

6/29

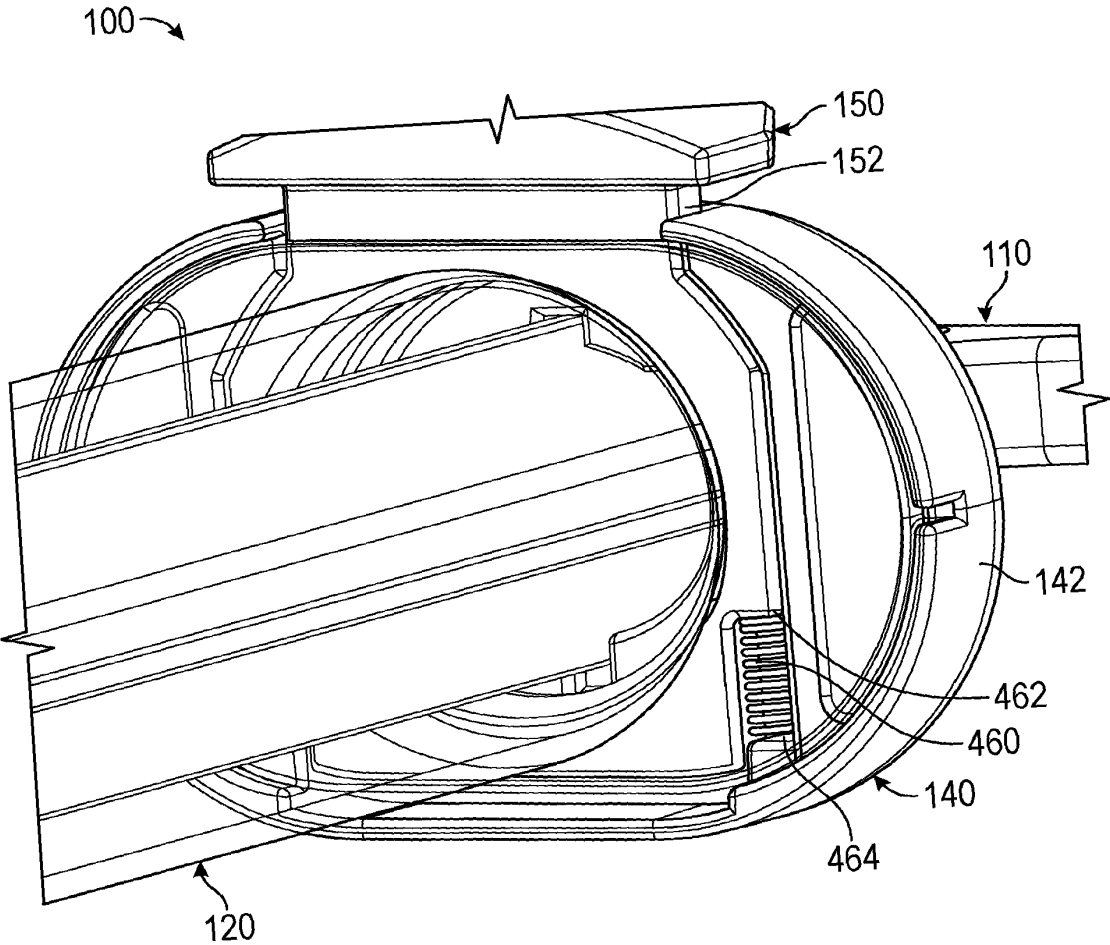


FIG. 4

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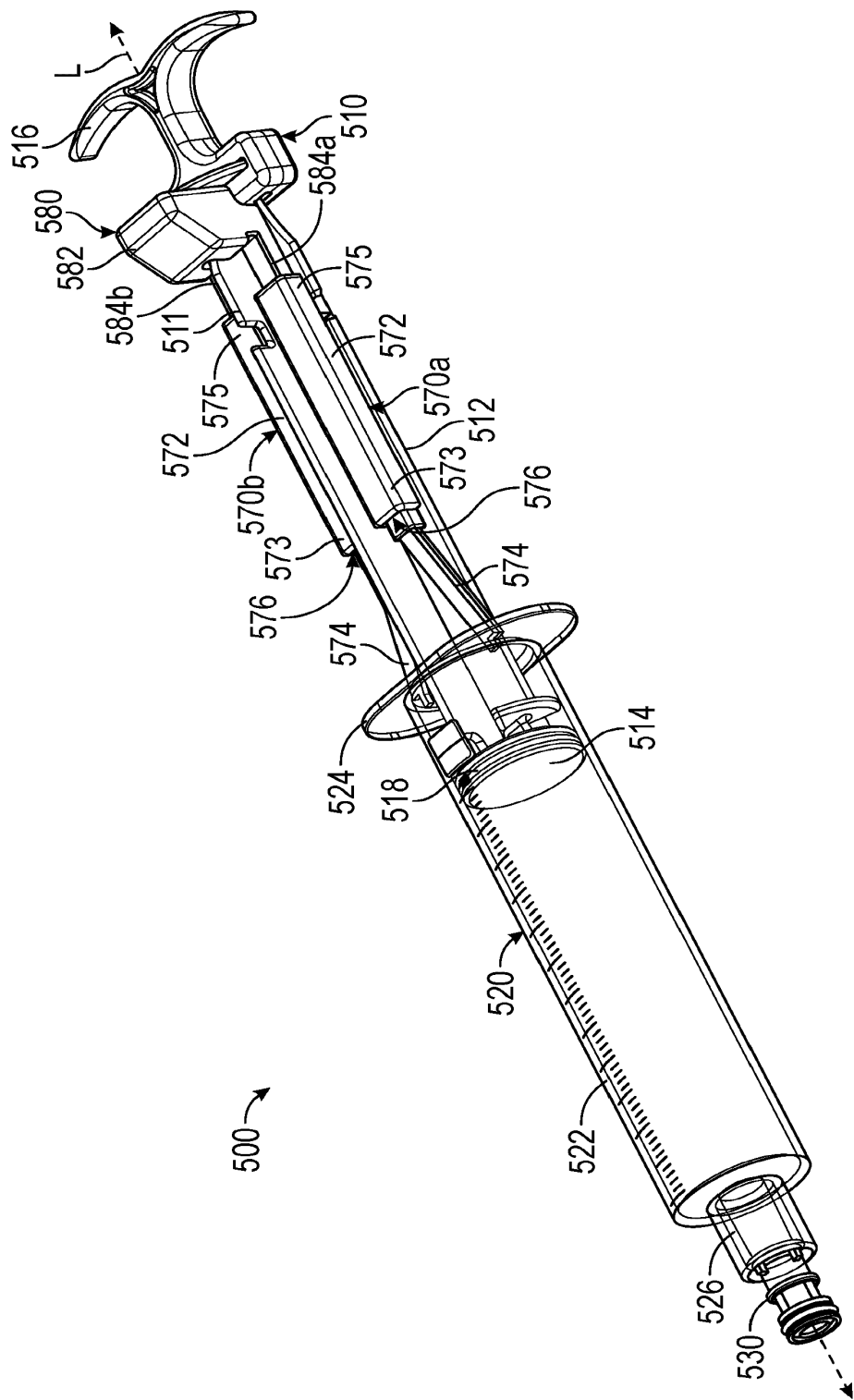


FIG. 5A

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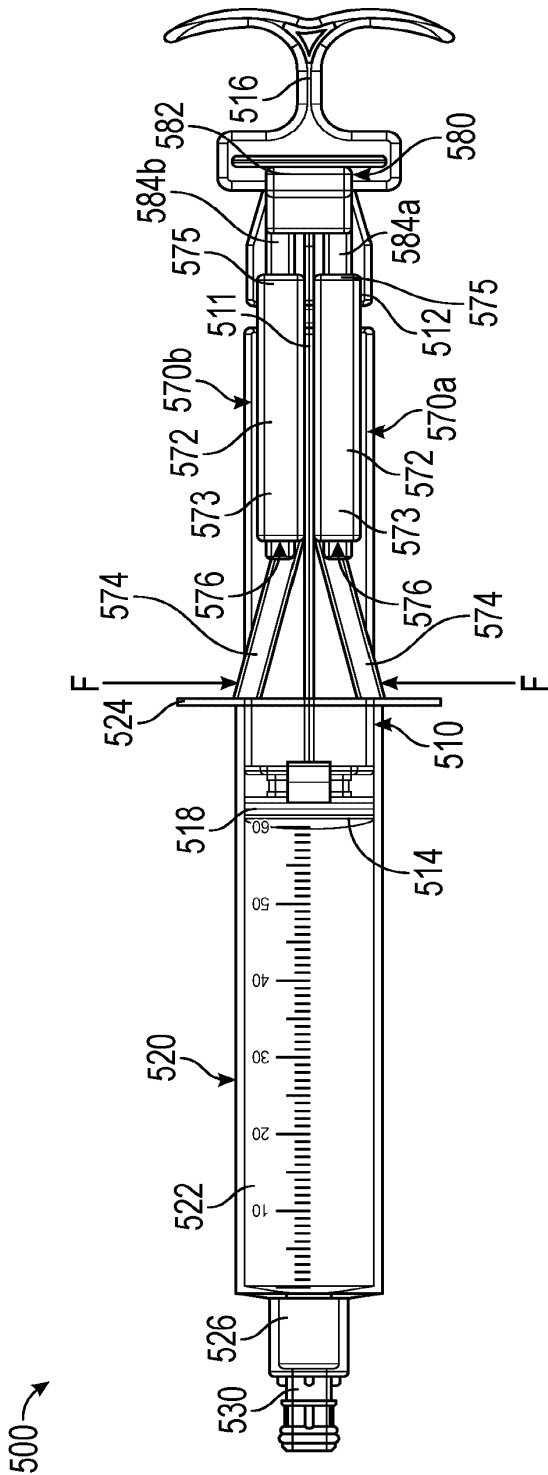


FIG. 5B

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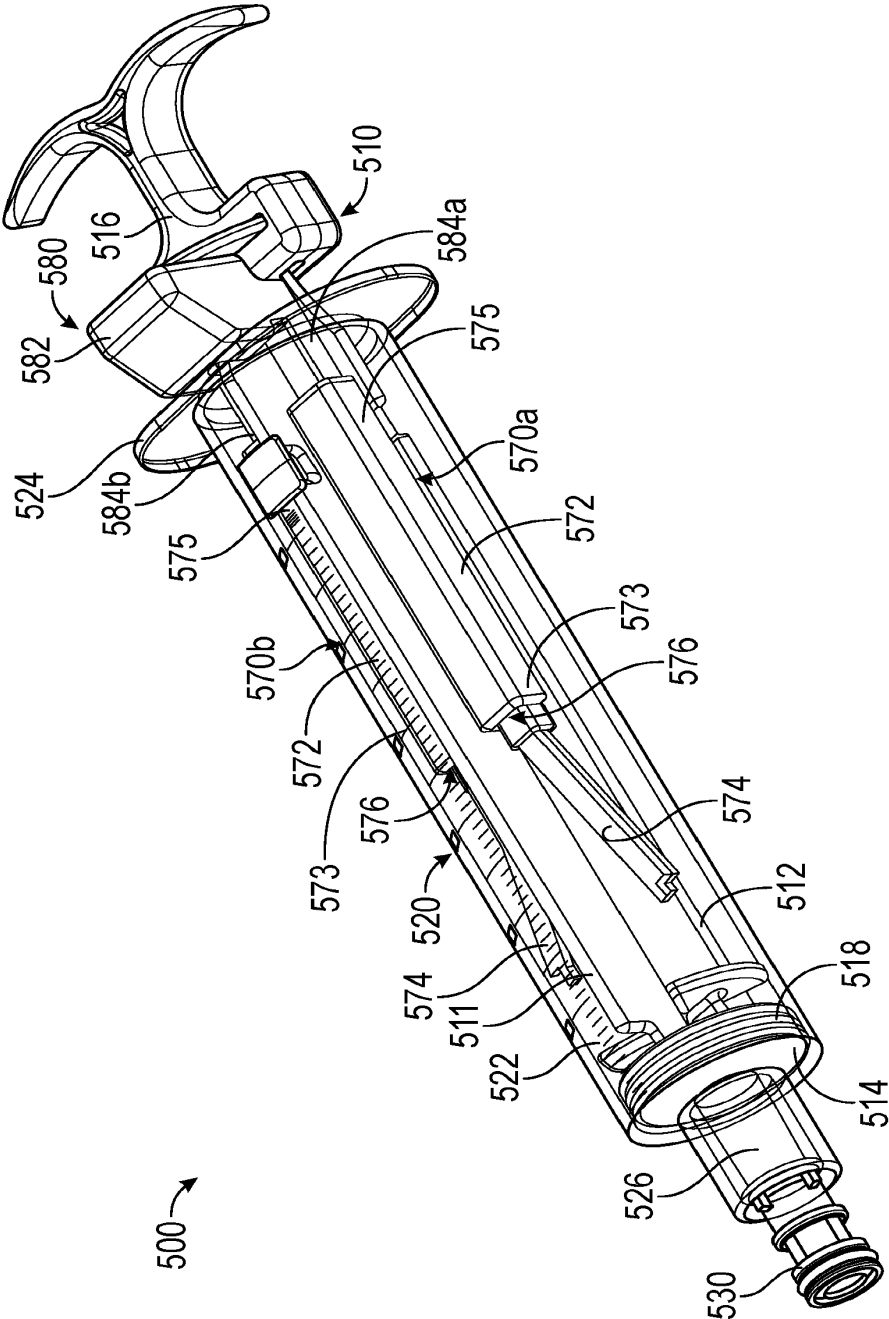


FIG. 5C

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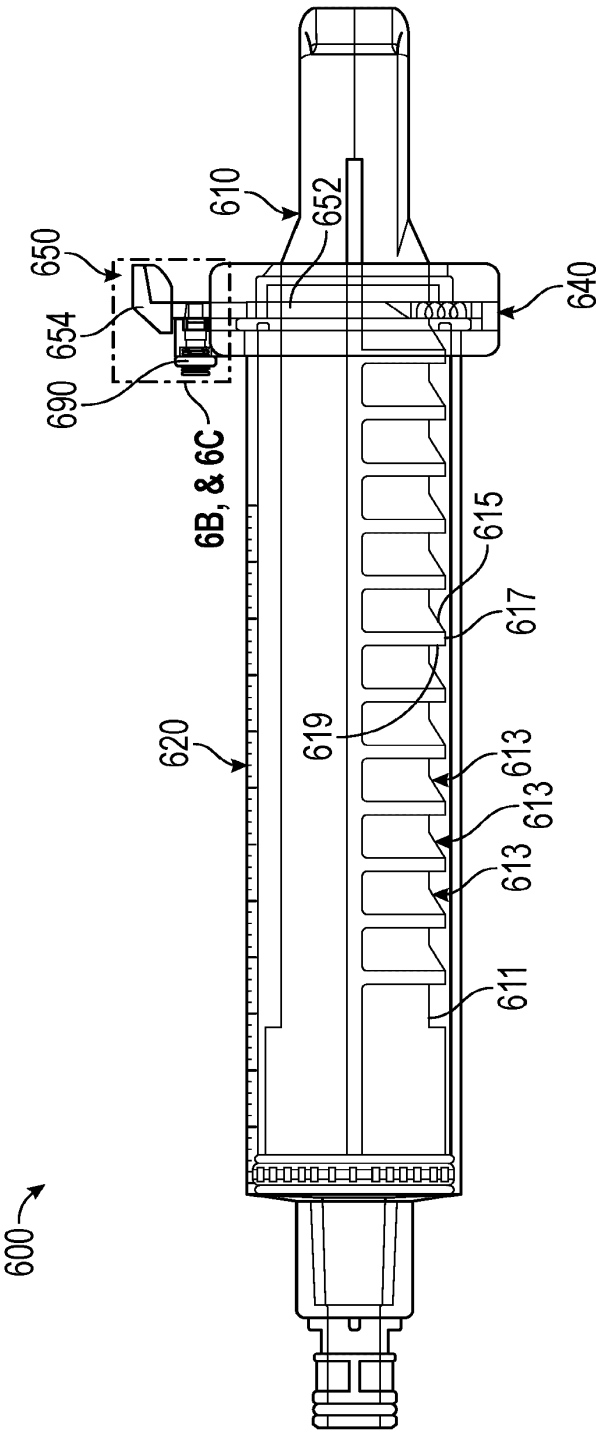


FIG. 6A

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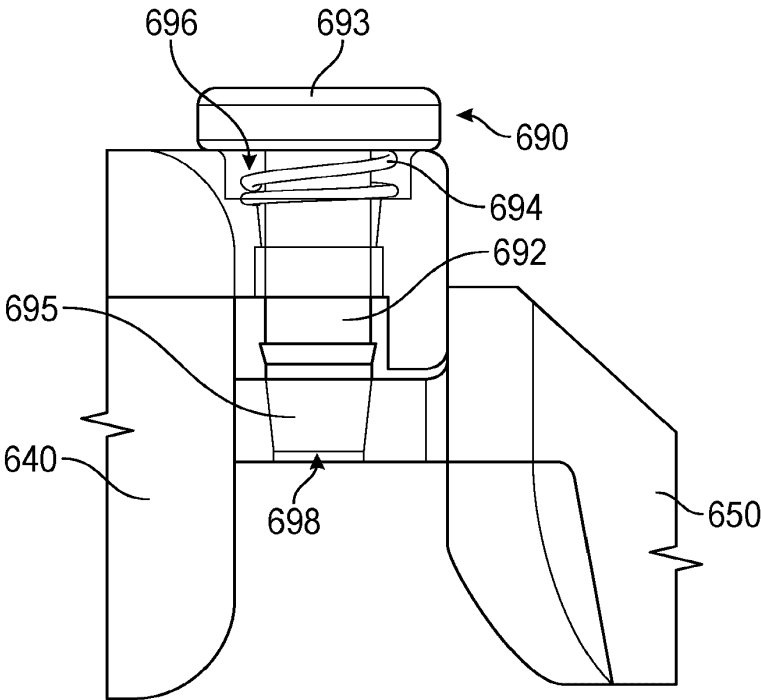


FIG. 6B

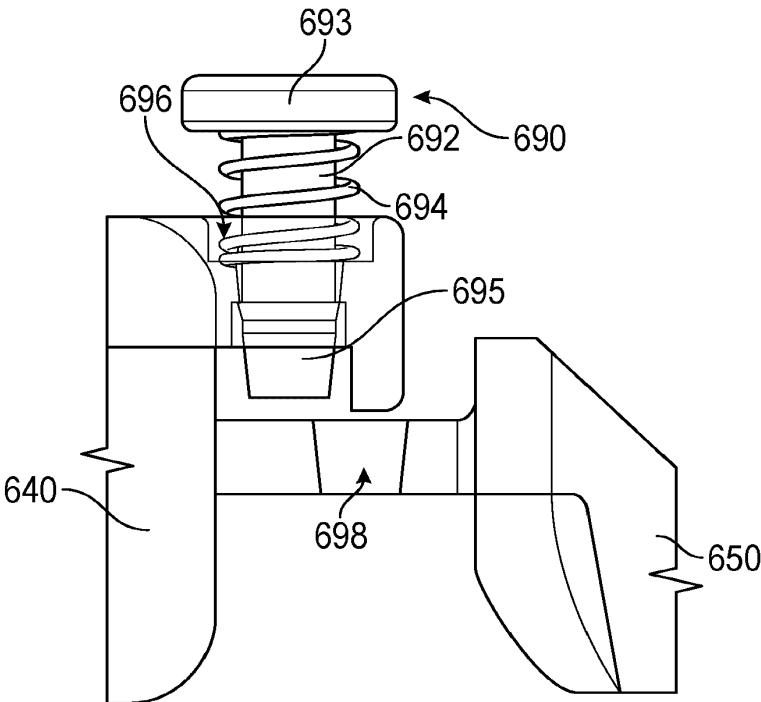


FIG. 6C

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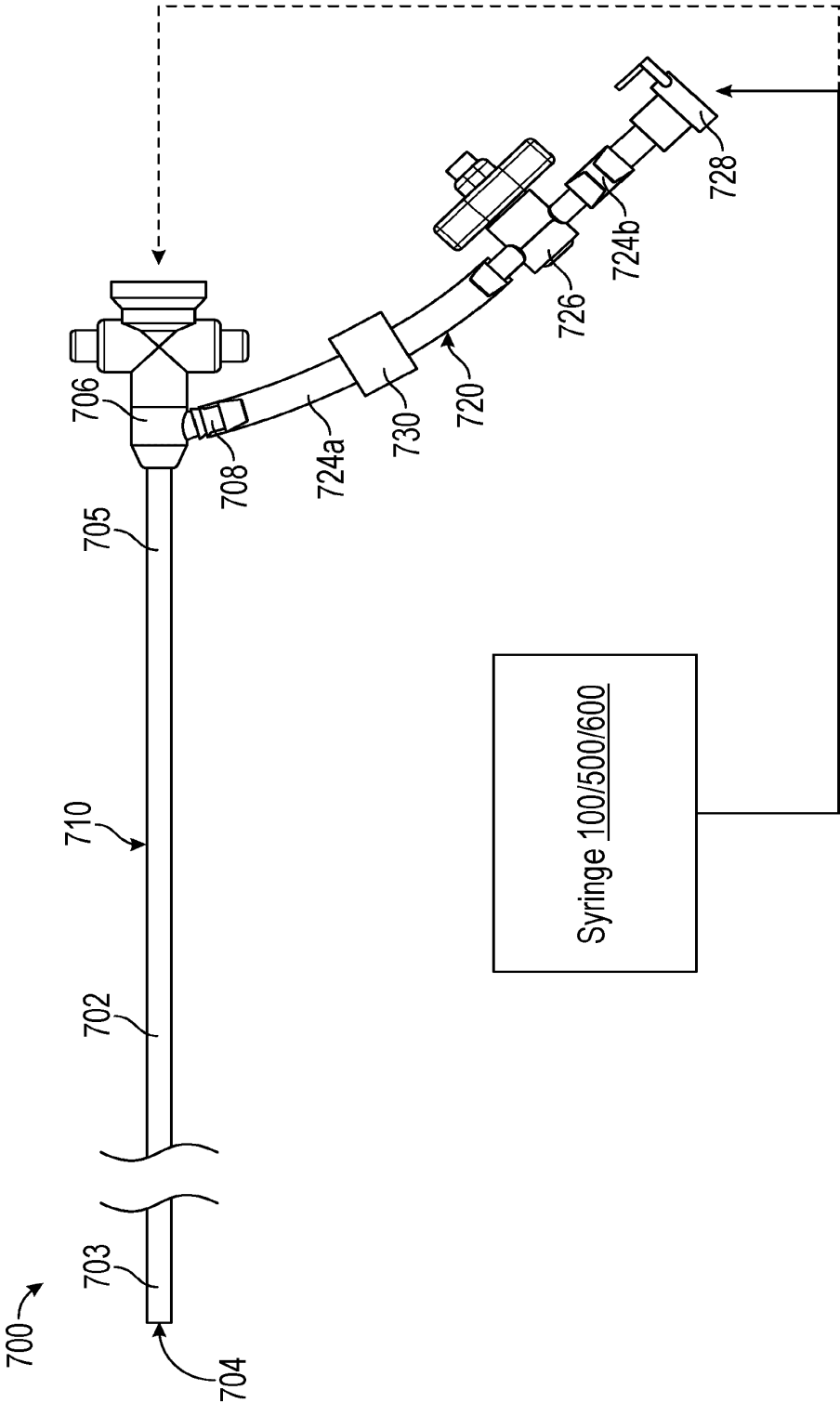


FIG. 7

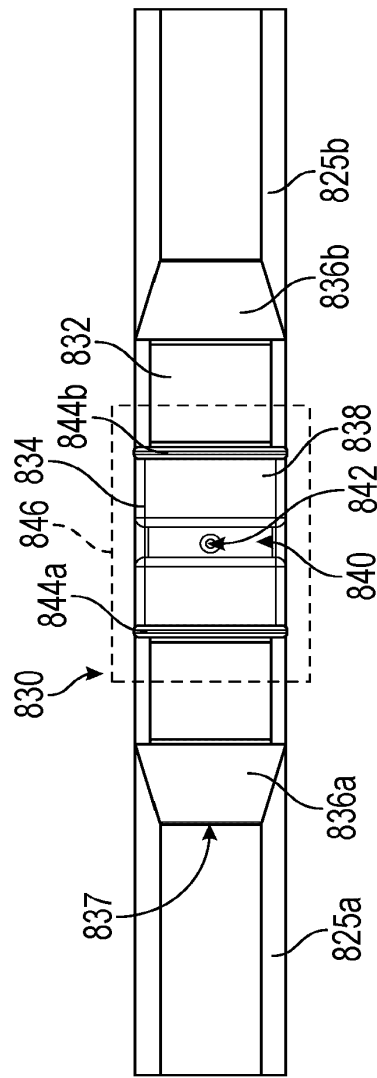


FIG. 8A

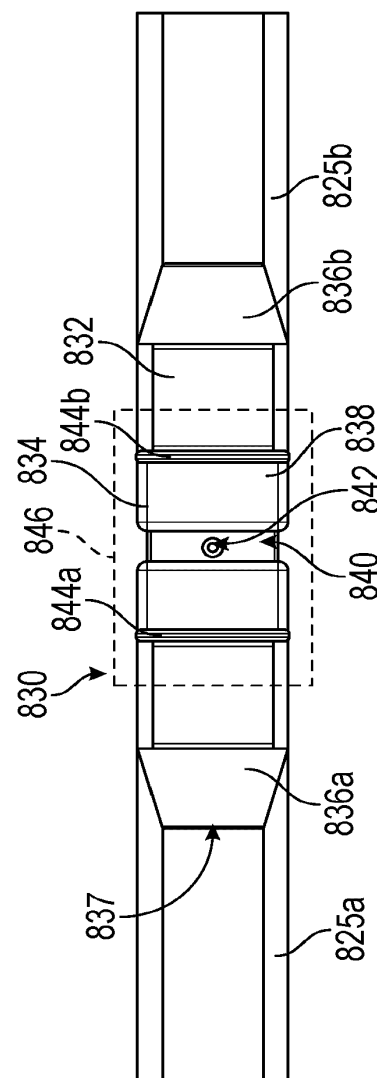


FIG. 8B

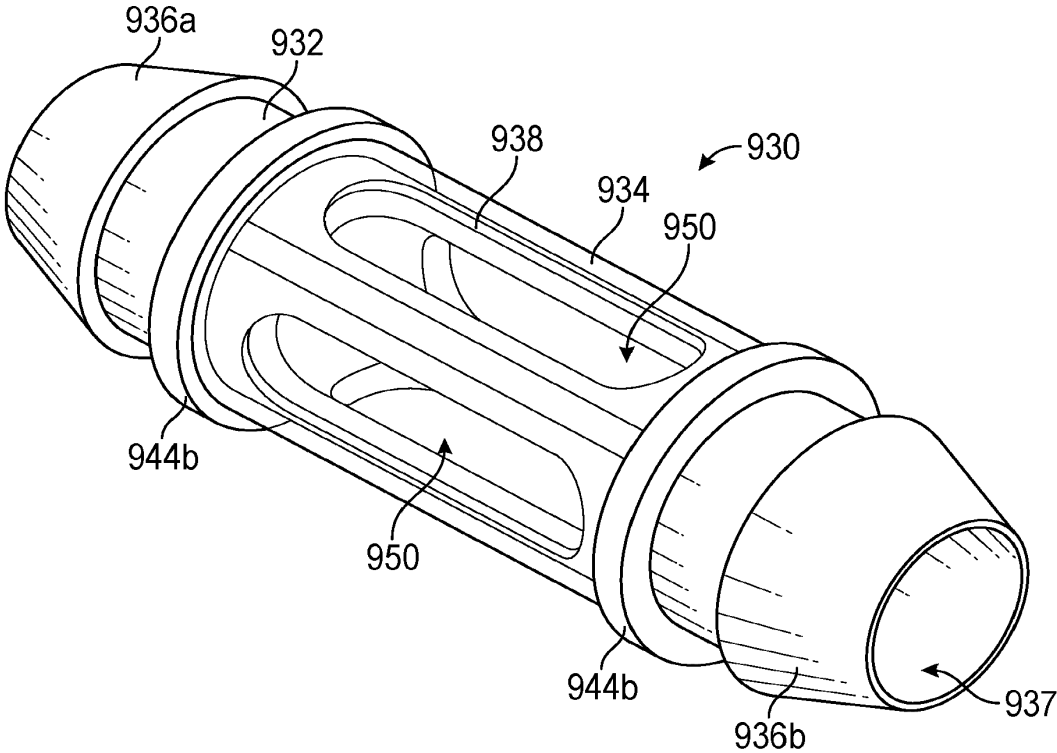


FIG. 9

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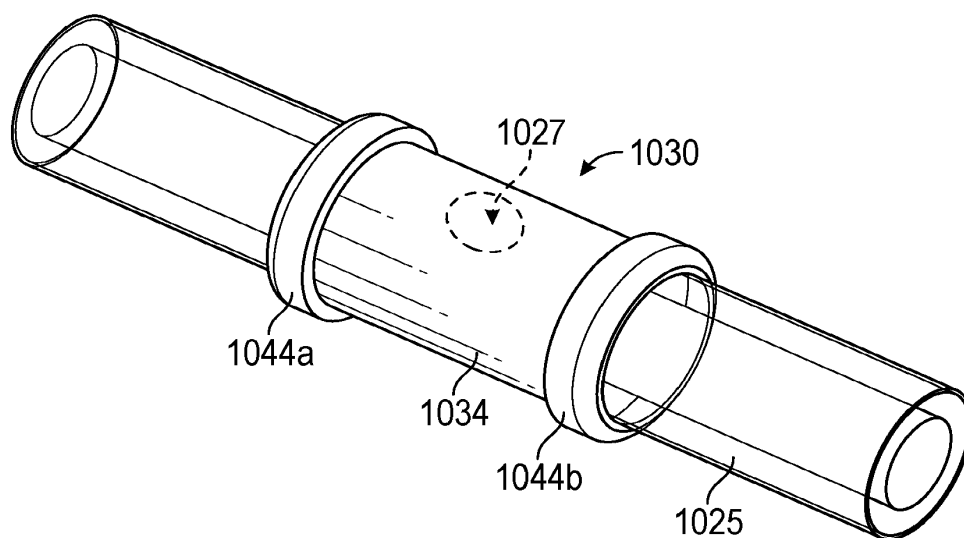


FIG. 10A

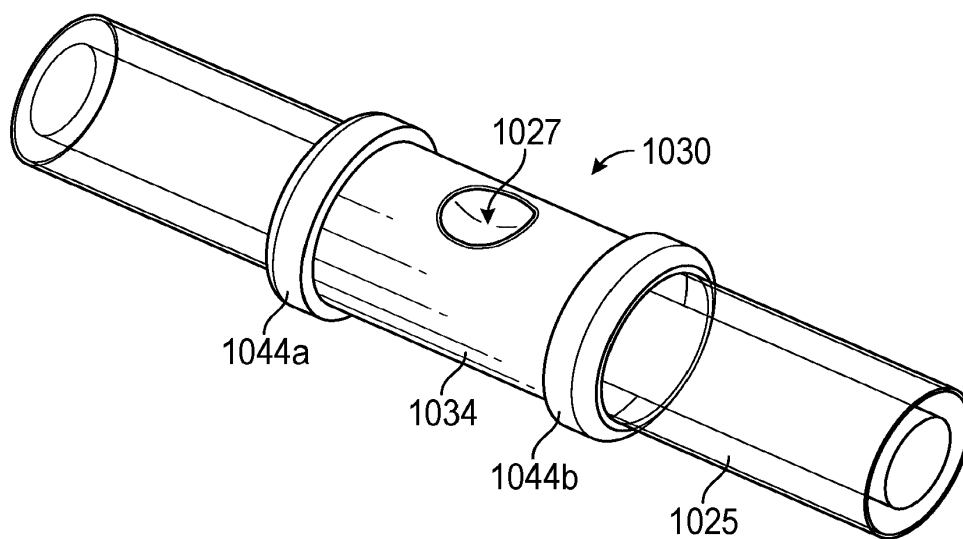


FIG. 10B

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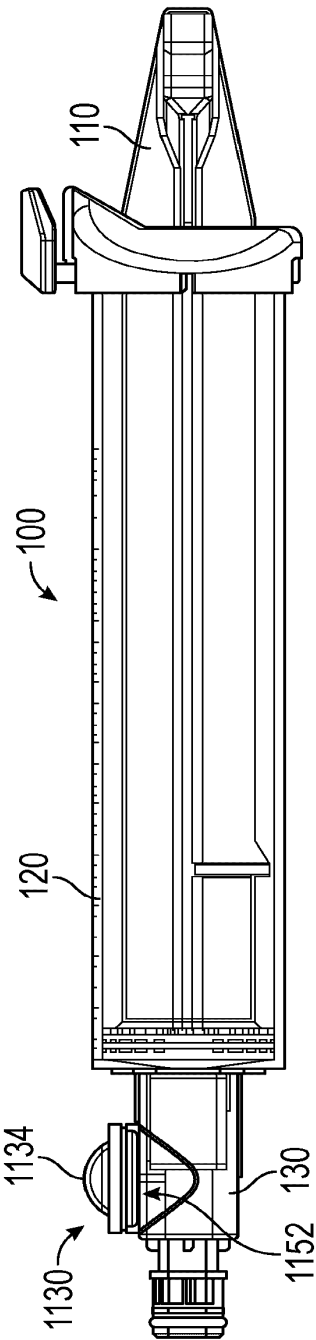


FIG. 11

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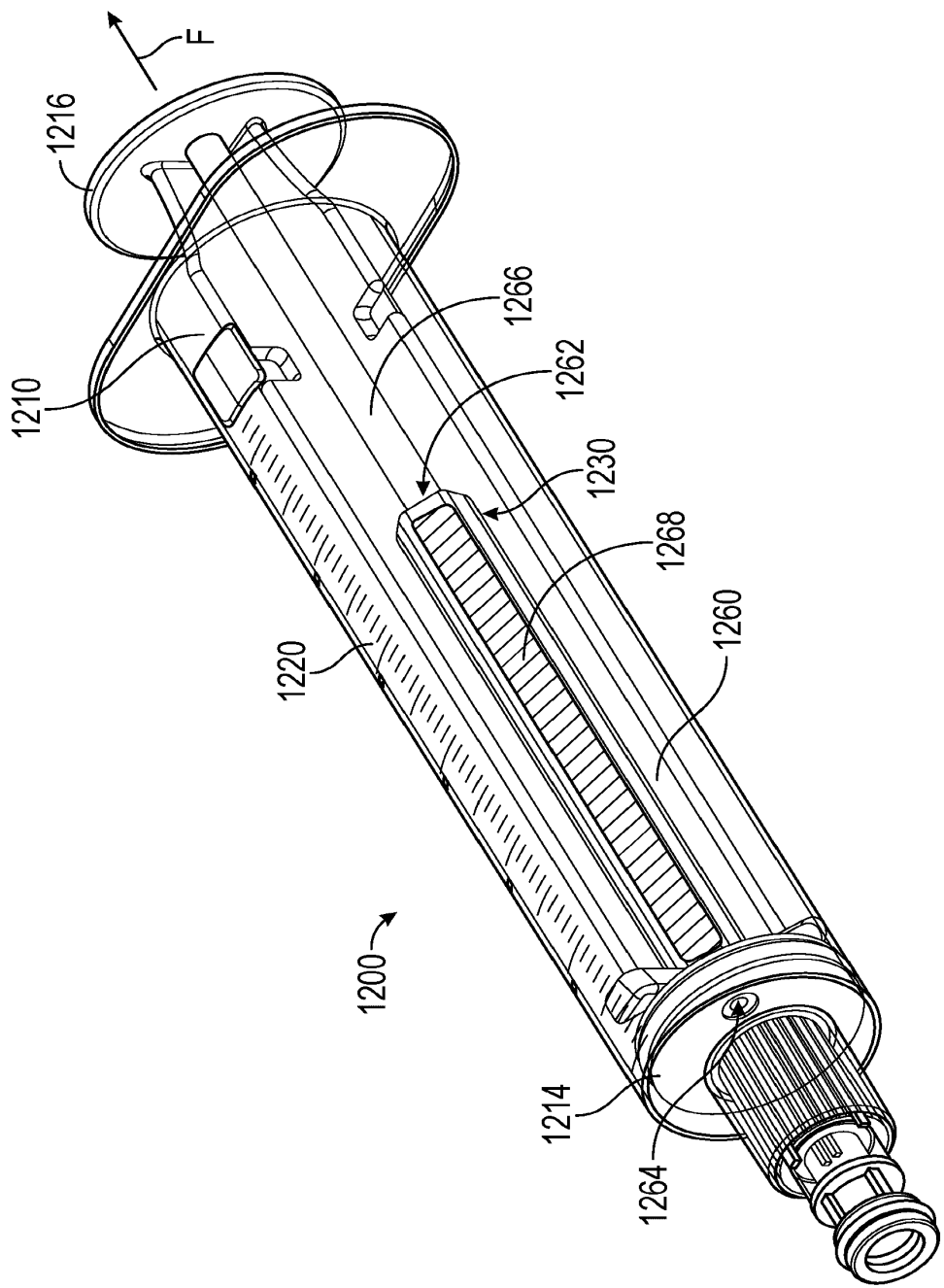


