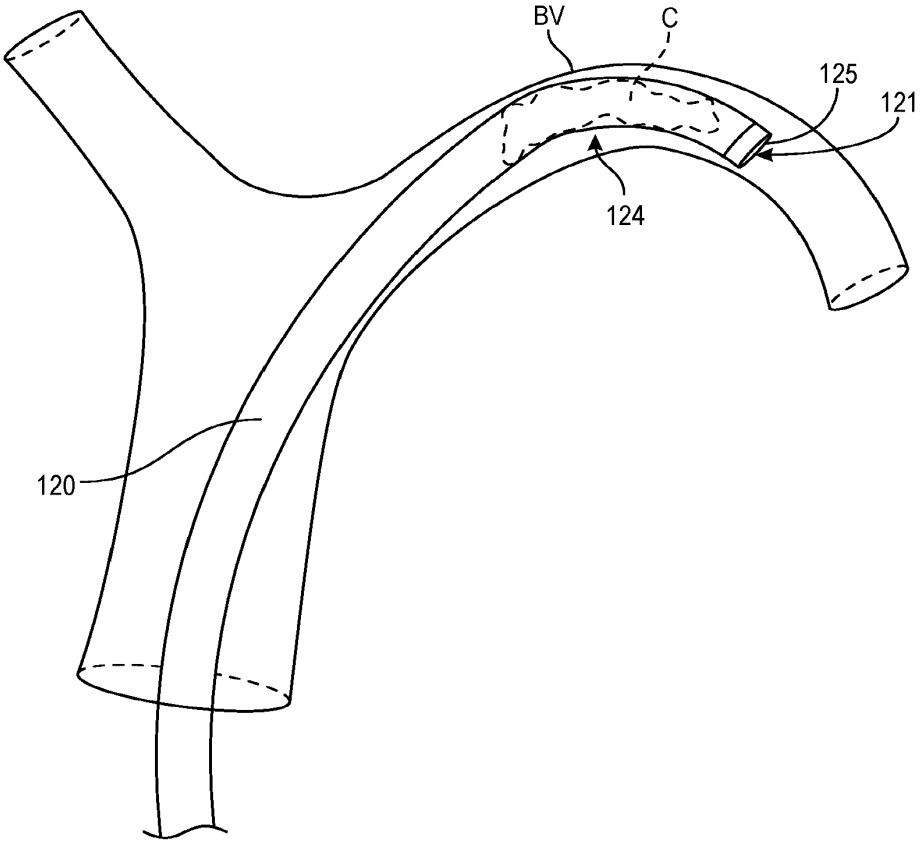



*FIG. 7B*

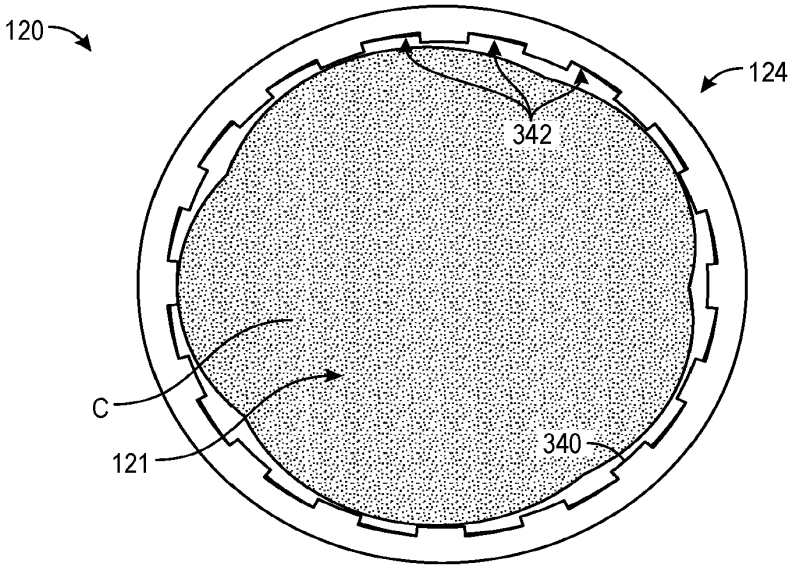



*FIG. 8A*

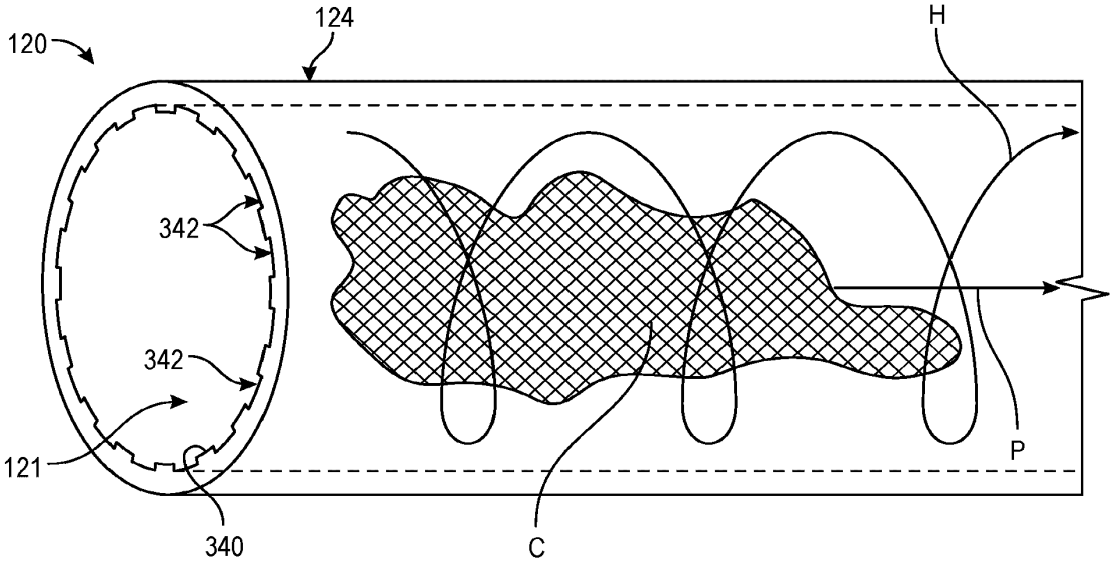



*FIG. 8B*

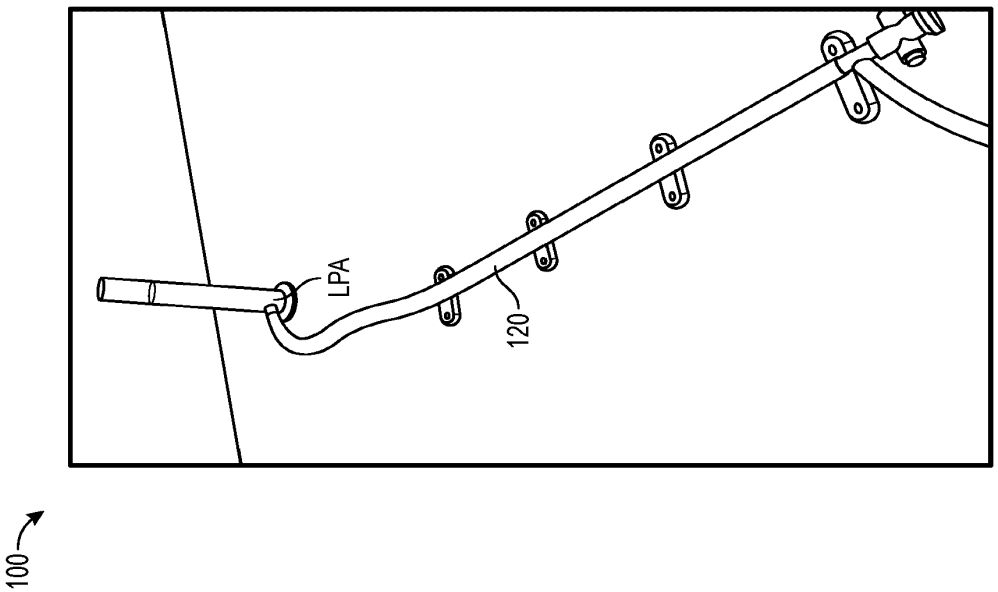



FIG. 9B

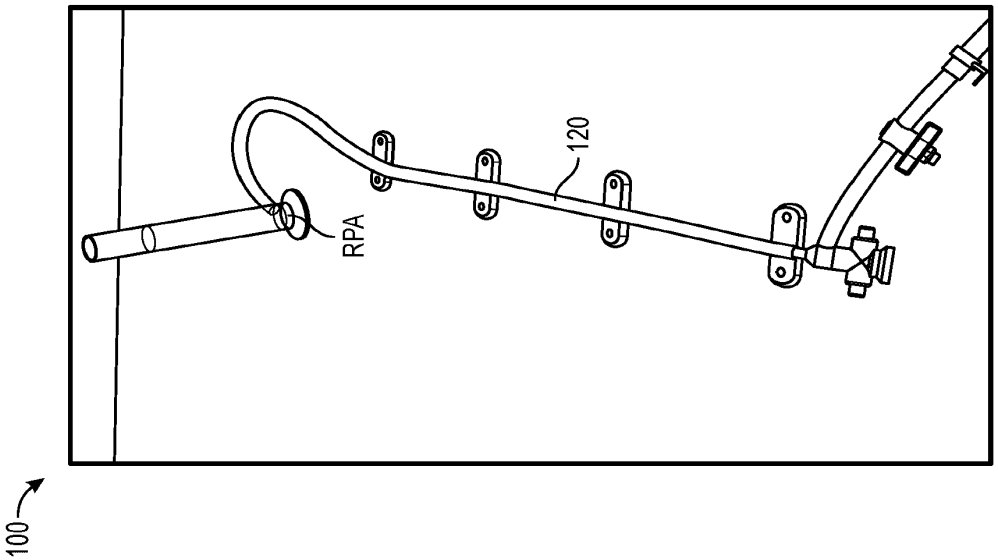



FIG. 9A

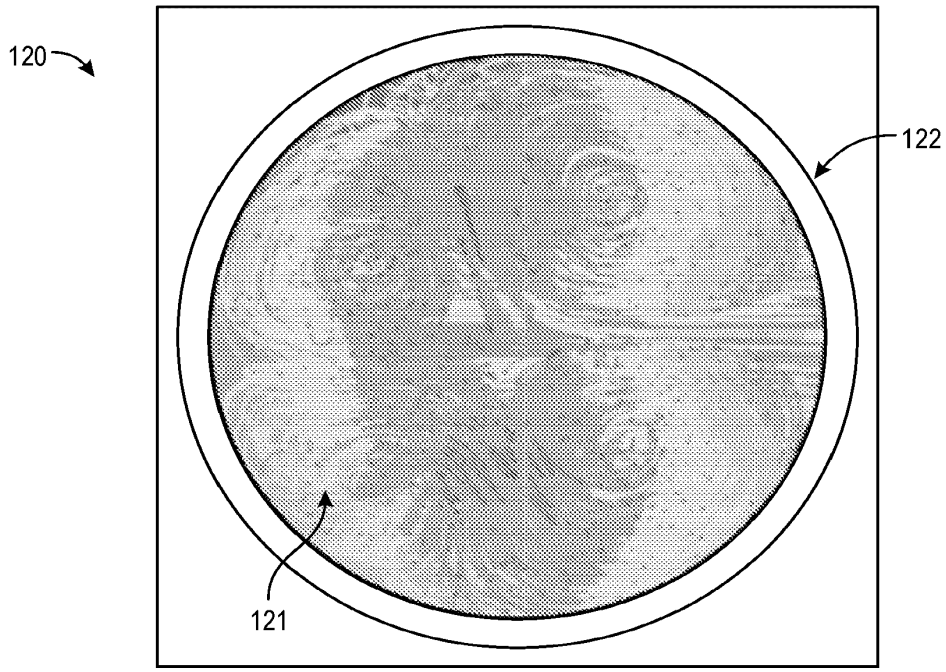



*FIG. 9C*

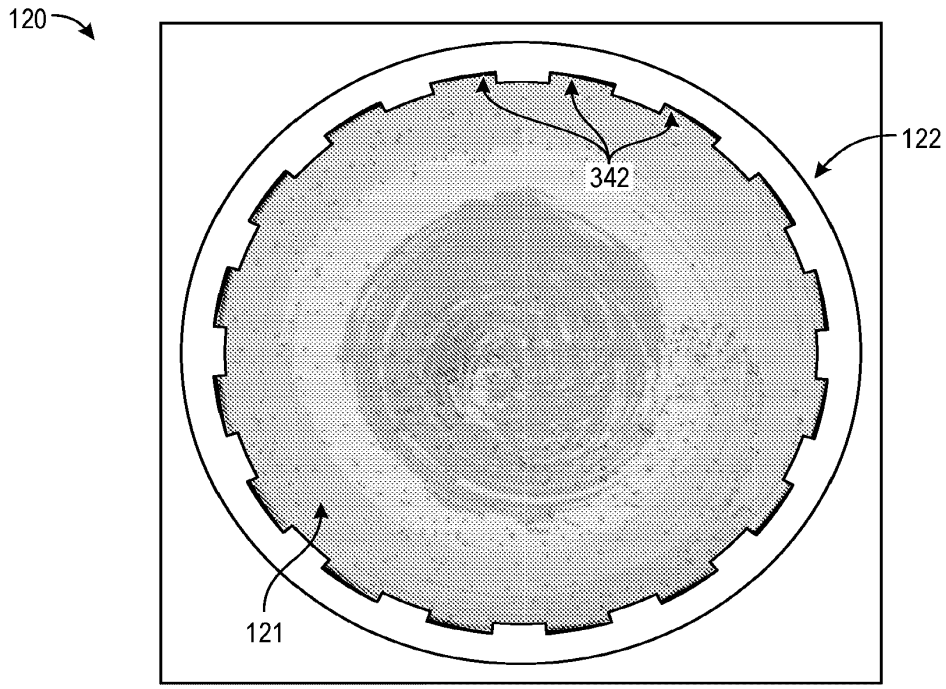



*FIG. 9D*

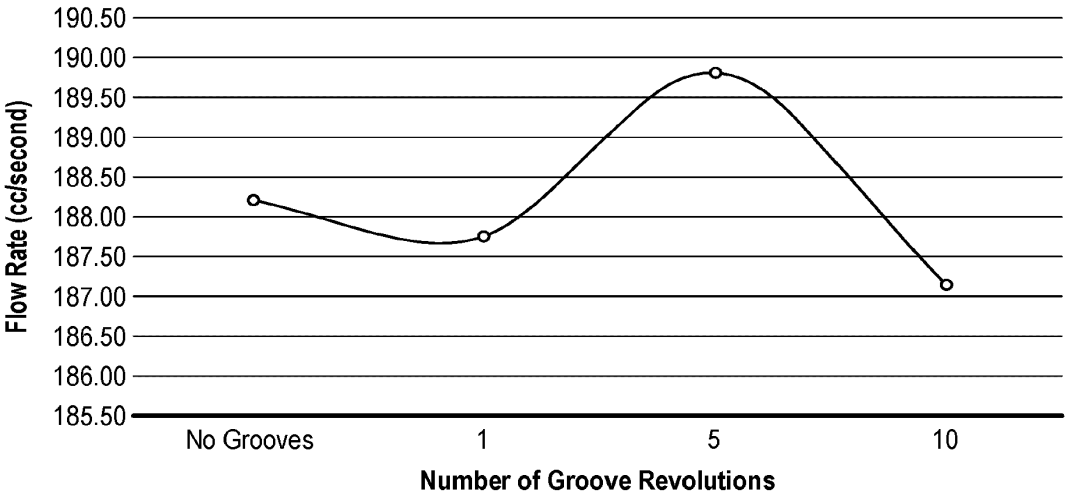



*FIG. 10A*

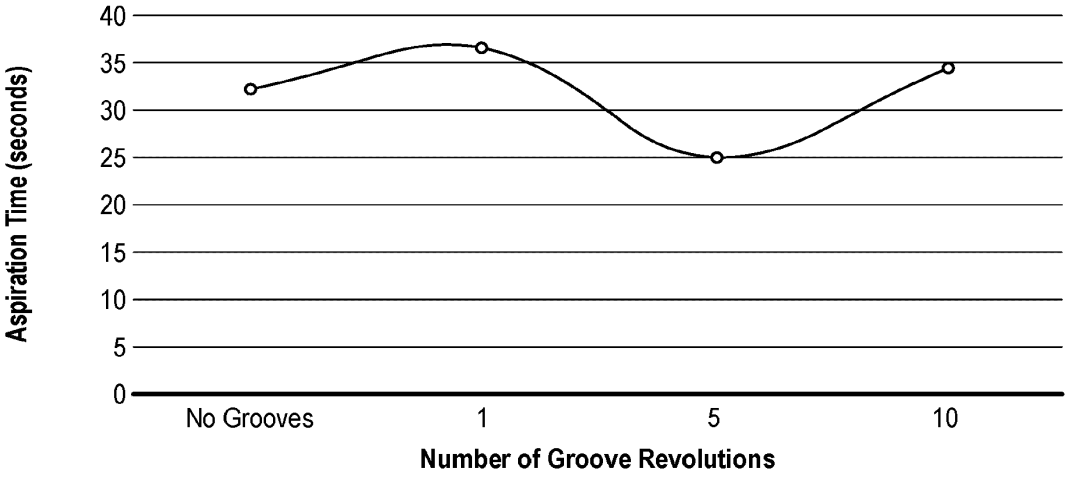



*FIG. 10B*

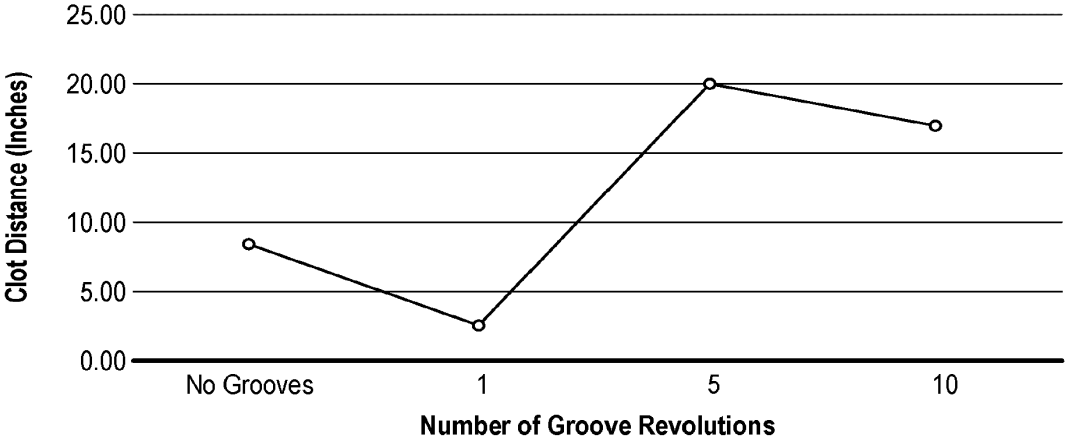



*FIG. 11A*

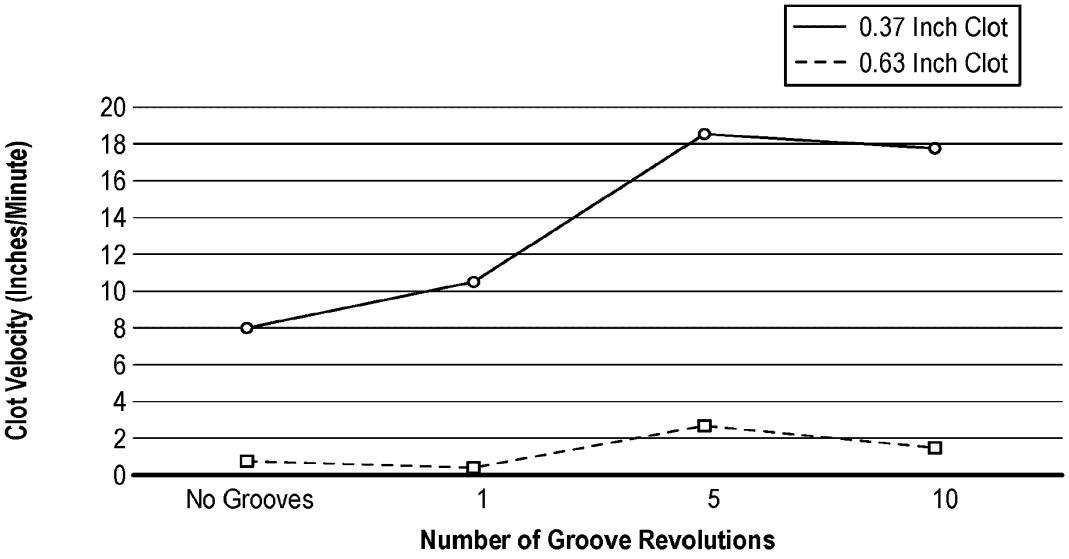



*FIG. 11B*

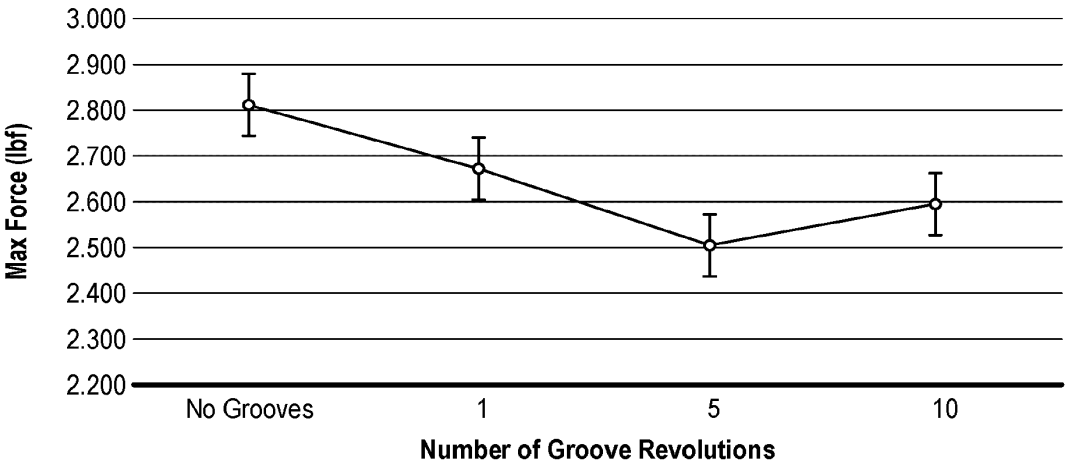

3.000
2.900
2.800
2.700
2.600
2.500
2.400
2.300
2.200
Max Force (lbf)
No Grooves
1
5
10
Number of Groove Revolutions

*FIG. 12*

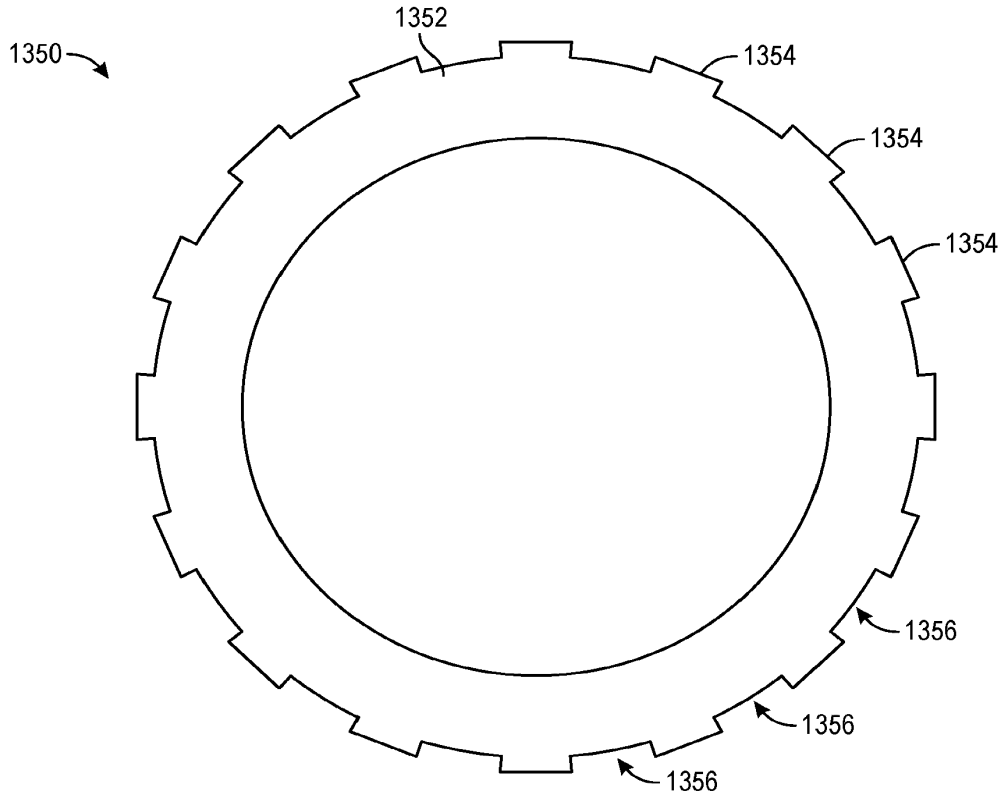

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*FIG. 13*

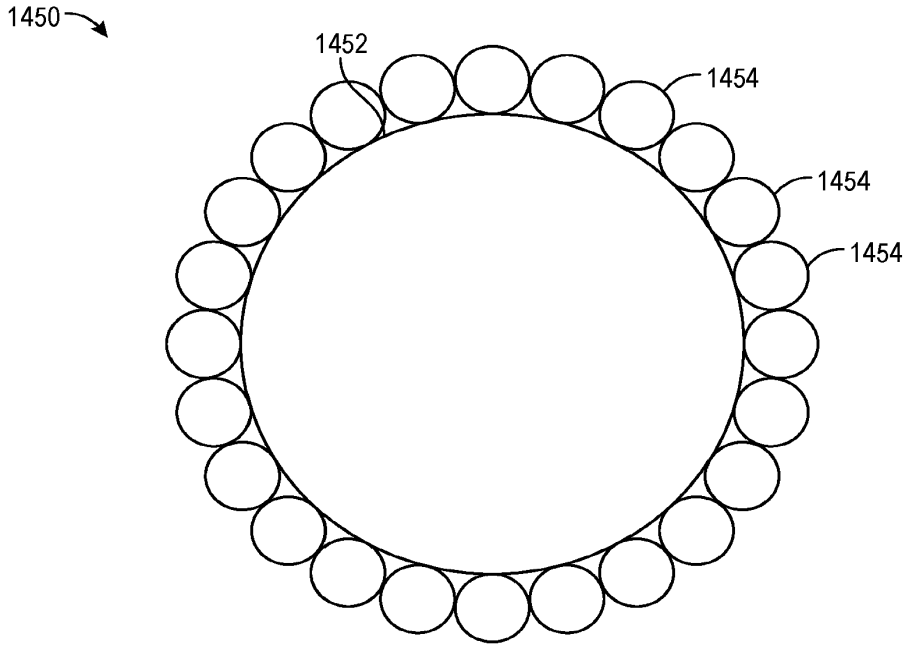



*FIG. 14A*




*FIG. 14B*

## INTERNATIONAL SEARCH REPORT

International application No.
PCT/US23/61256

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61M 1/00 (2023.01)
ADD. A61B 17/22; A61M 25/00 (2023.01)
CPC - INV. A61M 1/84; A61M 25/0043; A61M 25/0045; A61M 25/005
ADD. A61B 2017/22079; A61B 2217/005; A61M 25/0023; A61M 2025/0073; A61M 2206/16; A61M 2206/20

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

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

Electronic database consulted during the international search (name of database 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<br>---<br>Y | US 2016/0030708 A1 (ANGIODYNAMICS INC.) 04 February 2016; figures 4, 8b; paragraphs 0008, 0009, 0030, 0036, 0038, 0039; abstract; claim 3 | 1-13, 15-21<br>---<br>14 |
| X | US 2016/0135829 A1 (ANGIODYNAMICS INC.) 19 May 2016; figures 2a-4c, 7; paragraphs 0037, 0049 | 22-24 |
| Y | US 2006/0264905 A1 (ESKRIDGE ET AL.) 23 November 2006; paragraphs 0005, 0027 | 14 |
| A | US 5,244,619 A (BURNHAM) 14 September 1993; entire document | 1-24 |
| A | US 2017/0021130 A1 (DYE) 26 January 2017; entire document | 1-24 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 24 April 2023 (24.04.2023) | JUN 07 2023 |
| Name and mailing address of the ISA/<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | Authorized officer<br>Shane Thomas<br>Telephone No. PCT Helpdesk: 571-272-4300 |

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PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

| U.S. PATENTS AND PUBLICATIONS | | | | | |
|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | 1. | 20230233311 | 07-27-2023 | Merritt et al. | |
| | 2. | 20070233043 | 10-04-2007 | Dayton et al. | |
| | 3. | 8343167 | 01-01-2023 | Henson | |
| | 4. | 8568465 | 10-29-2013 | Freudenthal et al. | |
| | 5. | 20230241302 | 08-03-2023 | Merritt et al. | |
| | 6. | 20230240705 | 08-03-2023 | Rosenbluth et al. | |
| | 7. | 20230240706 | 08-03-2023 | Rosenbluth et al. | |
| | 8. | 10183159 | 01-22-2019 | Nobles et al. | |
| | 9. | 20190366036 | 12-05-2019 | Jalgaonkar et al. | |
| | 10. | 20110071503 | 03-24-2011 | TAKAGI et al. | |
| | 11. | 20120109109 | 05-03-2012 | KAJII | |
| | 12. | 20100016837 | 01-21-2010 | HOWAT | |
| | 13. | 20180250498 | 09-06-2018 | Stern et al. | |
| | 14. | 11744691 | 09-05-2023 | Merritt et al. | |
| | 15. | 20230248380 | 08-10-2023 | Long et al. | |
| | 16. | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Foreign Document Number[3] | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[5] |
| | 1. | WO2023137341 | 07-20-2023 | Inari Medical, Inc. | | |
| | 2. | WO2015179329 | 11-26-2015 | WALK VASCULAR, LLC | | |
| | 3. | WO2023147353 | 08-03-2023 | Inari Medical, Inc. | | |

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
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| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

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

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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).

**OR**

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

☐ See attached certification statement.

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

☐ None

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information that may be material to the examination of this

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, Applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

**COPIES OF REFERENCES**

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

## SIGNATURE

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

| | | | |
|---|---|---|---|
| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2023-08-29 |
| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

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

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# ELECTRONIC ACKNOWLEDGEMENT RECEIPT

| APPLICATION # | RECEIPT DATE / TIME | ATTORNEY DOCKET # |
|---|---|---|
| **17/498,642** | **08/29/2023 02:05:28 PM ET** | **111552-8023.US02** |

## Title of Invention

SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

## Application Information

| | | | |
|---|---|---|---|
| APPLICATION TYPE | Utility - Nonprovisional Application under 35 USC 111(a) | PATENT # | - |
| CONFIRMATION # | 1040 | FILED BY | JiYoung Anderson |
| PATENT CENTER # | 62698540 | FILING DATE | 10/11/2021 |
| CUSTOMER # | 25096 | FIRST NAMED INVENTOR | Richard Quick |
| CORRESPONDENCE ADDRESS | - | AUTHORIZED BY | Matthew Williams |

## Documents

**TOTAL DOCUMENTS: 7**

| DOCUMENT | | PAGES | DESCRIPTION | SIZE (KB) |
|---|---|---|---|---|
| 2023-8-29 Response to 2023-06-26 Non-Final OA - 111552.8023.US02.pdf | | 9 | - | 60 KB |
| 2023-8-29 Response to 2023-06-26 Non-Final OA - 111552.8023.US02-A....pdf | (1-1) | 1 | Amendment/Request for Reconsideration-After Non-Final Rejection | 16 KB |
| 2023-8-29 Response to 2023-06-26 Non-Final OA - 111552.8023.US02-IACS.pdf | (2-6) | 5 | Amendment Copy Claims/Response to Suggested Claims | 30 KB |
| 2023-8-29 Response to | (7-9) | 3 | Applicant Arguments/Remarks | 36 KB |

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| 2023-06-26 Non-Final OA - 111552.8023.US02-REM.pdf | | Made in an Amendment | |
| 2023-8-29- IDS SB08 - 111552-8023US2.pdf | 3 | Information Disclosure Statement (IDS) Form (SB08) | 127 KB |

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|---|---|---|---|
| FOR_WO2023137341.PDF | 75 | Foreign Reference | 3594 KB |
| FOR_WO2015179329.PDF | 56 | Foreign Reference | 2433 KB |
| FOR_WO2023147353.pdf | 52 | Foreign Reference | 2162 KB |

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| DOCUMENT | MESSAGE DIGEST(SHA-512) |
|---|---|
| 2023-8-29 Response to 2023-06-26 Non-Final OA - 111552.8023.US02.pdf | 902644C2E47CE173AAA3174EAF0BEECB7B34A9EBF17B7C2A2B230FD8835014C51E0BE1CE8E46B651AC3D55119512847C86D0B3522698CA22A5D4F87FF9847602 |
| 2023-8-29 Response to 2023-06-26 Non-Final OA - 111552.8023.US02-A....pdf | 4033DE6BE904E06764DFD08C3348CB6D3390E27AFA58D66CBC72E575ABE5E283189884F20A42F8C694F77B3DDEFFDFC656AB1DF2087D3EC3BB56727B9D2C29F7 |
| 2023-8-29 Response to 2023-06-26 Non-Final OA - 111552.8023.US02-IACS.pdf | FA07E3F87B9217C0BED9D5FE27006D6051350BD7FD3D01C9D86A43AB2AD96425F751C36E8EEDFEEFF92074675FC9C1FADAC00FE03278D4BF216C77BAF4B5FF1D |
| 2023-8-29 Response to 2023-06-26 Non-Final OA - 111552.8023.US02-REM.pdf | 94DE4E3A67197795C06AE4C3DA1DB59364587305D8F3BD6167BD837B945FF997DB8D7DFEA9E96068D3F726AF743DAB4A6821C5200E603906F02CA1DCBE9EF974 |
| 2023-8-29- IDS SB08 - 111552-8023US2.pdf | BC46131B719C695A02DB2327932F91693810FACF63E87219F52542AF318C43EB2206208565AF365E3A85A50B89B92EC98261 |

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| | AF25C64378468C81A53207E2CF0B |
| FOR_WO2023137341.PDF | 0EED4348CDC2BC929DF5488A6BB3299B1CF492244B5F17616<br>256350DF062C9C554456D996FCC48B4DE6BB3EEAC7495B022<br>74727C8C04E2B6D5366DA5E9C17349 |
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| FOR_WO2023147353.pdf | 3EDDA3111BC6ED8E432E598FC32288322B61AF18C24BFAB05<br>BF37C01EAF38BAD33A653B0775A5C1DF112797E9683B7A435<br>B4776198241AFD4A04CAA25ACB509E |

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**New Applications Under 35 U.S.C. 111**

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

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

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

**New International Application Filed with the USPTO as a Receiving Office**

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

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

In re Application of:

Richard Quick

Application No.: 17/498,642

Filed: October 11, 2021

For: SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

Conf. No.: 1040

Art Unit: 3771

Examiner: Tuan Van Nguyen

Customer No. 25096

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

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

Dear Commissioner:

In response to the Office Action mailed on June 26, 2023, please amend and consider the above-identified application as follows:

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

**Remarks** begin on page 7.

## AMENDMENTS TO THE CLAIMS

Please amend claim 29, cancel claims 28[1] and 32–40, and add new claims 41–63. Following is a complete listing of the claims pending in the application, as amended:

1–20. (Canceled)

21. (Previously Presented) A method for the intravascular treatment of clot material within a blood vessel, the method comprising:

positioning a distal portion of an elongated shaft proximate to the clot material within the blood vessel;

pre-charging a vacuum in a pressure source;

fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft;

unsealing an attachment member coupled to a proximal portion of the elongated shaft;

advancing an interventional device distally through the attachment member and the elongated shaft; and

engaging the interventional device with a second portion of the clot material remaining within the blood vessel.

22. (Previously Presented) The method of claim 21 wherein the method further comprises withdrawing the interventional device and the second portion of the clot material into the elongated shaft.

23. (Previously Presented) The method of claim 22 wherein the method further comprises withdrawing the interventional device and the second portion of the clot material through the attachment member.

[1] The Applicant notes that two claims were erroneously labeled as "claim 28." The Applicant cancels the second of the two listed claims 28 herein and re-presents this claim as new claim 41.

24. (Previously Presented) The method of claim 23 wherein the method further comprises unsealing the attachment member before withdrawing the interventional device and the second portion of the clot material through the attachment member.

25. (Previously Presented) The method of claim 21 wherein unsealing the attachment member includes exercising a valve of the attachment member such that a lumen of the attachment member has a diameter that is about equal to an inner diameter of the elongated shaft.

26. (Previously Presented) The method of claim 21 wherein unsealing the attachment member includes pressing one or more buttons on the attachment member.

27. (Previously Presented) The method of claim 21 wherein the pressure source is a syringe.

28. (Previously Presented) The method of claim 27 wherein pre-charging the vacuum includes withdrawing a plunger of the syringe.

28. (Canceled)

29. (Currently Amended) The method of claim ~~28~~ 41 wherein pre-charging the vacuum in the pressure source includes activating the pressure source while the fluid control device is closed, and wherein fluidly connecting the pressure source to the elongated shaft includes opening the fluid control device.

30. (Previously Presented) The method of claim 21 wherein fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum generates suction at the distal portion of the elongated shaft.

31. (Previously Presented) The method of claim 21 wherein the blood vessel is a pulmonary blood vessel.

32–40. (Canceled)

41. (New) The method of claim 21 wherein the pressure source is fluidly coupled to the elongated shaft via a fluid control device, and wherein (a) opening of the fluid control device fluidly connects the pressure source to the elongated shaft and (b) closing of the fluid control device fluidly disconnects the pressure source from the elongated shaft.

42. (New) The method of claim 41 wherein the fluid control device comprises a user-actuatable valve.

43. (New) The method of claim 21 wherein the attachment member comprises a hemostasis valve.

44. (New) The method of claim 43 wherein the hemostasis valve includes a tubular member, a button, and a filament coupled to the button and the tubular member, and wherein unsealing the hemostasis valve includes pressing the button to loosen the filament to allow the tubular member to expand.

45. (New) The method of claim 44 wherein the method further comprises, after at least partially advancing the interventional device distally through the hemostasis valve, releasing the button to tighten the filament to allow the tubular member to collapse and seal about a portion of the interventional device.

46. (New) The method of claim 45 wherein the hemostasis valve further includes a spring, and wherein releasing the button to tighten the filament includes driving the button with the spring to tighten the filament.

47. (New) The method of claim 21 wherein the method further comprises collecting at least some of the first portion of the clot material within a filter chamber fluidly coupled between the pressure source and the elongated shaft.

48. (New) The method of claim 47 wherein the method further comprises removing a filter from within the filter chamber to provide access to the at least some of the first portion of the clot material.

49. (New) The method of claim 48 wherein the filter includes a plurality of pores sized to inhibit the clot material from flowing therethrough and to permit blood to flow therethrough.

50. (New) The method of claim 47 wherein the filter chamber is spaced apart from the pressure source and connected to the pressure source via at least one tube.

51. (New) The method of claim 47 wherein the filter chamber comprises a housing and a filter within the housing, and wherein the housing includes—

a port configured to be fluidly coupled to the elongated shaft via at least one first tube; and

a fluid connector configured to be coupled to the pressure source via at least one second tube, wherein the filter is in the housing and fluidly coupled between the port and the fluid connector, and wherein the elongated shaft is fluidly coupled to the pressure source via the filter chamber.

52. (New) The method of claim 51 wherein the elongated shaft is fluidly coupled to the pressure source via the filter chamber along a first fluid path.

53. (New) The method of claim 52 wherein the attachment member is fluidly coupled to the elongated shaft along a second fluid path at least partially different than the first fluid path.

54. (New) The method of claim 53 wherein the attachment member comprises a hemostasis valve.

55. (New) The method of claim 54 wherein unsealing the hemostasis valve includes actuating at least one button of the hemostasis valve.

56. (New) The method of claim 47 wherein the filter chamber is fluidly coupled to the elongated shaft via a first fluid path, wherein the attachment member is fluidly coupled to the elongated shaft along a second fluid path, and wherein the first fluid path branches from the second fluid path.

57. (New) The method of claim 56 wherein the attachment member is a hemostasis valve.

58. (New) The method of claim 57 wherein unsealing the hemostasis valve includes actuating at least one button of the hemostasis valve.

59. (New) The method of claim 21 wherein engaging the interventional device with the second portion of the clot material remaining within the blood vessel includes translating the interventional device relative to the elongated shaft.

60. (New) The method of claim 21 wherein the method further comprises flushing the clot container with a fluid after aspirating the first portion of the clot material into the elongated shaft and/or after engaging the interventional device with the second portion of the clot material.

61. (New) The method of claim 60 wherein the fluid is saline.

62. (New) The method of claim 21 wherein the pressure source is coupled to the elongated shaft via at least one tube, and wherein the method further comprises flushing the at least one tube with a fluid after aspirating the first portion of the clot material into the elongated shaft and/or after engaging the interventional device with the second portion of the clot material.

63. (New) The method of claim 62 wherein the fluid is saline.

## REMARKS

Claims 21–40 were pending when the present Office Action was mailed on June 26, 2023. In this response, claims 32–40 have been canceled without commenting on or conceding the merits of the rejections of these claims and without prejudice to or disclaimer of pursuing the subject matter of these claims in a continuation or other related application. Further, the Applicant notes that two claims were erroneously labeled as "claim 28." The second of the two listed claims 28 has been canceled herein and re-presented as new claim 41. Further, new claims 42–63 have been added in this response. Accordingly, claims 21–31 and 41–63 are currently pending.

The status of the application in light of this Office Action is as follows:

(A) Claims 32 and 37–39 were rejected under 35 U.S.C. § 102(a)(1) over U.S. Patent Application Publication No. 2015/0352325 to Quick ("Quick"); and claims 33–36 and 40 were rejected under 35 U.S.C. § 103 over a combination of Quick and U.S. Patent No. 5,256,150 to Quiachon et al. ("Quiachon"); and

(B) Claims 21–31 were allowed.

A. Response to the Section 102/103 Rejections of Claims 32–40

Claims 32 and 37–39 were rejected under 35 U.S.C. § 102(a)(1) over Quick. Claims 22–36 and 40 were rejected under 35 U.S.C. § 103 over the combination of Quick and Quiachon. Without commenting on or conceding the merits of the rejections of these claims, claims 32–40 have been canceled in this response to expedite prosecution of this application. Accordingly, the rejection of these claims is now moot.

B. Indication of Allowable Subject Matter

Claims 21–31 were allowed. The Applicant thanks the Examiner for indicating that claims 21–31 are allowable. Although the undersigned attorney agrees with the Examiner's conclusion that claims 21–31 are allowable, the undersigned attorney notes that these claims may be allowable for reasons other than those identified by the Examiner and does not concede that the Examiner's characterization of the terms of these claims and the prior art are correct.

C. New Claims 41–63

New claims 41–63 depend from independent claim 21. Accordingly, new claims 41–63 are patentable for at least the same reasons as allowable claim 21, and for the additional features of these dependent claims.

Conclusion

In view of the foregoing, the pending claims comply with 35 U.S.C. § 112 and are patentable over the applied references. The Applicant accordingly requests reconsideration of the application and respectfully submits that the application be allowed. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to contact the undersigned practitioner at 206.359.3343.

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or applied references, the Applicant is not conceding that previously pending claims are not patentable over the cited references; instead, any alteration or characterizations are made to expedite prosecution of this application. Silence regarding a position taken, or argument made, in the Office Action does not indicate Applicant acquiesces to that position or argument. Furthermore, arguments made with respect to a particular claim or claims apply only to those claim or claims, and not to other claims or patents/applications, unless specifically noted herein.

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

Please charge any underpayment or credit any overpayment to Deposit Account No. 50-0665, under Order No. 111552-8023.US02 from which the undersigned is authorized to draw.

Respectfully submitted,

Dated: _____August 29, 2023_____ By: /Matthew S. Williams/

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(54) Title: DEVICES FOR REMOVING CLOT MATERIAL FROM INTRAVASCULARLY IMPLANTED DEVICES, AND ASSOCIATED SYSTEMS AND METHODS

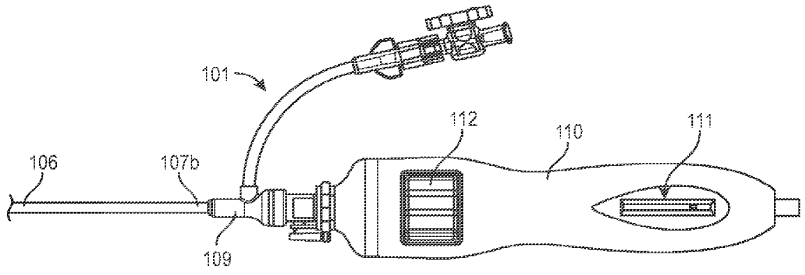



*FIG. 1A*

(57) Abstract: Disclosed herein are devices for mechanically removing clot and/or other material from implants implanted in the vasculature of a patient, and associated systems and methods. In some embodiments, a system for removing clot material from an implant—such as a stent—includes a clot treatment device configured to be deployed within the stent, a handle, and a first elongate member and a second elongate member coupling the clot treatment device to the handle. The first elongate member couples a first end portion of the clot treatment device to the handle, and the second elongate member couples a second end portion of the clot treatment device to an actuator of the handle. Actuation of the actuator is configured to move the second elongate member relative to the first elongate member to move the first and second end portions toward one another to radially expand the clot treatment device.

WO 2023/137341 A1

# DEVICES FOR REMOVING CLOT MATERIAL FROM INTRAVASCULARLY IMPLANTED DEVICES, AND ASSOCIATED SYSTEMS AND METHODS

## CROSS-REFERENCE TO RELATED APPLICATION

**[0001]** This application claims the benefit of U.S. Provisional Patent Application No.63/298,399, filed January 11, 2022, and titled "DEVICES FOR REMOVING CLOT MATERIAL FROM INTRAVASCULARLY IMPLANTED STENTS, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

## TECHNICAL FIELD

**[0002]** The present technology generally relates to devices for cleaning stents, embolic protection devices, other implants, and/or bare vessels and, more particularly, for example, to devices for intravascularly removing clot and/or other material from stents implanted in the vasculature of a patient (e.g., the venous vasculature).

## BACKGROUND

**[0003]** Stents are tubes or similar structures that can be implanted within a blood vessel of a patient to mechanically keep the vessel open, restore flow, and/or bypass a diseased region of the blood vessel. Stents are typically made of metal or plastic, and can be crimped or packed down into a delivery catheter before being intravascularly delivered to a target location within the blood vessel.

**[0004]** After a stent is delivered to and implanted within a blood vessel of a patient, unwanted material can form around and/or adhere to the stent. For example, clot material can form and adhere to an inner surface of the stent. Similarly, vascular wall cells can abnormally accumulate within the stent (e.g., intimal hyperplasia).

**[0005]** Physicians are currently limited in their abilities to remove adherent clot or intimal hyperplasia from implanted stents and, in particular, venous stents. For example, while aspiration mechanisms exist to remove clot material from venous stents, these aspiration mechanisms are limited to non-adherent, acute clot, and cannot treat chronic adherent clot or intimal hyperplasia. Further, while mechanical clot treatment devices exist to target adherent

clot material, many such devices are currently contraindicated for removing clot material from stents because the mechanical clot treatment devices can catch on the stent, causing damage. Other methods of medical management such as ballooning or re-stenting do not remove the clot that has been formed, likely causing additional clot to form. Pharmacological methods—such as administering tissue plasminogen activator (tPA)—do not work on aged, more adherent clot, and also carry other risks such as systemic bleeding. Surgery carries risks of adverse events and is more invasive than transcatheter methods.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0006]** Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

**[0007]** Figure 1A is a side view of a stent cleaning system in accordance with embodiments of the present technology. Figures 1B and 1C are an enlarged side view and an enlarged proximally-facing view, respectively, of a distal portion of the system of Figure 1A including a clot treatment device in accordance with embodiments of the present technology.

**[0008]** Figures 2A–2C are enlarged proximally-facing views of a distal portion of the system of Figure 1A including the clot treatment device in accordance with additional embodiments of the present technology.

**[0009]** Figures 3A–3D are enlarged side views of a distal portion of the system of Figure 1A including the clot treatment device in accordance with additional embodiments of the present technology.

**[0010]** Figures 4A–4C are enlarged isometric views of a distal portion of the system of Figure 1A including the clot treatment device in accordance with additional embodiments of the present technology.

**[0011]** Figure 5 is a partially cut-away view of a handle of the system of Figure 1A in accordance with embodiments of the present technology.

**[0012]** Figures 6A and 6B are side views of a distal portion of the system of Figure 1A including the clot treatment device in a first position and a second position, respectively, in accordance with embodiments of the present technology.

**[0013]** Figure 7 is a flow diagram of a process or method for operating the system of Figure 1A during an intravascular procedure to remove clot material from an implanted stent in accordance with embodiments of the present technology.

**[0014]** Figure 8 is a distally-facing perspective view of a distal portion of the system of Figure 1A including the clot treatment device expanded within a stent implanted in a vessel in accordance with embodiments of the present technology.

**[0015]** Figures 9A and 9B are distally-facing perspective views of a distal portion of the system of Figure 1A including the clot treatment device positioned within the stent of Figure 6 in accordance with embodiments of the present technology.

**[0016]** Figures 10A–10C are distally-facing perspective views of a distal portion of the system of Figure 1A including the clot treatment device deployed within an implant with differing amounts of radial expansion in accordance with embodiments of the present technology.

**[0017]** Figure 11A is a side view of a stent cleaning system in accordance with embodiments of the present technology. Figures 11B and 11C are side views of a distal portion of the system of Figure 11A including a clot treatment device in a first position and a second position, respectively, in accordance with embodiments of the present technology.

**[0018]** Figure 12 is a side view of a clot treatment device in accordance with embodiments of the present technology.

**[0019]** Figure 13 is a side view of a clot treatment device in accordance with embodiments of the present technology.

**[0020]** Figure 14 is a side view of a clot treatment device in accordance with embodiments of the present technology.

**[0021]** Figure 15 is a side view of a clot treatment device in accordance with embodiments of the present technology.

**[0022]** Figures 16A–16C are side views of a clot treatment device in accordance with embodiments of the present technology.

**[0023]** Figures 17A and 17B are side views of a distal portion of a stent cleaning system in accordance with embodiments of the present technology.

**[0024]** Figure 18 illustrates several different chamfers that can be used in a clot treatment device in accordance with embodiments of the present technology.

**[0025]** Figure 19 is an enlarged side view of a pair of struts of a clot treatment device in accordance with embodiments of the present technology.

**[0026]** Figure 20 is a side cross-sectional view of a handle in accordance with additional embodiments of the present technology that can be used in the system of Figure 1A.

**[0027]** Figure 21 is a side cross-sectional view of a handle in accordance with additional embodiments of the present technology that can be used in the system of Figure 1A.

**[0028]** Figure 22 is a side cross-sectional view of an actuation mechanism of a handle in accordance with embodiments of the present technology that can be used in the system of Figure 1A.

**[0029]** Figure 23 is a side cross-sectional view of a handle in accordance with additional embodiments of the present technology that can be used in the system of Figure 1A.

**[0030]** Figure 24 is a side cross-sectional view of a handle in accordance with additional embodiments of the present technology that can be used in the system of Figure 1A.

**[0031]** Figures 25A–25C are an enlarged perspective view, an enlarged side view, and an enlarged cross-sectional side view, respectively, of a handle in accordance with additional embodiments of the present technology that can be used in the system of Figure 1A.

**[0032]** Figure 26 is an enlarged cross-sectional side view of a handle in accordance with additional embodiments of the present technology that can be used in the system of Figure 1A.

**[0033]** Figure 27 is an enlarged cross-sectional side view of a handle in accordance with additional embodiments of the present technology that can be used in the system of Figure 1A.

**[0034]** Figure 28 is a side view of a distal portion of a clot removal system positioned within a vessel to treat clot material in accordance with embodiments of the present technology.

## DETAILED DESCRIPTION

**[0035]** The present technology is generally directed to devices for mechanically removing clot and/or other material from the vasculature of a patient, and associated systems and methods. In particular, some of the embodiments are directed to devices for mechanically removing clot and/or other material from implants implanted in the vasculature of the patient, such as stents

implanted within the venous vasculature. In some embodiments described below, a system for removing clot material from an implant—such as a venous stent—includes a (i) clot treatment device, (ii) a handle, and (iii) a first elongate member and a second elongate member coupling the clot treatment device to the handle. The clot treatment device is configured to be deployed within the implant, and includes a first end portion, a second end portion, and a plurality of struts extending between the first and second end portions. The first elongate member couples the first end portion of the clot treatment device to the handle, and the second elongate member couples the second end portion of the clot treatment device to the handle (e.g., to an actuator of the handle). Actuation of the actuator in a first direction is configured to move the second elongate member relative to the first elongate member and/or the first elongate member relative to the second elongate member to move the first and second end portions toward one another to radially expand the struts. The actuator can be actuated in a second direction (e.g., opposite the first direction) to move the second elongate member relative to the first elongate member and/or the first elongate member relative to the second elongate member to move the first and second end portions away from one another to radially collapse the struts.

**[0036]** When expanded within the implant, the clot treatment device can be (i) translated proximally and/or distally through the implant by translating the handle and (ii) rotated within the implant by rotating the handle. Such movements can mechanically engage the clot treatment device with clot material adhered to the implant to dislodge the clot material. In some aspects of the present technology, the clot treatment device is configured to be translated and/or rotated within the implant without catching on the implant, avoiding potential damage, deformation, movement, and/or migration of the implant. For example, the struts can extend generally axially between the first and second end portions—and not include any cross-members connected therebetween that are configured to contact the implant—to reduce the likelihood of the struts damaging the implant.

**[0037]** Certain details are set forth in the following description and in Figures 1–28 to provide a thorough understanding of various embodiments of the present technology. In other instances, well-known structures, materials, operations, and/or systems often associated with intravascular procedures, stents, vascular implants, clot removal procedures, catheters, and the like are not shown or described in detail in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. Those of ordinary skill in the art will recognize, however, that the present technology can be practiced without one or more of the details set forth herein, and/or with other structures, methods, components, and so

forth. Moreover, although many of the devices and systems are described herein in the context of removing and/or treating clot material (e.g., clot material adhered to an implant), the present technology can be used to remove and/or treat other unwanted material in addition or alternatively to clot material, such as thrombi, emboli, plaque, intimal hyperplasia, post-thrombotic scar tissue, etc. Accordingly, the terms "clot" and "clot material" as used herein can refer to any of the foregoing materials.

**[0038]** The terminology used below is to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain examples of embodiments of the technology. Indeed, certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

**[0039]** The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope unless expressly indicated. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles and features without departing from the present technology. In addition, those of ordinary skill in the art will appreciate that further embodiments of the present technology can be practiced without several of the details described below.

**[0040]** With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user. To the extent any materials incorporated herein by reference conflict with the present disclosure, the present disclosure controls.

**[0041]** Figure 1A is a side view of a stent cleaning system 100 ("system 100") in accordance with embodiments of the present technology. Figures 1B and 1C are an enlarged side view and an enlarged proximally-facing view, respectively, of a distal portion of the system 100 including a clot treatment device 130 in accordance with embodiments of the present technology. The stent cleaning system 100 can be used to remove clot material from (e.g., adhered to) the implant, to clean clot material from a native vessel in which the implant is implanted, and/or to remove clot material from a native vessel in which no implants are implanted. Accordingly, the system 100 can also be referred to as a clot treatment system, a clot removal system, a thrombectomy system, and/or the like. The clot treatment device 130 can also be referred to as a clot removal device, a coring element, a clot engagement member, a thrombectomy device, and/or the like.

**[0042]** Referring to Figures 1A and 1B together, in the illustrated embodiment the system 100 includes a proximal handle 110 operably coupled to a clot treatment device 130 via an inner elongate member 102 (obscured in Figure 1A; e.g., a second elongate member) and a middle elongate member 104 (e.g., a first elongate member). The inner elongate member 102 can extend through a lumen of the middle elongate member 104 such that the inner and middle elongate members 102, 104 (collectively "elongate members 102, 104") are coaxial. The system 100 can further include an outer elongate member 106 (e.g., a third elongate member, a guide catheter), and the elongate members 102, 104 can at least partially extend through the outer elongate member 106 such that the inner, middle, and outer elongate members 102, 104, 106 (collectively "elongate members 102–106") are coaxial. In other embodiments, the elongate members 102, 104 are not coaxial and can instead extend side-by-side and/or through separate lumens of the outer elongate member 106. The elongate members 102–106 can comprise catheters, tubes (e.g., hypotubes), sheathes, shafts, and/or the like and can be formed from metal (e.g., stainless steel, nitinol), plastic, fluoropolymers (e.g., polytetrafluoroethylene (PTFE)), polymers, and/or other suitable materials. The outer elongate member 106 can comprise a guide catheter.

**[0043]** Referring to Figure 1A, the outer elongate member 106 can include a distal end portion 107a and a proximal end portion 107b. The proximal end portion 107b can be coupled to a tubing assembly 101 (e.g., including one or more tubes, fluid control devices, and/or the like) via a valve device 109. In some embodiments, the tubing assembly 101 can be used to flush the lumen of the outer elongate member 106. In some embodiments, the handle 110 is movable (translatable, rotatable) relative to the valve device 109 and the outer elongate member 106. In the illustrated embodiment, the handle 110 has been advanced toward the valve device

109 such that the clot treatment device 130 extends from the distal end portion 107a of the outer elongate member 106. In some embodiments, the handle 110 can be retracted away from the outer elongate member 106 and/or the outer elongate member 106 can be advanced away from the handle 110 such that the clot treatment device 130 is captured/positioned within the outer elongate member 106. When the clot treatment device 130 is captured within the lumen of the outer elongate member 106, the clot treatment device 130 is in a radially-compressed state. In some embodiments, the clot treatment device 130 can be positioned within the outer elongate member 106 during delivery of the system 100 through the vasculature.

**[0044]** In the illustrated embodiment, the system 100 includes a tip 108 coupled to the clot treatment device 130 and/or the inner elongate member 102 (Figure 1B). The tip 108 can have an atraumatic shape configured to minimize or even prevent damage to the vasculature as the system 100 is advanced therethrough. In other embodiments, the tip 108 can have other shapes or can be omitted entirely. In some embodiments, when the clot treatment device 130 is constrained within the outer elongate member 106, the tip 108 can engage the distal end portion 107a of the outer elongate member 106 and can be shaped and sized to seal the lumen of the outer elongate member 106. In some embodiments, the tip 108 and the inner elongate member 102 (Figure 1B) can define a lumen configured (e.g., shaped and sized) to receive a guidewire (not shown) therethrough. The system 100 can be advanceable/trackable over the guidewire.

**[0045]** Referring to Figure 1B, in the illustrated embodiment the inner elongate member 102 includes a distal end portion 103a coupled to a distal end portion 131a of the clot treatment device 130. Similarly, the middle elongate member 104 includes a distal end portion 105a coupled to a proximal end portion 131b of the clot treatment device 130. Accordingly, as described in detail below with reference to Figures 6A and 6B, relative movement of the elongate members 102, 104 can longitudinally shorten/lengthen and radially expand/compress the clot treatment device 130 via the relative movement of the end portions 131a-b. The end portions 131a-b of the clot treatment device 130 can be identical and can have a cylindrical or hub-like shape. In some embodiments, the end portions 131a-b are secured to the elongate members 102, 104, respectively, via adhesive (e.g., glue bonds), welding, fasteners, crimping (e.g., via a crimp tube), and/or the like. For example, in some embodiments one or both of the end portions 131a-b of the clot treatment device 130 can be directly welded to the elongate members 102, 104, or one or both of the end portions 131a-b can be crimped via a crimp tube to the elongate members 102, 104 (e.g., the proximal end portion 131b can be crimped to the middle elongate member 104). In some embodiments, the distal end portion 131a includes/defines a distal window 132a

extending therethrough, and the proximal end portion 131b includes/defines a proximal window 132b extending therethrough. Coupling members (not shown), such as steel discs, can be placed in one or both of the windows 132a-b and welded, soldered, crimped, or otherwise fastened to the elongate members 102, 104, respectively, to secure the end portions 131a-b to the elongate members 102, 104 via a rivet-like lock. In some embodiments, the end portions 131a-b can include multiple ones of the windows 132a-b extending circumferentially thereabout, each configured to receive a corresponding coupling member.

**[0046]** The elongate members 102, 104 can comprise (i) metal, polymeric, and/or metallic (e.g., solid stainless steel, cobalt chrome, nitinol) tubes, (ii) metal, polymeric, and/or metallic (e.g., solid stainless steel, cobalt chrome, nitinol) tubes with relief cuts (e.g., laser-cuts) for flexibility, (iii) hollow helical spirals (e.g., including one or more axial metal (e.g., stainless-steel, cobalt chrome, nitinol) wires turned to create a closed-pitch coil with a hollow central lumen), (iv) reinforced polymeric shafts, and/or (v) the like. In the illustrated embodiment, for example, the inner elongate member 102 comprises a solid nitinol tube and the middle elongate member 104 comprises a hollow helical spiral (HHS). The hollow helical spiral can be a single layer spiral, or a multilayer spiral (e.g., two-layer, three-layer, or more layer spiral) to provide greater torque and/or tensile response. In some aspects of the present technology, such a hollow helical spiral allows the overall system 100 to be more flexible such that the system 100 can, for example, be inserted to treat clot material in more tortuous anatomies with less biasing of the clot treatment device 130 (e.g., to one side of an implant or vessel). In some aspects of the present technology, the elongate members 102, 104 can have a relatively high tensile, compression, and/or torque capability/response that allow for the controlled expansion and movement of the clot treatment device 130 during a procedure to remove clot material from an implanted stent, embolic protection device, other implant, and/or bare vessel, as described in greater detail below.

**[0047]** Referring to Figures 1B and 1C together, the clot treatment device 130 includes a plurality of beams or struts 133 extending between the end portions 131a-b and generally axially relative to a longitudinal axis L of the clot treatment device 130. More specifically, the struts 133 can be generally similar or identical to one another and can each include: (i) a distal portion 134 extending from the distal end portion 131a in a direction away from the longitudinal axis L and proximally toward the proximal end portion 131b (e.g., at an angle relative to the longitudinal axis L), (ii) a middle portion 135 extending from the distal portion 134 proximally and generally parallel to the longitudinal axis L, and (iii) a proximal portion 136 extending from

the middle portion 135 to the proximal end portion 131b in a direction toward the longitudinal axis L (e.g., at an angle relative to the longitudinal axis L). In the illustrated embodiment, the clot treatment device 130 does not include any cross struts or other cross-members extending between (e.g., circumferentially between) the struts 133. That is, the struts 133 can each extend separately in a generally axial direction between the end portions 131a-b. In some aspects of the present technology, this absence of cross struts can permit the clot treatment device 130 to be advanced and retracted through an implanted stent (or other implant) without catching on the stent (e.g., catching on apices or ends of the stent), which could potentially damage, disrupt, and/or move the stent. In some embodiments, the clot treatment device 130 can include one or more cross-members between the struts 133—but that are not configured to contact the implanted stent when the clot treatment device 130 is expanded. For example, such cross-members can be positioned near the end portions 131a-b.

**[0048]** As best seen in Figure 1B, in the illustrated embodiment the struts 133 each have an undulating (e.g., wave-like, sawtooth-like, periodic) pattern. The undulating pattern of the struts 133 can create an abrasive surface for disrupting/engaging with clot and/or other material adhered to an implanted stent. More specifically, because of the undulating pattern, each of the struts 133 can include one or circumferential portions 137 that extend at least partially circumferentially relative to the longitudinal axis L. The circumferential portions 137 can together define the abrasive surface for disrupting the clot material. In some aspects of the present technology, the undulations are relatively small such to reduce the likelihood of the struts 133 catching on the stent when the clot treatment device 130 is advanced and retracted through the implanted stent.