FIG. 12A

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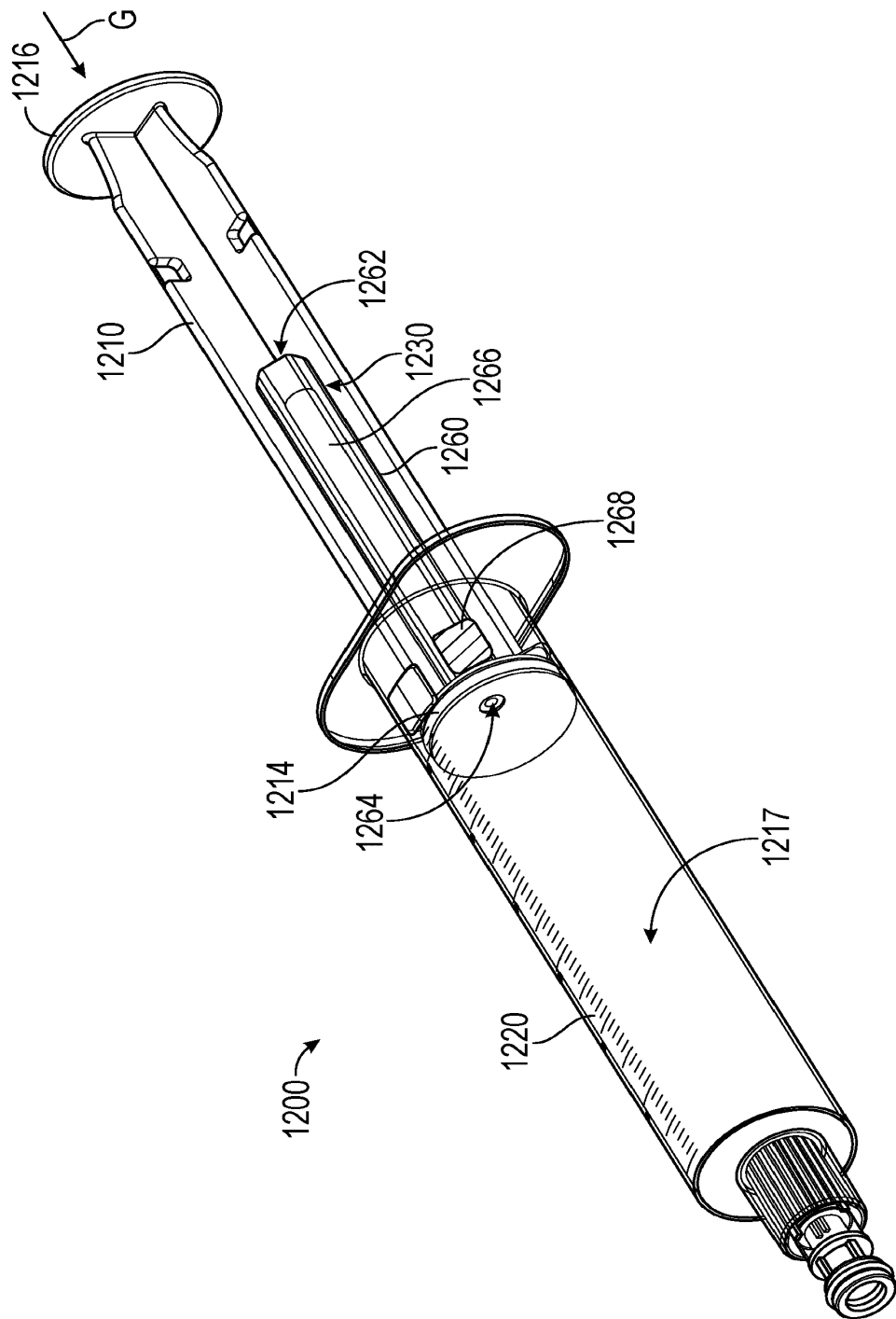


FIG. 12B

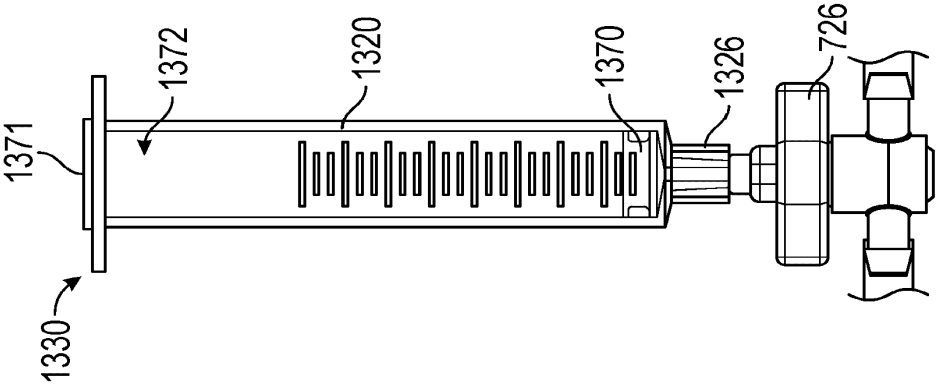


FIG. 13C

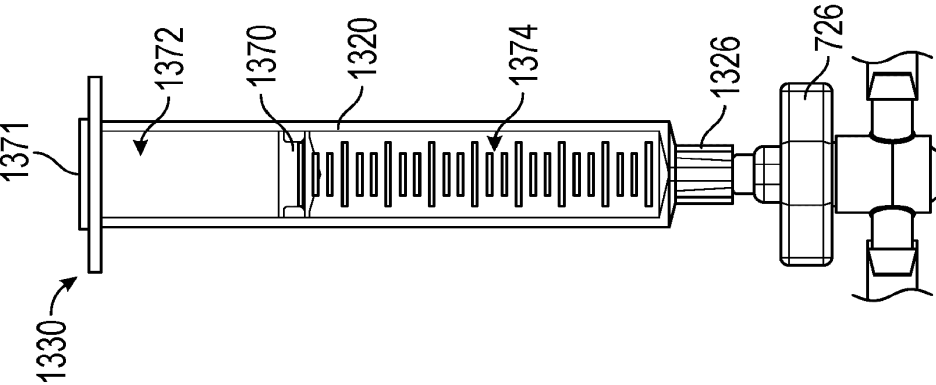


FIG. 13B

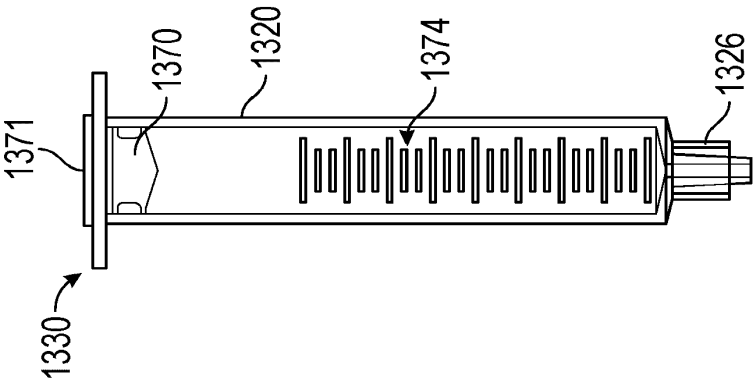


FIG. 13A

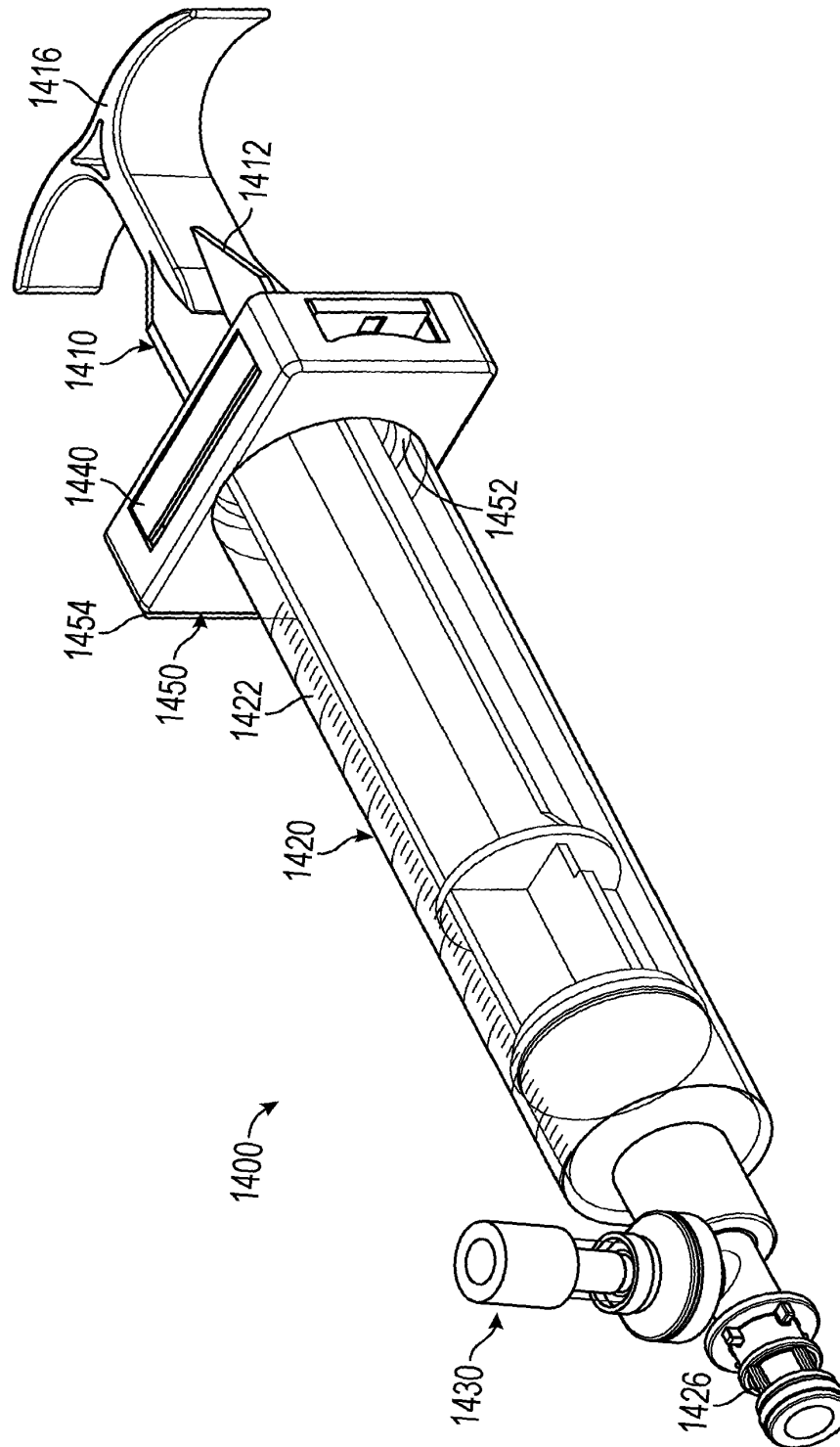


FIG. 14A

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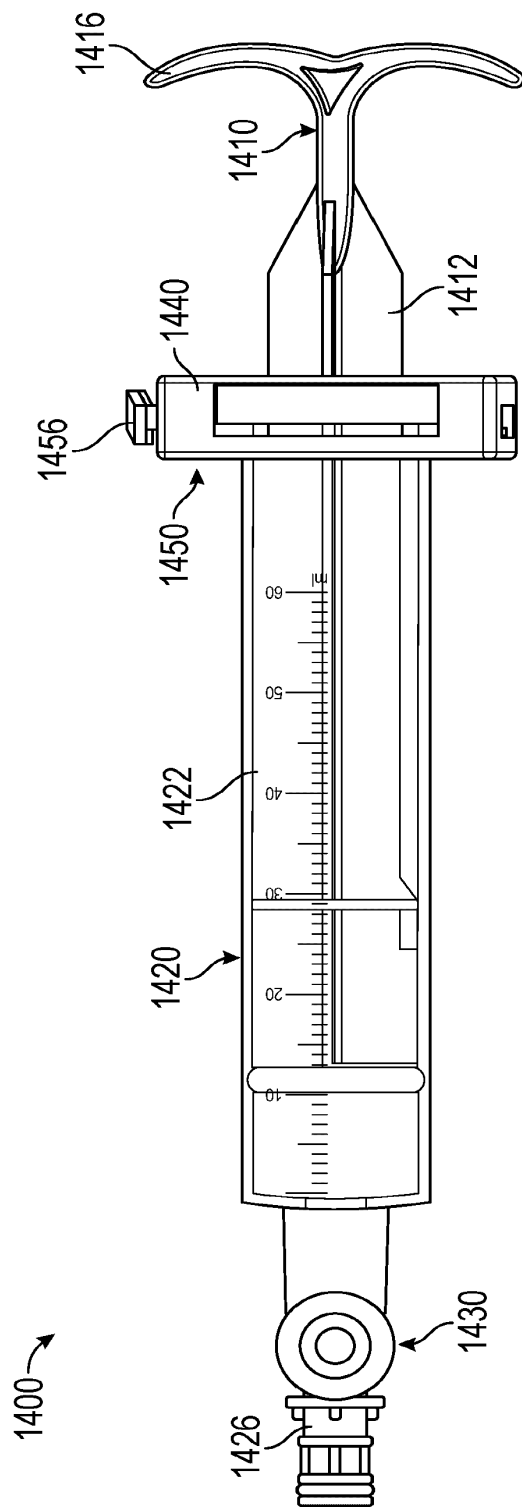


FIG. 14B

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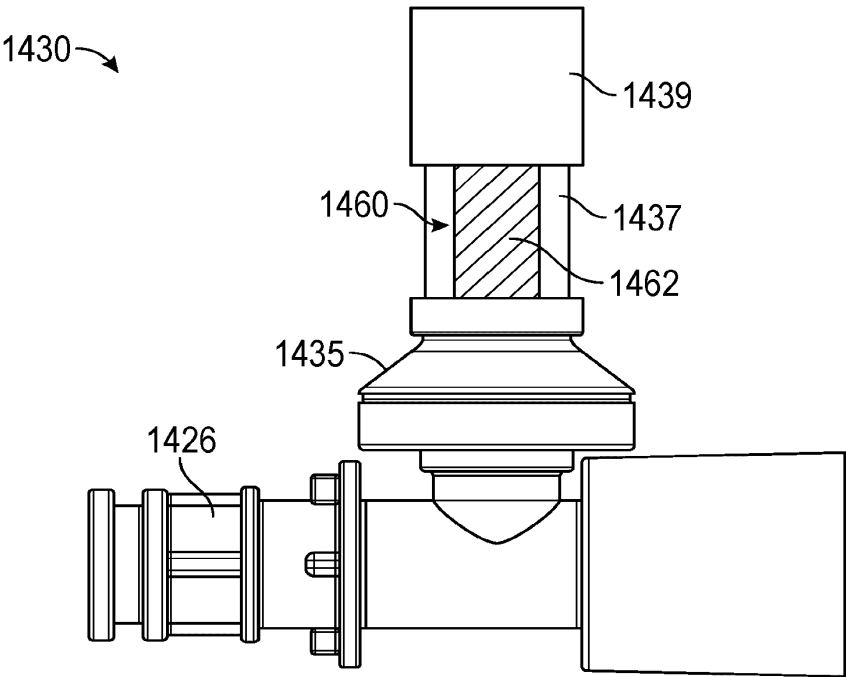


FIG. 14C

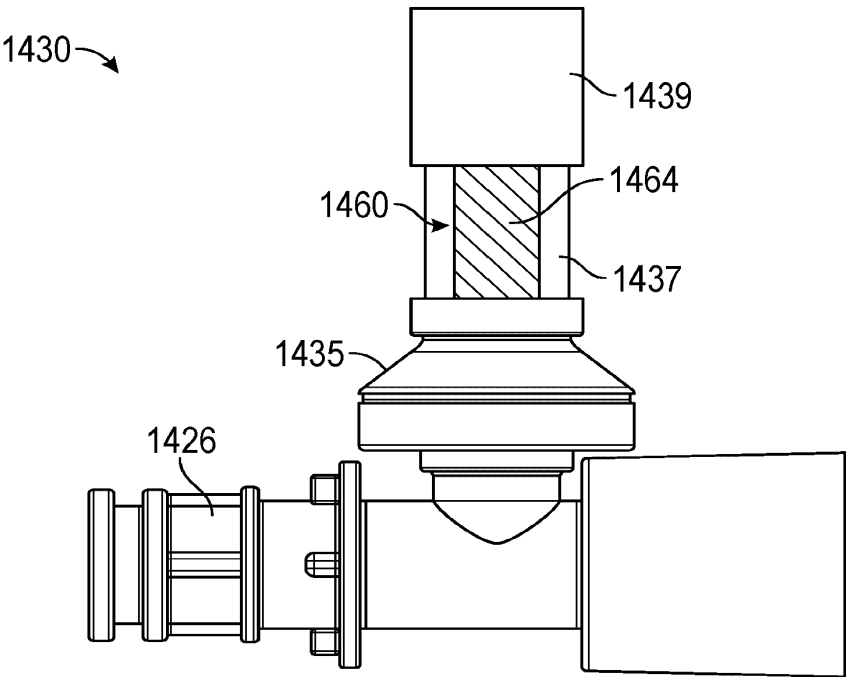


FIG. 14D

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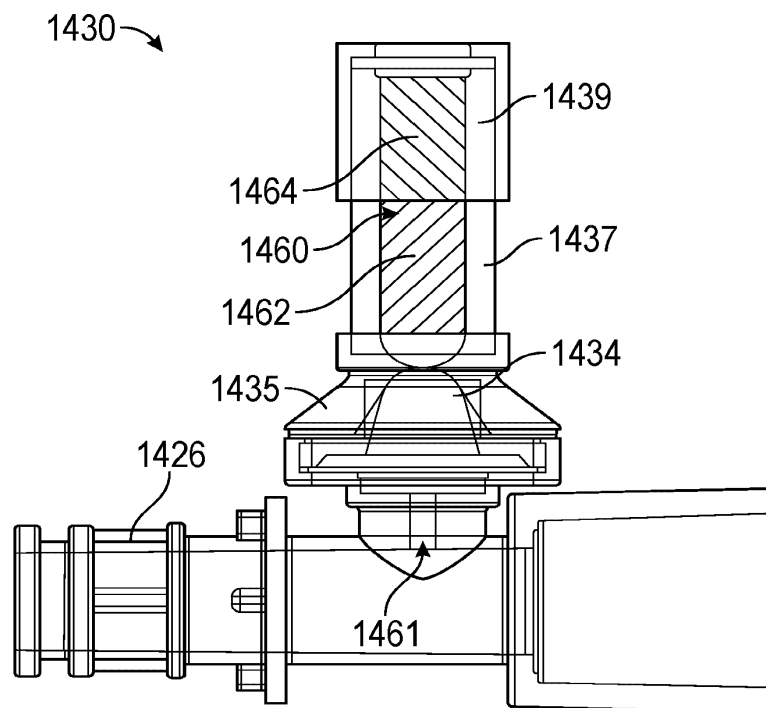


FIG. 14E

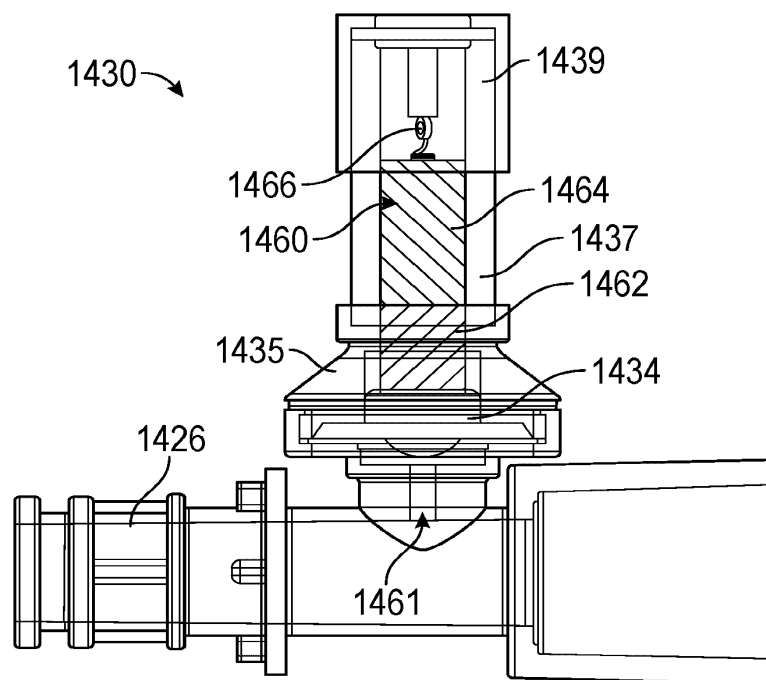


FIG. 14F

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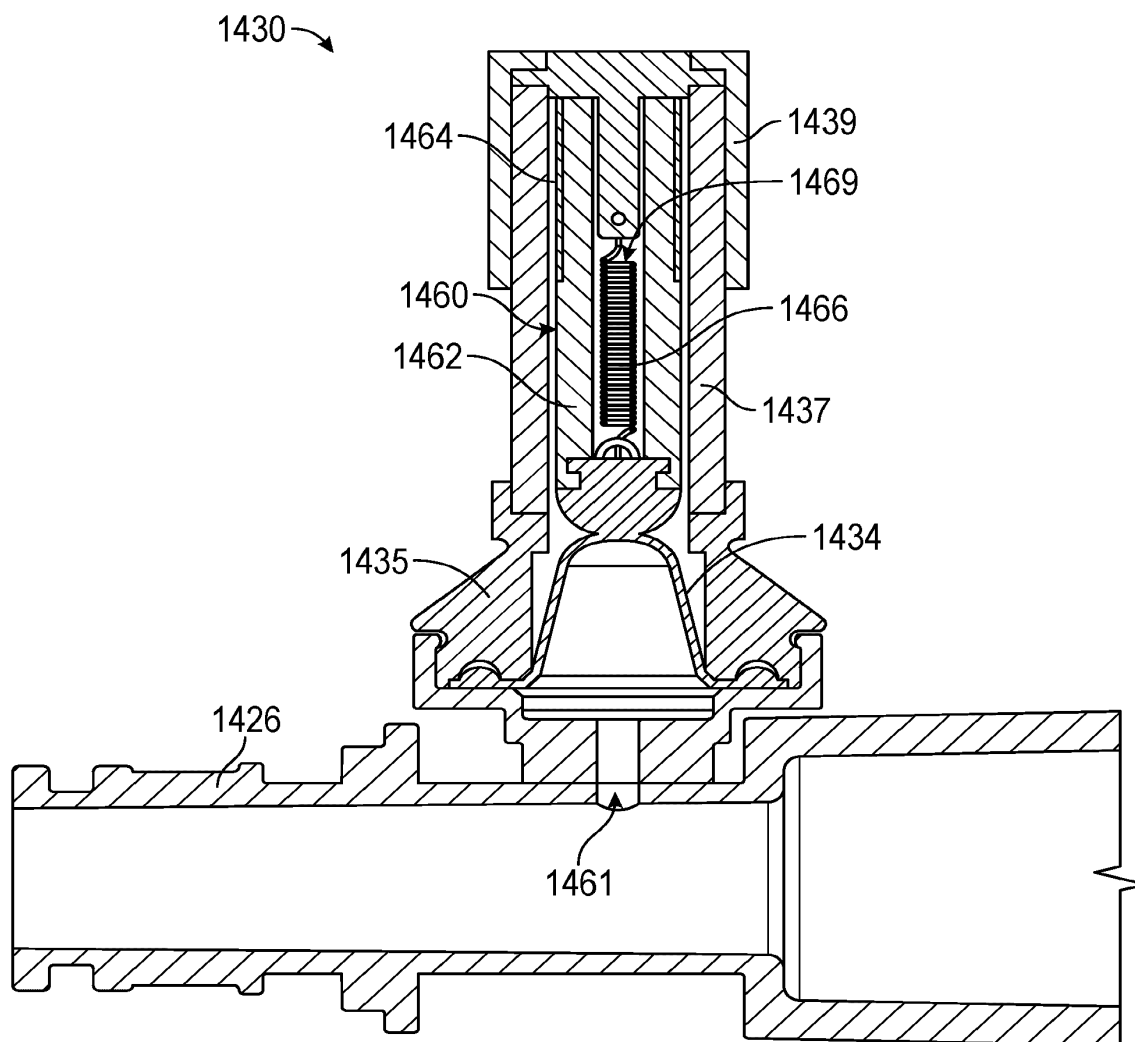


FIG.14G

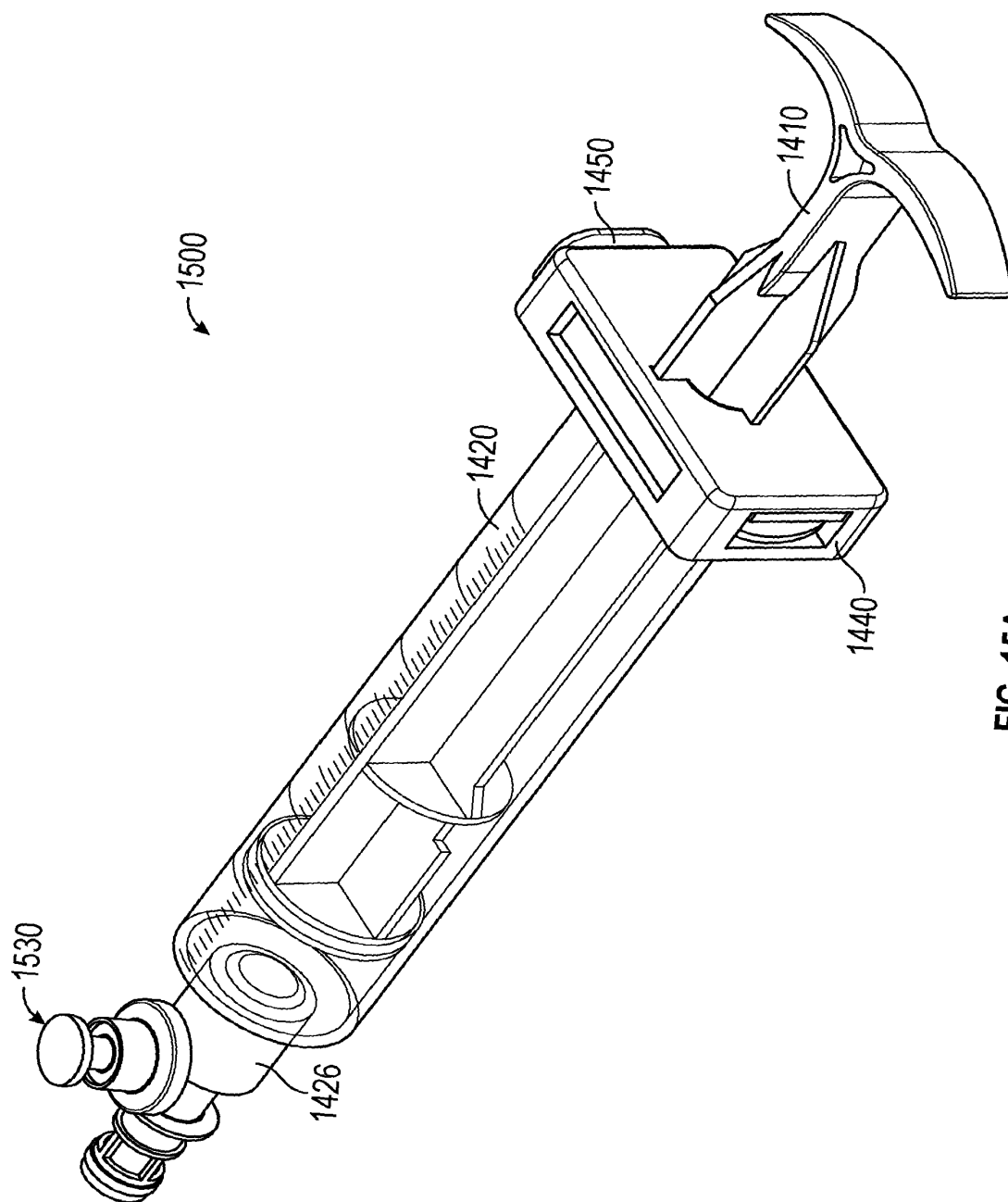


FIG. 15A

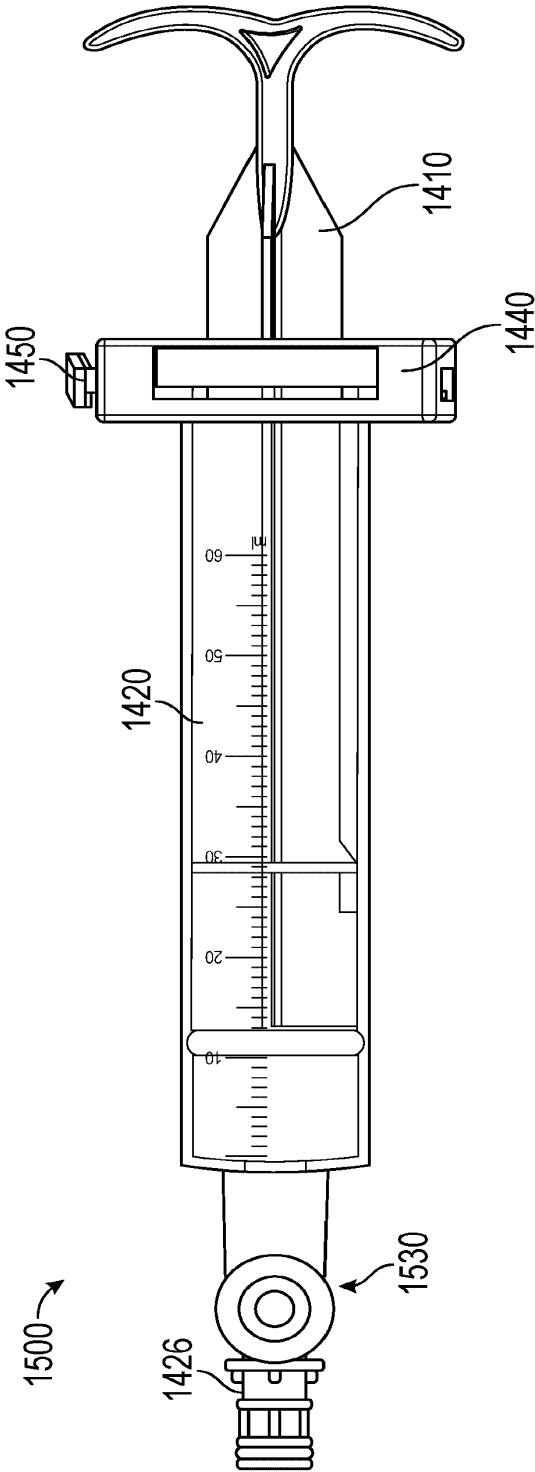


FIG. 15B

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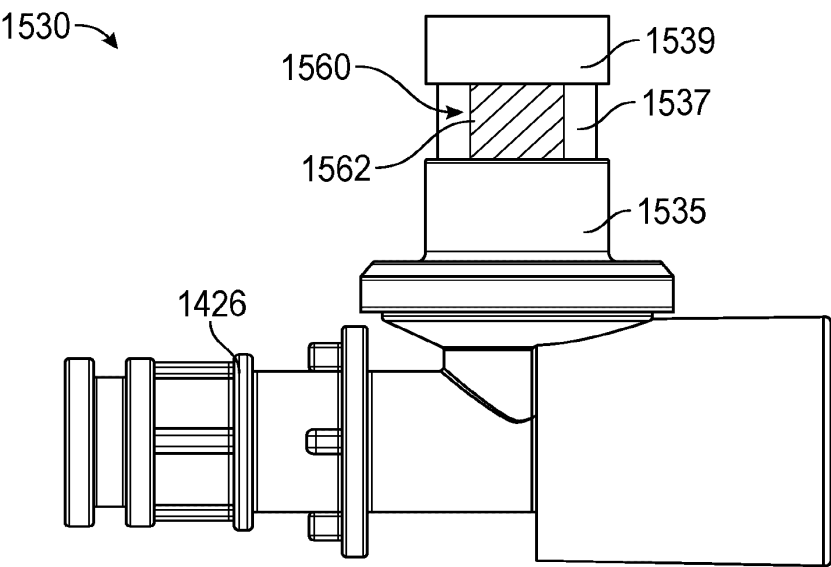


FIG. 15C

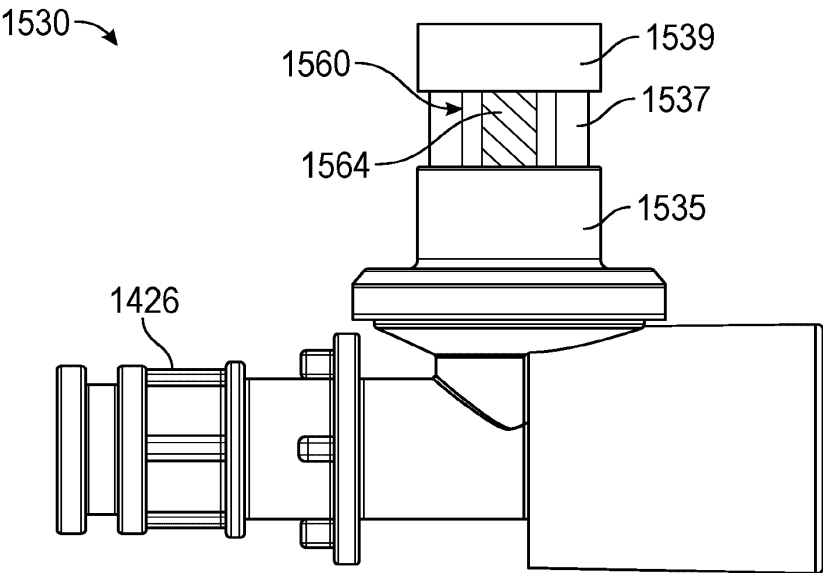


FIG. 15D

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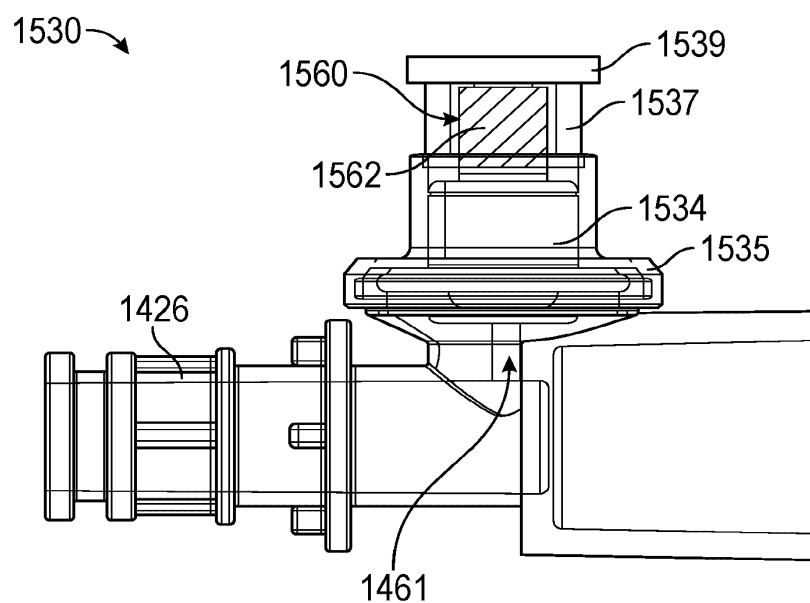


FIG. 15E

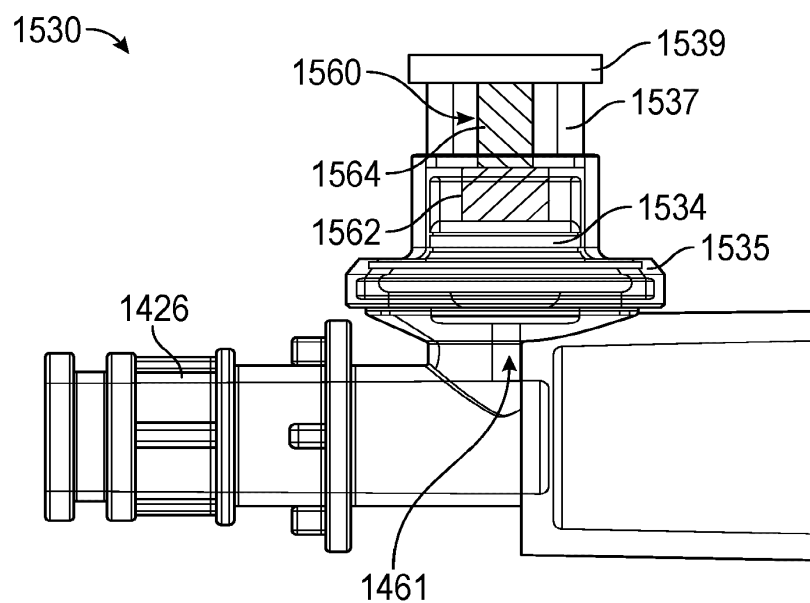


FIG. 15F

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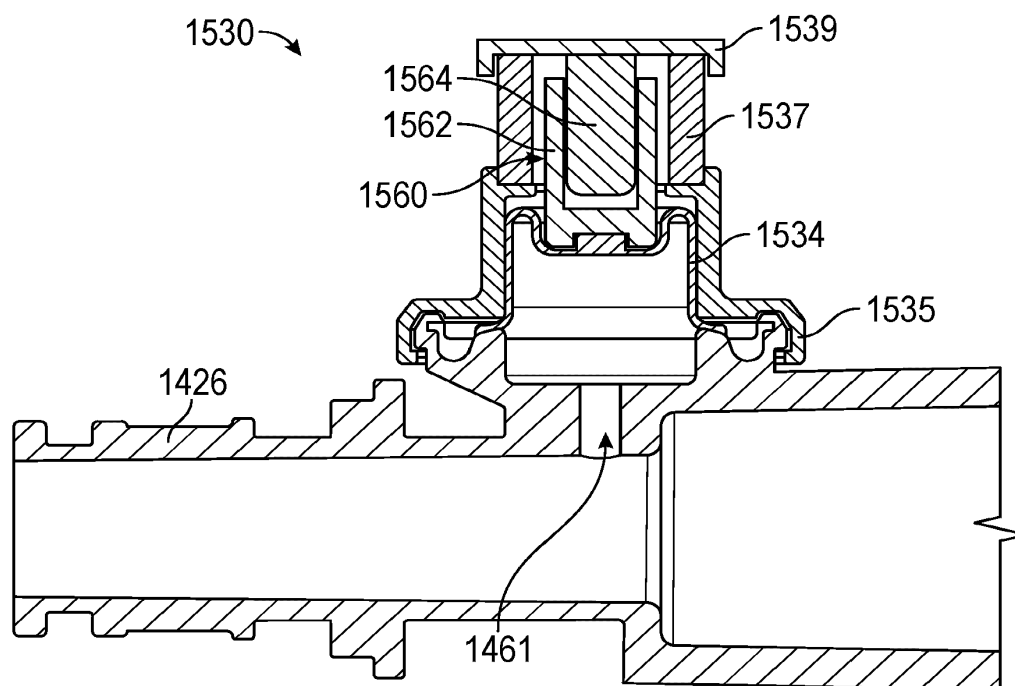


FIG. 15G

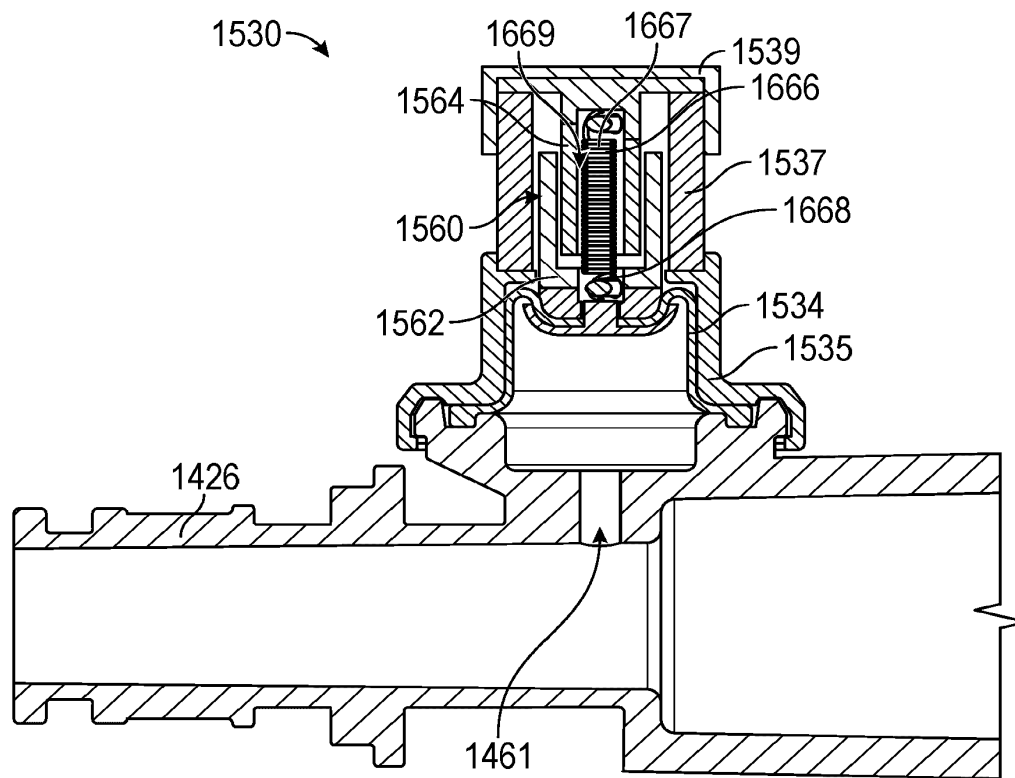


FIG. 16

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/45072

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61M 5/32; A61M 5/315 (2021.01)

CPC - A61M 5/32; A61M 5/502; A61M 5/3243; A61M 5/150641; A61M 5/3234; A61M 5/3232; A61M 5/5013; A61M 2005/5026; A61M 2005/3247; A61M 2005/3223; A61M 5/315

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

See Search History document

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2013/0126559 A1 (COWAN et al.) 23 May 2013 (23.05.2013); entire document, especially para [0028], and Fig. 1-2.	1-10
A	US 2004/0122359 A1 (WENZ et al.) 24 June 2004 (24.06.2004); entire document, especially para [0063]-[0066], and Fig. 7.	1-15
A	WO 2011/073176 A1 (NOVARTIS AG) 23 June 2011 (23.06.2011); especially pg 6 ln 33 to pg 7 ln 2, and Fig. 1-3.	10-15
A, P	WO 2021/067134 A1 (BECTON, DICKINSON AND COMPANY) 8 April 2021 (08.04.2021); entire document.	1-15
A	US 2004/0267272 A1 (HENNIGES et al.) 30 December 2004 (30.12.2004); entire document.	1-15

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

* Special categories of cited documents:

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

"D" document cited by the applicant in the international application

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

2 December 2021

Date of mailing of the international search report

JAN 20 2022

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents

P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Kari Rodriguez

Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

INARI_021439

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/45072

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

Group I: Claims 1-15 directed to an automatically-locking syringe.

Group II: Claims 16-20 directed to a clot treatment system.

Group III: Claims 21-28 directed to a syringe having a barrel and a vacuum indicator having a transparent tube and an indicator with a visual characteristic.

-- See Supplemental Box --

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-15

Remark on Protest

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

Form PCT/ISA/210 (continuation of first sheet (2)) (July 2019)

INARI_021440

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/US 21/45072

-*- Box III.0 - Explanations where unity of invention is lacking

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

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a lock plate, not required by the claims of Groups II-III.

The invention of Group II includes the special technical feature of a catheter, not required by the claims of Groups I or III.

The invention of Group III includes the special technical feature of a transparent tube and an indicator movably positioned within the tube, not required by the claims of Groups I-II.

COMMON TECHNICAL FEATURES

Groups I and III share the common technical feature of a syringe having a barrel and a plunger movable through the barrel. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 5,788,463 A (CHAN) (hereinafter Chan), which discloses a syringe (10; Fig. 1-10; col 4 ln 66 to col 5 ln 20) having a barrel (50; Fig. 1-10; col 5 ln 21-23) and a plunger movable through the barrel (60; Fig. 1-10; col 5 ln 21-23).

Groups II-III share the common technical feature of a vacuum indicator. However, this shared technical feature does not represent a contribution over prior art as being anticipated by Chan, which discloses a vacuum indicator (15; Fig. 1-10; col 8 ln 36-50).

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

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

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW S. WILLIAMS PERKINS COIE LLP P.O. BOX 1247 SEATTLE, WA 98111-1247
RECEIVED PATENT DOCKETING MAR 25 2022 PERKINS COIE LLP

PCT

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

(PCT Rule 44.1)

Applicant's or agent's file reference 111552-8029W000	Date of mailing <i>(day/month/year)</i> MAR 22 2022
International application No. PCT/US 21/59735	International filing date <i>(day/month/year)</i> 17 November 2021 (17.11.2021)
Applicant INARI MEDICAL, INC.	

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

Filing of amendments and statement under Article 19:
 The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46).
When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.
How? Directly to the International Bureau preferably through ePCT, or on paper to:
 The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland.

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

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

3. ☐ With regard to any protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices,

☐ no decision has been made yet on the protest, the applicant will be notified as soon as a decision is made.

4. **Reminders**

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

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.2).

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/patent/txts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

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

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-5300	Authorized officer Kari Rodriguez Telephone No. PCT Helpdesk: 571-272-4300
---	---

Form PCT/ISA/220 (Revised January 2020)

INARI_021442

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 111552-8029W000		FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No PCT/US 21/58735	International filing date (day/month/year) 17 November 2021 (17.11.2021)	(Earliest) Priority Date (day/month/year) 18 November 2020 (18.11.2020)	
Applicant INARI MEDICAL, INC.			

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

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

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

1. Basis of the report

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

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

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

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

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

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

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

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

6. With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. 1B

- ☒ as suggested by the applicant.
☐ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.

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

Form PCT/ISA/210 (first sheet) (July 2019)

INARI_021443

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/59735

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

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

1. ☐ Claims Nos. _____
because they relate to subject matter not required to be searched by this Authority, namely: _____
2. ☐ Claims Nos. _____
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically: _____
3. ☐ Claims Nos. _____
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-7 directed to a proximal ring, a distal ring and a tube portion.

Group II: Claims 8-20 directed to a handle and an actuator.

➤ Continued in Supplemental Box.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos. _____.
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos. 1-7.

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)) (July 2019)

INARI_021444

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/68735

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61M 25/00 (2022.01)

CPC - A61M 25/0147; A61M 25/0138

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	WO 2019/249240 A1 (INTUITIVE SURGICAL OPERATIONS, INC.) 26 December 2019 (26.12.2019), entire document, especially Fig 4A, 4C; para [0071]-[0084]	1-5, 8-7
Y		4-5
Y	US2010/0616837 A1 (Howat) 21 January 2010 (21.01.2010), entire document, especially Fig 1-8; para [0034]-[0042]	4-8
A	US 2004/0138625 A1 (Saadat et al.) 15 July 2004 (15.07.2004), entire document	1-2
A	US 2020/0113412 A1 (AMBU A/S) 18 April 2020 (18.04.2020), entire document	1-7
A	US 2009/0192495 A1 (Ostrovsky et al.) 30 July 2009 (30.07.2009), entire document	1-7

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

* Special categories of cited documents:

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

"T" document cited by the applicant in the international application

"E" earlier application of 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 a prior disclosure, use, exhibition or other means

"I" 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

"Z" document member of the same patent family

Date of the actual completion of the international search

20 February 2022

Date of mailing of the international search report

MAR 29 2022

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
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Authorized officer

Karl Rodriguez

Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

INARI_021445

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/59735

Box No. III - Observations where unity of invention is lacking.

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 feature of a proximal ring; a distal ring configured to be fixedly attached to a pull wire, and a tube portion extending between the proximal and distal rings, wherein the tube portion includes a plurality of openings extending therethrough to define a plurality of ribs, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally, not required by Group II.

The invention of Group II includes the special technical feature of a handle coupled to the proximal region of the aspiration catheter, wherein the handle includes an actuator, and pull wire extending between the actuator and the deflectable member, wherein actuation of the actuator is configured to pull the pull wire, not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of an aspiration catheter including a proximal region and a distal region, wherein the distal region includes a deflectable member, and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2004/0138525 A1 to Saadat et al. (hereinafter "Saadat"), which discloses an aspiration catheter (30; Fig. 21A-21B; para [0097]; see analogous Fig. 41, para [0126] describing tool arm 30 used for aspiration, wherein the tool arm 30 is interpreted as an aspiration catheter) including a proximal region (proximal half of 30; Fig. 21A-21B; para [0097]; the proximal half of 30 being the bottom-most half of the entire tool arm 30 in the orientation shown in Fig. 21A) and a distal region (distal half of 30; Fig. 21A-21B; para [0097]; the distal half of 30 being the top-most half of the entire tool arm 30 in the orientation shown in Fig. 21A), wherein the distal region includes a deflectable member (portion of 30 from bottom slot 132 to the distal-most end of 30; Fig. 21A-21B; para [0097]); and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region (96; Fig. 21A-21B; para [0097]; pullwire 96 is shown to be attached to the portion of 30 extending distally from distal-most slot 132 via fixation point 104 wherein pulling the pullwire 96 causes the distal tip of tool arm 30 to deflect relative to the proximal region of tool arm 30).

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

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

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: MATTHEW S. WILLIAMS PERKINS COIE LLP P.O. BOX 1247 SEATTLE, WA 98111-1247 RECEIVED PATENT DOCKETING MAR 25 2022 PERKINS COIE LLP		Date of mailing <i>(day/month/year)</i> MAR 22 2022	
Applicant's or agent's file reference 111552-8029WOOD		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US 21/59735	International filing date <i>(day-month-year)</i> 17 November 2021 (17.11.2021)	Priority date <i>(day month year)</i> 18 November 2020 (18.11.2020)	
International Patent Classification (IPC) or both national classification and IPC IPC - A61M 25/00 (2022.01) CPC - A61M 25/0147; A61M 25/0138			
Applicant INARI MEDICAL, INC.			

1. This opinion contains indications relating to the following items: ☒ Box No. I Basis of the opinion ☐ Box No. II Priority ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability ☒ Box No. IV Lack of unity of invention ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(1) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement ☐ Box No. VI Certain documents cited ☐ Box No. VII Certain defects in the international application ☒ Box No. VIII Certain observations on the international application	
2. FURTHER ACTION If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered. If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/230 or before the expiration of 22 months from the priority date, whichever expires later. For further options, see Form PCT/ISA/226.	

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1460, Alexandria, Virginia 22313-1460 Facsimile No. 571-273-8300	Date of completion of this opinion 20 February 2022	Authorized officer Kari Rodriguez PCT Help Desk Telephone No. 571-273-4390
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Form PCT/ISA/237 (cover sheet) (revised January 2019)

INARI_021447

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JS 21/05735

Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(b)).
3. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. ☐ forming part of the international application as filed:
 - ☐ in the form of an Annex C/ST.25 text file.
 - ☐ on paper or in the form of an image file.
 - b. ☐ furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
 - ☐ in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
 - ☐ on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 7(3)).
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/59735

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/286) 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 has been complied with and chose not to invite the applicant to pay additional fees.

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

- ☐ complied with.
- ☒ not complied with for the following reasons:

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

Group I: Claims 1-7 directed to a proximal ring, a distal ring and a tube portion.

Group II: Claims 8-20 directed to a handle and an actuator.

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 feature of a proximal ring, a distal ring configured to be fixably attached to a pull wire, and a tube portion extending between the proximal and distal rings, wherein the tube portion includes a plurality of openings extending therethrough to define a plurality of ribs, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally, not required by Group II.

The invention of Group II includes the special technical feature of a handle coupled to the proximal region of the aspiration catheter, wherein the handle includes an actuator, and pull wire extending between the actuator and the deflectable member, wherein actuation of the actuator is configured to pull the pull wire, not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of an aspiration catheter including a proximal region and a distal region, wherein the distal region includes a deflectable member, and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2004/0138525 A1 to Saadat et al. (hereinafter "Saadat"), which discloses an aspiration catheter (30; Fig. 21A-21B; para [0067]; see analogous Fig. 41, para [0125] describing tool arm 30 used for aspiration, wherein the tool arm 30 is interpreted as an aspiration catheter) including a proximal region (proximal half of 30; Fig. 21A-21B; para [0097]; the proximal half of 30 being the bottom-most half of the entire tool arm 30 in the orientation shown in Fig. 21A) and a distal region (distal half of 30; Fig. 21A-21B; para [0097]; the distal half of 30 being the top-most half of the entire tool arm 30 in the orientation shown in Fig. 21A), wherein the distal region includes a deflectable member (portion of 30 from bottom slot 132 to the distal-most end of 30; Fig. 21A-21B; para [0067]); and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region (98; Fig. 21A-21B; para [0067]); pullwire 98 is shown to be attached to the portion of 30 extending distally from distal-most slot 132 via fixation point 104 wherein pulling the pullwire 98 causes the distal tip of tool arm 30 to deflect relative to the proximal region of tool arm 30).

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

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

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

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-7

Form PCT/ISA/237 (Box No. IV) (revised January 2019)

INARI_021449

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US 21/58735

Box No. 5 Reasoned statement under Rule 43bis.1(a)(ii) with regard to novelty, inventive step and industrial applicability:
claims and explanations supporting such statement

1. Statement		
Novelty (9)	Claims	YES
	Claims	NO
Inventive step (35)	Claims	YES
	Claims	NO
Industrial applicability (36)	Claims	YES
	Claims	NO

2. Claims and explanations:

Claims 1-2 and 8 lack novelty under PCT Article 33(2) as being anticipated by WO 2019248260 A1 to INTUITIVE SURGICAL OPERATIONS, INC. (hereinafter "Intuitive").

As per claim 1, Intuitive teaches an aspiration catheter (Fig. 4A, 4C; para. [0071]-[0084]; the flexible elongate device 400 is taught to correspond to minimally invasive device 252, which is taught in para. [0084]) to be used for suction. Further, para. [0072] teaches wherein flexible elongate device 400 comprises a main lumen 411, which receives medical fluids and is considered to be capable of receiving a suction flow or having suction applied therethrough), comprising:

a proximal region (422; Fig. 4A, para. [0072]); and
a distal region (404, portion of 408 extending distally from 425 collectively; Fig. 4A, para. [0075]) including a deflectable member (422, 424, 425 collectively; Fig. 4A, 4C; para. [0077]-[0078]), wherein the deflectable member includes:

a proximal ring (425; Fig. 4A, para. [0078]);
a distal ring configured to be fixedly attached to a pull wire (422; Fig. 4A, para. [0073]); control elements 421, taught to be pull wires, are taught to attach to distal mount 423; and
a tube portion extending between the proximal and distal rings (424; Fig. 4A, para. [0076]-[0078]); axial support structure 424 is shown to extend between proximal 425 and distal mount 423, wherein the tube portion includes a plurality of openings extending therethrough (openings extending through left corners of 424; Fig. 4A; para. [0076]-[0078]); the axial support structure 424 is shown to comprise openings extending through many other circular portions of 424 on the left side) to define a plurality of ribs (left sides of 424; Fig. 4A, para. [0076]-[0078]); the left half of axial support structure 424 includes portions extending between the left openings, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally (Fig. 4A, para. [0076]-[0078]); intuitive teaches wherein when unequal forces are applied to control elements, the distal section 404, with axial support structure 424, bends in the direction defined by the net activation forces, such that outwardly when a right control element 421 is pulled, the support structure 424 bends right, which causes the left portions of 424 extending between the left openings to flex away from each other).

As per claim 2, Intuitive teaches the aspiration catheter of claim 1 wherein the tube portion includes a spine extending in a direction between the proximal and distal rings (right-most edge of 424; Fig. 4A, para. [0076]-[0078]); the axial support structure comprises a right-most edge extending between the distal mount 422 and stopper 423, wherein the ribs extend away from the spine (Fig. 4A, para. [0076]-[0078]); the left portions of 424 extend away from the right-most edge of 424, and wherein the spine is configured to extend generally parallel to and over the pull wire (Fig. 4A, para. [0076]-[0078]); the control elements 421 are taught to extend through control element lumens 412, wherein Fig. 4C shows the edges of axial support 424 to extend over the control element lumens 412, wherein the right-most edge of the axial support inherently extends over the right control elements 421 within the control element lumens 412).

As per claim 3, Intuitive teaches the aspiration catheter of claim 1 wherein the tube portion extends along a longitudinal axis in a relaxed state (Fig. 4A, para. [0072]-[0078]); the control elements 421 are taught to be used to bend the distal section 404 when force is applied to control elements 421, para. [0077]; wherein Fig. 4A is reasonably considered to be a relaxed state such that control elements 421 are not actuated, wherein the axial support structure 424 is shown to extend along the longitudinal axis of the flexible elongate device 400, shown to be the horizontal axis extending through the main lumen 411 in Fig. 4A), and wherein the plurality of openings (Box VII; extend circumferentially about the longitudinal axis and generally parallel to one another in the relaxed state (Fig. 4A, para. [0076]-[0078]); the left openings of axial support structure 424 are shown to extend circumferentially about the longitudinal axis of the flexible elongate device 400 and further shown to be substantially parallel to one another in Fig. 4A).

Claims 3 and 7 lack an inventive step under PCT Article 33(3) as being obvious over Intuitive.

As per claim 3, Intuitive teaches the aspiration catheter of claim 1, wherein the proximal region and the distal region define a lumen having a diameter of 20 French or greater (d 11; Fig. 4A, 4C; para. [0072]). While Intuitive teaches a similar catheter used to be positioned within an endotracheal tube of a patient (Fig. 3A-3B; para. [0069]; the medical instrument shown in Fig. 3A-3B is shown to be relatively large and inserted into the endotracheal tube of the patient), Intuitive is silent as to the diameter of the lumen. However, it is well known in the art that optimizing size, shape and angle is of the ordinary skill in the art. Accordingly, it would have been obvious to one of ordinary skill in the art to have optimized the size of the lumen to have arrived at the lumen having a diameter of 20 French or greater, in order to allow for the lumen to receive more instrument (para. [0072]).

Continued in Supplemental Box 1.

Form PCT/ISA/237 (Box No. V) (revised January 2019)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JS 21/58735

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 6: The term "the openings" is confusing and lacks proper antecedent basis. The term "the openings" appears to be referring to the plurality of openings previously referred to. For purposes of this opinion, the term "the openings" has been interpreted to be "the plurality of openings."

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/58735

Supplemental Box

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

Continuation of:

^Box V 2 - Citations and explanations^.

As per claim 7, Intuitive teaches the aspiration catheter of claim 1. While Intuitive teaches wherein the proximal ring includes an annular lumen configured to slidably receive the pull wire therethrough (Fig 4A; para [0072], the control element lumen 412, shown to be annular in Fig 4C, is shown to extend through stopper 425) and an annular member extending through the lumen (425; Fig 4A-4D; para [0073], [0076], coil pipe 423 is taught to extend through the control element lumen 412 and terminate at the transition section 406 proximal to the distal section 404). Intuitive does not specifically teach wherein the proximal ring includes an annular member configured to slidably receive the pull wire therethrough. However, it is well known that routine experimentation and various engineering design choices could have been made to have arrived at wherein the proximal ring includes an annular member configured to slidably receive the pull wire therethrough (Noting providing the coil pipe 423 to extend through the control element lumen 412 within stopper 425, allows for the coil pipe 423 to still terminate proximal to distal section 404, as taught in para [0073]). Accordingly, it would have been obvious to one of ordinary skill in the art to have arrived at wherein the proximal ring includes an annular member configured to slidably receive the pull wire therethrough, in order to improve the structural integrity of the lumen within the proximal ring.

Claims 4-5 lack an inventive step under PCT Article 33(3) as being obvious over Intuitive in view of US 2010/0916837 A1 to Howat.

As per claim 4, Intuitive teaches this aspiration catheter of claim 1, further comprising an intermediate region between the proximal and distal regions (portion of 406 extending proximally from 425; Fig 4A; para [0072]). While Intuitive teaches wherein select portions of the aspiration catheter can be stiffened (para [0105]), Intuitive does not specifically teach wherein the proximal region and the intermediate region include a braid of wires extending therethrough. However, Howat teaches a similar catheter (Fig 5-6; para [0034]-[0042]) wherein a proximal region and an intermediate region include a braid of wires extending therethrough (Fig 5; para [0034]-[0037]; Howat teaches wherein an introducer sheath 20 is assembled, in which a braided member 40 is shown to extend along the entire length of the inner tube of the introducer sheath such that the braided member 40 extends through a proximal and intermediate region of the introducer sheath 20). Accordingly, it would have been obvious to one of ordinary skill in the art to have employed the braid of wires taught by Howat with the aspiration catheter taught by Intuitive, in order to improve the structural integrity of the aspiration catheter.

As per claim 5, Intuitive in view of Howat teach the aspiration catheter of claim 4, and Howat further teaches wherein the intermediate region includes a wire coiled around the braid (Fig 7; para [0038]; a coiled member 50, wherein para [0022] further teaches wherein coiled member is a flat wire coil, wherein the coiled member 50 extends along the length of the inner tube 30, such that the coiled member 50 is considered to be included in the intermediate region with the modification as combined).

Claims 1-7 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.



UNITED STATES
PATENT AND TRADEMARK OFFICE

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www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
17/498,642

RECEIPT DATE / TIME
09/06/2022 04:16:41 PM ET

ATTORNEY DOCKET #
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 Christina Flores

PATENT CENTER # 60940434

FILING DATE 10/11/2021

CUSTOMER # 25096

FIRST NAMED
INVENTOR Richard Quick

CORRESPONDENCE
ADDRESS -

AUTHORIZED BY Matthew Williams

Documents

TOTAL DOCUMENTS: 58

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
IDS SB08 - 111552-8023US2.pdf	29	Information Disclosure Statement (IDS) Form (SB08)	313 KB
Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
WO2010002549.PDF	4	Foreign Reference	505 KB
WO2021127202.PDF	66	Foreign Reference	3492 KB
CN108348319B.PDF	117	Foreign Reference	2099 KB
CN111281482A.PDF	117	Foreign Reference	2627 KB

CN103764049A.PDF	92	Foreign Reference	13655 KB
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WO2015189354A1.PDF	76	Foreign Reference	2491 KB
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WO0032118A1.PDF	46	Foreign Reference	973 KB
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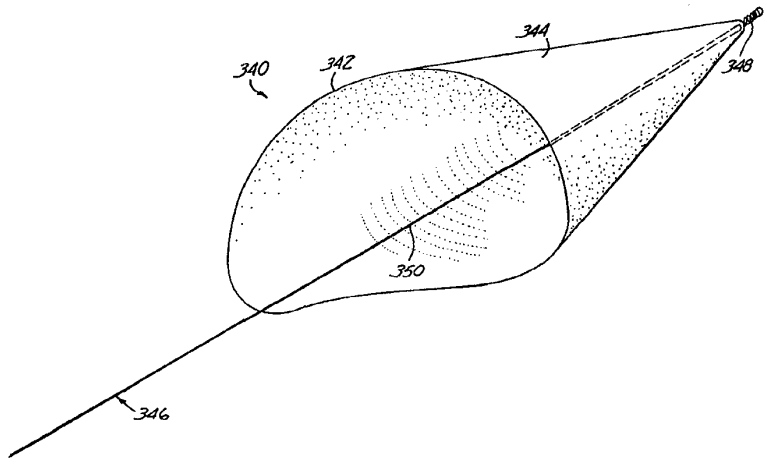
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: DISTAL PROTECTION DEVICE AND METHOD  (57) Abstract An emboli capturing system (366) captures emboli in a body lumen. A first elongate member (346) has a proximal end and a distal end. An expandable emboli capturing device (344) is mounted proximate the distal end of the first elongate member (346), and is movable between a radially expanded position and a radially contracted position. When in the expanded position, the emboli capturing device (344) forms a basket with a proximally opening mouth (368). A second elongate member (376) has a proximal and a distal end with a lumen extending therebetween. The lumen is sized to slidably receive a portion of the first elongate member (346). An expandable delivery device (378) is mounted to the distal end of the second elongate member (376) and is movable from a radially retracted position to a radially expanded position. The delivery device has a receiving end (382) configured to receive the emboli capturing device (344), and retains at least the mouth (368) of the emboli capturing device (344) in a radially retracted position.		

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DISTAL PROTECTION DEVICE AND METHOD**BACKGROUND OF THE INVENTION**

The present invention deals with an emboli capturing system. More specifically, the present
5 invention deals with an emboli capturing system and method for capturing embolic material in a blood vessel during an atherectomy or thrombectomy procedure.

Blood vessels can become occluded (blocked) or stenotic (narrowed) in one of a number of ways. For
10 instance, a stenosis may be formed by an atheroma which is typically a harder, calcified substance which forms on the lumen walls of the blood vessel. Also, the stenosis can be formed of a thrombus material which is typically much softer than an atheroma, but can
15 nonetheless cause restricted blood flow in the lumen of the blood vessel. Thrombus formation can be particularly problematic in a saphenous vein graft (SVG).

Two different procedures have developed to
20 treat a stenotic lesion (stenosis) in vasculature. The first is to deform the stenosis to reduce the restriction within the lumen of the blood vessel. This type of deformation (or dilatation) is typically performed using balloon angioplasty.

Another method of treating stenotic
25 vasculature is to attempt to completely remove either the entire stenosis, or enough of the stenosis to relieve the restriction in the blood vessel. Removal of the stenotic lesion has been done through the use of
30 radio frequency (RF) signals transmitted via conductors, and through the use of lasers, both of which treatments are meant to ablate (i.e., super heat and vaporize) the stenosis. Removal of the stenosis has also been accomplished using thrombectomy or atherectomy. During

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thrombectomy and atherectomy, the stenosis is mechanically cut or abraded away from the vessel.

Certain problems are encountered during thrombectomy and atherectomy. The stenotic debris which is separated from the stenosis is free to flow within the lumen of the vessel. If the debris flows distally, it can occlude distal vasculature and cause significant problems. If it flows proximally, it can enter the circulatory system and form a clot in the neural vasculature, or in the lungs, both of which are highly undesirable.

Prior attempts to deal with the debris or fragments have included cutting the debris into such small pieces (having a size on the order of a blood cell) that they will not occlude vessels within the vasculature. However, this technique has certain problems. For instance, it is difficult to control the size of the fragments of the stenotic lesion which are severed. Therefore, larger fragments can be severed accidentally. Also, since thrombus is much softer than an atheroma, it tends to break up easier when mechanically engaged by a cutting instrument. Therefore, at the moment that the thrombus is mechanically engaged, there is a danger that it can be dislodged in large fragments which would occlude the vasculature.

Another attempt to deal with debris severed from a stenosis is to remove the debris, as it is severed, using suction. However, it may be necessary to pull quite a high vacuum in order to remove all of the pieces severed from the stenosis. If a high enough vacuum is not used, all of the severed pieces will not be removed. Further, when a high vacuum is used, this can tend to cause the vasculature to collapse.

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A final technique for dealing with the fragments of the stenosis which are severed during atherectomy is to place a device distal to the stenosis during atherectomy to catch the pieces of the stenosis as they are severed, and to remove those pieces along with the capturing device when the atherectomy procedure is complete. Such capture devices have included expandable filters which are placed distal of the stenosis to capture stenosis fragments. Problems are also associated with this technique. For example, delivery of such devices in a low profile, pre-deployment configuration can be difficult. Further, some devices include complex and cumbersome actuation mechanisms. Also, retrieving such capture devices, after they have captured emboli, can be difficult as well.

SUMMARY OF THE INVENTION

An emboli capturing system captures emboli in a body lumen. A first elongate member has a proximal end and a distal end. An expandable emboli capturing device is mounted proximate the distal end of the first elongate member, and is movable between a radially expanded position and a radially contracted position. When in the expanded position, the emboli capturing device forms a basket with a proximally opening mouth. A second elongate member has a proximal and a distal end with a lumen extending therebetween. The lumen is sized to slidably receive a portion of the first elongate member. An expandable delivery device is mounted to the distal end of the second elongate member and is movable from a radially retracted position to a radially expanded position. The delivery device has a receiving end configured to receive the emboli capturing device,

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and retains at least the mouth of the emboli capturing device in a radially retracted position.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a distal protection device of the present invention in a deployed position.

FIG. 2 shows the distal protection device shown in FIG. 1 in a collapsed position.

FIG. 3 shows an end view of a portion of the distal protection device shown in FIGS. 1 and 2.

FIG. 4 shows a cross-sectional view of a portion of the distal protection device shown in FIGS. 1-3 in the deployed position.

FIG. 5 shows a second embodiment of the distal protection device according to the present invention in a deployed position.

FIG. 6 shows an end view of the distal protection device shown in FIG. 5.

FIG. 7 shows a cross-sectional view of the distal protection device shown in FIGS. 5 and 6 in the collapsed position.

FIG. 8 shows a third embodiment of a distal protection device according to the present invention in a deployed position.

FIG. 9 is a side sectional view of an alternate embodiment illustrating how the expandable members of the present invention are attached to a guidewire.

FIG. 10 is a sectional view taken along section lines 10-10 in FIG. 9.

FIGS. 11A and 11B show a fourth and fifth embodiment, respectively, of a distal protection device according to the present invention in a deployed position.

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FIG. 12 illustrates the operation of a distal protection device in accordance with the present invention.

5 FIGS. 13A-17B show additional embodiments of distal protection devices which expand and collapse based on movement of a mechanical actuator.

10 FIGS. 18A-18D illustrate an additional embodiment of a distal protection device which is deployed and collapsed using a rolling flap configuration.

FIG. 19 illustrates another embodiment in accordance with the present invention in which the protection device is deployed using fluid pressure and a movable collar.

15 FIGS. 20A and 20B illustrate another aspect of the present invention in which two longitudinally movable members used to deploy the distal protection device are disconnectably locked to one another.

20 FIGS. 21A-21C illustrate another embodiment in accordance with the present invention in which the protection device is formed with a shape memory alloy frame and an attached filter or mesh mounted to the frame.

25 FIGS. 22A-22C illustrate another embodiment in accordance with the present invention in which the distal protection devices shown in FIGS. 21A-21C are delivered and deployed.

30 FIGS. 23A-23E illustrate another embodiment in accordance with the present invention in which the distal protection devices shown in FIGS. 21A-21C are retrieved.

FIGS. 24A-24C illustrate another embodiment in accordance with the present invention in which the

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distal protection devices shown in FIGS. 21A-21C are retrieved.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 illustrates protection device 10 in a
5 deployed position within the lumen of a blood vessel 12. Protection device 10 preferably includes hollow guidewire 14 (or a hypotube having the same general dimensions as a guidewire) having a coil tip 16, and a capturing assembly 18. Capturing assembly 18, in the
10 embodiment shown in FIG. 1, includes an inflatable and expandable member 20 and mesh 22.

An interior of expandable member 20 is preferably coupled for fluid communication with an inner lumen of guidewire 14 at a distal region of guidewire
15 14. When deployed, inflatable member 20 inflates and expands to the position shown in FIG. 1 such that capturing assembly 18 has an outer periphery which approximates the inner periphery of lumen 12.

Mesh 22 is preferably formed of woven or
20 braided fibers or wires, or a microporous membrane, or other suitable filtering or netting-type material. In one preferred embodiment, mesh 22 is a microporous membrane having holes therein with a diameter of approximately 100 μm . Mesh 22 can be disposed relative
25 to inflatable member 20 in a number of different ways. For example, mesh 22 can be formed of a single generally cone-shaped piece which is secured to the outer or inner periphery of inflatable member 20. Alternatively, mesh
30 22 can be formed as a spiral strip which is secured about the outer or inner periphery of inflatable member 20 filling the gaps between the loops of inflatable member 20. Alternatively, mesh 22 can be formed of a number of discrete pieces which are assembled onto inflatable member 20.

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Hollow guidewire 14 preferably has a valve 24 coupled in a proximal portion thereof. During operation, a syringe is preferably connected to the proximal end of guidewire 14, which preferably includes a fluid hypotube. The syringe is used to pressurize the fluid such that fluid is introduced through the lumen of hollow guidewire 14, through valve 24, and into inflatable member 20. Upon being inflated, inflatable member 20 expands radially outwardly from the outer surface of guidewire 14 and carries mesh 22 into the deployed position shown in FIG. 1. In this way, capturing assembly, or filter assembly, 18 is deployed distally of stenosis 26 so that stenosis 26 can be severed and fragmented, and so the fragments from stenosis 26 are carried by blood flow (indicated by arrow 28) into the basket or chamber formed by the deployed filter assembly 18. Filter assembly 18 is then collapsed and removed from vessel 12 with the fragments of stenosis 26 contained therein.

FIG. 2 illustrates protection device 10 with filter assembly 18 in the collapsed position. Similar items to those shown in FIG. 1 are similarly numbered. FIG. 2 illustrates that mesh 22 is easily collapsible with inflatable member 20. In order to collapse filter assembly 18, fluid is preferably removed from inflatable member 20 through the lumen of hollow guidewire 14 and through two-way valve 24. This can be done using the syringe to pull a vacuum, or using any other type of suitable fluid removal system.

Inflatable member 20 is preferably formed of a material having some shape memory. Thus, when inflatable member 20 is collapsed, it collapses to approximate the outer diameter of hollow guidewire 14. In one preferred embodiment, inflatable member 20 is

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formed of a resilient, shape memory material such that it is inflated by introducing fluid under pressure through the lumen in hollow guidewire 14 into inflatable member 20. When pressure is released from the lumen in hollow guidewire 14, inflatable member 20 is allowed to force fluid out from the interior thereof through two-way valve 24 and to resume its initial collapsed position. Again, this results in filter assembly 18 assuming its collapsed position illustrated in FIG. 2.

FIG. 3 illustrates a view taken from the distal end of device 10 with mesh 22 removed for clarity. FIG. 3 shows that, when inflatable member 20 is deployed outwardly, mesh 22 (when deployed between the loops of inflatable member 20) forms a substantially lumen-filling filter which allows blood to flow therethrough, but which provides a mechanism for receiving and retaining stenosis fragments carried into mesh 22 by blood flow through the vessel.

FIG. 3 also shows that inflatable member 20 preferably has a proximal end portion 29 which is connected to the outer periphery of guidewire 14. Although end 29 need not be connected to guidewire 14, it is preferably connected using adhesive or any other suitable connection mechanism. By fixedly connecting proximal end portion 29 to guidewire 14, this increases the stability of the filter assembly 18 upon deployment.

FIG. 4 is a cross-sectional view of a portion of protection device 10. FIG. 4 shows protection device 10 with filter assembly 18 in the expanded or deployed position. FIG. 4 also better illustrates that guidewire 14 is hollow and has a longitudinal lumen 30 extending therethrough. Longitudinal lumen 30 is connected in fluid communication with an interior of inflatable member 20 through aperture 32 which is provided in the

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wall of guidewire 14. FIG. 4 also shows that, in one preferred embodiment, a core wire 34 extends through lumen 30 from a proximal end thereof where it is preferably brazed to a portion of a hypotube which may be connected to the proximal portion of guidewire 14. The core wire 34 extends to the distal end of guidewire 14 where it is connected to coil tip 16. In one preferred embodiment, coil tip 16 is brazed or otherwise welded or suitably connected to the distal portion of core wire 34.