**[0049]** As best seen in Figure 1C, each of the struts 133 can curve radially at least partially back toward the longitudinal axis L in the middle portion 135 (and/or at a transition region between the middle portion 135 and distal and proximal portions 134, 136) such that the struts 133 have a wave-like or hook-like shape when viewed along the longitudinal axis L. In some embodiments, this shape can help facilitate the uniform collapse of the clot treatment device 130. In additional aspects of the present technology, the hook-like shape of the struts 133 can improve the ability of the clot treatment device 130 to engage and disrupt clot material within an implant while still being atraumatic to regions of the native vessel outside the implant (e.g., proximal and distal of the implant).

**[0050]** The clot treatment device 130 has nine of the struts 133 in Figure 1B and six of the struts 133 in Figure 1C for illustration. In other embodiments, the clot treatment device 130 can include any number of the struts 133 (e.g., one, two, three, four, five, seven, eight, ten, or more than ten) and the struts 133 can be positioned symmetrically or asymmetrically about the longitudinal axis L. For example, in some embodiments the struts 133 can be asymmetrically positioned about the longitudinal axis L to facilitate targeted engagement of the struts 133 with a region of adherent clot and/or to inhibit or even prevent catching of the clot treatment device 130 on bent portions of an implant (e.g., when the implant is positioned within tortuous anatomy). In some embodiments, the distal portions 134 of the struts 133 can be circumferentially offset from the proximal portions 136 of the struts 133—either permanently or via differential rotation of the elongate members 102, 104—to cause the struts 133 to assume a "scoop-like" shape when radially compressed, as described in greater detail below with reference to Figures 10A–10C. That is, for example, the distal portion 134 of each of the struts 133 can connect to the distal end portion 131a at a different circumferential position (e.g., relative to the longitudinal axis L) than the proximal portion 136 of the strut 133 connects to the proximal end portion 131b.

**[0051]** In some embodiments, the clot treatment device 130 is an integral/continuous structure, such as a laser-cut metal (e.g., nitinol, cobalt chrome, stainless steel) element. In some embodiments, the clot treatment device 130 is configured (e.g., heat set) to self-expand from a compressed delivery state (e.g., when the clot treatment device 130 is positioned within the outer elongate member 106) to the expanded deployed state illustrated in Figures 1B and 1C. In other embodiments, the clot treatment device 130 is configured (e.g., heat set) to collapse to the compressed delivery state from the expanded state. In such embodiments, biasing the clot treatment device 130 to collapse can help ensure that the clot treatment device 130 can be removed from the patient if one of the struts 133 or a connection point breaks during operation, as the clot treatment device 130 will automatically collapse for removal.

**[0052]** In some embodiments, the struts 133 can curve more or less back toward the longitudinal axis L. Figures 2A–2C, for example, are enlarged proximally-facing views of a distal portion of the system 100 including the clot treatment device 130 in accordance with additional embodiments of the present technology. Referring to Figures 2A–2C together, the middle portion 135 of each of the struts 133 of the clot treatment device 130 has (i) a relatively flat profile in the embodiment of Figure 2A, (ii) a hook-shaped profile in the embodiment of Figure 2B, and (iii) a further hook-shaped profile in the embodiment of Figure 2C. In some

aspects of the present technology, (i) the flatter profile shown in Figure 2A can provide a longer cutting edge for engaging clot material adhered to an implant, (ii) the more hook-shaped profile shown in Figure 2B can provide for a smaller contact area between the clot treatment device 130 and an implant that can reduce the likelihood of the clot treatment device 130 damaging the implant and that can be more atraumatic to a native vessel when the clot treatment device 130 is deployed at least partially outside the implant, and (iii) the further hook-shaped profile shown in Figure 2C can provide an even smaller cutting surface than the profile shown in Figure 2B to further reduce the likelihood of implant or native vessel damage as compared to the profile of Figure 2B. In some embodiments, the flatter profile shown in Figure 2A can be utilized to treat adherent clot material that is firmly attached to the implant.

**[0053]** Similarly, in other embodiments one or more of the struts 133 can have different shapes and/or profiles. For example, Figures 3A–3D are enlarged side views of a distal portion of the system 100 including the clot treatment device 130 in accordance with additional embodiments of the present technology. In some embodiments, as shown in Figure 3A, the tip 108 (Figure 3B) can be omitted and the struts 133 can extent to and past the distalmost end of the inner elongate member 102 in the expanded position. As shown in Figure 3B, one or more of the struts 133 can have a profile including multiple (e.g., two) bumps or peaks between the end portions 131a-b. As shown in Figure 3C, one or more of the struts 133 can have an axial apex positioned near the distal end portion 131a (e.g., including a proximal tapered portion). As shown in Figure 3D, one or more of the struts 133 can have an axial apex positioned near the proximal end portion 131b (e.g., including a distal tapered portion).

**[0054]** Further, Figures 4A–4C are enlarged isometric views of a distal portion of the system 100 including one of the struts 133 of the clot treatment device 130 in accordance with additional embodiments of the present technology. As shown in Figure 4A, one or more of the struts 133 can have a profile including multiple (e.g., two) bumps or peaks between the end portions 131a-b and that does not extend radially about the longitudinal axis L and the inner elongate member 102 (Figure 1B). As shown in Figure 4B, one or more of the struts 133 can have a profile including a smoothly sloping shape between the distal and proximal end portions 131a-b. As shown in Figure 4C, one or more of the struts 133 can extend radially about (e.g., spiral about) the longitudinal axis L and the inner elongate member 102 (Figure 1B) between the end portions 131a-b.

**[0055]** Figure 5 is a partially cut-away view of the handle 110 of Figure 1A in accordance with embodiments of the present technology. In the illustrated embodiment, the handle 110 includes a housing 514 having a distal portion 515a and a proximal portion 515b and defining an internal chamber or lumen 516. The housing 514 is shown as partially-cut away in Figure 5 for clarity. A proximal portion 105b of the middle elongate member 104 can be fixedly coupled to the distal portion 515a of the housing 514. In some embodiments, the handle 110 includes a flush port 517 operably (e.g., fluidly) coupled to the lumen of the middle elongate member 104. The inner elongate member 102 can extend through the lumen of the middle elongate member 104, past the proximal portion 105b of the middle elongate member 104, and into the lumen 516 of the housing 514. In some embodiments, the inner elongate member 102 can extend entirely through the housing 514 to a flush port 518 coupled to the proximal portion 515 of the housing 514.

**[0056]** In the illustrated embodiment, the handle 110 further comprises a leadscrew 520 attached to the inner elongate member 102 and movably positioned within the lumen 516 over one or more guiderails 522 (e.g., a pair of guiderails 522). The leadscrew 520 can have a threaded outer surface configured to mate with a threaded inner surface of the actuator 112 (shown as partially transparent in Figure 5 for clarity). Alternatively, the leadscrew 520 can have a threaded inner surface configured to mate with a threaded outer surface of the actuator 112 as described, for example, in detail below with reference to Figure 26. The actuator 112 can extend out of the housing 514 from one or more openings 519 therein (e.g., a pair of openings on opposing sides of the housing 514) such that the actuator 112 is accessible outside the housing 514 by a user of the handle 110 (e.g., a physician). In some embodiments, the handle 110 further includes a leadscrew knob 521 (shown as partially transparent in Figure 2 for clarity) coupled to the actuator 112 and configured to threadably engage the leadscrew 520 over an entire range of movement of the actuator 112.

**[0057]** Rotation of the actuator 112 relative to the housing 514 (e.g., by the user) can drive the leadscrew 520 to translate proximally and/or distally (e.g., between the distal and proximal portions 515a-b of the housing 514) to thereby drive the attached inner elongate member 102 to translate relative to the middle elongate member 104. This relative movement of the elongate members 102, 104 lengthens/shortens the clot treatment device 130 (Figures 1A–1C) to radially compress/expand the clot treatment device 130. More specifically, Figures 6A and 6B are side views of a distal portion of the system 100 including the clot treatment device 130 in a first position (e.g., a radially-expanded position) and a second position (e.g., a radially-compressed

position), respectively, in accordance with embodiments of the present technology. Referring to Figures 5–6B together, in the first position (Figure 6A) the clot treatment device 130 is radially expanded, having a first diameter $D_1$ and a first length $X_1$, and in the second position the clot treatment device 130 is radially compressed, having a second diameter $D_2$ less than the first diameter $D_1$ and a second length $X_2$ greater than the first length $X_1$. In both the first and second positions the clot treatment device 130 has been advanced distally out of the outer elongate member 106 (e.g., past the distal end portion 107a thereof).

**[0058]** To move the clot treatment device 130 from the first position to the second position, the user can rotate the actuator 112 in a first direction to drive the leadscrew 520 distally through the housing 514. This movement drives the inner elongate member 102 distally through the lumen of the middle elongate member 104, thereby driving the distal end portion 131a of the clot treatment device 130 distally relative to the proximal end portion 131b to radially compress the clot treatment device 130 while lengthening the clot treatment device 130. Conversely, to move the clot treatment device 130 from the second position to the first position, the user can rotate the actuator 112 in a second direction opposite the first direction to drive the leadscrew 520 proximally through the housing 514. This movement drives the inner elongate member 102 proximally through the lumen of the middle elongate member 104, thereby driving the distal end portion 131a of the clot treatment device 130 proximally relative to the proximal end portion 131b to radially expand the clot treatment device 130 while shortening the clot treatment device 130. Although two discrete positions are shown in Figures 6A and 6B, the clot treatment device can be expanded to any number of continuous positions therebetween, to a position further radially expanded than the first position, and/or to a position less radially expanded than the second position. Moreover, in other embodiments the middle elongate member 104 can be operably coupled to the leadscrew 520 and the actuator 112 instead of or in addition to the inner elongate member 102 such that actuation of the actuator 112 drives the middle elongate member 104 relative to the inner elongate member 102, or both the inner elongate member 102 and the middle elongate member 104 relative to the handle 110, to radially expand/compress the clot treatment device 130.

**[0059]** Referring to Figure 1A, in some embodiments the handle 110 can further include an indicator 111, such as a slider, configured to provide a visual indication of an amount of radial expansion of the clot treatment device 130. The indicator 111 can, for example, indicate whether the clot treatment device 130 is in the first position or the second position. In some embodiments, the indicator 111 includes detents and/or other features that provide an indication (e.g., a

"clicking" sound) as the clot treatment device 130 is incrementally expanded/collapsed (e.g., millimeter by millimeter). Similarly, the indicator 111 can include markings that indicate an expanded size of the clot treatment device 130 as described in, for example, detail below with reference to Figures 25A–26.

**[0060]** Referring to Figures 1A–1C together, in other embodiments a handle of the system 100 can include a first member coupled to the inner elongate member 102 and a second member coupled to the middle elongate member 104. One or both of the first and second members can be manually moved relative to one another (e.g., without any mechanical advantage provided by a leadscrew, gear, or the like) to radially expand/compress the clot treatment device 130 as shown in Figures 6A and 6B.

**[0061]** Figure 7 is a flow diagram of a process or method 740 for operating the system 100 during an intravascular procedure to remove material from an implant with a patient in accordance with embodiments of the present technology. Although some features of the method 740 are described in the context of the embodiments shown in Figures 1A–6B for the sake of illustration, one skilled in the art will readily understand that the method 740 can be carried out using other suitable systems and/or devices described herein.

**[0062]** At block 741, the method 740 can include advancing the system 100 through the vasculature of a patient to at or proximate the implant implanted within the patient. The implant can be identified as having clot material or other unwanted material (e.g., intimal hyperplasia) adhered thereto that would be beneficial to remove. In some embodiments, the implant is a stent implanted within the venous vasculature of the patient. In other embodiments, the implant can be a graft, embolic filter, inferior vena cava (IVC) filter, and/or other type of implant. In other embodiments, the method 740 can be used to clean and remove clot material from a bare vessel of the patient. In some embodiments, the elongate members 102–106 can be advanced together through the vasculature with the clot treatment device 130 constrained within the outer elongate member 106. The tip 108 can provide for atraumatic advancement of the system 100 through the vasculature to the implant. In other embodiments, the outer elongate member 106 can be positioned within the vasculature first, and the clot treatment device 130 can then be advanced through the vasculature to the implant.

**[0063]** At block 742, the method 740 can include deploying the clot treatment device 130 within the implant. For example, the handle 110 can be advanced distally (e.g., pushed by a physician) relative to the outer elongate member 106 to advance the elongate members 102, 104

and the coupled clot treatment device 130 distally from the distal end portion 107a of the outer elongate member 106. In some embodiments, the clot treatment device 130 can at least partially radially expand (e.g., self-expand) when the clot treatment device 130 is no longer constrained by the outer elongate member 106.

**[0064]** At block 743, the method 740 can include further radially expanding the clot treatment device 130. For example, the clot treatment device 130 can be radially expanded by actuating the actuator 112 of the handle 110 to drive the inner elongate member 102 proximally relative to the middle elongate member 104 to thereby move the distal end portion 131a of the clot treatment device 130 toward the proximal end portion 131b—thereby causing the struts 133 to flex radially outwardly away from the longitudinal axis L. In some embodiments, the clot treatment device 130 is radially expanded outwardly to contact the clot material adhered to the implant or the implant itself. In some aspects of the present technology, such radial expansion can comprise a mechanical "ballooning" effect of the clot treatment device 130. For example, the clot treatment device 130 can be expanded within a deformed or compressed stent to balloon open the stent and/or to disrupt clot material, intimal hyperplasia, and/or other material within the stent such that clot treatment device 130 can more effectively engage and disrupt clot material within the stent (block 744). In some embodiments, the clot treatment device 130 can be expanded within a bare vessel (e.g., outside a stent) to perform angioplasty. The clot treatment device 130 can provide a radial outward mechanical force (e.g., pressure) of between about 0.1–30 atmospheres, between about 0.1–6 atmospheres, etc. The outward mechanical force can be determined by the width and thickness of the struts 133 and/or the amount the clot treatment device 130 can be expanded (e.g., how far the leadscrew 520 can travel)—with greater strut thickness, strut width, and/or device expansion causing a greater outward mechanical force (and vice versa) In some aspects of the present technology, the clot treatment device advantageously does not include a burst failure mode like many conventional balloon treatment devices.

**[0065]** At block 744, the method 740 includes mechanically engaging the clot treatment device 130 with the clot material within the implant to at least partially dislodge the clot material. For example, the clot treatment device 130 can be rotated, translated, and/or radially compressed/expanded within the implant to engage and dislodge the clot material. Accordingly, in some aspects of the present technology the clot treatment device 130 can function similarly to a mechanical scoring balloon. More specifically, Figure 8 is a distally-facing perspective view of a distal portion of the system 100 including the clot treatment device 130 expanded within an implant 850 (e.g., a stent) implanted in a vessel V in accordance with embodiments of

the present technology. The clot material to be removed is omitted in Figure 8 for clarity. The implant 850 can comprise a plurality of interconnected struts, graft material, a mesh, and/or other components know in the art of intravascularly implantable medical devices (e.g., stents).

**[0066]** In the illustrated embodiment, the clot treatment device 130 is expanded within a lumen 852 of the implant 850 such that the struts 133 contact an inner surface of the implant 850. In some embodiments, the struts 133 are the only part of the clot treatment device 130 that contacts the implant 850 when the clot treatment device 130 is expanded. With reference to Figures 1A and 8 together, the clot treatment device 130 can be (i) translated distally or proximally within the implant 850 (e.g., as indicated by arrow A in Figure 8) by moving the handle 110 distally or proximally and/or (ii) rotated clockwise or counterclockwise within the implant 850 (e.g., as indicated by arrows C and CC, respectively, in Figure 8) by rotating the handle 110. As described in detail above, the elongate members 102, 104 can be formed to be highly torqueable and to have high compression/tension resistance such that the movements of the handle 110 are translated without much loss to the clot treatment device 130. In some aspects of the present technology, the struts 133 are configured not to catch, grab, or damage the implant 850 when the clot treatment device 130 is moved relative to the implant 850 as, for example, the struts 133 extend generally axially along the direction of translation and do not include any cross-members or open cells. Additionally, the undulating shapes of the struts 133 (e.g., the circumferential portions 137) together define an abrasive surface for disrupting, cutting, and/or dislodging the clot material adhered to the implant 850. Accordingly, in some aspects of the present technology the system 100 can be used to remove chronic adherent clot while significantly reducing the risk of damaging the implant 850.

**[0067]** Referring again to Figure 7, at block 745, the method 740 optionally includes collapsing and repositioning the clot treatment device 130. For example, if the clot treatment device 130 catches or becomes entangled with the implant, the clot treatment device 130 can be radially compressed (e.g., from the first position to the second position shown in Figures 6A and 6B, respectively) to disengage the implant. For example, Figures 9A and 9B are distally-facing perspective views of a distal portion of the system 100 including the clot treatment device 130 positioned within the implant 850 in the vessel V in accordance with embodiments of the present technology. Figure 9A illustrates the clot treatment device 130 in a radially-expanded position and at least partially entangled with an end portion 954 of the implant 850. If such entanglement occurs, the clot treatment device 130 can be radially compressed as shown in Figure 9B to free the struts 133 from the implant 850. In some aspects of the present technology, because the clot

treatment device 130 does not include any cross-members between the struts 133, radially compressing the clot treatment device 130 can disengage the struts 133 from the implant 850 without catching or pulling the implant 850 therewith.

**[0068]** Referring again to Figure 7, at block 746, the method 740 can include at least partially capturing the dislodged clot material within, for example, the outer elongate member 106. In some embodiments, the clot material dislodged from the implant (block 744) can flow into the outer elongate member 106 via the blood pressure within the vessel. In some embodiments, the clot treatment device 130 can be retracted proximally into the outer elongate member 106 to pull the clot material into the outer elongate member 106.

**[0069]** Finally, at block 747, the system 100 can be withdrawn from the patient. For example, the clot treatment device 130 can be retracted proximally into the outer elongate member 106 (e.g., by proximally withdrawing the handle 110 relative to the outer elongate member 106) and radially constrained therein. The outer elongate member 106 and the constrained clot treatment device 130 can then be withdrawn together from the patient.

**[0070]** Figures 10A–10C are distally-facing perspective views of a distal portion of the system 100 including the clot treatment device 130 expanded within an implant 1050 with differing amounts of radial expansion in accordance with embodiments of the present technology. More specifically, Figures 10A–10C illustrate progressively increasing amounts of radial expansion caused by for, example, further actuation of the actuator 112 of the handle 110 to move the distal end portion 131a of the clot treatment device 130 proximally toward proximal end portion 131b of the clot treatment device as shown in and described in detail with reference to Figures 1A–6B. Alternatively, Figures 10A–10C illustrate the same amount of radial expansion of the clot treatment device 130 where the implant 1050 has a progressively decreasing diameter $E_1$–$E_3$.

**[0071]** Referring to Figures 10A–10C together, as the clot treatment device 130 is further expanded within the implant 1050, the struts 133 can progressively flex inward and turn to each have a scoop-like shape. More specifically, the distal and proximal portions 134, 136 of each strut can flex to be circumferentially offset relative to the longitudinal axis L (Figure 1B) of the clot treatment device 130. Such radial offset can be facilitated by the different properties of the elongate members 104, 106. For example, as described in detail above, the inner elongate member 102 can comprise a solid tube while the middle elongate member 104 can comprise a hollow helical spiral such that there is more rotational give in the middle elongate member 104.

Accordingly, when the clot treatment device 130 is rotated when it is engaged with a stent or other implant, the friction/engagement forces on the clot treatment device 130 can cause the relatively more flexible middle elongate member 104 to rotate less than the inner elongate member 102—thereby rotating the distal end portion 131a (Figures 6A and 6B) of the clot treatment device 130 more than the proximal end portion 131b (Figures 6A and 6B) and causing the scoop-like shape. In some aspects of the present technology, the scoop-like shape of the struts 133 shown in Figures 10B and 10C can facilitate a more effective removal of clot material from implant 1050. In other embodiments, the elongate members 104, 106 can be coupled to a handle configured to rotate the elongate members 104, 106 at different speeds to circumferentially offset the distal and proximal end portions of the struts 133 to thereby facilitate the scoop-like shape.

**[0072]** Figure 11A is a side view of a stent cleaning system 1100 ("system 1100") in accordance with embodiments of the present technology. The system 1100 can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the system 1100 described in detail above with reference to Figures 1A–10C, and can operate in a generally similar or identical manner to the system 100. For example, in the illustrated embodiment, the system 1100 includes a clot treatment device 1130 having a distal end portion 1131a coupled to the inner elongate member 102 and a proximal end portion 1131b coupled to the middle elongate member 104. The elongate members 102, 104 extend through the outer elongate member 106 and are operably coupled to a handle 1110 configured to radially expand/compress the clot treatment device 1130. In some embodiments, the system 1100 is configured for use in the peripheral vasculature to treat chronic peripheral clot either within a stent or other implant, or within a bare vessel.

**[0073]** Figures 11B and 11C are side views of a distal portion of the system 1100 including the clot treatment device 1130 in a first position (e.g., a radially-expanded position) and a second position (e.g., a radially-compressed position), respectively, in accordance with embodiments of the present technology. In the illustrated embodiment, the clot treatment device 1130 includes a plurality of interconnected struts 1133 that extend between the distal and proximal end portions 1131a-b. In some embodiments, the struts 1133 define a plurality of proximal cells 1160 and a plurality of distal cells 1162. In the illustrated embodiment, the proximal cells 1160 are larger than the distal cells 1162. That is, the clot treatment device 1130 can have fewer of the struts 1133 near the proximal end portion 1131b than near the distal end portion 1131a. The clot treatment device 1130 can be formed of a self-expanding material, such as nitinol, and can be a

unitary/integral structure. In some embodiments, the clot treatment device 1130 can be at least generally similar in structure and function, or identical in structure and function, to any of the clot treatment devices disclosed in U.S. Patent Application No. 17/072,909, titled "SYSTEMS, DEVICES, AND METHODS FOR TREATING VASCULAR OCCLUSIONS," and filed October 16, 2020, which is incorporated herein by reference in its entirety.

**[0074]** Referring again to Figure 11A, the handle 1110 can include a first actuator 1112 coupled to one of the elongate members 102, 104 (e.g., the inner elongate member 102). The other one of the elongate members 102, 104 (e.g., the middle elongate member 104) can be fixedly coupled to the handle 1110. In the illustrated embodiment, the first actuator 1112 is a pull member configured to be pulled proximally or advanced distally to move the elongate members 102, 104 relative to one another to radially compress or expand the clot treatment device 1130. In some embodiments, the handle 1110 further includes a second actuator 1119 operably coupled to both of the elongate members 102, 104 and configured to be rotated to rotate the elongate members 102, 104 together to rotate the clot treatment device 1130.

**[0075]** Referring to Figures 11A–11C together, in operation, the handle 1110 can be advanced distally and withdrawn proximally relative to the outer elongate member 106 to advance the clot treatment device 1130 from within the outer elongate member 106 and/or to withdraw the clot treatment device 1130 into the outer elongate member 106. When the clot treatment device 1130 is advanced out of the outer elongate member 106, the clot treatment device 1130 can self-expand within, for example, a stent or other implant to be cleaned. The first actuator 1112 can be pulled/withdrawn to move the clot treatment device 1130 between the first and second positions shown in Figures 11B and 11C. For example, when the first actuator 1112 is coupled to the inner elongate member 102, the first actuator 1112 can be advanced distally to drive the inner elongate member 102 distally relative to the middle elongate member 104 to drive the distal end portion 1131a of the clot treatment device 1130 distally relative to the proximal end portion 1131b to compress the clot treatment device 1130 (e.g., to move the clot treatment device 1130 from the first position to the second position). Likewise, the first actuator 1112 can be retracted proximally to drive the inner elongate member 102 proximally relative to the middle elongate member 104 to drive the distal end portion 1131a of the clot treatment device 1130 proximally relative to the proximal end portion 1131b to expand the clot treatment device 1130 (e.g., to move the clot treatment device 1130 from the second position to the first position). The second actuator 1119 can be rotated to rotate elongate members 102, 104 together to rotate the clot treatment device 1130 in either the first or second positions. Accordingly, when

expanded within a stent or other implant, the system 1100 is operable to radially expand, translate, and/or rotate the clot treatment device 1130 within the stent to mechanically engage and dislodge clot or other material adhered thereto.

**[0076]** Figure 12 is a side view of a clot treatment device 1230 in accordance with embodiments of the present technology. The clot treatment device 1230 can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the clot treatment devices 130 and/or 1130 described in detail above with reference to Figures 1A–11C, and can be employed within a clot treatment system (e.g., the systems 100 or 110) in a generally similar or identical manner to mechanically engage and dislodge clot material within an implanted stent or other implant.

**[0077]** In the illustrated embodiment, the clot treatment device 1230 includes a plurality of interconnected struts extending between a distal end portion 1231a and a proximal end portion 1231b. More specifically, the clot treatment device 1230 can include (i) distal struts 1264 that extend from the distal end portion 1231a generally axially relative to a longitudinal axis L of the clot treatment device 1230, (ii) proximal struts 1266 that extend from the proximal end portion 1231b generally axially relative to the longitudinal axis L of the clot treatment device 1230, and (iii) bracing struts 1265 connecting the distal struts 1264 to the proximal struts 1266. The bracing struts 1265 can extend at least partially circumferentially relative to the longitudinal axis L in a middle region of the clot treatment device 1230 and can have a chevron- or ring-like pattern. In some aspects of the present technology, the bracing struts 1265 can facilitate an increased torque response of the clot treatment device 1230, while the distal and proximal struts 1264, 1266 extend generally axially to allow the clot treatment device 1230 to be advanced and retracted through an implanted stent without catching on the stent, which could potentially damage or move the stent.

**[0078]** Figure 13 is a side view of a clot treatment device 1330 in accordance with embodiments of the present technology. The clot treatment device 1330 can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the clot treatment devices 130, 1130, and/or 1230 described in detail above with reference to Figures 1A–12, and can be employed within a clot treatment system (e.g., the systems 100 or 1100) in a generally similar or identical manner to mechanically engage and dislodge clot material within an implanted stent or other implant.

**[0079]** In the illustrated embodiment, the clot treatment device 1330 includes a plurality of interconnected struts extending between a distal end portion 1331a and a proximal end portion 1331b. More specifically, the clot treatment device 1330 can include (i) distal struts 1364 extending from the distal end portion 1331a, (ii) proximal struts 1366 extending from the proximal end portion 1331b, and (iii) middle struts 1365 (e.g., spanning struts, axial struts) extending between the distal and proximal struts 1364, 1366. In some embodiments, the clot treatment device 1330 includes fewer of the middle struts 1365 than the distal and proximal struts 1364, 1366, and the middle struts 1365 can be longer than the distal and proximal struts 1364, 1366. In the illustrated embodiment, the middle struts 1365 extend in a spiral or helical pattern relative to a longitudinal axis L of the clot treatment device 1330. The distal and proximal struts 1364, 1366 can have a chevron- or ring-like pattern. In some aspects of the present technology, the spiral shape of middle struts 1365 can facilitate an increased torque response of the clot treatment device 1330 while also reducing engagement of the clot treatment device 1330 with an implanted stent. In some embodiments, the clot treatment device 1330 can be rotated such that the middle struts 1365 turn away from the ends of an implanted stent (e.g., by rotating the distal and proximal end portions 1331a-b in opposite directions) to further reduce stent engagement.

**[0080]** Figure 14 is a side view of a clot treatment device 1430 in accordance with embodiments of the present technology. The clot treatment device 1430 can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the clot treatment devices 130, 1130, 1230, and/or 1330 described in detail above with reference to Figures 1A–13, and can be employed within a clot treatment system (e.g., the systems 100 or 1100) in a generally similar or identical manner to mechanically engage and dislodge clot material within an implanted stent or other implant.

**[0081]** In the illustrated embodiment, the clot treatment device 1430 includes a plurality of interconnected struts extending between a distal end portion 1431a and a proximal end portion 1431b. More specifically, the clot treatment device 1430 can include (i) distal struts 1464 extending from the distal end portion 1431a, (ii) proximal struts 1466 extending from the proximal end portion 1431b, and (iii) middle struts 1465 (e.g., spanning struts, axial struts) extending between the distal and proximal struts 1464, 1466 and generally axially relative to a longitudinal axis L of the clot treatment device 1430. In some embodiments, the clot treatment device 1430 includes fewer of the middle struts 1465 than the distal and proximal struts 1464, 1466, and the middle struts 1465 can be longer than the distal and proximal struts 1464, 1466.

In some aspects of the present technology, the distal and proximal struts 1464, 1466 can facilitate an increased torque response of the clot treatment device 1430, while the axially-extending middle struts 1465 reduce engagement of the clot treatment device 1430 with an implanted stent. In some embodiments, the clot treatment device 1430 further includes bumps 1467 (e.g., radially-extending portions) on the middle struts 1465 configured to increase the radial force of the clot treatment device 1430 for, for example, engaging and dislodging the most adhered clot or other material within the implanted stent.

**[0082]** Figure 15 is a side view of a clot treatment device 1570 in accordance with embodiments of the present technology. The clot treatment device 1570 can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the clot treatment devices 130, 1130, 1230, 1330, and/or 1430 described in detail above with reference to Figures 1A–14, and can be employed within a clot treatment system (e.g., the systems 100 or 1100) in a generally similar or identical manner to mechanically engage and dislodge clot material within an implanted stent or other implant.

**[0083]** In the illustrated embodiment, the clot treatment device 1570 includes an inner clot treatment device 1530 and an outer clot treatment device 1572 (e.g., a stent protection element) that houses the inner clot treatment device 1530. The inner clot treatment device 1530 can be identical to any of the clot treatment devices 130, 1130, 1230, 1330, and/or 1430 described in detail above with reference to Figures 1A–14 and, in the illustrated embodiment, is identical to the clot treatment devices 1330 of Figure 13. In the illustrated embodiment, the outer clot treatment device 1572 includes a distal end portion 1571a, a proximal end portion 1571b, and a plurality of struts 1573 extending (e.g., axially) between the distal and proximal end portions 1571a-b. The proximal end portion 1571b can be coupled to an elongate member 1574, and the inner clot treatment device 1530 can be advanceable through a lumen of the elongate member 1574 or fixed relative to the elongate member 1574. In some embodiments, the outer clot treatment device 1572 is configured to be radially expanded and/or compressed via movement of the inner clot treatment device 1530. For example, the outer clot treatment device 1572 can be formed of nitinol or another relatively flexible material such that expansion (e.g., via any of the handles described above) of the inner clot treatment device 1530 also expands the outer clot treatment device 1572.

**[0084]** During a clot treatment procedure, the outer clot treatment device 1572 can directly engage an implanted stent while the inner clot treatment device 1530 is rotated therein and/or while the clot treatment device 1570 is translated distally and/or proximally within the implanted stent. Moreover, the outer clot treatment device 1572 can be fixed so that it does not rotate with the inner clot treatment device 1530 via its connection to the elongate member 1574. In some aspects of the present technology, the outer clot treatment device 1572 can partially or fully protect the implanted stent from being directly contacted by the inner clot treatment device 1530—thereby reducing stent engagement that might damage or disrupt the stent. Further, the outer clot treatment device 1572 can still provide a large inner diameter that allows the inner clot treatment device 1530 to engage and disrupt clot or other material adhered to the stent.

**[0085]** Figures 16A–16C are side views of a clot treatment device 1630 in accordance with embodiments of the present technology. The clot treatment device 1630 can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the clot treatment devices 130, 1130, 1230, 1330, 1430, and/or 1530 described in detail above with reference to Figures 1A–15, and can be employed within a clot treatment system (e.g., the systems 100 or 1100) in a generally similar or identical manner to mechanically engage and dislodge clot material within an implanted stent or other implant.

**[0086]** Referring to Figures 16A–16C together, the clot treatment device 1630 includes a plurality of struts 1633 extending between a distal end portion 1631a and a proximal end portion 1631b. Referring to Figure 16A, the clot treatment device 1630 can include a distal clot collection member 1678. The clot collection member 1678 can comprise a plurality of dense cells formed by the struts 1633, or a separate member attached to the struts 1633, such as a bag (e.g., a mesh bag, a short nitinol bag, and/or the like). In some aspects of the present technology, the clot collection member 1678 can capture clot material as the clot treatment device 1630 is moved (e.g., translated, rotated) within an implanted stent. Referring to Figure 16B, in some embodiments the clot treatment device 1630 can further include an expandable member 1679, such as a balloon, positioned radially within the struts 1633. The expandable member 1679 can be expanded to force the struts 1633 radially outward to, for example, provide additional support for dislodging adherent clot material from an implanted stent. In the illustrated embodiment, the expandable member 1679 is positioned only within a proximal portion of the clot treatment device 1630. In other embodiments, the expandable member 1679 can be positioned along the entire length of the clot treatment device 1630, or in a different portion of the clot treatment

device 1630 (e.g., a distal portion). For example, as shown in Figure 16C, the expandable member 1679 is positioned along an entire length of the clot treatment device 1630. Moreover, in the illustrated embodiment the clot collection member 1678 is omitted.

**[0087]** Figures 17A and 17B are side views of a distal portion of a stent cleaning system 1700 ("system 1700") in accordance with embodiments of the present technology. Referring to Figures 17A and 17B together, the system 1700 includes an elongate member 1706 and a clot treatment device 1780 advanceable through the elongate member 1706. The clot treatment device 1780 includes a pair of expandable arms 1782 that can be formed of nitinol or similar materials. In Figure 17A, the clot treatment device 1780 is constrained within the elongate member 1706 such that the arms 1782 extend generally linearly through the lumen of the elongate member 1706. Figure 17B illustrates the clot treatment device 1780 after advancement of the clot treatment device 1780 from the elongate member 1706. In the illustrated embodiment, the arms 1782 are configured to expand radially and curve back proximally (e.g., each forming a U-like shape) when unconstrained by the elongate member 1706. The clot treatment device 1780 can be deployed within an implanted stent and rotated to engage and dislodge (e.g., cut) clot or other material adhered to the stent. In some embodiments, the arms 1782 can each have a tapered end portion 1784 configured to inhibit the arms 1782 from interacting with or damaging the stent.

**[0088]** In any of the embodiments described above with reference to Figures 1A–17B, a clot treatment device can include struts with a chamfer or angle to improve the ability of the clot treatment device to cut through adhered clot surfaces. At the same time, such a chamfer can allow the struts to be made relatively thick to increase their radial force. More specifically, for example, Figure 18 illustrates several struts having different chamfers that can be used in a clot treatment device in accordance with embodiments of the present technology. Figure 19 is and enlarged side view of a pair of struts 1933 of a clot treatment device each having a chamfered edge 1986 in accordance with embodiments of the present technology.

**[0089]** In other embodiments, a handle in accordance with the present technology can have other configurations for (i) driving a pair of elongate members (e.g., the elongate members 102, 104 of Figures 1A–1C) relative to one another to radially expand/compress a clot treatment device (e.g., the clot treatment device 130) and/or (ii) rotating the clot treatment device. Figures 21–27, for example, illustrate handles and/or handle components in accordance with embodiments of the present technology that can be incorporated into the system 100, the system

1100, and/or another suitable system instead of or in addition to the handle 110 and/or the handle 1110. The various handles can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of one another, the handle 110 described in detail above with reference to Figures 1A–C and 5, and/or the handle 1110 described in detail above with reference to Figures 11A–11C, and can operate in a generally similar or identical manner to one another, the handle 110, and/or the handle 1110. Moreover, although frequently described in the context of manipulating the clot treatment device 130 shown in Figures 1A–1C, the handles of the present technology can be used to manipulate/control any of the clot treatment devices of the present technology.

**[0090]** Figure 20, for example, is a side cross-sectional view of a handle 2010 in accordance with embodiments of the present technology that can be incorporated into (e.g., used in) the system 100 (e.g., instead of the handle 110). In the illustrated embodiment, the handle 2010 includes a housing 2014 and a leadscrew 2020 movably positioned within the housing 2014 and constrained by/over one or more guiderails 2022 (e.g., a pair of the guiderails 2022). The leadscrew 2020 can have a threaded outer surface configured to mate with a threaded inner surface of an actuator 2012, which extends out of the housing 2014 such that the actuator 2012 is accessible outside the housing 2014 by a user of the handle 2010 (e.g., a physician). The inner elongate member 102 can be fixed to the leadscrew 2020, and the middle elongate member 104 (not shown) can be fixed to the housing 2014. Accordingly, actuation (e.g., rotation) of the actuator 2012 can drive the leadscrew 2020 proximally/distally through the housing 2014 to drive the inner elongate member 102 relative to the middle elongate member 104 to radially compress/expand the clot treatment device 130 as shown in Figures 6A and 6B.

**[0091]** In the illustrated embodiment, the handle 2010 further includes a lock mechanism 2024 coupled to the housing 2014. The lock mechanism 2024 can include a lock member 2025 configured to engage the leadscrew 2020 and/or the actuator 2012 to inhibit movement of the leadscrew 2020 through the housing 2014. In the illustrated embodiment, the lock mechanism 2024 is in a locked position in which the lock member 2025 engages the actuator 2012 to inhibit movement of the actuator 2012 and the leadscrew 2020. In some embodiments, the user can actuate (e.g., push, translate, rotate, depress) the lock mechanism 2024 to withdraw the lock member 2025 away from the actuator 2012 to allow the leadscrew 2020 to move through the housing 2014. Accordingly, with additional reference to Figures 6A and 6B, the user can selectively engage the lock mechanism 2024 to lock the clot treatment device 130 in the first position, the second position, or and/or another position.

**[0092]** Figure 21 is a side cross-sectional view of a handle 2110 in accordance with additional embodiments of the present technology that can be incorporated into the system 100 (e.g., instead of the handle 110). In the illustrated embodiment, the handle 2110 includes a housing 2114 containing a working fluid 2180. A fluid port 2182 is coupled to the housing 2114 and configured to remove/insert the working fluid 2180 into the housing 2114 via a fluid control system (not shown). The inner elongate member 102 can be coupled to a flange 2181 positioned within the housing 2114 and configured to sealingly engage the housing 2114 such that the working fluid 2180 is positioned only between the flange 2181 and the fluid port 2182. Accordingly, in operation, the working fluid 2180 can be pumped into/out of the housing 2114 to drive the flange 2181 distally/proximally through the housing 2114 to drive the inner elongate member 102 relative to the middle elongate member 104 to radially expand/compress the clot treatment device 130 as shown in Figures 3A and 3B. Therefore, in some aspects of the present technology the handle 2110 can be a pneumatically and/or hydraulically operated handle.

**[0093]** Figure 22 is an isometric view of an actuation mechanism 2290 of a handle that can be incorporated into the system 100 in accordance with embodiments of the present technology. In the illustrated embodiment, the actuation mechanism 2290 includes an actuator 2212 that is operably coupled to a housing or other component of the handle (not shown) via one or more biasing members 2291, such as coil springs. The actuator 2212 can be operably coupled to (e.g., integrally formed with) a gear rack 2292 having a plurality of teeth configured to engage a first gear 2293 mounted on a first shaft 2294. A second gear 2295 can be mounted on the first shaft 2294, coupled to the first gear 2293, and configured to engage a third gear 2297 mounted on a second shaft 2296. In some embodiments, the second gear 2295 is larger than the first gear 2293. In the illustrated embodiment, the second shaft 2296 is coupled to a unidirectional ratchet mechanism 2298 including, for example, a tooth 2286 that interfaces with circumferentially disposed indents 2288 to allow only counterclockwise rotation.

**[0094]** Accordingly, in operation, a user can press the actuator 2212 linearly against the biasing force of the biasing members 2291 to drive the gear rack 2292 linearly relative to the first gear 2293. The movement of the gear rack 2292 rotates the first gear 2293 via the engagement of the gear rack 2292 and the first gear 2293. The rotation of the first gear 2293 rotates the coupled second gear 2295, which in turn rotates the third gear 2297 via the engagement of the second and third gears 2295, 2297. In some embodiments, the larger size of the second gear 2295 steps up the rotation speed of the first gear 2293. In some embodiments, the second gear can 2295 can be omitted and the first gear 2293 can directly engage the third

gear 2297 or the first shaft 2294 can directly engage the ratchet mechanism 2298. The ratchet mechanism 2298 inhibits or even prevents the third gear 2297 from rotating in multiple directions, such as when the biasing members 2291 return the actuator 2212 to an initial position after being depressed. Accordingly, the actuation mechanism 2290 translates the linear motion of the actuator 2212 to unidirectional rotation of the ratchet mechanism 2298 and the third gear 2297. The ratchet mechanism 2298 and/or the third gear 2297 can be coupled directly to one or both of the elongate members 102, 104 (Figures 1A–1C) such that the actuation mechanism 2290 is configured to rotate the elongate members 102, 104, or the ratchet mechanism 2298 and/or the third gear 2297 can be coupled to a leadscrew or other device such that the actuation mechanism 2290 is configured to drive the elongate members 102, 104 relative to one another to radially expand/compress the clot treatment device 130 as shown in Figures 3A and 3B, as described in detail above.

**[0095]** In some embodiments, a handle coupled to a clot treatment device can include one or more features for inhibiting or even preventing over expansion and/or over torquing of the clot treatment device. Figure 23, for example, is a side view of a handle 2310 in accordance with additional embodiments of the present technology that can be incorporated into the system 100 (e.g., instead of the handle 110). In the illustrated embodiment, the handle 2310 includes a distal handle portion 2370 and a proximal handle portion 2372. The distal handle portion 2370 can be coupled to a leadscrew 2320 that is coupled to one of the elongate members 102, 104 (e.g., the inner elongate member 102). In the illustrated embodiment, the distal handle portion 2370 is coupled to the proximal handle portion 2372 via a plurality of balls 2371, such as spring-loaded ball bearings, positioned in corresponding detents formed between the distal and proximal handle portions 2370, 2372. Accordingly, in operation, rotation of the proximal handle portion 2372 below a predetermined torque level determined by the balls 2371 and associated detents rotates the distal handle portion 2370 and the leadscrew 2320 to advance one of the elongate members 102, 104 (e.g., the inner elongate member 102) relative to the other one of the elongate members 102, 104 and radially compress/expand the attached clot treatment device 130. However, rotation of the proximal handle portion 2372 above the predetermined torque level (e.g., when a user turns the proximal handle portion 2372 too fast and/or continues to torque the proximal handle portion 2372 when the clot treatment device 130 is significantly engaged with an implant) will cause the balls 2371 to slip from the detents such that the proximal handle portion 2372 rotates relative to the distal handle portion 2370 without rotating the distal handle

portion 2370. In this manner, the handle 2310 is configured to maintain a torque level of the clot treatment device 130 and associated force on an implant below a predetermined level.

**[0096]** In other embodiments, some or all of the balls 2371 and corresponding detents can be replaced with other mechanisms for inhibiting over torquing of the clot treatment device 130. For example, some or all of the balls 2371 can be replaced with pairs of magnets including a first one of the pair coupled to the distal handle portion 2370 and a second one of the pair coupled to the proximal handle portion 2372. The magnets can be selected such that, when the handle 2310 is over torqued, the pairs of magnets disengage (e.g., shear apart) from one another to permit the proximal handle portion 2372 to rotate relative to the distal handle portion 2370 without rotating the distal handle portion 2370.

**[0097]** Figure 24 is a side view of a handle 2410 in accordance with additional embodiments of the present technology that can be incorporated into the system 100 (e.g., instead of the handle 110). In the illustrated embodiment, the handle 2410 includes a leadscrew 2420 coupled to an intermediary shaft 2474 having a first stop 2475. Rotation of the leadscrew 2420 in a first direction can drive the intermediary shaft 2474 to translate distally, and rotation of the leadscrew 2420 in a second direction can drive the intermediary shaft 2474 to translate proximally. In the illustrated embodiment, the inner elongate member 102 is configured to at least partially telescope within the intermediary shaft 2474 and includes a second stop 2476. A biasing member 2477 (e.g., a coil spring) can extend between the first stop 2475 and the second stop 2476 to couple the inner elongate member 102 to the intermediary shaft 2474. In operation, when the intermediary shaft 2474 is driven proximally via the leadscrew 2420, the biasing member 2477 pulls the inner elongate member 102 proximally to radially expand the clot treatment device 130. However, the proximal movement also forces the biasing member 2477 to elongate—reducing the proximal movement of the inner elongate member 102 compared to, for example, embodiments where the inner elongate member 102 is directly coupled to the leadscrew 2420. Accordingly, in some aspects of the present technology the biasing member 2477 can limit the radial expansion of the clot treatment device 130 to inhibit over expansion that may damage an implant.

**[0098]** Figures 25A–25C are an enlarged perspective view, an enlarged side view, and an enlarged cross-sectional side view, respectively, of a handle 2510 in accordance with additional embodiments of the present technology that can be incorporated into the system 100 (e.g., instead of the handle 110). Referring to Figures 25A–25C together, in the illustrated embodiment, the

handle 2510 includes a housing 2514 (shown as partially transparent in Figures 25A and 25B for clarity) defining an internal chamber or lumen 2516 (Figure 25C). The middle elongate member 104 can be fixedly coupled to the housing 2514. The inner elongate member 102 (not shown; Figures 1A–1C) can extend through the lumen of the middle elongate member 104 into the lumen 2516 of the housing 2514. The handle 2510 can further comprise a leadscrew 2520 attached to the inner elongate member 102 and an actuator 2512 (e.g., a rotatable knob). The leadscrew 2520 is movably positioned within the lumen 2516 and can have a threaded outer surface configured to mate with a threaded inner surface of the actuator 2512. The actuator 112 can extend out of the housing 2514 from one or more first openings 2519 therein (e.g., a pair of openings on opposing sides of the housing 2514) such that the actuator 2512 is accessible outside the housing 2514 by a user of the handle 2510 (e.g., a physician). In operation, the actuator 2512 can be rotated relative to the housing 2514 to drive the leadscrew 2520 proximally and/or distally through the housing 2514 to thereby drive the attached inner elongate member 102 to translate relative to the middle elongate member 104 and thereby radially expand/collapse the clot treatment device 130.

**[0099]** In the illustrated embodiment, the handle 2510 further comprises an indicator 2511 coupled to the leadscrew 2520. The indicator 2511 can be coupled to (e.g., integrally formed with, rotatably mounted to) the leadscrew 2520 and can project into and/or otherwise be visible through one or more second openings 2518 (e.g., slots) in the housing 2514 (e.g., a pair of openings on opposing sides of the housing 2514). The housing 2514 can further include one or more markings 2517 (Figures 25A and 25B) adjacent to one or more of the second openings 2518 that indicate an amount of expansion of the clot treatment device 130 (e.g., a measurement of the radial expansion of the clot treatment device 130, a state of the clot treatment device 130, a position of the clot treatment device 130, and/or the like). For example, when the actuator 2512 is actuated to drive the inner elongate member 102 and expand/collapse the clot treatment device 130, the indicator 2511 can move with the leadscrew 2520 through and/or along the second openings 2518, and the one of the markings 2517 adjacent the indicator 2511 can indicate the amount of expansion (e.g., in millimeters). In some aspects of the present technology, combining the indicator 2511 with the leadscrew 2520 in such a manner allows to indicator 2511 to more accurately indicate the amount of radial expansion of the clot treatment device 130 because additional component attachment and manufacturing steps for forming the indicator are not needed.

**[0100]** Figure 26 is an enlarged cross-sectional side view of a handle 2610 in accordance with additional embodiments of the present technology that can be incorporated into the system 100 (e.g., instead of the handle 110). In the illustrated embodiment, the handle 2610 includes a housing 2614 defining an internal chamber or lumen 2616. The middle elongate member 104 can be fixedly coupled to the housing 2614. The inner elongate member 102 can extend through the lumen of the middle elongate member 104 into the lumen 2616 of the housing 2614. The handle 2610 can further comprise a leadscrew 2620 attached to the inner elongate member 102 and an actuator 2612 (e.g., a rotatable knob). The leadscrew 2620 is movably positioned within the lumen 2616 and, in the illustrated embodiment, has a threaded inner surface configured to mate with a threaded outer surface of the actuator 2612. That is, the threaded surfaces of the leadscrew 2620 and the actuator 2612 are opposite those shown in Figures 5 and 25A–25C. The actuator 112 can extend out of the housing 2614 such that a user can rotate the actuator 2612 relative to the housing 2614 to drive the leadscrew 2620 to proximally and/or distally through the housing 2614 to thereby drive the attached inner elongate member 102 to move relative to the middle elongate member 104 and radially expand/collapse the clot treatment device 130.

**[0101]** In the illustrated embodiment, the handle 2610 further comprises an indicator 2611 coupled to the leadscrew 2620 and that is visible through one or more slot/openings in the housing 2614 to provide an indication of an amount of radial expansion of the clot treatment device 130. In some aspects of the present technology, forming the outer surface of the actuator 2612 and the corresponding inner surface of the leadscrew 2620 to be threaded can allow for easier visualization of the indicator 2611, as the actuator 2612 does not block the view of the indicator 2611 and the leadscrew 2620 anywhere along the path of the leadscrew 2620.

**[0102]** Figure 27 is an enlarged cross-sectional side view of a handle 2710 in accordance with additional embodiments of the present technology that can be incorporated into the system 100 (e.g., instead of the handle 110). In the illustrated embodiment, the handle 2710 includes a housing 2714 defining an internal chamber or lumen 2716. The middle elongate member 104 can be rotatably coupled to the housing 2714 via a first adaptor 2790 (e.g., a mid-adaptor). In some embodiments, the first adaptor 2790 comprises a flange 2791 configured (e.g., shaped, sized, positioned) to be positioned in and rotatably retained within a corresponding circumferential groove or recess 2792 in the housing 2714. The inner elongate member 102 can extend through the lumen of the middle elongate member 104 into the lumen 2716 of the housing 2714. The handle 2710 can further comprise a leadscrew 2720 rotatably coupled to the inner elongate member 102 via a second adaptor 2794 and an actuator 2712 (e.g., a rotatable knob).

In some embodiments, the second adaptor 2794 comprises a flange 2795 configured (e.g., shaped, sized, positioned) to be positioned in and rotatably retained within a corresponding circumferential groove or recess 2796 in the leadscrew 2720. The first adaptor 2790 can be fixedly attached to the middle elongate member 104, and the second adaptor 2794 can be fixedly attached to the inner elongate member 102 such that rotation of the elongate guide members 2784 rotates the elongate members 102, 104 together to rotate the clot treatment device 130 attached thereto. The leadscrew 2720 is movably positioned within the lumen 2716 and, in the illustrated embodiment, has a threaded outer surface configured to mate with a threaded inner surface of the actuator 2712. In operation, the actuator 2712 can be rotated relative to the housing 2714 to drive the leadscrew 2720 proximally and/or distally through the housing 2714 to thereby drive the attached inner elongate member 102 to move relative to the middle elongate member 104 and radially expand/collapse the clot treatment device 130.

**[0103]** In the illustrated embodiment, the handle 2710 further comprises one or more elongate guide members 2784 (e.g., torque guide pins) coupling the first adaptor 2790 to the second adaptor 2740 and a rotary motor 2782. The rotary motor 2782 can be operably coupled to an actuator 2780 (e.g., a switch, a button), a power source, a controller, and/or the like, and is actuatable to cause the rotary motor 2782 to rotate the elongate guide members 2784 to thereby rotate the first and second adaptors 2790, 2794 to thereby rotate the elongate members 102, 104. Accordingly, the handle 2710 is motorized to rotate the clot treatment device 130 (e.g., via actuation of the actuator 2780 and operation of the rotary motor 2782) while still being manually actuatable by a user (e.g., via actuation of the actuator 2712 and corresponding movement of the leadscrew 2720) to radially expand the clot treatment device 130.

**[0104]** In some embodiments, the rotary motor 2782 is configured to fully rotate (e.g., 360°) the clot treatment device 130 in one or both of the clockwise and counterclockwise directions. In some embodiments, the rotary motor 2782 is configured to only partially rotate the clot treatment device 130 (e.g., by about 10°–60°) in the clockwise and/or counterclockwise directions. In some embodiments, of the rotary motor 2782 (e.g., a controller operably coupled thereto) and/or other aspects of the present technology described herein may take the form of computer- or machine- or controller-executable instructions, including routines executed by a programmable computer or controller. Those skilled in the relevant art will appreciate that the technology can be practiced on computer/controller systems other than those shown and described below. The technology can be embodied in a special-purpose computer, controller or data processor that is specifically programmed, configured or constructed to perform one or more

of the computer-executable instructions described below. Accordingly, the terms "computer" and "controller" as generally used herein refer to any data processor and can include Internet appliances and hand-held devices (including palm-top computers, wearable computers, cellular or mobile phones, multi-processor systems, processor-based or programmable consumer electronics, network computers, mini computers and the like). Information handled by these computers can be presented at any suitable display medium, including a liquid crystal display (LCD).

**[0105]** The technology can also be practiced in distributed environments, where tasks or modules are performed by remote processing devices that are linked through a communications network. In a distributed computing environment, program modules or subroutines may be located in local and remote memory storage devices. Aspects of the technology described below may be stored or distributed on computer-readable media, including magnetic or optically readable or removable computer disks, as well as distributed electronically over networks. Data structures and transmissions of data particular to aspects of the technology are also encompassed within the scope of the embodiments of the technology.

**[0106]** Figure 28 is a side view of a distal portion of a clot removal system 2800 ("system 2800") positioned within a vessel V to treat clot material C in accordance with embodiments of the present technology. The system 2800 can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the system 100 described in detail above with reference to Figures 1A–10C, and can operate in a generally similar or identical manner to the system 100. For example, in the illustrated embodiment, the system 2800 includes the clot treatment device 130, the inner elongate member 102 (obscured in Figure 28), the middle elongate member 104, the outer elongate member 106, and the tip 108.

**[0107]** In the illustrated embodiment, the system 2800 further includes a first balloon 2870 coupled to the outer elongate member 106 (e.g., coupled to a distal portion thereof) and a second balloon 2872 coupled to an innermost (e.g., fourth) elongate member 2807. The innermost elongate member 2807 can be moved (e.g., advanced and/or retracted) through the lumen in the tip 108 and the inner elongate member 102. The first and second balloons 2870, 2872 can be inflated via one or more components of the handle 110 (Figure 5), a separate handle, and/or a different inflation component to an inflated state shown in Figure 28 in which the balloons at least partially engage the wall of the vessel V. Accordingly, the outer elongate member 106, the

innermost elongate member 2807, and/or other components of the system 2800 can include one or more inflation lumens (not shown) for inflating the first and second balloons 2870, 2872.

**[0108]** The system 2800 can be used to treat the clot material C when the clot material C is positioned within a bare vessel and/or an implant. The clot material C can be chronic or adherent clot material that may otherwise be difficult to treat and remove. In operation, during a clot removal procedure, the outer elongate member 106 can be positioned proximal to the clot material C such that the first balloon 2870 is positioned proximal to the clot material C within the vessel V. The innermost elongate member 2807 can be positioned such that the second balloon 2872 is distal to the clot material C within the vessel V. The clot treatment devices 130 can be deployed between the first and second balloons 2870, 2872 within the clot material C. With the first and second balloons 2870, 2872 inflated, the clot treatment device 130 can be translated and/or rotated through the clot material C to treat and remove the clot material C as described in detail above with reference to, for example, Figure 7. In some aspects of the present technology, the first and second balloons 2870, 2872 can help stabilize the vessel V—inhibiting or even prohibiting it from moving—when the clot treatment device 130 is moved to treat the clot material C. This can help improve the treatment efficiency of the system 2800. In some embodiments, the first balloon 2870 and/or the second balloon 2872 can provide embolic protection during a clot treatment procedure with the clot treatment device 130 in addition to or alternatively to vessel stabilization.

**[0109]** Several aspects of the present technology are set forth in the following examples:

1. A system for removing clot material from an implant positioned within a body vessel, comprising:

a clot treatment device configured to be deployed within the implant, wherein the clot treatment device includes a first end portion, a second end portion, and a plurality of struts extending between the first end portion and the second end portion;

a handle including an actuator;

a first elongate member coupling the first end portion of the clot treatment device to the handle; and

a second elongate member coupling the second end portion of the clot treatment device to the handle, wherein actuation of the actuator is configured to move the second elongate member relative to the first elongate member to reduce a distance

between the first end portion and the second end portion to radially expand the struts.

2. The system of example 1 wherein the implant is a stent.

3. The system of example 1 or example 2 wherein the first end portion is a proximal end portion of the clot treatment device, and wherein the second end portion is a distal end portion of the clot treatment device.

4. The system of example 3 wherein the second elongate member extends through a lumen of the first elongate member.

5. The system of example 1 or example 2 wherein the first end portion is a distal end portion of the clot treatment device, and wherein the second end portion is a proximal end portion of the clot treatment device.

6. The system of any one of examples 1–5 wherein actuation of the actuator is configured to move both the first elongate member and the second elongate member relative to the handle.

7. The system of any one of examples 1–6 wherein the handle is rotatable to rotate the clot treatment device relative to the implant.

8. The system of any one of examples 1–7 wherein the handle is longitudinally movable to move the clot treatment device longitudinally relative to the implant.

9. The system of any one of examples 1–8 wherein the handle is rotatable and longitudinally movable to rotate and longitudinally move the clot treatment device relative to the implant.

10. The system of any one of examples 1–9, further comprising a guide catheter, wherein the clot treatment device is configured to be (a) covered within the guide catheter in a first state and (b) uncovered from the guide catheter and expanded to a second state.

11. The system of any one of examples 1–10 wherein the struts extend generally axially between the first and second end portions and each have an undulating shape.

12. The system of any one of examples 1–11 wherein the struts each extend axially between the first and second end portions, and wherein the clot treatment device does not include any cross-members interconnecting the struts.

13. The system of any one of examples 1–12 wherein the actuator is a rotatable knob or a slider.

14. The system of any one of examples 1–13 wherein the handle includes an indicator configured to indicate an amount that the struts are radially expanded.

15. A method of removing clot material from an implant positioned within a body vessel, the method comprising:

positioning a clot treatment device at least partially within the implant, wherein the clot treatment device has (a) a first end portion, (b) a second end portion, and (c) a plurality of struts extending between the first end portion and the second end portion;

moving the second elongate member relative to the first elongate member to reduce a distance between the first end portion and the second end portion to radially expand the struts; and

after radially expanding the struts, rotating and/or translating the clot treatment device within the implant to materially engage the clot material with at least a portion of the struts.

16. The method of example 15 wherein the first end portion of the clot treatment device is coupled to a first elongate member, wherein the second end portion of the clot treatment device is coupled to a second elongate member, and wherein moving the second elongate relative to the first elongate member comprises actuating an actuator on a handle coupled to the first elongate member and the second elongate member to move the second elongate member relative to the first elongate member.

17. The method of example 15 or example 16 wherein the struts each extend axially between the first and second end portions, and wherein the clot treatment device does not include any cross-members interconnecting the struts.

18. The method of any one of examples 15–17 wherein the implant is a stent.

19. A clot treatment device, compressing:

a proximal end portion;

a distal end portion; and

a plurality of struts extending generally axially along a longitudinal axis between the proximal end portion and the distal end portion, wherein—

movement of the first end portion toward the second end portion is configured to radially expand the struts;

individual ones of the struts include a proximal portion extending from the proximal end portion, a distal portion extending from the distal end portion, and a middle portion (a) extending between the proximal portion and the distal portion and (b) having a hook-like shape in a direction about the longitudinal axis; and

individual ones of the struts have an undulating shape in a direction along the longitudinal axis.

20. The clot treatment device of example 19 wherein the clot treatment device does not include any cross-members interconnecting the struts.

**[0110]** The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

**[0111]** From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures

and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

**[0112]** Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A system for removing clot material from an implant positioned within a body vessel, comprising:

a clot treatment device configured to be deployed within the implant, wherein the clot treatment device includes a first end portion, a second end portion, and a plurality of struts extending between the first end portion and the second end portion;

a handle including an actuator;

a first elongate member coupling the first end portion of the clot treatment device to the handle; and

a second elongate member coupling the second end portion of the clot treatment device to the handle, wherein actuation of the actuator is configured to move the second elongate member relative to the first elongate member to reduce a distance between the first end portion and the second end portion to radially expand the struts.

2. The system of claim 1 wherein the implant is a stent.

3. The system of claim 1 wherein the first end portion is a proximal end portion of the clot treatment device, and wherein the second end portion is a distal end portion of the clot treatment device.

4. The system of claim 3 wherein the second elongate member extends through a lumen of the first elongate member.

5. The system of claim 1 wherein the first end portion is a distal end portion of the clot treatment device, and wherein the second end portion is a proximal end portion of the clot treatment device.

6. The system of claim 1 wherein actuation of the actuator is configured to move both the first elongate member and the second elongate member relative to the handle.

7. The system of claim 1 wherein the handle is rotatable to rotate the clot treatment device relative to the implant.

8. The system of claim 1 wherein the handle is longitudinally movable to move the clot treatment device longitudinally relative to the implant.

9. The system of claim 1 wherein the handle is rotatable and longitudinally movable to rotate and longitudinally move the clot treatment device relative to the implant.

10. The system of claim 1, further comprising a guide catheter, wherein the clot treatment device is configured to be (a) covered within the guide catheter in a first state and (b) uncovered from the guide catheter and expanded to a second state.

11. The system of claim 1 wherein the struts extend generally axially between the first and second end portions and each have an undulating shape.

12. The system of claim 1 wherein the struts each extend axially between the first and second end portions, and wherein the clot treatment device does not include any cross-members interconnecting the struts.

13. The system of claim 1 wherein the actuator is a rotatable knob or a slider.

14. The system of claim 1 wherein the handle includes an indicator configured to indicate an amount that the struts are radially expanded.

15. A method of removing clot material from an implant positioned within a body vessel, the method comprising:

positioning a clot treatment device at least partially within the implant, wherein the clot treatment device has (a) a first end portion, (b) a second end portion, and (c) a plurality of struts extending between the first end portion and the second end portion;

moving the second elongate member relative to the first elongate member to reduce a distance between the first end portion and the second end portion to radially expand the struts; and

after radially expanding the struts, rotating and/or translating the clot treatment device within the implant to materially engage the clot material with at least a portion of the struts.

16. The method of claim 15 wherein the first end portion of the clot treatment device is coupled to a first elongate member, wherein the second end portion of the clot treatment device is coupled to a second elongate member, and wherein moving the second elongate relative to the first elongate member comprises actuating an actuator on a handle coupled to the first elongate member and the second elongate member to move the second elongate member relative to the first elongate member.

17. The method of claim 15 wherein the struts each extend axially between the first and second end portions, and wherein the clot treatment device does not include any cross-members interconnecting the struts.

18. The method of claim 15 wherein the implant is a stent.

19. A clot treatment device, compressing:

a proximal end portion;

a distal end portion; and

a plurality of struts extending generally axially along a longitudinal axis between the proximal end portion and the distal end portion, wherein—

movement of the first end portion toward the second end portion is configured to radially expand the struts;

individual ones of the struts include a proximal portion extending from the proximal end portion, a distal portion extending from the distal end portion, and a middle portion (a) extending between the proximal portion and the distal portion and (b) having a hook-like shape in a direction about the longitudinal axis; and

individual ones of the struts have an undulating shape in a direction along the longitudinal axis.

20. The clot treatment device of claim 19 wherein the clot treatment device does not include any cross-members interconnecting the struts.