FIG. 4 further shows that, in the preferred embodiment, inflatable member 20 inflates to a generally helical, conical shape to form a basket opening toward the proximal end of guidewire 14. FIG. 4 further illustrates, in the preferred embodiment, mesh 22 has a distal portion 38 which is connected to the exterior surface of guidewire 14, at a distal region thereof, through adhesive 36 or any other suitable connection mechanism.

FIG. 5 illustrates a second embodiment of a distal protection device 40 in accordance with the present invention. Device 40 includes hollow guidewire 42, filter assembly 44 and coil tip 16. Filter assembly 44 includes a plurality of inflatable struts 46 and mesh 47. Each strut 46 has a distal end 48 and proximal end 50. Inflatable struts 46 also have an interior which is coupled in fluid communication, through distal end 48 thereof, with the lumen in hollow guidewire 42. Struts 46 are preferably configured such that, upon being inflated, the proximal ends 50 deploy radially outwardly away from the outer surface of hollow guidewire 42 to assume a dimension which approximates the inner dimension of lumen 58 in which they are inserted.

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Mesh 47, as with mesh 22 shown in FIG. 1, is deployed either on the outer or inner surface of inflatable struts 46, such that, when the inflatable struts 46 are deployed radially outwardly, mesh 47 forms a generally conical basket opening toward the proximal end of hollow guidewire 42. As with the embodiment shown in FIG. 1, mesh 47 can be applied to either the outer or the inner surface of struts 46. It can be applied to struts 46 as one unitary conical piece which is adhered about distal ends 48 of struts 46 using adhesive (or about the distal end of guidewire 42 using adhesive) and secured to the surface of the struts 46 also using adhesive. Alternatively, mesh 47 can be applied to struts 46 in a plurality of pieces which are individually or simultaneously secured to, and extend between, struts 46.

FIG. 6 is an end view of distal protection device 40 shown in FIG. 5 taken from the distal end of distal protection device 40. When struts 46 are deployed outwardly, mesh 47 forms a substantially lumen-filling filter which allows blood to flow therethrough, but which provides a mechanism for receiving and retaining stenosis fragments from stenosis 56 carried into mesh 47 by blood flow through the vessel.

FIG. 7 is a cross-sectional view of a portion of distal protection device 40 shown in FIGS. 5 and 6. FIG. 7 shows filter assembly 44 in the collapsed position in which it approximates the outer diameter of guidewire 42. FIG. 7 also shows that, in the preferred embodiment, the distal ends 48 of struts 46 are in fluid communication with an inner lumen 52 in hollow guidewire 42 through apertures 54 in the wall of guidewire 42.

FIG. 8 illustrates another embodiment of a distal protection device 60 in accordance with the

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present invention. Distal protection device 60 is similar to those shown in other figures, and similar items are similarly numbered. However, distal protection device 60 includes hollow guidewire 63 which
5 has a lumen in fluid communication with an interior of a pair of inflatable struts 62. Inflatable struts 62 have an inner surface 64 which is generally concave, or hemispherical, or otherwise appropriately shaped such that it extends about a portion of the outer surface of
10 hollow guidewire 63. Mesh portions 66 extend between the inflatable struts 62 so that inflatable struts 62 and mesh portions 66, when deployed outwardly as shown in FIG. 8, form a basket shape which opens toward the proximal end of hollow guidewire 63.

15 FIG. 9 illustrates another system for attaching inflatable struts to a hollow guidewire for a distal protection device 70 in accordance with the present invention. Distal protection device 70 is similar to the distal protection devices shown in the
20 previous figures in that a plurality of inflatable struts 72 are provided and preferably have a mesh portion extending therebetween. For the sake of clarity, the mesh portion is eliminated from FIG. 9. However, it will be understood that, when deployed,
25 distal protection device 70 forms a generally basket-shaped filter assembly which opens toward the proximal end of hollow guidewire 74.

In the embodiment shown in FIG. 9, hollow guidewire 74 has a distal end 75 which is open. An
30 endcap 76 is disposed about the distal end 75 of hollow guidewire 74 and defines an internal chamber or passageway 78. Endcap 76 has a proximal end 80 which has openings therein for receiving the ends of inflatable struts 72. Thus, in order to inflate

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inflatable struts 72, the operator pressurizes fluid within the lumen of hollow guidewire 74 forcing fluid out through distal end 75 of hollow guidewire 74, through passageway 78, and into inflatable struts 72.

- 5 In order to collapse distal protection device 70, the operator draws a vacuum which pulls the fluid back out of inflatable struts 72, through passageway 78 and, if necessary, into the lumen of hollow guidewire 74.

FIG. 10 is an end view of endcap 76 taken
10 along lines 10-10 in FIG. 9. FIG. 10 shows that proximal end 80 of endcap 76 preferably includes a first generally central aperture 82 for receiving the distal end of hollow guidewire 74. Aperture 82 is sized just larger than, or approximating, the outer diameter of
15 hollow guidewire 74 such that it fits snugly over the distal end 75 of hollow guidewire 74. Endcap 76 is then fixedly connected to the distal end 75 of hollow guidewire 74 through a friction fit, a suitable adhesive, welding, brazing, or another suitable
20 connection technique.

FIG. 10 also shows that proximal end 80 of endcap 76 includes a plurality of apertures 84 which are spaced from one another about end 80. Apertures 84 are sized to receive open ends of inflatable struts 72. In
25 the preferred embodiment, inflatable struts 72 are secured within apertures 84 using a suitable adhesive, or another suitable connection technique. Also, in the preferred embodiment, spring tip 16 is embedded in, or otherwise suitably connected to, endcap 76.

30 FIGS. 11A and 11B show two other preferred embodiments of a distal protection device in accordance with the present invention. FIG. 11A shows distal protection device 90 which includes hollow guidewire 92 having a lumen running therethrough, inflatable member

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94 and mesh portion 96. FIG. 11A shows that inflatable member 94, when inflated, forms a ring about the outer surface of hollow guidewire 92. The ring has an inner periphery 98 which is spaced from the outer surface of hollow guidewire 92 substantially about the entire radial periphery of hollow guidewire 92. Mesh portion 96 extends between the outer surface of hollow guide 92 and the inner periphery 98 of inflatable member 94. Thus, a substantially disc-shaped filter assembly is provided upon deployment of distal protection device 90. As with the other embodiments, deployment of distal protection device 90 is accomplished by providing fluid through the inner lumen of hollow guidewire 92 into an interior of inflatable member 94 which is in fluid communication with the inner lumen of hollow guidewire 92.

In one preferred embodiment, end 100 of inflatable member 94 is coupled to a coupling portion 102 of inflatable member 94 such that stability is added to inflatable member 94, when it is inflated.

FIG. 11B illustrates another distal protection device 104 which includes a hollow guidewire 106 and an inflatable member 108. Device 104 is similar to distal protection device 90 except that, rather than having only a single inflatable ring upon deployment of distal protection device 104, a plurality of generally equal-diameter rings are formed into a helix shape. In the preferred embodiment, distal protection device 104 includes a mesh sleeve 110 which extends about the outer or inner surface of the helix formed by inflatable member 108. In one embodiment, mesh sleeve 110 is connected to the outer surface of hollow guidewire 106 in a region 112 proximate, but distal of, inflatable member 108. In another preferred embodiment, the

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proximal end of mesh sleeve 110 is connected to the outer perimeter of inflatable member 108. Thus, distal protection device 104 forms a generally basket-shaped filter assembly which opens toward a proximal end of guidewire 106.

As with the other embodiments, both distal protection device 90 shown in FIG. 11A and distal protection device 104 shown in FIG. 11B are preferably collapsible. Therefore, when collapsed, the distal protection devices 90 and 104 preferably have an outer dimension which approximates the outer dimension of hollow guidewires 92 and 106, respectively. Further, as with the other embodiments, distal protection devices 90 and 104 can either be biased in the deployed or collapsed positions, and deployment and collapse can be obtained either by pulling a vacuum, or pressurizing the fluid within the lumen of the hollow guidewires 92 and 106.

FIG. 12 illustrates the use of a distal protection device in accordance with the present invention. For the sake of clarity, the present description proceeds with respect to distal protection device 10 only. Device 10 is shown filtering stenosis fragments from the blood flowing through the lumen of vessel 12. FIG. 12 also shows a dilatation device 120 which can be any suitable dilatation device for dilating, cutting, fragmenting, or abrading, portions of stenosis 26. In the preferred embodiment, device 120 is used in an over-the-wire fashion over hollow guidewire 14. Thus, filter assembly 18 is first advanced (using guidewire 14) distal of stenosis 26. Then, filter assembly 18 is deployed outwardly to the expanded position. Dilatation device 120 is then advanced over guidewire 14 to stenosis 26 and is used to fragment or

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abrade stenosis 26. The fragments are received within the basket of filter assembly 18. Filter assembly 18 is then collapsed, and filter assembly 18 and dilatation device 120 are removed from vessel 12. Alternatively, dilatation device 120 can be removed first and filter assembly 18 is then removed along with guidewire 14.

It should be noted that the stenosis removal device (or atherectomy catheter) 120 used to fragment stenosis 26 can be advanced over guidewire 14. Therefore, the device according to the present invention is dual functioning in that it captures emboli and serves as a guidewire. The present invention does not require adding an additional device to the procedure. Instead, the present invention simply replaces a conventional guidewire with a multi-functional device.

FIGS. 13A-17B illustrate embodiments of various distal protection devices wherein deployment and contraction of the distal protection device is accomplished through a mechanical push/pull arrangement.

FIGS. 13A and 13B illustrate a distal protection device 122. FIG. 13A shows device 122 in an undeployed position and FIG. 13B shows device 122 in a deployed position. Distal protection device 122 includes a slotted Nitinol tube 124 which has a lumen 126 extending therethrough. Tube 124 has a plurality of slots 128 at a distal region thereof. The distal portion of slots 128 are covered by mesh 130 which, in the preferred embodiment, is a flexible microporous membrane. Device 122 also preferably includes a mandrel 132 which extends through the inner lumen 126 of tube 124 and is attached to the distal end of tube 124. In the preferred embodiment, mandrel 132 is attached to the distal end of tube 124 by an appropriate adhesive, brazing, welding, or another suitable connection

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technique. Tube 124 also has, on its inner periphery in a proximal region thereof, a plurality of locking protrusions 134. Lock protrusions 134 are preferably arranged about a proximal expandable region 136 disposed on mandrel 132.

In order to deploy device 122 into the deployed position shown in FIG. 13B, the operator preferably first advances tube 124 distally of the lesion to be fragmented. In the preferred embodiment, tube 124 has a size on the order of a guidewire, such as a 0.014 inch outer diameter. Therefore, it easily advances beyond the stenosis to be fragmented. The operator then pushes on the proximal region of tube 124 and pulls on the proximal end of mandrel 132. This causes two things to happen. First, this causes the struts formed by slots 128 to expand radially outwardly, and carry with them, microporous membrane 130. Thus, microporous membrane 130 forms a generally basket-shaped filter assembly which opens toward the proximal end of tube 124. In addition, proximal expandable member 136 expands and engages protrusions 134. This locks device 122 in the deployed and expanded position. In order to move the device 122 to the collapsed position, the physician simply pushes on mandrel 132 and pulls on the proximal end of tube 124. This causes device 122 to return to the undeployed position shown in FIG. 13A.

It should be noted that device 122 can optionally be provided with a stainless steel proximal hypotube attachment. Also, the struts defined by slots 128 can be expanded and retracted using a fluid coupling instead of a mandrel. In other words, the proximal end of tube 124 can be coupled to a pressurizable fluid source. By making slots 128 very thin, and pressurizing the fluid, the struts expand outwardly. Further, by

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pulling vacuum on the pressurizable fluid, the struts collapse.

FIG. 14A illustrates distal protection device 140 which is similar to that shown in FIGS. 13A and 13B, except that the struts 142 are formed of a metal or polymer material and are completely covered by mesh 144. Mesh 144 includes two mesh portions, 146 and 148. Mesh portion 146 is proximal of mesh portion 148 on device 140 and is a relatively loose mesh which will allow stenosis fragments to pass therethrough. By contrast, mesh 148 is a fairly tight mesh, or a microporous membrane, (or simply loose mesh portion 146 with a microporous membrane or other suitable filter material bonded or cast or otherwise disposed thereover) which does not allow the fragments to pass therethrough and therefore captures and retains the fragments therein. The mesh portions can provide a memory set which, in the relaxed position, is either deployed or collapsed.

FIG. 14B illustrates a device 150 which is similar to device 140 shown in FIG. 14A, except struts 142 are eliminated and the two mesh portions 146' and 148' are simply joined together at a region 152. Also, the two mesh portions 146' and 148' are not two different discrete mesh portions but are formed of the same braided mesh material wherein the braid simply has a different pitch. The wider pitch in region 146' provides a looser mesh, whereas the narrower pitch in region 148' provides a tighter mesh that traps the embolic material.

FIG. 14C illustrates a distal protection device 160 which is similar to that shown in FIG. 14A. However, rather than simply providing a slotted tube, distal protection device 160 includes a plurality of struts 162 on a proximal region thereof and a plurality

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of struts 164 on the distal region thereof. Struts 162 are spaced further apart than struts 164 about the periphery of protection device 160. Therefore, struts 162 define openings 166 which are larger than the openings 168 defined by struts 164 and allow stenosis fragments to pass therethrough. Also, struts 164 have secured to the interior surface thereof a filter or mesh portion 170. When deployed, filter portion 170 forms a substantially basket-shaped filter device opening toward the proximal region of tube 172.

FIG. 15 illustrates the operation of another distal protection device 176. Distal protection device 176 includes a tube 178 and a push/pull wire 180. Tube 178 has, at the distal end thereof, a filter assembly 182. Filter assembly 182 includes a plurality of preferably metal struts 184 which have a microporous membrane, or other suitable mesh 186 disposed thereon. Tube 178 also preferably includes end cap 188 and umbrella-like expansion structure 190 disposed at a distal region thereof. Expansion structure 190 is connected to the distal region of tube 178 and to metal struts 184 such that, when push/pull wire 180 is pulled relative to tube 178, expansion member 190 exerts a radial, outwardly directed force on struts 184 causing them to expand radially outwardly relative to the outer surface of tube 178. This causes microporous membrane or mesh 186 to be deployed in a manner opening toward the proximal end of tube 178 to catch embolic material. Struts 184 can also be formed of an appropriate polymer material.

FIGS. 16A and 16B illustrate a protection device in accordance with another embodiment of the present invention. FIG. 16A illustrates distal protection device 192. Device 192 includes guidewire

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194, actuator wire 196, and filter assembly 198. Filter assembly 198 includes an expandable ring 200, such as an expandable polymer or metal or other elastic material, which has attached thereto mesh 202. Mesh 202 is also
5 attached to guidewire 194 distally of ring 200. Actuator wire 196 is attached to sleeve or sheath 204 which is positioned to fit about the outer periphery of expandable ring 200, when expandable ring 200 is in the collapsed position.

10 Thus, when sheath 204 is moved distally of expandable ring 200, expandable ring 200 has shape memory which causes it to expand into the position shown in FIG. 16A. Alternatively, when sheath 204 is pulled proximally by pulling actuator wire 196 relative to
15 guidewire 194, sheath 204 collapses ring 200 and holds ring 200 in the collapsed position within sheath 204. Manipulating wires 194 and 196 relative to one another causes device 192 to move from the deployed position to the collapsed position, and vice versa.

20 FIG. 16B is similar to device 192 except that, instead of having an expandable ring 200 connected at one point to wire 194, distal protection device 206 includes expandable member 208 which is formed of an elastic coil section of wire 194. Thus, elastic coil
25 section 208 has a shape memory which causes it to expand into the generally helical, conical shape shown in FIG. 16B. However, when sheath 204 is pulled proximally relative to expandable member 208, this causes sheath 204 to capture and retain expandable member 208 in a
30 collapsed position. When sheath 204 is again moved distally of expandable member 208, expandable member 208 returns to its expanded position shown in FIG. 16B carrying with it mesh 210 into a deployed position. In the preferred embodiment, sheath 204 is formed of a

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suitable polymer material and expandable member 208 and expandable ring 200 are preferably formed of Nitinol.

FIGS. 17A and 17B illustrate the operation of another distal protection device 212. Protection device 212 includes guidewire 214 and filter assembly 216. In the preferred embodiment, filter assembly 216 includes a wire braid portion 218 which extends from a distal region of guidewire 214 proximally thereof. Braid portion 218 is formed of braided filaments or fibers which have a shape memory causing them to form a deployed, basket-shaped filter, such as that shown in FIG. 17A, in the unbiased position. Braided portion 218 terminates at its proximal end in a plurality of eyelets 220. One or more cinch wires 222 are preferably threaded through eyelets 220. By pushing on guidewire 214 and pulling on cinch wires 222, the operator is able to cinch closed, and pull proximally, the proximal portion of mesh 218. This causes mesh 218 to collapse tightly about the outer surface of wire 214.

Therefore, during operation, the operator holds mesh 218 in the collapsed position and inserts protection device 212 distally of the desired stenosis. The operator then allows cinch wire 222 to move distally relative to guidewire 214. This allows mesh 218 to open to the deployed position shown in FIG. 17A which has an outer diameter that approximates the inner diameter of the lumen within which it is disposed. Filter assembly 216 is then disposed to capture embolic material from blood flowing therethrough. Once the embolic material is captured, the operator again moves cinch wire 222 proximally relative to guidewire 214 to collapse filter assembly 216 and capture and retain the embolic material in filter assembly 216. The device 212 is then removed.

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FIG. 17B shows distal protection device 212 except that in the embodiment shown in FIG. 17B, protection device 212 is not disposed distally of the stenosis, but rather proximally. This results, for example, in an application where the blood flow is proximal of the stenosis rather than distal. Further, in the embodiment shown in FIG. 17B, guidewire 214 is preferably hollow and the cinch wire 222 extends through the lumen therein. By pushing on guidewire 214, a force is exerted on mesh 218 in the distal direction. This causes cinch wire 222 to tightly close the distal opening in filter assembly 216 and to collapse mesh portion 218. By contrast, by allowing cinch wire 222 to move distal relative to hollow guidewire 214, mesh portion 218 expands and filter assembly 216 is deployed as shown in FIG. 17B.

FIGS. 18A and 18B illustrate a distal protection device 250 in accordance with another aspect of the present invention. Device 250 includes inner wire 252 and outer tube 254. In the preferred embodiment, inner wire 252 is a core wire and outer tube 254 has a lumen 256 therein large enough to accommodate longitudinal movement of inner wire 252 therein. Also, in the preferred embodiment, inner wire 252 has, coupled to its distal end 258, a spring tip 260.

Device 250 includes expandable mesh or braid portion 262. Expandable portion 262 has a proximal end 264 which is attached to the distal end 266 of tube 254. Also, expandable member 262 has a distal end 268 which is attached to the distal end 258 of inner wire 252.

Expandable member 262 is preferably a mesh or braided material which is coated with polyurethane. In one preferred embodiment, a distal portion of expandable member 262 has a tighter mesh than a proximal portion

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thereof, or has a microporous membrane or other suitable filtering mechanism disposed thereover. In another preferred embodiment, expandable member 262 is simply formed of a tighter mesh or braided material which, itself, forms the filter. FIG. 18A illustrates device 250 in a collapsed, or insertion position wherein the outer diameter of mesh portion 262 closely approximates the outer diameters of either inner wire 252 or outer tube 254.

FIG. 18B illustrates device 250 in the deployed position in which expandable member 262 is radially expanded relative to the collapsed position shown in FIG. 18A. In order to deploy device 250, the outer tube 254 is moved distally with respect to inner wire 252 such that the distal ends 266 and 258 of wires 254 and 252 move longitudinally toward one another. Relative movement of ends 266 and 258 toward one another causes the mesh of expandable member 262 to buckle and fold radially outwardly. Thus, the outer diameter of expandable member 262 in the deployed position shown in FIG. 18B closely approximates the inner diameter of a vessel within which it is deployed.

FIG. 18C illustrates device 250 in a partially collapsed position. In FIG. 18C, the distal end 266 of outer tube 254 and the distal end 258 of inner wire 252 are moved even closer together than they are as shown in FIG. 18B. This causes expandable mesh portion 262 to fold over itself and form a rolling, proximally directed flap 270. As longitudinal movement of inner wire 252 proximally with respect to outer tube 254 continues, mesh portion 262 continues to fold over itself such that the rolling flap portion 270 has an outer radial diameter which continues to decrease. In other words, expandable mesh portion 262 continues to fold over

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itself and to collapse over the outer periphery of outer tube 254.

FIG. 18D illustrates device 250 in a fully collapsed position in which it retains emboli captured therein. In FIG. 18D, the distal end 266 of outer tube 254 has been advanced as far distally as it can relative to the distal end 258 of inner wire 252. This causes expandable mesh portion 262 to fold all the way over on itself such that it lies against, and closely approximates the outer diameter of, outer tube 254. Device 250 thus captures any emboli filtered from the vessel within which it was deployed, and can be removed while retaining that embolic material.

FIG. 19 illustrates device 280 which depicts a further aspect in accordance with the present invention. Device 280 includes outer tube 282, core wire 284, transition tube 286, movable plunger 288, expandable member 290, fixed collar 292 and bias member 294.

In the preferred embodiment, tube 282 comprises a proximal hypotube which is coupled to a plunger that selectively provides fluid under pressure through an inflation lumen 296. Inner wire 284 is preferably a tapered core wire which terminates at its distal end in a spring coil tip 298 and which is coupled at its proximal end 300 to transition tube 286. Transition tube 286 is preferably an outer polymer sleeve either over hypotube 282, or simply disposed by itself and coupled to a hypotube 282. Transition tube 286 is capable of withstanding the inflation pressure provided by the fluid delivered through the inflation lumen 296.

Movable collar 288 is preferably slidably engageable with the interior surface of transition tube

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286 and with the exterior surface of core wire 284, and is longitudinally movable relative thereto. Slidable collar 288 has, attached at its distal end, bias spring 294 which is preferably coiled about core wire 284 and extends to fixed collar 292. Fixed collar 292 is preferably fixedly attached to the exterior surface of a distal portion of core wire 284.

Expandable member 290 is preferably formed, at a proximal portion thereof, of either discrete struts, or another suitable frame (such as a loose mesh) which allows blood and embolic material to flow therethrough. The proximal end 302 of expandable member 290 is coupled to a distal region of movable collar 288. The distal portion of expandable member 290 is preferably formed of a filtering material which is suitable for allowing blood flow therethrough, but which will capture embolic material being carried by the blood.

In one preferred embodiment, spring 294 is biased to force collars 288 and 292 away from one another. Thus, as spring 294 urges collars 288 and 292 away from one another, collar 288 retracts within transition tube 286 pulling expandable member 290 into a collapsed position about core wire 284. However, in order to deploy collapsible member 290 as shown in FIG. 19, the operator preferably actuates a plunger (not shown) which delivers pressurized fluid through lumen 296. The pressurized fluid enters transition tube 286 and travels about the outer periphery of inner core wire 284, thus forcing movable collar 288 to move distally along core wire 284. This overcomes the spring force exerted by spring 294 thus causing collars 288 and 292 to move toward one another, relatively. This motion causes expandable member 290 to buckle and expand outwardly to the deployed position shown in FIG. 19.

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Expandable member 290 is collapsed by releasing the pressure applied through lumen 296 (i.e., by causing the plunger to move proximally). This allows spring 294 to again urge collars 288 and 292 away from one another to collapse expandable member 290. In an alternative embodiment, the frame supporting expandable member 290 is imparted with a memory (such as a heat set, or a thermally responsive material which assumes a memory upon reaching a transition temperature) such that the resting state of the frame supporting expandable member 290 is in a collapsed position. This eliminates the need for spring 294. The expandable member 290, in that preferred embodiment, is expanded using the hydraulic pressure provided by the pressurized fluid introduced through lumen 296, and it is collapsed by simply allowing the memory in expandable member 290 to force fluid from transition tube 286 back through lumen 296.

FIGS. 20A and 20B illustrate another aspect in accordance with the present invention. A device 310 includes a mesh portion 312 supported by a frame 314. Expansion of frame 314 to the radially expanded position shown in FIG. 20A is driven by an expandable member, such as a balloon, 316 which is coupled to frame 314. Balloon 316 is coupled to a distal end of a distal hypotube 318, which is formed of a suitable material, such as nitinol. It should be noted that the distal tip of hypotube 318 includes a spring tip 320.

Distal hypotube 318 is shown coupled to a proximal hypotube 322 which has a tapered portion 324 therein. In the preferred embodiment, proximal hypotube 322 is formed of a suitable material, such as stainless steel. A plunger 326 is longitudinally movable within

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the lumen of both proximal hypotube 322 and distal hypotube 318.

Frame 314, and consequently mesh portion 312, are deployed by the operator moving plunger 326 distally within the lumens of hypotubes 318 and 322. This causes pressurized fluid to enter balloon 316, thereby inflating balloon 316 and driving deployment of frame 314 and mesh 312. In order to collapse frame 314 and mesh 312, the operator preferably moves plunger 326 proximally within the lumens of tubes 318 and 322 to withdraw fluid from within balloon 316. Alternatively, mesh 312 or frame 314 can have a memory set which is either in the inflated or collapsed position such that the operator need only affirmatively move frame 314 and mesh 312 to either the deployed or collapsed position, whichever is opposite of the memory set.

In either case, it is desirable that the operator be able to lock plunger 326 in a single longitudinal position relative to hypotubes 318 and 322. Thus, device 310 includes a locking region 328.

FIG. 20B illustrates locking region 328 in greater detail. FIG. 20B illustrates that, in locking region 328, plunger 326 has a plurality of grooves 330 formed in the outer radial surface thereof. Also, in accordance with the present invention, FIG. 20B illustrates that one of hypotubes 318 or 322 has an inwardly projecting portion 332. In one preferred embodiment, inwardly projecting portion 332 includes an inwardly extending, deflectable, annular rim which extends inwardly from either hypotube 318 or 322. In another preferred embodiment, the inwardly projecting portion 332 includes a plurality of discrete fingers which extend inwardly from one of hypotubes 318 or 322

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and which are angularly displaced about the interior periphery of the corresponding hypotube 318 or 322.

In operation, as the operator advances plunger 326 distally within the lumens of hypotubes 318 and 322, inwardly projecting portion 332 rides along the exterior periphery of plunger 326 until it encounters one of grooves 330. Then, inwardly projecting portion 332 snaps into the groove 330 to lock plunger 326 longitudinally relative to tubes 318 and 322.

It should be noted that, in the preferred embodiment, both inwardly projecting portions 332 and grooves 330 are formed such that, when gentle pressure is exerted by the operator on plunger 326 relative to hypotubes 318 and 322, projection portions 332 follow the contour of grooves 330 up and out of grooves 330 so that plunger 326 can again be freely moved within the lumens of hypotubes 318 and 322. Thus, the relative interaction between projecting portions 332 and grooves 330 provides a ratcheting type of operation wherein plunger 326 can be releasably locked into one of a plurality longitudinal positions relative hypotubes 318 and 322, since a plurality of grooves 330 are provided. Plunger 326 can be moved back and forth longitudinally within the lumens of hypotubes 318 and 322 in a ratcheting manner and can be locked into one of a plurality of relative longitudinal positions because there are a plurality of grooves 330 in the exterior of plunger 326. It should also be noted, however, that in another preferred embodiment, a plurality of sets of inwardly projecting portions 332 are provided along the inner longitudinal surface of hypotubes 318 and/or 322. In that case, only a single groove 330 needs to be formed in the exterior surface of plunger 326, and the same type of ratcheting locking operation is obtained.

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In the preferred embodiment, at least the exterior of hypotubes 318 and 322, and preferably the exterior of plunger 326, are tapered. This allows device 310 to maintain increased flexibility. It should
5 also be noted that, in the preferred embodiment, hypotubes 318 and 322 are preferably sized as conventional guidewires.

FIG. 21A illustrates a protection device in accordance with another embodiment of the present
10 invention. FIG. 21A illustrates distal protection device 340. Device 340 is similar to devices 192 and 206 shown in FIGS. 16A and 16B. However, in the preferred embodiment, device 340 includes hoop-shaped frame 342, filter portion 344, and wire 346. Hoop-
15 shaped frame 342 is preferably a self-expanding frame formed of a wire which includes a shape memory alloy. In a more preferred embodiment hoop-shaped frame 342 is formed of a nitinol wire having a diameter in a range of approximately 0.002 - 0.004 inches.

20 Filter portion 344 is preferably formed of a polyurethane material having holes therein such that blood flow can pass through filter 344, but emboli (of a desired size) cannot pass through filter 344 but are retained therein. In one preferred embodiment, filter
25 material 344 is attached to hoop-shaped frame 342 with a suitable, commercially available adhesive. In another preferred embodiment, filter 344 has a proximal portion thereof folded over hoop-shaped frame 342, and the filter material is attached itself either with adhesive,
30 by stitching, or by another suitable connection mechanism, in order to secure it about hoop-shaped frame 342. This connection is preferably formed by a suitable adhesive or other suitable connection mechanism.

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Also, the distal end of filter 344 is preferably attached about the outer periphery of wire 346, proximate coil tip 348 on wire 346.

5 In one preferred configuration, filter 344 is approximately 15 mm in longitudinal length, and has a diameter at its mouth (defined by hoop-shaped frame 342) of a conventional size (such as 4.0 mm, 4.5 mm, 5 mm, 5.5 mm, or 6 mm). Of course, any other suitable size can be used as well.

10 Also, in the preferred configuration, filter 344 is formed of a polyurethane material with the holes laser drilled therein. The holes are preferably approximately 100 μ m in diameter. Of course, filter 344 can also be a microporous membrane, a wire or polymer
15 braid or mesh, or any other suitable configuration.

Wire 346 is preferably a conventional stainless-steel guidewire having conventional guidewire dimensions. For instance, in one embodiment, wire 346 is a solid core wire having an outer diameter of
20 approximately 0.014 inches and an overall length of up to 300 cm. Also, in the preferred embodiment, wire 346 has a distal end 350, in a region proximate filter 344, which tapers from an outer diameter at its proximal end which is the same as the outer diameter of the remainder
25 of wire 346, to an outer diameter of approximately 0.055 inches at its distal end. At distal region 350, guidewire 346 is preferably formed of stainless steel 304.

Of course, other suitable guidewire dimensions
30 and configurations can also be used. For example guidewires having an outer diameter of approximately 0.018 inches may also be used. For other coronary applications, different dimensions may also be used, such as outer diameters of approximately 0.010 inches to

-30-

0.014 inches. Further, it will be appreciated that the particular size of wire 346 will vary with application. Applications involving neural vasculature will require the use of a smaller guidewire, while other applications will require the use of a larger guidewire. Also, wire 346 can be replaced by a hollow guidewire, or hypotube of similar, or other suitable dimensions.

In addition, in order to make wire 342, hoop 346, or filter 344 radiopaque, other materials can be used. For example, radiopaque loaded powder can be used to form a polyurethane sheath which is fitted over wire 346 or hoop 342, or which is implemented in filter 344. Also, hoop 342 and wire 346 can be gold plated in order to increase radiopacity. Also, marker bands can be used on wire 346 or filter 344 to increase the radiopacity of the device.

In operation, hoop 342 (and thus filter 344) is preferably collapsed to a radially contracted position which more closely approximates the outer diameter of wire 346. Methods of performing this contraction are described later in the specification. Once retracted to a more low profile position, wire 346 is manipulated to position hoop 342 and filter 344 distal of a restriction to be treated. Then, the restraining force which is used to restrain hoop 342 in the predeployment, low profile position is removed, and the superelastic properties of nitinol hoop 342 (or the shape memory properties of another shape memory alloy) are utilized in allowing hoop 342 to assume its shape memory position. This causes hoop 342 to define a substantially lumen filling mouth to filter 344 which is positioned distal of the restriction to be treated.

A suitable dilatation device is then advanced over wire 346 and is used to treat the vascular

-31-

restriction. Emboli which are carried by blood flow distal of the restriction are captured by filter 344. After the dilatation procedure, filter 344, along with the emboli retained therein, are retrieved from the vasculature. Various retrieval procedures and devices are described later in the specification.

By allowing hoop-shaped frame 342 to be unattached to wire 346, and only connected to wire 346 through filter 344 (or other super structure used to support filter 344), wire 346 is allowed to substantially float within hoop 342. This configuration provides some advantages. For instance, hoop 342 can better follow the vasculature without kinking or prolapsing (i.e., without collapsing upon itself). Thus, certain positioning or repositioning of filter 344 can be accomplished with less difficulty.

FIG. 21B illustrates a protection device 352 in accordance with another embodiment of the present invention. Protection device 352 is similar to protection device 340, and similar items are similarly numbered. However, rather than having simply a hoop-shaped frame 342 to support filter 344, and drive filter 344 into its expanded and deployed position, device 352 includes frame 354 which includes a hoop-shaped portion 356, and a pair of tails 358 and 360.

Tails 358 and 360 extend proximally from hoop-shaped portion 356 to an attachment region 362. In the preferred embodiment, tails 358 and 360 are attached to wire 346 at attachment region 362 by soldering, welding, brazing, adhesive, or any other suitable attachment mechanism. In the embodiment shown in FIG. 21B, attachment sleeve 364, formed of a weldable material, is attached at its inner periphery to tails 358 and 360.

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Sleeve 364 is then attached, using welding or brazing, to wire 346.

By providing tails 358 and 360, frame 354 is directly connected to wire 346. However, tails 358 and 360 are provided so that the point of attachment of frame 354 to wire 346 is located several millimeters proximal of hoop-shaped portion 356. This provides some additional structural integrity to frame 354, but still allows frame 354 to substantially float about wire 346 in the region of hoop-shaped frame portion 356.

FIG. 21C illustrates a protection device 366 in accordance with another embodiment of the present invention. Protection device 366 is similar to protection devices 340 and 352 shown in FIGS. 21A and 21B, and similar items are similarly numbered. However, device 366 includes hoop-shaped frame 368. Frame 368 is similar to frame 342 shown in FIG. 21A. However, unlike frame 342, hoop 368 does not allow wire 346 to float freely therein. Instead, hoop 368 is directly attached to wire 346 at attachment point 370. This causes hoop-shaped frame 368 and filter 344 to reside eccentrically about wire 346.

FIGS. 22A-22C illustrate one preferred embodiment for delivering one of devices 340, 352 and 366. For the sake of clarity, only device 352 is illustrated in FIGS. 22A-22C.

FIG. 22A illustrates delivery device 372. In the preferred embodiment, delivery device 372 includes proximal hub 374, shaft 376, and distal retaining section 378. Also, in one preferred embodiment, device 372 also includes marker band 380. In the preferred embodiment, delivery device 372 is similar to a conventional balloon catheter in that proximal hub 374 is a conventional hub, and shaft 376 is a conventional

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balloon catheter shaft. Further, distal retaining section 378 is preferably a conventional angioplasty balloon having an inflated diameter of approximately 1.5 - 2.0 millimeters, but having its distal end cutoff such that the distal end 382 of balloon 378 is open.

Prior to insertion of device 372 into the vasculature, hoop-shaped frame 354 is retracted into its low profile deployment position and is withdrawn through end 382 into balloon 378. Then, the distal end of balloon 378 is exposed to heat to heat shrink or heat set the distal end of balloon 378 around the radially retracted device 352. Device 372, including device 352, is then inserted in the vasculature either through a preplaced guide catheter, along with a guide catheter, or simply without a guide catheter utilizing coil tip 348.

In any case, once device 372 is properly placed such that balloon 378 is located distal of the restriction to be treated, distal protection device 352 is then removed from within heat collapsed balloon 378. In one preferred embodiment, the physician simply accomplishes longitudinal movement of wire 346 relative to catheter 376. For instance, the physician may simply hold wire 346 longitudinally in place and withdraw catheter 376 proximally relative to wire 346 by pulling on hub 374. This causes balloon 378 to move proximally relative to device 352, and thereby to expose device 352 to the vasculature.

FIG. 22B illustrates another preferred embodiment for removing device 352 from within balloon 378. In the embodiment shown in FIG. 22B, syringe 384, which contains fluid, is inserted into coupling 386 in hub 374. The physician then introduces pressurized fluid into the lumen of catheter 376. The pressurized

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fluid advances down the lumen of catheter 376 to the distal end where it encounters collapsed balloon 378. The pressure exerted on balloon 378 by the pressurized fluid causes balloon 378 to open radially. Then, the physician withdraws catheter 376 relative to device 352 thereby exposing device 352 to the vasculature.

In any case, once device 352 is no longer restrained by balloon 378, device 352 assumes its shape memory position in the vasculature, as illustrated in FIG. 22C. Thus, device 352 substantially forms a lumen-filling basket or filter which allows blood to pass distally therethrough, but which retains or captures embolic material carried by the blood flow. The physician then simply removes device 372 from the vasculature, leaving device 352 in place during subsequent procedures. In one preferred embodiment, shaft 376 includes a predefined slit or score from a region just proximal of marker band 380 to, or through, hub 374. Thus, as the physician removes device 372, it can be peeled away from device 352. Also, or alternatively, device 372 can be provided with an aperture in shaft 376 near its distal end. The proximal end of wire 346 will thus lie outside of shaft 376. Wire 346 can enter shaft 376 through the aperture and extend through the distal end of shaft 376. This also facilitates easier withdrawal of device 372 over wire 346.

FIGS. 23A-23E illustrate one preferred embodiment for retrieving one of the devices 340, 352 and 366 described in FIGS. 21A-21C. For the sake of clarity, only device 352 is illustrated in FIGS. 23A-23E. FIG. 23A illustrates retrieval device 388. Retrieval device 388 is preferably formed of proximal shaft 390, mesh portion 392, and end cap 394. Items

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390, 392 and 394 preferably each have lumens therein to define a passageway for receiving wire 346. Also, wire 346 may optionally be provided with an positive stop 396 (which can be embodied as a radiopaque marker band).

- 5 Optional stop 396 may also simply be an annular ring attached to wire 346 proximate to filter 344, or may be any other suitable stop.

Proximal shaft 390 is preferably simply a polymer or nitinol tube sized and configured to track
10 over wire 346. End cap 394 is also preferably formed to track over wire 346, but also contains radiopaque material to serve as a distal marker band for retrieval device 388. Mesh 392 is preferably a braid or mesh formed of wire or polymer material having sufficient
15 flexibility that it can be deflected as described below.

Mesh 392 preferably has a proximal end coupled to proximal shaft 390, by adhesive, welding, or other suitable attachment mechanisms. Mesh 392 also preferably includes a distal end connected to end cap
20 394, also by a suitable connection mechanism.

In order to retrieve filter 344, which likely contains embolic material, device 388 is inserted in the low profile position shown in FIG. 23A, over wire 346, to a position proximate filter 344. Then, device 388 is
25 advanced toward filter 344, until end cap 394 abuts positive stop 396, or the hoop-shaped frame 354. Continued advancement of proximal shaft 390 relative to wire 346 causes compression of mesh 392. This results in a radial expansion of an intermediate portion of mesh
30 392 (between the proximal and distal ends of mesh 392). The radial expansion of mesh portion 392 is illustrated in FIG. 23B.

By continuing to advance proximal shaft 390 relative to wire 346, the intermediate portion of mesh

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392 is configured to bend over on itself such that it is axially displaced toward filter 344, in the direction generally indicated by arrows 398 in FIG. 23C. In the preferred embodiment, mesh 392 is sized and configured
5 such that, with continued advancement of proximal shaft 390 relative to wire 346, this action continues as shown in FIGS. 23D and 23E until the intermediate portion of mesh 392 encompasses at least the mouth of filter 344. Also, in the preferred embodiment, the intermediate
10 portion of mesh 392, when driven as described above, engages and contracts the mouth of filter 344 to a lower profile position, such as that shown in FIG. 23E. In yet another preferred embodiment, mesh 392 is sized and configured to substantially engulf the entire filter
15 344.

Once at least the mouth of filter 344 is encompassed by mesh 392, device 388, along with device 352, are simply withdrawn from the vasculature. In one preferred embodiment in which a guide catheter is used,
20 devices 388 and 352 are simply withdrawn either into the guide catheter and the guide catheter is removed with those devices, simultaneously, or devices 388 and 352 are removed from the guide catheter prior to removal of the guide catheter. In another preferred embodiment, in
25 which no guide catheter is used, devices 388 and 352 are simply removed from the vasculature simultaneously.

It will also be appreciated, of course, that rather than providing device 388 with a single proximal tube 390 and end cap 394, a second actuation tube or
30 wire can also be provided which is attached to end cap 394, and which extends back through the lumen in proximal tube 390 and is longitudinally movable relative to proximal shaft 390. In that way, the actuation wire or elongate member can be used to pull cap 394 closer to

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the distal portion of proximal shaft 390 in order to accomplish the action illustrated in FIGS. 23A-23E. This feature is also illustrated in FIGS. 18A-18D which illustrate the mesh portion folded proximally rather than distally.

FIGS. 24A-24C illustrate another preferred embodiment in accordance with the present invention, for retrieving any of the distal protection devices 340, 352 or 366 shown in FIGS. 21A-21C. For the sake of clarity, only device 352 is illustrated in FIGS. 24A-24C.

FIG. 24A illustrates retrieval device 400. Retrieval device 400 preferably includes retrieval sheath 402, proximal locking device 404, dilator sheath 405, and nose cone 406. In the preferred embodiment, retrieval sheath 402 is preferably formed of polyether block amide (PEBAX) material having an outer diameter of approximately six French (i.e., approximately 2 mm) and having a shore D hardness of approximately 40. Also, retrieval sheath 402 preferably has a wall thickness of approximately 0.004 inches. Dilator sheath 405, and nose cone 406, are preferably formed of low density polyethylene, or high density polyethylene. Sheath 405 preferably has an outer diameter which is approximately equal to the inner diameter of sheath 402. In addition, the inner diameter of sheath 405 and nose cone 406 is preferably just large enough to fit over, and track over, wire 346. Nose cone 406 preferably has a proximal portion which is either attached to, or formed integrally with, sheath 405. The outer diameter of the proximal portion of nose cone 406 is also approximately the same as the outer diameter of sheath 405. However, nose cone 406 also preferably has a distal portion which tapers, or reduces along preferably a smooth curve, to

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an outer diameter which terminates at the inner diameter of nose cone 406.

Proximal locking device 404 is preferably any suitable, and commercially available, locking device which can be configured to lock dilator sheath 405 to guidewire 346.

In order to retrieve device 352 from the vasculature, device 400 is preferably advanced over guidewire 346 to a position shown in FIG. 24B, in which the distal portion of nose cone 406 is closely proximate, or adjacent to, either optional stop 396 or the mouth of filter 344. Then, proximal locking device 404 is actuated to lock dilator sheath 405 to wire 346 so that wire 346 and dilator sheath 405 (as well as nose cone 406) can be moved as a unitary piece.

Next, wire 346 (and hence dilator sheath 405 and nose cone 406) are withdrawn longitudinally relative to retrieval sheath 402. This causes the mouth of filter 344 to enter within the distal opening in retrieval sheath 402. This results in device 352 being positioned relative to sheath 402 as shown in FIG. 24C. Of course, wire 346, dilator sheath 405 and nose cone 406 can be withdrawn further into sheath 402 such that the entire filter 344, and wire tip 348, are disposed within the lumen of sheath 402.

In any case, once at least the mouth of filter 344 is within sheath 402, device 352 is configured to be removed from the vasculature. This can be accomplished by either removing dilator sheath 405, nose cone 406 and device 352 as a unitary piece, leaving sheath 402 in place for later removal, or by removing sheath 402 with the remainder of the system, either through a guide catheter or simply through the vasculature, simultaneously. Also, where a guide catheter is used,

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device 352 and device 400 can be removed through the guide catheter leaving the guide catheter in place, or the guide catheter can be removed simultaneously with the other devices 352 and 400.

5 It should be noted that all of the devices according to the present invention can optionally be coated with an antithrombotic material, such as heparin (commercially available under the tradename Duraflow from Baxter), to inhibit clotting.

10 Thus, in accordance with one preferred embodiment of the present invention, the superelastic properties of nitinol are used to form a frame at least in the area of the mouth of the distal protection filter. Thus, the distal protection device can be
15 deployed, retrieved, and re-deployed any number of times without incurring plastic deformation. In addition, in other preferred embodiments in accordance with the present invention, various deployment and retrieval techniques and systems are provided which address
20 various problems associated with such systems.

 Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from
25 the spirit and scope of the invention.

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WHAT IS CLAIMED IS:

1. An emboli capturing system for capturing emboli in a body lumen, comprising:
 - a first elongate member having a proximal end and a distal end;
 - an expandable emboli capturing device mounted proximate the distal end of the first elongate member, the emboli capturing device being movable between a radially expanded position and a radially retracted position, the expandable emboli capturing device forming a basket with a proximally opening mouth when in the radially expanded position;
 - a second elongate member having a proximal end and a distal end and a lumen extending between the proximal and distal ends, the lumen being sized to slidably receive a portion of the first elongate member therein; and
 - an expandable delivery device mounted to the distal end of the second elongate member and being movable from a radially retracted position to a radially expanded position, the delivery device having a receiving end configured to receive the emboli capturing device, the delivery device retaining at least the mouth of the emboli capturing device in the radially retracted position when the delivery device is in the radially retracted position, the emboli capturing device being longitudinally movable out from within the delivery device when the

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delivery device is in the radially expanded position.

2. The emboli capturing system of claim 1 and further comprising:

a retrieval device, configured to be longitudinally movable relative to the emboli capturing device in the body lumen and having a receiving end configured to receive at least the mouth of the emboli capturing device when the emboli capturing device is in the radially expanded position.

3. The emboli capturing system of claim 2 wherein the retrieval device comprises the expandable delivery device in the radially expanded position.

4. The emboli capturing system of claim 2 wherein the receiving end of the retrieval device is contractible from a radially expanded position to a radially contracted position to at least partially collapse the emboli capturing device therein.

5. The emboli capturing system of claim 4 wherein the retrieval device comprises:

a third elongate member having proximal and distal ends and a lumen extending therebetween, the lumen being sized to slidably receive at least a portion of the first elongate member therein, the lumen at the distal end of the third elongate member forming the receiving end and being sized to receive a most radially expanded portion of the emboli capturing device; and

a fourth elongate member movable within the lumen of the third elongate member, the

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fourth elongate member having an intermediate region sized to substantially fill the receiving end and a distal tip having an outer diameter less than an outer diameter of the intermediate region.

6. The emboli capturing system of claim 5 wherein the distal tip of the fourth elongate member is configured with an aperture therein sized to track over the first elongate member.

7. The emboli capturing system of claim 6 wherein the fourth elongate member is formed in a substantially conical shape between the distal tip thereof and the intermediate region thereof.

8. The emboli capturing system of claim 2 wherein the retrieval device includes:

- a third elongate member having proximal and distal ends and a lumen extending therebetween, the lumen being sized to slidably receive at least a portion of the first elongate member; and

- a mesh sleeve having a first end coupled to the third elongate member, a second end distal of the first end and an intermediate portion between the first and second ends, the mesh sleeve being configured such that relative longitudinal movement of one of the first and second ends thereof relative to another of the first and second ends thereof drives movement of the mesh portion from a radially retracted position, to a radially expanded position in which the intermediate

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portion expands radially outward relative to the first and second ends, and to a collapsed position in which the mesh sleeve bends such that the intermediate portion is displaced in a direction toward one of the first and second ends of the mesh sleeve.

9. The emboli capturing system of claim 8 wherein the retrieval device is configured such that sufficient longitudinal movement of the emboli capturing device toward the mesh sleeve causes the emboli capturing device to drive the second end of the mesh sleeve toward the first end of the mesh sleeve.

10. The emboli capturing system of claim 9 wherein the mesh sleeve is sized to encompass at least the mouth of the emboli capturing device as the mesh sleeve moves from the radially expanded position to the collapsed position.

11. The emboli capturing system of claim 2 wherein the retrieval device includes:

- a third elongate member having proximal and distal ends and a lumen extending therebetween, the lumen being sized to slidably receive at least a portion of the first elongate member;

- a fourth elongate member longitudinally movable relative to the third elongate member; and

- a mesh sleeve having a first end coupled to the third elongate member and a second end coupled to the fourth elongate member and an intermediate portion between the first and second ends, the mesh sleeve being configured such that

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relative longitudinal movement of one of the third and fourth elongate members relative to another of the third and fourth elongate members drives movement of the mesh portion from a radially retracted position, to a radially expanded position in which the intermediate portion expands radially outward relative to the first and second ends, and to a collapsed position in which the mesh sleeve bends such that the intermediate portion is displaced in a direction toward one of the first and second ends of the mesh sleeve.

12. The emboli capturing system of claim 1 wherein the receiving end of the delivery device is defined by a portion of a dilatation balloon.

13. The emboli capturing system of claim 1 wherein the receiving end of the delivery device is thermally shrunk over at least the mouth of the emboli capturing device to retain the emboli capturing device in the radially contracted position during delivery.

14. The emboli capturing system of claim 1 wherein the receiving end of the delivery device is movable from the radially retracted position to the radially expanded position by delivery of pressurized fluid through the lumen in the second elongate member.

15. The emboli capturing system of claim 1 wherein the emboli capturing device is a self-expanding device biased in the radially expanded position.

16. The emboli capturing system of claim 15 wherein the emboli capturing device includes:

a frame formed of a shape memory alloy; and

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a filter portion supported by the frame, the filter portion being configured to permit blood flow therethrough and to capture emboli carried by blood flow therethrough.

17. The emboli capturing system of claim 16 wherein the filter portion has a first end connected to the first elongate member and a second end connected to the frame and wherein the frame comprises:

a loop disposed about the first elongate member to define the mouth of the emboli capturing device.

18. The emboli capturing system of claim 17 wherein the loop is directly connected to the first elongate member.

19. The emboli capturing system of claim 17 wherein the shape memory alloy comprises an alloy having superelastic properties.

20. The emboli capturing system of claim 19 wherein the shape memory alloy includes nitinol.

21. The emboli capturing system of claim 20 wherein the emboli capturing device is substantially conical in shape.

22. The emboli capturing system of claim 21 wherein the filter portion comprises a polyurethane member having a plurality of holes therein.

23. The emboli capturing system of claim 1 wherein the first elongate member comprises a guidewire.

24. A method of capturing emboli carried by flow of fluid through a body lumen, the method comprising:

providing a first elongate member having a proximal end and a distal end;

providing an expandable emboli capturing device mounted proximate the distal end

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of the first elongate member, the emboli capturing device being movable between a radially expanded position and a radially retracted position, the expandable emboli capturing device defining a proximally opening mouth when in the radially expanded position;

providing a second elongate member having a proximal end and a distal end and a lumen extending between the proximal and distal ends, the lumen being sized to slidably receive a portion of the first elongate member therein;

providing an expandable delivery device mounted to the distal end of the second elongate member and being movable from a radially retracted position to a radially expanded position, the delivery device having a receiving end configured to receive the emboli capturing device, the delivery device retaining at least the mouth of the emboli capturing device in the radially retracted position when the delivery device is in the radially retracted position;

inserting the expandable delivery device into the lumen with the mouth of the emboli capturing device retained in the radially retracted position within the delivery device;

expanding the expandable delivery device into the radially expanded position; and

longitudinally moving the delivery device relative to the emboli capturing device

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to remove the emboli capturing device from within the delivery device.

25. The method of claim 24 and further comprising:

providing a retrieval device, configured to be longitudinally movable relative to the emboli capturing device in the body lumen and having a receiving end configured to receive at least the mouth of the emboli capturing device when the emboli capturing device is in the radially expanded position; and longitudinally moving the delivery device relative to the emboli capturing device such that at least the mouth of the emboli capturing device is in the receiving end of the retrieval device.

26. The method of claim 25 wherein the receiving end of the retrieval device is contractible from a radially expanded position to a radially contracted position, and further comprising:

contracting the receiving end of the retrieval device to at least partially collapse the emboli capturing device therein.

27. The method of claim 26 wherein providing a retrieval device comprises:

providing a third elongate member having proximal and distal ends and a lumen extending therebetween, the lumen being sized to slidably receive at least a portion of the first elongate member therein, the lumen at the distal end of the third elongate member forming the

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receiving end and being sized to receive a most radially expanded portion of the emboli capturing device;

providing a fourth elongate member movable within the lumen of the third elongate member, the fourth elongate member having an intermediate region sized to substantially fill the receiving end and a distal tip having an outer diameter less than an outer diameter of the intermediate region;

advancing the third and fourth elongate members over the first elongate member, with the intermediate region of the fourth elongate member positioned within the third elongate member to fill the receiving end thereof, to a point proximate the emboli capturing device;

withdrawing the distal tip of the fourth elongate member within the lumen of the third elongate member; and

positioning at least the mouth of the emboli capturing device within the receiving end of the retrieval device.

28. The method of claim 27 and further comprising: withdrawing the first, third, and fourth elongate members from the body lumen.

29. The method of claim 25 wherein providing the retrieval device includes:

providing a third elongate member having proximal and distal ends and a lumen extending therebetween, the lumen being sized to slidably receive at least a portion of the first elongate member;

-49-

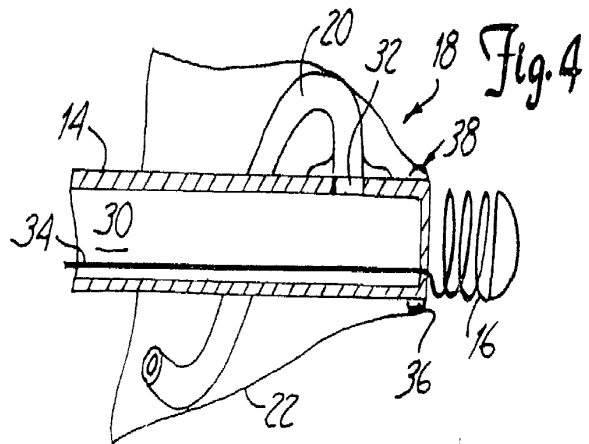
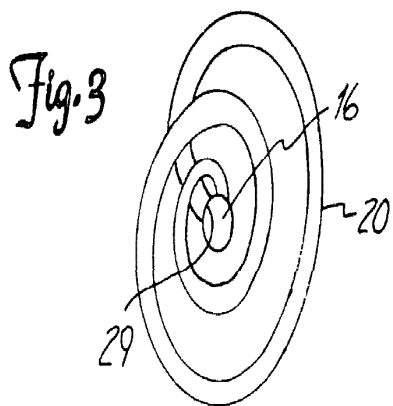
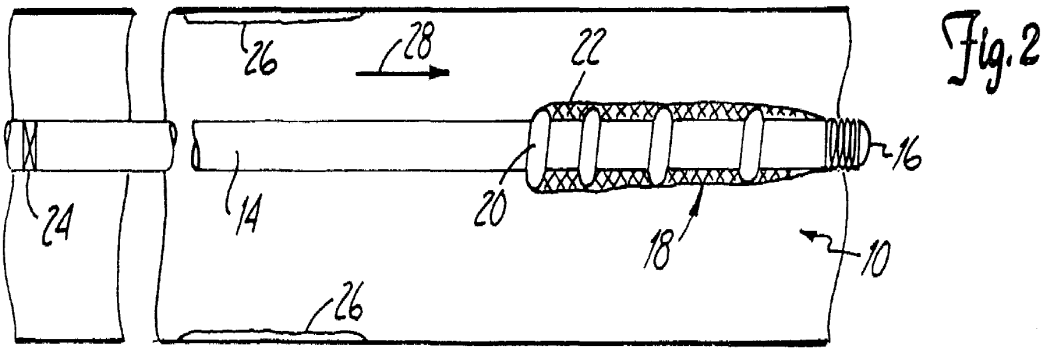
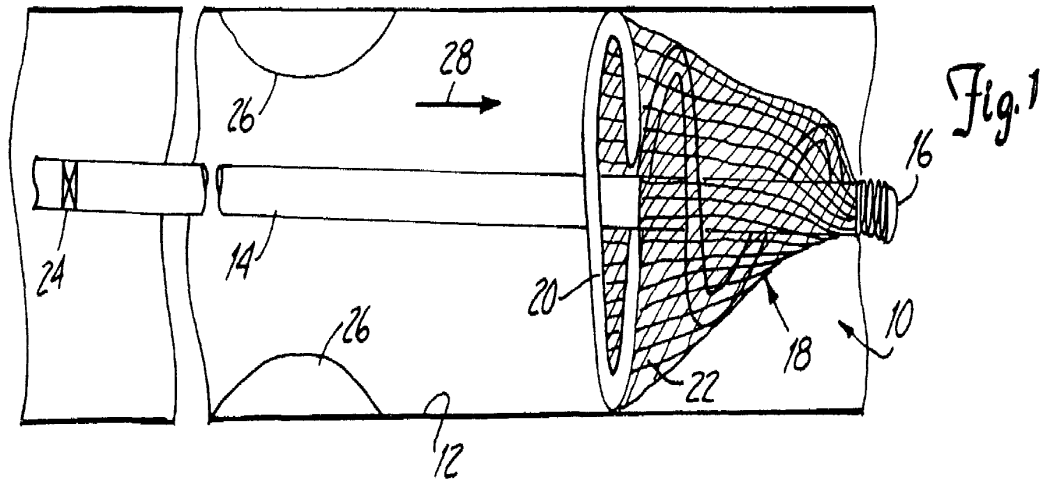
providing a mesh sleeve having a first end coupled to the third elongate member, a second end distal of the first end and an intermediate portion between the first and second ends, the mesh sleeve being configured such that relative longitudinal movement of one of the first and second ends thereof relative to another of the first and second ends thereof drives movement of the mesh portion from a radially retracted position, to a radially expanded position in which the intermediate portion expands radially outward relative to the first and second ends, and to a collapsed position in which the mesh sleeve bends such that the intermediate portion is displaced in a direction toward one of the first and second ends of the mesh sleeve;

advancing the third elongate member into the body lumen over the first elongate member to a point proximate the mouth of the emboli capturing device; and

accomplishing relative longitudinal movement of the emboli capturing device and the mesh sleeve toward one another, driving the second end of the mesh sleeve toward the first end of the mesh sleeve such that the mesh sleeve encompasses at least the mouth of the emboli capturing device as the mesh sleeve moves from the radially expanded position to the collapsed position.

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30. The method of claim 24 wherein expanding comprises:
delivering pressurized fluid through the lumen in the second elongate member.



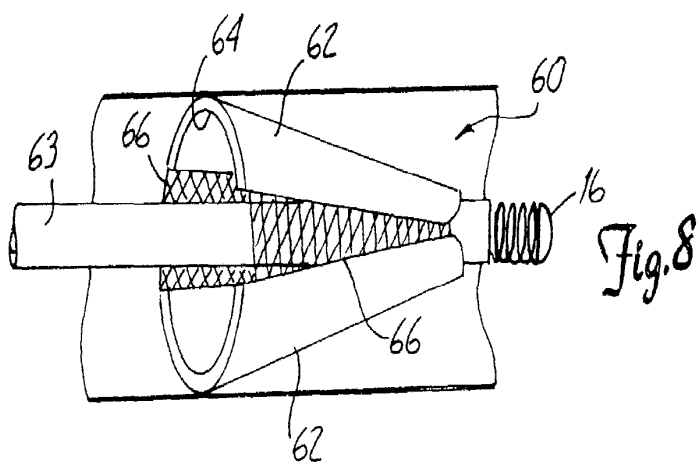
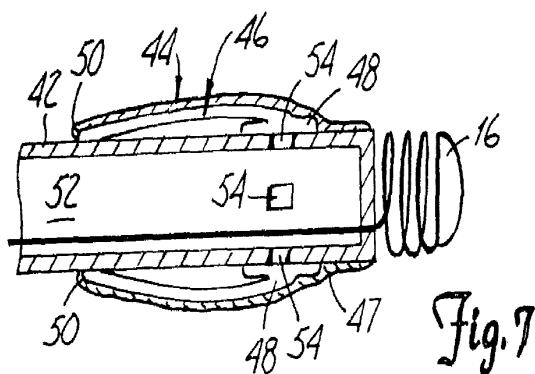
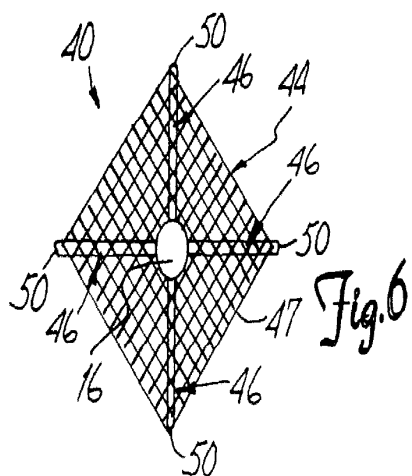
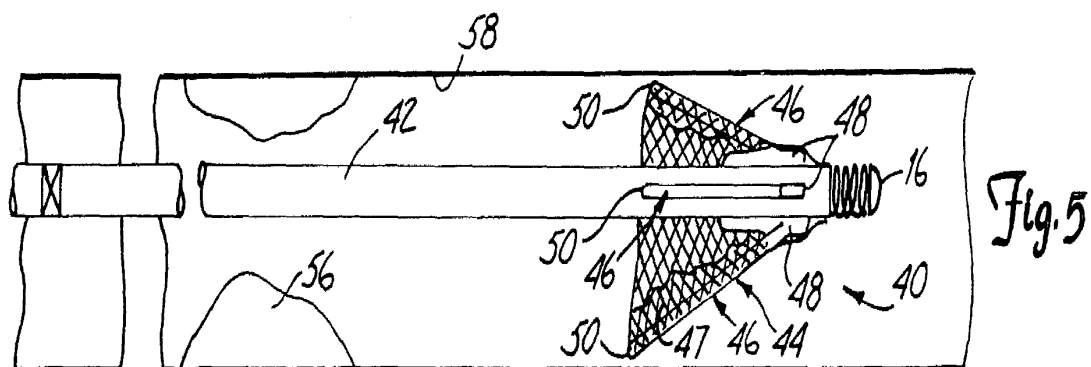


Fig. 9

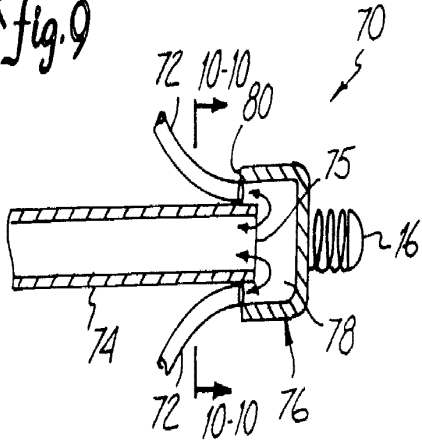


Fig. 10

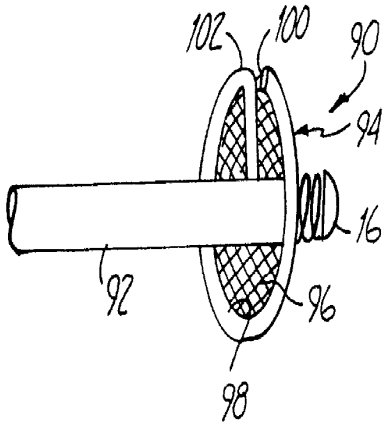
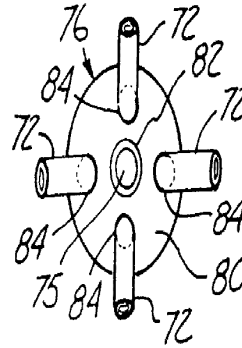


Fig. 11A

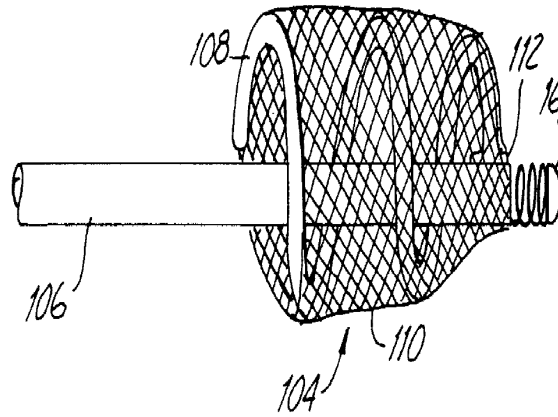
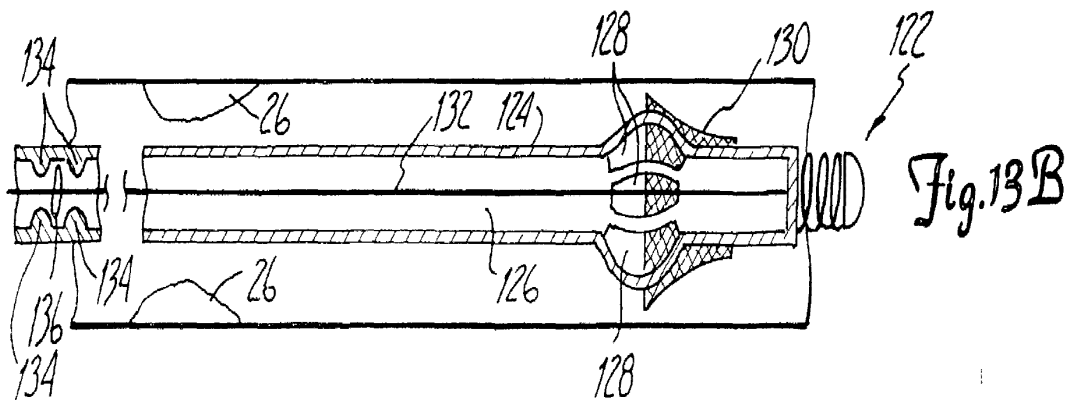
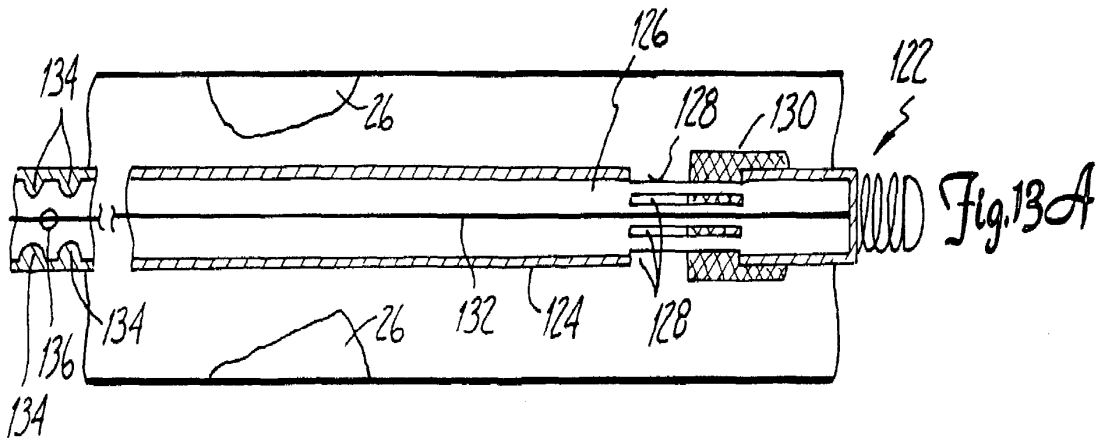
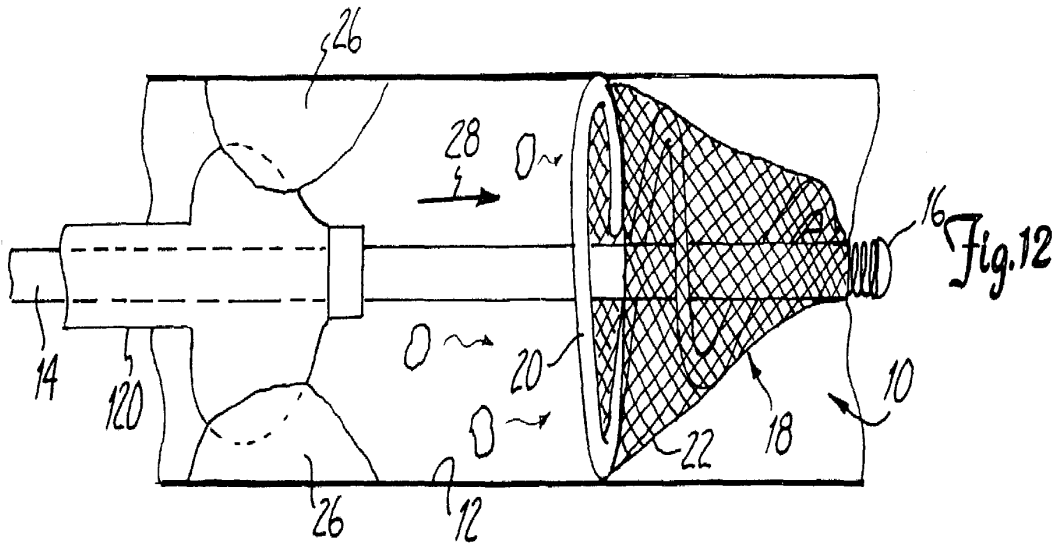


Fig. 11B



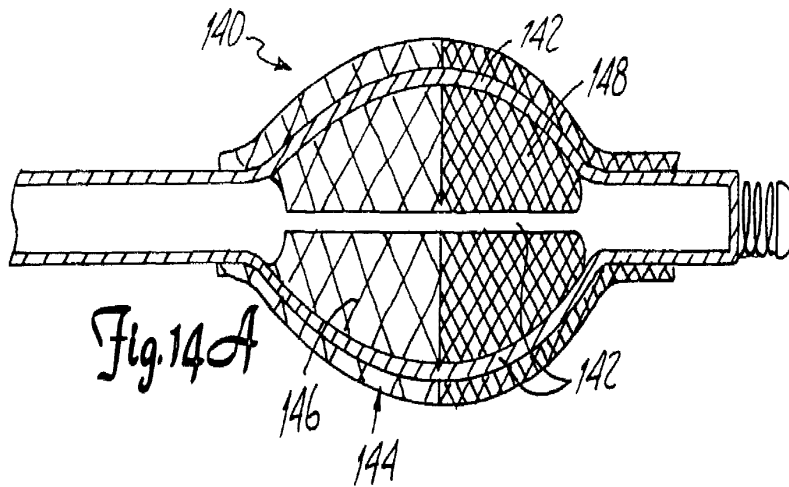


Fig. 14A

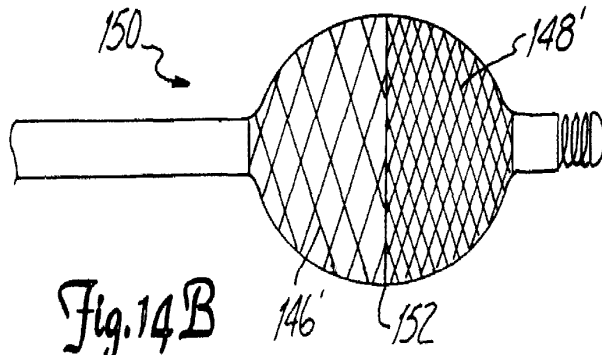


Fig. 14B

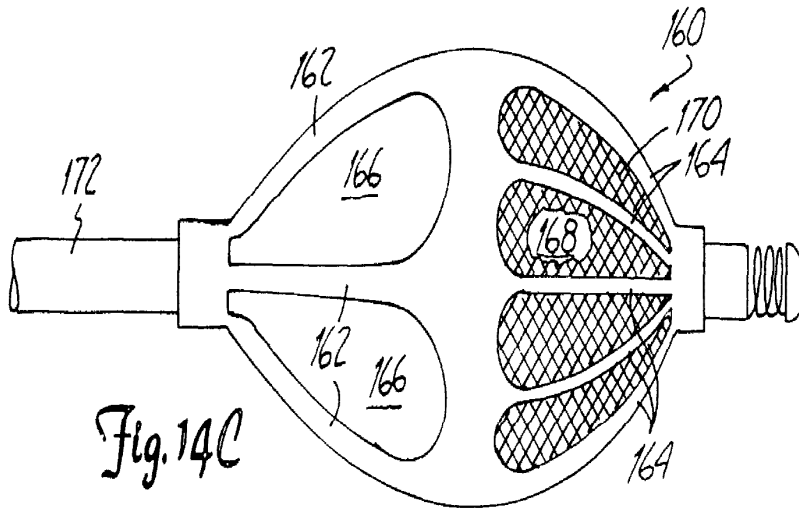


Fig. 14C

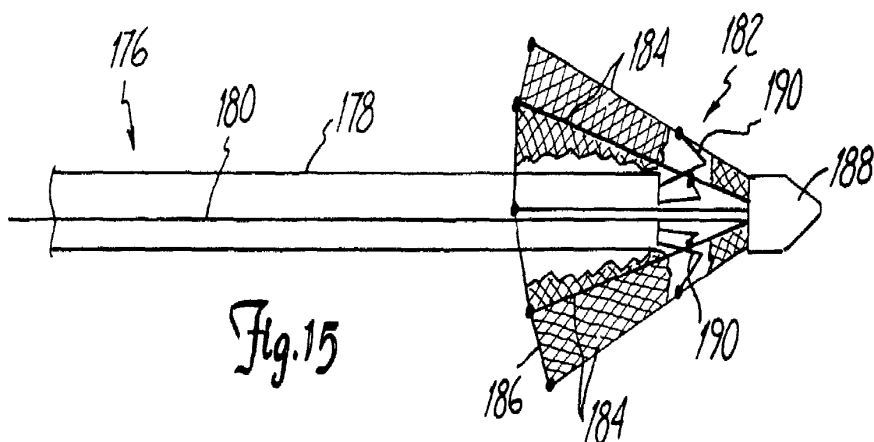


Fig. 15

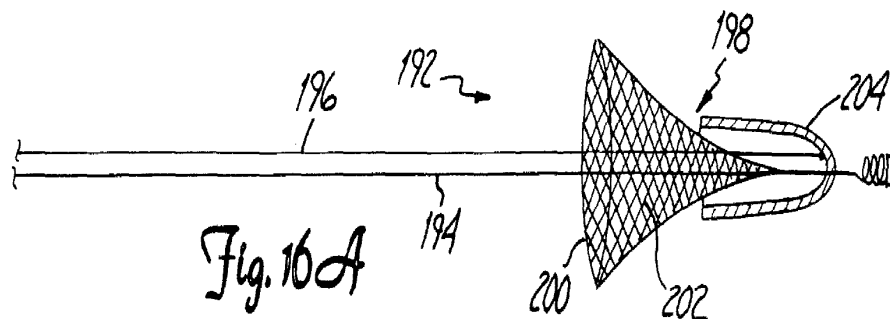


Fig. 16A

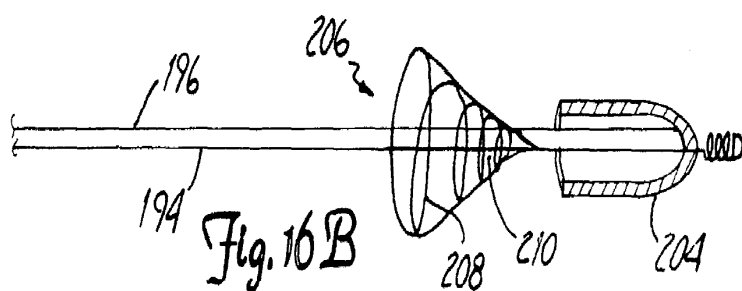
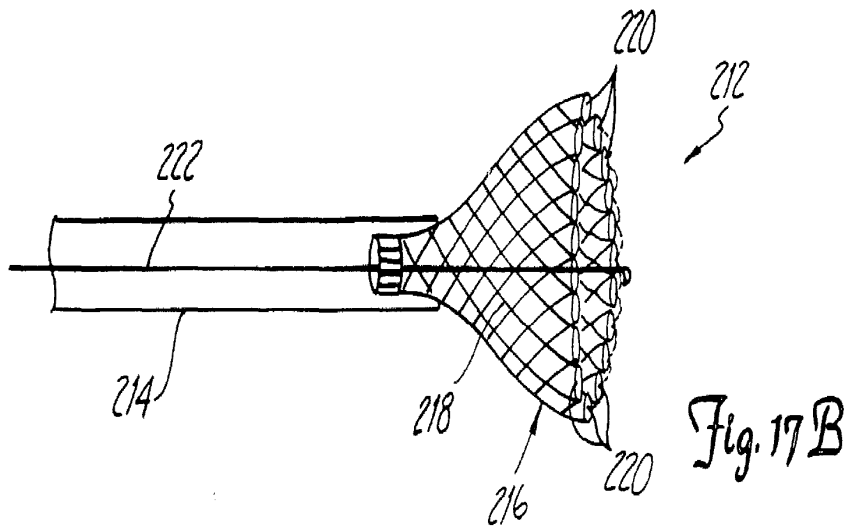
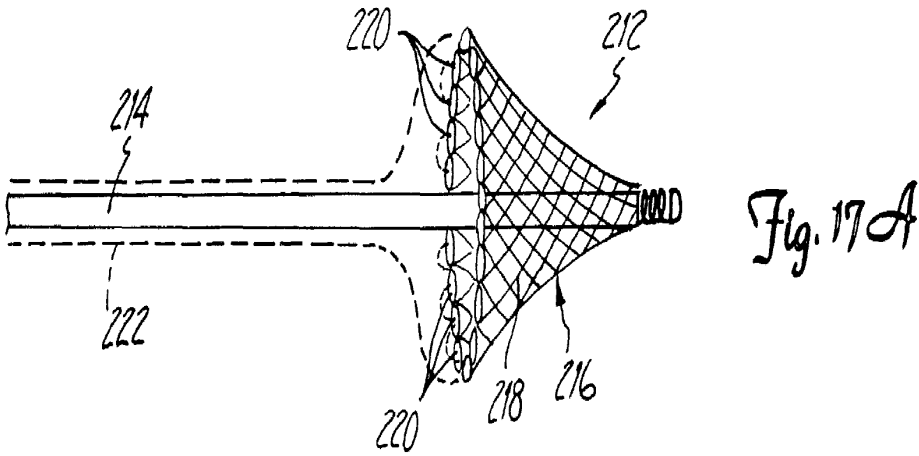