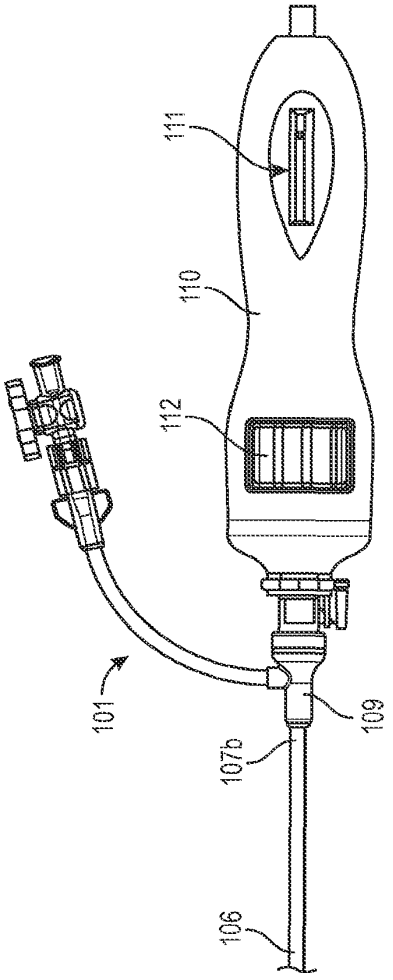



FIG. 1A

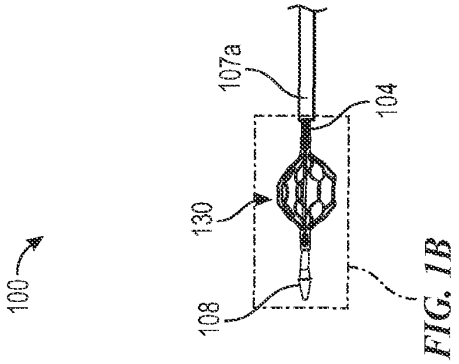



FIG. 1B

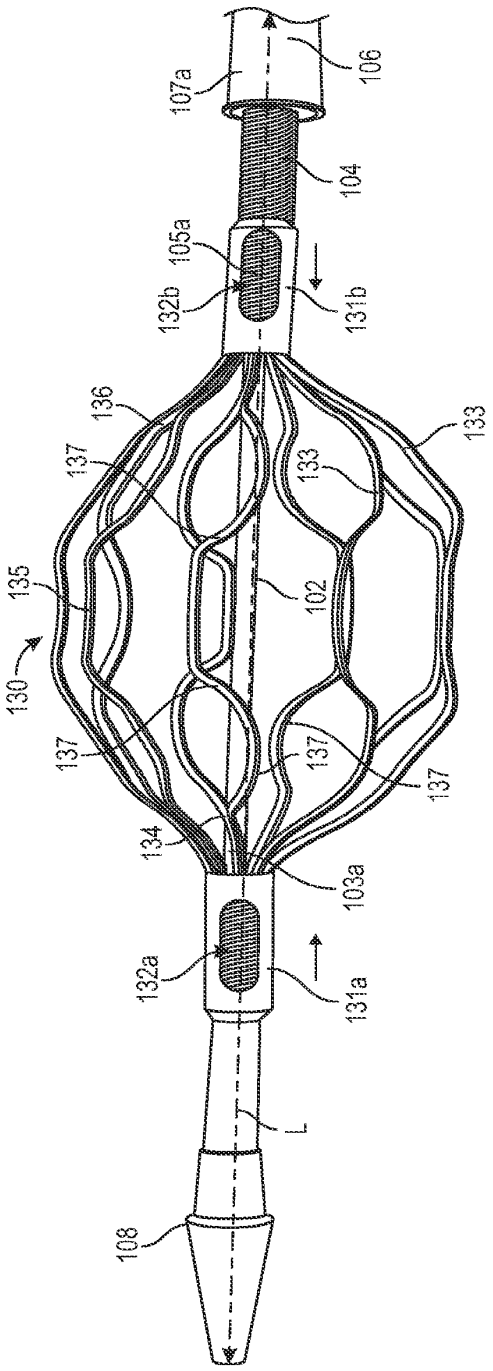

107a
106
104
105a
132b
131b
136
137
133
135
102
130
134
103a
132a
131a
L
108

FIG. 1B

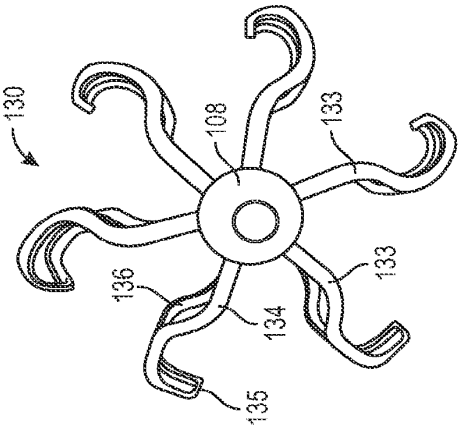

130
108
133
136
134
135

FIG. 1C

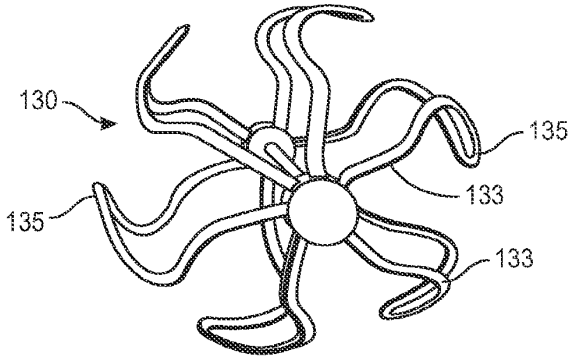



FIG. 2A

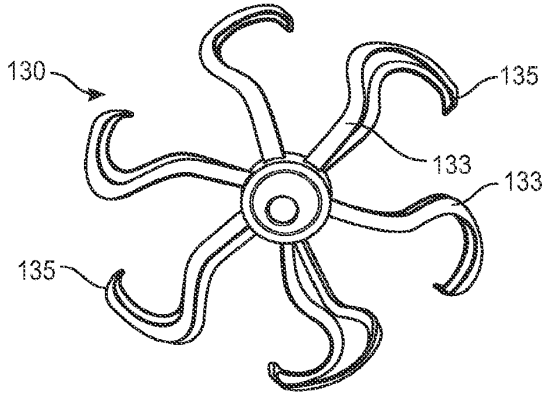



FIG. 2B

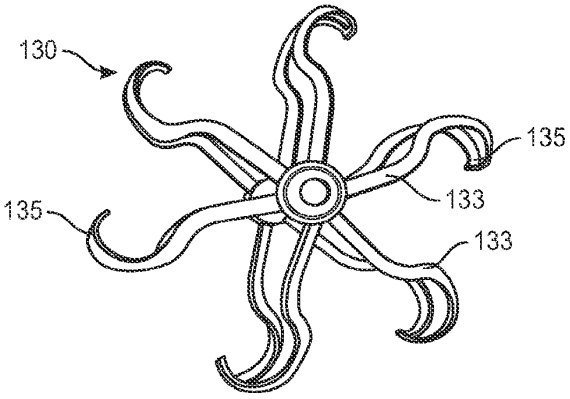



FIG. 2C

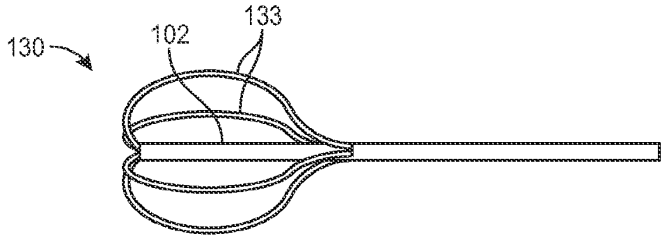



*FIG. 3A*

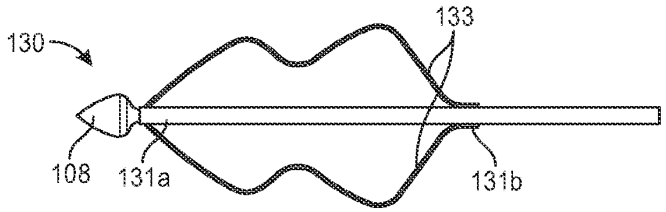



*FIG. 3B*

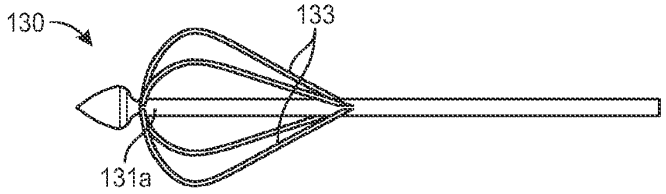



*FIG. 3C*

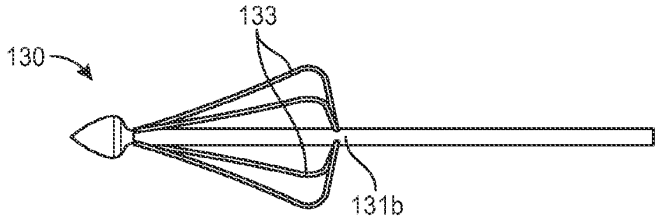



*FIG. 3D*

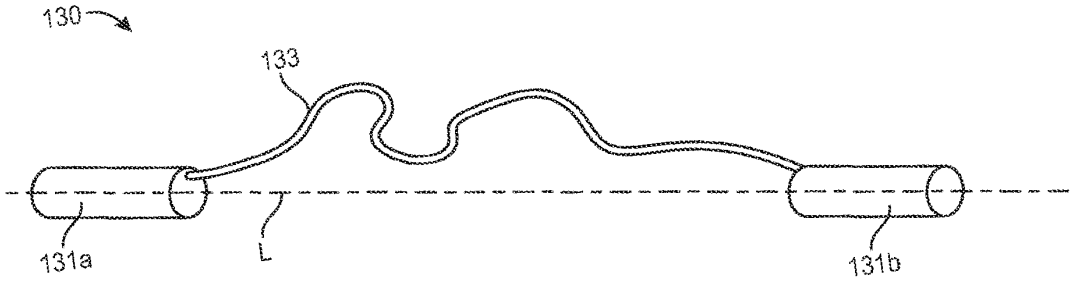



*FIG. 4A*

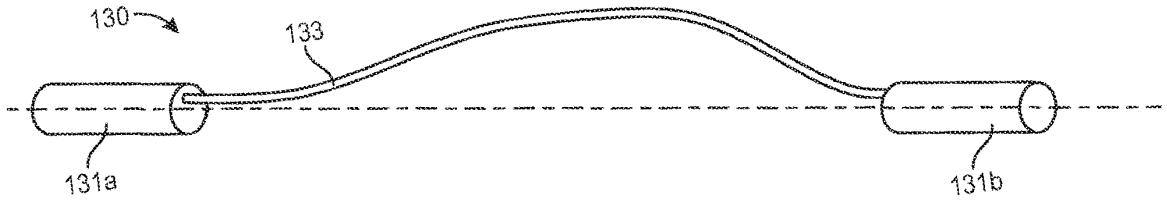



*FIG. 4B*

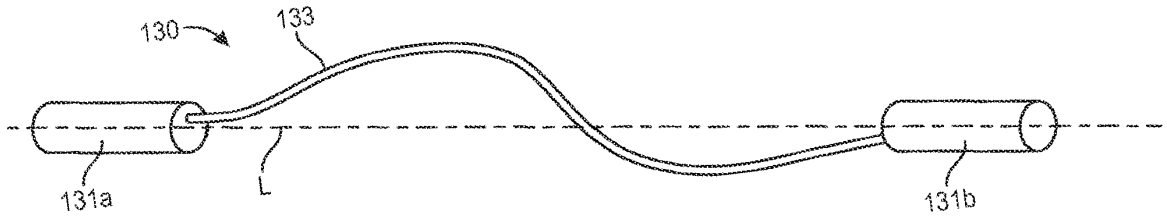



*FIG. 4C*

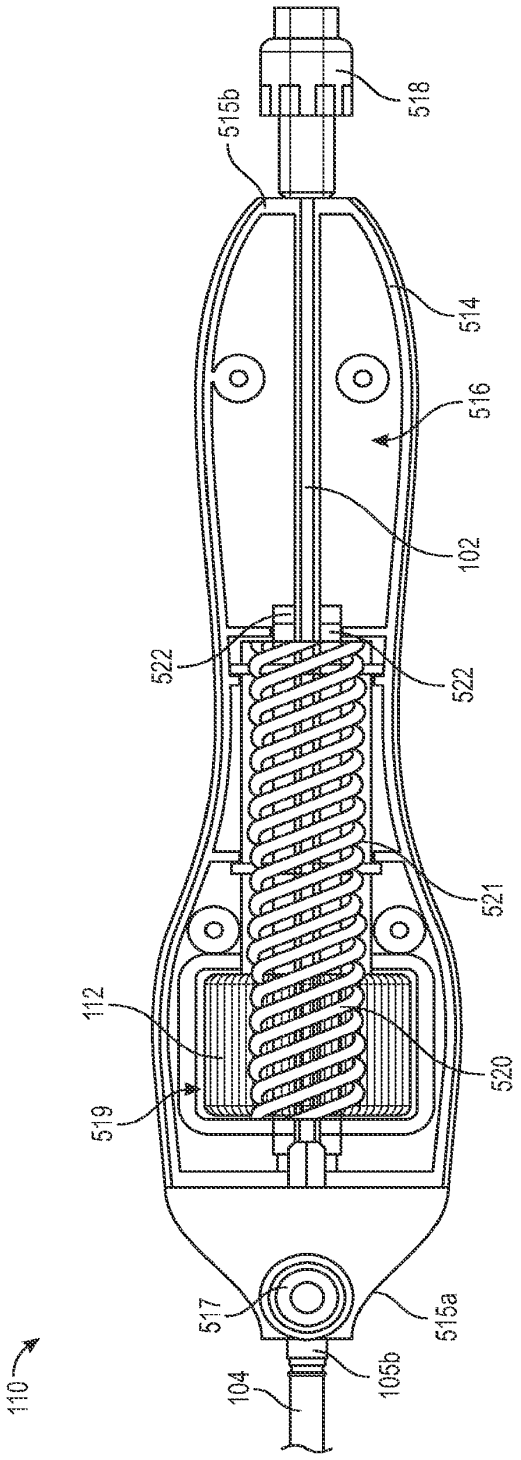

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105b
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FIG. 5

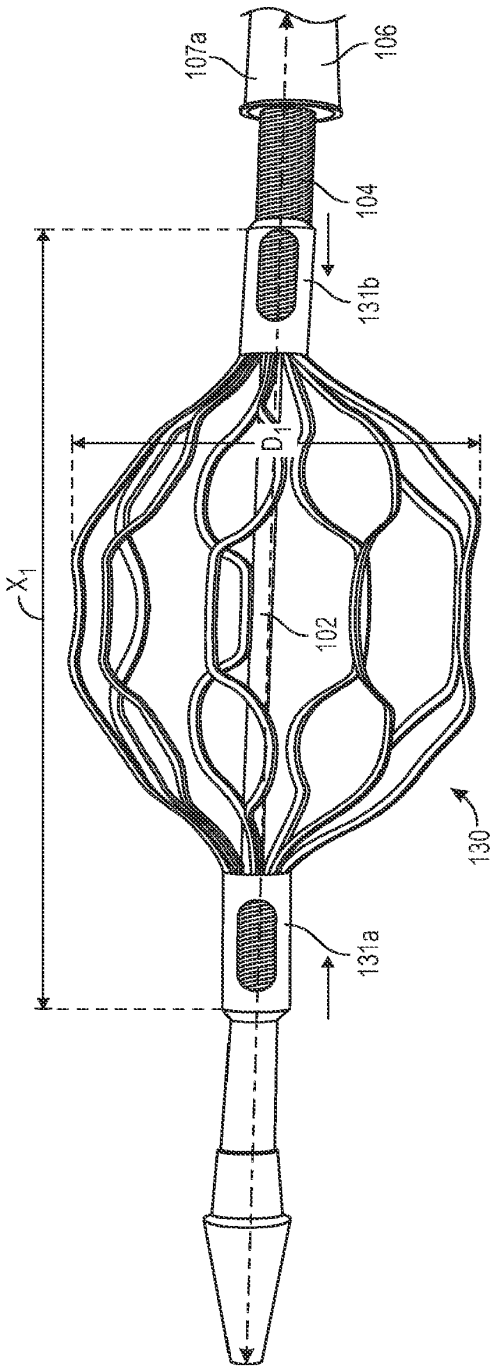

107a
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131b
$D_1$
$X_1$
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131a

FIG. 6A

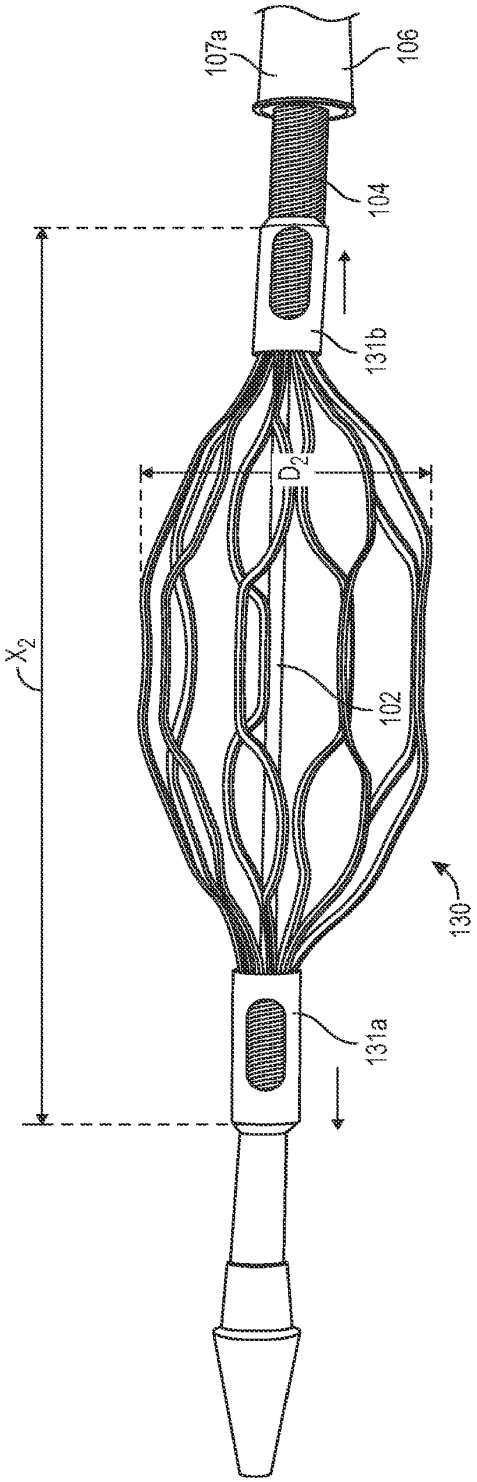

107a
106
104
131b
$D_2$
$X_2$
102
130
131a

FIG. 6B

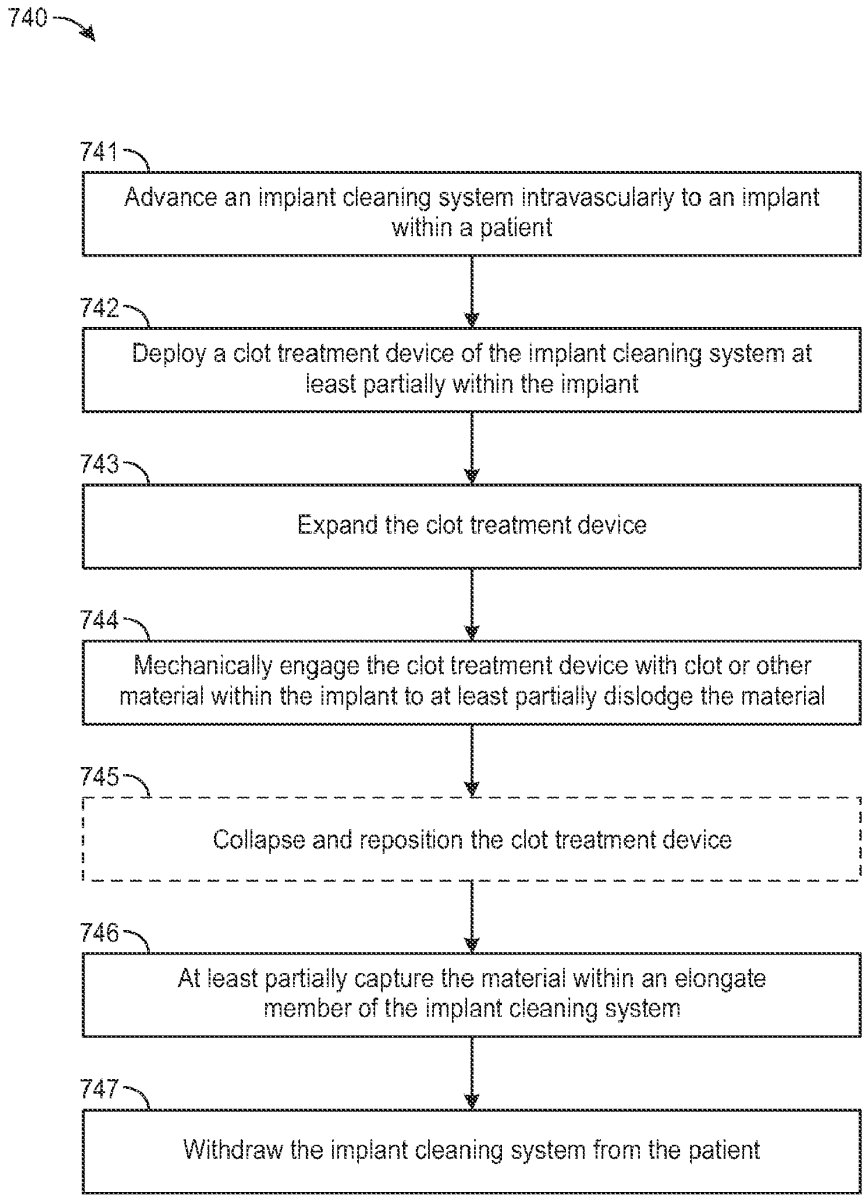

740
741
Advance an implant cleaning system intravascularly to an implant within a patient
742
Deploy a clot treatment device of the implant cleaning system at least partially within the implant
743
Expand the clot treatment device
744
Mechanically engage the clot treatment device with clot or other material within the implant to at least partially dislodge the material
745
Collapse and reposition the clot treatment device
746
At least partially capture the material within an elongate member of the implant cleaning system
747
Withdraw the implant cleaning system from the patient