Fig. 16B



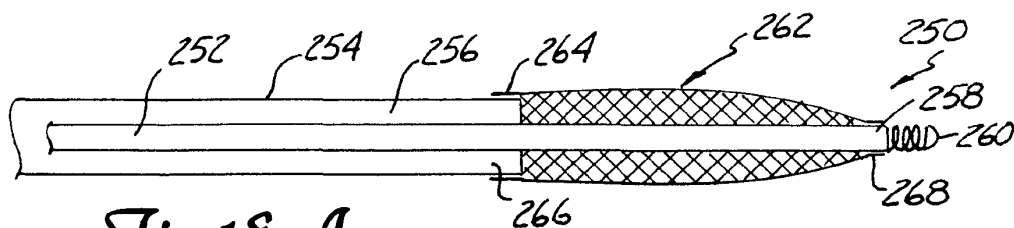


Fig. 18 A

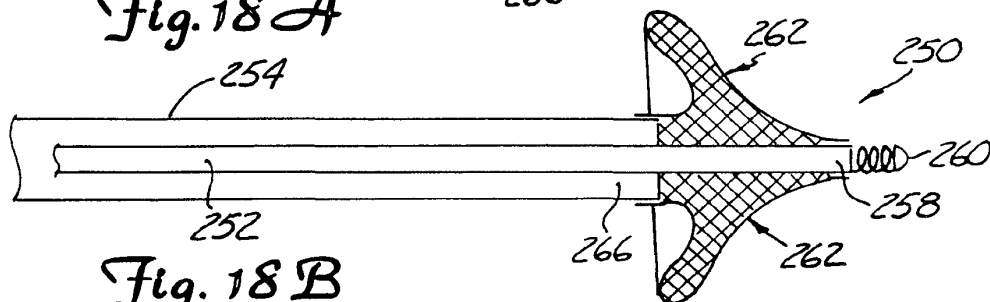


Fig. 18 B

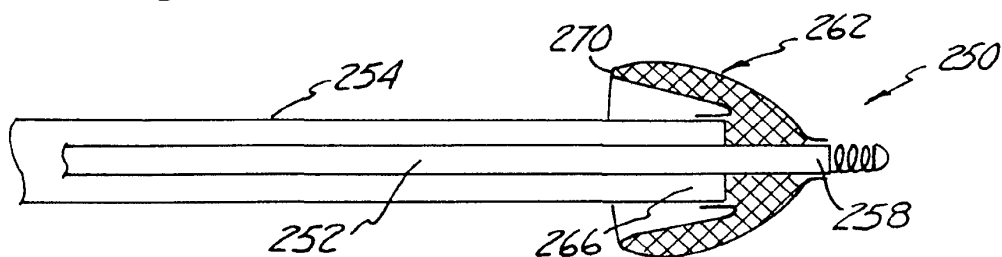


Fig. 18 C

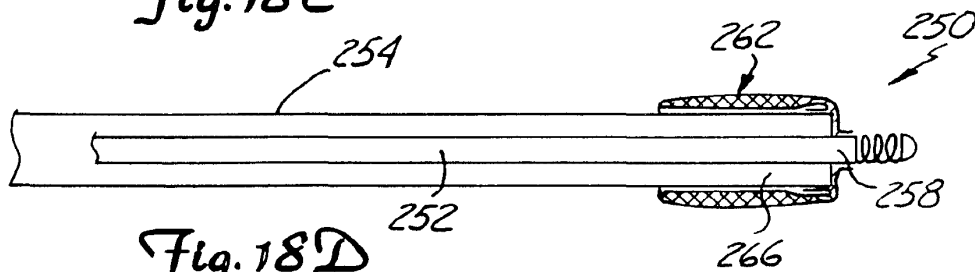


Fig. 18 D

SUBSTITUTE SHEET (rule 26)

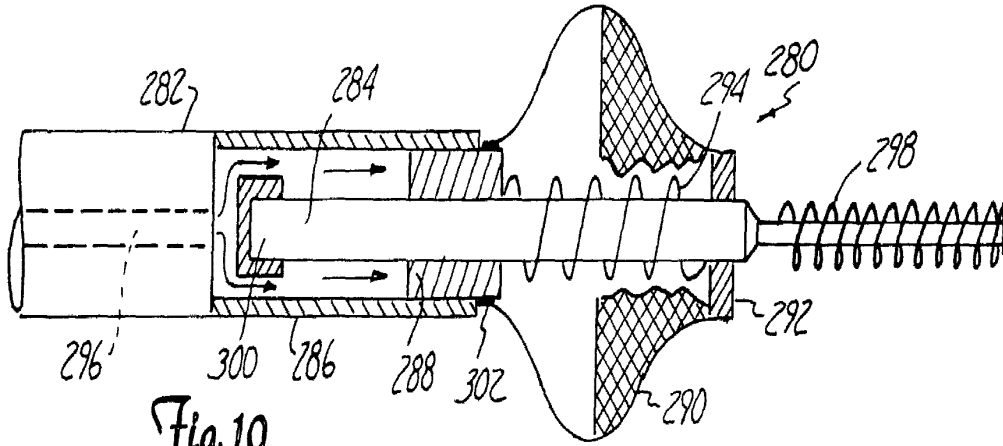


Fig. 19

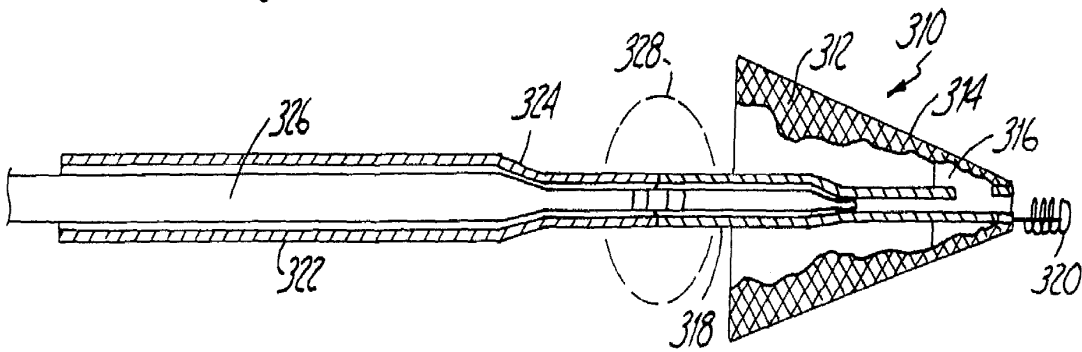


Fig. 20A

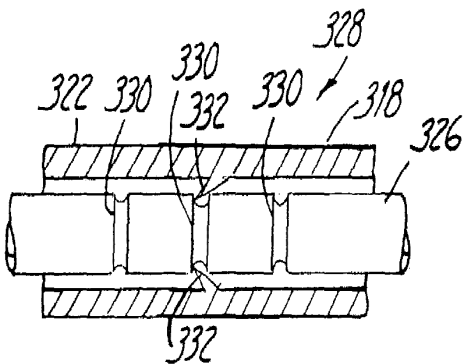
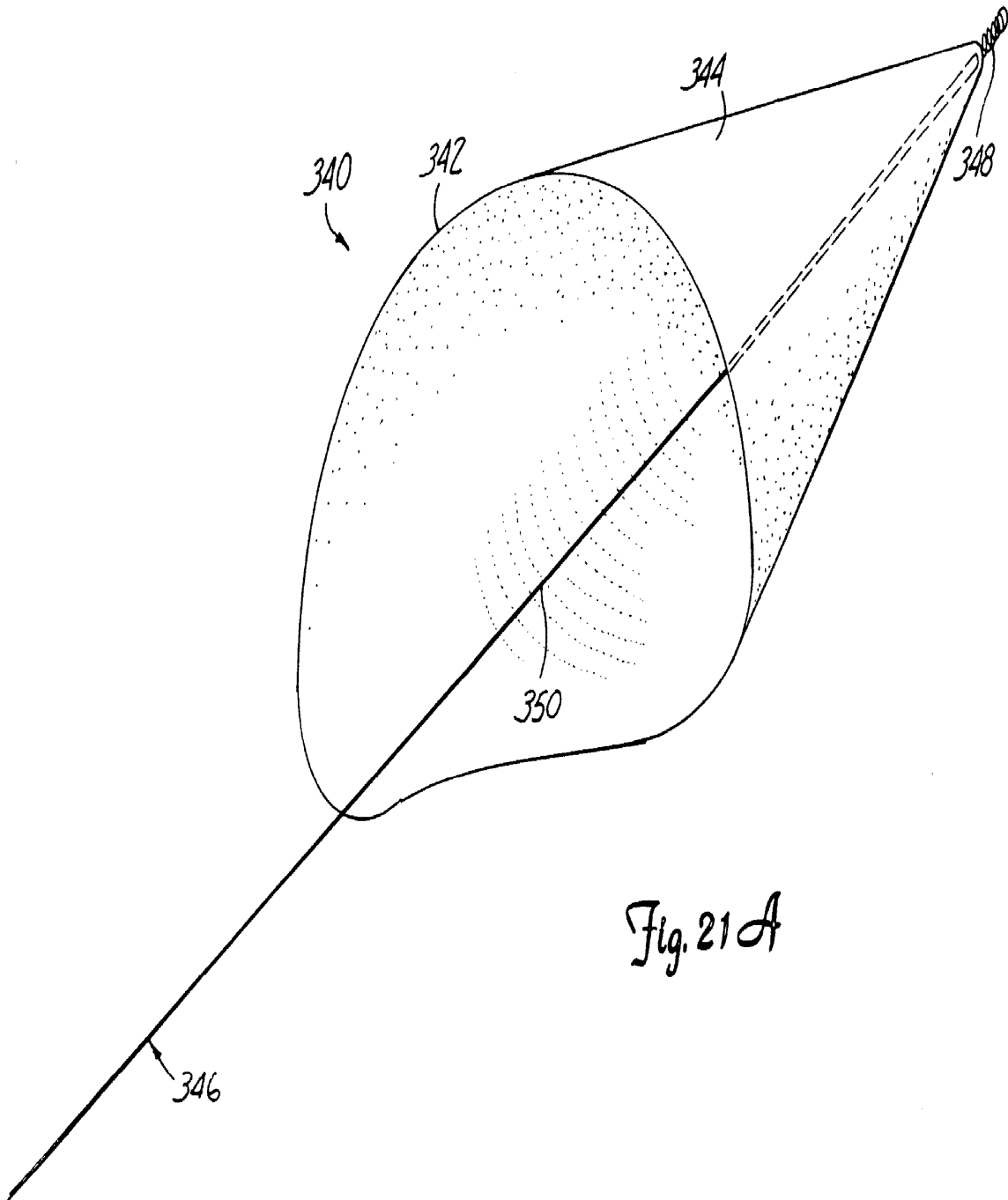


Fig. 20B



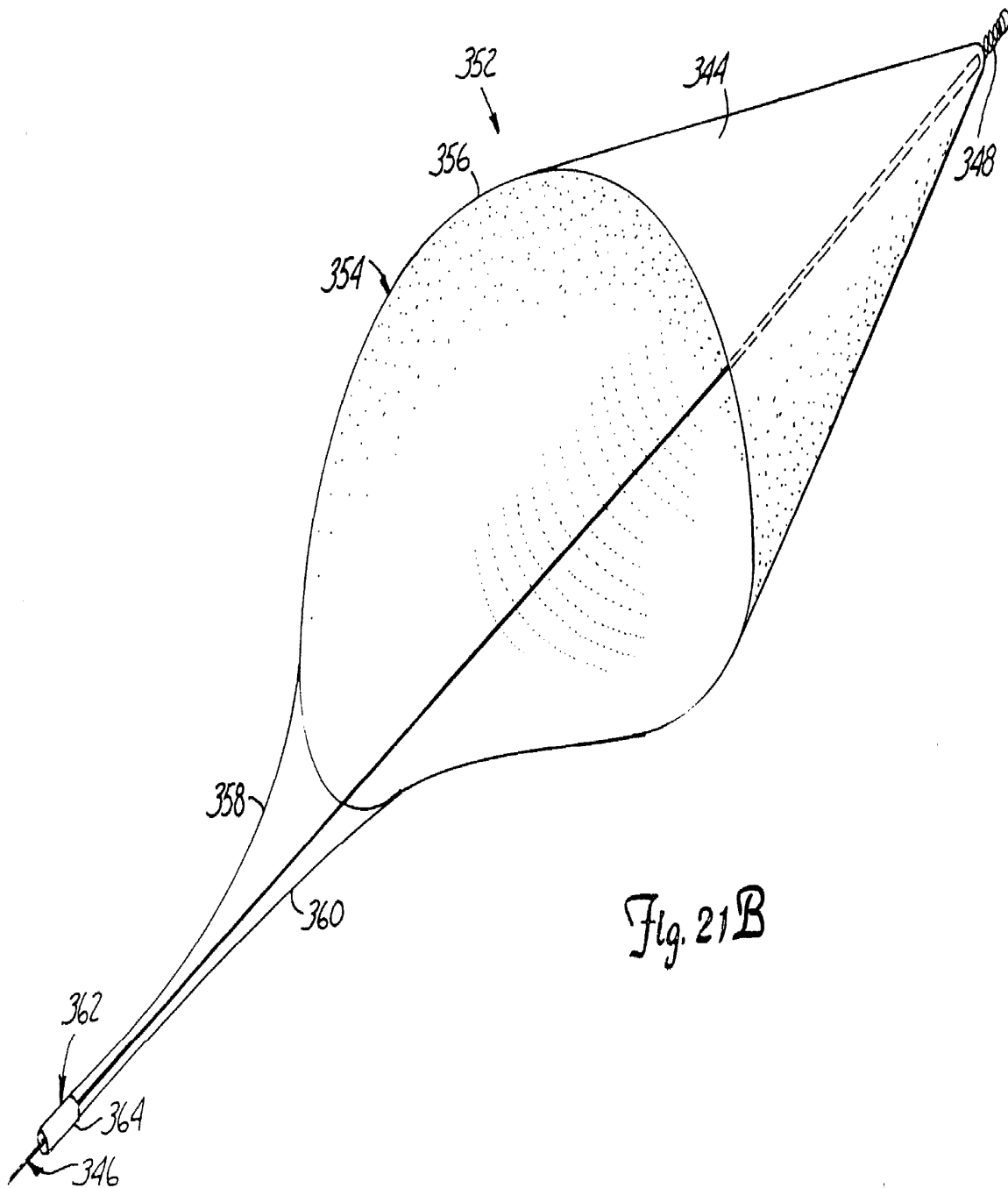


Fig. 21B

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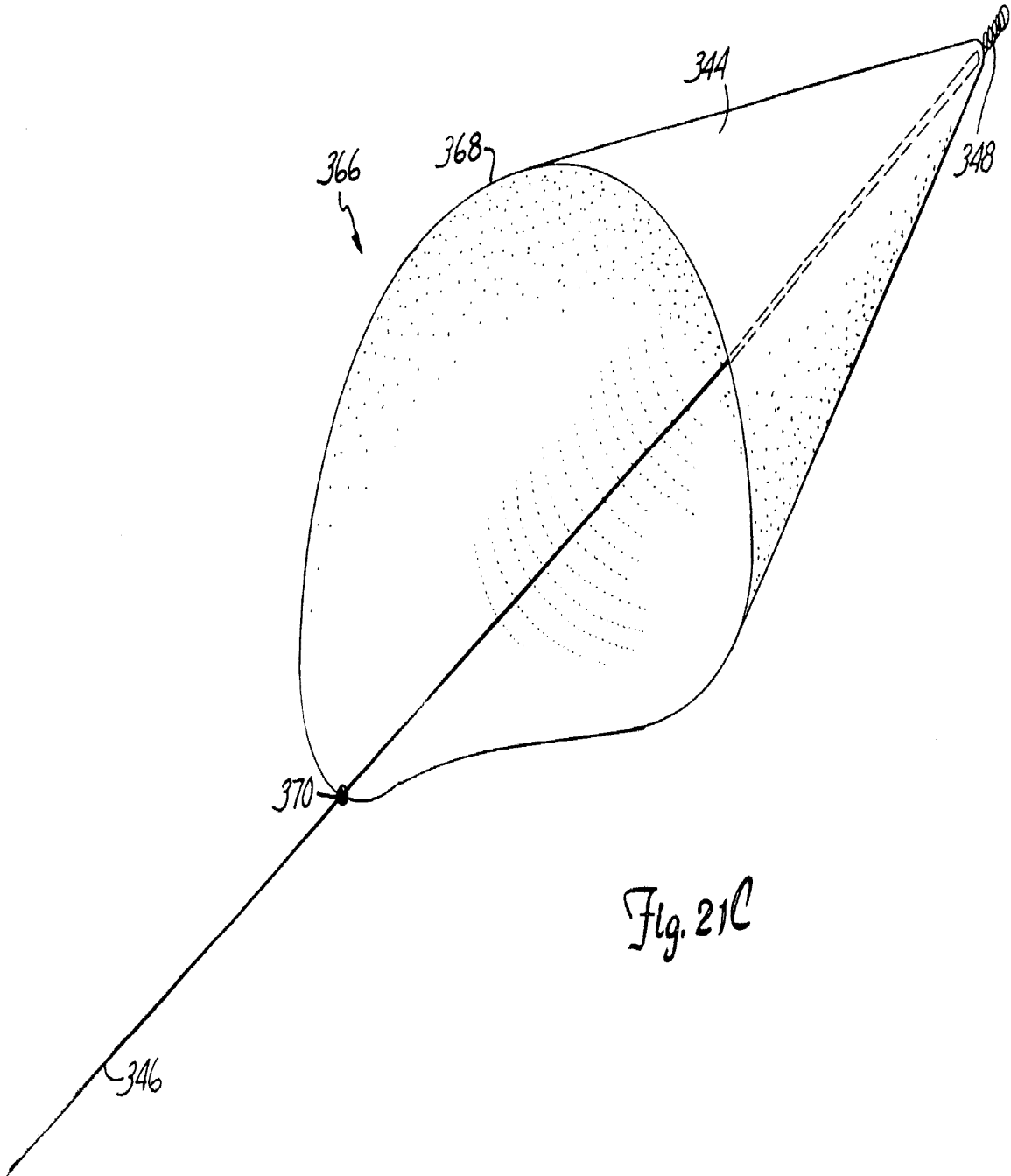
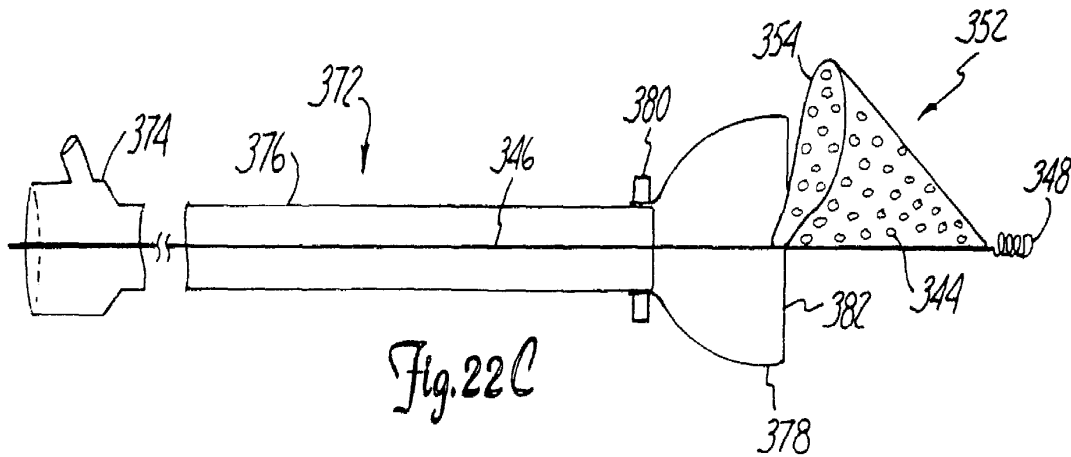
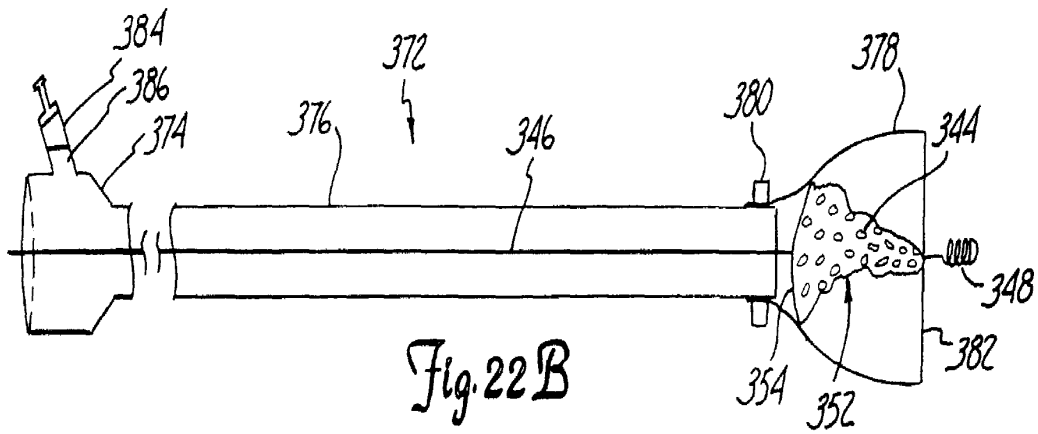
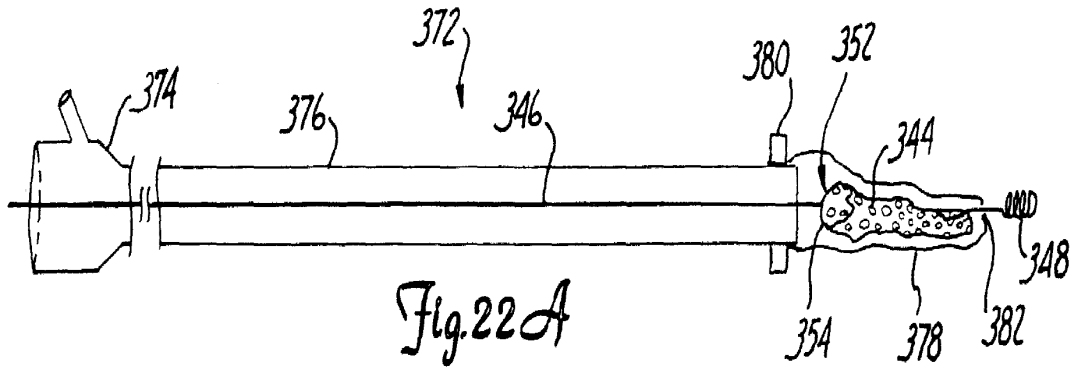
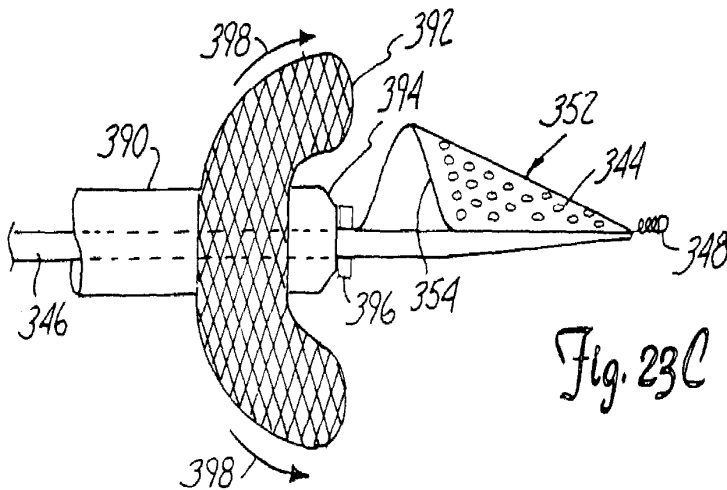
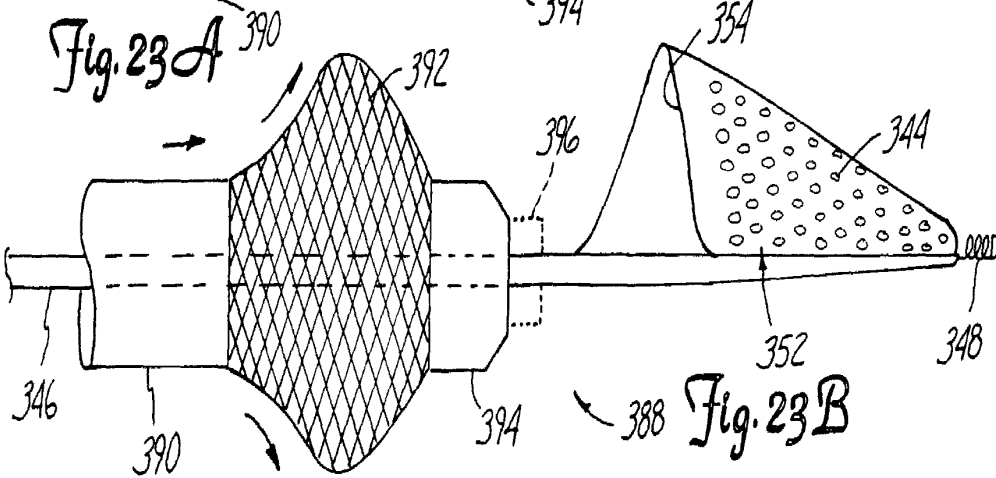
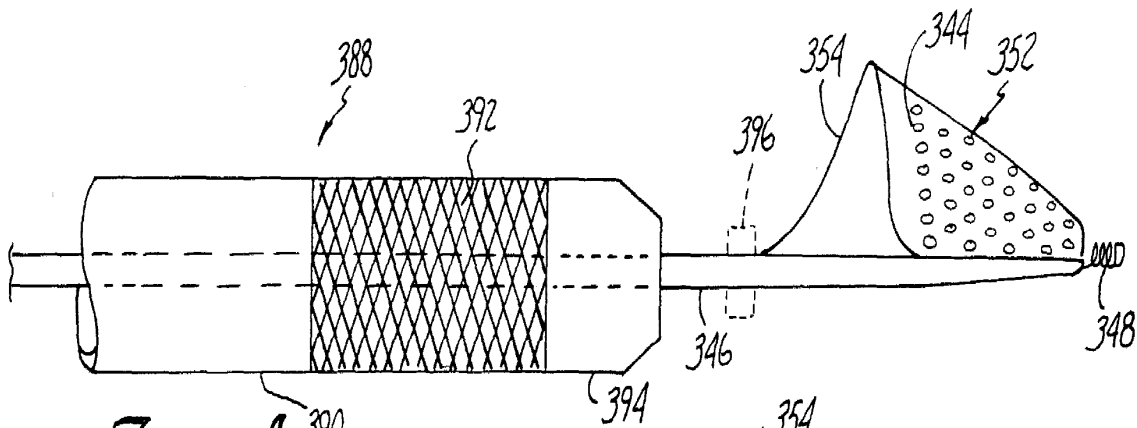


Fig. 21C





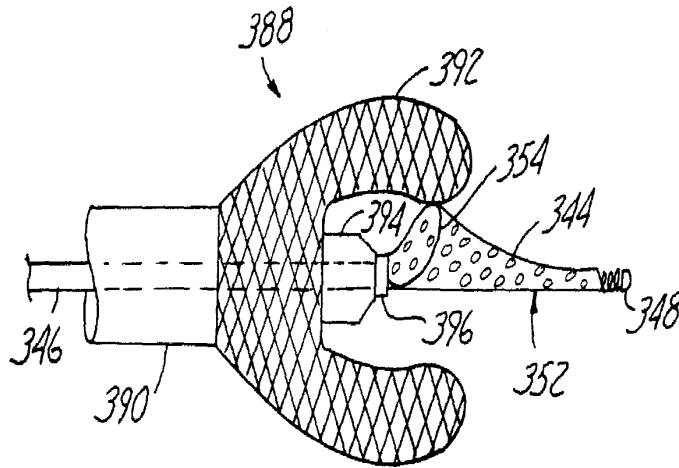


Fig. 23D

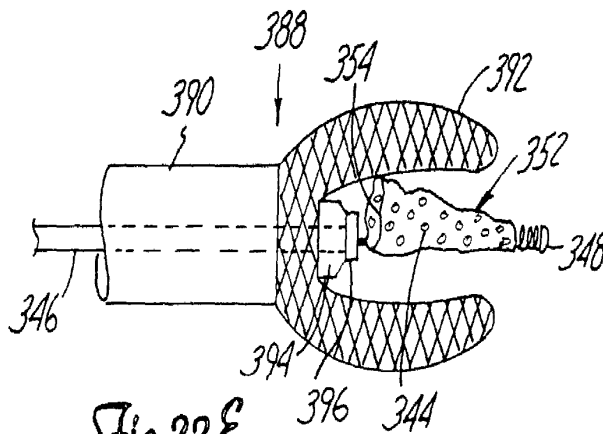
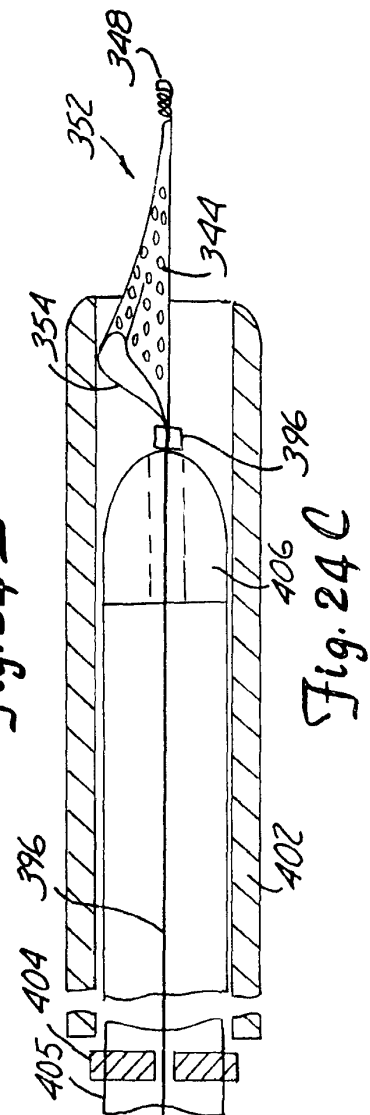
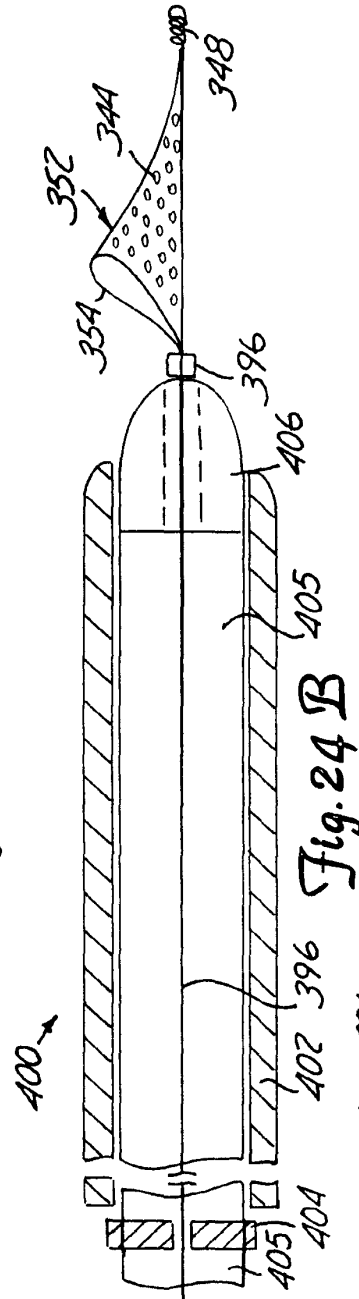
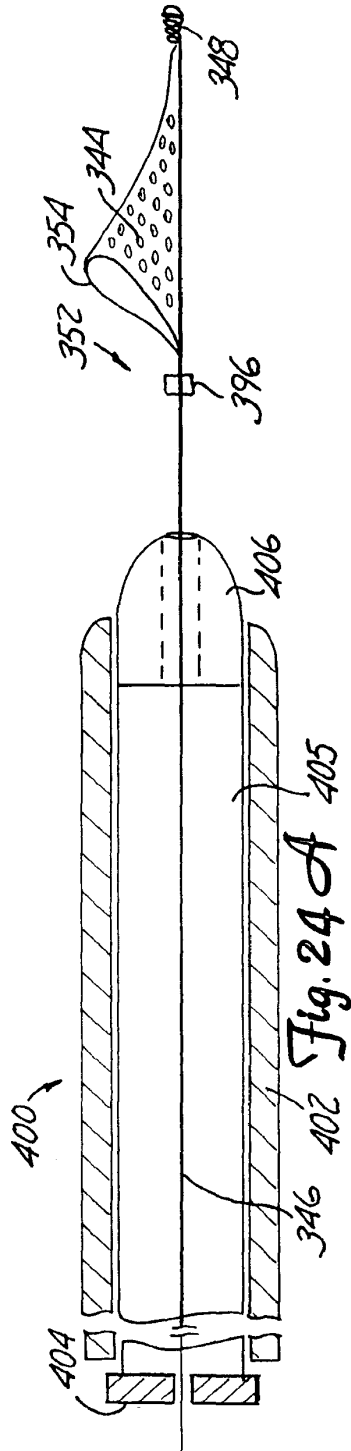


Fig. 23E



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INTERNATIONAL SEARCH REPORT

International application No.
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A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 29/00

US CL :604/22; 606/194, 198, 200

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)

U.S. : 604/22, 104; 606/159, 180, 191, 194, 195, 198, 200

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,102,415 A (GUENTHER ET AL) 07 APRIL 1992, COL. 2 LINES 1-61.	1-30
A	US 4,723,549 A (WHOLEY ET AL) 09 FEBRUARY 1988, COL. 2 LINES 3-36.	1-30
A	US 5,071,407 A (TERMIN ET AL) 10 DECEMBER 1991, COL. 2 LINES 20-68, AND COL. 3 LINES 1-57.	1-30

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

* Special categories of cited documents:	"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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"B" earlier document published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"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	

Date of the actual completion of the international search

02 JUNE 1998

Date of mailing of the international search report

23 JUN 1998

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(54) Title: CATHETERS HAVING SHAPED DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS

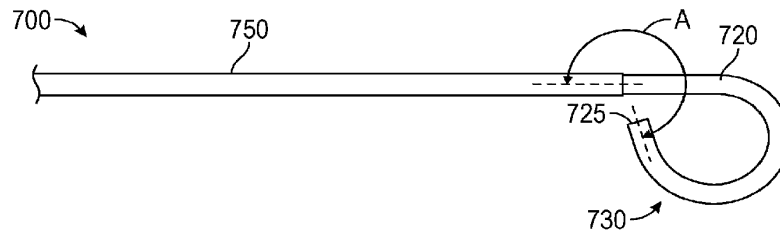


FIG. 7C

(57) Abstract: Disclosed herein are aspiration guide catheters having a pre-shaped distal portion configured to deflect away from a longitudinal axis of the catheter, and associated systems and methods. In some embodiments, an aspiration guide catheter includes an inner liner defining a lumen and having a proximal region and a distal region. The catheter further includes a braid of wires over the inner liner, and a wire coiled around the braid over at least a portion of the distal region of the inner liner. At least a portion of the braid over the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region. The catheter can further include an outer sheath over the braid, the wire, and the inner liner.

WO 2022/109021 A1

INARI_021533

CATHETERS HAVING SHAPED DISTAL PORTIONS,
AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/115,512, filed November 18, 2020, and titled "CATHETERS HAVING SHAPED DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to catheters having shaped (e.g., pre-shaped) distal portions, such as a distal curved portion, to facilitate positioning of the catheter in hard-to-reach regions of the vasculature of a patient.

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-stenosis 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] Figure 2 is an enlarged, partial cut-away side view of a portion of a proximal region of the catheter of Figure 1 in accordance with embodiments of the present technology.

[0013] Figure 3A is an enlarged, partial cut-away side view, and Figure 3B is an enlarged, partial cut-away perspective view, of a portion of a distal region of the catheter of Figure 1 in accordance with embodiments of the present technology.

[0014] Figure 3C is an enlarged cross-sectional view of the distal region of the catheter of Figure 1 taken along the line 3C-3C in Figure 3B in accordance with embodiments of the present technology.

[0015] Figures 4A and 4B are side views of the distal portion of the catheter 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.

[0016] Figures 5A and 5B are side views of the distal portion of the catheter of Figure 1 during a procedure for removing clot material from within a blood vessel of a patient in accordance with additional embodiments of the present technology.

[0017] Figure 6 illustrates various shapes for the distal portion of the catheter of Figure 1 in accordance with additional embodiments of the present technology.

[0018] Figures 7A–7C are side views of a distal portion of a clot treatment system in accordance with additional embodiments of the present technology.

DETAILED DESCRIPTION

[0019] The present technology is generally directed to aspiration guide catheters having a pre-shaped distal portion for improved flexibility through tortuous/hard-to-reach vascular

anatomy, and associated systems and methods. In some embodiments, an aspiration guide catheter includes an inner liner defining a lumen and having a proximal region and a distal region. The catheter can further include a braid of wires over the inner liner, and a wire coiled around the braid over at least a portion of the distal region of the inner liner. At least a portion of the braid over the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region to define a distal shaped portion of the catheter. In some embodiments, the distal shaped portion of the catheter can comprise a curved portion. The catheter can further include an outer sheath over the braid, the wire, and the inner liner and securing these components together.

[0020] In some aspects of the present technology, the catheter is configured to be steered to and positioned in difficult-to-reach regions of the anatomy (e.g., the venous anatomy) of a patient while still having a relatively large lumen (e.g., 20 French, 24 French, greater than 24 French). More particularly, the catheter can have an improved torque response and flexibility compared to conventional catheters having the same lumen size. For example, the braid can provide good torque response along the entire length of the catheter, while the shaped portion is configured to flex into and be positioned within the difficult-to-reach regions of the anatomy. In some embodiments, the outer sheath can have a hardness that decreases in the distal direction to provide (i) good pushability/torquability at the proximal region and (ii) good flexibility at the distal region. Further, the coil can be configured to provide a selected hoop strength at the distal region while still allowing the catheter to flex. For example, the coil can inhibit or even prevent kinking or other unwanted movement of the catheter when the lumen is aspirated during a clot removal procedure.

[0021] Certain details are set forth in the following description and in Figures 1–7C 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.

[0022] 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.

[0023] 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.

[0024] 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.

[0025] 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, and/or a thrombectomy system. In the illustrated embodiment, the clot treatment system 100 includes a tubing assembly 110 fluidly coupled to a catheter 120 via a valve 102. 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.

[0026] In the illustrated embodiment, the catheter 120 includes (i) a proximal region or portion 122, (ii) an intermediate region 124 adjacent to and distal of the proximal region 122, (iii) a distal region 126 adjacent to and distal of the intermediate region 124, and (iv) a distal tip region 128 adjacent to and distal of the distal region 126 (collectively "regions 122–128"). The catheter 120 further defines a lumen 121 extending entirely therethrough from the proximal region 122 to the distal tip region 128. The proximal region 122 defines a proximal terminus 123 of the catheter 120, and the distal tip region 128 defines a distal terminus 125 of the catheter 120. In the illustrated embodiment, the distal tip region 128 includes a marker band 129, 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.

[0027] In some embodiments, the proximal region 122 has a first length, the intermediate region 124 has a second length less than the first length, the distal region 126 has a third length greater than the second length but less than the first length, and the distal tip region 128 has a fourth length less than the first, second, and third lengths. For example, the first length can be between about 20.0–28.0 inches (e.g., about 24.0 inches), the second length can be between about 2.0–3.0 inches (e.g., about 2.50 inches), the third length can be between about 11.00–15.00 inches (e.g., about 13.25 inches), and the fourth length can be between about 0.10–0.50 inch (e.g., about 0.25 inch). In other embodiments, the lengths of one or more of the regions 122–128 can be different.

[0028] In some embodiments, the catheter 120 can have varying flexibilities, shapes, thicknesses, and/or other properties in/along the various regions 122–128. For example, the distal region 126 can include a shaped portion 130 configured (e.g., heat set) to deflect away from a longitudinal axis Z of the catheter 120 relative to the rest of the distal region 126, the intermediate region 124, and the proximal region 122. That is, the shaped portion 130 can be configured to deflect away from the longitudinal axis Z that is aligned with the proximal region 122, the intermediate region 124, and/or the unshaped portion of the distal region 126 proximal to the shaped portion 130. In the illustrated embodiment, the shaped portion 130 has a generally curved shape. In some embodiments, the shaped portion 130 can move between (i) a relaxed position in which the shaped portion 130 has the curved shape illustrated in Figure 1 and (ii) a constrained position in which the shaped portion 130 is more closely aligned with the

longitudinal axis Z, as shown in phantom lines in Figure 1. In some embodiments, the shaped portion 130 has (i) a length L that can be between about 1.0–5.0 inches (e.g., about 2.35 inches), (ii) a bend radius R of between about 0.5–1.0 inch (e.g., about 0.8 inch, less than about 0.8 inch), and/or (iii) a bend angle A of between about 165–195 degrees (e.g., about 180 degrees) or greater than 195 degrees (e.g., between about 250–290 degrees, about 270 degrees). In other embodiments, the bend angle A can be less than 165 degrees.

[0029] In other embodiments, the shaped portion 130 can have other dimensions and/or shapes. For example, Figure 6 illustrates various shapes for the shaped portion 130 of the catheter 120 in accordance with additional embodiments of the present technology. The shaped portion 130 can have any of the shapes illustrated in Figure 6, such as a Tiger curve shape, a Jacky curve shape, an Amplatz left shape, an LCB shape, an RCB shape, a Judkins left shape, a Judkins right shape, a Multipurpose A2 shape, an IM shape, a 3DLIMA shape, a IM VB-1 shape, and so on.

[0030] 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. 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 the proximal direction through the valve 102 as various components such as 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. 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.

[0031] In the illustrated embodiment, the tubing assembly 110 fluidly couples the catheter 120 to a pressure source 106, such as a syringe. 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 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. 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.

[0032] Figure 2 is an enlarged, partial cut-away side view of a portion of the proximal region 122 of the catheter 120 in accordance with embodiments of the present technology. Figure 3A is an enlarged, partial cut-away side view, and Figure 3B is an enlarged, partial cut-away perspective view, of a portion of the distal region 126 of the catheter 120 in accordance with embodiments of the present technology. Referring to Figures 1–3B together, the catheter 120 includes an outer sheath 230 and an inner liner 232 extending through/defining each of the regions 122–128. 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.

[0033] The catheter 120 further includes (i) a braid 234 extending along each of the regions 122–128 between the outer sheath 230 and the inner liner 232 and (ii) a coil 336 (Figures 3A–3C) extending at least partially along the distal region 126 between the braid 234 and the outer sheath 230. In some embodiments, the coil 336 can extend from the distal region 126 at least partially (e.g., entirely) along the intermediate region 124 and/or the proximal region 122. In certain embodiments, the coil 336 is omitted in the proximal region 122 but extends substantially entirely along the intermediate region 124 and the distal region 126.

[0034] In some embodiments, the outer sheath 230 can be formed from a plastic material, elastomeric material, and/or thermoplastic elastomer (TPE) material. In some embodiments, 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." In some embodiments, the outer sheath 230 can have a varying hardness (e.g., durometer), thickness, flexibility, rigidity, and/or other property in one or more of the different regions 122–128. For example, the outer sheath 230 can have a first hardness along the proximal region 122, a second hardness along the intermediate region 124 that is less than the first hardness, a third hardness along the distal region 126 that is less than the first hardness and the second hardness, and a fourth hardness in the distal tip region 128 that is greater than third hardness. In some embodiments, the first hardness and

the fourth hardness can each be between about 65D–75D (e.g., about 72D), the second hardness can be between about 50D–60D (e.g., about 55D), and the third hardness can be between about 30D–40D (e.g., about 35D). In other embodiments, one or more of the regions 122–128 can have a different hardness.

[0035] The inner liner 232 defines the lumen 121 and, in some embodiments, 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 delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and the like. In some embodiments, the inner liner 232 can be 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 can have a diameter D (Figure 2) of greater than about 6 French, 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 8 French, about 16 French, about 20 French, or about 24 French. In certain embodiments, the diameter D of the inner liner 232 is the same in each of the regions 122–128 while, in other embodiments, the diameter D can vary along one or more of the regions 122–128.

[0036] 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. In some embodiments, the wires 238 can comprise metals, polymers, and/or composite materials. At least a portion of the wires 238 at the shaped portion 130 of the catheter 120 can be formed from a shape memory material, a shape memory alloy, and/or a shape memory polymer, such as nickel-titanium alloys (e.g., nitinol). In some embodiments, individual ones of the wires 238 can be 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).

[0037] In the illustrated embodiment, the coil 336 is a single wire wound around the braid 234 and the inner liner 232. In other embodiments, the coil 336 can include more than one wire wound about the braid 234. For example, the coil 336 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. In other embodiments, the coil 336 can be formed directly over the inner liner 232, and the braid 234 can be formed over the coil 336. The coil 336 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. In some embodiments, the coil 336 can include a shape memory material at least at the shaped portion 130 of the catheter 120.

[0038] Figure 3C is an enlarged cross-sectional view of a portion of the distal region 126 of the catheter 120 taken along the line 3C-3C in Figure 3B in accordance with embodiments of the present technology. In the illustrated embodiment, the outer sheath 230 has a first thickness T_1 , the coil 336 has a second thickness T_2 less than the first thickness T_1 , the braid 234 has a third thickness T_3 less than the first thickness T_1 but greater than the second thickness T_2 , and the inner liner 232 has a fourth thickness T_4 less than the first, second, and third thicknesses T_{1-3} . For example, the first thickness T_1 can be between about 0.005–0.010 inch (e.g., between about 0.006–0.007 inch, about 0.006 inch, about 0.007 inch), the second thickness T_2 can be between about 0.001–0.005 inch (e.g., about 0.003 inch), the third thickness T_3 can be between about 0.002–0.006 inch (e.g., about 0.004 inch), and the fourth thickness T_4 can be between about 0.001–0.004 inch (e.g., about 0.002 inch). In other embodiments, one or more of the first through fourth thicknesses T_{1-4} can be different.

[0039] In some embodiments, the catheter 120 can be formed about a mandrel or other elongate member. For example, the inner liner 232 can first be positioned about the mandrel. Then, the braid 234 can be formed (e.g., wound, braided) about the inner liner 232 around the mandrel. Next, the coil 336 can be wound around the mandrel about the braid 234 over the intermediate region 124 and the distal region 126 (e.g., of the inner liner 232 and the braid 234). In some embodiments, the marker band 129 can be positioned about the mandrel at the distal tip region 128. Next, the outer sheath 230 can be positioned over the inner liner 232, the braid 234, and the coil 336, and then heat shrunk or otherwise secured thereto. In some embodiments, the outer sheath 230 can be fused to the coil 336, the braid 234, and/or the inner liner 232 to secure these components of the catheter 120 together.

[0040] Finally, the shaped portion 130 of the catheter 120 can be shaped using a heat setting or other suitable process to have the curved shape illustrated in Figure 1, or another shape (e.g., any of the shapes shown in Figure 6). For example, as is known in the art of heat setting shape memory structures, a fixture, mandrel, or mold may be used to hold the shaped portion

130 in its desired shape, and then the shaped portion 130 can be subjected to an appropriate heat treatment such that the wires 238 of the braid 234 and/or the coil 336 assume or are otherwise shape-set to the outer contour of the mandrel or mold. In some embodiments, only the wires 238 of the braid 234 include a shape memory material that is shaped via the heat setting process. In other embodiments, the coil 336 can alternatively or additionally include a shape memory material that is shaped via the heat setting process. The heat setting process may be performed in an oven or fluidized bed, as is well-known. Therefore, the heat setting process can impart a desired shape, geometry, bend, and/or curve in the super-elastic and/or shape memory material or materials used to form the braid 234 and/or the coil 336. Accordingly, the shaped portion 130 may be radially constrained without plastic deformation (e.g., as shown in phantom in Figure 1) and will self-expand on release of the radial constraint to the position illustrated in Figure 1.

[0041] In some aspects of the present technology, the catheter 120 is configured to 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). More particularly, the catheter 120 can have an improved torque response and flexibility compared to conventional catheters having the same size. For example, the braid 234 can provide good torque response along the entire length of the catheter 120 because the braid 234 extends entirely through each of the regions 122–128 of the catheter 120. Moreover, the varying hardness (e.g., distally decreasing hardness) of the outer sheath 230 can provide (i) good torque response and/or pushability at the proximal region 122 and (ii) increased flexibility at the intermediate and distal regions 124, 126. Additionally, the shaped portion 130 is configured (e.g., shaped, sized, positioned) to flex into and be positioned within the difficult-to-reach regions of the anatomy. Further, the coil 336 can provide increased hoop strength at the distal region 126 while still allowing the catheter 120 to flex. For example, the coil 336 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.

[0042] Figures 4A and 4B are side views of the distal region 126 of the catheter 120 of the clot treatment system 100 during a procedure for removing clot material PE (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 4A and 4B 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.

[0043] With reference to Figures 1 and 4A together, the catheter 120 can be advanced through the patient to proximate the clot material PE 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 PE. In some embodiments, the position of the distal terminus 125 can be confirmed or located via visualization of the marker band 129 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 PE or distal of the clot material PE.

[0044] In some aspects of the present technology, the shaped portion 130 helps the catheter 120 flex/bend into tortuous (e.g., hard-to-reach) regions of the blood vessel BV. For example, in the illustrated embodiment the shaped portion 130 has flexed around a bend 440 in the blood vessel BV that can have a relatively small radius of curvature. The portion of the blood vessel BV distal of the bend 440 can be difficult to reach due to the required approach angle, varying anatomy of the blood vessel BV, and/or irregularities due to illness of the patient. In some embodiments, the blood vessel BV can be a portion of left pulmonary artery, the temporal arteries, the inferior vena cava, or the right atrium. In some embodiments, the clot material PE can be a clot in transit (CIT) within the right atrium.

[0045] In some embodiments, before advancing the catheter 120 to the position shown in Figure 4A, the catheter 120 can be rotated to align the shaped portion 130 with the bend 440 (e.g., to at least generally align a deflection direction of the shaped portion 130 with the bend 440). In contrast to the catheter 120 of the present technology, conventional catheters of the same size may be too stiff to easily position proximate the clot material PE. For example, such conventional catheters may "rainbow" over the clot material PE by following or tracking along the wall of the blood vessel BV at the outside of the bend 400. In addition to the shaped portion 130, both (i) the varying hardness of the outer sheath 230 (Figures 2–3C) and (ii) the flexibility of the braid 234 (Figures 2–3C) and the coil 446 (Figures 3A–3C) can help the catheter 120 flex through the anatomy of the blood vessel BV to the desired position proximate the clot material PE.

[0046] 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 PE, 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 PE. In other embodiments, the guidewire can be extended to a location just proximal of the clot material PE. After positioning the guidewire, the catheter 120 can be placed over the guidewire and advanced to the position proximate to the clot material PE as illustrated in Figure 4A. 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, etc., 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 PE.

[0047] With reference to Figures 1 and 4B 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 PE, 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.

[0048] 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 tip region 128 of the catheter 120 to suck/aspirate at least a portion of the clot material PE into the lumen 121 of the catheter 120, as shown in Figure 4B. 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 tip region 128 of the catheter 120 compared to simply activating the pressure source 106 while it is fluidly connected to the catheter 120.

[0049] Sometimes, as shown in Figure 4B, 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 PE from the blood vessel BV. That is, a single aspiration pulse may adequately remove the clot material PE from the blood vessel BV. In other embodiments, a portion of the clot material PE may remain in the blood vessel BV. In such instances, the user may wish to again apply vacuum pressure (conduct an "aspiration pass") to remove all or a portion of the remaining clot material PE 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 PE, the catheter 120 can be withdrawn from the patient.

[0050] In some aspects of the present technology, the relatively great flexibility and torquability of the catheter 120 allow the catheter 120 to be positioned in difficult-to-reach areas of the blood vessel BV (or elsewhere in the vasculature of the patient) without reducing the size of the lumen 121. It is expected that the increased size of the lumen 121 will provide greater suction forces over a smaller period of time (e.g., will provide a larger vacuum impulse). In some embodiments, the greater suction forces can facilitate the removal of clot material from a blood vessel of a patient even where the clot material is strongly lodged or attached within the blood vessel (e.g., a chronic clot). Accordingly, in contrast to conventional catheters, the catheter 120 can be used to generate greater aspirational forces for improved clot removal in hard-to-reach places of the vasculature. In additional aspects of the present technology, the coil 336 (Figures 3A–3C) can provide a high hoop strength along the distal region 126 of the catheter 120 that inhibits or even prevents kinking or other unwanted movement of the catheter 120 when

the pressure source 106 is used to generate a suction pulse at the distal region 126 of the catheter 120.

[0051] Figures 5A and 5B are side views of the distal region 126 of the catheter 120 of the clot treatment system 100 during another procedure for removing the clot material PE from within the blood vessel BV in accordance with additional embodiments of the present technology. As noted above, in some embodiments the clot removal procedure illustrated in Figures 5A and 5B 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.

[0052] Referring first to Figure 5A, the catheter 120 ("first catheter 120") can be advanced through the patient to proximate the clot material PE with the blood vessel BV as described in detail above with reference to Figure 4A. As shown in Figure 5A, in some embodiments a second catheter 550 can then be advanced over the first catheter 120 to proximate the clot material PE. The second catheter 550 can define a lumen 552 having a larger size (e.g., 20 French or greater, 24 French or greater) than the lumen 121 of the first catheter 120. In some embodiments, the second catheter 550 has a greater stiffness than the first catheter 120. In other embodiments, the second catheter 550 can be larger than but generally similar or identical to the first catheter 120 (e.g., having a distal heat-set shaped portion).

[0053] Accordingly, the first catheter 120 can act as a guide or rail for guiding the advancement of the second catheter 550 to proximate the clot material PE. In some aspects of the present technology, the larger size and/or stiffness of the second catheter 550 could make the second catheter 550 difficult to navigate to proximate the clot material PE (e.g., across the bend 440) without the first catheter 120 acting as a guide. That is, the first catheter 120 can be flexibly positioned proximate the clot material PE and used to guide the larger and/or stiffer second catheter 550 into a position it would otherwise be difficult or impossible to do so.

[0054] The second catheter 550 can be part of a clot treatment system (not shown) having features generally similar or identical to that of the clot treatment system 100 of Figure 1 including, for example, a fluid control device and a pressure source. Accordingly, with reference to Figure 5B, the pressure source can be used to generate a vacuum in the lumen 552 of the second catheter, and the fluid control device can be opened to fluidly connect the pressure source to the second catheter 550 and thereby apply or release the vacuum stored in the pressure source

to the lumen 552 of the second catheter 550. Opening of the fluid control device instantaneously or nearly instantaneously applies the stored vacuum pressure to the second catheter 550, thereby generating a suction pulse throughout the second catheter 550 that can suck at least a portion of the clot material PE into the lumen 552 of the second catheter 550. In some embodiments, the clot treatment system 100 (Figure 1) can also be operated to aspirate the clot material PE into the lumen 121 of the first catheter 120, as described in detail above with reference to Figures 4A and 4B. In some aspects of the present technology, the larger size of the lumen 552 of the second catheter 550 can be used to generate greater suction forces than the smaller lumen 121 of the first catheter 120. After removing a desired amount of the clot material PE, the first and second catheters 120, 550 can be withdrawn from the patient.

[0055] Referring to Figures 4A–5B together, in some embodiments one or more additional devices can be advanced through the catheter 120. For example, one or more aspiration catheters, mechanical thrombectomy devices, and/or the like can be advanced through the catheter 120 to proximate the clot material PE to aid in the clot removal process. In some such embodiments, the shaped portion 130 can facilitate the advancement of the one or more additional devices through the catheter 120. For example, the one or more additional devices can track through the shaped portion 130 of the catheter 120 to at and/or proximate the clot material PE.

[0056] Figures 7A–7C are side views of a distal portion of a clot treatment system 700 in accordance with embodiments of the present technology. Referring to Figures 7A–7C together, the clot treatment system 700 can include some features that are least at generally similar in structure and function, or identical in structure and function, to the corresponding features of the clot treatment system 100 described in detail above with reference to Figures 1–6, and can operate in a generally similar or identical manner to the clot treatment system 100. In the illustrated embodiment, for example, the clot treatment system 700 includes a first catheter 720 (e.g., a pre-shaped catheter) that can be advanced through a larger second catheter 750. The first catheter 720 can have a shaped distal portion 730 (obscured in Figure 7A) including a distal tip or terminus 725. In some embodiments the first catheter 720 has a size of about 20 French or greater than 20 French, and the second catheter 750 has a size of about 24 French or greater than 24 French.

[0057] Figures 7A–7C illustrate the sequential deployment of the shaped distal portion 730 from within the second catheter 750. More specifically, the shaped distal portion 730 is (i)

positioned substantially within and constrained by the second catheter 750 in Figure 7A, (ii) positioned partially within and partially outside the second catheter 750 in Figure 7B, and (iii) positioned substantially outside of (e.g., distal of) and constrained by the second catheter 750 in Figure 7C. In the illustrated embodiment, the shaped distal portion 730 is configured (e.g., heat set) to deflect away from a longitudinal axis Z (Figures 7A) of the first and second catheters 720, 750 to have a generally curved shape. In some embodiments, the shaped distal portion 730 can deflect by an angle A of between about 250–290 degrees (e.g., about 255 degrees, about 260 degrees, about 270 degrees) when fully unconstrained by the second catheter 750 as shown in Figure 7C. The shaped distal portion 730 can be deployed from the second catheter 750 via advancement of the first catheter 720 relative to the second catheter 750 and/or retraction of the second catheter 750 relative to the first catheter 720. That is, for example, the second catheter 750 can be retracted off of the shaped distal portion 730 such that the shaped distal portion 730 is no longer constrained by the second catheter 750 and thereby able to deflect away from the longitudinal axis Z as shown in Figure 7C.

[0058] Several aspects of the present technology are set forth in the following examples:

1. An aspiration catheter, comprising:
an inner liner defining a lumen and having a proximal region and a distal region;
a braid of wires over the inner liner, wherein a deflectable portion of the braid over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained;
a wire coiled over at least a portion of the distal region of the inner liner; and
an outer sheath over the braid, the wire, and the inner liner.
2. The aspiration catheter of example 1 wherein the wires in the deflectable portion of the braid is pre-shaped to deflect away from the longitudinal axis.
3. The aspiration catheter of example 1 or example 2 wherein the deflectable portion of the braid is configured to deflect away from the longitudinal axis to have a bend angle of between about 165–195 degrees when the aspiration catheter is unconstrained.

4. The aspiration catheter of example 1 or example 2 wherein the deflectable portion of the braid is configured to deflect away from the longitudinal axis to have a bend angle of between about 270 degrees when the aspiration catheter is unconstrained.

5. The aspiration catheter of any one of examples 1–4 wherein the lumen has a diameter of 20 French or greater.

6. The aspiration catheter of any one of examples 1–5 wherein the lumen has a diameter of 24 French or greater.

7. The aspiration catheter of any one of examples 1–6 wherein the inner liner is formed from polytetrafluoroethylene material, and wherein the outer sheath is formed from a thermoplastic elastomer material.

8. The aspiration catheter of any one of examples 1–7 wherein the outer sheath has a first hardness over the proximal region of the inner liner, and wherein the outer sheath has a second hardness over the distal region of the inner liner that is less than the first hardness.

9. An aspiration catheter, comprising:
a proximal region defining a longitudinal axis;
an intermediate region extending from the proximal region;
a distal region extending from the intermediate region;
an inner lining defining a lumen and extending through the proximal region, the intermediate region, and the distal region;
a braid of wires extending over the inner liner and through the proximal region, the intermediate region, and the distal region, wherein a deflectable portion of the braid in the distal region is configured to deflect away from the longitudinal axis when the aspiration catheter is unconstrained;
a wire coiled in the distal region; and
an outer sheath extending over the braid, the wire, and the inner liner and through the proximal region, the intermediate region, and the distal region.

10. The aspiration catheter of example 9 wherein the deflectable portion of the braid is configured to deflect away from the longitudinal axis to have a bend angle of between about 165–195 degrees when the aspiration catheter is unconstrained.

11. The aspiration catheter of example 9 or example 10 wherein the outer sheath has (a) a first hardness in the proximal region of between about 65D–75D, (b) a second hardness in the intermediate region of between about 50D–60D, and (c) a third hardness in the distal region of between about 30D–40D.

12. The aspiration catheter of any one of examples 9–11 wherein the outer sheath has (a) a first hardness in the proximal region, (b) a second hardness in the intermediate region less than the first hardness, and (c) a third hardness in the distal region less than the second hardness.

13. The aspiration catheter of example 12 wherein (a) the proximal region has a first length, (b) the intermediate region has a second length less than the first length, and (c) the distal region has a third length greater than the second length and less than the first length.

14. The aspiration catheter of example 13 wherein the first length is between about 20.0–28.0 inches, the second length is between about 2.0–3.0 inches, and the third length is between about 11.00–15.00 inches.

15. A method of removing clot material from a blood vessel, the method comprising:
advancing an aspiration catheter through the blood vessel, wherein the aspiration catheter includes a distal portion and a proximal portion, wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion;
positioning a distal tip of the aspiration catheter proximate the clot material;
activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and
opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter.

16. The method of example 15 wherein the distal portion of the aspiration catheter is configured to deflect away from the longitudinal axis in a deflection direction, and wherein the method further comprises rotating the aspiration catheter such that the deflection direction is at least partially aligned with a bend in the blood vessel.

17. The method of example 15 or example 16 wherein the aspiration catheter has a size of 20 French or greater.

18. The method of any one of examples 15–17 wherein the distal portion of the aspiration catheter is configured to deflect away from the longitudinal axis to have a bend angle of between about 165–195 degrees when the aspiration catheter is unconstrained.

19. The method of any one of examples 15–17 wherein the distal portion of the aspiration catheter is configured to deflect away from the longitudinal axis to have a bend angle of about 270 degrees when the aspiration catheter is unconstrained.

20. The method of any one of examples 15–19 wherein the distal portion of the aspiration catheter includes—

- an inner liner defining a lumen;
- a braid of wires extending over the inner liner;
- a wire coiled around the braid; and
- an outer sheath extending over the braid.

[0059] 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.

[0060] 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.

[0061] 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:
an inner liner defining a lumen and having a proximal region and a distal region;
a braid of wires over the inner liner, wherein a deflectable portion of the braid over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained;
a wire coiled over at least a portion of the distal region of the inner liner; and
an outer sheath over the braid, the wire, and the inner liner.
2. The aspiration catheter of claim 1 wherein the wires in the deflectable portion of the braid is pre-shaped to deflect away from the longitudinal axis.
3. The aspiration catheter of claim 1 wherein the deflectable portion of the braid is configured to deflect away from the longitudinal axis to have a bend angle of between about 165–195 degrees when the aspiration catheter is unconstrained.
4. The aspiration catheter of claim 1 wherein the deflectable portion of the braid is configured to deflect away from the longitudinal axis to have a bend angle of between about 270 degrees when the aspiration catheter is unconstrained.
5. The aspiration catheter of claim 1 wherein the lumen has a diameter of 20 French or greater.
6. The aspiration catheter of claim 1 wherein the lumen has a diameter of 24 French or greater.
7. The aspiration catheter of claim 1 wherein the inner liner is formed from polytetrafluoroethylene material, and wherein the outer sheath is formed from a thermoplastic elastomer material.

8. The aspiration catheter of claim 1 wherein the outer sheath has a first hardness over the proximal region of the inner liner, and wherein the outer sheath has a second hardness over the distal region of the inner liner that is less than the first hardness.

9. An aspiration catheter, comprising:
a proximal region defining a longitudinal axis;
an intermediate region extending from the proximal region;
a distal region extending from the intermediate region;
an inner lining defining a lumen and extending through the proximal region, the intermediate region, and the distal region;
a braid of wires extending over the inner liner and through the proximal region, the intermediate region, and the distal region, wherein a deflectable portion of the braid in the distal region is configured to deflect away from the longitudinal axis when the aspiration catheter is unconstrained;
a wire coiled in the distal region; and
an outer sheath extending over the braid, the wire, and the inner liner and through the proximal region, the intermediate region, and the distal region.

10. The aspiration catheter of claim 9 wherein the deflectable portion of the braid is configured to deflect away from the longitudinal axis to have a bend angle of between about 165–195 degrees when the aspiration catheter is unconstrained.

11. The aspiration catheter of claim 9 wherein the outer sheath has (a) a first hardness in the proximal region of between about 65D–75D, (b) a second hardness in the intermediate region of between about 50D–60D, and (c) a third hardness in the distal region of between about 30D–40D.

12. The aspiration catheter of claim 9 wherein the outer sheath has (a) a first hardness in the proximal region, (b) a second hardness in the intermediate region less than the first hardness, and (c) a third hardness in the distal region less than the second hardness.

13. The aspiration catheter of claim 12 wherein (a) the proximal region has a first length, (b) the intermediate region has a second length less than the first length, and (c) the distal region has a third length greater than the second length and less than the first length.

14. The aspiration catheter of claim 13 wherein the first length is between about 20.0–28.0 inches, the second length is between about 2.0–3.0 inches, and the third length is between about 11.00–15.00 inches.

15. A method of removing clot material from a blood vessel, the method comprising:
advancing an aspiration catheter through the blood vessel, wherein the aspiration catheter includes a distal portion and a proximal portion, wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion;
positioning a distal tip of the aspiration catheter proximate the clot material;
activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and
opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter.

16. The method of claim 15 wherein the distal portion of the aspiration catheter is configured to deflect away from the longitudinal axis in a deflection direction, and wherein the method further comprises rotating the aspiration catheter such that the deflection direction is at least partially aligned with a bend in the blood vessel.

17. The method of claim 15 wherein the aspiration catheter has a size of 20 French or greater.

18. The method of claim 15 wherein the distal portion of the aspiration catheter is configured to deflect away from the longitudinal axis to have a bend angle of between about 165–195 degrees when the aspiration catheter is unconstrained.

19. The method of claim 15 wherein the distal portion of the aspiration catheter is configured to deflect away from the longitudinal axis to have a bend angle of about 270 degrees when the aspiration catheter is unconstrained.

20. The method of claim 15 wherein the distal portion of the aspiration catheter includes—

- an inner liner defining a lumen;
- a braid of wires extending over the inner liner;
- a wire coiled around the braid; and
- an outer sheath extending over the braid.