*FIG. 7*

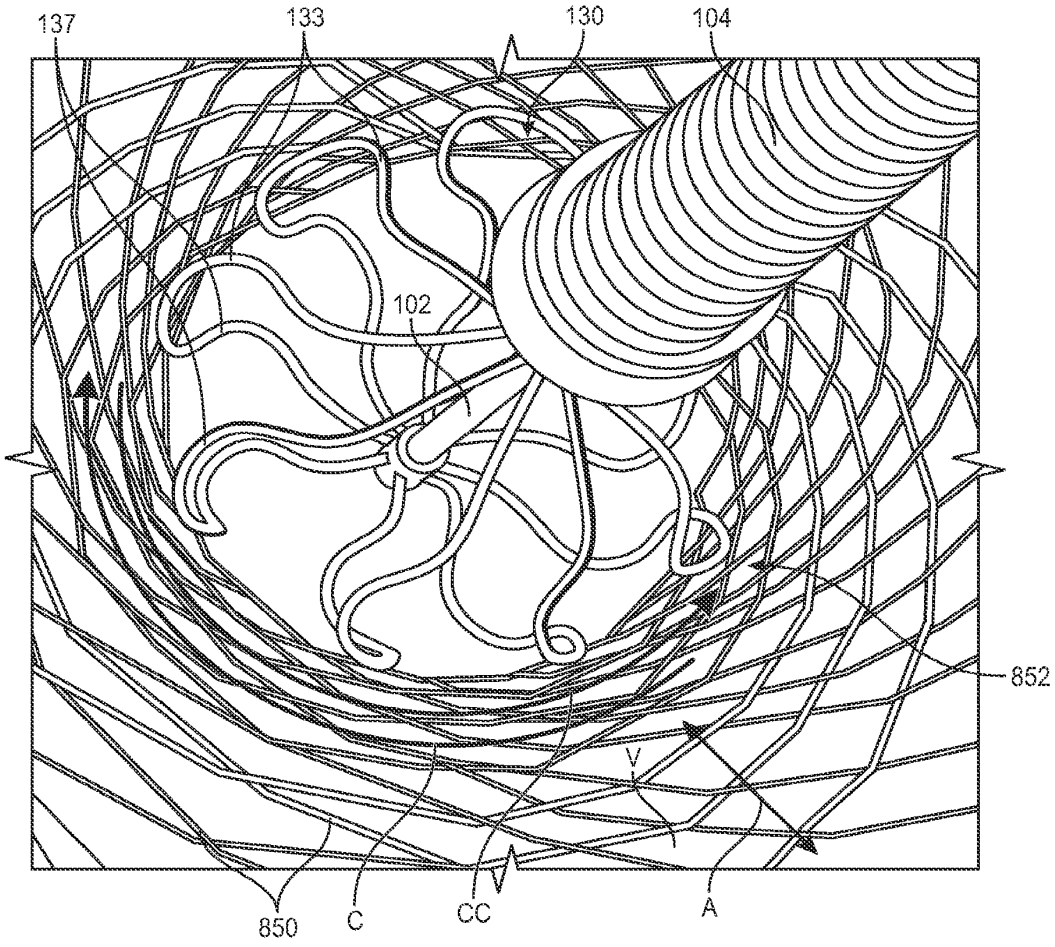



*FIG. 8*

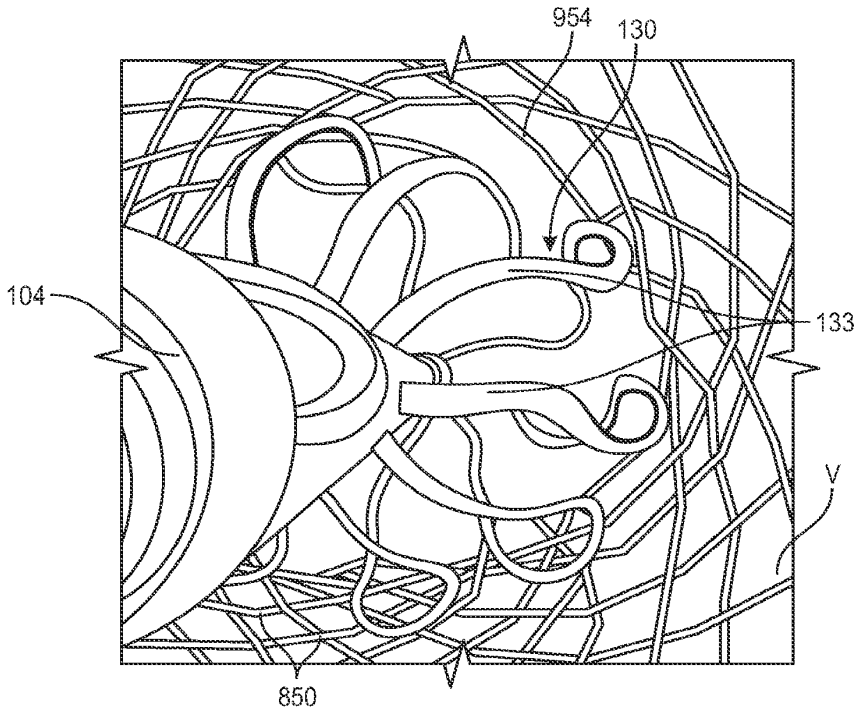



*FIG. 9A*

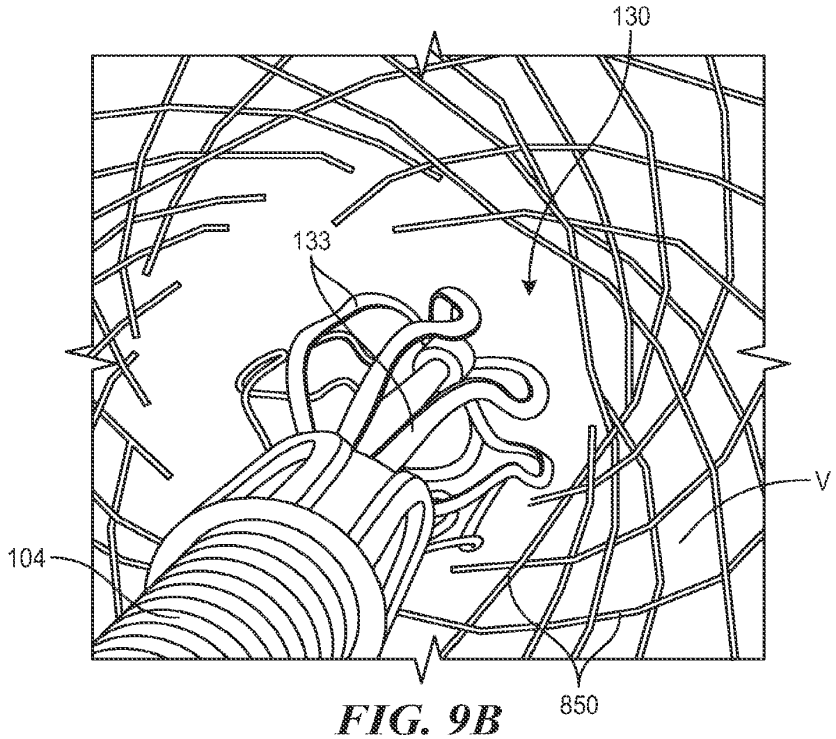



*FIG. 9B*

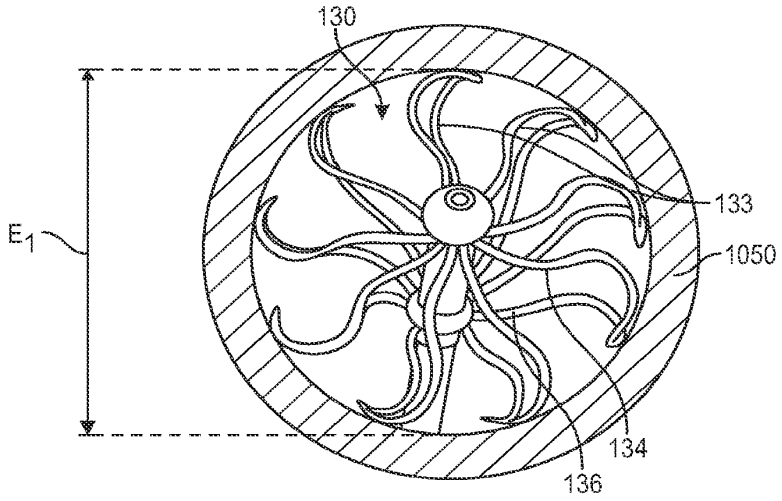



*FIG. 10A*

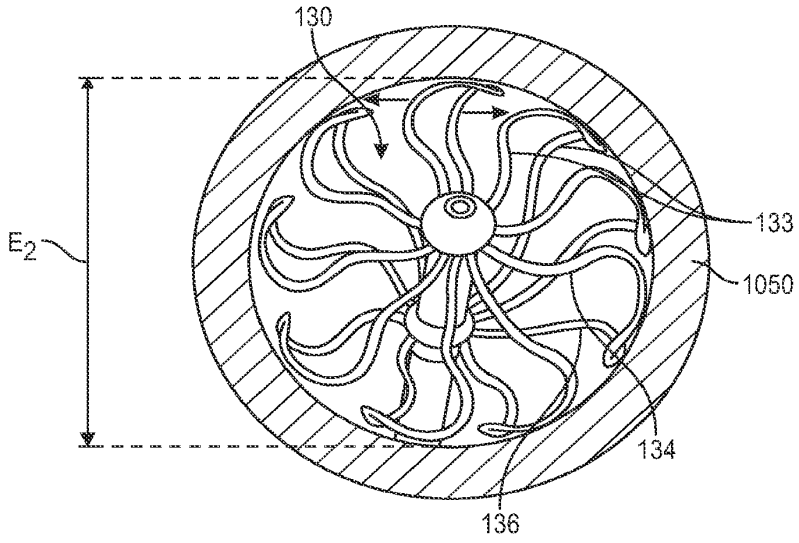



*FIG. 10B*

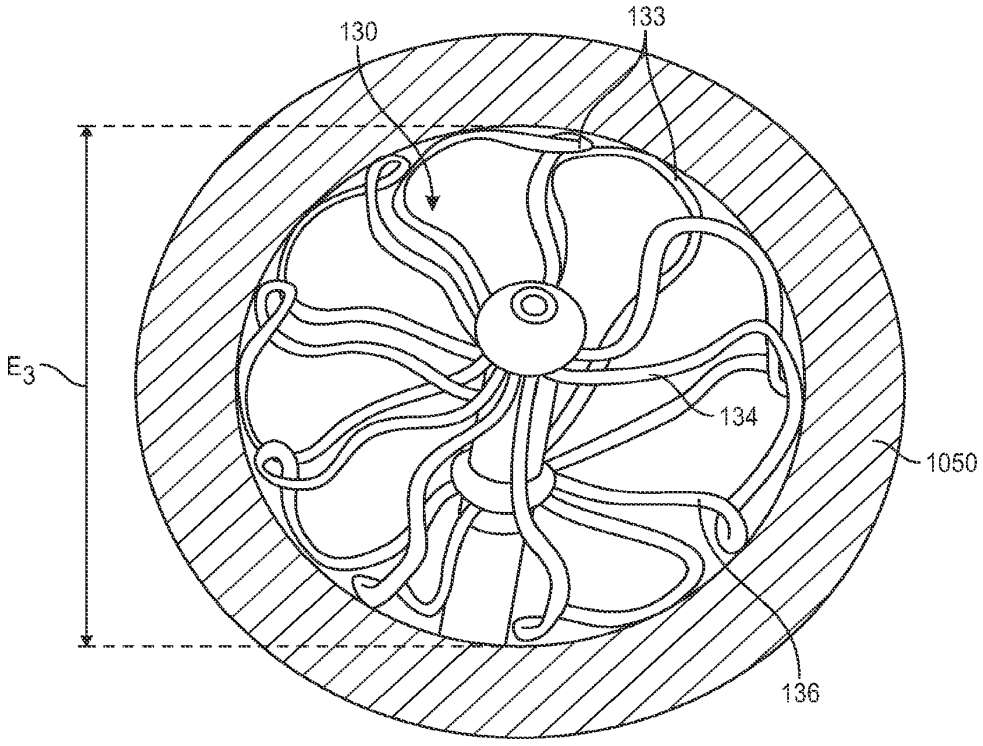



*FIG. 10C*

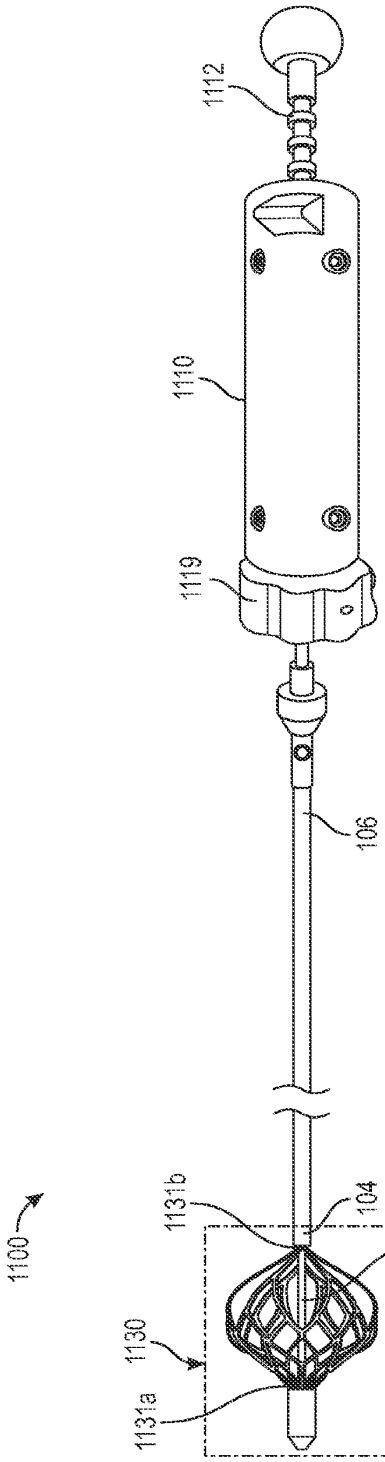



FIG. 11A

FIGS. 11B/11C

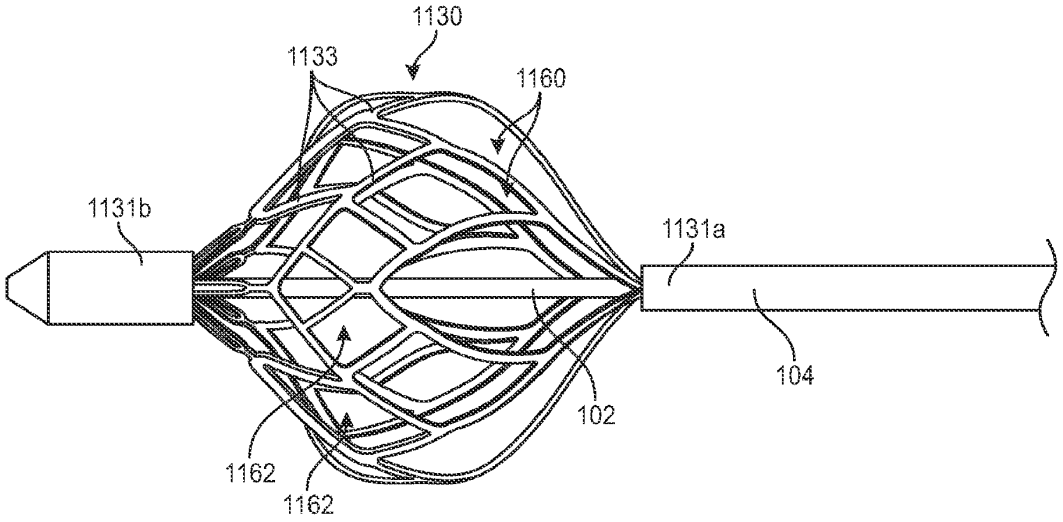



*FIG. 11B*

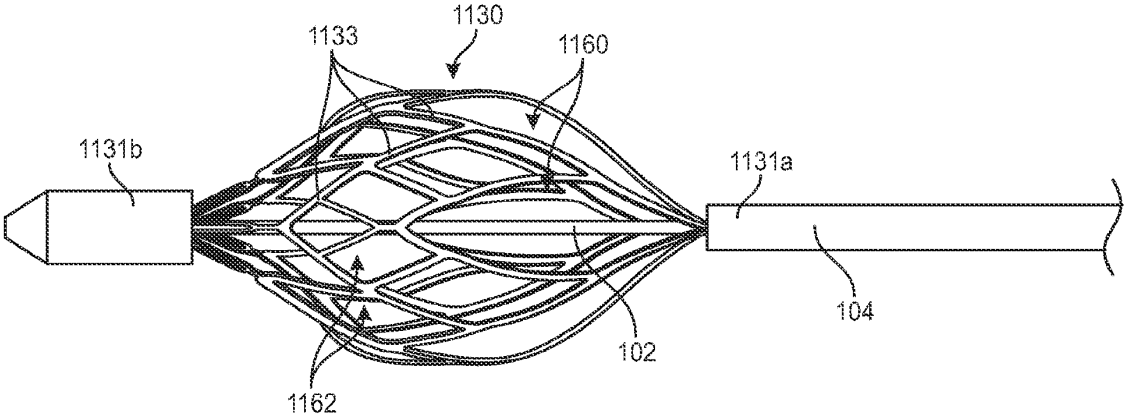



*FIG. 11C*

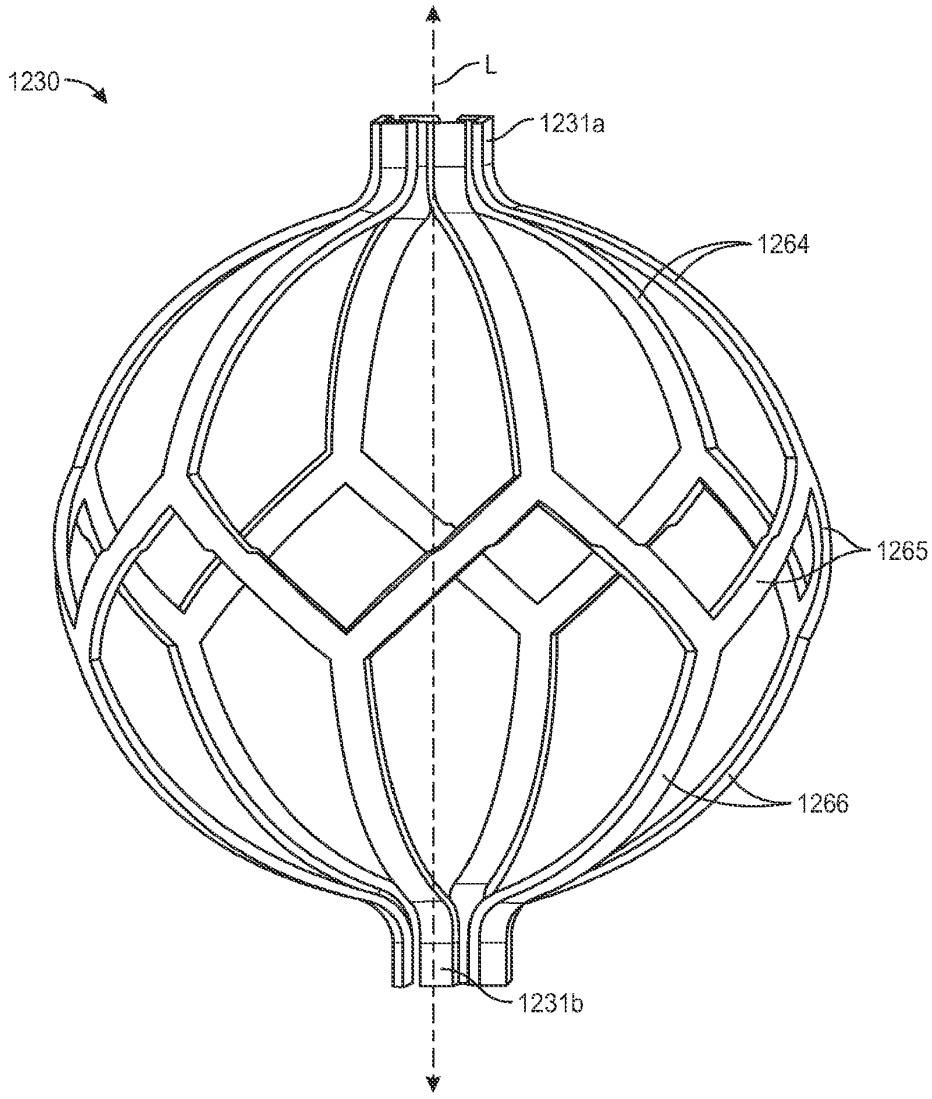



*FIG. 12*

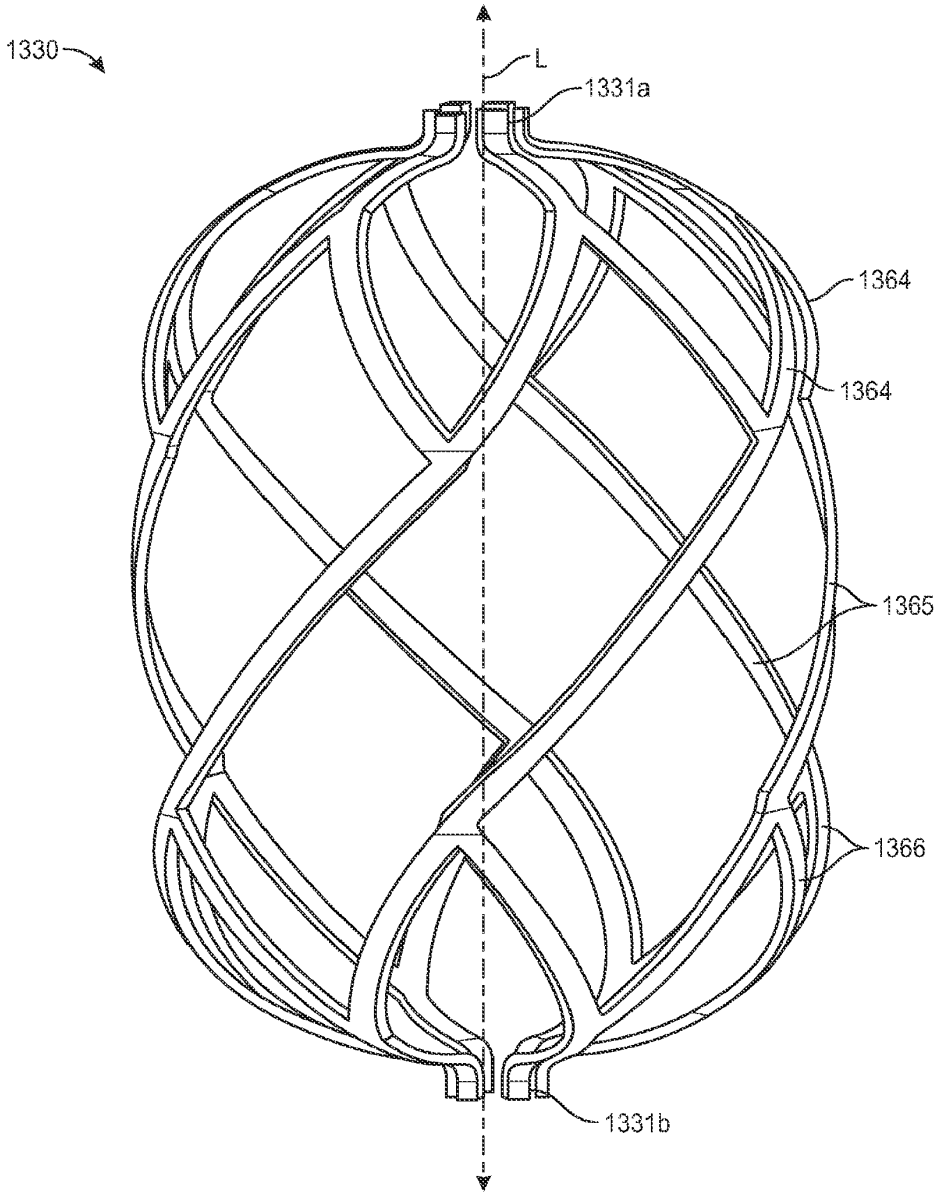



*FIG. 13*

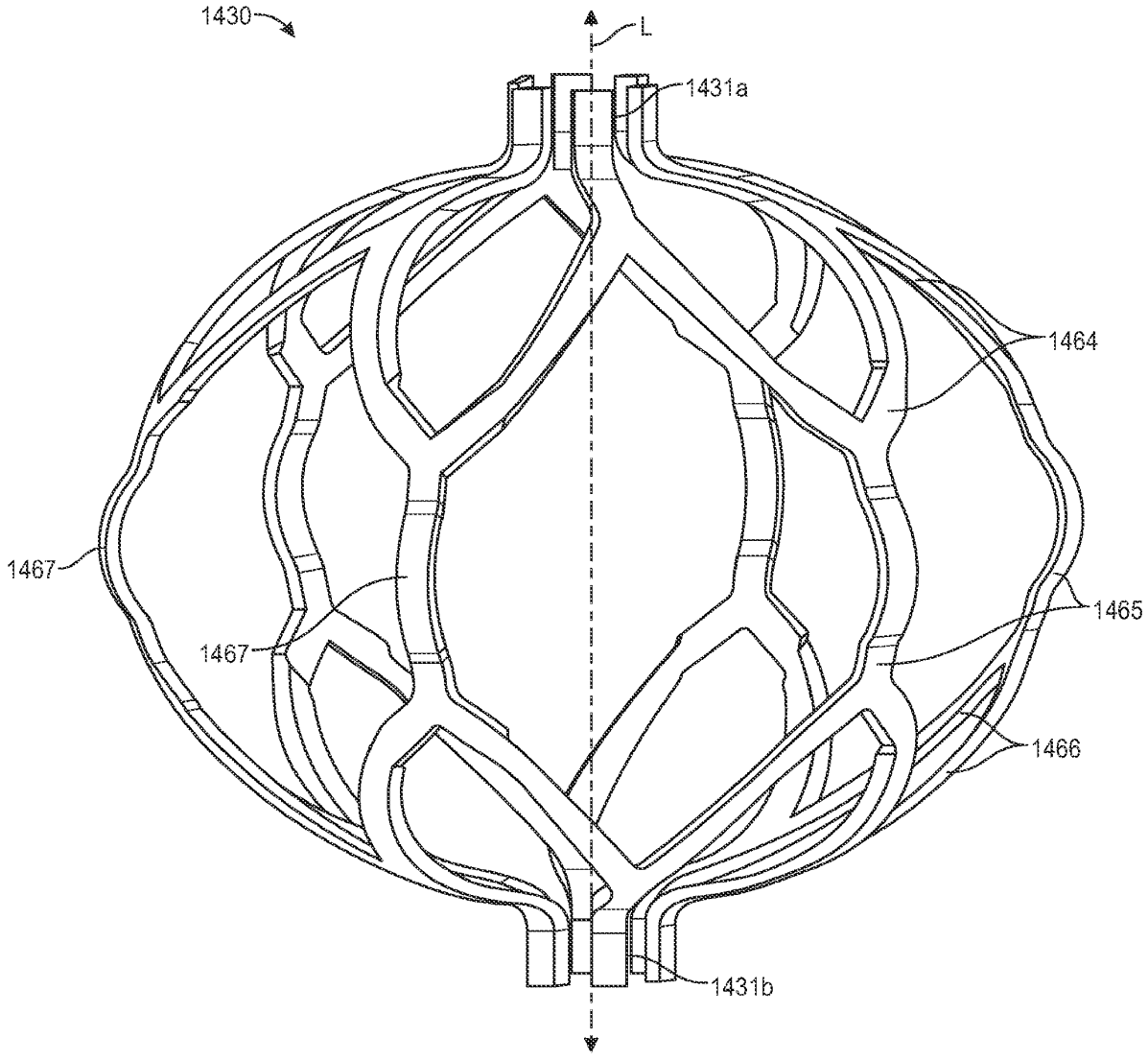



*FIG. 14*

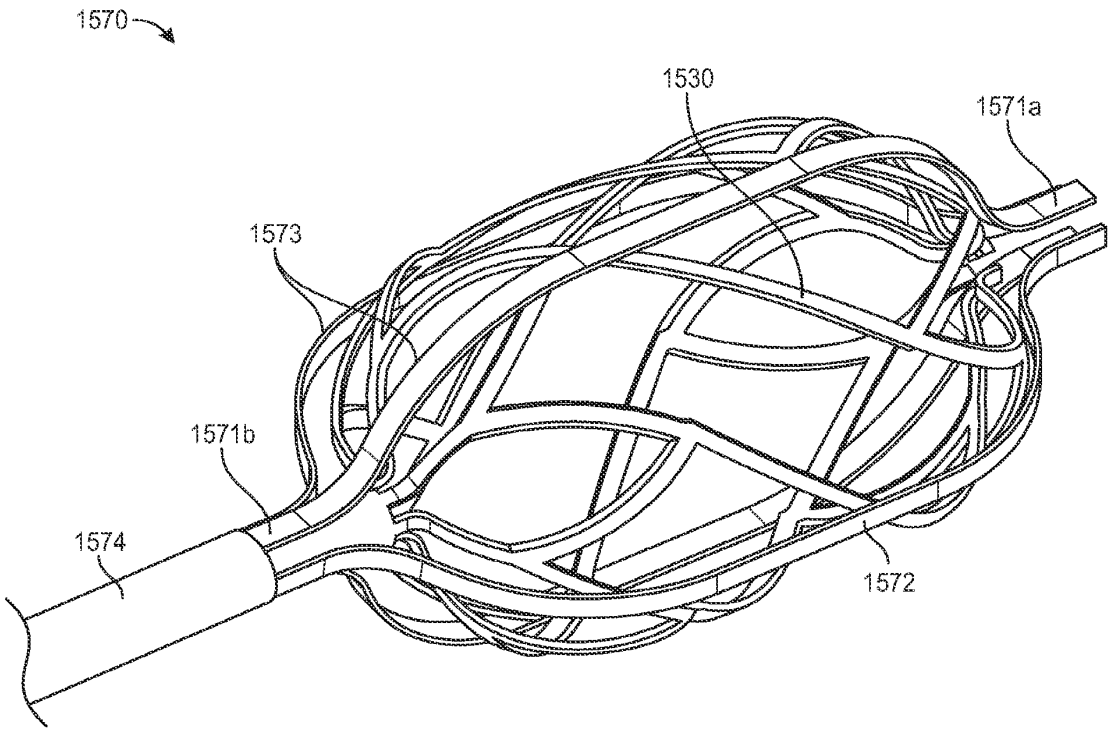



*FIG. 15*

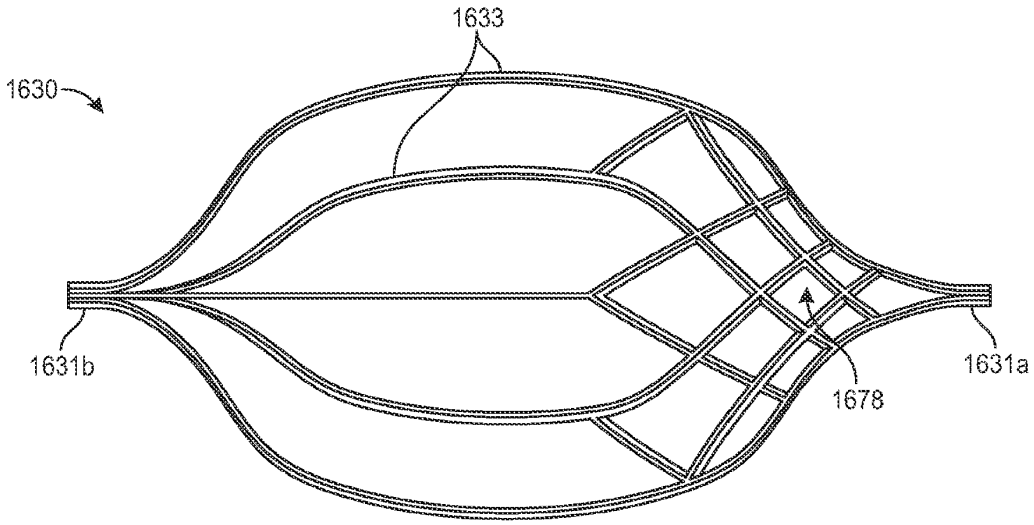



*FIG. 16A*

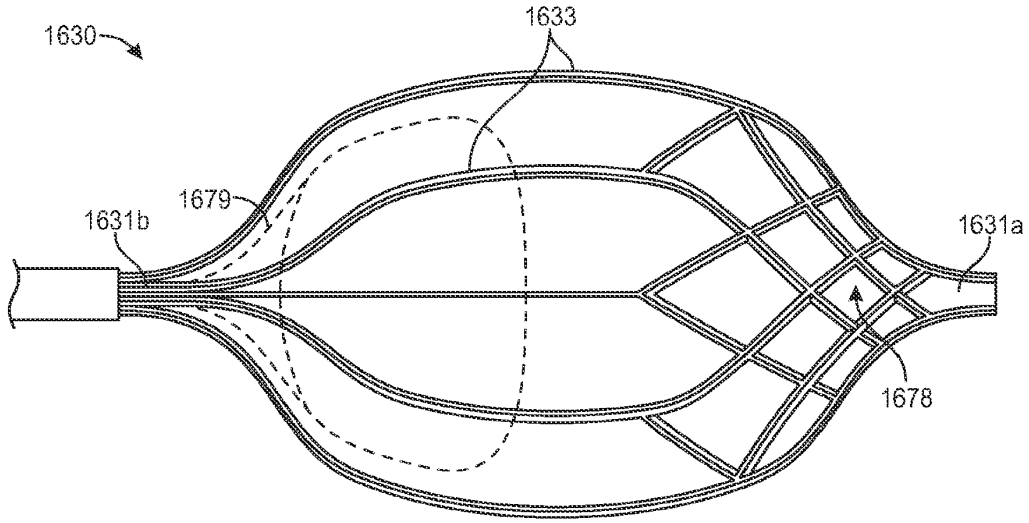



*FIG. 16B*

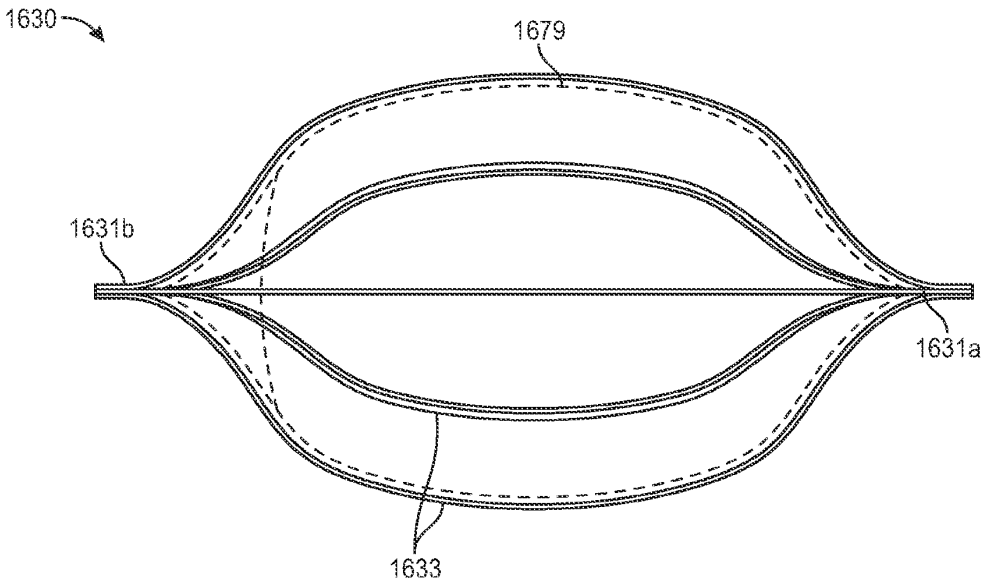



*FIG. 16C*

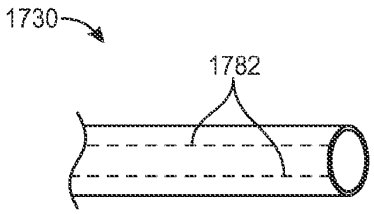



*FIG. 17A*

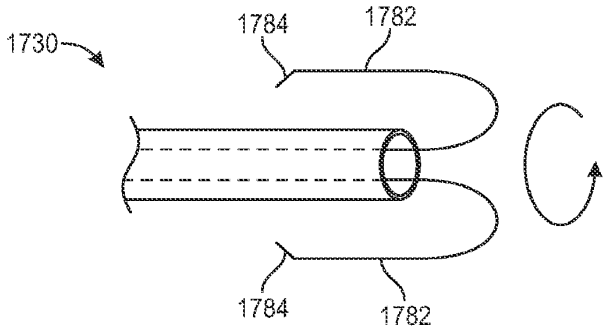



*FIG. 17B*

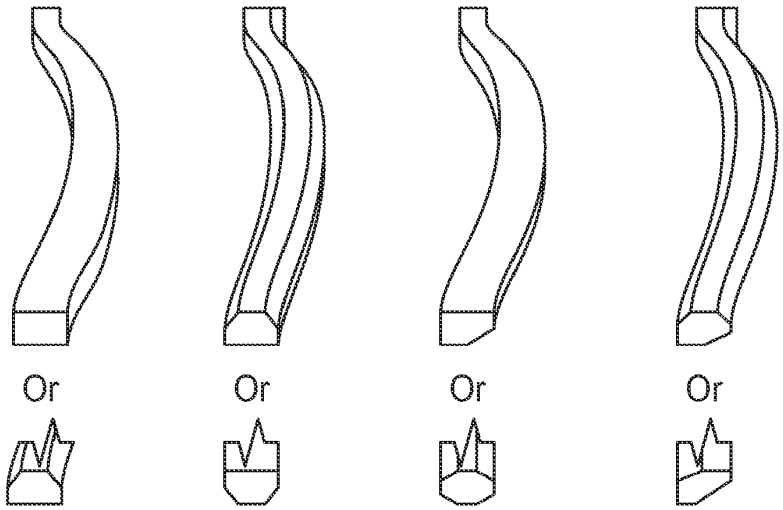



*FIG. 18*

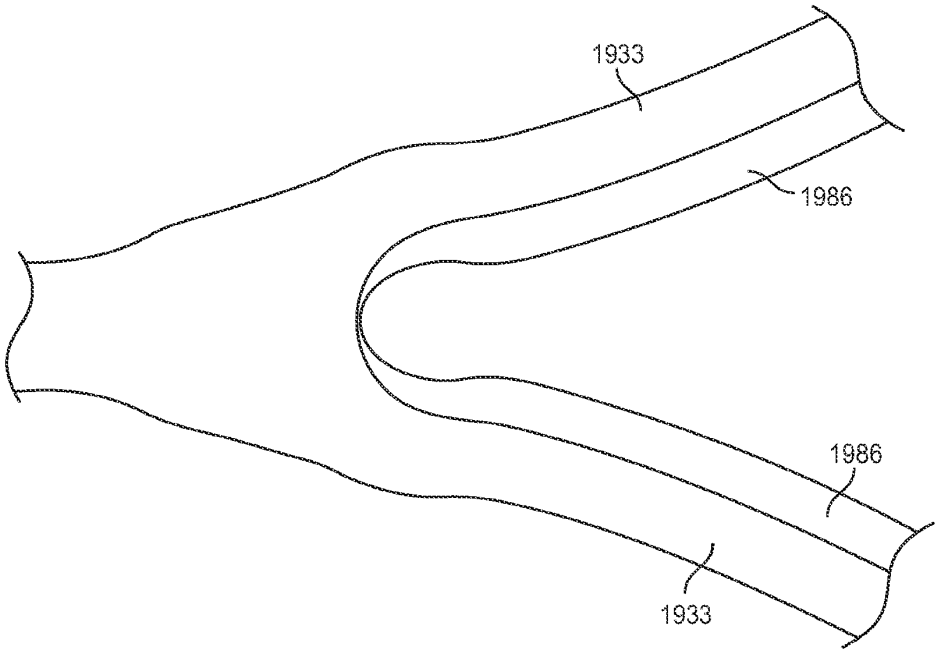



*FIG. 19*

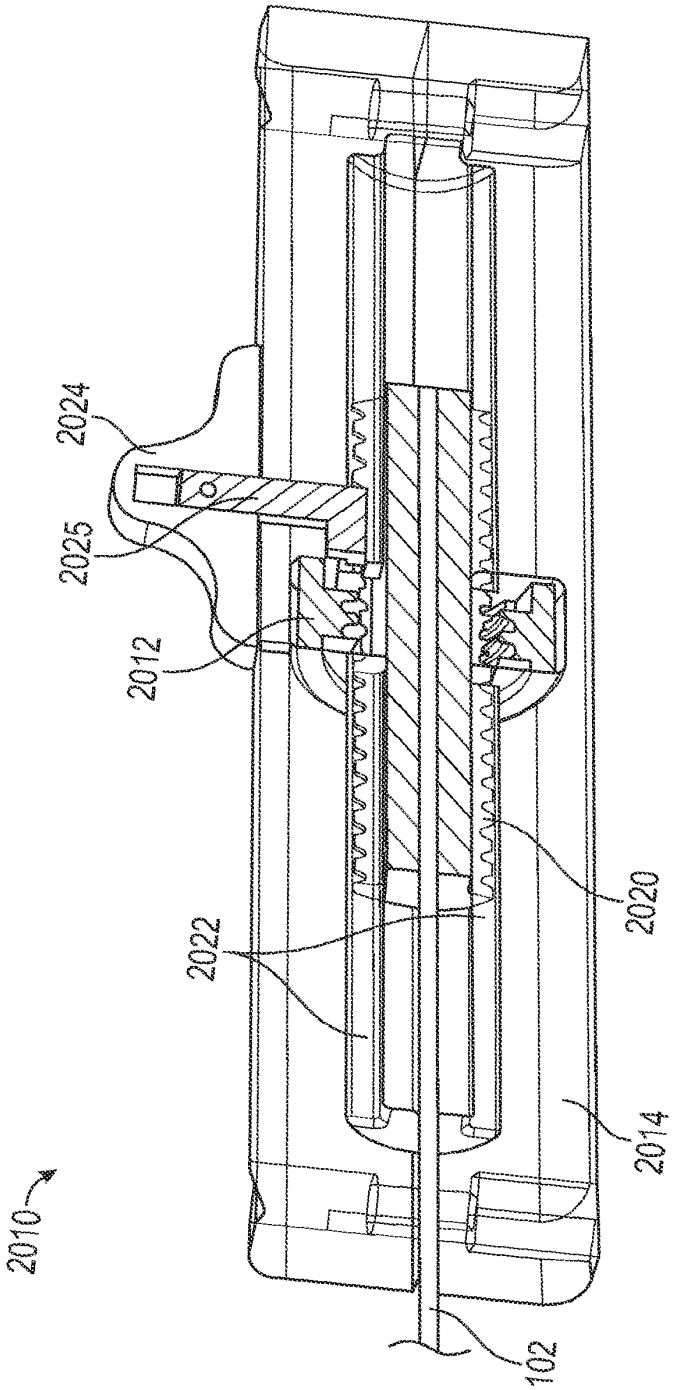



FIG. 20

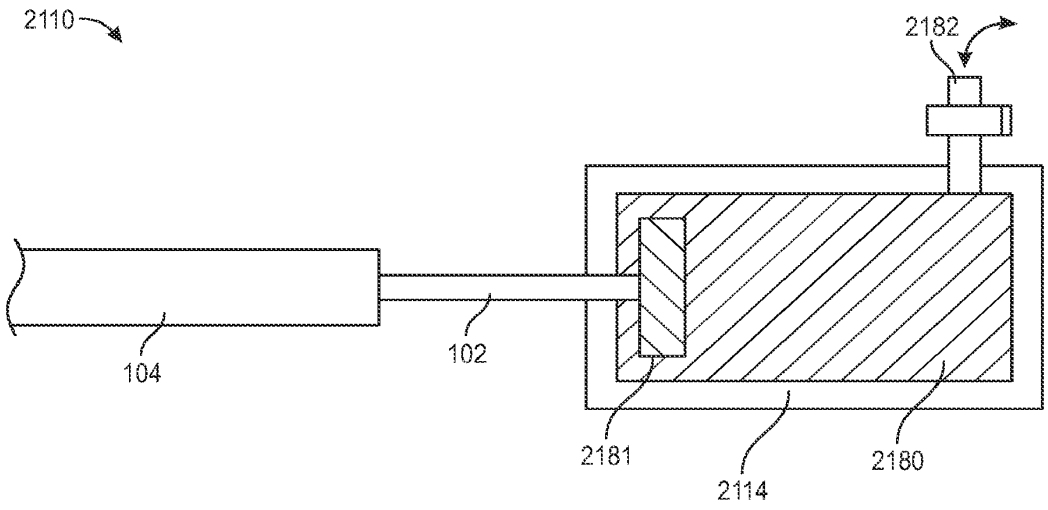



*FIG. 21*

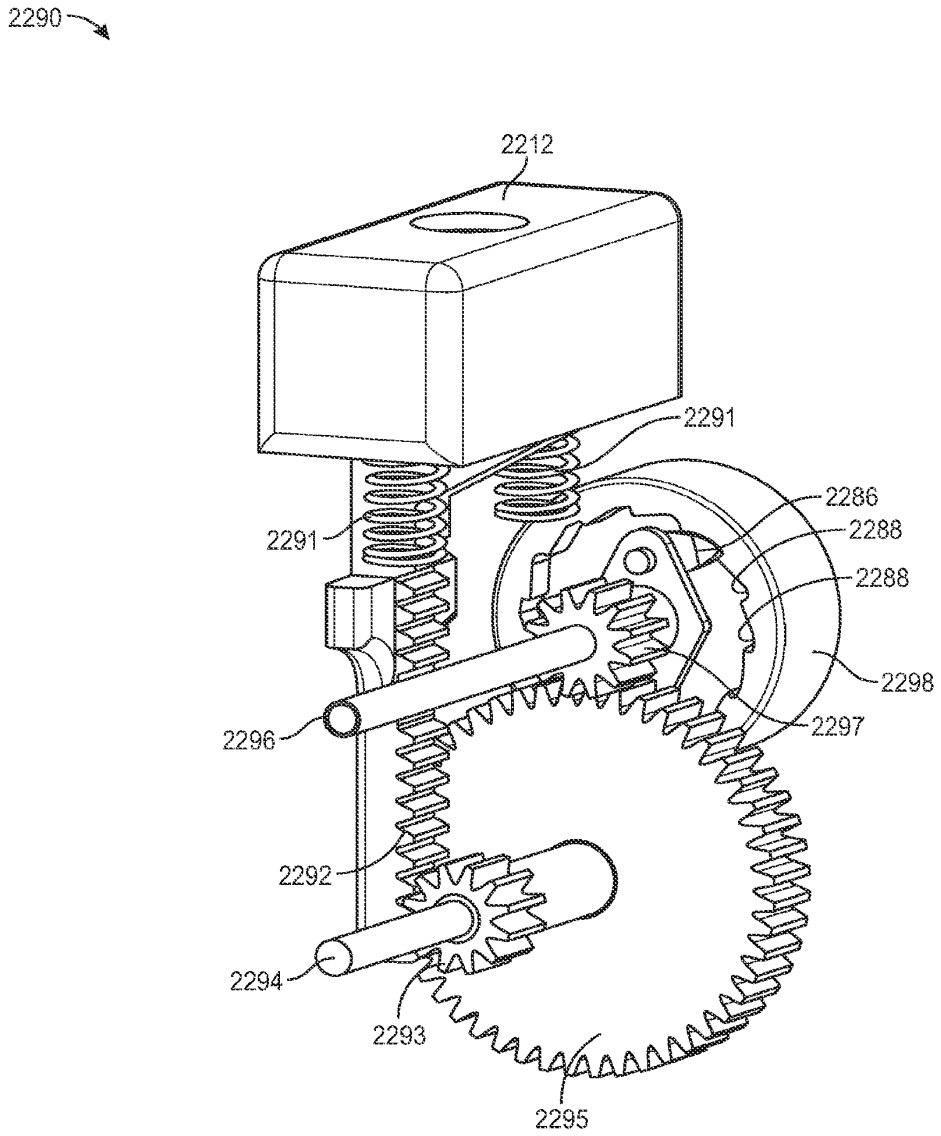

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*FIG. 22*

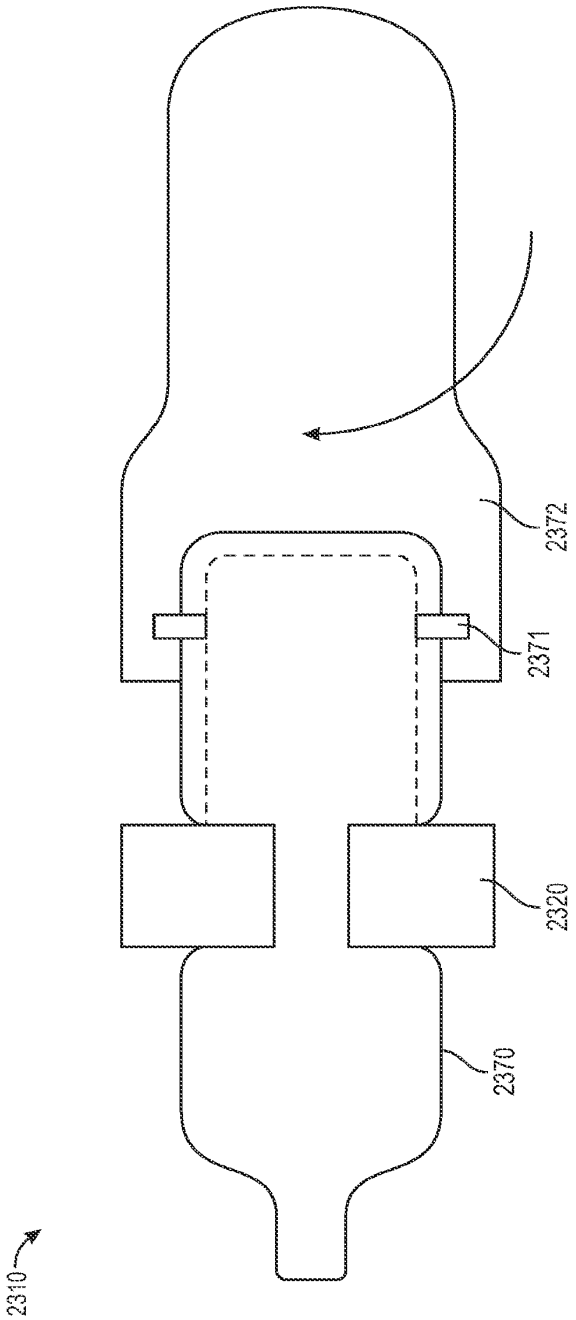



*FIG. 23*

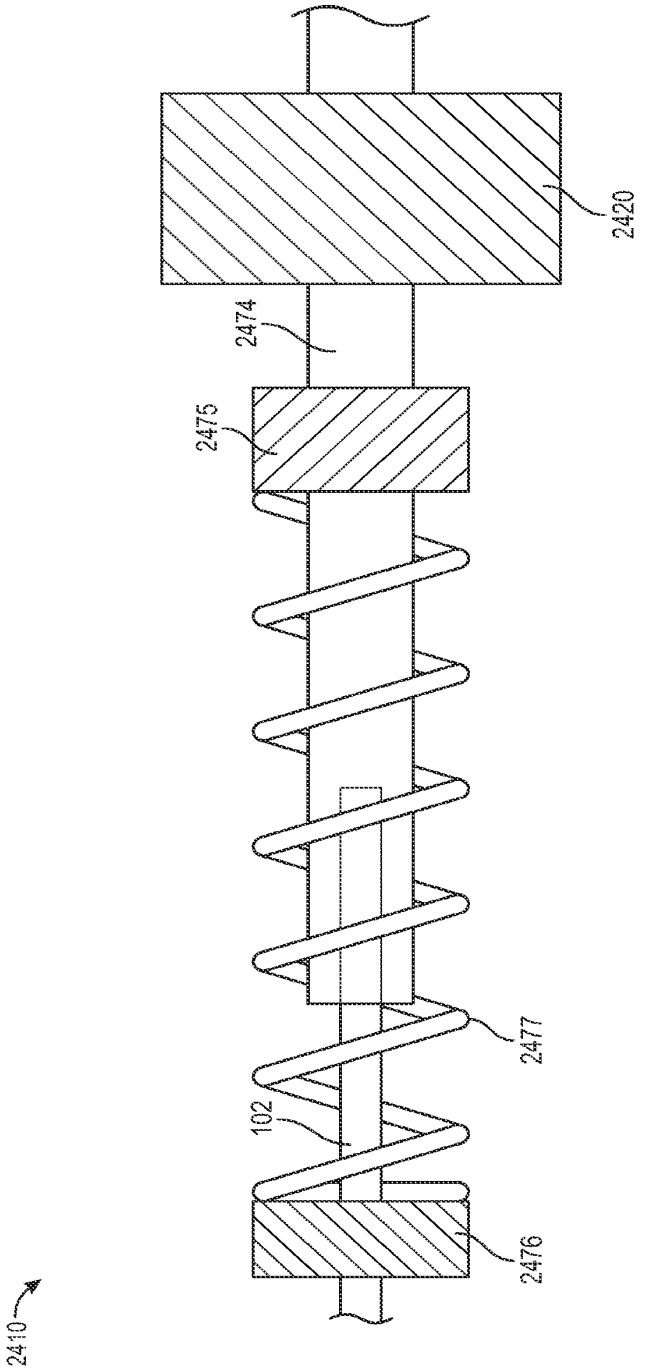



FIG. 24

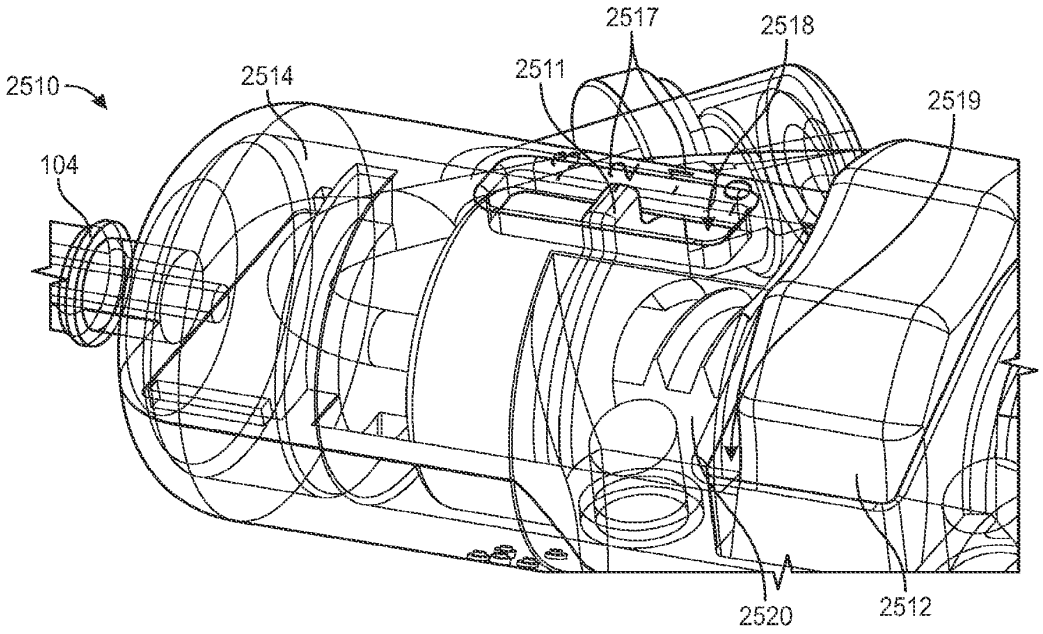



*FIG. 25A*

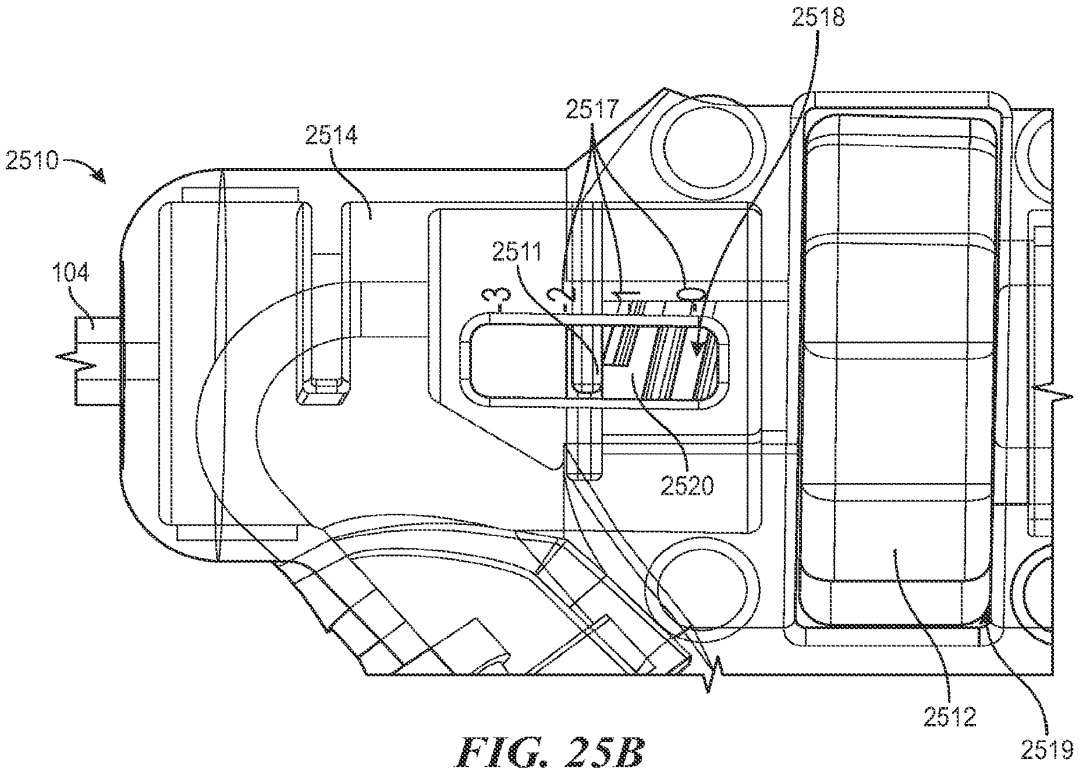



*FIG. 25B*

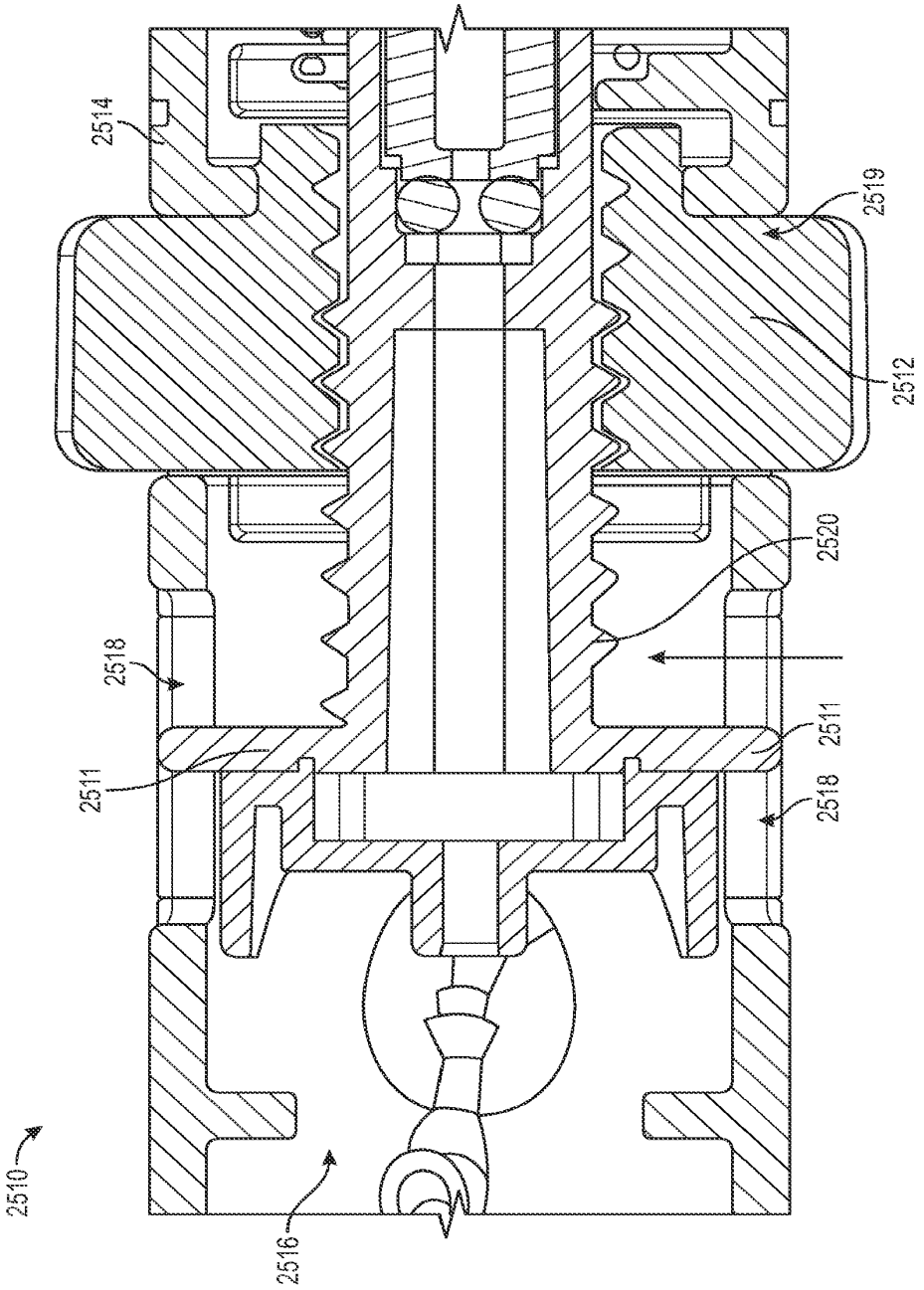



FIG. 25C

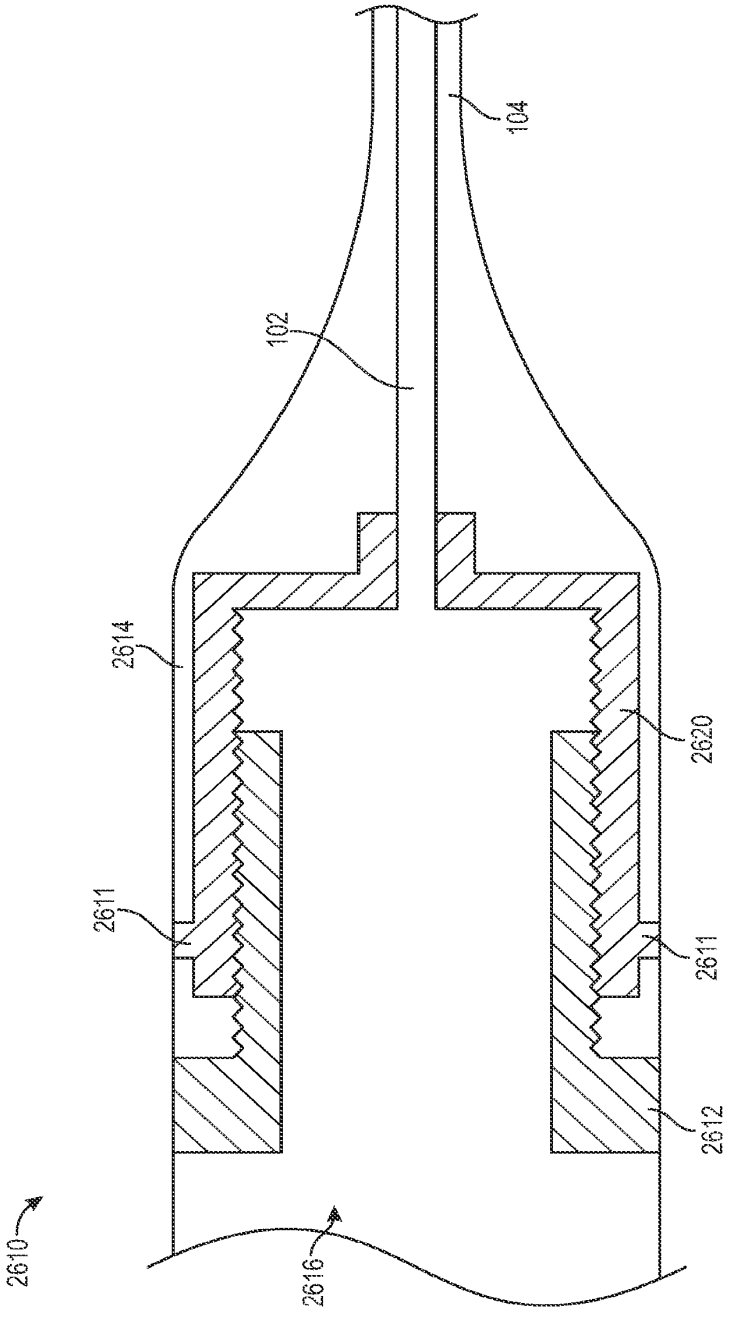



*FIG. 26*

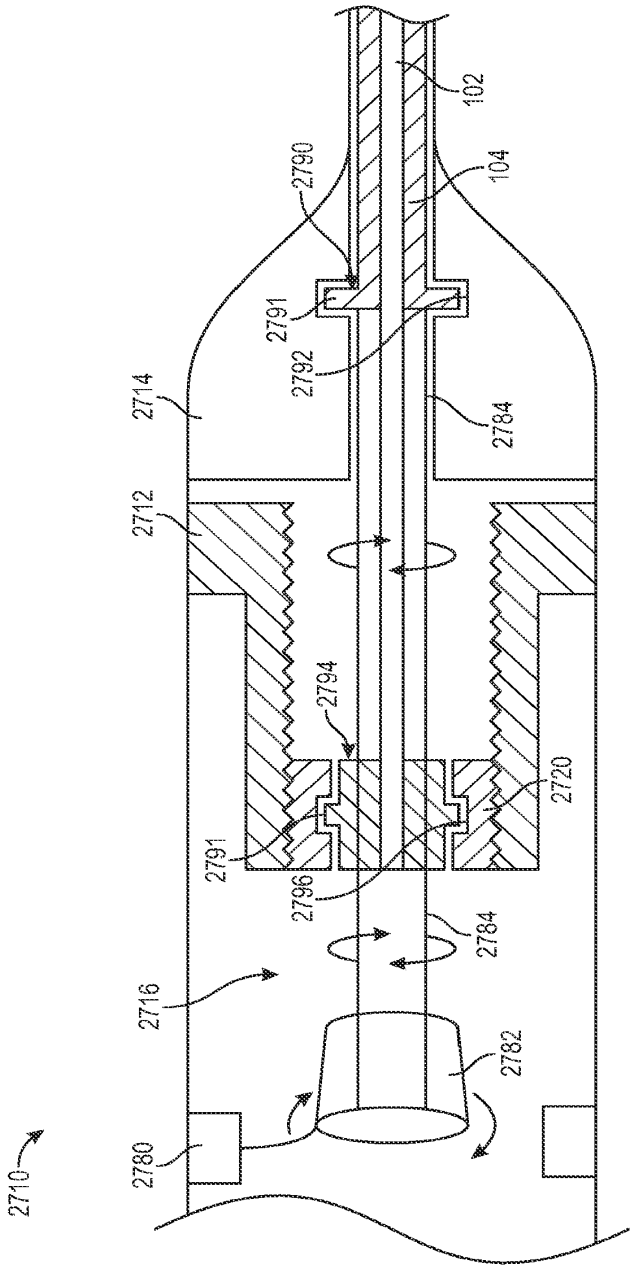

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*FIG. 27*

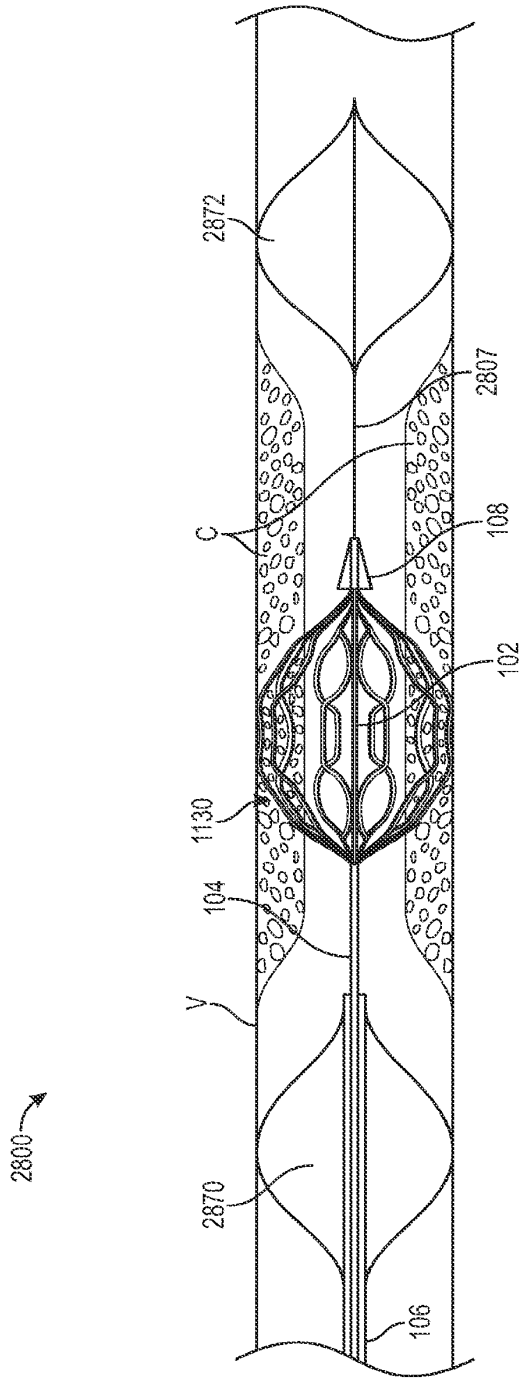



*FIG. 28*

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 23/60502

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61B 17/22, A61B 17/221 (2023.01)
ADD.

CPC - INV. A61B 17/221
ADD. A61B 2017/2212

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 9,301,769 B2 (Brady et al.) 05 April 2016 (05.04.2016), entire document | 1-13, 15-20 |
| --- | | --- |
| Y | | 14 |
| Y | US 2021/0393278 A1 (O'Malley et al.) 23 December 2021 (23.12.2021), entire document | 14 |
| A | US 2021/0038385 A1 (Popp et al.) 11 February 2021 (11.02.2021), entire document | 1-20 |
| A | US 2005/0203605 A1 (Dolan) 15 September 2005 (15.09.2005), entire document | 1-20 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 22 March 2023 | MAY 25 2023 |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | Authorized officer<br>Kari Rodriquez<br>Telephone No. PCT Helpdesk: 571-272-4300 |

Form PCT/ISA/210 (second sheet) (July 2022)

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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| **PATENT APPLICATION FEE DETERMINATION RECORD**<br>Substitute for Form PTO-875 | Application or Docket Number<br>17/498,642 | Filing Date<br>10/11/2021 | ☐ To be Mailed |
|---|---|---|---|

**ENTITY:** ☑ LARGE ☐ SMALL ☐ MICRO

**APPLICATION AS FILED - PART I**

| FOR | (Column 1)<br>NUMBER FILED | (Column 2)<br>NUMBER EXTRA | | RATE ($) | FEE ($) |
|---|---|---|---|---|---|
| ☐ BASIC FEE<br>(37 CFR 1.16(a), (b), or (c)) | N/A | N/A | | N/A | |
| ☐ SEARCH FEE<br>(37 CFR 1.16(k), (i), or (m)) | N/A | N/A | | N/A | |
| ☐ EXAMINATION FEE<br>(37 CFR 1.16(o), (p), or (q)) | N/A | N/A | | N/A | |
| TOTAL CLAIMS<br>(37 CFR 1.16(i)) | minus 20 = | * | | x $100 = | |
| INDEPENDENT CLAIMS<br>(37 CFR 1.16(h)) | minus 3 = | * | | x $480 = | |
| ☐ APPLICATION SIZE FEE (37 CFR 1.16(s)) | If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). | | | | |
| ☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j)) | | | | | |
| * If the difference in column 1 is less than zero, enter "0" in column 2. | | | | TOTAL | |

**APPLICATION AS AMENDED - PART II**

| AMENDMENT | 08/29/2023 | (Column 1)<br>CLAIMS REMAINING AFTER AMENDMENT | | (Column 2)<br>HIGHEST NUMBER PREVIOUSLY PAID FOR | (Column 3)<br>PRESENT EXTRA | | RATE ($) | ADDITIONAL FEE ($) |
|---|---|---|---|---|---|---|---|---|
| | Total<br>(37 CFR 1.16(i)) | * 34 | Minus | ** 21 | = 13 | | x $100 = | 1300 |
| | Independent<br>(37 CFR 1.16(h)) | * 1 | Minus | *** 3 | = 0 | | x $480 = | 0 |
| | ☐ Application Size Fee (37 CFR 1.16(s)) | | | | | | | |
| | ☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) | | | | | | | |
| | | | | | | | TOTAL ADD'L FEE | 1300 |

| AMENDMENT | | (Column 1)<br>CLAIMS REMAINING AFTER AMENDMENT | | (Column 2)<br>HIGHEST NUMBER PREVIOUSLY PAID FOR | (Column 3)<br>PRESENT EXTRA | | RATE ($) | ADDITIONAL FEE ($) |
|---|---|---|---|---|---|---|---|---|
| | Total<br>(37 CFR 1.16(i)) | * | Minus | ** | = | | x $0 = | |
| | Independent<br>(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 | |

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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
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| | **Attorney Docket Number** | 111552-8023.US02 |

| U.S. PATENTS AND PUBLICATIONS | | | | | |
|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | 1. | 11648028 | 05-16-2023 | Rosenbluth et al. | |
| | 2. | 5030201 | 07-09-1991 | Palestrant | |
| | 3. | 11642209 | 05-09-2023 | Merritt et al. | |
| | 4. | 6540722 | 04-01-2003 | Boyle et al. | |
| | 5. | 7678131 | 03-16-2010 | Muller | |
| | 6. | 9301769 | 04-05-2016 | Brady et al. | |
| | 7. | 20210393278 | 12-23-2021 | O'MALLEY et al. | |
| | 8. | 20210038385 | 02-11-2021 | Popp et al. | |
| | 9. | 20050203605 | 09-15-2005 | Dolan | |
| | 10. | 6152144 | 11-28-2000 | Lesh et al. | |
| | 11. | 9011551 | 04-21-2015 | Oral et al. | |
| | 12. | 8647367 | 02-11-2014 | Kassab et al. | |
| | 13. | 11166703 | 11-09-2021 | Kassab et al. | |
| | 14. | 8834519 | 09-16-2014 | van der Burg et al. | |
| | 15. | 7713282 | 05-11-2010 | Frazier et al. | |
| | 16. | 8080032 | 12-20-2011 | van der Burg et al. | |
| | 17. | 7722641 | 05-25-2010 | van der Burg et al. | |
| | 18. | 8523897 | 09-03-2013 | van der Burg et al. | |
| | 19. | 8535343 | 09-17-2013 | van der Burg et al. | |
| | 20. | 7152605 | 12-26-2006 | Khairkhahan et al. | |
| | 21. | 9168043 | 10-27-2015 | van der Burg et al. | |
| | 22. | 7128073 | 10-31-2006 | van der Burg et al. | |
| | 23. | 10772636 | 09-15-2020 | Kassab et al. | |
| | 24. | 8480708 | 07-09-2013 | Kassab et al. | |
| | 25. | 9717488 | 08-01-2017 | Kassab et al. | |
| | 26. | 8784469 | 07-22-2014 | Kassab | |
| | 27. | 9566073 | 02-14-2017 | Kassab et al. | |
| | 28. | 20160192912 | 07-07-2016 | Kassab et al. | |
| | 29. | 20160030708 | 02-04-2016 | Casiello et al. | |
| | 30. | 20160135829 | 05-19-2016 | Holoehwost et ah | |
| | 31. | 20060264905 | 11-23-2006 | Eskridge et al. | |

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
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| | **Attorney Docket Number** | 111552-8023.US02 |

| U.S. PATENTS AND PUBLICATIONS | | | | | |
|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | 32. | 5244619 | 09-14-1993 | Burnham | |
| | 33. | 20170021130 | 01-26-2017 | Dye | |
| | 34. | 20160106353 | 04-21-2016 | Schuetz et al. | |
| | 35. | 10960114 | 03-30-2021 | Goisis | |
| | 36. | 10531883 | 01-14-2020 | Deville et al. | |
| | 37. | 9581942 | 02-28-2017 | Shippert | |
| | 38. | 5234403 | 08-10-1993 | Yoda et al. | |
| | 39. | 20100106081 | 04-29-2010 | Brandeis | |
| | 40. | 20100094201 | 04-15-2010 | Mallaby | |
| | 41. | 20050004534 | 01-06-2005 | Lockwood et al. | |
| | 42. | 20190365395 | 12-05-2019 | Tran et al. | |
| | 43. | 20160038267 | 02-11-2016 | ALLEN et al. | |
| | 44. | 20140222070 | 08-07-2014 | BELSON et al. | |
| | 45. | 20130204297 | 08-08-2013 | Melsheimer et al. | |
| | 46. | 11697012 | 07-11-2023 | Merritt et al. | |
| | 47. | 11697011 | 07-11-2023 | Merritt et al. | |
| | 48. | 20230218310 | 07-13-2023 | Scheinblum et al. | |
| | 49. | 20230218383 | 07-13-2023 | Merritt et al. | |
| | 50. | 20230218313 | 07-13-2023 | Rosenbluth et al. | |
| | 51. | 20230200970 | 06-29-2023 | Merritt et al. | |
| | 52. | 20140324091 | 10-30-2014 | Rosenbluth et al. | |
| | 53. | 20150018859 | 01-15-2015 | Quick et al. | |
| | 54. | 20150196744 | 07-16-2015 | Aboytes | |
| | 55. | 20160367285 | 12-22-2016 | Sos | |
| | 56. | 20130144326 | 06-06-2013 | Brady et al. | |
| | 57. | 20140005715 | 01-02-2014 | Castella et al. | |
| | 58. | 20140180397 | 06-26-2014 | Gerberding et al. | |
| | 59. | 20150150672 | 06-04-2015 | Ma | |
| | 60. | 20130030460 | 01-31-2013 | Marks et al. | |
| | 61. | | | | |
| | 62. | | | | |

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
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| | **Examiner Name** | Tuan Van Nguyen |
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**FOREIGN PATENT DOCUMENTS**

| Examiner Initial* | Cite No | Foreign Document Number[3] | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[5] |
|---|---|---|---|---|---|---|
| | 1. | WO2016014955 | 01-28-2016 | OSTEOMEDIX, INC. | | |
| | 2. | EP2942624 | 11-11-2015 | Kim, Hong | | |
| | 3. | WO2006029270 | 03-16-2006 | SMITH & NEPHEW, INC. | | |

**NON-PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T[5] |
|---|---|---|---|
| | | International Search Report and Written Opinion for International App. No. PCT/US23/60502; Date of Filing: January 11, 2023, Applicant: Inari Medical, Inc., Date of Mailing: May 25, 2023, 9 pages. | |
| | | International Search Report and Written Opinion for International App. No. PCT/US23/61256; Date of Filing: January 25, 2023, Applicant: Inari Medical, Inc., Date of Mailing: June 7, 2023, 8 pages. | |
| | | Gross et al., "Dump the pump: manual aspiration thrombectomy (MAT) with a syringe is technically effective, expeditious, and cost-efficient," J NeuroIntervent Surg, 2018, 4 pages. | |
| | | | |

**EXAMINER SIGNATURE**

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| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

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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).

**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.

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

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

## 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.

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| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2023-07-18 |
| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

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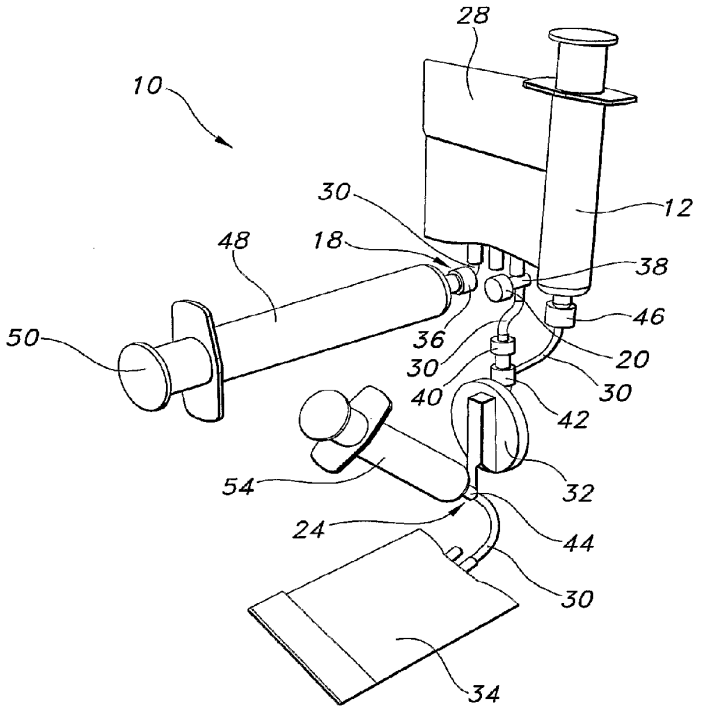
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(54) Title: METHODS AND DEVICES FOR STERILE FIELD TRANSFER




(57) Abstract: Devices and methods for facilitating the transfer of at least a component of a material into a sterile vessel (12). Such devices and methods may utilize a housing (14) at least partially enclosing the sterile vessel to facilitate maintaining the sterility of the vessel before and during the transfer of the at least a component of a material into the sterile vessel.

WO 2006/029270 A1

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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# METHODS AND DEVICES FOR STERILE FIELD TRANSFER

## RELATED APPLICATIONS

This application claims the benefit of United States Provisional Patent Application Serial No. 60/607,631, entitled "Sterile Field Transfer Method and Design" filed September 7, 2004, the entire contents of which are hereby incorporated by this reference.

## RELATED FIELDS

Embodiments of the present invention relate to methods and devices for transferring at least a component of a material into a sterile vessel for use in a sterile field.

## BACKGROUND

It is often necessary to ensure that items used in a sterile field, such as an operating room, research & development facility, or other sterile environment, are themselves sterile. Instruments, devices, containers, implants and other items intended for use in the sterile field may require sterilization and may need to be maintained in a sterile condition. Items that are non-sterile, or that potentially have contacted other non-sterile items or non-sterile persons (such as doctors, technicians or nurses who have come into contact with non-sterile items), may be unacceptable for use in the sterile field. Accordingly, doctors, nurses, technicians and other individuals working in or around sterile fields must follow strict guidelines and procedures for ensuring the sterility of items brought into and/or used in the sterile field. Some of the current sterilization procedures and guidelines, however, are undesirable, burdensome and inefficient.

For example, typical procedures for collecting and transporting blood platelets into a sterile field may be undesirable, as those procedures may require the transfer of the platelets between a number of different containers and devices. Typically, the nurse, technician, doctor or other individual collects a blood sample in a syringe. Next, he or she transfers the blood into a centrifuge. The centrifuge processes the blood to concentrate the blood platelets. Next, the

concentrated blood platelets are collected into another syringe and subsequently transferred into a sterile cup. The sterile cup is finally brought into the sterile field where it can be drawn into a sterile syringe. Such a technique is undesirable, as it requires the blood and blood platelets to be transferred multiple times from vessel to vessel in a manner that is inefficient and subject to spillage or even accidental contamination.

Other procedures, techniques and guidelines for ensuring the sterility of items used in sterile fields may also be undesirable, burdensome and inefficient.

## SUMMARY

Embodiments of the present invention provide safe and efficient methods and devices for transferring a material or a component of a material from a non-sterile vessel or potentially non-sterile vessel into a sterile vessel, while maintaining the sterility of the sterile vessel. Embodiments of the present invention may be suitable for transferring a wide variety of materials or material components into a sterile vessel, including, but not limited to, blood, blood components (such as platelets or blood plasma), bone cement, ceramics, allogenic bone, autologous bone, bone marrow, other fluids, polymers, composite materials, nanomaterials, or any other material or material component that is intended for use in a sterile field. Devices according to various embodiments of the present invention may also process the materials or material components introduced into the device prior to or during transfer into the sterile vessel. Exemplary processes include, but are not limited to, filtration to separate larger components of a material from smaller components (e.g, filtering blood to separate the platelets from other blood components), mixing materials together, separating materials, reacting various materials together, instrument fabrication, implant fabrication, sterilization or any other process that may be done to a material or a material component prior to use in a sterile field. In other embodiments, devices of the present invention do not process the materials introduced into them at all, but merely facilitate the material transfer into the sterile vessel without affecting the sterility of the sterile vessel.

Devices of the present invention may include a sterile vessel and a housing at least partially enclosing the sterile vessel. The device housing may enclose the sterile vessel to protect the vessel from direct contact with potentially non-sterile persons and items, which could potentially affect the sterility of the sterile vessel and prevent use of the vessel in the sterile field. In some embodiments, the housing may include a cover that limits access to the sterile vessel until the cover is removed or opened. In other embodiments, such a cover is unnecessary.

Devices according to the present invention may also include a material input accessible from outside the housing. The material input may facilitate the introduction of a material into the device, which eventually may be transferred by the device (or a component of the material may be transferred by the device) into the sterile vessel. In some embodiments, the material input interacts with a non-sterile syringe or other vessel external to the device. In some embodiments, the material input is associated with a conduit within the device that conveys the material to various internal components of the device (such as a filter) and to the sterile vessel. In other embodiments, the conduit is integral with the material input and conveys the material directly into the sterile vessel.

Some embodiments of the present invention may also include internal components, such as filters or other components, for processing the inputted material. In some embodiments, the device may also include additional material inputs and/or internal components for introducing and/or processing additional materials in the device. The additional materials introduced may facilitate various processes of the device and/or may facilitate the movement of other materials (or components thereof) within and between various internal components of the device. In other embodiments, the device does not include such components and merely conveys the material directly into the sterile vessel.

In some embodiments, the device is disposed of after use and is made with relatively inexpensive materials.

## STATEMENT OF THE INVENTION

Accordingly, embodiments of the present invention provide for a device for facilitating the transfer of at least a component of a material into a sterile vessel, characterized in that the device comprises: a sterile vessel; a housing at least partially enclosing the sterile vessel; a material input for facilitating the input of a material into the device, the material input accessible from outside the housing; and a conduit for guiding movement of at least a component of the material from the material input to the sterile vessel.

More preferably, embodiments of the present invention provide for a device further characterized in that the housing comprises a cover and wherein moving the cover facilitates accessing the sterile vessel.

Even more preferably, embodiments of the present invention provide for a device further characterized in that the cover is at least temporarily sealed on the device.

Also even more preferably, embodiments of the present invention provide for a device further characterized in that the cover comprises a removable cap or a moveable hatch.

Yet even more preferably, embodiments of the present invention provide for a device further characterized in that the housing comprises an at least semi-transparent window.

Also even more preferably, embodiments of the present invention provide for a device further characterized in that the housing comprises at least one actuator for actuating at least one valve, the at least one valve for at least partially regulating the movement of the at least a component of a material through the conduit.

Also more preferably, embodiments of the present invention provide for a device further characterized in that the device comprises a reservoir associated with the conduit.

Even more preferably, embodiments of the present invention provide for a device further characterized in that the reservoir is associated with the material input and receives material from the material input.

Also more preferably, embodiments of the present invention provide for a device further characterized in that the device comprises a filter for separating the component from a second component of the material.

Even more preferably, embodiments of the present invention provide for a device further characterized in that the conduit directs the component into the sterile vessel.

Yet even more preferably, embodiments of the present invention provide for a device further characterized in that the device comprises a second material input for receiving a second material, wherein introduction of the second material into the device facilitates moving the component from the filter to the sterile vessel.

Also yet even more preferably, embodiments of the present invention provide for a device further characterized in that the device comprises a second reservoir for collecting the second component from the filter.

Other embodiments of the present invention provide for a method for facilitating the transfer of at least a component of a material into a sterile field, characterized in that the method comprises: collecting a material into a vessel; transferring the material from the vessel into a device, characterized in that the device comprises: a sterile vessel; and a housing at least partially enclosing the sterile vessel; transporting the sterile vessel into a sterile field; and removing the sterile vessel from the device.

More preferably, embodiments of the present invention provide for a method further characterized in that the sterile vessel is transported into the sterile field prior to removing the sterile vessel from the device.

Also more preferably, embodiments of the present invention provide for a method further characterized in that the sterile vessel is removed from the device prior to transporting the sterile vessel into the sterile field.

Also more preferably, embodiments of the present invention provide for a method further characterized in that removing the sterile vessel from the device comprises moving a cover of the housing of the device to access the sterile vessel.

Even more preferably, embodiments of the present invention provide for a method further characterized in that moving the cover comprises removing the cover from the device.

Also even more preferably, embodiments of the present invention provide for a method further characterized in that moving the cover comprises opening a hatch.

Also more preferably, embodiments of the present invention provide for a method further characterized in that the method comprises filtering the material to separate the material into a first component and a second component.

Also more preferably, embodiments of the present invention provide for a method further characterized in that the method comprises disposing of the device.

## BRIEF DESCRIPTION OF FIGURES

Figure 1 is a schematic of a device according to a first embodiment of the present invention.

Figure 2 is a perspective view of a device according to another embodiment of the present invention, shown without the device's housing.

Figure 3 is a perspective view of a device according to another embodiment of the present invention, shown without the device's housing.

Figure 4 is a perspective view of a device according to another embodiment of the present invention, shown without the device's housing.

Figure 5(a) is a perspective view of the exterior of a device according to another embodiment of the present invention.

Figure 5(b) is a side view of the device of Fig. 5(a).

Figure 6(a) is a perspective view of the exterior of a device according to another embodiment of the present invention.

Figure 6(b) is a side view of the device of Fig. 6(a).

Figure 6(c) is a rear perspective view of the device of Fig. 6(a).

Figure 7(a) is a perspective view of the exterior of a device according to another embodiment of the present invention.

Figure 7(b) is a side view of the device of Fig. 7(a).

Figure 8(a) is a perspective view of the exterior of a device according to another embodiment of the present invention.

Figure 8(b) is a side view of the device of Fig. 8(a).

Figure 9(a) is a perspective view of the exterior of a device according to another embodiment of the present invention.

Figure 9(b) is a side view of the device of Fig. 9(a).

## DETAILED DESCRIPTION OF FIGURES

Fig. 1 shows a device 10 in accordance with embodiments of the present invention. In the configuration shown in Fig. 1, device 10 includes a sterile vessel 12, a housing 14 (which includes a cover 16), a material input 18, an actuator 20, a window 22, a second material input 24, a base 26, and a seal 100. In other embodiments, some or all of these features are unnecessary and/or are present in different configurations, positions, orientations, shapes and sizes.

The sterile vessel 12 shown in Fig. 1 is a syringe, however, sterile vessel may be any vessel suitable for receiving materials or components of materials, including test tubes, beakers, vials, IV bags, sample holders, pails, cups, bowls, trays, or gloved hands. Sterile vessel 12 may be sterilized prior to installation in device 10 or sterilized along with the rest of device 10 or components of device 10. Sterile vessel 12 (and other components of device 10 if desired or required) may be sterilized in any suitable procedure or technique, including, but not limited to, gas sterilization or gamma radiation. In other embodiments, it is unnecessary to subject sterile vessel 12 and/or other components of device 10 to a sterilization procedure and/or the sterile vessel may have been maintained in a sterile condition since its manufacture.

The housing 14 shown in Fig. 1 encloses sterile vessel 12. Housing 14 is preferably formed from a plastic, such as polycarbonate, however, housing 14 may be formed from other materials if desired. In some embodiments, it is desirable to form housing 14 (and other components of device 10) from relatively inexpensive materials, as device 10 may be intended to be disposable or intended for "one time use" in some configurations.

Because the housing 14 shown in Fig. 1 encloses sterile vessel 12, the sterility of vessel 12 may be preserved even if device 10 is used in non-sterile fields or comes into contact with non-sterile persons or things. In the embodiment of Fig. 1, the housing 14 (which includes the cover 16 in the configuration shown in Fig. 1) preserves the sterility of vessel 12 until such time as cover 16 is removed or repositioned to allow access to sterile vessel 12 by a sterile nurse, doctor, technician or other individual for use in a sterile field. In some embodiments, a non-sterile individual will remove or reposition the cover 16 and a sterile individual will remove the sterile vessel 12 such that the vessel 12 does not contact non-sterile persons or things and such that the sterile person does not contact the potentially non-sterile housing 14 of device 10. In other embodiments, device 10 may be configured to automatically move the cover 16 or otherwise facilitate access to sterile vessel 12 after the occurrence of one or more events. For instance, in some embodiments, the transfer or completion of transfer of a material into sterile vessel 12 may trigger the device 10 to automatically move the cover 16 or otherwise facilitate accessing vessel 12.

In some embodiments, one person will transport the device 10 into the sterile field and the sterile person will remove the sterile vessel 12. In other embodiments, the sterile person will remove the sterile vessel 12 from the device 10 outside of the sterile field, and then enter the sterile field with the sterile vessel 12.

As shown in Fig. 1, cover 16 is a removable lid. In other embodiments, a cover 16 similar to the one shown in Fig. 1 can be used in conjunction with the devices 10 shown in Figs. 5(a), 5(b), 7(a), 7(b), 8(a), 8(b), 9(a) and 9(b), although the devices 10 shown in these Figures may not necessarily require such a cover in all embodiments. In still other embodiments, such as shown in Fig. 6(c), cover 16 may be a hatch mounted to device 10 in a rotating fashion.

As shown in Fig. 1, cover 16 includes a removable or breakable seal 100 for indicating whether sterile vessel 12 has been previously accessed or tampered with (indicating a potential loss of sterility). A user (in some embodiments, the non-sterile nurse, doctor, technician or other non-sterile individual) may break or remove the seal 100 and remove or reposition the cover

16 to allow access to sterile vessel 12. The seal 100 may be any desired mechanism, structure, device or item for sealing cover 16 onto device 10, including frangible tabs, adhesive tape, gaskets, tamper indicating mechanisms, or any other suitable structure or mechanism for sealing cover 16 prior to removal or repositioning. Fig. 1 shows seal 100 as an adhesive tape at least partially encircling the connection between cover 16 and the rest of housing 14. In still other embodiments, a separate mechanism, structure, device or item is not necessary to seal cover 16 to the rest of housing 14 and the cover is formed integrally with the rest of housing 14. In such embodiments, cover 16 may be punctured, broken or otherwise destroyed once it is desired to access sterile vessel 12. In other embodiments, a seal is unnecessary.

In yet other embodiments, cover 16 is unnecessary. For example, the housing 14 may include an aperture in which sterile vessel 12 is located. Sterile vessel 12 may be positioned deep enough within the housing 14 such that non-sterile persons or things cannot easily contact sterile vessel 12. In such embodiments, device 10 may include a slider or other mechanism for facilitating access to the sterile vessel 12 at the appropriate time. For example, in some embodiments, actuation of the slider may raise sterile vessel 12 into an accessible position. In other embodiments, as the sterile vessel 12 fills with material (described further below), a plunger of the vessel may extend outside of the housing, allowing a sterile nurse, doctor or technician to grasp the end of the plunger and remove sterile vessel 12 from device 10. In some embodiments, the housing 14 may include a plastic film over the aperture or other portions of the housing 14, such that breaking the film allows access to the vessel 12.

The device 10 of Fig. 1 also includes a material input 18. As discussed above, material may be any material that a user desires to transfer into a sterile vessel 12, including blood, blood components (such as platelets or blood plasma), bone cement, ceramics, allogenic bone, autologous bone, bone marrow, other fluids, or any other material. Material input 18 may be configured to receive and convey any desired material into device 10. In one embodiment, material input 18 includes an aperture that corresponds to the size and shape of a syringe tip such that material input 18 receives the tip in a manner that substantially

prevents leakage. In some embodiments, material input 18 is an aperture in housing 14 that allows the syringe or other vessel to interact with internal components such that the syringe can introduce material into device 10. Material input 18 may also include a gasket or other appropriate structures or mechanisms for lessening the chance of leakage. In other embodiments, material input 18 does not interact with a syringe to receive material, but is sized, shaped and positioned for material to be poured directly into material input 18. For example, in some embodiments, material input 18 may be a funnel.

In still other embodiments, material input 18 may comprise other structures or mechanisms for facilitating the input of material into device 10. Additionally, material input 18 may or may not include a check valve or other appropriate structures and mechanisms for preventing material from flowing back out of material input. In some embodiments, material input 18 may include a filter, such as a screen, or other structure for separating impurities or other things from material during input into device 10.

The device 10 shown in Fig. 1 also includes an actuator 20. The actuator 20 may be a slide (such as shown in Figs. 1 and 5(a)), a knob, a button (such as shown in Figs. 6(a), 7(a), 8(a) and 9(a)) or other suitable structure or mechanism for commencing processes or otherwise affecting structures inside device 10, some examples of which are discussed further below. Although Fig. 1 shows device 10 as only including a single actuator 20, devices 10 in accordance with embodiments of this invention may include any number of actuators 20 for controlling or affecting various internal components of device 10. In still other embodiments, an actuator 20 is unnecessary.

The device 10 of Fig. 1 also includes a window 22. In some embodiments, window 22 may be a transparent or semi-transparent window. Window 22 may allow viewing of one or more of the internal components of device 10 and/or the progress of the inputted material through the same. As shown in Figs. 1, 5(a), 6(a), 7(a), 8(a) and 9(a), the size, shape, number and position of windows 22 may be varied to facilitate viewing various interior portions and/or components of device 10. In other embodiments, window 22 is unnecessary and/or other features of device 10 indicate the progress of the inputted material through

device 10. For example, sterile vessel 12 may include a plunger that extends as material fills the vessel 12, which may roughly indicate the amount of material that has moved into the vessel. In some embodiments, device 10 does not include any features or components for indicating the progress of material through device 10.

In the configuration shown in Fig. 1, device 10 includes a second material input 24. Like embodiments of material input 18 described above, second material input 24 may interact with the tip of a syringe 54 (shown in Figs. 2 – 4) to receive and convey a material into device 10 or may include other structures and mechanisms as discussed above for material input 18. Second material input 24 is also discussed further below.

In the configuration shown in Fig. 1, device 10 also includes a base 26. Base 26 may maintain the device 10 in an upright orientation when placed on a surface. Moreover, if desired, a user may push down on base 26 to stabilize device 10 during use. As shown in Figs. 5(a) – 9(b), base 26 may be formed in a wide variety of shapes, sizes and configurations.

The devices 10 shown in Figs. 1 – 9(b) are configured to separate the platelet component of a blood material and transfer those platelets into sterile vessel 12. Devices 10 in accordance with other embodiments of the present invention, however, may be configured to perform a wide variety of processes on a wide variety of materials. Exemplary processes include, but are not limited to, filtering, mixing, separating, reacting, fabrication, or sterilization. In still other embodiments, device 10 does not process the inputted material at all, but merely transfers the material into sterile vessel 12. Exemplary materials useable in conjunction with devices 10 in accordance with the present invention are discussed above.

Figs. 2 - 4 illustrate various configurations of internal components of device 10 for filtering and transferring the blood platelet component of an inputted blood material into sterile vessel 12. As shown in Figs. 2 - 4, the locations and orientations of the internal components can be varied based on the shape and size of housing 14 (e.g., the configuration of Fig. 2 may be suitable for the housings 14 of Figs. 5(a), 5(b), 7(a), 7(b), 8(a) and 8(b), the configuration of Fig.

3 may be suitable for the housing 14 of Figs. 6(a), 6(b) and 6(c), and the configuration of Fig. 4 may be suitable for the housing 14 of Figs. 9(a) and 9(b)). In the configurations shown in Figs. 2 - 4, device 10 includes the following internal components: material reservoir 28, conduits 30, filter 32, waste reservoir 34, and various valves 36, 38, 40, 42, 44 and 46. Device 10 configurations in accordance with other embodiments of the present invention may exclude some or all of these components and/or include other components.

In the configurations of Figs. 2 – 4, introduction of blood material into device 10 via material input 18 (as discussed above) directs the material into material reservoir 28. Syringe 48 interacts with material input 18 to facilitate the introduction of blood material into device 10 in the embodiments of Figs. 2 – 4, however, other vessels, devices or methods can also be used to introduce a material into devices 10 in accordance with the present invention (some examples of which, but not all, are discussed above). In the configurations of Figs. 2 – 4, depressing a plunger 50 associated with the syringe 48 may increase the pressure on blood material within syringe 48, causing it to flow through material input 18 into material reservoir 28.

Figs. 2 – 4 show a conduit 30 for directing material from syringe 48 into material reservoir 28. Other portions of conduit 30 shown in Figs. 2 – 4 direct the movement of materials and components of materials between other components of device 10. In the embodiments shown in Figs. 2 – 4, conduit 30 is a plastic tubing, although in other embodiments, conduit 30 may be any suitable device, structure or mechanism for containing and/or facilitating the movement of material between various components of device 10. In some embodiments, integral portions of material input 18 are a conduit for directing material into material reservoir 28 or other components of device 10.

The devices 10 of Figs. 2 – 4 include a check valve 36 positioned where material is input into material reservoir 28. Check valve 36 may regulate the flow of material such that material can enter material reservoir 28 through check valve 36, but may not exit material reservoir 28 through check valve 36. Check valve 36 may prevent leakage of material from device 10 once the material has entered material reservoir 28. In other embodiments, check valve 36 is unnecessary. For

example, material reservoir 28 may be a sufficient size to contain the material from syringe 48 and/or may include the material input at an upper portion of the reservoir to lessen the chance of undesired leakage.

In still other embodiments, material reservoir 28 is unnecessary and the introduced blood or other material passes directly to other internal components of the device 10 from material input 18 and/or check valve 36.

Figs. 2 – 4 show that material reservoir 28 includes another valve 38 for regulating the movement of material out of the material reservoir 28. Valve 38 may be operatively associated with actuator 20 shown in Fig. 1. Actuation of actuator 20 may open and/or close valve 38. Opening valve 38 may allow material to move from material reservoir 28 to other downstream components of device 10. In the embodiments of Figs. 2 – 4, gravity facilitates moving the material out of material reservoir 28 once valve 38 is opened by actuator 20. In other embodiments, actuator 20 is unnecessary and valve 38 may automatically open once a sufficient amount of material builds up in material reservoir 28. In still other embodiments, valve 38 is unnecessary and material can move directly from material reservoir 28 to down-stream components of device 10.

In the configuration shown in Figs. 2 – 4, once valve 38 opens, material may move from material reservoir 28 into filter 32. In the configurations of Figs. 2 – 4, wherein the material is a blood material, filter 32 may process the blood to separate platelets from other components of the blood. Filter 32 may include a screen having a plurality of apertures that allow smaller components of the blood material to pass through, while retaining the platelets that are too large to pass through the screen. Screens having different sized apertures may be used depending on the size of the components to be retained by filter 32. The components of material that pass through the screen may subsequently be directed by diverter valve 44 (discussed further below) into waste reservoir 34. In other embodiments, filter 32 may include other structures or mechanisms for separating material components from one another.

In other embodiments, the material components that pass through the filter 32 screen may be reserved while the components that are too large to pass through the screen may eventually be directed into a waste reservoir 34 or may

simply remain within the filter 32. In still other embodiments, both the material passing through the filter 32 and the material retained within the filter 32 may be reserved and collected into various vessels. In such embodiments, device 10 may include two sterile vessels to collect both material components.

In the embodiments shown in Figs. 2 – 4, a back-flush procedure may be used to transfer the material components retained in filter 32 into sterile vessel 12. During the back-flush procedure, a back-flush material may be introduced through a second material input 24 and travel through the filter 32 screen in the opposite direction that the blood or other material originally traveled through the filter 32. As the back-flush material travels through the filter 32, it may pick up the platelets or other material components reserved by the filter 32 and carry those reserved components out of the filter 32. The diverter valve 42 (discussed further below) shown in Figs. 2 – 4 may direct the back flush material carrying the reserved component into the sterile vessel. Back-flush material may be any material suitable for carrying the platelets or other material component reserved by filter 32 out of filter 32 and into sterile vessel 12, including, but not limited to, any fluid. Back-flush material may be introduced into device 10 using a syringe 54 or other suitable vessel, device or method. In other embodiments, back-flush procedures and/or back-flush materials are unnecessary.

The diverter valves 42 and 44 shown in Figs. 2 – 4 regulate the direction and sources / destinations of flow through the filter 32. During the filtration process, diverter valve 42 may be positioned to allow material to pass from material reservoir 28 into the filter 32 and diverter valve 44 may be positioned to allow the material components passing through filter 32 to move into waste reservoir 24. During the back-flush procedure, diverter valve 44 may be positioned allow the back-flush material introduced through second material input 24 to pass into filter 32 and diverter valve 42 may be positioned to allow the back-flush material and filtered component to pass into sterile vessel 12. In the embodiments shown in Figs. 2 – 4, device 10 also includes check valve 40, which may prevent back-flush material and the filtered components from entering material reservoir 28.

The diverter valves 42 and 44 shown in Figs. 2 – 4 are configured to automatically switch depending on the direction of flow through the valve body, thereby directing the material or material component to the proper component. In other embodiments, diverter valves 42 and 44 are manually switched using actuators accessible from outside of housing 14. In still other embodiments, diverter valves 42 and 44 and/or check valve 40 may be unnecessary and additional conduit or other structures may be utilized to direct the material flow through the components of device 10 in the proper directions and to the proper destinations.

In the embodiments shown in Figs. 1 and 6(a) – 8(a), device 10 includes indicia 52 for indicating the order of the various steps for processing and/or collecting blood platelets (or other materials or components of materials) into sterile vessel 12.

In some embodiments, device 10 may be disposed of after the removal of sterile vessel 12.

Modifications, additions and deletions may be made to the embodiments described above and shown in the accompanying figures without departing from the scope or spirit of the present invention.

Claims:

1. A device for facilitating the transfer of at least a component of a material into a sterile vessel, characterized in that the device comprises:

(a) a sterile vessel;

(b) a housing at least partially enclosing the sterile vessel;

(c) a material input for facilitating the input of a material into the device, the material input accessible from outside the housing; and

(d) a conduit for guiding movement of at least a component of the material from the material input to the sterile vessel.

2. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 1, further characterized in that the housing comprises a cover and wherein moving the cover facilitates accessing the sterile vessel.

3. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 2, further characterized in that the cover is at least temporarily sealed on the device.

4. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 2, further characterized in that the cover comprises a removable cap or a moveable hatch.

5. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 4, further characterized in that the housing comprises an at least semi-transparent window.

6. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 2, further characterized in that the housing comprises at least one actuator for actuating at least one valve, the at least one valve for at least partially regulating the movement of the at least a component of a material through the conduit.

7. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 1, further characterized in that the device comprises a reservoir associated with the conduit.

8. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 7, further characterized in that the reservoir is associated with the material input and receives material from the material input.

9. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 1, further characterized in that the device comprises a filter for separating the component from a second component of the material.

10. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 9, further characterized in that the conduit directs the component into the sterile vessel.

11. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 10, further characterized in that the device comprises a second material input for receiving a second material, wherein introduction of the second material into the device facilitates moving the component from the filter to the sterile vessel.

12. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 10, further characterized in that the device comprises a second reservoir for collecting the second component from the filter.

13. A method for facilitating the transfer of at least a component of a material into a sterile field, characterized in that the method comprises:

(a) collecting a material into a vessel;

(b) transferring the material from the vessel into a device, characterized in that the device comprises:

(i) a sterile vessel; and

(ii) a housing at least partially enclosing the sterile vessel;

(c) transporting the sterile vessel into a sterile field; and

(d) removing the sterile vessel from the device.

14. The method for facilitating the transfer of at least a component of a material into a sterile field of claim 13, further characterized in that the sterile vessel is transported into the sterile field prior to removing the sterile vessel from the device.

15. The method for facilitating the transfer of at least a component of a material into a sterile field of claim 13, further characterized in that the sterile vessel is removed from the device prior to transporting the sterile vessel into the sterile field.

16. The method for facilitating the transfer of at least a component of a material into a sterile field of claim 13, further characterized in that removing the sterile vessel from the device comprises moving a cover of the housing of the device to access the sterile vessel.

17. The method for facilitating the transfer of at least a component of a material into a sterile field of claim 16, further characterized in that moving the cover comprises removing the cover from the device.

18. The method for facilitating the transfer of at least a component of a material into a sterile field of claim 16, further characterized in that moving the cover comprises opening a hatch.

19. The method for facilitating the transfer of at least a component of a material into a sterile field of claim 13, further characterized in that the method comprises filtering the material to separate the material into a first component and a second component.

20. The method for facilitating the transfer of at least a component of a material into a sterile environment of claim 13, further characterized in that the method comprises disposing of the device.

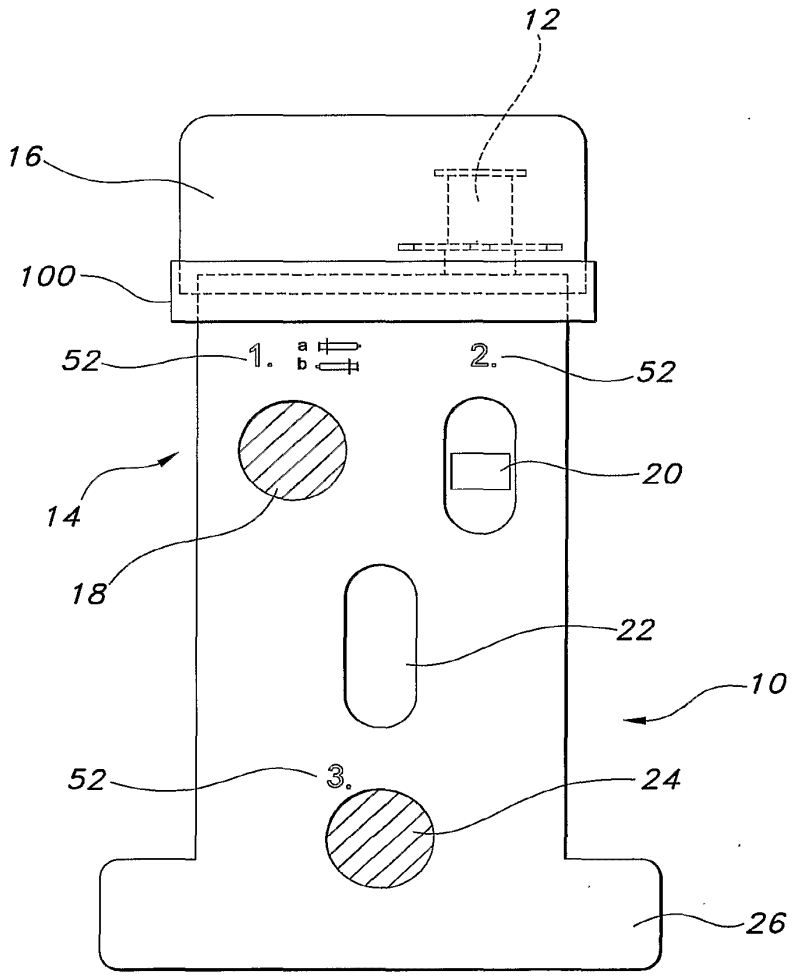



FIG. 1

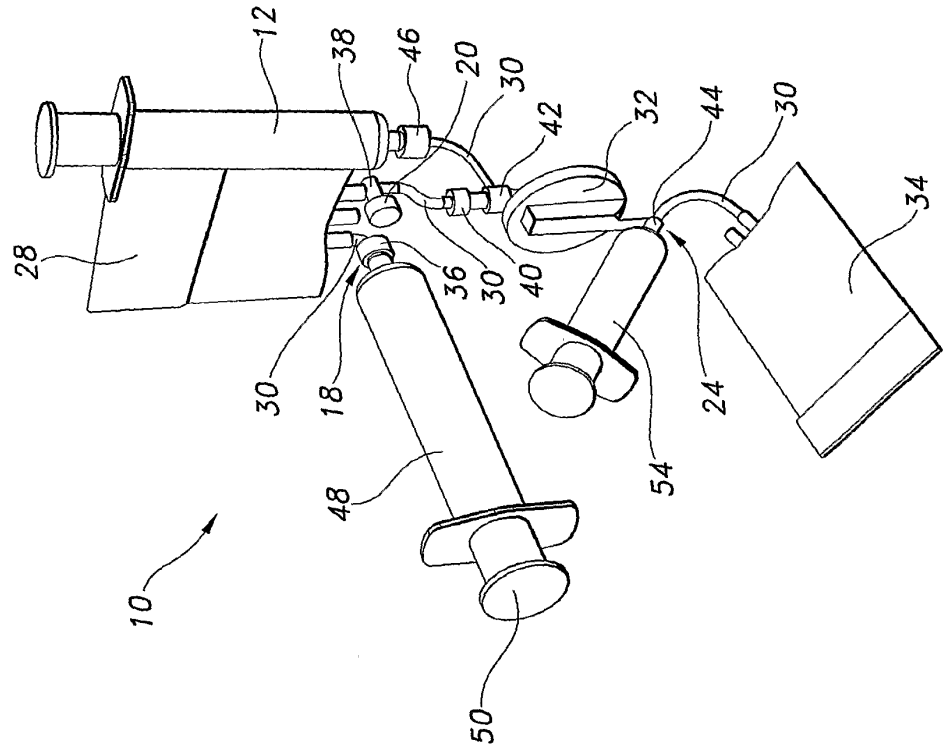



FIG. 2

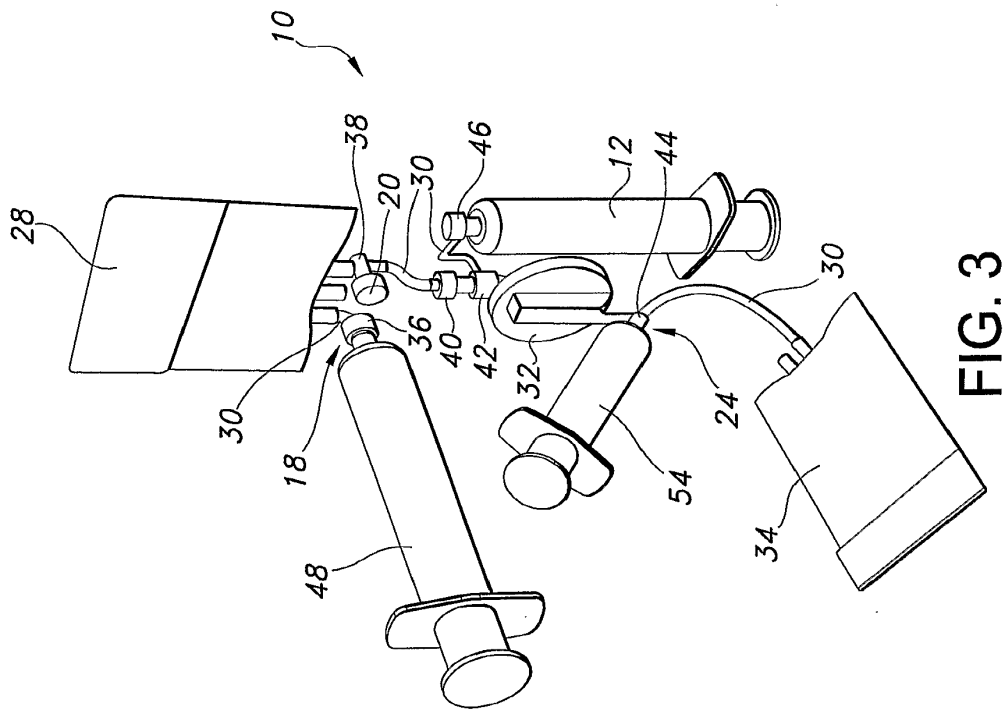



FIG. 3

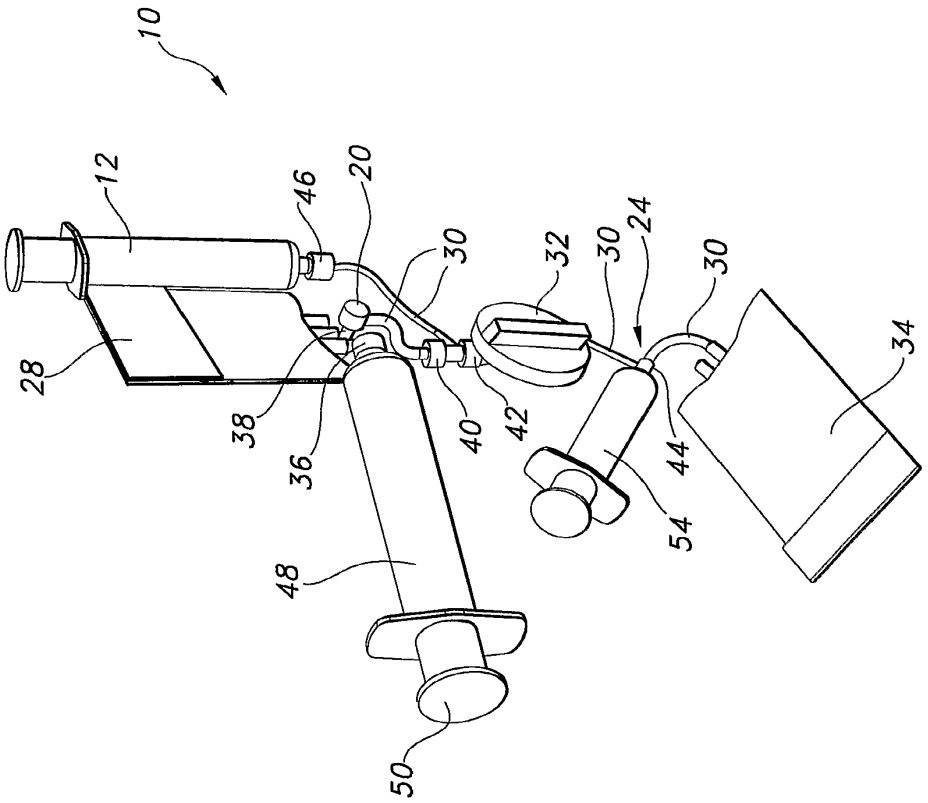



FIG. 4

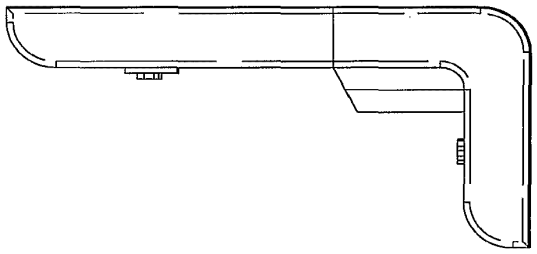


FIG. 5B

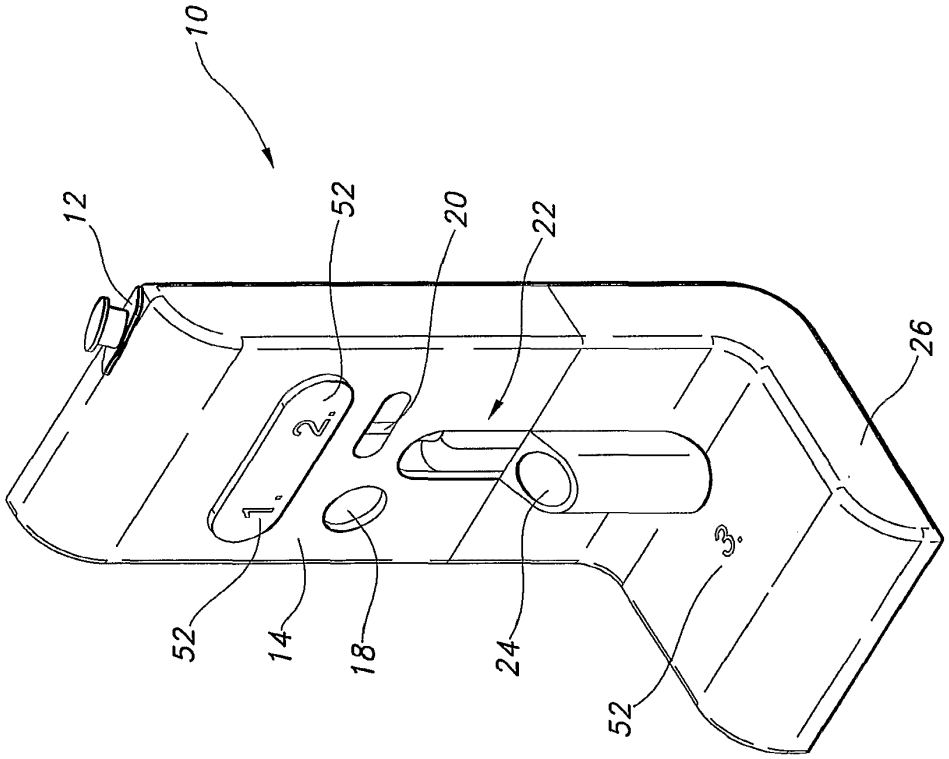



FIG. 5A

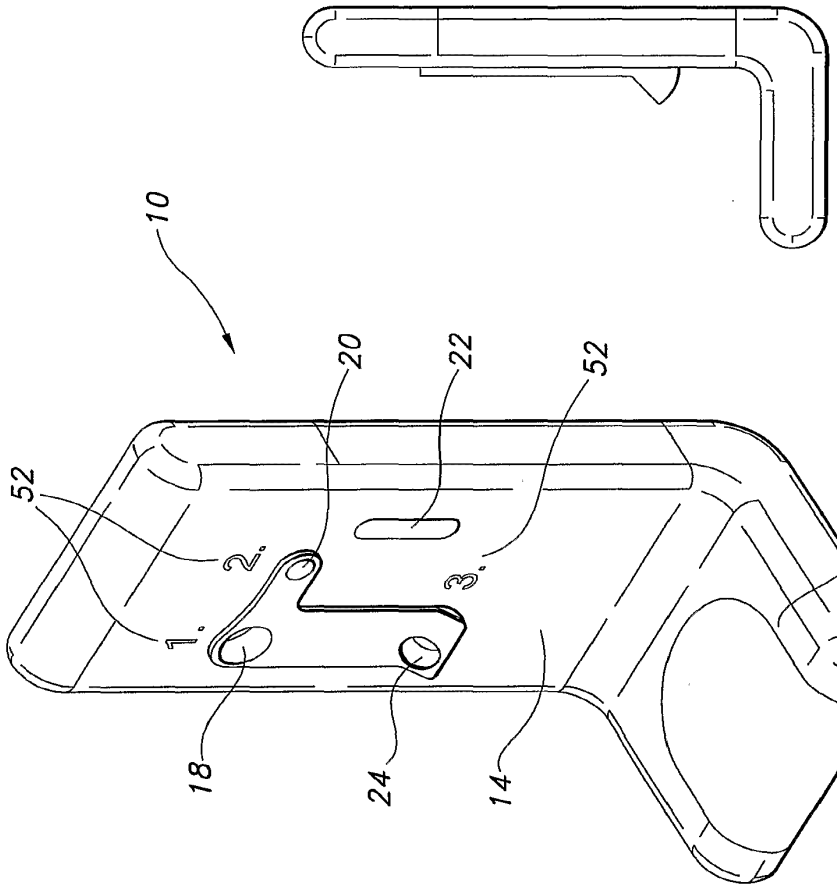



FIG. 6A

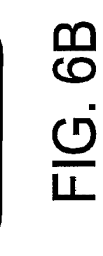


FIG. 6B

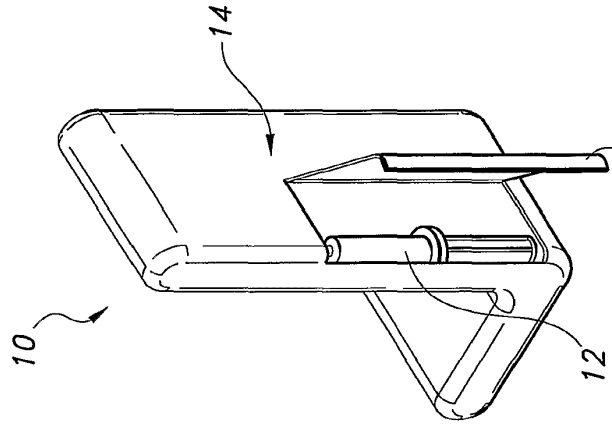



FIG. 6C

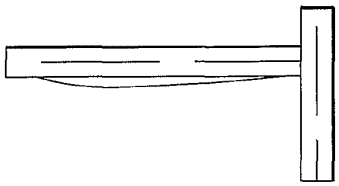


FIG. 7B

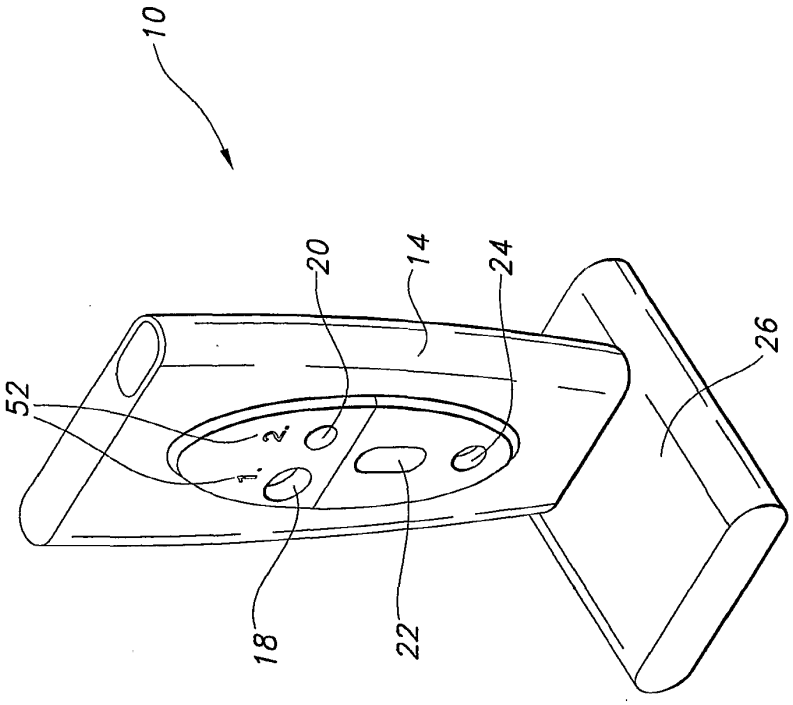



FIG. 7A

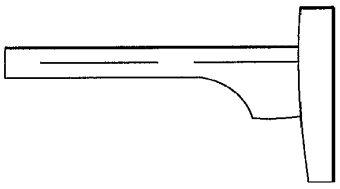


FIG. 8B

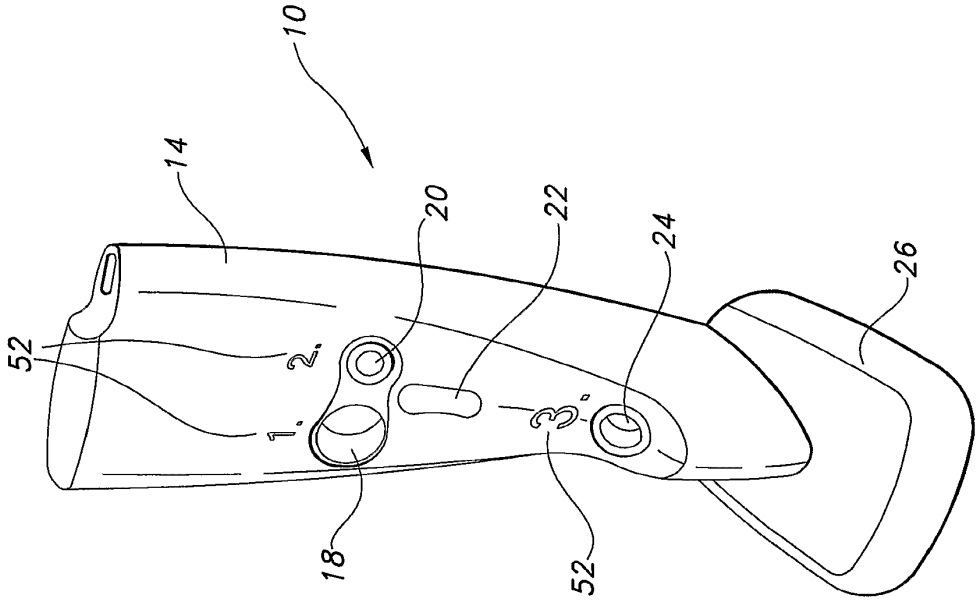



FIG. 8A

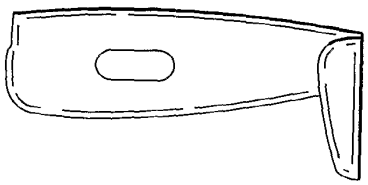


FIG. 9B

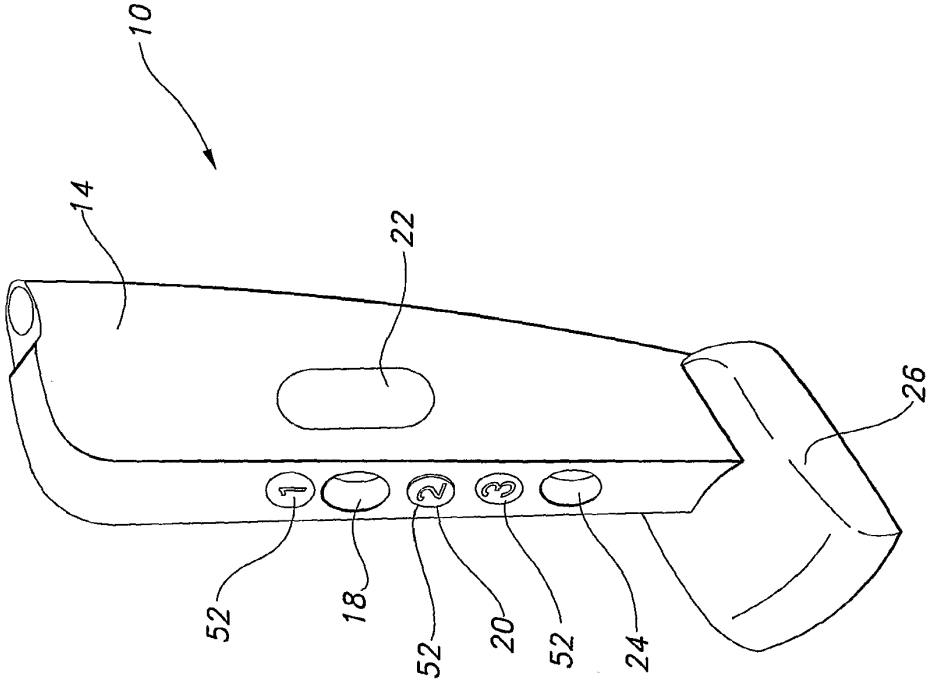



FIG. 9A

# INTERNATIONAL SEARCH REPORT

ıtional Application No
PCT/US2005/032006

A. CLASSIFICATION OF SUBJECT MATTER
B65B3/00

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)
B65B A61J

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 3 685 248 A (JOEZF GUIDO GODELAINE)<br>22 August 1972 (1972-08-22)<br>figures 3,5<br>column 1, line 4 - line 31 | 1-20 |
| X | US 2003/230521 A1 (SCHICK KARL G)<br>18 December 2003 (2003-12-18)<br>figures 1-3<br>paragraph '0027! | 1-20 |
| X | US 5 911 252 A (CASSEL ET AL)<br>15 June 1999 (1999-06-15)<br>column 5, line 11 - line 41<br>figures 1,1a | 1-20 |

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 10 January 2006 | 19/01/2006 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Damiani, A |

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INARI_018154

# INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/032006

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | WO 2004/004802 A (BIOANALYTICAL SYSTEMS, INC; KISSINGER, CANDICE, B; HAMPSCH, JAMES, M;) 15 January 2004 (2004-01-15) figures 1-4 abstract | 1-20 |
| X,P | WO 2004/108533 A (E-Z-EM, INC; HARTMAN, STEVEN; CROSS-HANSEN, ALAN; GODFREY, CLARK; WILL) 16 December 2004 (2004-12-16) the whole document | 1 |

Form PCT/ISA/210 (continuation of second sheet) (January 2004)

# INTERNATIONAL SEARCH REPORT

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PCT/US2005/032006

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| US 3685248 A | 22-08-1972 | BE 741479 A | 16-04-1970 |
| | | DE 2048459 A1 | 19-05-1971 |
| | | FR 2071717 A5 | 17-09-1971 |
| | | GB 1278160 A | 14-06-1972 |
| US 2003230521 A1 | 18-12-2003 | AU 2003238233 A1 | 31-12-2003 |
| | | CA 2489603 A1 | 24-12-2003 |
| | | EP 1525138 A1 | 27-04-2005 |
| | | WO 03106266 A1 | 24-12-2003 |
| | | US 2004155066 A1 | 12-08-2004 |
| US 5911252 A | 15-06-1999 | NONE | |
| WO 2004004802 A | 15-01-2004 | AU 2003247942 A1 | 23-01-2004 |
| | | CA 2491297 A1 | 15-01-2004 |
| | | EP 1539273 A2 | 15-06-2005 |
| WO 2004108533 A | 16-12-2004 | NONE | |

Form PCT/ISA/210 (patent family annex) (January 2004)

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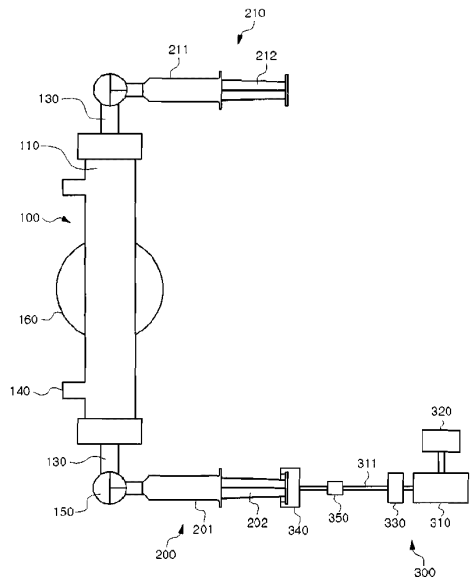
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## (54) Device and method for extracting concentrated plasma

(57) The present invention relates to a device and method for extracting concentrated plasma that includes a membrane filter unit for isolating a component based on a predetermined particle diameter from blood plasma, a first receiving member for providing a predetermined injection rate and a predetermined injection pressure to inject the blood plasma into the membrane filter unit and thereby to settle down platelets in the blood plasma, a pressurizing means mounted in connection to the first receiving member so as to provide an injection rate and an injection pressure for the blood plasma, and a second receiving member mounted on the membrane filter unit at a predetermined distance from the first receiving member and open into a second space to hold air, where the second receiving member is allowed to open or close. This can pass the blood plasma through the membrane filter unit for a sufficient period of time using a predetermined pressure, gravity and vacuum, thereby maximizing the settlement of the platelets in the blood plasma flowing into the membrane filter unit, achieving filtration while the platelets settle down, minimizing the contact area between the platelets and a filter built in the membrane filter unit, and finally reducing the quantity of the platelets adsorbed onto the membrane to obtain platelet rich plasma containing a maximum quantity of platelets.

In addition, the concentrated plasma can be readily gelated simply by repeating the filtration or adding calcium.

FIG. 2




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## Description

### TECHNICAL FIELD

**[0001]** The present invention relates to a device and method for extracting concentrated plasma. More particularly, the present invention relates to a device and method for extracting concentrated plasma that is designed to extract concentrated plasma from the blood plasma removed of red blood cells.

### BACKGROUND ART

**[0002]** In general, whole blood can be separated into blood corpuscles and blood plasma. The blood corpuscles fall into three general categories: red blood cells, white blood cells, and platelets. The blood plasma is mostly water, and contains clotting factors, electrolytes, and so forth.

**[0003]** To explain the blood plasma in further detail, the blood plasma consists of 60 to 85 % of water, 7 % of proteins, 1 % of fat, 0.1 % of sugar, and 0.9 % of other mineral ions. In this regard, the proteins in blood plasma can be classified into albumin and globulin, which are determined by using the difference in solubility in ammonium sulfate and individually consist of a combination of several proteins. The albumin constitutes about 55 % of the plasma protein and plays an important role in supplying proteins and maintaining the plasma colloid osmotic pressure. The globulin makes up about 38 % of the plasma protein and falls into one of the three categories: alpha globulin, beta globulin and gamma globulin. The alpha globulin contains lipoproteins and glycoproteins including fibrinogen and helps transport of vitamins, hormones, and so forth. The beta globulin performs a function as a carrier of prothrombin, plasma thromboplastin, iron, copper, or the like. The gamma globulin mostly contains immune antibodies.

**[0004]** The blood plasma, which plays a major role in the blood, can be injected into the human body to promote the transport of nutrient substances and thereby maximize its function such as inhibition of toxic substances.

**[0005]** Therefore, as illustrated in FIG. 1, the whole blood (Wb) is separated into red blood cells (RBCs), platelet rich plasma (PRP) and platelet poor plasma (PPP). Generally, the red blood cells are separated from the whole blood, and platelet rich plasma (PRP) and platelet poor plasma (PPP) are extracted. The platelet rich plasma (PRP) and the platelet poor plasma (PPP) are used in various treatment and cosmetic applications, including the treatment of wounds including sinus elevation surgery for dental implant, heart surgery, orthopedic surgery, dermatological treatment, and so forth.

**[0006]** In addition, the platelet poor plasma (PPP) is separated from the whole blood and contains proteins and a small quantity of platelets not isolated yet. Therefore, a reisolation process for the platelet poor plasma (PPP) is performed to re-extract the proteins and platelets from the platelet poor plasma (PPP). For this purpose, the conventional method involves a repetition of centrifugal isolation and filtration on the platelet poor plasma (PPP).

**[0007]** However, even after the process of centrifugal isolation and filtration is done again on the platelet poor plasma (PPP) remaining after extraction of platelet rich plasma (PRP) from the blood plasma, the concentrated plasma re-extracted from the platelet poor plasma (PPP) has such a low content that it hardly contains a large quantity of proteins having a low molecular weight and not separated in the conventional process of centrifugal isolation and filtration. And, there is also a problem suggested in regards to the low efficiency of the conventional device and method that obtains concentrated plasma with low content.

Prior Documents

Patent Documents

**[0008]**

(Patent Document 1) KR20100116160 10
(Patent Document 2) KR20100041436 10

### DISCLOSURE OF INVENTION

**[0009]** For solving the problems aforementioned, it is an object of the present invention to provide a device and method for extracting concentrated plasma that is designed to extract concentrated plasma with high concentration containing a maximum quantity of platelets while filtering the blood plasma out by passing the blood plasma removed of red blood cells through a filter by using a defined principle of pressure, gravity and vacuum.

**[0010]** To achieve the object of the present invention, there is provided a device for extracting concentrated plasma that includes: a membrane filter unit for isolating a component based on a predetermined particle diameter from blood plasma; and a first receiving member for providing a predetermined injection rate and a predetermined injection pressure to inject the blood plasma into the membrane filter unit and thereby to settle down platelets in the blood plasma.

**[0011]** The device further includes a pressurizing means mounted in connection to the first receiving member to provide the injection rate and the injection pressure of the blood plasma.

**[0012]** In this regard, the pressurizing means includes: a piston moving in connection to the membrane filter unit to inject the blood plasma in the first receiving member into the membrane filter unit; and a power source mounted to induce the movement of the piston.

**[0013]** The power source limits the moving distance of the piston to remain part of the blood plasma in the first receiving member for a predetermined period of time after the time that the blood plasma is completely injected

into the membrane filter unit.

**[0014]** The power source maintains the piston at a moved position for a predetermined period of time after the time that the movement of the piston is completed.

**[0015]** The power source moves the piston in a reverse direction at a predetermined speed in order to separate platelets, fibrinogens, proteins, and so forth filled in the filter after completion of the filtration.

**[0016]** The pressurizing means further includes: an adaptor for intermediating a coupling of a first plunger mounted in the first receiving member and the piston to inject the blood plasma in the first receiving member into the membrane filter unit; and a controller for controlling the operation of the power source to regulate the injection rate and the injection pressure of the blood plasma according to the moving distance and the moving rate of the piston and the first plunger.

**[0017]** The pressurizing means further includes a direction-diverting switch for diverting the moving direction of the piston.

**[0018]** The membrane filter unit includes: a body having the first receiving membrane mounted thereon and including an inlet portion provided on either side portion of the membrane filter unit to exhaust air from the membrane filter unit when the blood plasma of the first receiving member flows in, and an outlet portion for exhausting a component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the membrane filter unit; a hollow filter being mounted in the body and having a second space for receiving a component having a particle diameter equal to or smaller than the predetermined particle diameter which is filtered when the blood plasma of the first receiving member flows in through the inlet portion; and a first space formed between the hollow filter and the body to open into the outlet portion to temporarily receive a component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter and to exhaust the same through the outlet portion.

**[0019]** In addition, the membrane filter unit further includes a fixing member mounted on the body for arranging the membrane filter unit in the upright position to settle down platelets of the blood plasma flowing into the membrane filter unit under the effect of gravity.

**[0020]** The device for extracting concentrated plasma according to the present invention further includes a second receiving member mounted on the membrane filter unit at a predetermined distance from the first receiving member to open into the second space 180 and receive air.

**[0021]** In this regard, the membrane filter unit further includes a valve mounted as an intermediate on a coupling portion between the inlet portion and the first and second receiving members. The valve is arranged to have the second space and the first receiving member open into each other at normal times. And, the valve is arranged to close the second space and the second receiving member when blood plasma is injected into the second space, and to open the second space into the second receiving member and inject air in the second receiving member into the second space when a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space is to flow into the first receiving member.

**[0022]** On the other hand, according to the present invention, there is provided a method for extracting concentrated plasma that includes: a step S20 of injecting blood plasma into a membrane filter unit to settle down platelets in the blood plasma and thereby remaining a component having a particle diameter equal to or larger than the predetermined particle diameter which has not passed through a filter built in the membrane filter unit; and a step S40 of collecting a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the membrane filter unit.

**[0023]** The method for extracting concentrated plasma according to the present invention further includes a step S10 of arranging the membrane filter unit in the upright position to reduce the contact area between the filter in the membrane filter unit and the platelets, before the filtering step S20.

**[0024]** The method for extracting concentrated plasma according to the present invention further includes a step S30 of waiting for a predetermined period of time after the blood plasma is completely injected and reducing pressure in the membrane filter unit to exhaust a component having a particle diameter equal to or smaller than the predetermined particle diameter.

**[0025]** The filtering step S20 includes injecting part of the blood plasma into the membrane filter unit. The first collecting step S40 includes collecting both a component having a particle diameter equal to or larger than the predetermined particle diameter which has passed through the filter and the remaining the blood plasma in one position.

**[0026]** The method for extracting concentrated plasma according to the present invention further includes a second collecting step S50 of injecting air into the membrane filter unit to collect again both the remaining component having a particle diameter equal to or larger than the predetermined particle diameter and the remaining blood plasma in one position.

**[0027]** In all the steps other than the collecting step, first and second spaces are formed by mounting a filter in a body of the membrane filter, where the second space holds a component having a particle diameter equal to or larger than the predetermined particle diameter which is filtered out from the filter when the blood plasma flows in, and the second space momentarily collecting a component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter to exhaust the component through an outlet portion formed in the body of the membrane filter unit.

**[0028]** In addition, the filtering step S20 further includes a step S23 of injecting the blood plasma into the second space at a predetermined injection rate and a predetermined pressure to settle down the platelets. Here, the injection pressure of the blood plasma is determined to have the range of a load internal pressure imposed on the filter mounted in the membrane filter unit during the filtration is equal to or lower than the permissible internal pressure of the filter.

**[0029]** The injecting step S23 includes using a pressurizing means to move a first plunger mounted on a first receiving member holding the blood plasma and push the blood plasma. As a power source of the pressurizing means moves a piston to move the first plunger mounted on the piston, thereby injecting the blood plasma into the second space at a predetermined injection rate and a predetermined pressure. When part of the blood plasma is injected into the second space, the remainder of the blood plasma remains in the first receiving member. After filtration, the first plunger is moved back to collect a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space into the first receiving member holding the remaining blood plasma.

**[0030]** Further, air in a second receiving member mounted on the membrane filter unit is injected into the second space to collect a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space into the first receiving member holding the remaining blood plasma.

**[0031]** The first receiving member and the second receiving member are connected to the second space. Before the second collecting step S50, a valve is manipulated to have the second space open into the first receiving member and disconnect the second space from the second receiving member. In the second collecting step S50, the valve is manipulated to have the second space open into the first receiving member and the second receiving member.

**[0032]** In the filtering step S20, a valve 150 mounted on the opposite side of a first receiving member is closed to open into the membrane filter unit.

**[0033]** Therefore, in the filtering step S20, when the blood plasma is injected, an air layer is formed in part of the space of the membrane filter unit to limit the injection height of the blood plasma to a predetermined height or below.

**[0034]** The method for extracting concentrated plasma according to the present invention further includes a step S31 of completely closing the membrane filter unit and forming a vacuum pressure in the membrane filter, after the pressure-reducing step S30.

**[0035]** The collecting step S40 includes opening the valve to momentarily supply external air into the membrane filter unit and thereby collecting a component having a particle diameter equal to or larger than the predetermined particle diameter using the air.

**[0036]** In addition, the platelet rich plasma becomes gel by repeatedly filtering the blood plasma injected into the membrane filter unit or adding calcium and then repeatedly filtering the blood plasma.

## EFFECTS OF THE INVENTION

**[0037]** As described above, according to the present invention, the conventional process of separating platelet rich plasma and platelet poor plasma from the blood plasma can be omitted to simplify the process of extracting concentrated plasma which contains high concentration of platelets by passing the blood plasma removed of red blood cells through the membrane filter unit.

**[0038]** Further, the blood plasma can be passed through the membrane filter unit using a predetermined pressure and gravity for a sufficiently long period of time. This can allow the platelets in the blood plasma flowing into the membrane filter unit to settle down to the maximum, making it possible to perform the filtration while the platelets settle down, and minimize the contact area between the platelets and the filter built in the membrane filter unit. As a result, the quantity of the platelets adsorbed onto the membrane can be minimized, and the concentrated plasma can contain the maximum quantity of the platelets.

**[0039]** Furthermore, after the blood plasma is partly or completely injected into the membrane filter unit, the injection pressure is maintained for a predetermined period of time until the pressure in the membrane filter is sufficiently reduced. This can completely exhaust the component having a particle diameter equal to or smaller than the predetermined particle diameter and remaining in the membrane filter unit.

**[0040]** Moreover, the blood plasma is injected while the membrane filter unit is closed, so the injection height of the blood plasma can be limited to a predetermined height or below to prevent the contact between the blood plasma and the filter. This can minimize adsorption of the component in the blood plasma onto the filter.

**[0041]** In addition, the closed membrane filter unit is suddenly opened. This can flow away the component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the membrane filter unit momentarily, thereby readily releasing part of the components adsorbed onto the filter.

**[0042]** Further, the platelet rich plasma can be gelated by repeatedly filtering the blood plasma collected in the membrane filter unit or adding calcium to the blood plasma and then repeatedly filtering it.

## BRIEF DESCRIPTION OF DRAWINGS

**[0043]** The accompanying drawings, which are incorporated the specification, illustrate a preferred embodiment of the present invention and serve to explain the principles of the invention. It should be apparent that the accompanying drawings are not construed to limit the

scope of the present invention. In the drawings:

FIG. 1 is a side diagram showing the whole blood under centrifugal separation.

FIG. 2 is a schematic constructional diagram showing a device for extracting concentrated plasma according to a preferred embodiment of the present invention.

FIG. 3 is a cross-sectional diagram showing the inside of the membrane filter unit shown in FIG. 2.

FIGS. 4a and 4b are operational diagrams of FIG. 2.

FIG. 4c is a constructional diagram showing that a second receiving member is excluded in the membrane filter unit of FIG. 2.

FIG. 5 is a flow chart showing a first extraction method for concentrated plasma using the extracting device of FIG. 2.

FIG. 6 is a flow chart showing a second extraction method for concentrated plasma using the extracting device of FIG. 2.

## BEST MODES FOR CARRYING OUT THE INVENTION

**[0044]** Hereinafter, a detailed description will be given as to the preferred embodiments of the present invention with reference to the accompanying drawings so as for those skilled in the art to readily carry out the present invention. But, in the detailed description of the operational principles regarding the preferred embodiments of the present invention, the specific description as to the known functions or constructions is to be excluded when it is considered to unnecessarily depart from the conception of the present invention.

<Construction>

**[0045]** FIG. 2 is a schematic constructional diagram showing a device for extracting concentrated plasma according to a preferred embodiment of the present invention. FIG. 3 is a cross-sectional diagram showing the inside of the membrane filter unit shown in FIG. 2. FIGS. 4a and 4b are operational diagrams of FIG. 2.

**[0046]** The device for extracting concentrated plasma according to the present invention includes, as shown in FIG. 2, a membrane filter unit 100, a first receiving member 200, a second receiving member 210, and a pressurizing means 300.

**[0047]** The membrane filter unit 100 is a member for filtering blood plasma in order to exhaust a component having a particle diameter equal to or smaller than a predetermined particle diameter which is contained in the blood plasma. In this regard, the blood plasma used to extract platelet rich plasma in the present invention is preferably a blood plasma obtained by removing the whole blood of red blood cells through centrifugal separation, or it may be a platelet poor plasma generally available.

**[0048]** The membrane filter unit 100 includes a body 110, a filter 120 mounted in the body 110 and designed to have a component of a particle diameter equal to or smaller than the predetermined particle diameter which has passed through, an inlet portion 130 formed on either side portion of the body 110 and individually having the first and second receiving members 200 and 210, an outlet portion 140 mounted in the body 110 to exhaust the component of a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter 120, a three-way valve 150 mounted to open/close the inlet portion 130, and a fixing member 160 for maintaining the body 110 in the upright position.

**[0049]** In this regard, the membrane filter unit 100 is to separate platelets, proteins, albumins, etc. from water, uric acid, potassium, phosphates, etc. as contained in the blood plasma. For separation, the cross-sectional area of the filter 120 is preferably about 0.04 $m^2$ to 0.08 $m^2$, more preferably about 0.06 $m^2$.

**[0050]** The membrane filter unit 100 may be an example of membrane filter unit, which is preferably used for blood osmosis. Of course, the membrane filter unit 100 may be a general filter capable of filtering out a component having a particle diameter equal to or larger than the predetermined particle diameter, such as platelets, proteins, albumins, etc. of the blood plasma, in addition to the membrane filter unit.

**[0051]** On the other hand, the filter 120 is built in the body 110, and the inlet portion 130 and the outlet portion 140 are formed on either side portion of the body 110. The body 110 preferably has a cylindrical shape, or it may have a polygonal pillar shape such as a rectangular pillar shape.

**[0052]** Between the inner wall of the body 100 and the filter 120 is formed a defined first space 170, which temporarily receives a component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter 120. In other words, the first space 170 is an independent space disconnected from the inlet portion 130.

**[0053]** The filter 120 is a member through which a component having a particle diameter equal to or smaller than the predetermined particle diameter in the blood plasma is passed. The filter 120 has a hollow cylindrical shape or a hollow polygonal pillar shape that forms a second space 180 into which the blood plasma flows. In this regard, the second space 180 directly opens into the inlet portion 130 to have the blood plasma enter from the inlet portion 130. Accordingly, when the blood plasma flows into the second space 180, a component having a particle diameter equal to or smaller than the predetermined particle diameter in the blood plasma is passed through the filter 120 and flows into the first space 170, and a component having a particle diameter equal to or larger than the predetermined particle diameter in the blood plasma remains in the second space 180.

**[0054]** In this regard, there can be a modification of the embodiment in such a manner that the filter 120 has a panel shape and divides the inside of the body 110 into

the first and second spaces 170 and 180, where the first space 170 opens into the outlet portion 140 and the second space 180 opens into the inlet portion 130.

**[0055]** In addition, the inlet portion 130 is formed on either side portion of the body 110. The first receiving member 200 receiving the blood plasma is mounted on the inlet portion 130 formed on the one side of the body 110, and the second receiving member 210 receiving air is mounted on the inlet portion 130 formed on the other side of the body 110. The inlet portion 130 is formed in direct connection to the second space 180 of the filter 120. This is not only to have the blood plasma of the first receiving member 200 flow directly into the second space 180 but also to have a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180 flow into the first receiving member 200 by the pressure applied by the second receiving member 210. Other details in regards to the inlet portion 130 will be described later in association with the three-way valve 150.

**[0056]** In addition, the outlet portion 140 is formed on the one side of the body 100 or on either side of the body 100 to open into the first space 170. This is to exhaust a component having a particle diameter equal to or smaller than the predetermined particle diameter and flowing into the first space 170 through the filter 120.

**[0057]** The three-way valve 150 is mounted on either coupling portion of the inlet portion 130 and the first and second receiving members 200 and 210. The three-way valve 150 is operated to disconnect the first receiving member 200 and the second space 180 from the second receiving member 210 while the blood plasma of the first receiving member 200 is flowing into the second space 180 of the filter 100. Further, the three-way valve 150 is operated to have the second receiving member 210 open into the second space 180 and the first receiving member 200 so that, after the filtration of the blood plasma is completed, the air in the second receiving member 210 enters the second space 180 to flow a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180 into the first receiving member 200.

**[0058]** The fixing member 160 is a member for maintaining the membrane filter unit 100 in the upright position, and it may be any general member designed so that the body 110 can be put in it, suspended from it, inserted into it or picked up from it. The fixing member 160 is excluded when the membrane filter unit 100 is used in a position other than the upright position. For this purpose, the membrane filter unit 100 is formed to have a wider bottom portion or to have a varied shape designed not to let off the blood plasma from the inlet portion 130 when the membrane filter unit having a cylindrical shape is laid on the side. In this case, there is no need of using the membrane filter unit in the upright position, if the platelets in the blood plasma settle down and have a minimum contact area with the filter 120.

**[0059]** In this regard, the purpose of using the fixing member 160 to fix the membrane filter unit 100 in the upright position is having the blood plasma flow in from the bottom portion of the body 110 and carrying out the filtration while the platelets in the blood plasma settle down under the effect of gravity. The settlement of the platelets minimizes the contact area between the platelets and the filter 120 to reduce the adsorption of the platelets onto the filter 120 to the minimum. This can minimize a loss of the platelets caused by the adsorption onto the filter 120 and render a maximum amount of platelets contained in the platelet rich plasma that is going to be extracted later.

**[0060]** The first receiving member 200 is a member for receiving the blood plasma, injecting it into the membrane filter unit 100 and collecting the filtered blood plasma, that is, platelet rich plasma. The first receiving member 200 includes a first receiving portion 201 for receiving the blood plasma or the platelet rich plasma obtained after the filtration and a first plunger 202 mounted to push the blood plasma in the first receiving portion 201 into the second space 180 of the membrane filter unit 100. The first receiving member 200 is preferably, for example, a syringe without a needle, and it may be constructed to include at least two separate members for receiving or pushing the blood plasma or receiving the concentrated plasma after the filtration.

**[0061]** On the other hand, the second receiving member 210 is a member for receiving air and injecting it into the second space 180 of the membrane 100 after the filtration to push a component having a predetermined particle diameter or a larger particle diameter remaining in the second space 180 into the first receiving member 200. The second receiving member 210 includes a second receiving portion 211 for receiving air and a second plunger 212 mounted to inject the air in the second receiving portion 211 into the second space 180 of the membrane filter unit 100. The second receiving member 210 is preferably, for example, a syringe without a needle, and it may be constructed to include at least two separate members for receiving or pushing air. In this regard, the mounting positions of the first and second receiving members 200 and 210 are the bottom portion and the top portion, respectively, and exchangeable with each other.

**[0062]** The pressurizing means 300 is a means for injecting the blood plasma in the first receiving member 200 into the second space 180 under a predetermined pressure, and includes a power source 310 having a piston 311 mounted to push or pull the first plunger 202. In addition to the power source 310, the pressurizing means 300 may further include a controller 320 mounted to control the operation of the power source 310, a decelerator 330 mounted on the power source 310, an adaptor 340 mounted to intermediate a coupling of the first plunger 202 and the piston 311, and a direction-diverting switch 350 mounted to divert the moving direction of the piston 311. In this regard, the piston 311 without the first plunger 202 may move by directly sliding inside the first receiving

member 200.

**[0063]** First of all, the power source 310 is a device that enables the piston 311 coupled to the first plunger 202 of the first receiving member 200 to make a reciprocating movement in order to push or pull the first plunger 202. The power source 310 is preferably, for example, a motor. Otherwise, the power source 310 may also be a device with a separate piston 311 that enables the piston 311 to make a reciprocating movement.

**[0064]** In this regard, the pressure applied to inject the blood plasma into the membrane filter unit 100, that is, the pressure provided by the power source 310 may be equal to the permissible internal pressure of the filter 120 or below. For example, when the permissible internal pressure of the filter 120 is 500 mmHg, the load internal pressure of the filter 120 during the filtration is preferably in the range of about 300 to 450 mmHg.

**[0065]** In addition, the power source 310 provides an injection rate that allows the platelets in the blood plasma to settle down under the effect of gravity while the blood plasma is injected into the second space 180.

**[0066]** The controller 320 controls all the functions of the power source 310, including determination on whether to operate the power source 310 or not, the torque, that is, the magnitude of the pressure to inject the blood pressure into the second space 180, the running time, the moving distance of the piston 311, the moving direction of the piston 311, the stand-by time after movement of the piston 311, the injection pressure and the injection rate of the blood plasma, and so forth.

**[0067]** In one embodiment for extracting concentrated plasma from blood plasma, 5 portions of platelet rich plasma can be obtained by combining 3 portions of a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180 and 2 portions of a blood plasma remaining in the first receiving member 200. For this purpose, the first plunger 202 in the first receiving member 200 moves only to the scale of 2 in the first receiving member 200 and then stops until a component having a particle diameter equal to or smaller than the predetermined particle diameter is completely exhausted through the outlet portion 140. The movement of the piston 311 in association with the movement of the first plunger 202 is under the control by the controller 320. It is of course possible to obtain 5 portions of the platelet rich plasma by injecting all the blood plasma of the receiving member 200 into the membrane filter unit 100 and filtering out a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180.

**[0068]** In another embodiment for extracting concentrated plasma from blood plasma, 6 or 7 portions of platelet rich plasma can be obtained by combining 3 portions of the component having particle diameter equal to or larger than a predetermined particle diameter and remaining in the second space 180 and 3 or 4 portions of blood plasma remaining in the first receiving member 200. For this, the first plunger 202 moves only to the scale of 3 or 4 in the first receiving member 200 and then stops. The movement of the piston 311 is also under the control by the controller 320.

**[0069]** In other words, the controller 320 controls the movement of the piston 311 so that the quantity of the blood plasma remaining in the first receiving member 200 is regulated according to a desired amount of the component having a particle diameter equal to or larger than the predetermined particle diameter in the membrane filter unit 100.

**[0070]** Contrarily, the controller 320 can simply set the torque range of the power source 310 and control the power source 310 to operate within the range of the predetermined torque. In this case, each of the other functions of the power source 310 aforementioned can be activated independently or at least two of the other functions can be activated simultaneously, by way of separate switches or control buttons.

**[0071]** The decelerator 330 enhances the torque of the power source 310 and enables the stable occurrence of the torque.

**[0072]** The adaptor 340 is an intermediate for a stable coupling of the piston 311 and the first plunger 202. The one side of the adaptor 340 is firmly coupled to the first plunger 202, and the other side of the adaptor 340 is fixed to the piston 311.

**[0073]** The direction-diverting switch 350 is mounted to divert the moving direction of the piston 311 for injecting the blood plasma into the second space 180 or collecting a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180 into the first receiving member 200 after the filtration. The direction-diverting switch 350 may be excluded, in which case the power source 310 can directly divert the moving direction of the piston 311. For example, when the power source 310 is a motor, it can divert the moving direction of the piston 311 by changing its rotational direction.

<Examples>

**[0074]** FIG. 4c is a constructional diagram showing the membrane filter unit of FIG. 2 without the second receiving member.

**[0075]** FIG. 4c is almost the same in construction as FIG. 2, excepting that the second receiving member 210 is excluded. Such a construction of FIG. 4c is to carry out a second method mentioned later, and its detailed description will be given in association with the description of the second method.

<First Method>

**[0076]** FIG. 5 is a flow chart showing a method for extracting concentrated plasma using the extracting device of FIG. 2.

**[0077]** Firstly, the membrane filter unit 100 is fixed in

the upright position, in step S10. The arrangement is to make the platelets in the blood plasma settle down under the effect of gravity and then to filter the blood plasma. This can minimize the contact area between the platelets and the filter 120 and thereby reduce a loss of the platelets caused by the adsorption onto the filter 120.

**[0078]** Subsequently, the blood plasma is injected into the membrane filter unit 100 to undergo filtration, while allowing the platelets to settle down, in step S20. For this purpose, there is included a step S21 of receiving the blood plasma in the first receiving member 200 and then mounting the first receiving member 200 on the membrane filter unit 100. In this regard, the first receiving member 200 is mounted on the inlet portion 130 formed on the one side of the body 110 of the membrane filter unit 100, so it opens to the second space in the body 110. In this construction, the first receiving member 200 and the inlet portion 130 are coupled together via the three-way valve 150, which is manipulated to open or close the first receiving member 200 and the second space 180. For injecting the blood plasma into the second space 180, the three-way valve 150 can be manipulated to open the first receiving member 200 and the second space 180. Also, the first receiving member 200 and the second space 180 is kept open in order to collect the platelet rich plasma remaining in the second space into the first receiving member 200 after the subsequent filtration. Ultimately, a two-way valve 150 may be used in place of the three-way valve 150, and the first receiving member 200 may be mounted on the inlet portion 130 without using a valve.

**[0079]** For obtaining blood plasma, for example, 9 portions of whole blood is mixed with 1 portion of an anticoagulant, and the mixture is removed of red blood cells through centrifugal separation to extract about 4 to 5.5 portions of blood plasma. It is of course possible to extract a larger amount of the blood plasma by mixing a larger quantity of whole blood and a larger quantity of an anticoagulant and then preforming extraction of the blood plasma through centrifugal separation and removal of red blood cells.

**[0080]** Also, this step S20 may further include a step S22 of receiving air in the second receiving member 210 and then mounting the second receiving member 210 on the membrane filter unit 100. In this regard, the second receiving member 210 may be mounted on the inlet portion 130 formed on the other side of the body 110 via the three-way valve 150, which can be manipulated to open or close the second space 180. The mounting step S22 may be carried out right before the second collecting step S50 described later, or the second collecting step S50 may involve injecting external air into the second space 180, while the mounting step S22 is excluded.

**[0081]** When the blood plasma is injected into the second space 180, the three-way valve 150 is manipulated to open the inlet portion 130 of the second receiving member 210 to the exterior and thereby to exhaust the air of the membrane filter unit 100. In addition, when a component having a particle diameter equal to or larger than the predetermined particle diameter in the second space 180 is collected into the first receiving member 200 after the filtration, the second receiving member 210 is mounted on the inlet portion 130 and the three-way valve 150 is manipulated to close the second space 180 of the membrane filter unit 100 from the exterior and allow the second space 180 to open into the second receiving member 210. It is therefore possible to mount the second receiving member 210 and the inlet portion 130 without a two-way valve or another valve other than the three-way valve 150.

**[0082]** The step S20 may further include a step S23 of moving the piston 311 in one direction by using the pressurizing means 300, that is the power source 310 to move the first plunger 202 of the first receiving member 200 and thereby injecting the blood plasma into the second space 180. In this regard, the pressure that the pressurizing means 300 applies to inject the blood plasma into the second space 180 is in a predetermined pressure range equal to the permissible internal pressure of the filter 120 of the membrane filter unit 100 or below. In the case when the permissible internal pressure of the filter 120 is 500 mmHg, the load internal pressure of the filter 120 during the filtration is in the range of 300 mmHg to 450 mmHg, that is, approximately 60 to 90 %. And, the injection rate for the pressurizing means 300 injecting the blood plasma into the second space 180 is within the range that allows the platelets to settle down in the blood plasma injected in to the second space 180 and enables the continuous injection of the blood plasma while the platelets settle down. The injection pressure and the injection rate can be regulated under the control of the power source 310 and the decelerator 330. When the power source 310 is a motor, the decelerator 330 controls the motor velocity (rpm) of the motor to adjust the injection pressure and the injection rate.

**[0083]** When the injection pressure is 1,200 kg, for example, the pressure per unit area of the filter 120 in consideration of the gravity is $1{,}200 kg/s^2 = 0.5 kg/cm^2$, which can be applied to calculate the injection pressure and the injection rate.

**[0084]** As the blood plasma is injected, the air in the membrane filter unit 100 is exhausted through the three-way valve 150 on the side of the second receiving member 210.

**[0085]** When the blood plasma is completely injected, the pressure in the membrane filter unit 100 is dropped in a predetermined period of time after the completion of the injection, in step S30. This can activate the settlement of the platelets more by reducing the pressure in the filter 120 of the membrane filter unit 100 and completely exhaust the component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter 120 in the second space 180 and temporarily held in the first space 170 through the outlet portion 140.

**[0086]** In this regard, as a predetermined quantity of

the blood plasma remains in the first receiving member 200 at the time when the injection of the blood plasma is completed, the first plunger 202 stops at a specific position. This is to remain a predetermined quantity of the blood plasma in the first receiving member 200. For extracting 5 portions of platelet rich plasma, for example, about 3 portions of the component having a particle diameter equal to or larger than the predetermined particle diameter which is obtained through filtration with the membrane filter unit 100 is mixed with about 2 portions of the blood plasma remaining in the first receiving member 200. Accordingly, a defined amount of the platelet rich plasma can be obtained by mixing a defined amount of the component having a particle diameter equal to or greater than the predetermined particle diameter which is obtained through filtration with the membrane filter unit 100 and a defined amount of the blood plasma remaining in the first receiving member 200. The amount of the blood plasma remaining in the first receiving member 200 can be determined based on the amount of the component obtained through the membrane filter unit 100, or the amount of the component obtained through the membrane filter unit 100 can be determined based on the amount of the blood plasma remaining in the first receiving member 200.

**[0087]** Contrarily, it is possible to obtain no more than the platelet rich plasma filtered through the membrane filter unit 100 by moving the first plunger 202 to a threshold moving position, stopping it and then injecting all the blood plasma of the first receiving member 200 into the membrane filter unit 100.

**[0088]** Of course, the moving and stop motions of the first plunger 202 are carried out by the movement of the piston 311 mounted on the first plunger 202, and the piston 311 is moved by the power source 310.

**[0089]** Subsequently, a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the membrane filter unit 100 is first collected into the first receiving member 200, in step S40. In this regard, when the power source 310 forces the piston 311 to make a back motion and the first plunger 202 makes a back motion, most of the component having a particle diameter equal to or larger than the predetermined particle diameter in the second space 180 of the membrane filter unit 100 flows into the first receiving member 200. Here, the direction-diverting switch 350 is manipulated for the back motion of the piston 311.

**[0090]** Finally, air is injected into the membrane filter unit 100 to collect the remaining component having a particle diameter equal to or larger than the predetermined particle diameter into the first receiving member 200, in step S50. For this purpose, the three-way valve 150 of the second receiving member 210 is manipulated to make the second receiving member 210 open into the second space 180, and then the second plunger 212 is moved to inject the air in the second receiving member 210 into the second space 180, thereby forcing all the component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180 to flow into the first receiving member 200. It is of course possible to repeat the step S50 in order to completely flow the component having a particle diameter equal to or greater than the predetermined particle diameter into the first receiving member 200.

<Second Method>

**[0091]** FIG. 6 is a flow chart showing a second extraction method for concentrated plasma using the extracting device of FIG. 2. The second method according to the present invention is a method of collecting a component having a particle diameter equal to or larger than the predetermined particle diameter without using the second receiving member 210. The second method is similar to the first method on the whole, except for a little difference in the steps. The steps of the second method the same as or similar to the steps of the first method are mentioned as the common content and described briefly under necessity.

**[0092]** Firstly, the membrane filter unit 100 is fixed in the upright position, in step S10. The step S10 is as defined in the first method.

**[0093]** Subsequently, the valve 150 mounted in the opposing side of the first receiving member 200 and open into the second space 180 is closed, and the blood plasma is injected into the membrane filter unit 100 and passed through the filter while the platelets are allowed to settle down, in step S20. As the valve 150 is closed, the second space 180 opens into the exterior through the outlet portion 140, so that the first plunger 202 of the first receiving member 200 is pressurized under the same pressure of the first method or the stronger pressure to inject the blood plasma into the second space 180. The valve 150 may be a three-way valve, but preferably a two-way valve because the second receiving member 210 is excluded.

**[0094]** Accordingly, the step S20 includes the step S21 of mounting the first receiving member 200 on the membrane filter unit 100 and the step S23 of moving the piston 311 in one direction by the power source 310 to move the first plunger 202 of the first receiving member 200 and thereby to inject the blood plasma into the second space 180, but it excludes the step S22 of mounting the second receiving member 210 on the membrane filter unit 100.

**[0095]** As the second space 180 is mostly closed, an air layer is formed on the opposite side to the first receiving member 200 in the second space 180 while the blood plasma is injected, and the air layer prevents the blood plasma from penetrating above a predetermined height. This can force the component having a relatively high force of adhesion such as platelets to remain below a predetermined height and limit the range of adsorbing the components of the blood plasma onto the filter 120

to the maximum.

**[0096]** Of course, the component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter 120 is exhausted through the outlet portion 140 during the filtration.

**[0097]** Subsequently, it waits for a predetermined period of time after completion of the injection of the blood plasma and then the pressure in the membrane filter unit 100 is dropped, in step S30. The step S120 is also the same as defined in the first method.

**[0098]** Subsequently, the outlet portion 140 is blocked to close the second space 180 and then move the first plunger 202 of the first receiving member 200 back, thereby forming a vacuum pressure in the membrane filter unit 100, in step S31. In other words, when the outlet portion 140 is blocked, the second space 180 is completely closed, with the valve 150 closed. At this time, the power source 310 forces the piston 311 to make a back motion and moves the first plunger 202 back, so a strong vacuum pressure is formed in the membrane filter unit 100.

**[0099]** Finally, the valve 150 is momentarily opened to collect a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180 into the first receiving member 200 all at once, in step S40. By part of the air momentarily introduced, the components adsorbed onto the filter 120 are released from the filter 120 and flow into the first receiving member 200.

**[0100]** This decompression method has an advantage that the components adsorbed onto the filter 120 during the filtration can be released from the filter 120 to the maximum. It is of course possible to repeat the steps S31 and S40 in a manual, semi-automatic, or automatic manner, in which case the operation of the valve 150 can be controlled through the controller in such a manner of controlling a solenoid valve.

**[0101]** The above-described first and second methods are applied to extract concentrated plasma from the blood plasma. In this regard, the concentrated plasma extracted according to the present invention has a platelet count about 4 to 5 times higher than the platelet rich plasma obtained by the conventional method using the centrifugal separation. A comparison between the concentrated plasma of the present invention and the whole blood is given in Table 1.

[Table 1]

| Whole blood | Platelet rich plasma |
|---|---|
| Platelet count | 4 to 11-fold |
| Protein count | 2 to 4-fold |
| Fibrinogen count | 3 to 5-fold |
| White blood cell count | 3 to 5-fold |
| Red blood cell count | 0.2 to 0.4-fold |

**[0102]** Particularly, the blood plasma is changed into a gel and used for many applications. In the conventional method of making the blood plasma containing an anticoagulant into a gel, bovine thrombin or collagen is added to the blood plasma. But, the bovine thrombin is a substance extracted from livestock and thus possibly contains a component harmful to the human body (e.g., mad cow disease factor, etc.).

**[0103]** Accordingly, the present invention repeats the filtration of the blood plasma using a membrane filter, more preferably adds calcium to promote the conversion of prothrombin into thrombin as the first step of the blood coagulation mechanism and thereby to form a large quantity of thrombin from the prothrombin in the blood plasma. Such a large quantity of thrombin serves as a factor to convert fibrinogens into fibrin monomers and is enough to form a large quantity of fibrin monomers. Finally, the fibrin monomers form fibrin clots and the platelet rich plasma is extracted in the form of a gel and thus can be used for various use purposes instead of fibrin glue.

**[0104]** As described above, those skilled in the art will appreciate that the present invention described herein is susceptible to variation other than those specifically described without changing its technical conception and essential features. Therefore, it should be understood that the foregoing description of preferred embodiments of the present invention has been presented for purposes of illustration and not intended to limit the scope of the present invention.

**[0105]** It should also be understood that the scope of the present invention is defined by the scope of the following claims other than the detailed description and construed to include all the variations and modifications derived from the meanings and scope of the claims and their equivalents.

100: membrane filter unit
110: body
120: filter
130: inlet portion
140: outlet portion
150: valve
160: fixing member
170: first space
180: second space
200: first receiving member
201: first receiving portion
202: first plunger
210: second receiving member
211: second receiving portion
212: second plunger
300: pressurizing means
310: power source
311: piston
320: controller
330: decelerator
340: adaptor
350: direction-diverting switch

## Claims

1. A device for extracting concentrated plasma, which is to extract concentrated plasma, the device comprising:

   a membrane filter unit (100) for isolating a component based on a predetermined particle diameter from blood plasma; and
   a first receiving member (200) for providing a predetermined injection rate and a predetermined injection pressure to inject the blood plasma into the membrane filter unit (100) and let thereby platelets in the blood plasma settle down by gravity.

2. The device for extracting concentrated plasma as claimed in claim 1, further comprising:

   a pressurizing means (300) mounted in connection to the first receiving member (200) to provide the injection rate and the injection pressure of the blood plasma.

3. The device for extracting concentrated plasma as claimed in claim 2, wherein the pressurizing means (300) comprises:

   a piston 311 moving relative to the membrane filter unit (100) to inject the blood plasma in the first receiving member (200) into the membrane filter unit (100); and
   a power source (310) mounted to induce the movement of the piston (311).

4. The device for extracting concentrated plasma as claimed in claim 3, wherein the power source (310) limits the moving distance of the piston (311) to remain part of the blood plasma in the first receiving member (200) for a predetermined period of time after the time that the injection of the blood plasma into the membrane filter unit (100) is completed.

5. The device for extracting concentrated plasma as claimed in claim 3 or 4, wherein the power source (310) maintains the piston (311) at a position for the predetermined period of time after the time that the movement of the piston (311) is completed.

6. The device for extracting concentrated plasma as claimed in claim 3, wherein the pressurizing means (300) further comprises:

   an adaptor (340) for intermediating a coupling of a first plunger (202) mounted in the first receiving member (200) and the piston (311) to inject the blood plasma in the first receiving member (200) into the membrane filter unit (100); and
   a controller (320) for controlling the operation of the power source (310) to regulate the injection rate and the injection pressure of the blood plasma according to the moving distance and the moving rate of the piston (311) and the first plunger (202).

7. The device for extracting concentrated plasma as claimed in claim 3 or 6, wherein the pressurizing means (300) further comprises:

   a direction-diverting switch (350) for diverting the moving direction of the piston (311).

8. The device for extracting concentrated plasma as claimed in claim 1, wherein the membrane filter unit (100) comprises:

   a body 110 having the first receiving member (200) mounted thereon, the body comprising a first and a second inlet portion (130), wherein the air is exhausted through the second inlet portion (130) at one end of the membrane filter unit 100 when the blood plasma flows in through the first inlet portion (130) at the other end of the membrane filter unit (100), and an outlet portion (140) for exhausting a component having a particle diameter equal to or smaller than the predetermined particle diameter passed through the membrane filter unit (100);
   a hollow filter (120) being mounted in the body (110) and having a second space (180) for receiving the component having a particle diameter equal to or smaller than the predetermined particle diameter which was filtered when the blood plasma of the first receiving member (200) flows in through the first inlet portion (130); and
   a first space (170) formed between the hollow filter (120) and the body (110) to open into the outlet portion (140) to temporarily receive the component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter (120) and exhaust the same through the outlet portion (140).

9. The device for extracting concentrated plasma as claimed in claim 1 or 8, wherein the membrane filter unit further comprises:

   a fixing member (160) mounted on the body (110) for arranging the membrane filter unit in the upright position to settle down platelets of the blood plasma flowing into the membrane filter unit under the effect of gravity.

10. The device for extracting concentrated plasma as



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claimed in claim 8, further comprising:

a second receiving member (210) being mounted on the membrane filter unit (100) at a predetermined distance from the first receiving member (200) to open into the second space (180) and receiving air.

**11.** The device for extracting concentrated plasma as claimed in claim 10, wherein the membrane filter unit (100) further comprises a first valve (150) being mounted as an intermediate on a coupling portion between the first inlet portion (130) and the first receiving member (200) and a second valve (150) being mounted as an intermediate on a coupling portion between the second inlet portion (130) and the second receiving member (210),
the first valve being arranged to have the second space (180) and the first receiving member (200) open into each other at normal times, and
the second valve being arranged to close the second space (180) and the second receiving member (210) when blood plasma is injected into the second space (180), and to open the second space (180) into the second receiving member (210) and inject air in the second receiving member (210) into the second space (180) when a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space (180) is to flow into the first receiving member (200).

**12.** A method for extracting concentrated plasma, which is to extract concentrated plasma, the method comprising:

a filtering step (S20) of injecting blood plasma into a membrane filter unit (100) to let the platelets settle down by gravity in the blood plasma and thereby remaining a component having a particle diameter equal to or larger than the predetermined particle diameter which has not passed through a filter (120) built in the membrane filter unit (100); and
a step (S40) of collecting the component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the membrane filter unit (100).

**13.** The method for extracting concentrated plasma as claimed in claim 12, further comprising:

a step (S10) of arranging the membrane filter unit (100) in the upright position to reduce the contact area between the filter (120) in the membrane filter unit (100) and the platelets, before the filtering step (S20).

**14.** The method for extracting concentrated plasma as claimed in claim 12, further comprising:

a step (S30) of waiting for a predetermined period of time after the blood plasma is completely injected and reducing pressure in the membrane filter unit (100) after the predetermined period of time to exhaust a component having a particle diameter equal to or smaller than the predetermined particle diameter.

**15.** The method for extracting concentrated plasma as claimed in claim 12, wherein the filtering step (S20) includes injecting part of the blood plasma into the membrane filter unit (100),
wherein the first collecting step (S40) includes collecting both a component, having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the filter, and the remaining blood plasma in one position.

**16.** The method for extracting concentrated plasma as claimed in claim 15, further comprising:

a second collecting step (S50) of injecting air into the membrane filter unit (100) to collect again both the remaining component having a particle diameter equal to or larger than the predetermined particle diameter and the remaining blood plasma in one position.

**17.** The method for extracting concentrated plasma as claimed in claim 12, 14, 15, or 16, wherein in all the steps other than the collecting step, first and second spaces (170) and (180) are formed by mounting a filter (120) in a body (110) of the membrane filter (100), wherein the second space (180) holds a component having a particle diameter equal to or larger than the predetermined particle diameter which is filtered out from the filter (120) when the blood plasma flows in, the first space (170) temporarily collecting a component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter (120) to exhaust the component through an outlet portion (140) formed in the body (110) of the membrane filter unit (100).

**18.** The method for extracting concentrated plasma as claimed in claim 17, wherein the filtering step (S20) further includes a step (S23) of injecting the blood plasma into the second space (180) at a predetermined injection rate and a predetermined pressure to let the platelets settle down by gravity,
wherein the injection pressure of the blood plasma is determined to have the range of a load internal pressure imposed on the filter (120) mounted in the membrane filter unit (100) during the filtration is equal to or lower than the permissible internal pres-

sure of the filter (120).

**19.** The method for extracting concentrated plasma as claimed in claim 18, wherein the injecting step (S23) includes using a pressurizing means (300) to move a first plunger (202) mounted on a first receiving member (200) holding the blood plasma and push the blood plasma,
wherein as a power source (310) of the pressurizing means (300) moves a piston (311) to move the first plunger (202) mounted on the piston (311), thereby injecting the blood plasma into the second space 180 at a predetermined injection rate and a predetermined pressure,
wherein when part of the blood plasma is injected into the second space (180), the remainder of the blood plasma remains in the first receiving member (200),
wherein after filtration, the first plunger (202) is moved back to collect a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space into the first receiving member (200) holding the remaining blood plasma.

**20.** The method for extracting concentrated plasma as claimed in claim 19, wherein air in a second receiving member (210) mounted on the membrane filter unit (100) is injected into the second space (180) to collect a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space (180) into the first receiving member (200) holding the remaining blood plasma.

**21.** The method for extracting concentrated plasma as claimed in claim 20, wherein the first receiving member (200) and the second receiving member (210) are connected to the second space (180),
wherein before the second collecting step (S50), a first valve (150) is manipulated to have the second space (180) open into the first receiving member (200) and a second valve (150) is manipulated to disconnect the second space (180) from the second receiving member (210),
wherein in the second collecting step (S50), the first valve (150) is manipulated to have the second space (180) open into the first receiving member (200) and the second valve (150) is manipulated to have the second space (180) open into the second receiving member (210).

**22.** The method for extracting concentrated plasma as claimed in claim 14, wherein the filtering step (S20) includes opening a first valve (150) at a side of a receiving member (200) to have the second space (180) open into the first receiving member (200) and closing a second valve (150) mounted on the opposite side of the first receiving member (200).

**23.** The method for extracting concentrated plasma as claimed in claim 22, wherein in the filtering step (S20), when the blood plasma is injected, an air layer is formed in part of the space of the membrane filter unit (100) to limit the injection height of the blood plasma to a predetermined height or below.

**24.** The method for extracting concentrated plasma as claimed in claim 22, further comprising:

a step S31 of completely closing the membrane filter unit and forming a vacuum pressure in the membrane filter (100), after the pressure-reducing step (S30).

**25.** The method for extracting concentrated plasma as claimed in claim 24, wherein the collecting step S40 includes opening the second valve (150) to momentarily supply external air into the membrane filter unit (100) and thereby collecting a component having a particle diameter equal to or larger than the predetermined particle diameter using the air.

**26.** The method for extracting concentrated plasma as claimed in claim 12, wherein the concentrated plasma becomes gel by repeatedly filtering the blood plasma injected into the membrane filter unit (100) or adding calcium and then repeatedly filtering the blood plasma.

FIG. 1

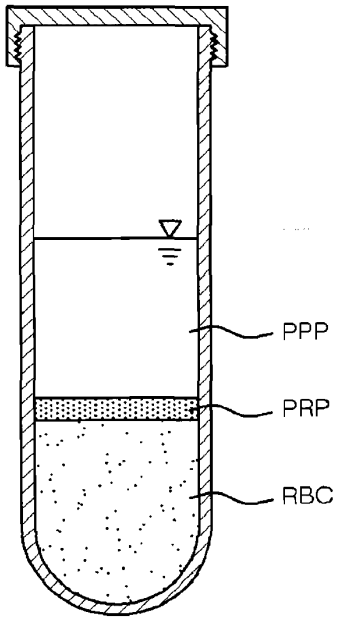


FIG. 2

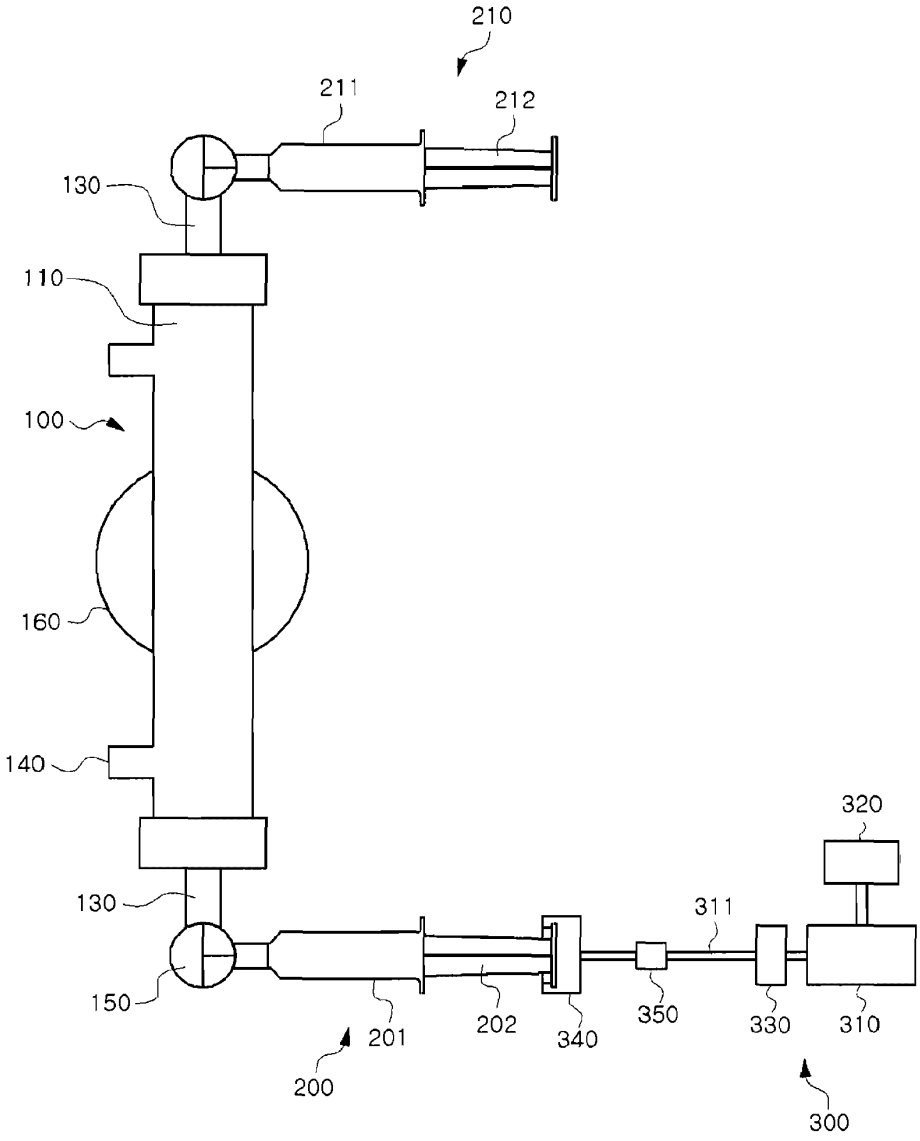

210
211
212
130
110
100
160
140
130
150
200
201
202
340
350
311
320
330
310
300

FIG. 3

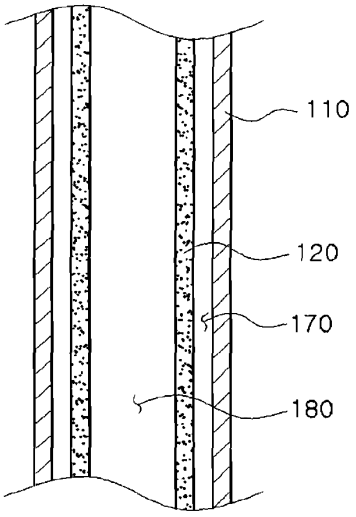


FIG. 4a

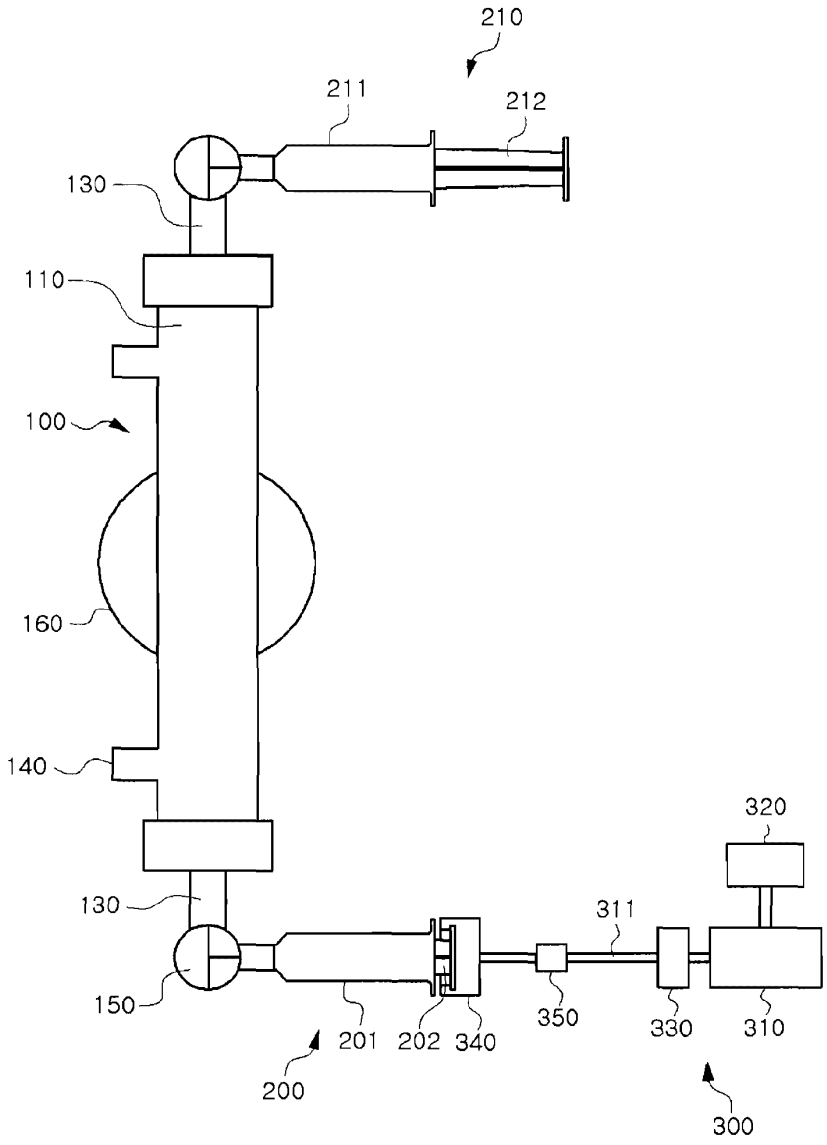

210
211
212
130
110
100
160
140
130
150
320
311
350
330
310
201
202
340
200
300

FIG. 4b

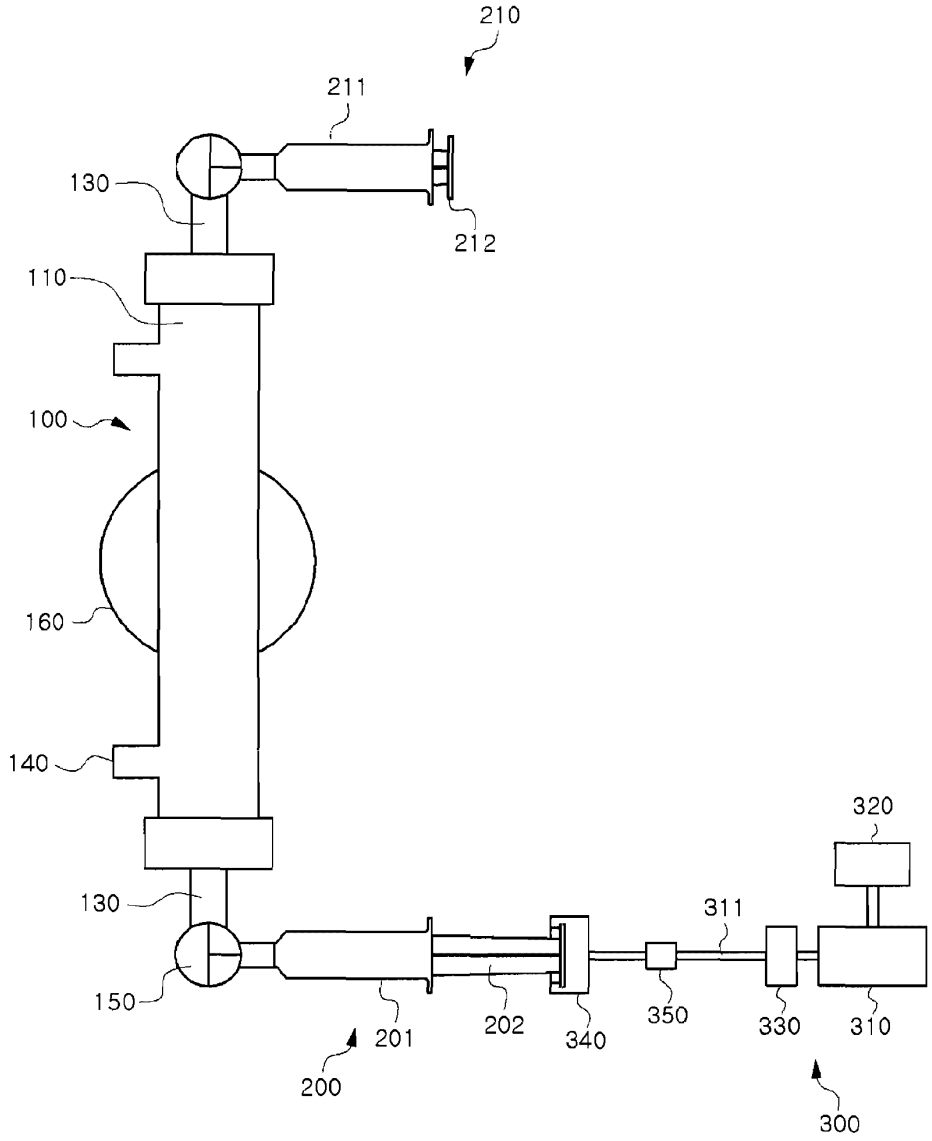

210
211
130
212
110
100
160
140
320
130
311
150
201
202
340
350
330
310
200
300

FIG. 4c

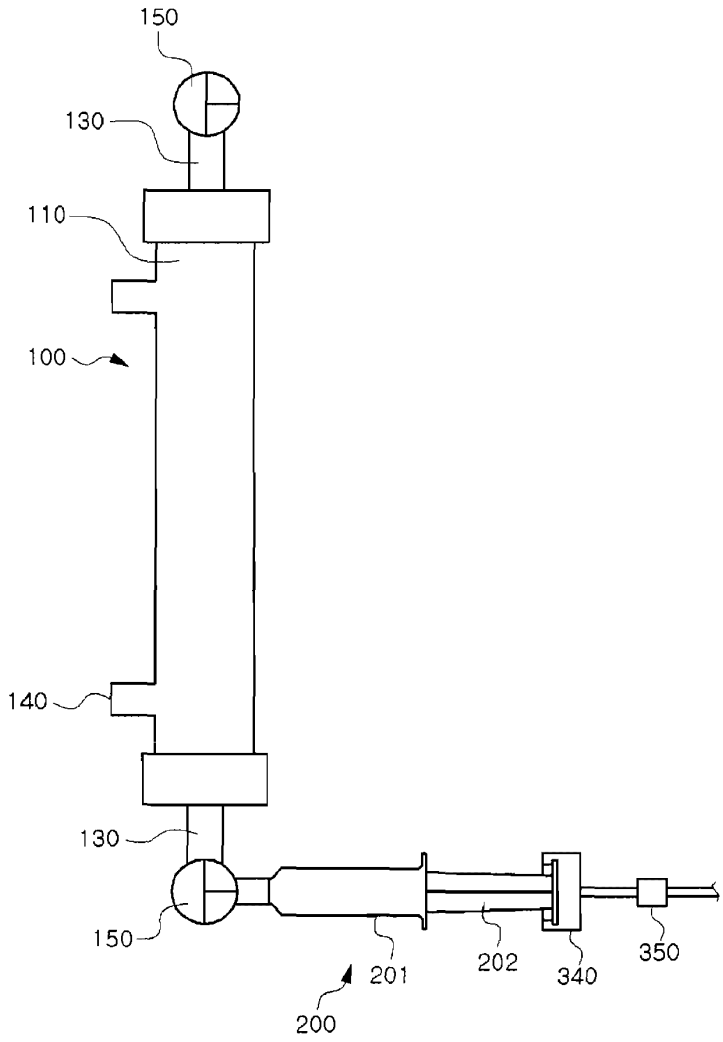


FIG. 5

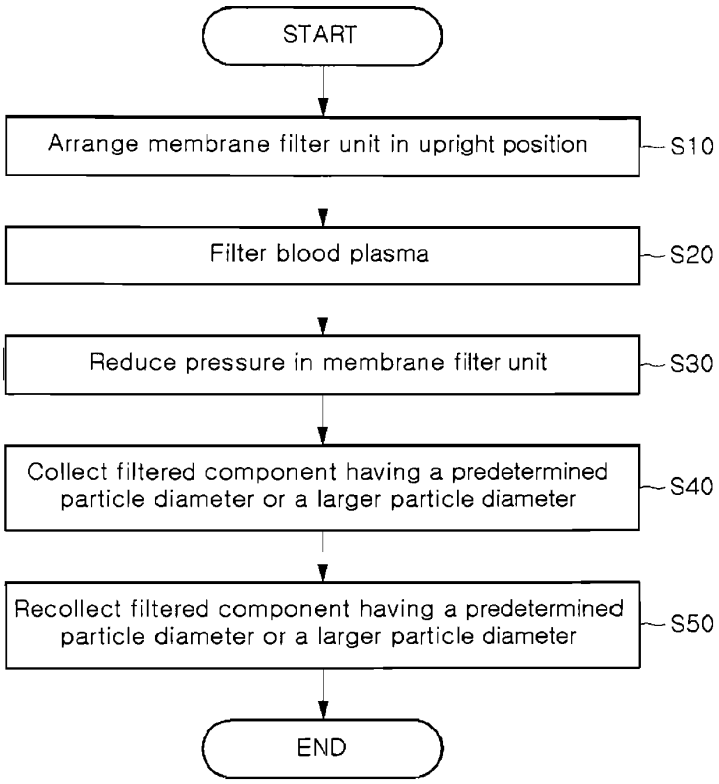
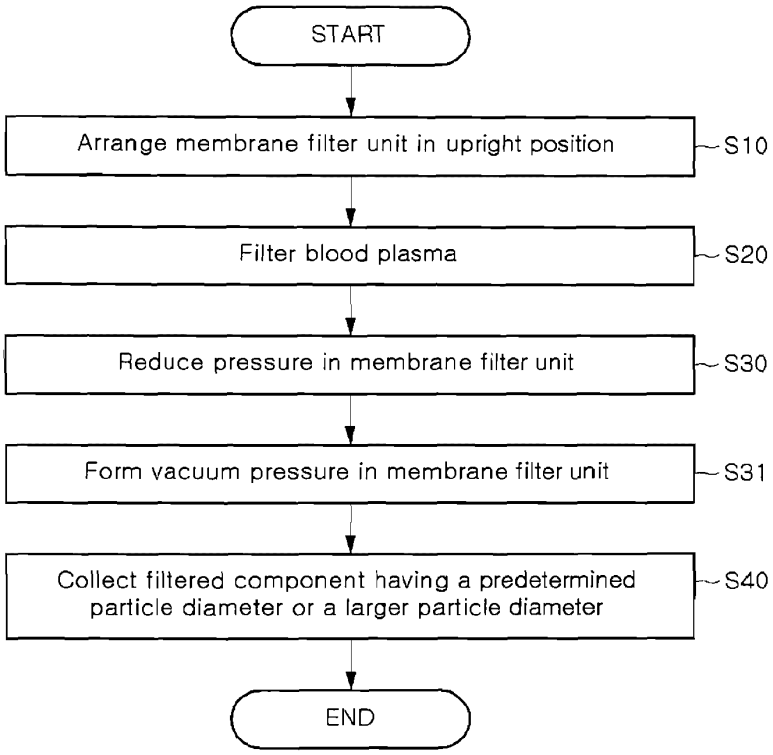

START
Arrange membrane filter unit in upright position
S10
Filter blood plasma
S20
Reduce pressure in membrane filter unit
S30
Collect filtered component having a predetermined particle diameter or a larger particle diameter
S40
Recollect filtered component having a predetermined particle diameter or a larger particle diameter
S50
END

FIG. 6


START
Arrange membrane filter unit in upright position
S10
Filter blood plasma
S20
Reduce pressure in membrane filter unit
S30
Form vacuum pressure in membrane filter unit
S31
Collect filtered component having a predetermined particle diameter or a larger particle diameter
S40
END

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# EUROPEAN SEARCH REPORT

Application Number
EP 14 17 6323

## DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document with indication, where appropriate, of relevant passages | Relevant to claim | CLASSIFICATION OF THE APPLICATION (IPC) |
|---|---|---|---|
| X | US 6 342 157 B1 (HOOD III ANDREW G [US]) 29 January 2002 (2002-01-29) * column 7, line 1 - line 39 * * column 8, line 29 - line 67 * * figure 3 * | 1-26 | INV. G01N33/49 A61M1/34 B01D61/14 |
| X | US 4 424 132 A (IRIGUCHI NORIO [JP]) 3 January 1984 (1984-01-03) * column 5, line 30 - column 7, paragraph 17 * | 1-26 | |
| A | EP 2 407 245 A2 (GLOTECH CO LTD [KR]; IHM KHI PYO [KR]) 18 January 2012 (2012-01-18) * the whole document * | 1-26 | |

TECHNICAL FIELDS SEARCHED (IPC)

G01N
A61M
B01D

The present search report has been drawn up for all claims

| Place of search | Date of completion of the search | Examiner |
|---|---|---|
| The Hague | 23 September 2015 | Baranski, Jörg |

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

## ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 14 17 6323

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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23-09-2015

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| US 6342157 B1 | 29-01-2002 | US 6010627 A | 04-01-2000 |
| | | US 6342157 B1 | 29-01-2002 |
| US 4424132 A | 03-01-1984 | NONE | |
| EP 2407245 A2 | 18-01-2012 | CN 102438757 A | 02-05-2012 |
| | | EP 2407245 A2 | 18-01-2012 |
| | | JP 5725517 B2 | 27-05-2015 |
| | | JP 2013504755 A | 07-02-2013 |
| | | KR 20110045980 A | 04-05-2011 |
| | | RU 2011144825 A | 10-05-2013 |
| | | US 2012053041 A1 | 01-03-2012 |
| | | WO 2011052910 A2 | 05-05-2011 |

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82



INARI_018179

## REFERENCES CITED IN THE DESCRIPTION

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### Patent documents cited in the description


- KR 2010011616010 **[0008]**
- KR 2010004143610 **[0008]**

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# ELECTRONIC ACKNOWLEDGEMENT RECEIPT

| APPLICATION # | RECEIPT DATE / TIME | ATTORNEY DOCKET # |
|---|---|---|
| **17/498,642** | **07/18/2023 04:26:29 PM ET** | **111552-8023.US02** |

## Title of Invention

SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

## Application Information

| | | | |
|---|---|---|---|
| APPLICATION TYPE | Utility - Nonprovisional Application under 35 USC 111(a) | PATENT # | - |
| CONFIRMATION # | 1040 | FILED BY | JiYoung Anderson |
| PATENT CENTER # | 62462180 | FILING DATE | 10/11/2021 |
| CUSTOMER # | 25096 | FIRST NAMED INVENTOR | Richard Quick |
| CORRESPONDENCE ADDRESS | - | AUTHORIZED BY | Matthew Williams |

## Documents

**TOTAL DOCUMENTS: 7**

| DOCUMENT | PAGES | DESCRIPTION | SIZE (KB) |
|---|---|---|---|
| 2023-7-18 IDS SB08 - 111552-8023US2.PDF | 4 | Information Disclosure Statement (IDS) Form (SB08) | 139 KB |
| Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems. | | | |
| FOR_WO2016014955.PDF | 63 | Foreign Reference | 2325 KB |
| FOR_EP2942624.PDF | 24 | Foreign Reference | 1188 KB |
| FOR_WO2006029270.PDF | 33 | Foreign Reference | 1157 KB |
| NPL_ISR_WO_PCTUS20230 | 9 | Non Patent Literature | 3976 KB |

| | | | |
|---|---|---|---|
| 60502_May_25_2023_9pages.PDF | | | |
| NPL_ISR_PCT_2023-61256-June-7-2023-8-pages.PDF | 8 | Non Patent Literature | 1063 KB |
| NPL-Gross-Dump the Pump.PDF | 4 | Non Patent Literature | 870 KB |

## Digest

| DOCUMENT | MESSAGE DIGEST(SHA-512) |
|---|---|
| 2023-7-18 IDS SB08 - 111552-8023US2.PDF | 2F6FC4DE44336D81D0063D291F2E1D769F396ED6CDD7C847EF50265AA97D7ADEB701903FCB4EFFE164F3BDFB9D03DBE013DB923F4650FDE506BFC90453EBF9DF |
| FOR_WO2016014955.PDF | DE12ACD76BAE4B0E156B6F9D382CAEBE3E6243ED877F035256811EF33F0A9463A0204B3777321B5207E9E06058DD462E99A3EA229302CDF42B2A63C4E5792EF2 |
| FOR_EP2942624.PDF | 76F180E3DB96728ABCFFD31B77A2404E0AC8EA38F6420ED879A30A22CD22FA1628FB338AD6869D29C985D62AFB79F292882F89866AD893AB9B9EB39BC5CE38DF |
| FOR_WO2006029270.PDF | 9F9FCC67AFD589CE61E4B384802B8F1B3B2118E927157C959323391A302F028ADA8961E7CC81A93CDF03C5DD57AD1D8FB16AE710689466AD8D1ED27132ACD968 |
| NPL_ISR_WO_PCTUS2023060502_May_25_2023_9pages.PDF | D531F14961694901D7333C4BAA563CF184EF439838AFD5147B2BDDC50612BF18C97B659466792D95F507F17FF02F9D7F5C1806B1068BFC456412E490186AEEF2 |
| NPL_ISR_PCT_2023-61256-June-7-2023-8-pages.PDF | E29F558402CAA5ECA7B480DBF767FC910107364FF8EB3919C86E39BC20664311EDA23D81B18626667115B85F0FF8707387E626478C646A16AA39EB2CD5DE7AAA |
| NPL-Gross-Dump the | D44985D30C015BE8DA101967568EDF70598C9DCC517B882F1 |

Pump.PDF 524CC5F8D5C8C53620135568E11D3A8E76C94DABDD42BADC
78DE5603483BF94B00DA3679A300F1D

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**New Applications Under 35 U.S.C. 111**

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

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**New International Application Filed with the USPTO as a Receiving Office**

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

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| **17/498,642** | **07/18/2023 04:26:29 PM ET** | **111552-8023.US02** |

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| CUSTOMER # | 25096 | FILING DATE | 10/11/2021 |
| CORRESPONDENCE ADDRESS | - | FIRST NAMED INVENTOR | Richard Quick |

## Payment Information

| PAYMENT METHOD | PAYMENT TRANSACTION ID | PAYMENT AUTHORIZED BY |
|---|---|---|
| **CARD / 3369** | **E20237HG27288023** | **JiYoung Anderson** |

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

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

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*A61B 10/02* (2006.01) *A61B 17/32* (2006.01)

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(74) Agents: **LIKOUREZOS, George** et al.; Carter, Deluca, Farrell & Schmidt, LLP, 445 Broad Hollow Road, Suite 420, Melville, NY 11747 (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, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

*[Continued on next page]*

(54) **Title**: ANATOMICAL SPECIMEN COLLECTION DEVICE AND SYSTEM

(57) **Abstract**: A bone dust collection device includes a bone dust collection structure defining a longitudinal axis and having a proximal end and a distal end. The bone dust collection structure has a transverse plate member connected at or in the vicinity of the proximal end to a cylindrical wall defining an aperture at the distal end for receiving and collecting bone dust. The aperture extends proximally and includes a filtration member disposed therein. The filtration member causes at least partial separation of fluid from the bone dust via the fluid passing proximally through the filtration member. The bone dust collection structure enables removal of bone dust collected therein. A method of collecting an anatomical specimen includes generating an anatomical specimen in particulate form at a surgical site of a subject; collecting the particulate accumulated in the collection device; and packing the collected particulate into a region of interest in the subject.

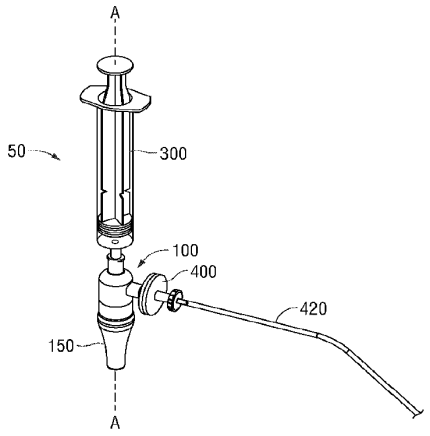



FIG. 1

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**Published**:

— *with international search report (Art. 21(3))*

# ANATOMICAL SPECIMEN COLLECTION DEVICE AND SYSTEM

## CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to, and benefit of, U.S. Provisional Patent Application No. 62/028,552 filed on July 24, 2015, entitled "ANATOMICAL SPECIMEN COLLECTION DEVICE AND SYSTEM", by John M. Abrahams and to U.S. Provisional Patent Application No. 62/030,882 filed on July 30, 2015 of the same title, by John M. Abrahams et al., the entire contents of both of which are incorporated herein by reference.

## BACKGROUND

[0002] 1. Technical Field

[0003] The present disclosure relates to anatomical specimen collectors.

[0004] 2. Discussion of Related Art

[0005] During orthopaedic surgery, bone is drilled and bone dust is formed. During the surgical procedure, bone replacement is performed by harvesting bone dust from a subject other than the patient or subject in the form of allograft. In addition to the expense of supplying bone replacement from a source other than the patient or subject, the equipment used for such procedures is bulky and difficult to work with.

## SUMMARY

[0006] The present disclosure relates to novel and non-obvious device, system and method for harvesting an anatomical specimen such as bone dust from a subject and replacing the anatomical specimen in the subject.

[0007] More particularly, the present disclosure relates to a bone dust collection device that includes a bone dust collection structure defining a longitudinal axis and having a proximal end and a distal end. The bone dust collection structure has a transverse plate member connected at or in the vicinity of the proximal end to a cylindrical wall defining an aperture at the distal end for receiving and collecting bone dust, the aperture extending proximally and including a filtration member disposed therein. The filtration member is configured and disposed wherein the filtration member causes at least partial separation of fluid from the

bone dust via the fluid passing proximally through the filtration member. The bone dust collection structure is configured to enable removal of bone dust collected therein.

[0008] In one embodiment, at least one aperture may be defined in the transverse plate member that enables the fluid at least partially separated from the bone dust by the filtration member to pass therethrough. A flow interruption member may be configured and disposed with respect to the bone dust collection structure wherein flow of fluid through the at least one aperture of the bone dust collection structure occurs by suction pressure induced on the flow interruption member causing the flow interruption member to change position to enable flow through the at least one aperture defined in the transverse plate member.

[0009] In one embodiment, least another aperture may be defined in the transverse plate member wherein the flow interruption member includes a shaft member disposed through the at least another aperture wherein the change of position of the flow interruption member occurs via the suction pressure induced on the flow interruption member to enable flow through the at least one aperture defined in the transverse plate member.

[00010] In one embodiment, the bone dust collection device may further include a syringe including a plunger in fluid communication with the bone dust collection structure wherein the suction pressure is caused by retraction of the plunger away from the bone dust collection structure to enable flow through the at least one aperture defined in the transverse plate member.

[00011] In one embodiment, advancement of the plunger may cause the flow interruption member to interrupt flow from the bone dust collection structure. The bone dust collection device may further include a conduit in fluid communication with the bone dust collection structure, wherein advancement of the plunger causes the fluid received through the at least one aperture defined in the transverse plate member to discharge through the conduit away from the bone dust collection device.

[00012] In one embodiment, the conduit may be structured such that the conduit discharges the fluid in a direction generally perpendicular to the direction of fluid flow through the filtration member.

[00013] In still a further embodiment, the bone dust collection device may further include another flow interruption device configured and disposed with respect to the flow interruption device and with respect to the bone dust collection structure wherein suction pressure induced on the another flow interruption device causes the another flow interruption device to be in a closed position and causes the flow interruption member to change position to enable flow through the at least one aperture defined in the transverse plate member.

[00014] In a further embodiment, the bone dust collection device may further include another flow interruption device configured and disposed with respect to the flow interruption device and with respect to the bone dust collection structure wherein the another flow interruption device is a plug member to seal off flow therethrough during connection of the bone dust collection device to a continuous vacuum system.and suction pressure induced on the flow interruption device causes the flow interruption member to change position to enable flow through the at least one aperture defined in the transverse plate member.

[00015] In yet another embodiment, the bone dust collection device may further include a bone dust removal structure defining an aperture having a proximal end and a distal end. The aperture may be configured and disposed for facilitating transport of bone dust from the distal end of the bone dust removal structure to the bone dust collection structure.

[00016] In a still further embodiment, the bone dust removal structure may include a nozzle that defines the aperture of the bone dust removal structure, the nozzle defining a proximal end and a distal end, wherein the nozzle facilitates transport of the bone dust to the bone dust collection structure. In yet another embodiment, the nozzle may be removably attached to the bone dust collection structure, wherein removal of the nozzle from the bone dust collection structure enables removal of bone dust collected within the bone dust collection structure.

[00017] In one embodiment, the bone dust collection device may further include a guide member configured and disposed with respect to the suction source and the bone dust collection structure for enabling a user to manually control the location of the bone dust removal structure during a surgical procedure.

[00018] In one embodiment, the flow interruption member may be an umbrella valve. In yet another embodiment, the another flow interruption member is a check valve.

[00019] The present disclosure relates also to a bone dust collection device that includes a bone dust collection structure defining a proximal end and a distal end, the bone dust collection structure including a filtration member at the proximal end and defining an aperture at the distal end for receiving and collecting bone dust, the filtration member causing at least partial separation of fluid from the bone dust via the fluid passing proximally through the filtration member; and a bone dust removal structure defining an aperture having a proximal end and a distal end, the aperture configured and disposed for facilitating transport of bone dust from the distal end of the bone dust removal structure to the bone dust collection structure, the bone dust removal structure removably attached to the bone dust collection structure, wherein removal of the bone dust removal structure from the bone dust collection structure enables removal of bone dust collected within the bone dust collection structure.

[00020] The present disclosure relates also to an anatomical collection system that includes an anatomical specimen collection structure defining a proximal end and a distal end, the anatomical specimen collection structure including a filtration member at the proximal end and defining an aperture at the distal end for receiving and collecting an anatomical specimen, the filtration member causing at least partial separation of fluid from the anatomical specimen via the fluid passing proximally through the filtration member; and an anatomical specimen removal structure defining an aperture having a proximal end and a distal end, the aperture configured and disposed for facilitating transport of the anatomical specimen from the distal end of the anatomical specimen removal structure to the anatomical specimen collection structure. The anatomical specimen removal

structure is removably attached to the anatomical specimen collection structure wherein detachment of the anatomical specimen removal structure from the anatomical specimen collection structure enables removal of the anatomical specimen collected within the anatomical specimen collection structure.

[00021] In one embodiment, the anatomical specimen is bone dust.

[00022] The present disclosure relates also to a method of collecting an anatomical specimen that includes generating an anatomical specimen in particulate form at a surgical site of a subject; irrigating the surgical site to suspend the particulate in a particulate fluid mixture; disposing a tip of a collection device in the particulate fluid mixture; aspirating the collection device to filter and separate the particulate from the particulate fluid mixture therein accumulating the particulate in the collection device; and collecting the particulate accumulated in the collection device.

[00023] The method may further include packing the collected particulate into a region of interest in the subject.

[00024] In one embodiment, the collecting the particulate accumulated in the collection device is preceded by disassembling the collection device, and the method may further include reassembling the collection device; generating additional anatomical specimen in particulate form at a surgical site of the subject; irrigating the surgical site to suspend the particulate in a particulate fluid mixture; disposing the tip of the collection device in the particulate fluid mixture; aspirating the collection device to filter and separate the particulate from the particulate fluid mixture therein accumulating the particulate in the collection device; and collecting the particulate accumulated in the collection device.

[00025] The method may further include packing the additionally collected particulate into a region of interest in the subject.

[00026] In one embodiment, the aspirating of the collection device may include connecting the collection device to a vacuum source, which in one embodiment, may be in an operating room, wherein the vacuum source is in fluid communication with the fluid in the particulate fluid mixture to filter and separate the particulate from the particulate fluid mixture.

[00027] In one embodiment, the aspirating of the collection device may include actuating a syringe in fluid communication with the collection device and in fluid communication with the particulate fluid mixture wherein the actuating of the syringe effects filtering and separating the particulate from the particulate fluid mixture.

**BRIEF DESCRIPTION OF THE DRAWINGS**

[00028] The advantages of the embodiments of the present disclosure will become apparent from the following detailed description of the various embodiments of the present disclosure with reference to the drawings wherein:

[00029] FIG. 1 is a transparent perspective view of a bone dust collection system according to one embodiment of the present disclosure;

[00030] FIG. 2 is an exploded view of a bone dust collection device that is included within the bone dust collection system of FIG. 1;

[00031] FIG. 3 is a profile view of one embodiment of a bone dust collection device that may be included within the bone dust collection system of FIG. 1;

[00032] FIG. 4 is a partial profile cross-sectional view of the bone dust collection system of FIGS. 1 and 2 having one embodiment of a filtration member according to the present disclosure;

[00033] FIG. 5 is a cross-sectional enlarged view of the bone dust collection housing and valve support structure of the bone dust collection device of FIG. 3 having an embodiment of a filtration member according to the present disclosure;

[00034] FIG. 6A is an end view of a filter that is included within the bone dust collection device of FIGS. 1-5;

[00035] FIG. 6B is a side view of the filter of FIG. 6A;

[00036] FIG. 6C is a view of Detail 6C of FIG. 6B;

[00037] FIG. 6D is a proximal perspective view of the filter of FIGS. 6A-6C;

[00038] FIG. 7A is an end view of one embodiment of a nozzle that may be included within the bone dust collection device of the bone dust collection system of FIGS. 1-5;

[00039] FIG. 7B is a cross-sectional view of the nozzle of FIG. 7A taken along cross-section line 7B-7B;

[00040] FIG. 8A is an end view of another embodiment of a nozzle that may be included within the bone dust collection device of the bone dust collection system of FIGS. 1-5;

[00041] FIG. 8B is a cross-sectional view of the nozzle of FIG. 8A taken along cross-section line 8B-8B;

[00042] FIG. 9A is an end view of one embodiment of a valve cap that that may be included with the bone dust collection device of the bone dust collection system of FIGS. 1-5;

[00043] FIG. 9B is a cross-sectional view of the valve cap of FIG. 9A taken along section line 9B-9B;

[00044] FIG. 10 is an exploded partially transparent view of a handle assembly that may be included as part of the bone dust collection device of the bone dust collection system of FIGS. 1-5;

[00045] FIG. 10A is a cross-sectional view of the handle assembly of FIG. 10;

[00046] FIG. 11 is a perspective, partially transparent view of the handle assembly of FIGS. 10 and 10A and the bone dust collection device of FIG. 3 that includes a plug seal;

[00047] FIG. 12 is a perspective, partially transparent view of the handle assembly of FIG. 11 and the bone dust collection device of FIGS. 1-2 and 4-5 that includes a check valve seal;

[00048] FIG. 13 is a partially transparent view of one embodiment of a self-contained bone dust collection device according to the present disclosure that includes a check valve and a flow diversion member for diverting fluid flow from the bone dust collection device;

[00049] FIG. 13A is a partially transparent view of another embodiment of the self-contained bone collection device of FIG. 13;

[00050] FIG. 14 is a zoomed out partial profile cross-sectional view of the bone dust collection system of FIG. 1-3;

[00051] FIG. 15A is a detailed view of an extraction flow interruption member illustrated in the form of an umbrella valve that is positioned on an upper surface of the housing in a closed position;

[00052] FIG. 15B is a detailed view of the umbrella valve positioned on the upper surface of the housing in an open position to enable flow of fluid past the umbrella valve;

[00053] FIG. 16 is a cross-sectional view of the bone dust collection device when the umbrella valve is in the closed position as illustrated in FIG. 15A;

[00054] FIG. 17 is a cross-sectional view of the bone dust collection device when the umbrella valve is in the open position for permitting passage of fluid past the umbrella valve;

[00055] FIG. 18 is a cross-sectional view of the bone dust collection device when the umbrella valve is in the closed position for discharging and diverting fluid which has been collected by syringe;

[00056] FIG. 19 is a cross-sectional view of another embodiment of the bone dust collection device having the alternate filtration member shown in FIG. 4 and wherein the umbrella valve is in the open position;

[00057] FIG. 20 is cross-sectional view of the bone dust collection device of FIG. 19 wherein the umbrella valve is in the closed position and fluid is diverted through a check valve;

[00058] FIG. 21 is a cross-sectional view of the bone dust collection device having the filtration member of FIG. 5 in an inverted position to allow removal of collected bone dust;

[00059] FIG. 22 is a cross-sectional view of the bone dust collection device of FIG. 19 in an inverted position to allow removal of collected bone dust;

[00060] FIG. 23 is a perspective transparent view of a kit package that houses bone dust collection devices according to embodiments of the present disclosure;

[00061] FIG. 24 is a perspective view of the bone dust collection device of FIG. 3 having a plug member to seal off flow during connection of the bone dust collection device to a continuous vacuum system;

[00062] FIG. 25 is a perspective view of the bone dust collection device of FIGS. 1-2 and 4-5 having a fluid flow diversion member and a check valve wherein fluid flow is directed vertically downward;

[00063] FIG. 26 is a cross-sectional view of the bone dust collection device of FIG. 25;

[00064] FIG. 27 is a perspective view of the bone dust collection device of FIGS. 25 and 26 wherein the fluid flow is directed horizontally;

[00065] FIG. 28 is a perspective view of the bone dust collection device of FIG. 24 wherein the plug member is replaced by a flow diversion member to enable diversion of fluid back to a surgical site;

[00066] FIG. 29 is a transparent elevation view of the bone dust collection device of FIG. 28;

[00067] FIG. 30 is a perspective view of the bone dust collection device of FIG. 28 wherein a tubular portion of the flow diversion member has been removed;

[00068] FIG. 31 is a perspective view of the bone dust collection device of FIG. 30 wherein the flow diversion member is oriented at an angle to enable diversion of fluid in an alternative direction with respect to a surgical site; and

[00069] FIG. 32 is a perspective view of the bone dust collection device of FIG. 30 wherein the flow diversion member is oriented at an angle to enable diversion of fluid in yet another alternative direction with respect to a surgical site.

**DETAILED DESCRIPTION**

[00070] To advance the state of the art of bone dust collection, the present disclosure relates to a bone dust collection system where a user, e.g., a surgeon or other medical professional, is able to simply collect bone dust using a hand-held device during aspiration from a surgical site.

[00071] As defined herein, a bone dust collection device refers to an assembly of components which may either be employed independently or in a self-contained manner to collect bone dust while a bone dust collection system refers to utilization of the device and its assembly of components in conjunction with an external suction source such as via fluid communication with an operating room suction or vacuum system. The suction or vacuum system may also be located outside of an operating room under appropriately certified conditions. The device can be used to collect other anatomical specimen besides bone dust, such as, for example, bone marrow or other biological cells.

[00072] The bone dust collection device enables collection of bone dust, defined herein as generally in the range of about 25 micron to about 600 micron cross-section bone particles, during a surgical procedure in order to harvest and use the bone dust for bone fusion mass in orthopedic surgery of the same patient. In actuality, the bone dust collection device enables collection of bone dust of sizes generally known to be created during surgical procedures.

[00073] The device generally may be applied to one or more medical procedures performed on a single patient. The device may be utilized as a stand-alone bone collection device that includes a syringe or the device may be adapted as a bone collection system by fluidically coupling the device to a vacuum source such as commonly found in an operating room environment. The device may be used multiple times on the same patient during the same operating procedure but is discarded after completion of usage.

[00074] The output of the device may be a "plug" of bone that can be held with forceps and placed into an intervertebral cage or used for any other procedure that requires bone or fusion construct. The output of the device may also be bone dust that is concentrated and can be manually placed into an intervertebral cage or construct or placed therein using instruments.

[00075] The device is configured to allow fluids, e.g., blood and saline, to pass through a separator or filtration member, .e.g., a filter or a valve mechanism, thus separating bone dust from fluids. The bone dust collection device aspirates surgical fluid and filters out bone dust for use during a surgical procedure.

[00076] The bone dust so collected may be processed by the user during the procedure wherein the processing of the bone dust may include cleaning, compacting, and transfer of the bone dust.

[00077] As described above, the bone dust collection device may be disposed of, and in most cases is intended to be discarded, following usage.

[00078] After using a surgical drill, the user aspirates surgical fluid to filter and then harvest bone dust; Fluid is discarded and bone dust is removed from a collection chamber defined within the bone dust collection device. Bone dust may be used for fusion or reconstruction procedures. Procedures include, but are not limited

to, e.g., spinal fusion, long bone fusion, cranial reconstruction, craniofacial reconstruction, orthopaedic reconstruction, or dental reconstruction.

[00079] Turning now to FIGS. 1, 2 and 3, there is illustrated a bone dust collection system 50 that includes a bone dust collection device according to one embodiment of the present disclosure. More particularly, bone dust collection device 100 includes a cylindrically-shaped bone dust collection structure 110 that extends from a proximal end 114a to a distal end 114b of the bone dust collection structure 110. The proximal end 114a of the bone dust collection structure 110 is configured as a valve support plate 116 such that the bone dust collection structure 110 also serves as a valve support structure. Cylindrical wall 118 extends distally from the valve support plate 116 to define a central aperture and volume 120 for receiving and collecting bone dust (see FIG. 3).

[00080] As best illustrated in FIG. 2 and FIG. 3, the valve support structure or bone dust collection structure 110 includes a valve supporting surface or plate 116 near the proximal end 114a.

[00081] The central aperture 120 extends proximally towards proximal end 114a of the bone dust collection structure 110 and includes a filtration member 122 disposed therein that may be part of a filter assembly 124. The filter assembly 124 may include a ring-shaped filter mounting member 126 that is configured to be disposed within the central aperture 120.

[00082] As explained in more detail below, the filtration member 122 and the filter assembly 124 are configured and disposed wherein the filtration member 122 causes at least partial separation of fluid from the bone dust via the fluid passing proximally through the filtration member 122. Thus, the bone dust collection structure 110 is configured to enable removal of bone dust collected therein.

[00083] As best shown in FIG. 2, the bone dust collection device 100 defines a central longitudinal axis **A-A** that extends from a proximal end 100a to a distal end 100b. At least one fluid flow aperture 116a is defined in the transverse plate member 116 that enables the fluid at least partially separated from the bone dust by the filtration member 122 to pass therethrough. A fluid extraction valve shaft aperture 116' is also defined in the transverse plate member 116 generally

through the center **C** of the transverse plate member 116 through which longitudinal axis **A-A** passes. A second fluid flow aperture 116b may also be defined in the transverse plate member 116 on a side of the longitudinal axis **A-A** opposite to the first fluid flow, e.g., at a position 180° from the first fluid flow aperture 116a, which is at position 0°. Additional fluid flow apertures (not shown) may also be positioned at 90° or 270° or other suitable locations if desired. It should be noted also that the bone dust collection structure 110 may be oriented such that the first and second fluid flow apertures 116a and 116b may coincide with the 90° and 270° positions, respectively, or vice versa. Such interchangeability of the orientation of the first and second fluid flow apertures 116a and 116b is taken advantage of throughout the description which follows where necessary or desirable to explain the operation of the bone dust collection device 100.

[00084] The bone dust collection device 100 further includes a fluid extraction flow interruption member 130 that is configured and disposed with respect to the bone dust collection structure 110 wherein, as explained in more detail below, flow of fluid through at least one aperture or, for example, fluid flow apertures 116a and 116b, of the bone dust collection structure 110 occurs by suction pressure induced on the fluid extraction flow interruption member 130 causing the flow interruption member 130 to change position to enable flow through fluid flow apertures 116a and 116b.

[00085] As indicated above, fluid extraction valve shaft aperture 116' is defined in the transverse plate member 116. As shown in FIG. 3, the extraction flow interruption member 130 may be an umbrella valve as shown and which includes a shaft member 132 that is disposed through the fluid extraction valve shaft aperture 116'. The extraction flow interruption member 130 includes a diaphragm 134 that is formed with the shaft member 132. The diaphragm 134 is made from an elastomeric and flexible material and which overlays the fluid flow apertures 116a and 116b on the proximal side of transverse plate member 116 such that the change of position of the extraction flow interruption member 130 occurs via the suction pressure induced on the flow interruption member, and

more particularly on the diaphragm 134, such that the diaphragm 134 flips away from the transverse plate member 116 to expose the fluid flow apertures 116a and 116b, thereby enabling flow through the apertures 116a and 116b. The shaft member 132 includes a proximal portion 132a and a distal portion 132b wherein the distal portion 132b defines a diameter that is greater than the diameter of the proximal portion 132a. The fluid extraction valve shaft aperture 116' is thus shaped accordingly to define a proximal narrow diameter portion and a distal wide diameter portion to match the proximal and distal portions 132a and 132b of the shaft member 132.

[00086] In the embodiment of the housing 110 illustrated in FIG. 3, a portion 1161 of the transverse plate member 116 extends distally into the central aperture 120 to define a circumferential channel 136 between inner surface 118a of the housing wall 118 and the distally extending portion 1161 of the transverse plate member 116. The filter assembly 124 is configured and disposed wherein the ring-shaped filter mounting member 126 is received in the circumferential channel 136 such that the filtration member 122 overlays the distal ends of the fluid flow apertures 116a and 116b.

[00087] The bone dust collection device 100 may further include a bone dust removal structure 150 that defines an aperture 152 having a proximal end 152a and a distal end 152b. In one embodiment, the bone dust removal structure 150 may include, or be formed in the shape of, a nozzle wherein proximal end 154a of the nozzle 150 may engage with outer surface 118b of housing wall 118 for structural stability of the nozzle 150 during usage for collecting bone dust. The aperture 152 of the nozzle 150 is configured and disposed for facilitating transport of bone dust, or a mixture of bone dust and irrigating fluid such as saline solution, as represented by arrow **B**, from the distal end 152b of the bone dust removal structure or nozzle 150 to the central aperture 120 of the bone dust collection structure 110. When in the form of a nozzle, the nozzle thus defines the aperture 152 of the bone dust removal structure 150. The nozzle defines the proximal end 152a and distal end 152b, wherein the nozzle facilitates transport of the bone dust **B**, which includes fluid from the surgical site, to the bone dust

collection structure 110. The nozzle may be removably attached to the bone dust collection structure 110 by disengaging from outer surface 118b of housing wall 118. Removal of the nozzle 150 from the bone dust collection structure 110 enables removal of bone dust collected within the bone dust collection structure 110, as described in more detail below. The nozzle 150 may be made from flexible, elastomeric materials, such as, but not limited to, silicone or urethane.

[00088] The bone dust collection device 100 may further include a tee-shaped port member or cap 160 that defines a bone dust collection interface aperture 162b at a distal portion 160b of the tee-shaped port member or cap 160. The tee-shaped port member or cap 160 may further define a suction device interface aperture 162a at a proximal portion 160a. Additionally, tee-shaped port member or cap 160 defines a fluid diversion aperture 162c at branch connection 160c. As described in more detail below, when in operation, the bone dust collection device 100 in FIG. 3 is connected to a continuous suction source, such as an operating room suction system, at suction device interface aperture 162a. When in this mode of operation for collecting bone dust, the fluid diversion aperture 162c is sealed via a plug 164 inserted therethrough. Fluid from the surgical site is separated from the bone dust (arrow **B**) by the filtration member 122 and passes through to the suction device interface aperture 162a. Suction is maintained by the presence of the plug 164.

[00089] FIG. 4 is a cross-sectional view of the bone dust collection system of FIGS. 1 and 2 having another embodiment of a bone dust collection device according to the present disclosure. More particularly, bone dust collection system 50' is identical to bone dust collection system 50 except that bone dust collection structure 110 is replaced by bone dust collection structure 210 which differs from bone dust collection structure 110. For simplicity, only those features of bone dust collection structure 210 which differ from the corresponding features of bone dust collection structure 110 are described. Additionally, those features are numbered as 210 instead of 110, 216 instead of 116, etc. Reference to FIG. 3 is implied where features not explicitly shown in FIG. 4 are described.

[00090] Bone dust collection device 200 includes cylindrically-shaped bone dust collection structure 210 that extends from proximal end 214a to distal end 214b of the bone dust collection structure 210. The proximal end 214a of the bone dust collection structure 210 is also configured as a valve support plate 216 such that the bone dust collection structure 210 also serves as a valve support structure in the same manner as described above with respect to bone dust collection device 100. Cylindrical wall 118 extends distally from the valve support plate 216 to define a central aperture and volume 220 for receiving and collecting bone dust.

[00091] Valve support structure or bone dust collection structure 210 includes valve supporting surface or plate 216 near the proximal end 214a.

[00092] The central aperture 220 extends proximally towards proximal end 214a of the bone dust collection structure 210 and includes filtration member 122 disposed therein that may be part of filter assembly 224. The filter assembly 224 may now include ring-shaped filter mounting member 226 that is configured to be disposed within the central aperture 220.

[00093] Again, as explained in more detail below, the filtration member 122 and the filter assembly 224 are configured and disposed wherein the filtration member 122 causes at least partial separation of fluid from the bone dust via the fluid passing proximally through the filtration member 122. The filter assembly 224 and filtration member 122 are mounted within the central aperture 220 wherein the ring-shaped filter mounting member 226 has an outside diameter approximately corresponding to the inside diameter of the cylindrical wall 118 such that the ring-shaped filter mounting member 226 may be disposed in a snug fit within the bone dust collection structure 210. Thus, the bone dust collection structure 210 is also configured to enable removal of bone dust collected therein.

[00094] Although illustrated as an assembly of filtration member 122 and the filter mounting member 226, the filter assembly 224 may be a molded construction. In either case, the filtration member 122 may be a mesh with an over-under weave knit material or be a molded membrane with small holes or apertures formed therein, on the order of 100 microns (μm) in cross-sectional distance. The

filtration member 122 may be made from, but not limited to, materials such as fiberglass, copper or stainless steel. The ring-shaped filter mounting member 226 may be made from a thermoplastic elastomer such as polyvinyl chloride and urethane.

[00095] Bone dust collection device 200 also defines a central longitudinal axis **A'-A'** that extends from proximal end 100a to distal end 100b. At least one fluid flow aperture 216a is defined in transverse plate member 216 that enables the fluid at least partially separated from the bone dust by the filtration member 122 to pass therethrough. Fluid extraction valve shaft aperture 216' is also defined in the transverse plate member 216 generally through the center **C** of the transverse plate member 216 through which longitudinal axis **A'-A'** passes. Second fluid flow aperture 216b may also be defined in the transverse plate member 216 again on a side of the longitudinal axis **A'-A'** opposite to the first fluid flow, e.g., at a position 180° from the first fluid flow aperture 216a, which is at position 0°. Additional fluid flow apertures (not shown) may also be positioned at 90° or 270° or other suitable locations if desired. It should be noted again that the bone dust collection structure 210 may also be oriented such that the first and second fluid flow apertures 216a and 216b may coincide with the 90° and 270° positions, respectively, or vice versa. Such interchangeability of the orientation of the first and second fluid flow apertures 216a and 216b is taken advantage of throughout the description which follows where necessary or desirable to explain the operation of the bone dust collection device 200.

[00096] The bone dust collection device 200 further includes also fluid extraction flow interruption member 130 that is configured and disposed with respect to the bone dust collection structure 210 wherein, as explained in more detail below, flow of fluid through at least one aperture or, for example, fluid flow apertures 216a and 216b, of the bone dust collection structure 210 occurs by suction pressure induced on the fluid extraction flow interruption member 130 causing the flow interruption member 130 to change position to enable flow through fluid flow apertures 216a and 216b.

[00097] As indicated above, fluid extraction valve shaft aperture 216' is defined in the transverse plate member 216. As shown in FIG. 3, the extraction flow interruption member 130 may be an umbrella valve as shown and which includes shaft member 132 that is disposed through the fluid extraction valve shaft aperture 216'. The extraction flow interruption member 130 again includes diaphragm 134 that is formed with the shaft member 132. The diaphragm 134 is again made from an elastomeric and flexible material and which overlays the fluid flow apertures 216a and 216b on the proximal side of transverse plate member 216. Again, the change of position of the extraction flow interruption member 130 occurs via the suction pressure induced on the flow interruption member, and more particularly on the diaphragm 134, such that the diaphragm 134 flips away from the transverse plate member 216 to expose the fluid flow apertures 216a and 216b, thereby enabling flow through the apertures 216a and 216b. The shaft member 132 includes again proximal portion 132a and distal portion 132b wherein the distal portion 132b defines a diameter that is greater than the diameter of the proximal portion 132a. However, in contrast to fluid extraction valve shaft aperture 116', fluid extraction valve shaft aperture 216' is thus shaped accordingly to define a narrow diameter portion to match the proximal portion 132a of the shaft member 132. The transverse plate member 216 is not characterized by the portion 1161 of the transverse plate member 116 that extends distally into the central aperture 120. Thus there is no circumferential channel 136 between inner surface 118a of the housing wall 118 and the distally extending portion 1161 of the transverse plate member 116.

[00098] The bone dust collection device 200 also includes the bone dust removal structure 150 mounted on cylindrical wall 118 and tee-shaped port member or cap 160 mounted to bone dust collection structure 210 at proximal end 214a in a similar manner as described above with respect to FIG. 3. However, a suction device 300 is now inserted into the suction device interface aperture 162a while a fluid flow diversion interruption device 400 is in fluid communication with fluid diversion aperture 162c at branch connection 160c.

[00099] Fluid flow diversion interruption device 400 is configured and disposed with respect to the flow interruption member 130 and with respect to the bone dust collection structure 210 wherein suction pressure induced on the flow interruption member 130 causes the flow interruption member 130 to change position to enable flow through the apertures 216a and 216b defined in the transverse plate member 216 while fluid flow diversion interruption device 400 is in a closed position.

[000100] In one embodiment, suction device 300 may be a syringe 302 including a plunger 304 in fluid communication with the bone dust collection structure 210 via distal port 302b of the syringe 302 inserted into the suction device interface aperture 162a of tee-shaped port member or cap 160. Suction pressure is caused by retraction of the plunger 304 in the proximal direction away from the bone dust collection structure 210 to enable flow through the apertures 216a and 216b defined in the transverse plate member 216.

[000101] Conversely, advancement of the plunger 304 distally causes the flow interruption member 130 to interrupt flow from the bone dust collection structure 210 while fluid is diverted through the fluid flow diversion interruption device 400 which includes an upstream port 400a that is inserted in fluid diversion aperture 162c of the tee-shaped port member or cap 160.

[000102] On downstream side 400b of fluid flow diversion interruption device 400, there is disposed a conduit 410 in fluid communication with the bone dust collection structure 210, wherein advancement of the plunger 304 causes the fluid (as represented by arrow **F**) received through the apertures 216a and 216b defined in the transverse plate member 216 to discharge through the fluid conduit 410 away from the bone dust collection device 200 in the direction of arrow **F**. Fluid communication between the fluid conduit 410 and the fluid flow diversion interruption device 400 may be established via a luer valve 412 connecting the fluid conduit 410 to the downstream side 400b. In one embodiment, the fluid flow diversion interruption device 400 may be a check valve installed so as to enable flow of fluid in the direction of arrow **F** and to prevent flow in the direction opposite to arrow **F.** In one embodiment, the conduit 410 is structured such that

the conduit 410 discharges the fluid in a direction generally perpendicular, e.g., in the direction of arrow **F,** to the direction of fluid flow through the filtration member 122.

[000103] FIG. 5 is a cross-sectional enlarged view of the bone dust collection housing and valve support structure 110 of the bone dust collection device of FIG. 3 having an embodiment of the filtration member 122 and transverse plate member 116 with circumferential channel 136 described above with respect to FIG. 3.

[000104] FIG. 6A is an end view of the filter assembly 124 that is included within the bone dust collection device 200 of FIGS. 1-3 and 5. FIG. 6B is a side view of the filter assembly 124 of FIG. 6B illustrating wherein ring-shaped filter mounting member 126 includes a cylindrical wall 128 which is configured and disposed to be received within the circumferential channel 136 illustrated in FIGS. 3 and 5. The cylindrical wall 128 has a height dimension **H** above the filtration member 122. The cylindrical wall 128 may be characterized by a partially contoured profile at the proximal end having a radius of curvature **R**. The ring-shaped filter mounting member 126 may define an inner diameter **D1** and an outer diameter **D2**.

[000105] FIG. 6C is a view of Detail 6C of FIG. 6B wherein ring-shaped filter mounting member 126 includes cylindrical wall 128.

[000106] FIG. 6D is a proximal perspective view of the filter assembly 124 of FIGS. 6A-6C.

[000107] FIG. 7A is an end view of the bone dust removal structure 150 in the form of a nozzle that may be included within the bone dust collection device 100 or 200 of the bone dust collection systems 50 or 50' of FIGS. 1-5.

[000108] FIG. 7B is a cross-sectional view of the nozzle 150 of FIG. 7A taken along cross-section line 7B-7B. The diameter **D3** of central aperture 152 at proximal end 152a tapers in the distal direction to diameter **D4** at distal end 152b such that diameter **D3** is greater than diameter **D4.** Having the tapered configuration such that the diameter of the central aperture 152 increases from the distal end 152b

to the proximal end 152a tends to minimize flow obstruction during operation of the bone collection device 100.

[000109] FIG. 8A is an end view of another embodiment of bone dust removal structure in the form of a nozzle 250 that may be included within the bone dust collection device 100 or 200 of the bone dust collection systems 50 or 50' of FIGS. 1-5.

[000110] FIG. 8B is a cross-sectional view of the nozzle of FIG. 8A taken along cross-section line 8B-8B. More particularly, nozzle 250 defines a generally constant diameter D5 circular aperture 251 at proximal end 250a wherein the circular aperture 251 is configured and disposed to receive the filter assembly 124 (see FIG. 1-5). Nozzle 250 further defines another generally constant diameter D6 circular aperture 252 that extends distally from an interface 254 with circular aperture 251 wherein bone dust B is suctioned from distal end 250b. In a similar manner as with respect to nozzle 150, nozzle 250 may be made from flexible, elastomeric materials, such as, but not limited to, silicone.

[000111] FIG. 9A is an end view of one embodiment of valve tee-shaped port member or cap 160 that that may be included with the bone dust collection device 100 or 200 of the bone dust collection systems 50 or 50' of FIGS. 1-5.

[000112] FIG. 9B is a cross-sectional view of the valve cap tee-shaped port member or cap 160 of FIG. 9A taken along section line 9B-9B.

[000113] As described above with respect to FIG. 4, tee-shaped port member or cap 160 that defines bone dust collection interface aperture 162b at distal portion 160b of the tee-shaped port member or cap 160. The tee-shaped port member or cap 160 may further define suction device interface aperture 162a at proximal portion 160a. Additionally, tee-shaped port member or cap 160 defines fluid diversion aperture 162c at branch connection 160c at generally a right angle with respect to interface apertures 162a and 162b.

[000114] FIG. 10 is an exploded partially transparent view of a handle assembly 500 that may be included as part of the bone dust collection devices 100 or 200 of the bone dust collection systems 50 or 50' of FIGS. 1-5. The handle assembly 500 includes a central handle member 502 having a generally cylindrical

configuration with a knurled outer surface 502a having a series of ridges to assist a user in gripping the handle member 502. The central handle member 502 also defines a central bore or aperture 504 that extends from proximal end 506a of the handle member 502 to distal end 506b of the handle member 502.

[000115] The handle assembly 502 may further include a connector member 510 at proximal end 506a. The connector member 510 defines a barbed proximal end 512a and a barbed distal end 512b and a central bore 514 extending through each end. Distal barbed end 512b of connector member 510 is configured and disposed to engage with proximal end 506a of the central handle member 502 and be received within the central bore or aperture 504.

[000116] Additionally, the handle assembly 500 may include at distal end 506a of central handle member 502 a luer fitting 516 having a proximal barbed end 518a. The luer fitting 516 defines a central bore 520 such that the proximal barbed end 518a is configured to be received within the central bore or aperture 504.

[000117] FIG. 10A is a cross-sectional view of the handle assembly 500 of FIG. 10.

[000118] FIG. 11 is a perspective, partially transparent view of the handle assembly of FIGS. 10 and 10A and the bone dust collection device of FIG. 3 that includes a plug seal forming a bone dust collection system 600. As can be appreciated by the foregoing description of FIGS. 110 and 10A, when the handle assembly 500 is assembled as shown wherein the luer fitting 516, the central handle member 502 and the connector member 510 are connected in series, fluid communication is established from the luer fitting 516 to the connector member 510 via the central bore 520 of the luer fitting 516, the central bore 504 of the central handle member 502 and the central bore 514 of the connector member 510. In this configuration, suction is established through the handle assembly 500 in the proximal direction of arrow **S** by connection to a continuous suction source such as an operating room such system (not shown). Bone dust as represented by arrow **B** at bone dust removal structure 150 is collected by the bone dust collection device 100 or 200 by the establishment of the suction condition **S.** The fluid extraction flow interruption member 130 (see FIG. 3) is now in an open position to permit the passage of fluid through the handle assembly 500 while

fluid flow through the fluid diversion aperture 162c at branch connection 160c is sealed via the plug member 164. Bone dust is collected in the bone dust collection device 100 or 200.

[000119] FIG. 12 is a transparent view of the handle assembly 500 of FIG. 11 and the bone dust collection device 100 or 200 of FIGS. 1-5 forming bone dust collection system 600'. As can be appreciated by the foregoing description of FIG. 11, when the handle assembly 500 is assembled as shown wherein the luer fitting 516, the central handle member 502 and the connector member 510 are connected in series, fluid communication is again established from the luer fitting 516 to the connector member 510 via the central bore 520 of the luer fitting 516, the central bore 504 of the central handle member 502 and the central bore 514 of the connector member 510. In this configuration, suction is again established through the handle assembly 500 in the proximal direction of arrow **S** by connection to a continuous suction source such as an operating room such system (not shown). Bone dust as represented by arrow **B** at bone dust removal structure 150 is collected by the bone dust collection device 100 or 200 by the establishment of the suction condition **S.** The fluid extraction flow interruption member 130 (see FIG. 3) again is now in an open position to permit the passage of fluid through the handle assembly 500 while, in contrast to the sealing provided by plug member 164, the fluid flow diversion interruption device 400 is in a closed position. Bone dust is collected in the bone dust collection device 110 or 210.

[000120] FIG. 13 is a partially transparent view of one embodiment of a self-contained bone dust collection device according to the present disclosure. More particularly, referring to FIG. 4 above, self-contained bone dust collection device 700 includes the suction device 300 which may be a syringe 302 including a plunger 304 in fluid communication with the bone dust collection structure 110 (see FIG. 3) or bone dust collection structure 210. However, as described above with respect to FIG. 5, in lieu of fluid conduit 410, self-contained bone collection device 700 includes flow diversion member 420 that is in fluid communication with the fluid flow diversion interruption device 400 on the downstream side 400b.

[000121] Again, flow diversion member 420 may be a right angle or 90 degree luer valve and is further described below. When the plunger 304 is advanced distally following retraction and accumulation of fluid within the syringe 302, fluid flow diversion interruption device 400 shifts to the open position (while fluid extraction flow interruption member 130 shifts to the closed position) to divert fluid through flow diversion member 420. Flow diversion member 420 may be utilized to divert fluid back to a surgical site by directing the fluid vertically downward as shown by arrow **F1.**

[000122] FIG. 13A is a partially transparent view of another embodiment of the self-contained bone collection device of FIG. 13. More particularly, bone dust collection device 700' differs from bone dust collection device 700 in that fluid flow diversion interruption device 400 is now downstream of flow diversion member 420.

[000123] FIG. 14 is a zoomed out partial profile cross-sectional view of the bone dust collection systems 50 or 50' that includes fluid conduit 410 of FIG. 1-3. FIG. 15A is a detailed view of extraction flow interruption member 130 illustrated in the form of umbrella valve 130 that is positioned on upper surface 115 of the housing in a closed position. The extraction flow interruption member 130 again includes diaphragm 134 that is formed with the shaft member 132. The diaphragm 134 is again made from an elastomeric and flexible material and which overlays the fluid flow apertures 116a and 116b on the proximal side or upper surface 115 of transverse plate member 116. FIG. 15B is a detailed view of the umbrella valve positioned on the upper surface 115 of the housing in an open position to enable flow of fluid past the umbrella valve. Again, the change of position of the extraction flow interruption member 130 occurs via the suction pressure induced on the flow interruption member, and more particularly on the diaphragm 134, such that the diaphragm 134 flips away from the transverse plate member 116 to expose the fluid flow apertures 116a and 116b, thereby enabling flow of fluid through the apertures 116a and 116b, as indicated by arrows F2A and F2B, respectively. Those skilled in the art will recognize that the actual flexing and flipping of the diaphragm 134 to establish the open position is a very

small rise away from the transverse plate member 116. That is, the diaphragm 134 must flex upwardly sufficiently to enable passage of the fluid, such as blood and/or saline solution, with any particulates including bone dust or other anatomical specimens contained therein that have passed through the filtration member 124 (see FIG. 3) while the anatomical specimen is being collected. The umbrella valve may be made from thermoplastic elastomers such as, but not limited to, polyvinyl chloride or urethane or the like.

[000124] FIG. 16 is a cross-sectional view of the bone dust collection device 100 or 200 when the umbrella valve 130 is in the closed position as described above with respect to FIG. 15A.

[000125] FIG. 17 is a cross-sectional view of the bone dust collection device 100 or 200 when the umbrella valve 130 is in the open position for permitting passage of fluid past the umbrella valve 130 as shown by arrows **F2A** and **F2B** and then through suction device interface aperture 162a at proximal portion 160a as shown by arrow **F3**. In this configuration, the suction device 300 which may be in the form of syringe 302 as described above draws suction on the interface aperture 162a to enable the fluid to be drawn into the syringe. During this operation, the plunger 304 is retracted proximally through the syringe 302.

[000126] FIG. 18 is a cross-sectional view of the bone dust collection device 100 or 200 when the umbrella valve 130 is in the closed position for discharging and diverting fluid which has been collected by syringe 302 in the direction of arrow **F4** through fluid diversion aperture 162c at branch connection 160c. During this operation, the plunger 304 is advanced distally through the syringe 302.

[000127] FIG. 19 is a cross-sectional view of another embodiment of the bone dust collection device 200 having the alternate filtration member 224 shown in FIG. 4. During this operation, the fluid flow diversion interruption device 400 is in the closed position and the umbrella valve 130 is in the open position. for permitting passage of fluid past the umbrella valve 130 as shown by arrows **F2A** and **F2B** and then through suction device interface aperture 162a at proximal portion 160a as shown by arrow **F3**.

[000128] FIG. 20 is cross-sectional view of the bone dust collection device 200 of FIG. 19 wherein the umbrella valve 130 is in the closed position and fluid is diverted through fluid diversion aperture 162c and the fluid flow diversion interruption device 400 in the direction of arrow **F4**.

[000129] Although the flow interruption member 130 has been illustrated as an umbrella valve, other flow interruption members may be employed such as a miter valve or duck bill valve, a check or flapper valve, or a disk valve or the like. In such cases, the tee-shaped port member or cap 160 and/or the filtration assembly 224 may be reconfigured if or as necessary to accommodate the design, operation and configuration of the particular flow interruption member being employed.

[000130] FIG. 21 is a cross-sectional view of the bone dust collection device 100 having the filtration member 124 of FIG. 5 in an inverted position to allow removal of collected bone dust 180. The collected bone dust 180 may be removed manually with a flat instrument or spatula or by a power-assisted instrument including a suction source.

[000131] FIG. 22 is a cross-sectional view of the bone dust collection device 200 of FIG. 19 in an inverted position to allow removal of collected bone dust 180. Similarly, the collected bone dust 180 may be removed manually with a flat instrument or spatula or by a power-assisted instrument including a suction source.

[000132] FIG. 23 is a perspective transparent view of a kit package 800 that houses the bone dust collection devices 100 or 200 and associated components according to embodiments of the present disclosure.

[000133] More particularly, kit 800 includes a support tray 802 that defines a first depression 804a and an adjacent second depression 804b which are interconnected via a central depression 804c. As illustrated, suction device 300 is received in first depression 804a, handle assembly 500 is received in second depression 804b together with plug member 164 while bone dust collection device 100 or 200 may be received in central depression 804c. When provided

with a covering (not shown), the kit package and contents may be provided to the user in a sterile condition via means known in the art.

[000134] Alternatively, the contents may also be provided in a sterile condition in a taped banded bag such as, for example, a Sklar banded bag product no. 96-5582 or equivalent as necessary due to the size of the contents (not shown – by Sklar Instruments, West Chester, Pennsylvania, USA) or Tyvek® (DuPont de Nemours, Inc.) pouch or equivalent as known in the art.

[000135] FIG. 24 is a perspective view of the bone dust collection device 100 of FIG. 3 having plug member 164 to seal off flow through fluid diversion aperture 162c at branch connection 160c during connection of the bone dust collection device to a continuous vacuum system.

[000136] FIG. 25 is a perspective view of the bone dust collection device 100 or 200 of FIG. 24 wherein the plug member 164 is replaced by flow diversion member 420 in the form of a 90 degree elbow and fluid flow diversion interruption device 400 to enable diversion of fluid in a vertically downward direction back to a surgical site.

[000137] FIG. 26 is a cross-sectional view of the bone dust collection device 100 of FIG. 25 with fluid flow diversion member 420 in the form of a 90 degree elbow and fluid flow diversion interruption device 400 to enable diversion of fluid in a vertically downward direction back to a surgical site.

[000138] FIG. 27 is a perspective view of the bone dust collection device 100 or 200 of FIGS. 25 and 26 wherein the fluid flow is directed horizontally.

[000139] FIG. 28 is a perspective view of the bone dust collection device 100 or 200 of FIG. 25-27 wherein the fluid flow diversion interruption device 400 is replaced by a fluid port connection fitting member 430 and a tubular member 440 to enable diversion in a vertically downward direction of fluid back to a surgical site.

[000140] FIG. 29 is a cross-sectional elevation view of the bone dust collection device 100 or 200 of FIG. 28 wherein fluid port connection fitting member 430 and tubular member 440 enable diversion of fluid in a vertically downward direction.

[000141] FIG. 30 is a perspective view of the bone dust collection device 100 or 200 of FIG. 29 wherein tubular member 440 of the fluid port connection fitting member 430 has been removed.

[000142] FIG. 31 is a perspective view of the bone dust collection device 100 or 200 of FIG. 30 wherein the flow diversion member 430 is oriented at an angle of 45 degrees below the horizontal to enable diversion of fluid in an alternative direction with respect to a surgical site.

[000143] FIG. 32 is a perspective view of the bone dust collection device 100 or 200 of FIG. 28 wherein the flow diversion member 430 is oriented horizontally to enable diversion of fluid in yet another alternative direction with respect to a surgical site.

[000144] From the foregoing description, it can be appreciated that the harvested or collected bone may be used during:

[000145] (1) Fusion construct - spine or long bone - to promote fusion healing.

[000146] (2) Bone fusion wherein placement of bone dust into a fusion device such as a cage implant may be utilized to promote bone fusion.

[000147] (3) Replacement of bone after craniotomy or any skull base procedure where bone is removed.

[000148] (4) Dental reconstruction/fusion procedure.

[000149] Between the bone dust collection structure and the syringe, the one-way valve or check valve allows for continued suction and expulsion of air without disconnecting the syringe from the bone dust collection device.

[000150] The size of the central aperture and volume 120 (see FIG. 3) and 220 (see FIG. 4) for receiving and collecting bone dust can be altered depending on use of the device. The size of the bone collection devices 110 and 210 (see FIGS. 3 and 4, respectively) and respective central apertures and volumes 120 and 220 can be made smaller for cervical surgery or made larger for lumbar surgery or long bone repair.

[000151] Embodiments of the bone dust collection device may include a mechanism to include or mix bone marrow aspirate or also other biological cells.

[000152] Since bone marrow is flexible tissue, embodiments of the bone dust collection device may be used to filter bone marrow alone as a separate device and without the need for drilling. In such embodiments, the filter design parameters may be adjusted accordingly to suit collection of bone marrow or other biological cells.

[000153] The bone dust collecting structures 110 or 210 may be centrifuged to spin down bone products and separate blood products.

[000154] The harvesting or bone dust collection system or self-contained device generally is provided via a sterile cartridge, adaptable to a standard luer fitting. The harvesting system may be provided sterile by the medical device manufacturer.

[000155] The filter assembly allows blood and fluids to pass, but generally retains bone particles between about 75 to about 300 microns. Filter mesh size may be optimized, such as by empirical testing of various filter sizes and types, to result in minimal fluid flow restriction and clogging during the procedure and to result in maximal bone fragment collection. Consideration must also be given to optimization and alternate particle size ranges when collecting other anatomical specimens such as bone marrow or other biological cells.

[000156] The bone dust collection volume generally is about 0.5 cc (cubic centimeters) minimum.

[000157] The device may be designed to allow a clinician to cycle the syringe multiple times while harvesting bone dust, while dispensing blood/saline out of the side port.

[000158] The bone dust harvesting system allows easy removal of the bone dust from the device. The device allows cleaning of the bone dust using a sterile saline flush. The harvesting system allows easy consolidation and removal of the bone dust. Removal methods include utilizing a scoop (spatula, spoon or similar). Prior to removal of the bone dust, aspiration of the bone dust via air flow may assist in drying the bone dust to result in a more cohesive bone plug when removing the bone dust.

[000159] The device is generally provided sterile in a double Tyvek® pouch in order to comply with sterile transfer protocol in the sterile OR field.

[000160] Sterilization methods may include exposure to Gamma radiation.

[000161] The bone dust collection device may be reused on the same patient during the same surgical procedure. The device generally should not be re-sterilized. It is intended for use in the collection of bone dust created during a surgical procedure when using any high-speed drill that creates bone dust (cutting burrs, diamond burrs, etc.).

[000162] The device generally does not contain latex.

[000163] Bone dust collected by the surgeon is used for the procedure at his or her discretion. As indicated above, bone dust can be packed into an interbody cage device to augment a fusion construct. In conjunction with FIG. 11 or FIG. 12 and the foregoing disclosure.

[000164] TABLE 1 below indicates detailed method steps for "Using the Bone Dust Collection System with Operating Room Suction."

**TABLE 1**
**USING THE BONE DUST COLLECTION SYSTEM WITH OPERATING ROOM SUCTION**

| Step No. | Description |
|---|---|
| **1.** | Open the single-pouch in a sterile fashion onto the operating room surgical field. |
| **2.** | Insert side plug into valve body of the device. |
| **3.** | Attach handle assembly to the luer lock of the device. |
| **4.** | Attach operating room suction tubing to universal connector on handle assembly. |
| **5.** | Using a high-speed drill, create bone dust based on the procedure. |

| | |
|---|---|
| **6.** | Irrigate surgical site with saline to suspend the bone dust. |
| **7.** | Place the tip of the collection device into the saline/bone dust mixture and aspirate using suction system. |
| **8.** | Collect bone dust in the chamber and saline with blood products in the suction canister. |
| **9.** | Upon completely filling the collection chamber with bone dust, remove the tip and collect the bone dust with a flat instrument or spatula. |
| **10.** | Pack the collected bone dust into the region of interest in the subject – interbody cage, bone defect, etc. |
| **11.** | If necessary, replace tip and collect additional bone dust. |
| **12.** | If necessary, repeat usage of the bone dust collection system until enough bone for the procedure has been collected. |

[000165] In conjunction with FIG. 13 or FIG. 13A, and the foregoing disclosure, TABLE 2 below indicates detailed method steps for "Using the Self-Contained Bone Dust Collection Device with Syringe Suction."

**TABLE 2**

**USING THE SELF-CONTAINED DEVICE WITH SYRINGE SUCTION**

| Step No. | Description |
|---|---|
| **1.** | Open the single-pouch in a sterile fashion onto the operating room surgical field. |
| **2.** | Attach a 30 cc syringe to the luer lock of the device. |

| | |
|---|---|
| **3.** | Attach the right angle check valve assembly to the valve body. |
| **4.** | Using a high-speed drill, create bone dust based on the procedure. |
| **5.** | Suspend the bone dust using a small amount of saline irrigation. |
| **6.** | Place the tip of the collection device into the saline/bone dust mixture and aspirate by pulling back the syringe piston. Bone dust is collected in the chamber while saline and blood products are collected within the syringe. |
| **7.** | Recycle excess saline and blood collected within the syringe by pushing in the syringe piston allowing the excess fluid to be expelled through the side port back into the surgical wound. |
| **8.** | When the collection chamber is filled with bone dust, remove the tip and collect bone dust with a flat instrument or spatula. |
| **9.** | Pack the collected bone dust into the region of interest in the subject – interbody cage, bone defect, etc. |
| **10.** | If necessary, replace tip and collect additional bone dust. |
| **11.** | If necessary, repeat usage of the bone dust collection system until enough bone for the procedure has been collected. |

[000166] In view of the foregoing, the embodiments of the present disclosure relate to a general method of collecting an anatomical specimen that includes the following steps.

[000167] With reference particularly to FIGS. 11, 12, 13 and 13A, the method includes generating an anatomical specimen, e.g., bone dust 180 (see FIG. 21) in particulate form at a surgical site of a subject (not shown).

[000168] The method includes irrigating the surgical site to suspend the particulate in a particulate fluid mixture (not shown). Upon irrigating the surgical site, the method includes disposing a tip of a collection device, e.g., the collection device 100 in FIG. 1, in the particulate fluid mixture (e.g., represented in FIG. 15B by arrows **F2A** and **F2B** internally within the collection device 100 in FIG. 1); aspirating the collection device, e.g., collection device 100, to filter and separate the particulate from the particulate fluid mixture therein accumulating the particulate, e.g., bone dust 180 in FIG. 17, in the collection device, e.g., collection device 100; and collecting the particulate, e.g., bone dust 180, accumulated in the collection device 100.

[000169] The method may further include packing the collected particulate, e.g., bone dust 180, into a region of interest in the subject (not shown).

[000170] The step of collecting the particulate accumulated in the collection device may be preceded by disassembling the collection device. The method may further include reassembling the collection device and repeating the foregoing steps of generating additional anatomical specimen in particulate form at a surgical site of the subject; irrigating the surgical site to suspend the particulate in a particulate fluid mixture; disposing the tip of the collection device in the particulate fluid mixture; aspirating the collection device to filter and separate the particulate from the particulate fluid mixture therein accumulating the particulate in the collection device; and collecting the particulate accumulated in the collection device.

[000171] The method may then include again packing the additionally collected particulate, e.g., bone dust 180, into a region of interest in the subject.

[000172] As shown in FIGS. 11 and 12, the aspirating of the collection device 100 may include connecting the collection device 100 to a vacuum source, that

establishes suction through the handle assembly 500 in the proximal direction of arrow **S** in an operating room (not shown) wherein the vacuum source is in fluid communication with the fluid in the particulate fluid mixture, shown by arrow B, to filter and separate the particulate, bone dust 180 from the particulate fluid mixture, shown by arrow B.

[000173] Alternatively, as shown in FIGS. 13 and 13A, the aspirating of the collection device 100 may include actuating a syringe, e.g., syringe 300, in fluid communication with the collection device 100 and in fluid communication with the particulate fluid mixture, shown by arrow B, wherein the actuating of the syringe effects filtering and separating the particulate, e.g., bone dust 180, from the particulate fluid mixture.

[000174] In conjunction with the foregoing disclosure and FIGS. 1-32, TABLE 3 indicates "Consideration for Using the Bone Dust Collection System or Device".

**TABLE 3**

**CONSIDERATIONS FOR USING THE BONE DUST COLLECTION SYSTEM OR DEVICE**

| Consideration No. | Description |
|---|---|
| **1.** | The device functions better with saline and bone dust mixture while minimizing the amount of blood. |
| **2.** | If there is too much blood in the field, the tip or filter may become clogged making it difficult to aspirate bone dust. The surgeon should irrigate the field, stop bleeding as much as possible, and try the procedure for bone dust collection at this point with a dry field. |
| **3.** | The tip may detach with excessive force while pushing into the wound to collect bone dust. Simply re-attach. |

| | |
|---|---|
| **4.** | Occasionally, the tip can become clogged with minimal saline. Irrigate further and simply put gentle pressure on the tip to dislodge stuck bone dust. |
| **5.** | The device is not a fusion device; it is intended to assist the surgeon in collecting bone dust. |
| **6.** | It is not expected that the device promotes better fusion rates. |

[000175] The detailed description of exemplary embodiments herein makes reference to the accompanying drawings, which show the exemplary embodiments by way of illustration and their best mode. While these exemplary embodiments are described in sufficient detail to enable those skilled in the art to practice the disclosure, it should be understood that other embodiments may be realized and that logical and mechanical changes may be made without departing from the spirit and scope of the disclosure. Thus, the detailed description herein is presented for purposes of illustration only and not of limitation. For example, the steps recited in any of the method or process descriptions may be executed in any order and are not limited to the order presented. Moreover, any of the functions or steps may be outsourced to or performed by one or more third parties. Furthermore, any reference to singular includes plural embodiments, and any reference to more than one component may include a singular embodiment.

**CLAIMS:**

What is claimed is:

1. A bone dust collection device comprising:

a bone dust collection structure defining a longitudinal axis and having a proximal end and a distal end,

the bone dust collection structure having a transverse plate member connected at or in the vicinity of the proximal end to a cylindrical wall defining an aperture at the distal end for receiving and collecting bone dust, the aperture extending proximally and including a filtration member disposed therein, the filtration member configured and disposed wherein the filtration member causes at least partial separation of fluid from the bone dust via the fluid passing proximally through the filtration member, the bone dust collection structure configured to enable removal of bone dust collected therein.

2. The bone dust collection device according to claim 1, wherein at least one aperture is defined in the transverse plate member that enables the fluid at least partially separated from the bone dust by the filtration member to pass therethrough.

3. The bone dust collection device according to claim 2, further comprising a flow interruption member configured and disposed with respect to the bone dust collection structure wherein flow of fluid through the at least one aperture of the bone dust collection structure occurs by suction pressure induced on the flow interruption member causing the flow interruption member to change position to enable flow through the at least one aperture defined in the transverse plate member.

4. The bone dust collection device according to claim 3, wherein at least another aperture is defined in the transverse plate member wherein the flow interruption member includes a shaft member disposed through the at least another aperture wherein the change of position of the flow interruption member occurs via the suction pressure induced on the flow interruption member to enable flow through the at least one aperture defined in the transverse plate member.

5. The bone dust collection device according to claim 3, further comprising a syringe including a plunger in fluid communication with the bone dust collection structure wherein the suction pressure is caused by retraction of the plunger away from the bone dust collection structure to enable flow through the at least one aperture defined in the transverse plate member.

6. The bone dust collection device according to claim 5, wherein advancement of the plunger causes the flow interruption member to interrupt flow from the bone dust collection structure.

7. The bone dust collection device according to claim 6, further comprising a conduit in fluid communication with the bone dust collection structure, wherein advancement of the plunger causes the fluid received through the at least one aperture defined in the transverse plate member to discharge through the conduit away from the bone dust collection device.

8. The bone dust collection device according to claim 7, wherein the conduit is structured such that the conduit discharges the fluid in a direction generally perpendicular to the direction of fluid flow through the filtration member.

9. The bone dust collection device according to claim 3, further comprising another flow interruption device configured and disposed with respect to the flow interruption device and with respect to the bone dust collection structure wherein suction pressure induced on the another flow interruption device causes the another flow interruption device to be in a closed position and causes the flow interruption member to change position to enable flow through the at least one aperture defined in the transverse plate member.

10. The bone dust collection device according to claim 3, further comprising another flow interruption device configured and disposed with respect to the flow interruption device and with respect to the bone dust collection structure wherein the another flow

interruption device is a plug member to seal off flow therethrough during connection of the bone dust collection device to a continuous vacuum system and suction pressure induced on the flow interruption device causes the flow interruption member to change position to enable flow through the at least one aperture defined in the transverse plate member.

11. The bone dust collection device according to claim 1, further comprising:

a bone dust removal structure defining an aperture having a proximal end and a distal end, the aperture configured and disposed for facilitating transport of bone dust from the distal end of the bone dust removal structure to the bone dust collection structure.

12. The bone dust collection device according to claim 11, wherein the bone dust removal structure includes a nozzle that defines the aperture of the bone dust removal structure, the nozzle defining a proximal end and a distal end, wherein the nozzle facilitates transport of the bone dust to the bone dust collection structure.

13. The bone dust collection device according to claim 12, wherein the nozzle is removably attached to the bone dust collection structure, wherein removal of the nozzle from the bone dust collection structure enables removal of bone dust collected within the bone dust collection structure.

14. The bone dust collection device according to claim 3, further comprising a guide member configured and disposed with respect to the suction source and the bone dust collection structure for enabling a user to manually control the location of the bone dust removal structure during a surgical procedure.

15. The bone dust collection device according to claim 3, wherein the flow interruption member is an umbrella valve.

16. The bone dust collection device according to claim 9, wherein the another flow interruption member is a check valve.

17. A bone dust collection device comprising:

a bone dust collection structure defining a proximal end and a distal end, the bone dust collection structure including a filtration member at the proximal end and defining an aperture at the distal end for receiving and collecting bone dust, the filtration member causing at least partial separation of fluid from the bone dust via the fluid passing proximally through the filtration member; and

a bone dust removal structure defining an aperture having a proximal end and a distal end, the aperture configured and disposed for facilitating transport of bone dust from the distal end of the bone dust removal structure to the bone dust collection structure, the bone dust removal structure removably attached to the bone dust collection structure, wherein removal of the bone dust removal structure from the bone dust collection structure enables removal of bone dust collected within the bone dust collection structure.

18. An anatomical collection system comprising:

an anatomical specimen collection structure defining a proximal end and a distal end, the anatomical specimen collection structure including a filtration member at the proximal end and defining an aperture at the distal end for receiving and collecting an anatomical specimen, the filtration member causing at least partial separation of fluid from the anatomical specimen via the fluid passing proximally through the filtration member; and

an anatomical specimen removal structure defining an aperture having a proximal end and a distal end, the aperture configured and disposed for facilitating transport of the anatomical specimen from the distal end of the anatomical specimen removal structure to the anatomical specimen collection structure, the anatomical specimen removal structure removably attached to the anatomical specimen collection structure wherein detachment of the anatomical specimen removal structure from the

anatomical specimen collection structure enables removal of the anatomical specimen collected within the anatomical specimen collection structure.

19. The anatomical collection system according to claim 18, wherein the anatomical specimen is bone dust.

20. A method of collecting an anatomical specimen comprising:

generating an anatomical specimen in particulate form at a surgical site of a subject;

irrigating the surgical site to suspend the particulate in a particulate fluid mixture;

disposing a tip of a collection device in the particulate fluid mixture;

aspirating the collection device to filter and separate the particulate from the particulate fluid mixture therein accumulating the particulate in the collection device; and

collecting the particulate accumulated in the collection device.

21. The method according to claim 20, further comprising:

packing the collected particulate into a region of interest in the subject.

22. The method according to claim 20, wherein the collecting the particulate accumulated in the collection device is preceded by disassembling the collection device, the method further comprising:

reassembling the collection device;

generating additional anatomical specimen in particulate form at a surgical site of the subject;

irrigating the surgical site to suspend the particulate in a particulate fluid mixture;

disposing the tip of the collection device in the particulate fluid mixture;

aspirating the collection device to filter and separate the particulate from the particulate fluid mixture therein accumulating the particulate in the collection device; and

collecting the particulate accumulated in the collection device.

23. The method according to claim 22, further comprising:
packing the additionally collected particulate into a region of interest in the subject.

24. The method according to claim 20, wherein the aspirating of the collection device includes connecting the collection device to a vacuum source wherein the vacuum source is in fluid communication with the fluid in the particulate fluid mixture to filter and separate the particulate from the particulate fluid mixture.

25. The method according to claim 24, wherein the connecting the collection device to a vacuum source includes connecting the collection device to a vacuum source in an operating room.

26. The method according to claim 20, wherein the aspirating of the collection device includes actuating a syringe in fluid communication with the collection device and in fluid communication with the particulate fluid mixture wherein the actuating of the syringe effects filtering and separating the particulate from the particulate fluid mixture.

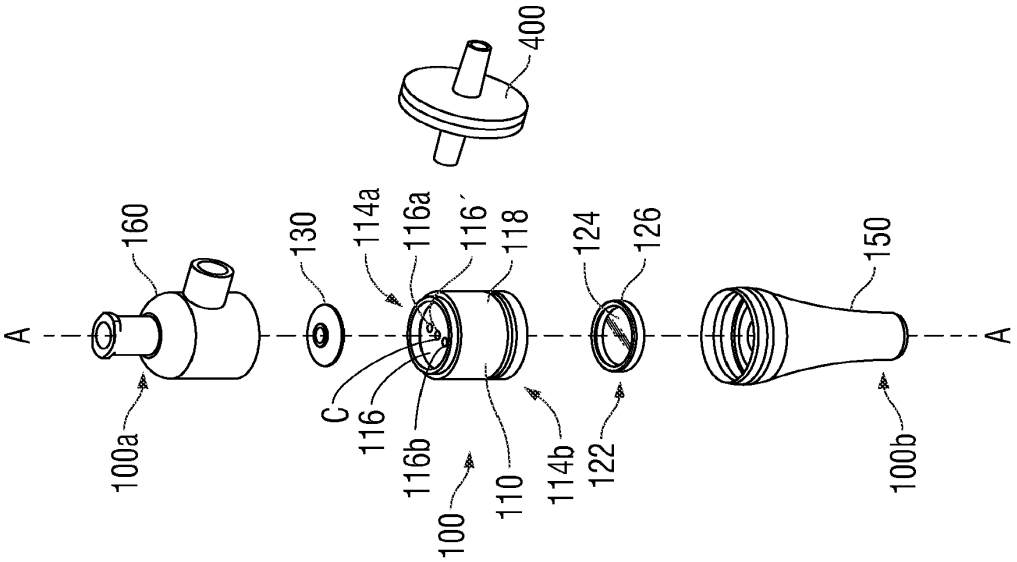

400
160
130
114a
116a
116'
118
124
126
150
A
A
C
116
116b
100
110
114b
122
100a
100b

FIG. 2

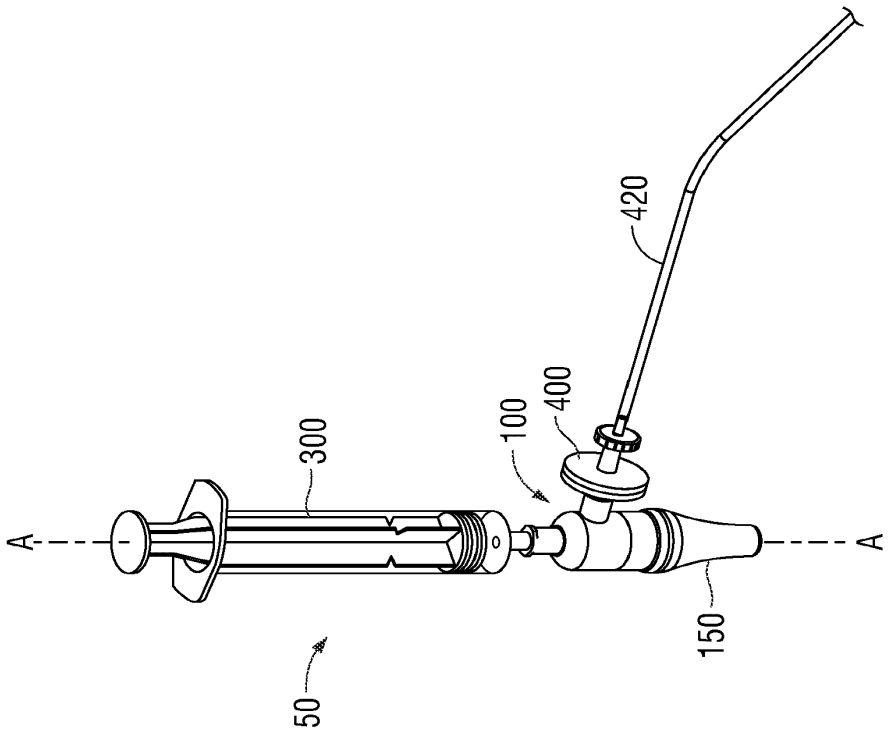

420
400
100
300
A
A
150
50

FIG. 1

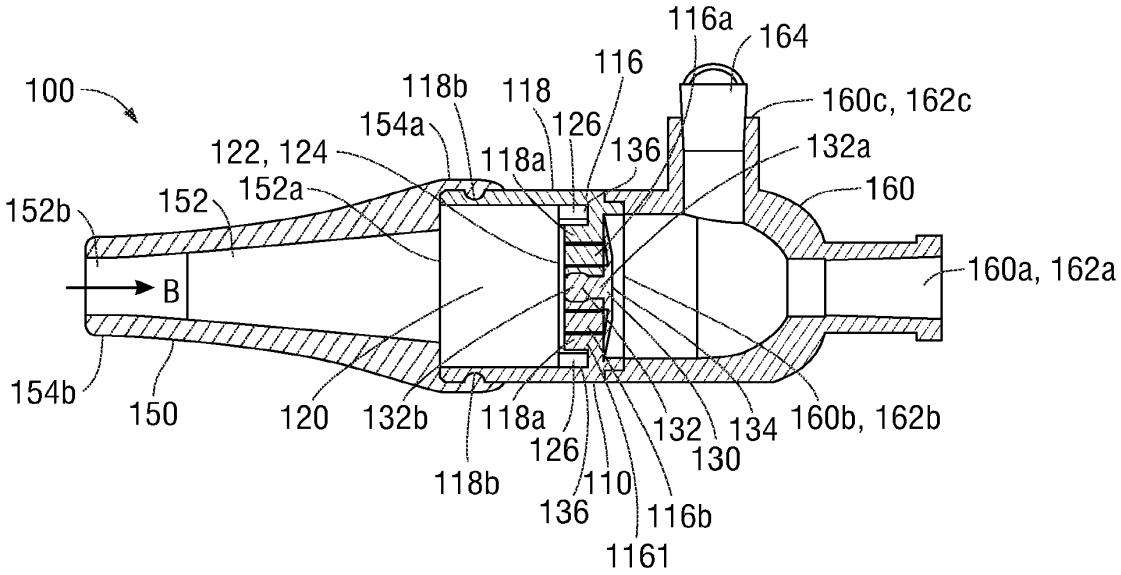

100
116a
164
116
118b
118
160c, 162c
154a
126
122, 124
118a
136
132a
152a
160
152
152b
160a, 162a
B
154b
150
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132b
118a
126
132
134
160b, 162b
130
118b
110
136
116b
1161

FIG. 3

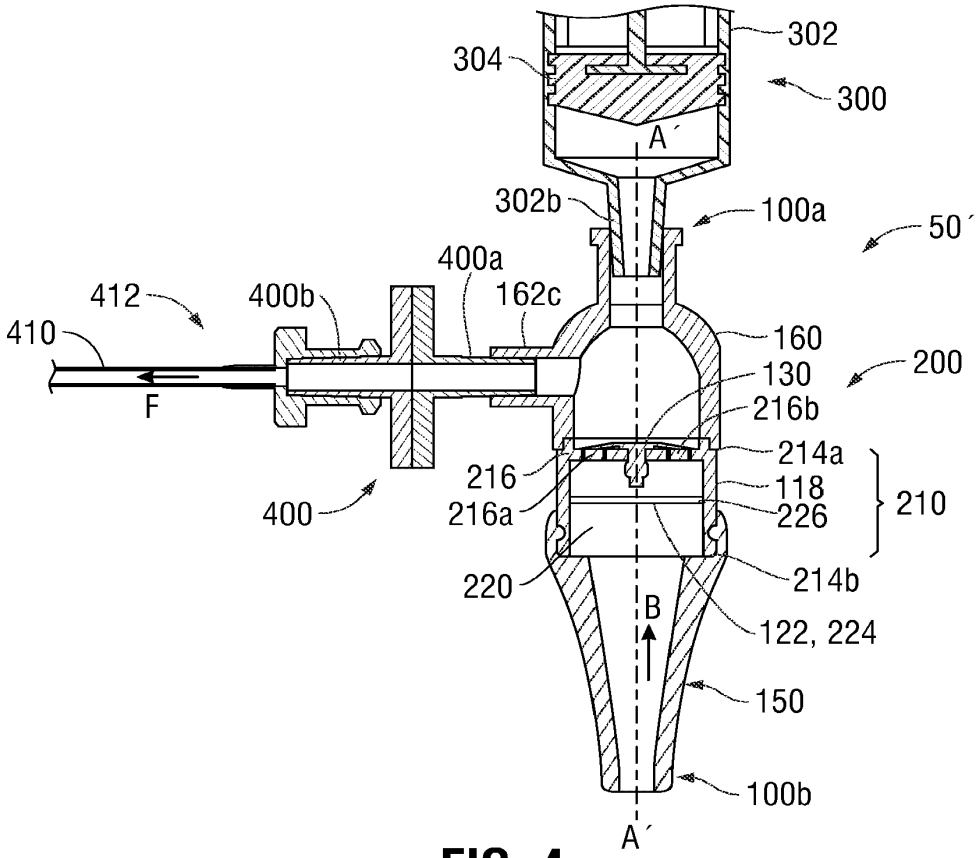

302
304
300
A´
302b
100a
50´
400a
412
400b
162c
160
410
130
200
F
216b
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118
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226
220
214b
B
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150
100b
A´

FIG. 4

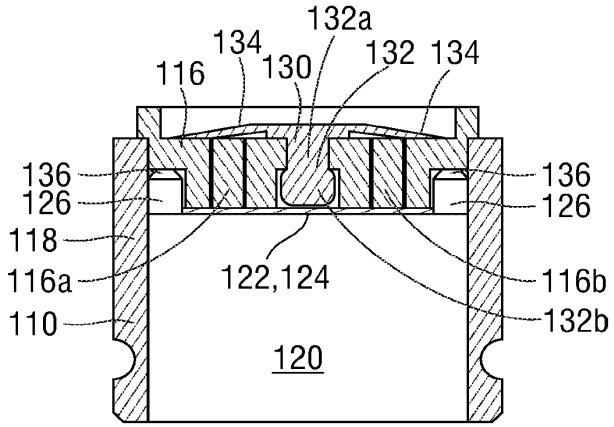



FIG. 5

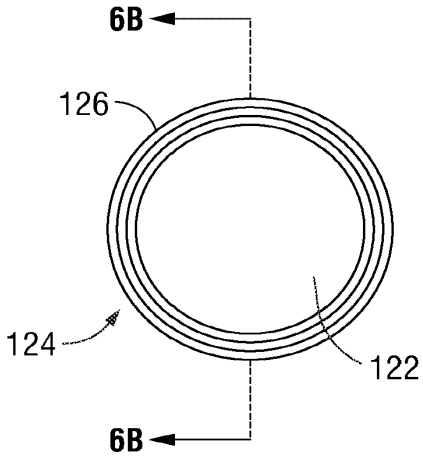



FIG. 6A

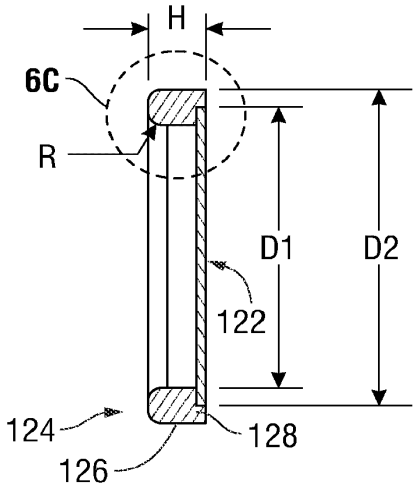



FIG. 6B

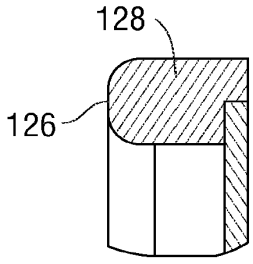



FIG. 6C

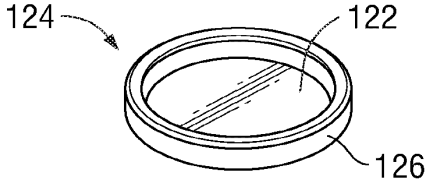



FIG. 6D

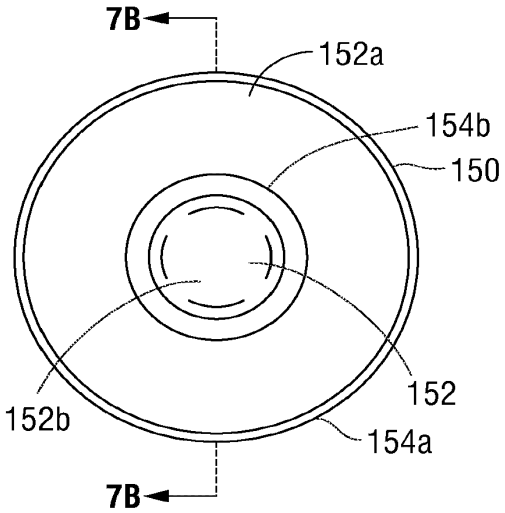



FIG. 7A

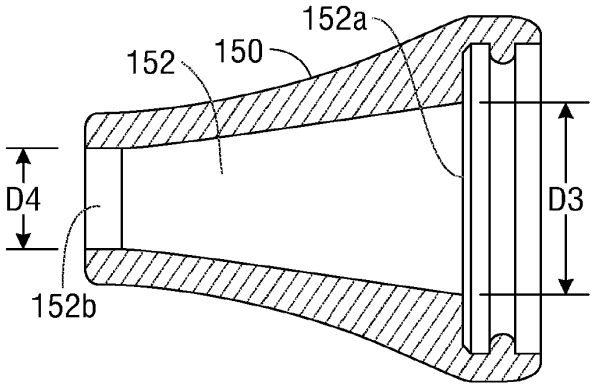



FIG. 7B

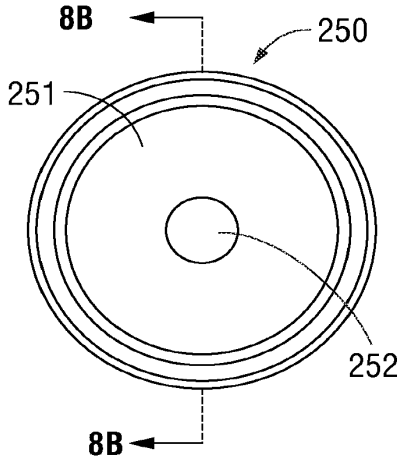



FIG. 8A

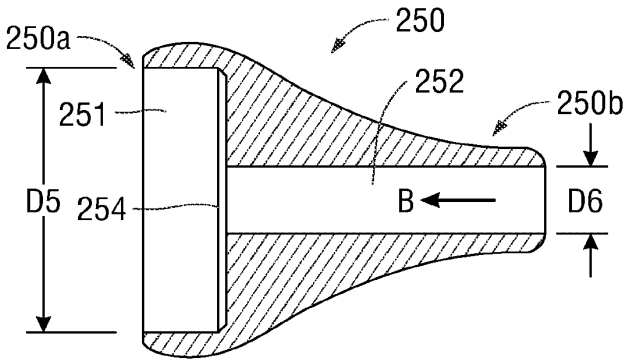



FIG. 8B

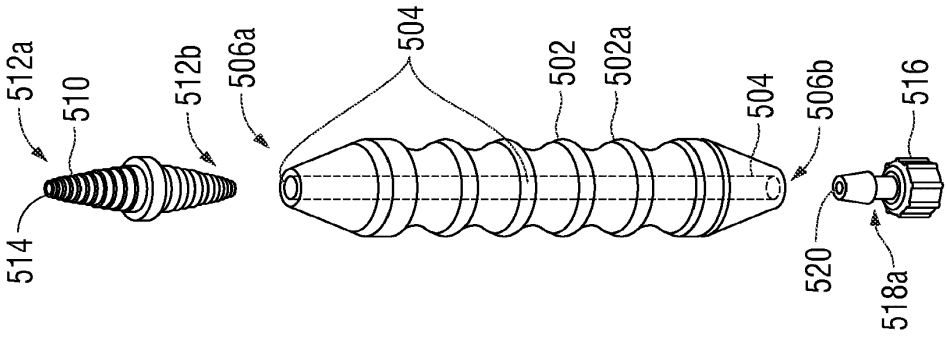



FIG. 10

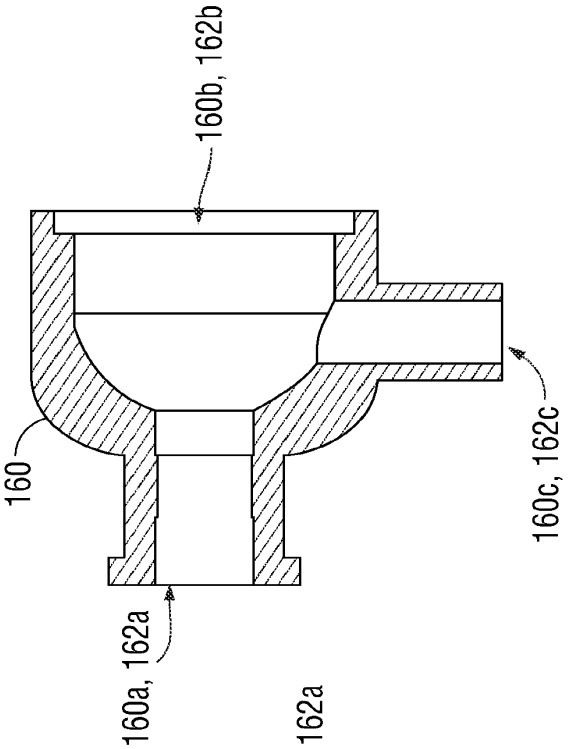



FIG. 9B

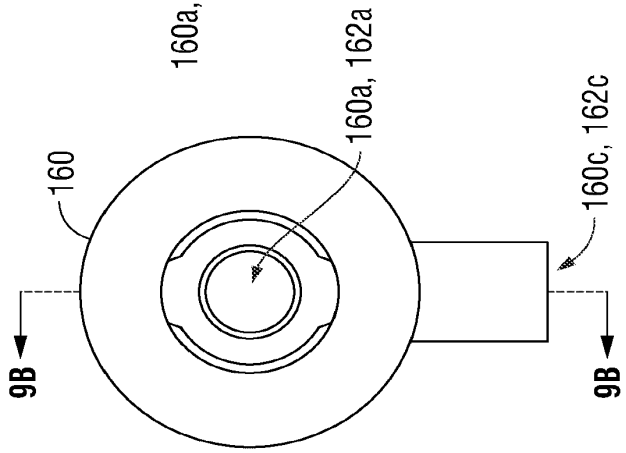



FIG. 9A

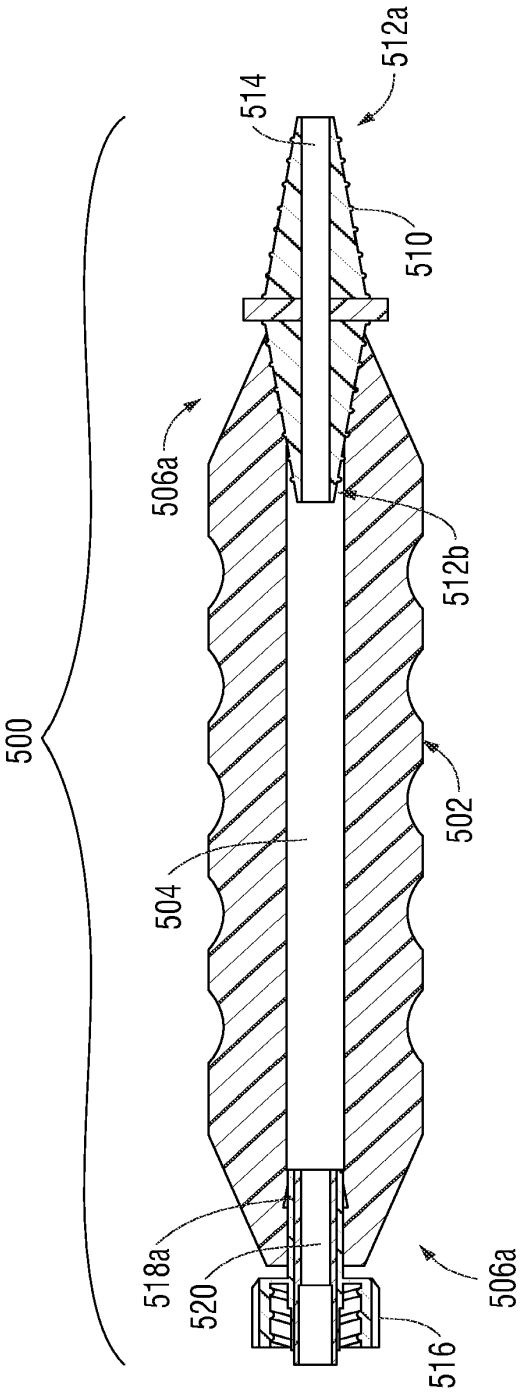



FIG. 10A

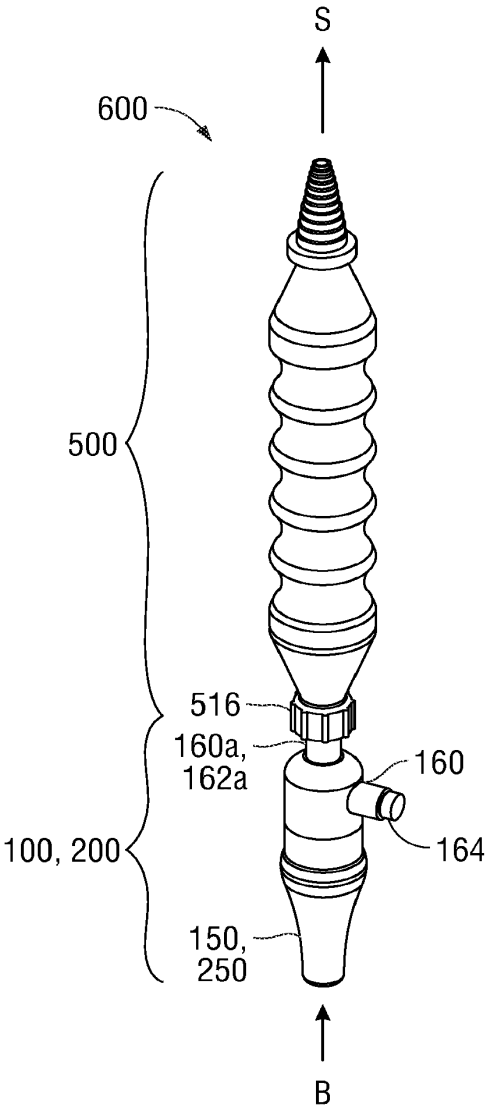

S
600
500
516
160a,
162a
160
164
100, 200
150,
250
B

FIG. 11

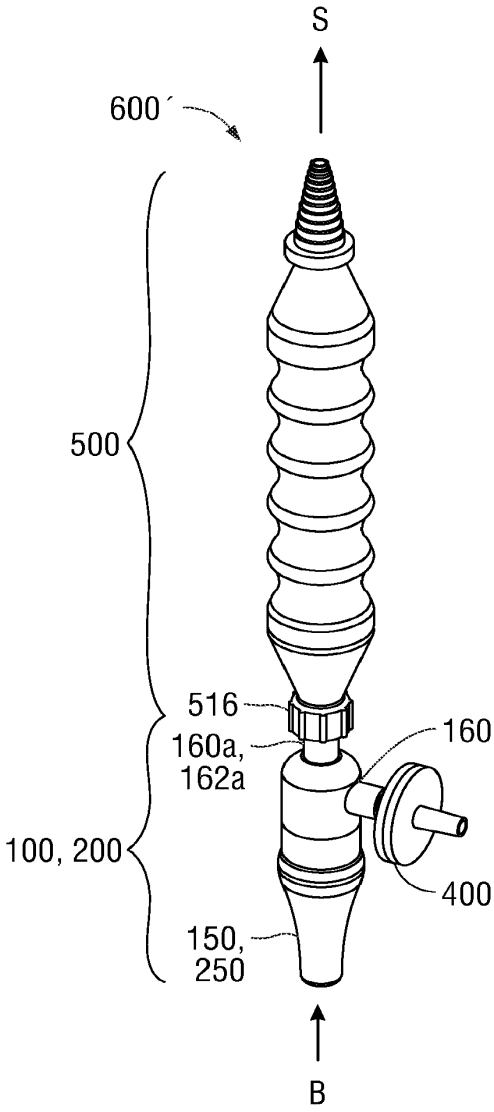

S
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B

FIG. 12

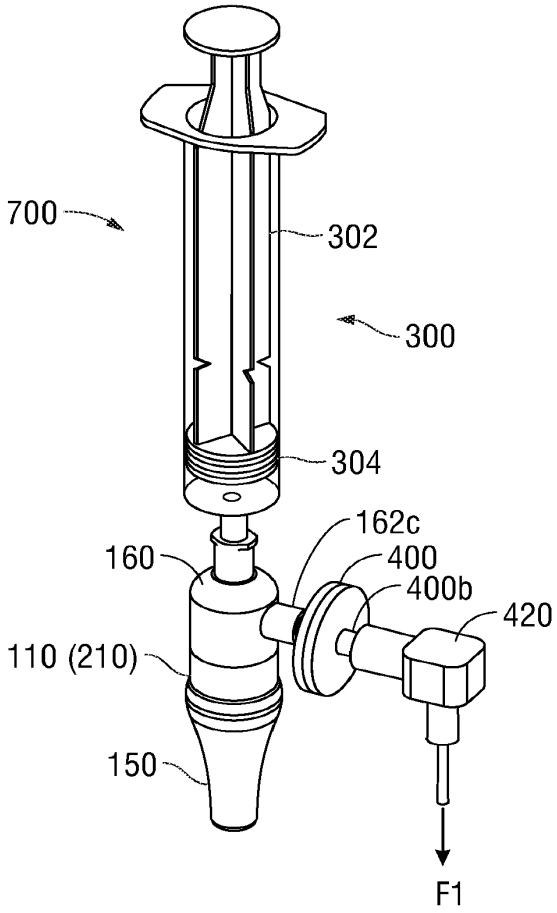



FIG. 13

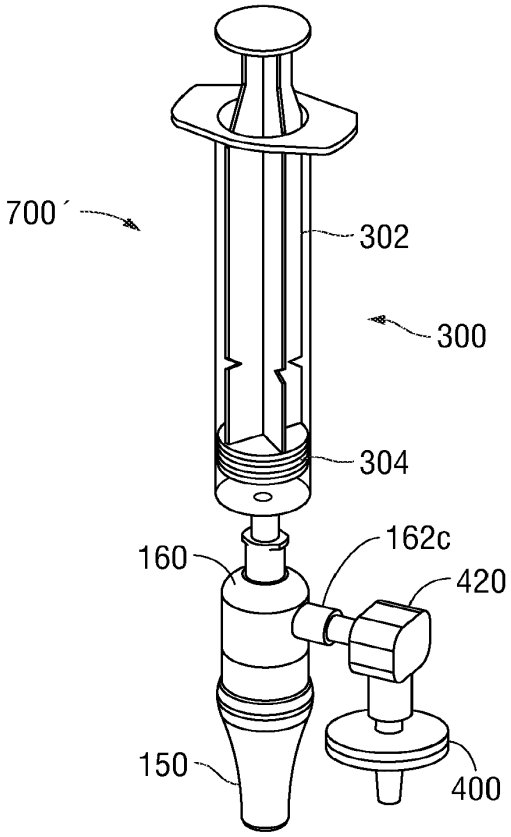



FIG. 13A

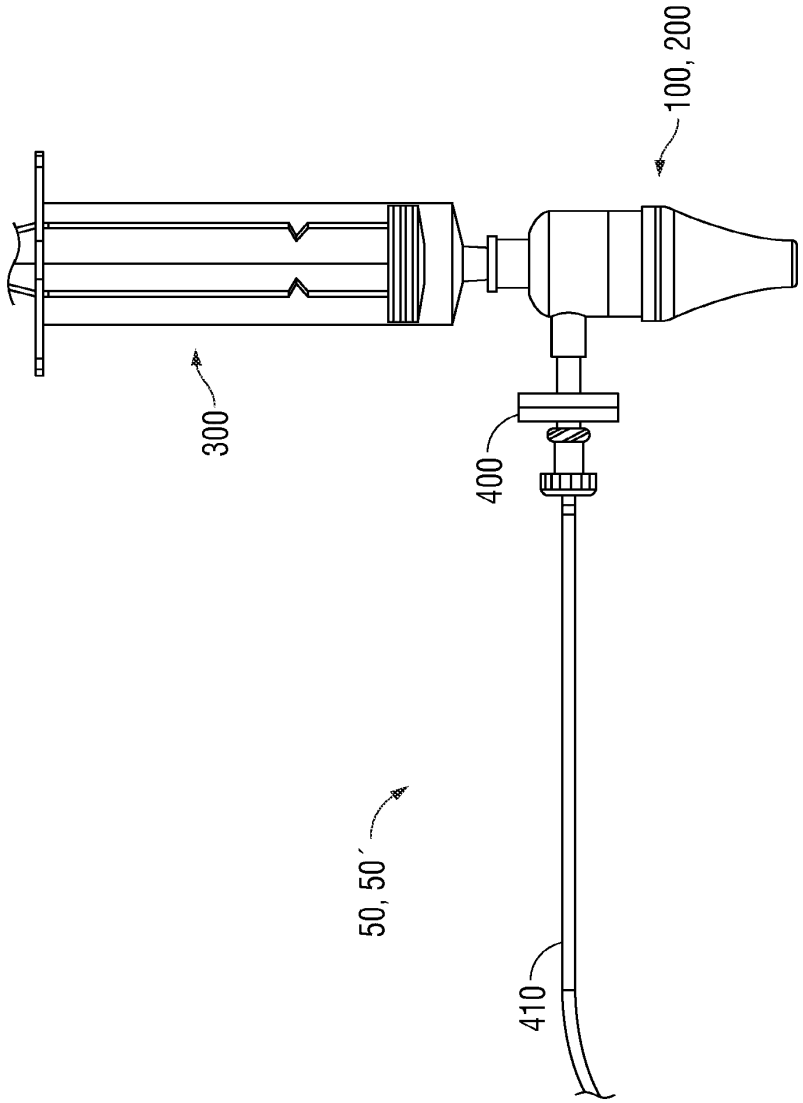



FIG. 14

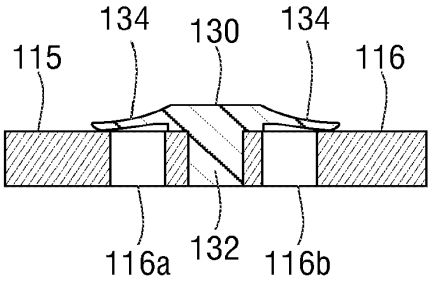



FIG. 15A

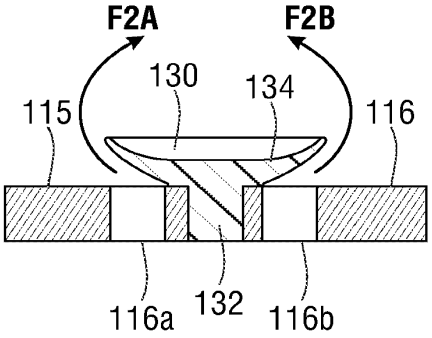



FIG. 15B

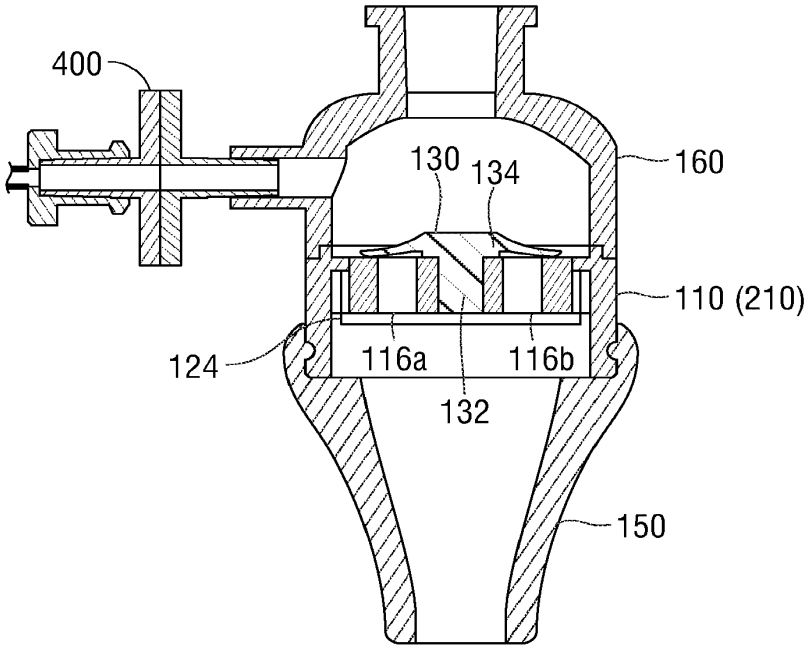



FIG. 16

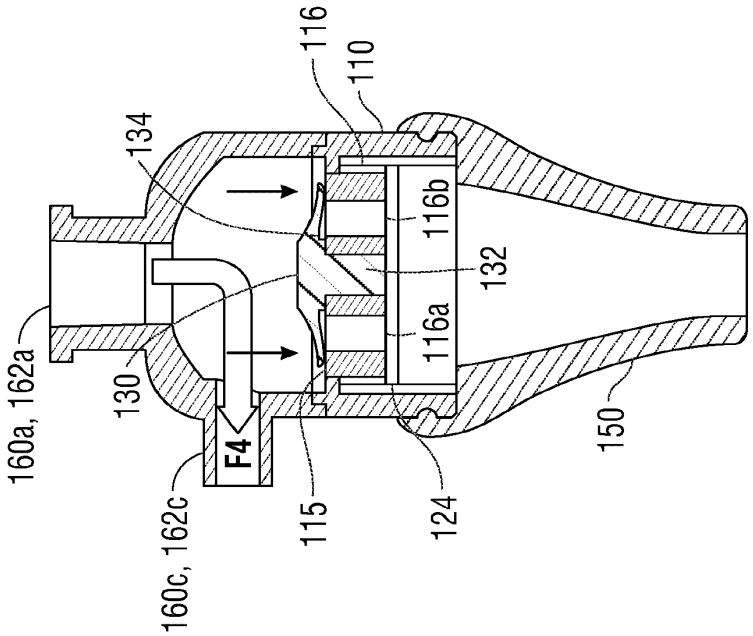

116
110
134
116b
132
116a
160a, 162a
130
F4
150
160c, 162c
115
124

FIG. 18

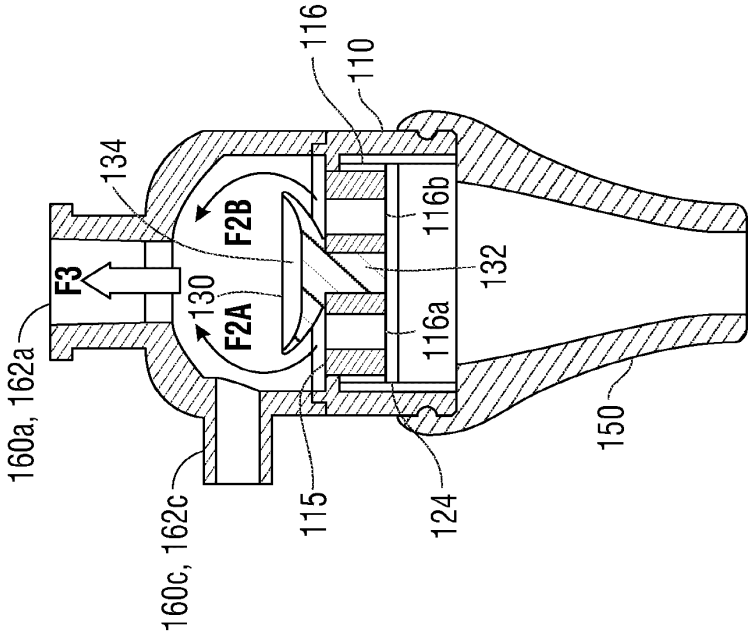

116
110
134
F2B
116b
F3
132
130
F2A
116a
160a, 162a
150
160c, 162c
115
124

FIG. 17

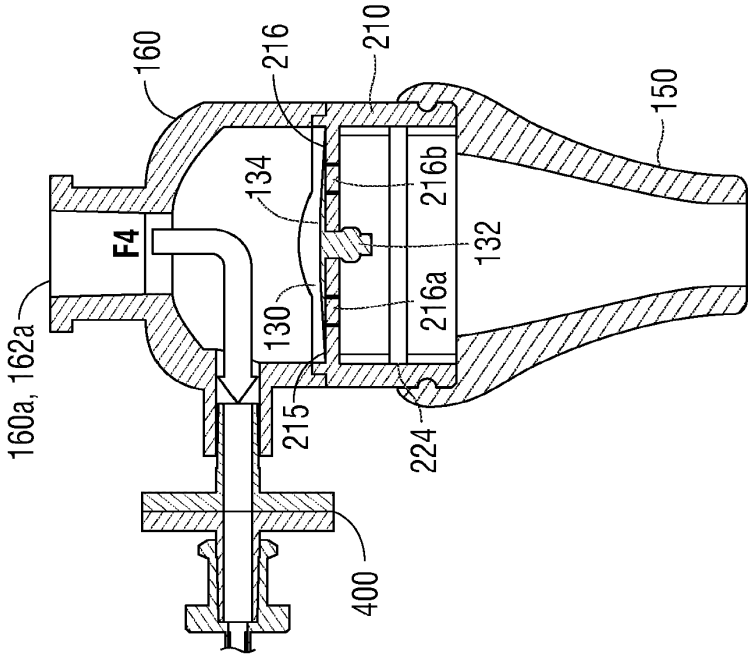

160
216
210
150
134
216b
F4
132
130
216a
160a, 162a
215
224
400

FIG. 20

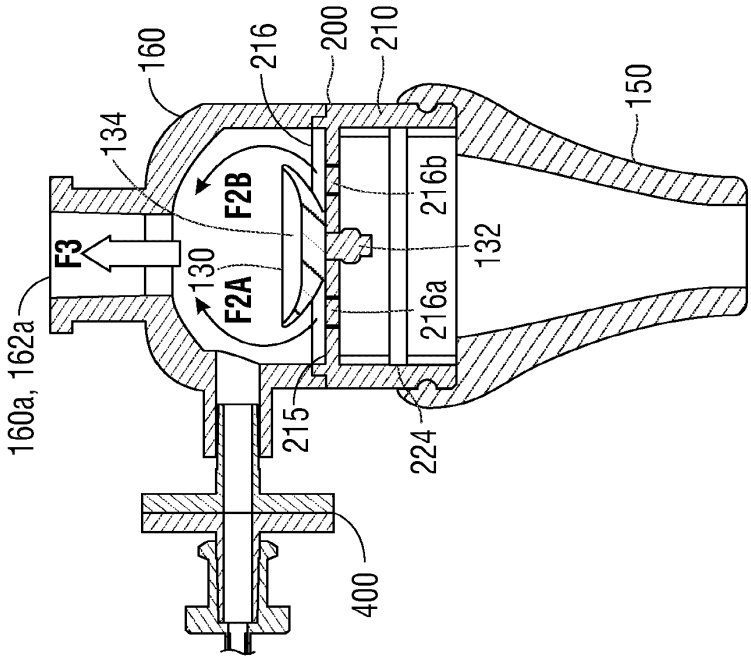

160
216
200
210
150
134
F2B
216b
F3
132
130
F2A
216a
160a, 162a
215
224
400

FIG. 19

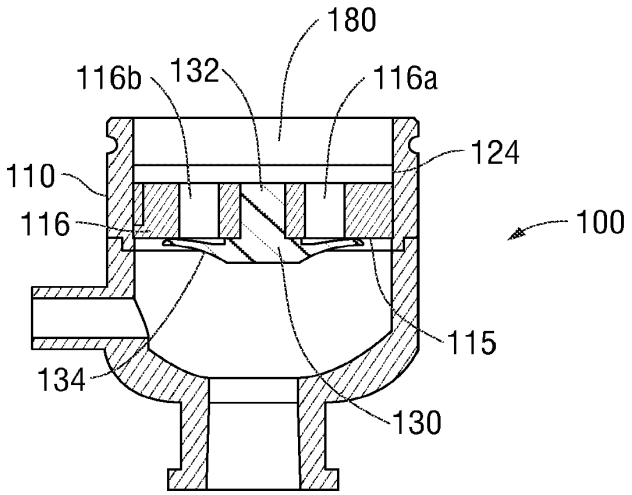

180
116b
132
116a
124
110
116
100
115
134
130

FIG. 21

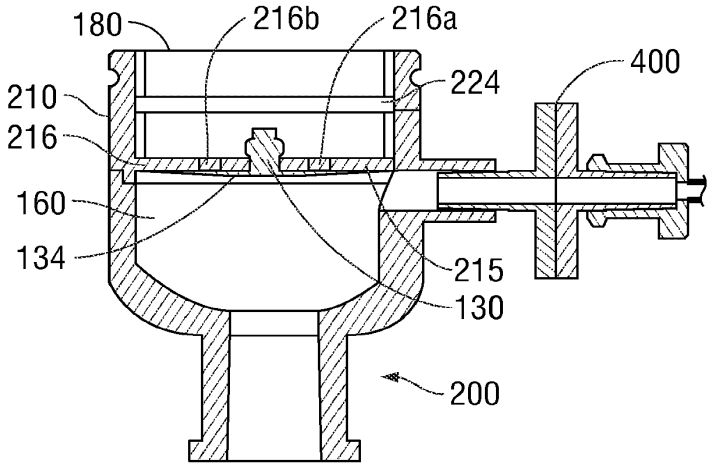

180
216b
216a
400
224
210
216
160
134
215
130
200

FIG. 22

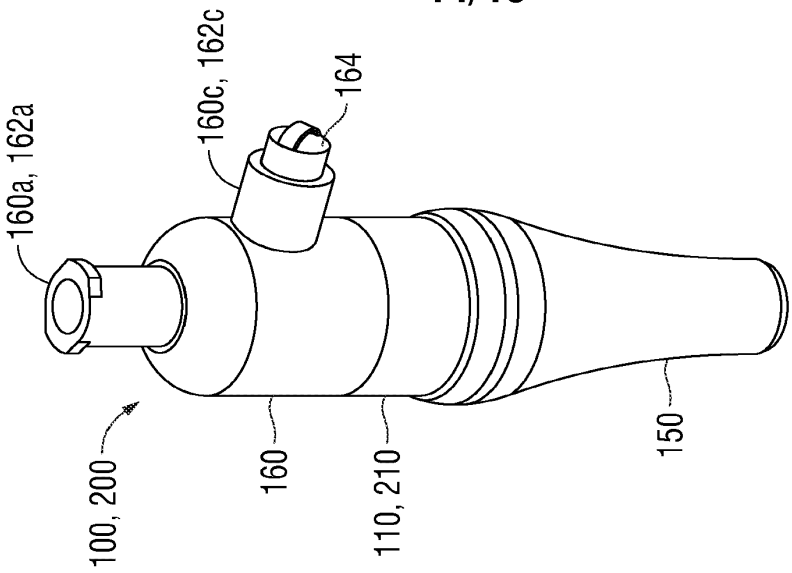

160a, 162a
160c, 162c
164
100, 200
160
110, 210
150

FIG. 24

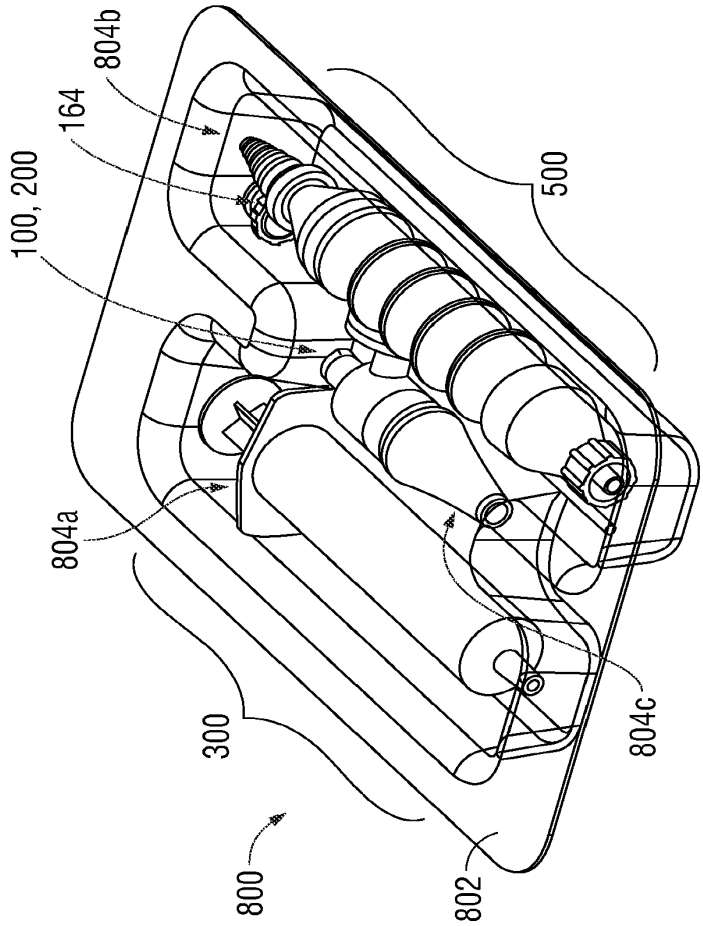

804b
164
100, 200
500
804a
300
804c
800
802

FIG. 23

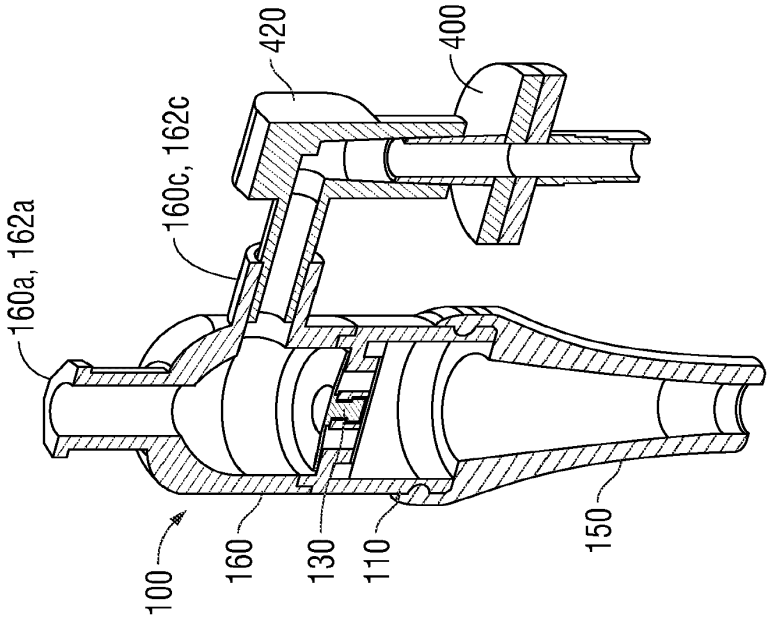

420
400
160c, 162c
160a, 162a
100
160
130
110
150

FIG. 26

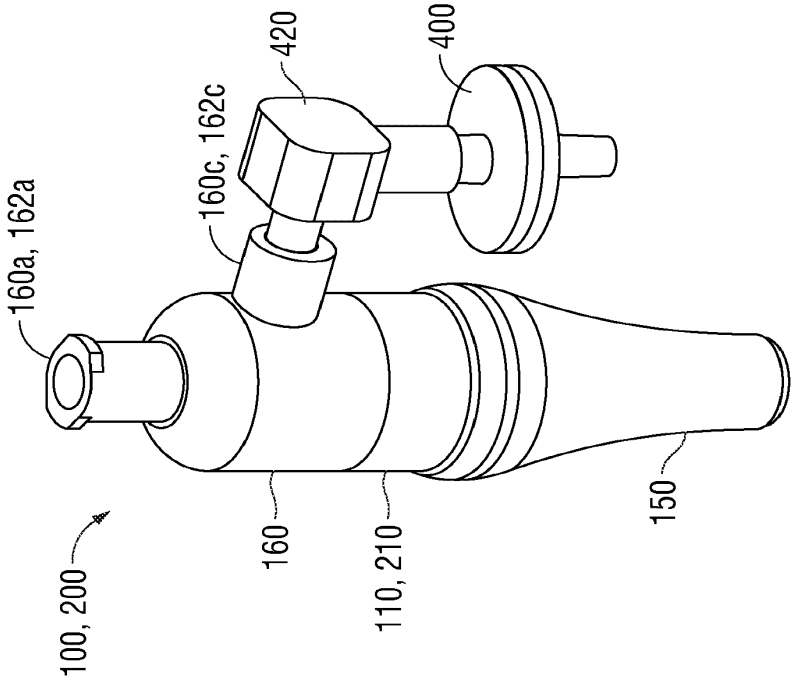

420
400
160c, 162c
160a, 162a
100, 200
160
110, 210
150

FIG. 25

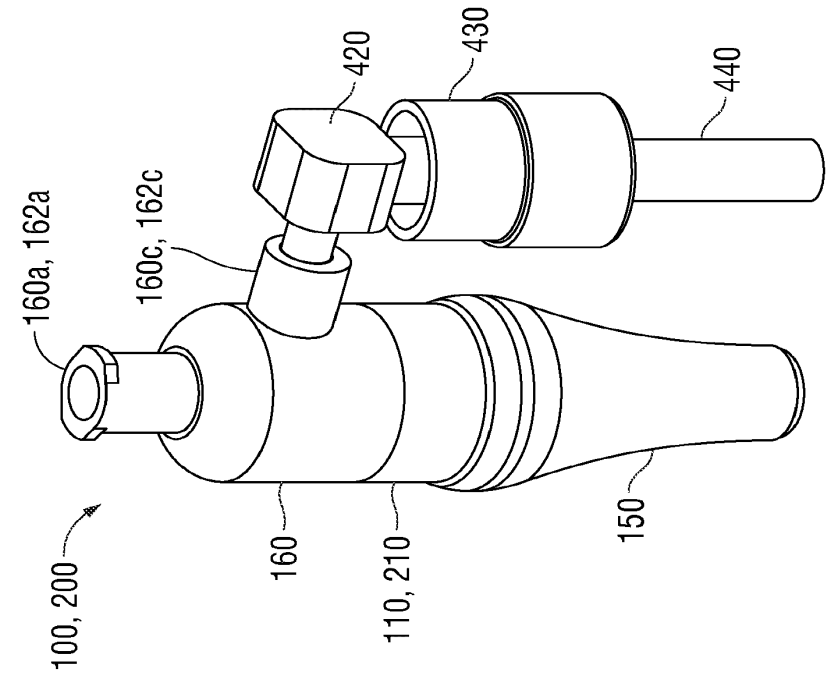

420
430
440
160a, 162a
160c, 162c
100, 200
160
110, 210
150

FIG. 28

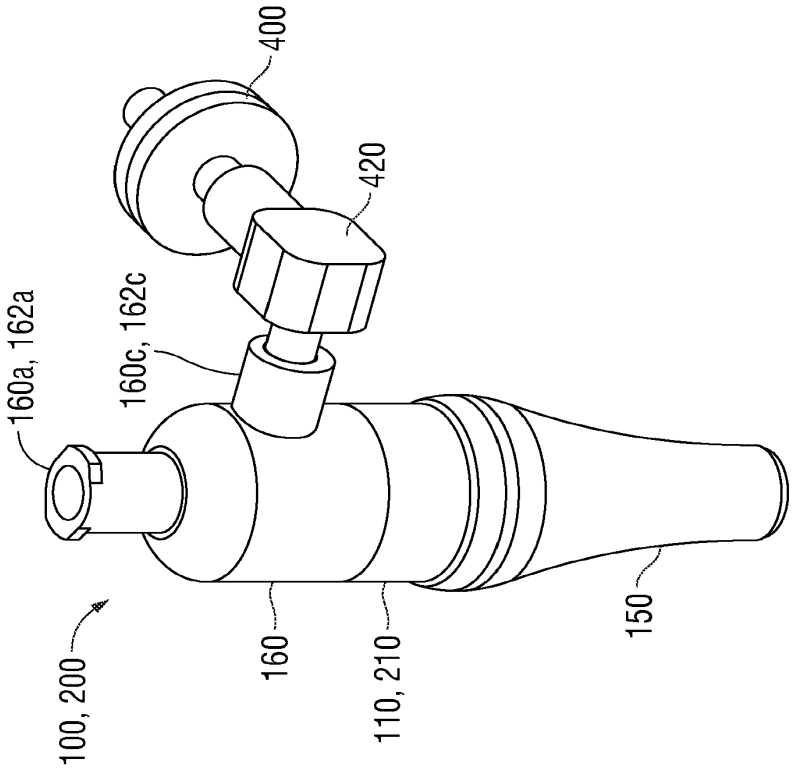

400
420
160a, 162a
160c, 162c
100, 200
160
110, 210
150

FIG. 27

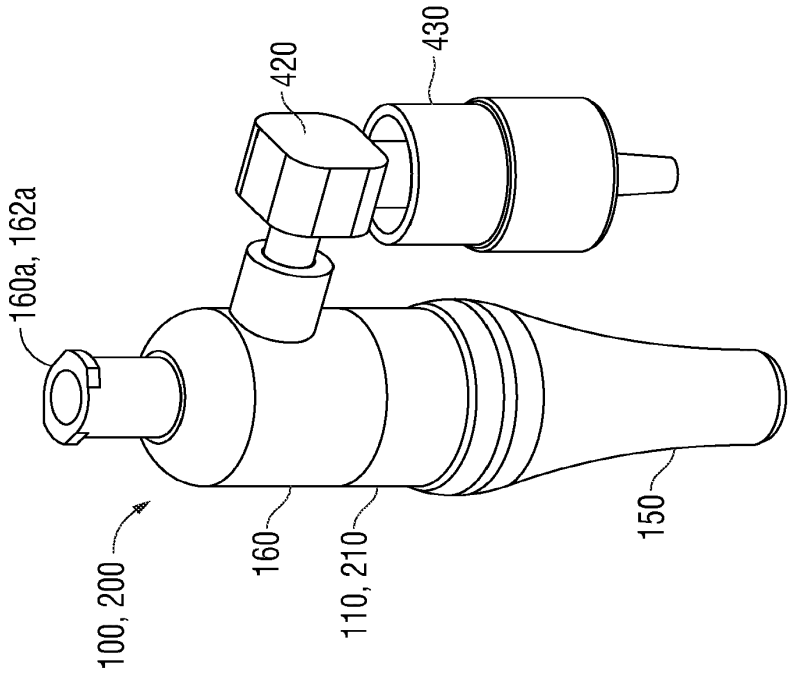

160a, 162a
420
430
100, 200
160
110, 210
150

FIG. 30

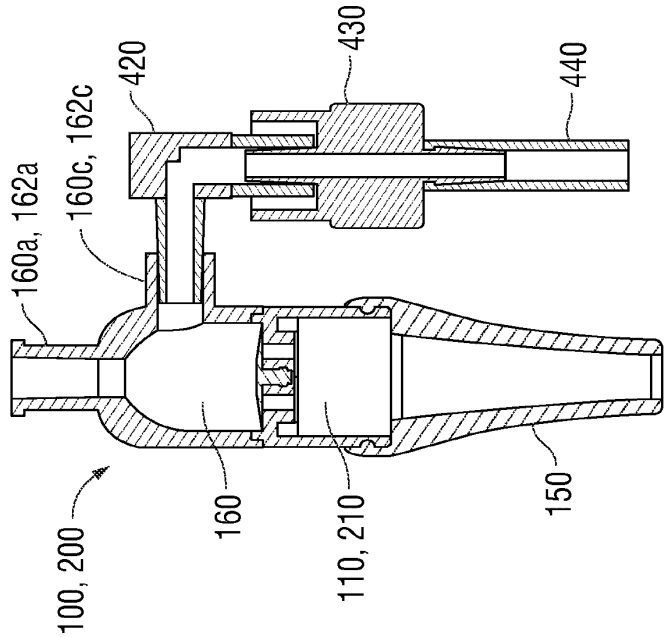

160a, 162a
160c, 162c
420
430
440
100, 200
160
110, 210
150

FIG. 29

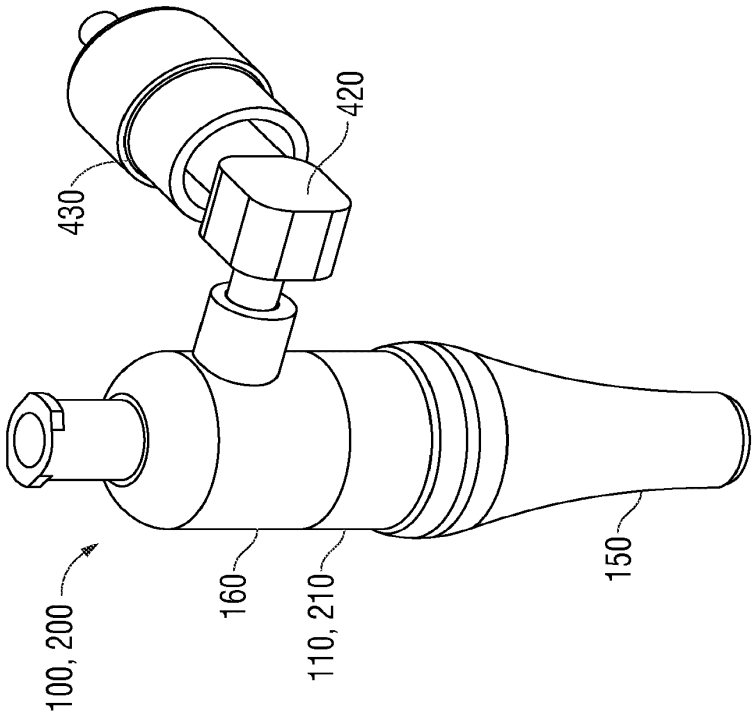



FIG. 32

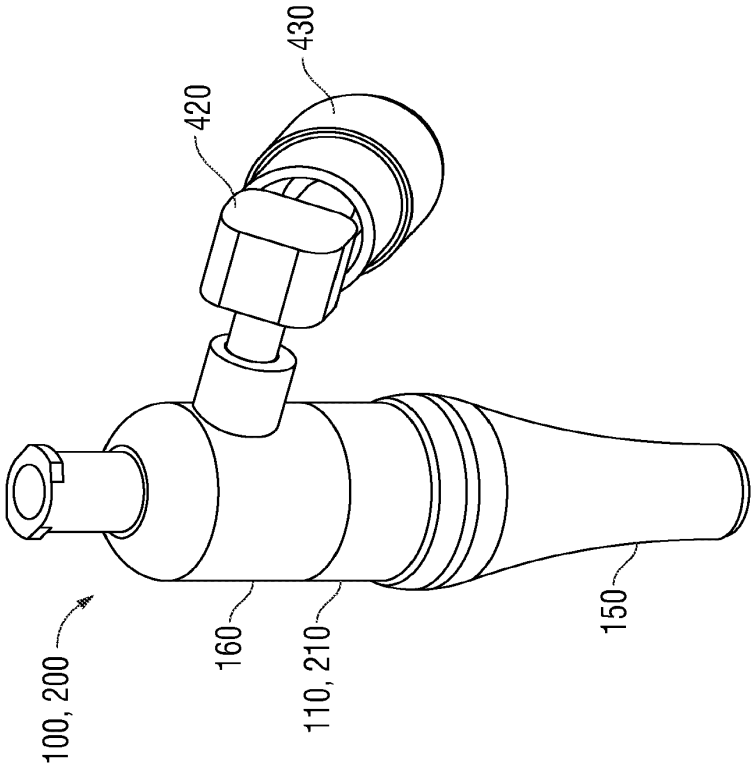



FIG. 31

# INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/042017

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/16 A61B10/02 A61M1/00
ADD. A61B17/32

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | CN 202 427 033 U (YONGTUAN LI)<br>12 September 2012 (2012-09-12)<br><br>figure 1<br>----- | 1,2,<br>11-13,<br>17-19 |
| X | CN 203 724 605 U (NANJING STOMATOLOGICAL HOSPITAL) 23 July 2014 (2014-07-23)<br><br>figure 1<br>----- | 1,2,<br>11-13,<br>17-19 |
| X | JP H07 79997 A (KOMIYAMA YATARO; HATTORI MORIHIRO) 28 March 1995 (1995-03-28)<br><br>figures 1,3<br>----- | 1,2,<br>11-13,<br>17-19 |

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

☒ See patent family annex.

* Special categories of cited documents :

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

"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 |
|---|---|
| 2 November 2015 | 09/11/2015 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Hamann, Joachim |

1

Form PCT/ISA/210 (second sheet) (April 2005)

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/042017

**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. [X] Claims Nos.: 20-26
because they relate to subject matter not required to be searched by this Authority, namely:

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

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

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

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

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

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

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

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

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

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2015/042017

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| CN 202427033 U | 12-09-2012 | NONE | |
| CN 203724605 U | 23-07-2014 | NONE | |
| JP H0779997 A | 28-03-1995 | JP 2563237 B2 | 11-12-1996 |
| | | JP H0779997 A | 28-03-1995 |

Form PCT/ISA/210 (patent family annex) (April 2005)

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Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 17/498,642 | 10/11/2021 | Richard Quick | 111552-8023.US02 | 1040 |

25096 7590 06/26/2023

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

| EXAMINER |
|---|
| NGUYEN, TUAN VAN |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3771 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 06/26/2023 | ELECTRONIC |

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

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

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

patentprocurement@perkinscoie.com

| *Office Action Summary* | Application No. 17/498,642 | Applicant(s) Quick, Richard | |
|---|---|---|---|
| | Examiner TUAN V NGUYEN | Art Unit 3771 | AIA (FITF) Status Yes |

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

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☑ Responsive to communication(s) filed on 10/11/21.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ 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.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims***

5) ☑ Claim(s) 21-40 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☑ Claim(s) 21-31 is/are allowed.

7) ☑ Claim(s) 32-40 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, 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.**

**Application Papers**

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 10/11/21 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

**Priority under 35 U.S.C. § 119**

12)☐ 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)).

** See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

## DETAILED ACTION

### *Notice of Pre-AIA or AIA Status*

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

### *Priority*

1. This application is a continuation of U.S. Patent Application No. 16/258,344, filed on January 25, 2019, which claims the benefit of U.S. Provisional Patent Application No. 62/622,691, filed on January 26, 2018.

### *Claim Rejections - 35 USC § 102*

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

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

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

3. Claim(s) 32 and 37-39 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Quick (US 20150352325, which is cited in the IDS filed on September 6, 2022).

4. Referring to claim 32, Quick discloses a system (Figs. 4A-4B) for the intravascular treatment of clot material within a blood vessel (Figs. 5A-5G), comprising:

an elongated shaft 206 (Fig. 4A-4B, para [0048]) having a distal portion and a proximal portion, wherein the distal portion of the elongated shaft is configured to be positioned proximate to the clot material PE within the blood vessel BV (Fig. 5A, para [0048]);

an attachment member 208 (Fig. 4A-4B, para [0051]) coupled to the proximal portion of the elongated shaft;

a pressure source configured to generate a vacuum (syringe 106, Figs. 3A-3B, para [0034]);

a fluid control device 310 (Figs. 4A-4B, para [0051]-[0052]) fluidly coupling the pressure source to the elongated shaft, wherein the fluid control device is movable between an open position and a closed position, wherein the fluid control device fluidly connects the pressure source to the elongated shaft in the open position, wherein the fluid control device fluidly disconnects the pressure source from the elongated shaft in the closed position, wherein the pressure source is configured to generate a pre-charged vacuum within the pressure source when the fluid control device is in the closed position, and wherein moving the fluid control device to the open position after generating the pre-charged vacuum is configured to apply the pre-charged vacuum to

the elongated shaft to aspirate a first portion of the clot material into the elongated shaft (para [0053]-[0055]. Examiner notes that the stop-cock 310 can be in closed position while lever 104 is moved from first position (Fig. 4A) to second position (Fig. 4B) to charge the syringe 106 then the user can open the stop-cock 310 to apply vacuum pressure to the lumen 205 of elongate shaft 206); and

an interventional device ID (Fig. 5A-5G, para [0048]) configured to be advanced through the attachment member 208 and the elongated shaft 206 to engage a second portion of the clot material remaining in the blood vessel.

5. Referring to claim 37, Quick discloses the system of claim 32 wherein the fluid control device 310 is a stopcock (para [0052]).

6. Referring to claim 38, Quick discloses the system of claim 32 wherein the pressure source is a syringe (syringe 106, Figs. 3A-3B, para [0034]).

7. Referring to claim 39, Quick discloses the system of claim 32 wherein the blood vessel is a pulmonary blood vessel (para [0028]).

***Claim Rejections - 35 USC § 103***

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

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

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

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

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

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claim(s) 33-36 and 40 is/are rejected under 35 U.S.C. 103 as being unpatentable over Quick in view of Quiachon et al. (US 5,256,150).

5. Referring to claims 33-35 and 40, Quick discloses the system of claim 32 wherein the attachment member 208 includes a lumen for receiving elongate member 202 of interventional device ID and delivery catheter 204 (Figs. 4A-4B). Quick discloses the invention substantially as clamed except for disclosing wherein the attachment member 208 is actuatable between a first position in which the lumen is sealed and a second position in which the lumen is unsealed.

6. Referring again to claims 33-35 and 40, however, Quiachon discloses a catheter system for use in introduce a catheter into a vessel in the body of a patient (Figs. 1 and 8-10). Quiachon discloses the catheter system includes a hemostasis valve 40 can be actuatable between a first position in which the lumen sealed and second position in which the lumen is unsealed and a button 66 configured to be depressed to move the hemostasis valve to from the sealed position to unsealed position and a spring 81 to bias the valve to a sealed position (col. 5, ln 58-63:3 "*Means is provided for yieldably returning the rack 61 into a position so that the valve member or diaphragm 40 is in a normally closed position and consists of a coil spring 81 coaxially mounted on the rod 62 and having one end engaging the actuator 66 and having the other end engaging a seat 82 provided in the body 22.*" Col. 7, ln 63 to col. 8, ln 15). The advantage of the valve is to accommodate large-diameter devices while still providing the desired hemostatic seal (col. 8, ln 20-24). Therefore, it would have been obvious to one of ordinary skill in the art, before the effective filling date of the application, to have provided a valve similar to valve 40 of Quiachon to the attachment member 208 of Quick so that it too would have the same advantage.

7. Referring to claim 36, examiner contends that the valve 40 of Quiachon, which is now in the attachment member 208 of Quick, is capable to being adjust to have a condition of the lumen has a diameter in the second position that is about equal to an inner diameter of the elongated shaft.

***Allowable Subject Matter***

1. Claims 21-31 are allowable.

2. Quick (US 20150352325), which is the best reference, discloses a method for the intravascular treatment of clot material within a blood vessel (Figs. 5A-5G), the method comprising: positioning a distal portion of an elongated shaft proximate to the clot material within the blood vessel (Figs. 5A-5G); unsealing an attachment member coupled to a proximal portion of the elongated shaft; fluidly connecting a vacuum pressure source to the elongated shaft; advancing an interventional device distally through the attachment member and the elongated shaft; engaging the interventional device with a second portion of the clot material remaining within the blood vessel; and apply vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft. In paragraphs [0054], [0058] and [0060] Quick specifically discloses when retraction of lever 204 from first position (Fig. 4A) to second position (Fig. 4B) to retract catheter 204 and/or shaft 202 of the interventional device ID aspiration also applied to the lumen of catheter 206. Quick discloses the advantage of synchronized aspiration and retraction of catheter 204 and/or shaft 202 of the interventional device ID is reducing the amount of fluid withdrawn from the patient's body during treatment (para [0058]). Thus, adding the step of pre-charging the syringe then release valve 310 to apply vacuum to the clot material during retraction of the catheter 204 and/or shaft 202 of the interventional device into catheter 206 would change the principal operation of Quick.

3. The art of record alone or in combination fails to disclose the step of pre-charging a vacuum in a pressure source and fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached Monday - Friday 8:30 AM - 5:30 PM.

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

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Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TUAN V NGUYEN/
Primary Examiner, Art Unit 3771

| Notice of References Cited | Application/Control No. 17/498,642 | Applicant(s)/Patent Under Reexamination Quick, Richard | |
|---|---|---|---|
| | Examiner TUAN V NGUYEN | 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-5256150-A | 10-1993 | Quiachon; Dinah B. | A61M39/0613 | 604/164.02 |
| * | B | US-5330436-A | 07-1994 | Heidmueller; Harald | A61B17/3462 | 604/174 |
| | C | | | | | |
| | D | | | | | |
| | E | | | | | |
| | F | | | | | |
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**FOREIGN PATENT DOCUMENTS**

| * | | Document Number Country Code-Number-Kind Code | Date MM-YYYY | Country | Name | CPC Classification |
|---|---|---|---|---|---|---|
| | N | | | | | |
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| | 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 |
|---|---|---|
| | 17/498,642 | Quick, Richard |
| | Examiner | Art Unit |
| | TUAN V NGUYEN | 3771 |

| CPC - Searched* | | |
|---|---|---|
| **Symbol** | **Date** | **Examiner** |
| A61M1/60,0001,0003 | 06/17/2023 | TN |
| A61M39/0613 | 06/17/2023 | TN |
| A61B2017/22035,22079,22042,22094,22034 | 06/17/2023 | TN |
| A61B17/221,22031 | 06/17/2023 | TN |
| A61M25/01,0122,0082 | 06/17/2023 | TN |
| A61F2/95 | 06/17/2023 | TN |
| A61M2210/12 | 06/17/2023 | TN |

| CPC Combination Sets - Searched* | | |
|---|---|---|
| **Symbol** | **Date** | **Examiner** |
| | | |

| US Classification - Searched* | | | |
|---|---|---|---|
| **Class** | **Subclass** | **Date** | **Examiner** |
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* 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** |
| Reviewed references cited in parent case | 06/17/2023 | TN |
| Group/subgroups combined with text (see search history printout) | 06/17/2023 | TN |

| /TUAN V NGUYEN/<br>Primary Examiner, Art Unit 3771 | |
|---|---|

| Search Notes | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 17/498,642 | Quick, Richard |
| | Examiner | Art Unit |
| | TUAN V NGUYEN | 3771 |

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

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|---|---|
| /TUAN V NGUYEN/<br>Primary Examiner, Art Unit 3771 | |

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

| U.S. PATENTS AND PUBLICATIONS | | | | | |
|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | 1. | 11406801 | 08-09-2022 | Fojtik et al. | |
| | 2. | 11554005 | 01-17-2023 | Merritt et al. | |
| | 3. | 11559382 | 01-24-2023 | Merritt et al. | |
| | 4. | 6818006 | 11-16-2004 | Douk et al. | |
| | 5. | 9078682 | 07-14-2015 | Lenker et al. | |
| | 6. | 20140052161 | 02-20-2014 | Cully et al. | |
| | 7. | 20180042623 | 02-15-2018 | Batiste | |
| | 8. | 20180184912 | 07-05-2018 | Al-Ali | |
| | 9. | 20160262774 | 09-15-2016 | HONDA | |
| | 10. | 20120172918 | 07-05-2012 | Fifer et al. | |
| | 11. | 20050054995 | 03-10-2005 | Barzell et al. | |
| | 12. | 5421824 | 06-06-1995 | Clement et al. | |
| | 13. | 20210236148 | 08-05-2021 | Marchand et al. | |
| | 14. | 5158533 | 10-27-1992 | Strauss et al. | |
| | 15. | 20230046775 | 02-16-2023 | Quick | |
| | 16. | 20140188127 | 07-03-2014 | Dubrul et al. | |
| | 17. | 20140074144 | 03-13-2014 | Shrivastava et al. | |
| | 18. | 8535283 | 09-17-2013 | Heaton et al. | |
| | 19. | 8753322 | 06-17-2014 | Hu et al. | |
| | 20. | 8808259 | 08-19-2014 | Walton et al. | |
| | 21. | 20230062809 | 03-02-2023 | Merritt et al. | |
| | 22. | 20230070120 | 03-09-2023 | Cox et al. | |
| | 23. | 20010031981 | 10-18-2001 | Evans et al. | |
| | 24. | 20040102807 | 05-27-2004 | Kusleika et al. | |
| | 25. | 6059814 | 05-09-2000 | Ladd | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Foreign Document Number[3] | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[5] |
| | 1. | WO2006124307 | 11-23-2006 | KERBEROS PROXIMAL SOLUTIONS, INC. | | |



161689285.1

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.V.N/

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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|---|---|---|
| | **Application Number** | 17/498,642- Conf# 1040 |
| | **Filing Date** | October 11, 2021 |
| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

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

| EXAMINER SIGNATURE | | | |
|---|---|---|---|
| Examiner Signature | /TUAN V NGUYEN/ | Date Considered | 06/14/2023 |

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.



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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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| | **Application Number** | 17/498,642- Conf# 1040 |
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| | **First Named Inventor** | Richard Quick |
| | **Art Unit** | 3771 |
| | **Examiner Name** | Tuan Van Nguyen |
| | **Attorney Docket Number** | 111552-8023.US02 |

## CERTIFICATION STATEMENT

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

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

**OR**

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

☐ See attached certification statement.

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

☒ None

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

### COPIES OF REFERENCES

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

## SIGNATURE

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

| | | | |
|---|---|---|---|
| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2023-04-04 |
| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

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



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## PE2E SEARCH - Search History (Prior Art)

| Ref # | Hits | Search Query | DBs | Default Operator | Plurals | British Equivalents | Time Stamp |
|---|---|---|---|---|---|---|---|
| L1 | 1 | "20190231373" | (US-PGPUB; USPAT) | OR | ON | ON | 2020/10/05 09:38 PM |
| L2 | 13 | ((("Inari") near3 ("Medical") near3 ("Inc"))).AS,AANM. | (USPAT) | OR | ON | ON | 2020/10/06 04:04 PM |
| L3 | 253 | ((("Quick") near3 ("Richard"))).INV. | (US-PGPUB; USPAT; USOCR) | OR | ON | ON | 2020/10/06 04:05 PM |
| L5 | 5718 | A61B2017/22042,22094,22034.cpc. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 06:42 PM |
| L6 | 4652 | A61M25/0082.cpc. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 06:43 PM |
| L7 | 2813 | A61B2017/22079.cpc. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 06:43 PM |
| L8 | 1954 | A61M2210/12.cpc. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 06:44 PM |
| L10 | 5718 | A61B2017/22042,22094,22034.cpc. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 08:30 PM |
| L11 | 22 | L10 and (adapt$3 connector) same seal same lock$4 same (catheter sheath) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 08:30 PM |
| L12 | 4652 | A61M25/0082.cpc. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 08:30 PM |
| L13 | 8 | L12 and (adapt$3 connector) same seal same lock$4 same (catheter sheath) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 08:30 PM |
| L14 | 2813 | A61B2017/22079.cpc. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 08:30 PM |
| L15 | 48 | L14 and (adapt$3 connector) same seal same lock$4 same (catheter sheath) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 08:30 PM |
| L16 | 1954 | A61M2210/12.cpc. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; | OR | ON | ON | 2020/10/06 08:30 PM |

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|---|---|---|---|---|---|---|---|
| | | | JPO; DERWENT; IBM_TDB) | | | | |
| L17 | 18 | L16 and (adapt$3 connector) same seal same lock$4 same (catheter sheath) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 08:30 PM |
| L18 | 36 | L16 and (adapt$3 connector) same seal and (adapt$3 connector) same lock$4 and lock$4 same (catheter sheath) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 08:31 PM |
| L19 | 3089 | A61B17/22031.cpc. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 08:31 PM |
| L20 | 24 | L19 and (adapt$3 connector) same seal and (adapt$3 connector) same lock$4 and lock$4 same (catheter sheath) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 08:31 PM |
| L21 | 53 | L10 and (adapt$3 connector) same seal and (adapt$3 connector) same lock$4 and lock$4 same (catheter sheath) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 08:31 PM |
| L22 | 33 | L12 and (adapt$3 connector) same seal and (adapt$3 connector) same lock$4 and lock$4 same (catheter sheath) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 08:31 PM |
| L23 | 84 | L14 and (adapt$3 connector) same seal and (adapt$3 connector) same lock$4 and lock$4 same (catheter sheath) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 08:31 PM |
| L24 | 36 | L16 and (adapt$3 connector) same seal and (adapt$3 connector) same lock$4 and lock$4 same (catheter sheath) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 08:31 PM |
| L25 | 12081 | A61B17/221.cpc. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 08:40 PM |
| L26 | 39 | L25 and clean$4 same repeat$4 | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 08:40 PM |

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|---|---|---|---|---|---|---|---|
| L27 | 24 | L25 and clean$4 same reinsert$4 | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 08:44 PM |
| L28 | 44 | L25 and (adapt$3 connector) same seal and (adapt$3 connector) same lock$4 and lock$4 same (catheter sheath) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 08:46 PM |
| L29 | 36 | L16 and (adapt$3 connector) same seal$4 and (adapt$3 connector) same lock$4 and lock$4 same (catheter sheath) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 09:00 PM |
| L30 | 55 | L10 and (adapt$3 connector) same seal$4 and (adapt$3 connector) same lock$4 and lock$4 same (catheter sheath) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 09:00 PM |
| L31 | 187 | L10 and (adapt$3 connector attachment coupl$4) same seal$4 and (adapt$3 connector attachment coupl$4) same lock$4 and lock$4 same (catheter sheath) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 09:01 PM |
| L32 | 61 | L12 and (adapt$3 connector attachment coupl$4) same seal$4 and (adapt$3 connector attachment coupl$4) same lock$4 and lock$4 same (catheter sheath) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 09:01 PM |
| L33 | 163 | L14 and (adapt$3 connector attachment coupl$4) same seal$4 and (adapt$3 connector attachment coupl$4) same lock$4 and lock$4 same (catheter sheath) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 09:01 PM |
| L34 | 137 | L16 and (adapt$3 connector attachment coupl$4) same seal$4 and (adapt$3 connector attachment coupl$4) same lock$4 and lock$4 same (catheter sheath) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 09:01 PM |
| L35 | 113 | L19 and (adapt$3 connector attachment coupl$4) same seal$4 and (adapt$3 connector attachment coupl$4) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/06 09:02 PM |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | same lock$4 and lock$4 same (catheter sheath) | | | | | |
| L36 | 226 | 604/159.ccls. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/07 09:16 AM |
| L37 | 7358 | A61M25/01.cpc. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/07 09:21 AM |
| L38 | 1983 | A61M25/01.cpc. | (US-PGPUB; USPAT) | OR | ON | ON | 2020/10/07 09:21 AM |
| L39 | 7358 | A61M25/01.cpc. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/07 03:21 PM |
| L40 | 1983 | A61M25/01.cpc. | (US-PGPUB; USPAT) | OR | ON | ON | 2020/10/07 03:22 PM |
| L41 | 5375 | L39 not L40 | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/07 03:22 PM |
| L42 | 47 | L41 and (adapt$3 connector attachment coupl$4) same seal$4 and seal$4 same (sheath catheter) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/07 03:25 PM |
| L43 | 126 | A61M25/0122.cpc. | (US-PGPUB; USPAT) | OR | ON | ON | 2020/10/07 09:08 PM |
| L45 | 3089 | A61B17/22031.cpc. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/07 09:11 PM |
| L47 | 1745 | A61B2017/22035.cpc. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/07 09:12 PM |
| L48 | 1 | ("20150335416").PN. | (US-PGPUB; USPAT) | OR | OFF | OFF | 2020/10/08 09:58 AM |
| L49 | 19178 | A61F2/95.cpc. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/09 09:39 AM |
| L50 | 12084 | A61B17/221.cpc. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/09 10:09 AM |
| L51 | 7 | L50 and clean$4 same reinsert$4 and clean$4 same (new prestine) | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/09 10:09 AM |
| L52 | 1 | ("20090163896").PN. | (US-PGPUB; USPAT) | OR | OFF | OFF | 2020/10/09 11:30 AM |

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| L53 | 338 | A61B17/22031.cpc. and clamp | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/09 04:53 PM |
| L54 | 135 | A61B17/22031.cpc. and clamp same tub$4 | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/09 04:53 PM |
| L55 | 21 | 606/159.ccls. and (releas$4 open$3 unlock$4) with seal with catheter | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/09 05:36 PM |
| L56 | 537 | (releas$4 open$3 unlock$4) with seal with catheter and 606/$.ccls. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/10 10:35 AM |
| L57 | 1 | ("5911710").PN. | (US-PGPUB; USPAT) | OR | OFF | OFF | 2020/10/10 10:46 AM |
| L58 | 7 | 604/249.ccls. and hemostasis with seal | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/10 10:59 AM |
| L59 | 875 | 604/249.ccls. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/10 11:02 AM |
| L60 | 2426 | 604/246.ccls. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/10 11:02 AM |
| L61 | 2881 | A61M2039/062.cpc. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2020/10/10 12:38 PM |
| L62 | 752 | A61M2039/062.cpc. | (US-PGPUB; USPAT) | OR | ON | ON | 2020/10/10 12:38 PM |
| L63 | 104 | ("4000739" \| "4029099" \| "4062363" \| "4205675" \| "4327723" \| "4327735" \| "4362150" \| "4424833" \| "4430081" \| "4483340" \| "4551137" \| "4564014" \| "4582181" \| "4613329" \| "4634433" \| "4638805" \| "4657536" \| "4684363" \| "4692200" \| "4696304" \| "4714461" \| "4715378" \| "4726374" \| "4748982" \| "4759751" \| "4767409" \| "4793351" \| "4811737" \| "4821722" \| "4844092" \| "4846174" \| "4917094" \| "4930341" \| "4983167" \| "5114408" \| "5149326").PN. OR | (US-PGPUB; USPAT; USOCR) | OR | ON | ON | 2020/10/10 01:42 PM |

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| | | ("5334153").URPN. | | | | | |
| L68 | 8 | (("10524811") or ("10912577") or ("20110152823") or ("20210113224") or ("20110160763") or ("20050283165") or ("20110125181") or ("20020095171")).PN. | (US-PGPUB; USPAT) | OR | ON | ON | 2021/06/18 08:07 AM |
| L71 | 2 | wo-2020036809-$.did. | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2021/06/18 02:54 PM |
| L72 | 1 | ("20200046368").PN. | (US-PGPUB; USPAT) | OR | ON | ON | 2021/06/18 02:56 PM |
| L73 | 19 | ((("Inari") near3 ("Medical") near3 ("Inc"))).AS,AANM. | (USPAT) | OR | ON | ON | 2022/09/01 02:14 PM |
| L74 | 277 | ((("Quick") near3 ("Richard"))).INV. | (US-PGPUB; USPAT; USOCR) | OR | ON | ON | 2022/09/01 02:16 PM |
| L77 | 17 | ("5102417" \| "5603698" \| "5662700" \| "5876436" \| "6719790" \| "7462191" \| "7544198" \| "8414632" \| "20030144670" \| "20030199849" \| "20040106900" \| "20040236403" \| "20060036263" \| "20060264905" \| "20070270780" \| "20080015625" \| "20080167522").pn. OR ("9408694").urpn. AND (PGPB \| USPT \| USOC).dbnm. | (US-PGPUB; USPAT; USOCR) | OR | ON | ON | 2022/09/01 04:38 PM |
| L78 | 1 | ("8876848").pn. | (US-PGPUB; USPAT) | OR | ON | ON | 2022/09/01 04:45 PM |
| L79 | 62 | ("4364391" \| "4884579" \| "5057083" \| "5058580" \| "5095915" \| "5465733" \| "5474535" \| "5773020" \| "5865826" \| "5885217" \| "5910134" \| "5980493" \| "6637435" \| "6695850" \| "6814718" \| "6926728" \| "7198631" \| "7306574" \| "7632277" \| "7695489" \| "7713193" \| "7776062" \| "8202289" \| "8396532" \| "8485969" \| "20020026207" \| "20020133128" \| "20040015138" \| "20040138589" \| | (US-PGPUB; USPAT; USOCR) | OR | ON | ON | 2022/09/01 04:45 PM |

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|---|---|---|---|---|---|---|---|
| | | "20040243212" \| "20050131393" \| "20050216007" \| "20050234437" \| "20060124134" \| "20060208028" \| "20070060927" \| "20070156219" \| "20080009797" \| "20080009823" \| "20080125791" \| "20080146967" \| "20090024089" \| "20090209912" \| "20090216238" \| "20090306657" \| "20090312784" \| "20090318896" \| "20100010334" \| "20100016984" \| "20100036226" \| "20100262158" \| "20100298832" \| "20110087234" \| "20110166579" \| "20110245800" \| "20110275935" \| "20110319898" \| "20120116323" \| "20120123464" \| "20120316565" \| "20130255694").pn. OR ("8876848").urpn. AND (PGPB \| USPT \| USOC).dbnm. | | | | | |
| L82 | 3748 | A61M1/0281.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2022/09/06 09:13 AM |
| L83 | 1730 | A61M1/0281.cpc. AND filter | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, | OR | ON | ON | 2022/09/06 09:13 AM |

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|---|---|---|---|---|---|---|---|
| | | | HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) | | | | |
| L84 | 676 | A61M1/0281.cpc. AND filter AND valve | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2022/09/06 09:13 AM |
| L85 | 32 | A61M1/008.cpc. AND filter AND valve | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2022/09/06 09:15 AM |
| L86 | 115 | A61B17/22031,22,221.cpc. AND (reservoir container collect$4) SAME filter SAME valve | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2022/09/06 10:23 AM |
| L87 | 12 | A61B17/220758,320725.cpc. AND (reservoir container collect$4) SAME filter SAME valve | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2022/09/06 10:24 AM |
| L88 | 122 | A61B2017/22034,22042,22079,22094.cpc. AND (reservoir container collect$4) WITH (debris thromb$5 embol$5) AND filter | (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2022/09/06 10:34 AM |

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|---|---|---|---|---|---|---|---|
| | | SAME valve | | | | | |
| L89 | 188 | ("4164223" \| "4315506" \| "4458877" \| "4662871" \| "4696669" \| "4767403" \| "4902276" \| "4911399" \| "5254085" \| "5318546" \| "5496267" \| "5704584" \| "6193732" \| "6226843" \| "6261283" \| "6423028" \| "6471683" \| "6689109" \| "6887220" \| "6960189" \| "7004931" \| "7033336" \| "7178699" \| "7472882" \| "7530976" \| "7641170" \| "7713276" \| "7717853" \| "7918822" \| "7931659" \| "7976515" \| "7998168" \| "8206374" \| "8287654" \| "8333796" \| "8366726" \| "8366735" \| "8435225" \| "8460312" \| "8465507" \| "8518017" \| "8568370" \| "8617106" \| "8636754" \| "8647294" \| "8690907" \| "8715314" \| "8721595" \| "8770542" \| "8814778" \| "8852218" \| "8911487" \| "8932321" \| "9017349" \| "9119656" \| "9186151" \| "9248228" \| "9402757" \| "9402985" \| "9526864" \| "9526865" \| "9554805" \| "9572933" \| "9615832" \| "9615951" \| "9623230" \| "9655633" \| "9775621" \| "9820761" \| "9883863" \| "9901351" \| "9901352" \| "9943321" \| "9980841" \| "10166024" \| "10299947" \| "20030023263" \| "20030229368" \| "20040102716" \| "20040267305" \| "20050149068" \| "20050182432" \| "20050256447" \| "20050273122" \| "20060025794" \| "20060058837" \| "20060264995" \| "20070060888" \| "20070100276" \| "20070129652" \| "20070239261" \| "20080015478" \| "20080154184" \| "20080163731" \| | (US-PGPUB; USPAT; USOCR) | OR | ON | ON | 2022/09/06 10:38 AM |