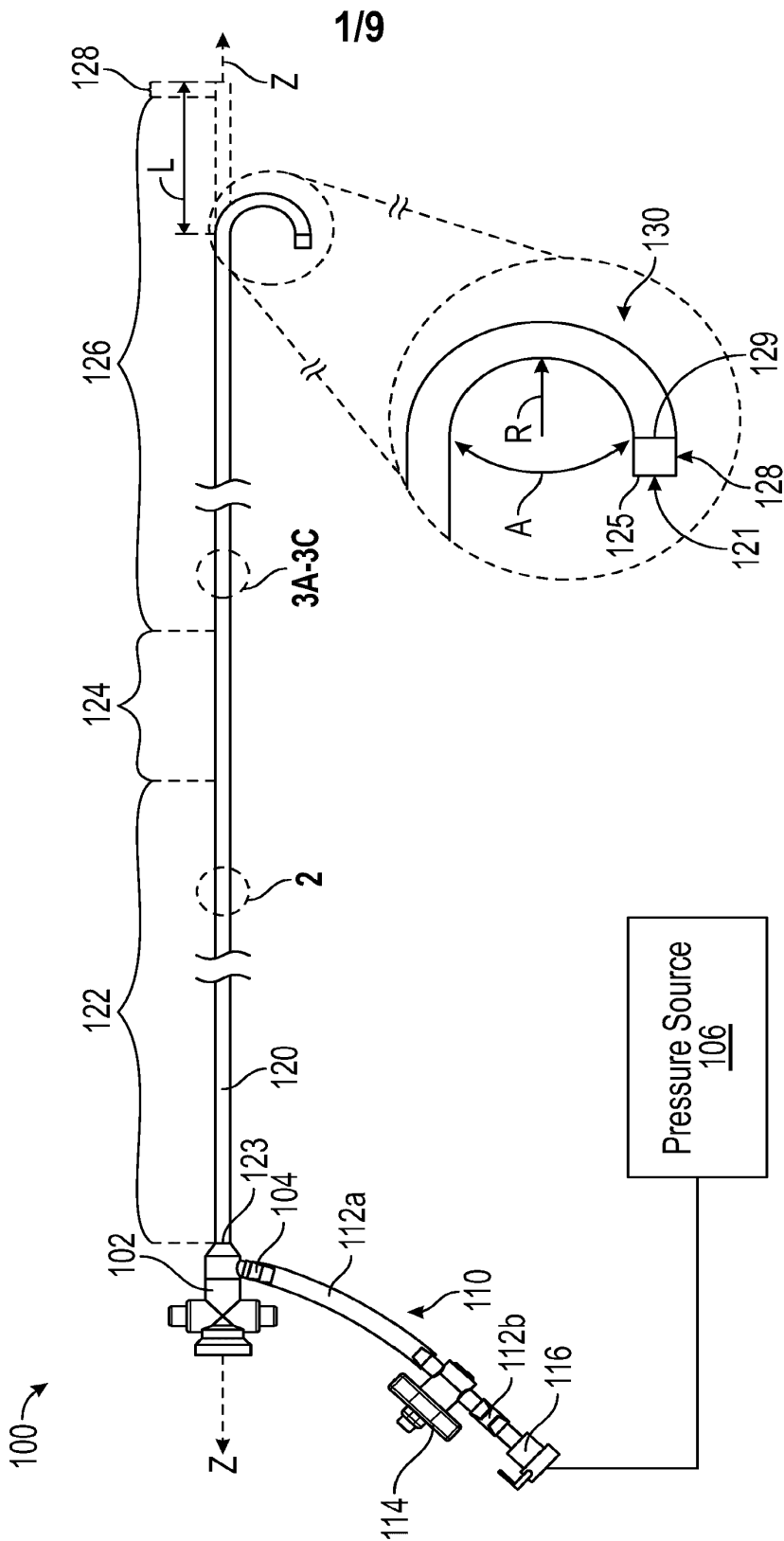


FIG. 1

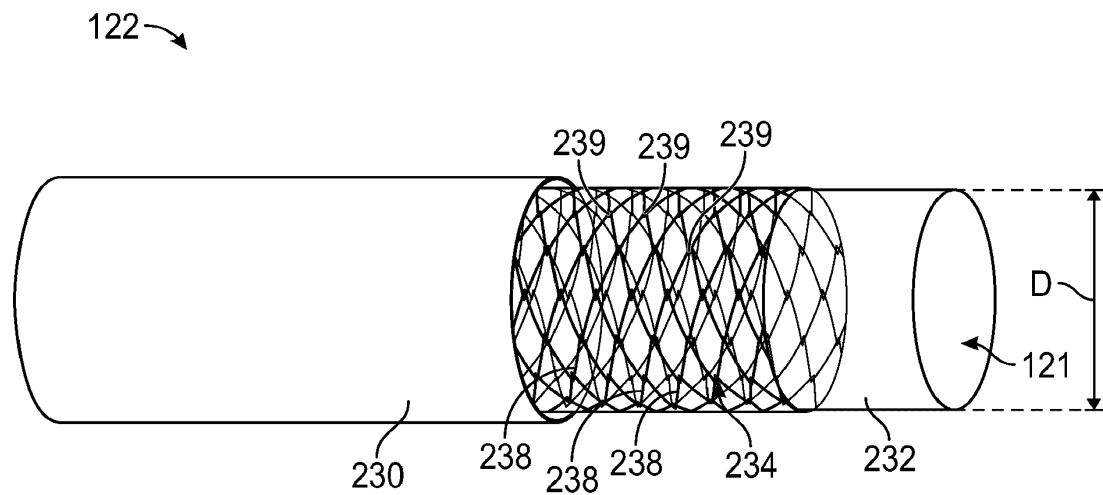


FIG. 2

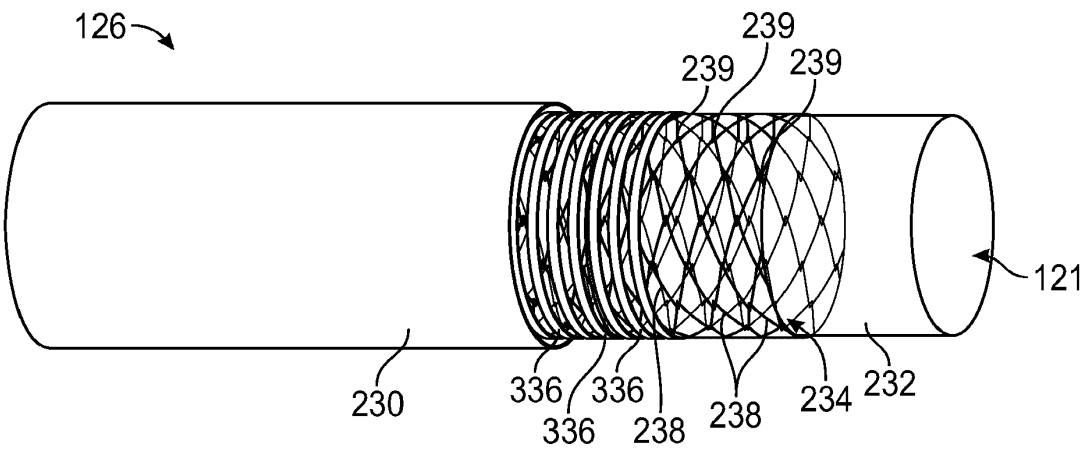


FIG. 3A

3/9

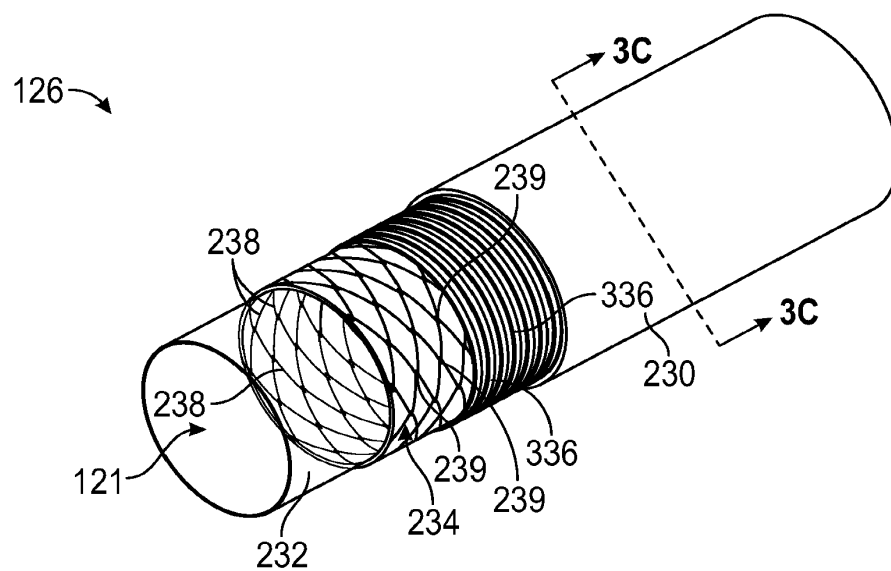


FIG. 3B

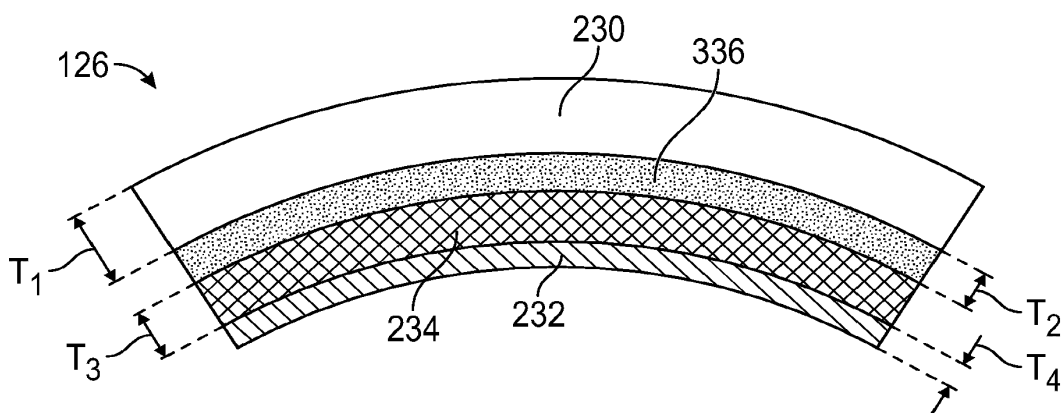


FIG. 3C

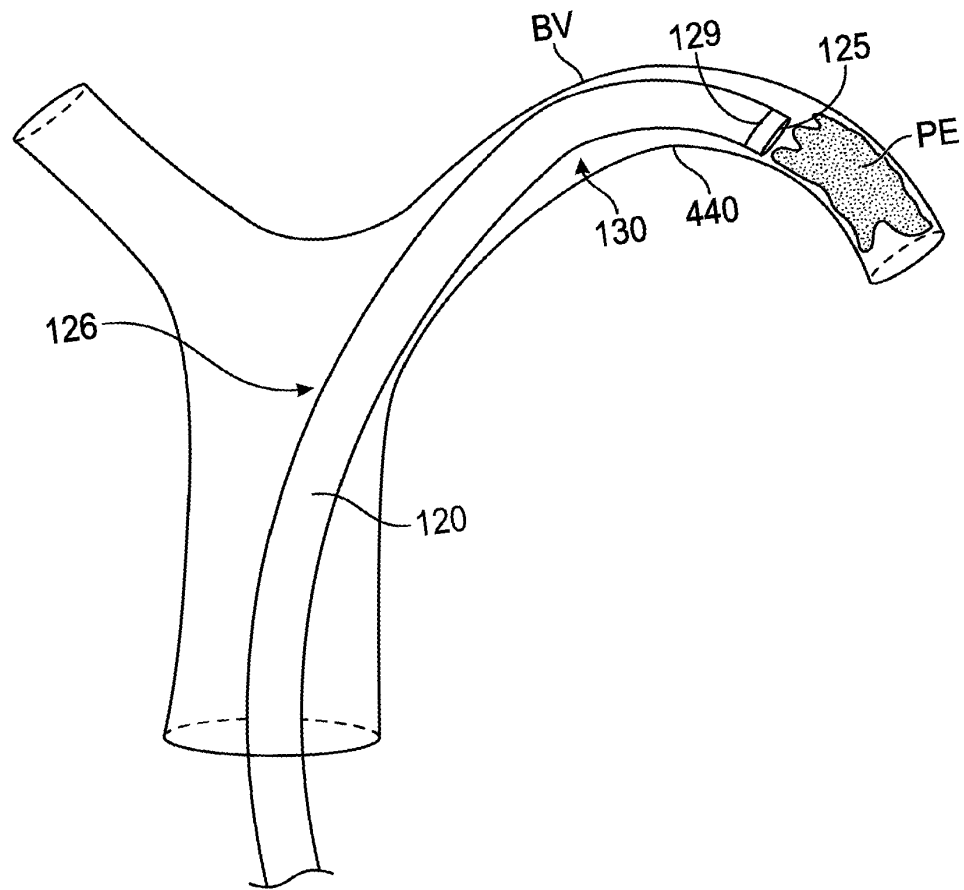


FIG. 4A

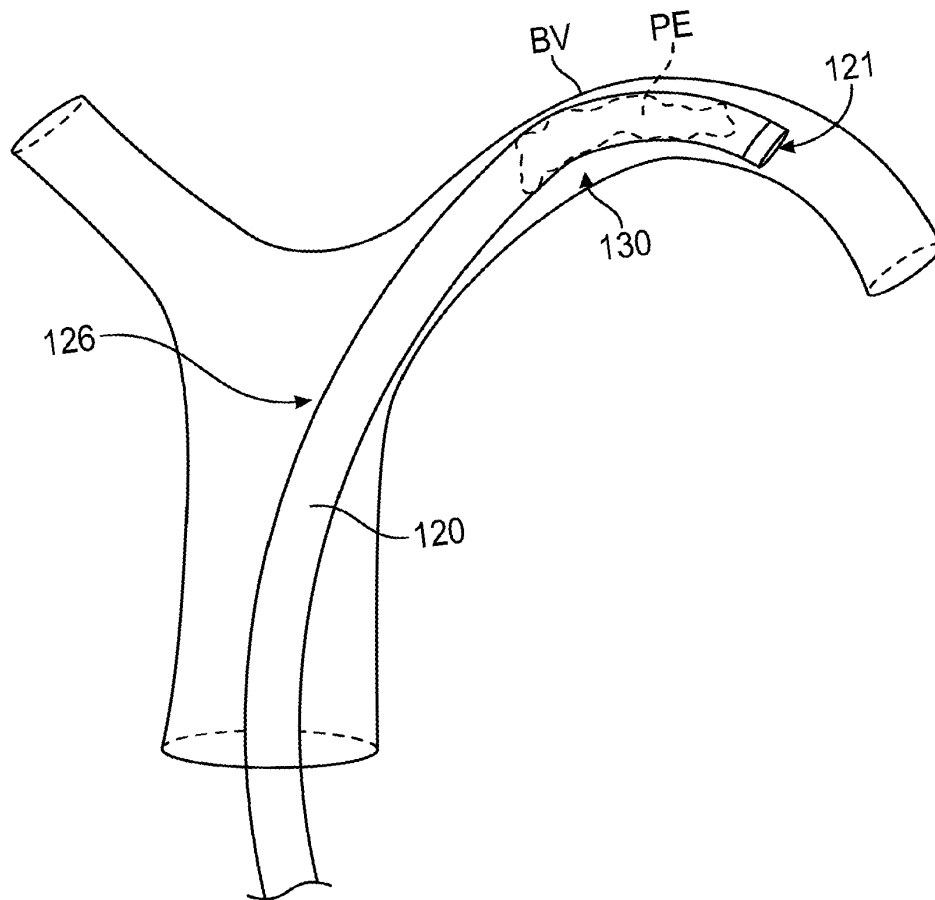


FIG. 4B

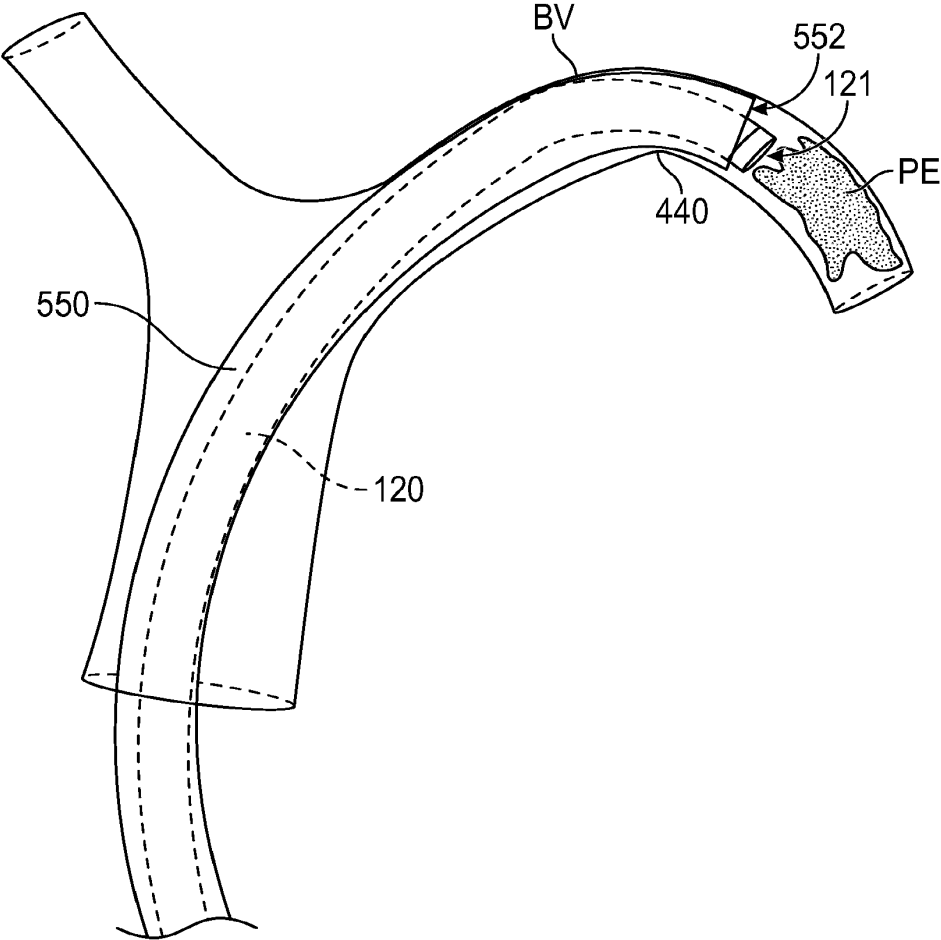


FIG. 5A

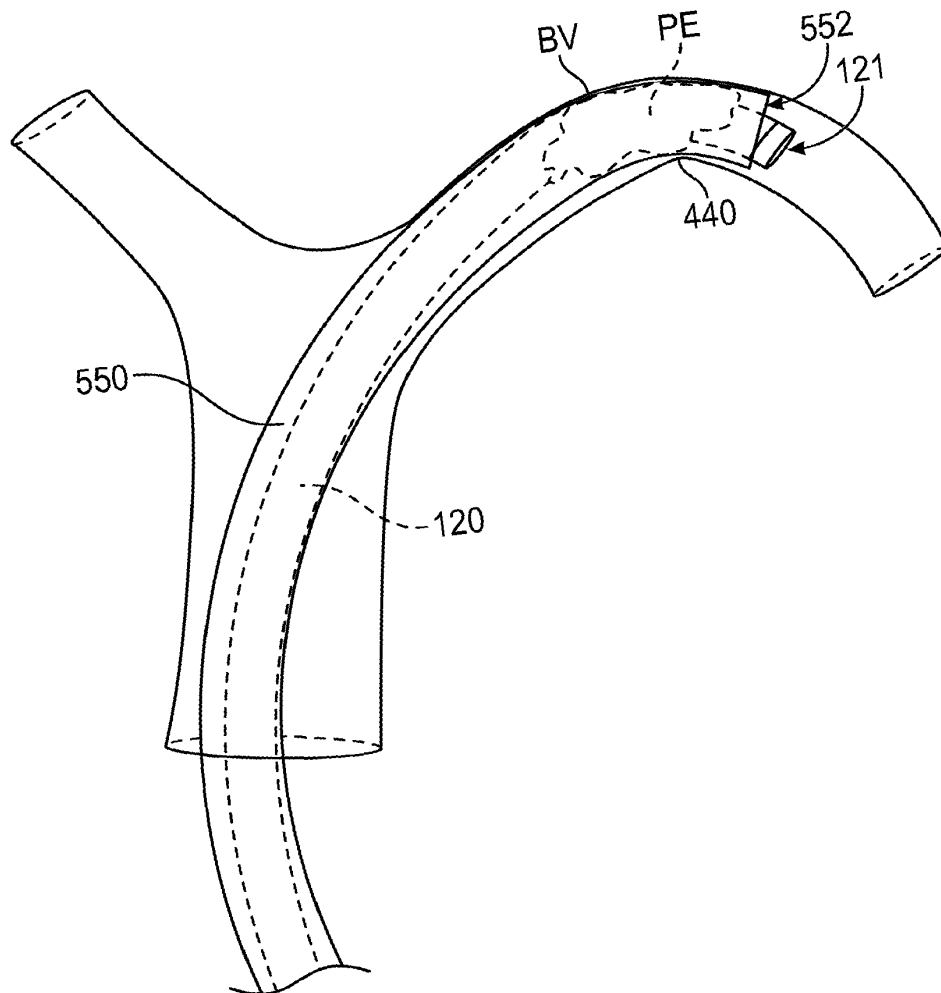


FIG. 5B

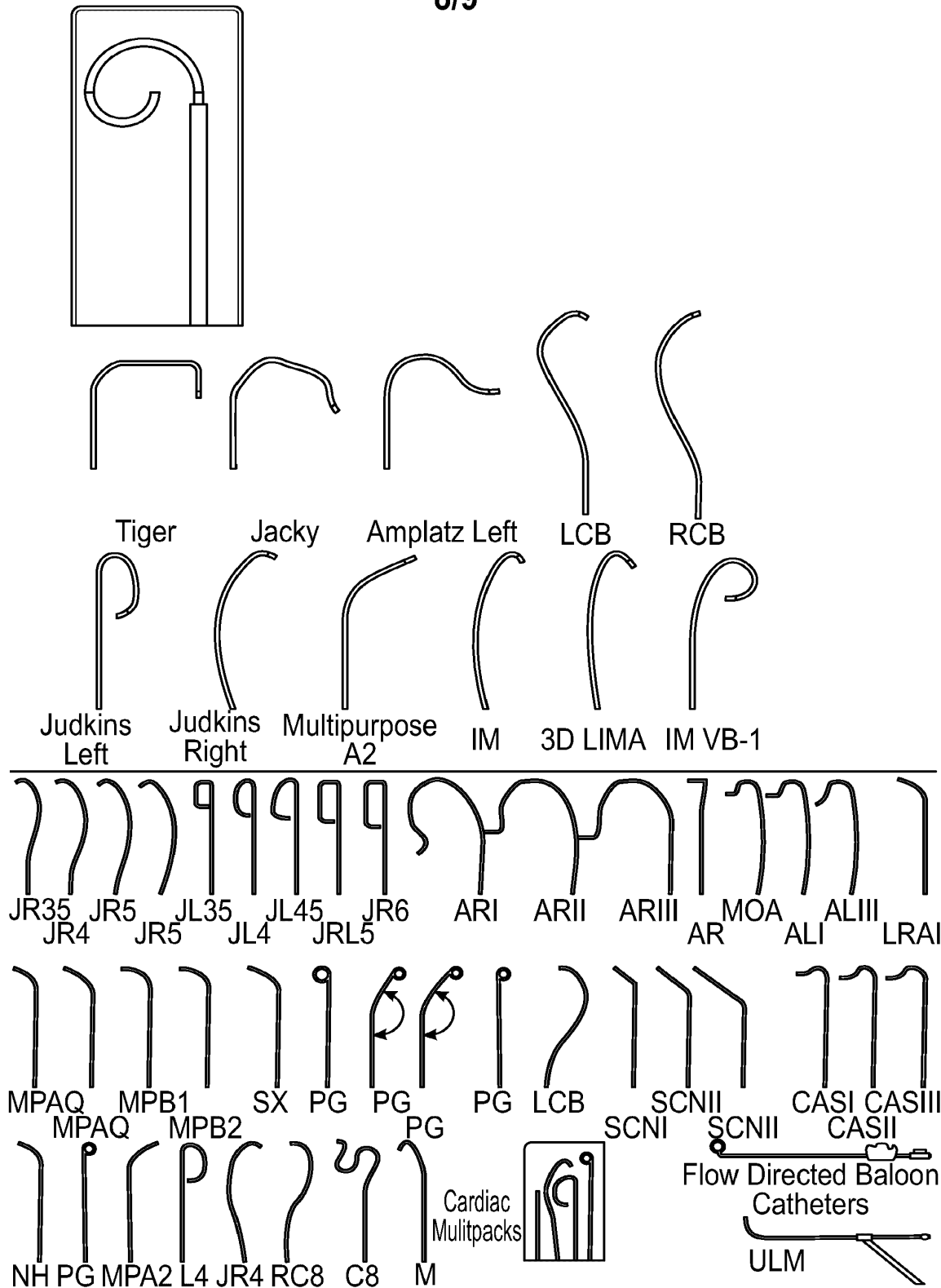


FIG. 6

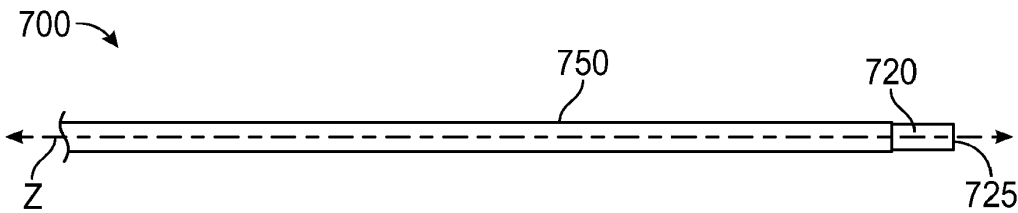


FIG. 7A

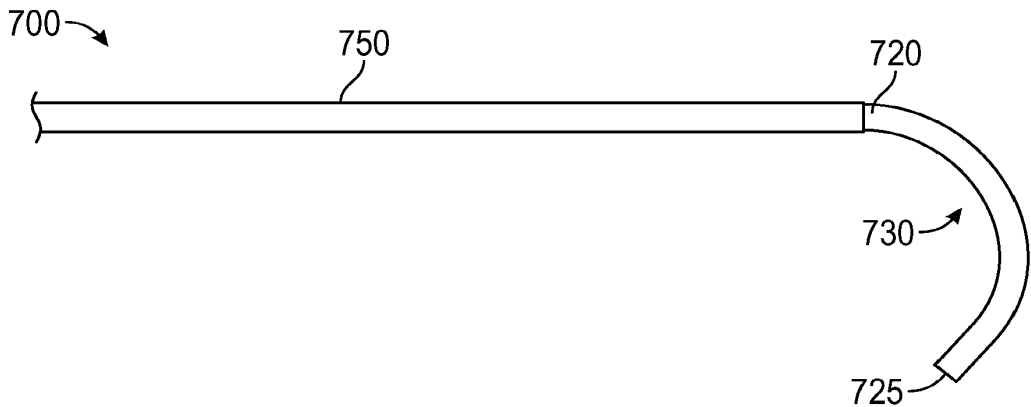


FIG. 7B

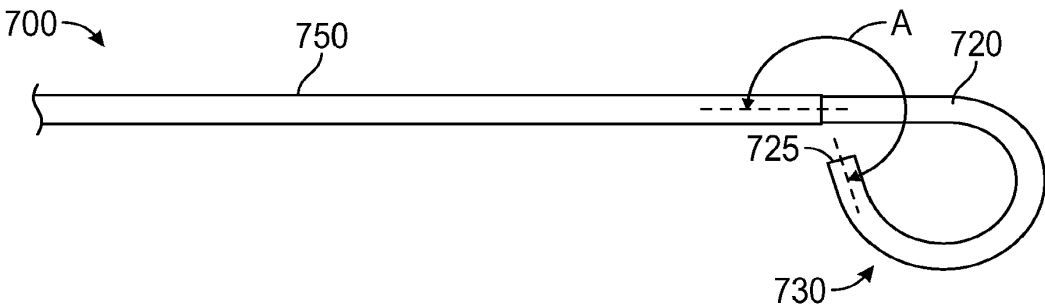


FIG. 7C

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/59718

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61M 25/00; A61B 17/22 (2022.01)

CPC - A61M 25/0041; A61M 25/0045

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

See Search History document

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	CN 110652645 A (Shanghai Warbey Medical Technology Co Ltd) 07 January 2020 (07.01.2020), entire document, especially	1-14
Y	US 2006/0074401 A1 (Ross) 06 April 2006 (06.04.2006), entire document, especially	1-14
A	US 2016/0151605 A1 (GMEDIX, INC.) 02 June 2016 (02.06.2016), entire document	1-14
A	US 2013/0197454 A1 (Terumo Kabushiki Kaisha) 01 August 2013 (01.08.2013), entire document	1-14

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

* Special categories of cited documents:

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"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

03 March 2022

Date of mailing of the international search report

MAR 22 2022

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
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Facsimile No. 571-273-8300

Authorized officer

Kari Rodriguez

Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

INARI_021568

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/59718

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-14 directed to an aspiration catheter.

Group II: Claims 15-20 directed to a method of removing clot material from a blood vessel.

-*-Continued in Supplemental Box-*-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-14

Remark on Protest

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

Form PCT/ISA/210 (continuation of first sheet (2)) (July 2019)

INARI_021569

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/59718

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

The invention of Group II includes the special technical feature of positioning a distal tip of the aspiration catheter proximate the clot material; activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter, not required in Group I.

The inventions of Groups I-II share the technical features of an aspiration catheter, comprising: a distal portion and a proximal portion, wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion. Specifically, Groups I and II are related as an apparatus (Group I) and methods for using the apparatus (Group II). The apparatus is known in prior art as shown in CN 110652645 A to Shanghai Warbey Medical Technology Co Ltd (hereinafter "Shanghai"). Therefore, Groups I and II lack unity since the shared technical features do not represent a contribution over Shanghai:

Shanghai discloses of an aspiration catheter (Fig 1A-1B; para [0093]-[0099]; para [0115] further teaches wherein the catheter can be used for aspiration), comprising: a distal portion (left half of 10; Fig 1A-1B; para [0093]) and a proximal portion (right half of 10; Fig 1A-1B; para [0093]), wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion (Fig 1A-1B; para [0076]; Shanghai teaches wherein the distal region of the aspiration catheter has good flexibility wherein the flexibility of the distal end of the catheter allows for a distal end of the braid of wires within the distal end of the catheter taught by Shanghai to be flexible and deflectable with respect to the longitudinal axis of the proximal portion taught by Shanghai).

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

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



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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

PUBLICATION NOTICE



OC000000135615162

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

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

Publication No.US-2022-0240959-A1

Publication Date:08/04/2022

NOTICE OF PUBLICATION OF APPLICATION

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

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

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In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <https://portal.uspto.gov/pair/PublicPair>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 17/498,642					
APPLICATION AS FILED - PART I											
		(Column 1)	(Column 2)		SMALL ENTITY		OR	OTHER THAN SMALL ENTITY			
FOR	NUMBER FILED	NUMBER EXTRA		RATE(\$)	FEE(\$)			RATE(\$)	FEE(\$)		
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A				N/A	320		
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A		N/A				N/A	700		
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A				N/A	800		
TOTAL CLAIMS (37 CFR 1.16(i))	21	minus 20 =	*	1				x 100 =	100		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2	minus 3 =	*					x 480 =	0.00		
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				TOTAL	1920		
APPLICATION AS AMENDED - PART II											
		(Column 1)	(Column 2)		(Column 3)		SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE(\$)	ADDITIONAL FEE(\$)			RATE(\$)	ADDITIONAL FEE(\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=			x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=			x	=
	Application Size Fee (37 CFR 1.16(s))										
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
				TOTAL ADD'L FEE				TOTAL ADD'L FEE			
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE(\$)	ADDITIONAL FEE(\$)			RATE(\$)	ADDITIONAL FEE(\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=			x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=			x	=
	Application Size Fee (37 CFR 1.16(s))										
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
				TOTAL ADD'L FEE				TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** 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 found in the appropriate box in column 1.											



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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	2080	111552-8023.US02	21	2

CONFIRMATION NO. 1040
UPDATED FILING RECEIPT



0000000133436133

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

Date Mailed: 04/27/2022

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.

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Inventor(s)

Richard Quick, Mission Viejo, CA;

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 11154314
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.

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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

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Office of the Chief Financial Officer

Document Code:WFEE

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Sale Accounting Date:04/21/2022

Sale Item Reference Number	Effective Date
17498642	04/20/2022

Document Number	Fee Code	Fee Code Description	Amount Paid	Payment Method
I20224KA40532418	1202	CLAIMS IN EXCESS OF 20	\$100.00	Deposit Account

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: Not Yet Known

**AUTHORIZATION FOR: EXTENSIONS OF TIME UNDER 37 C.F.R. § 1.136(a)(3) AND
PAYMENT OF FEES UNDER 37 C.F.R. § 1.17**

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

Dear Commissioner:

With respect to the above-identified application, the Commissioner is authorized to treat any concurrent or future reply requiring a petition for an extension of time under 37 C.F.R. § 1.136(a)(3) for its timely submission as incorporating a petition therefor for the appropriate length of time.

The Commissioner is also authorized to charge any extension of time fees or other fees that may be required under 37 C.F.R. § 1.17 for any paper filed concurrently herewith or in the future, or credit any overpayment, to Deposit Account No. 50-0665.

Dated: April 20, 2022

Respectfully submitted,

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

Application No.: 17/498,642

Docket No.: 111552-8023.US02

Authorization for: Extensions of Time under 37 C.F.R. § 1.136(a)(3) and
Payment of Fees under 37 C.F.R. § 1.17

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Phone: (206) 359-3343
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Attorney for Applicant

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Richard Quick

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: Not Yet Known

NOTIFICATION OF LOSS OF ENTITLEMENT TO SMALL ENTITY STATUS

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

Dear Commissioner:

Applicant, Inari Medical, Inc., hereby notifies the Patent and Trademark Office that it is not entitled to status as a small entity, and that the claim for small entity status filed by the Applicant is hereby withdrawn.

Dated: April 20, 2022

Respectfully submitted,

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

Perkins Coie LLP
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Fax: (206) 359-7198

Attorney for Applicant

Electronic Patent Application Fee Transmittal				
Application Number:		17498642		
Filing Date:		11-Oct-2021		
Title of Invention:		SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS		
First Named Inventor/Applicant Name:		Richard Quick		
Filer:		Matthew S. Williams/JiYoung Anderson		
Attorney Docket Number:		111552-8023.US02		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
UTILITY APPLICATION FILING	1011	1	320	320
UTILITY SEARCH FEE	1111	1	700	700
UTILITY EXAMINATION FEE	1311	1	800	800
Pages:				
Claims:				
Miscellaneous-Filing:				
LATE FILING FEE FOR OATH OR DECLARATION	1051	1	160	160
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 4 months with \$0 paid	1254	1	2320	2320
Miscellaneous:				
Total in USD (\$)				4300

Electronic Acknowledgement Receipt	
EFS ID:	45522079
Application Number:	17498642
International Application Number:	
Confirmation Number:	1040
Title of Invention:	SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS
First Named Inventor/Applicant Name:	Richard Quick
Customer Number:	25096
Filer:	Matthew S. Williams/JiYoung Anderson
Filer Authorized By:	Matthew S. Williams
Attorney Docket Number:	111552-8023.US02
Receipt Date:	20-APR-2022
Filing Date:	11-OCT-2021
Time Stamp:	17:45:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$4300
RAM confirmation Number	E20224JH46351849
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Preliminary Amendment	Preliminary_Amendment-111552-8023US2.PDF	89225	no	6
			ced69df760f4829ee8f2f5d72531777664214acb		
Warnings:					
Information:					
2	Authorization for Extension of Time all replies	General_Fee_Authorization-111552-8023US2.PDF	121057	no	2
			ff35215500d59c7719019a2a2113ddb4c31887f2		
Warnings:					
Information:					
3	Notification of loss of entitlement to small entity status	Loss_of_Small_Entity_Status-111552-8023US2.PDF	112906	no	1
			de1d8217b225e7aba1127374410082a567357880		
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	49585	no	2
			ab4786971a33908001f1b9de071beca3c6ffce79		
Warnings:					
Information:					
Total Files Size (in bytes):			372773		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

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: Not Yet Known

PRELIMINARY AMENDMENT UNDER 37 C.F.R. § 1.115

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

Dear Commissioner:

Prior to examination on the merits, please amend the above-identified U.S. patent application as follows:

Amendments to the Claims begin on page 2.

Remarks begin on page 6.

AMENDMENTS TO THE CLAIMS

Please cancel claims 1–20 and add new claims 21–40. Following is a complete listing of the claims pending in the application, as amended:

1-20. (Canceled)

21. (New) 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. (New) 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. (New) 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.

24. (New) 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. (New) 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. (New) The method of claim 21 wherein unsealing the attachment member includes pressing one or more buttons on the attachment member.

27. (New) The method of claim 21 wherein the pressure source is a syringe.

28. (New) The method of claim 27 wherein pre-charging the vacuum includes withdrawing a plunger of the syringe.

28. (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.

29. (New) The method of claim 28 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. (New) 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. (New) The method of claim 21 wherein the blood vessel is a pulmonary blood vessel.

32. (New) A system for the intravascular treatment of clot material within a blood vessel, comprising:

- an elongated shaft 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 within the blood vessel;

- an attachment member coupled to the proximal portion of the elongated shaft;

- a pressure source configured to generate a vacuum;

- a fluid control device 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; and

- an interventional device configured to be advanced through the attachment member and the elongated shaft to engage a second portion of the clot material remaining in the blood vessel.

33. (New) The system of claim 32 wherein the attachment member includes a lumen, and wherein the attachment member is actuatable between a first position in which the lumen is sealed and a second position in which the lumen is unsealed.

34. (New) The system of claim 33 wherein the attachment member includes a button configured to be depressed to move the attachment member to the second position.

35. (New) The system of claim 33 wherein the attachment member is biased to the second position.

36. (New) The system of claim 33 wherein the lumen has a diameter in the second position that is about equal to an inner diameter of the elongated shaft.

37. (New) The system of claim 32 wherein the fluid control device is a stopcock.

38. (New) The system of claim 32 wherein the pressure source is a syringe.

39. (New) The system of claim 32 wherein the blood vessel is a pulmonary blood vessel.

40. (New) The system of claim 32 wherein the attachment member is a hemostasis valve.

REMARKS

Prior to examining the present application, please enter the above amendment. Claims 1–20 have been canceled and new claims 21–40 have been added. No new matter has been added. Accordingly, claims 21–40 are currently pending.

If the Examiner has any questions or matters that can be expediently handled by telephone, he or she is encouraged to contact the undersigned at (206) 359-3343. Please charge any underpayment or credit any overpayment to our Deposit Account No. 50-0665, under Order No. 111552-8023.US02 from which the undersigned is authorized to draw.

Dated: April 20, 2022

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

Attorney 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
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

FORMALITIES LETTER



OC00000012925575

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

Date Mailed: 10/22/2021

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
- The application search fee must be submitted.
- The application examination fee must be submitted.
- Surcharge as set forth in 37 CFR 1.16(f) must be submitted.

The surcharge is due for any one of:

- late submission of the basic filing fee, search fee, or examination fee,
- late submission of inventor's oath or declaration,
- filing an application that does not contain at least one claim on filing, or
- submission of an application filed by reference to a previously filed application.

SUMMARY OF FEES DUE:

The fee(s) required within **TWO MONTHS** from the date of this Notice to avoid abandonment is/are itemized below. Small entity discount is in effect. If applicant is qualified for micro entity status, an acceptable Certification of Micro Entity Status must be submitted to establish micro entity status. (See 37 CFR 1.29 and forms PTO/SB/15A and 15B.)

- \$ 80 basic filing fee.
- \$ 80 surcharge.
- \$ 350 search fee.
- \$ 400 examination fee.
- \$(0) previous unapplied payment amount.
- \$ 910 TOTAL FEE BALANCE DUE.

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web, including a copy of this Notice and selecting the document description "Applicant response to Pre-Exam Formalities Notice".
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

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.

/hchin/

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 17/498,642					
APPLICATION AS FILED - PART I											
		(Column 1)	(Column 2)		SMALL ENTITY		OR	OTHER THAN SMALL ENTITY			
FOR	NUMBER FILED	NUMBER EXTRA		RATE(\$)	FEE(\$)			RATE(\$)	FEE(\$)		
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	80			N/A			
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A		N/A	350			N/A			
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	400			N/A			
TOTAL CLAIMS (37 CFR 1.16(i))	20	minus 20 =	*	x 50	= 0.00	OR					
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3	minus 3 =	*	x 240	= 0.00						
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).			0.00							
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00							
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	830			TOTAL			
APPLICATION AS AMENDED - PART II											
		(Column 1)	(Column 2)		(Column 3)		SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE(\$)	ADDITIONAL FEE(\$)			RATE(\$)	ADDITIONAL FEE(\$)	
	Total (37 CFR 1.16(l))	*	Minus	**	=	x	=	OR		x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=	OR		x	=
	Application Size Fee (37 CFR 1.16(s))							OR			
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR			
				TOTAL ADD'L FEE		OR		TOTAL ADD'L FEE			
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE(\$)	ADDITIONAL FEE(\$)			RATE(\$)	ADDITIONAL FEE(\$)	
	Total (37 CFR 1.16(l))	*	Minus	**	=	x	=	OR		x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=	OR		x	=
	Application Size Fee (37 CFR 1.16(s))							OR			
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR			
				TOTAL ADD'L FEE		OR		TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** 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 found in the appropriate box in column 1.											



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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Address: COMMISSIONER FOR PATENTS
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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	0.00	111552-8023.US02	20	3

CONFIRMATION NO. 1040

FILING RECEIPT



0000000129233756

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

Date Mailed: 10/22/2021

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;

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 11154314
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: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

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 37, Code of Federal Regulations, 5.11 & 5.15

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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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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 U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit <http://www.SelectUSA.gov> or call +1-202-482-6800.

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.

UTILITY PATENT APPLICATION TRANSMITTAL (Only for new nonprovisional applications under 37 CFR 1.53(b))	Attorney Docket No.	111552-8023.US02
	First Named Inventor	Richard Quick
	Title	SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS
	Priority Mail Express® Label No.	Electronically Filed

APPLICATION ELEMENTS <i>See MPEP chapter 600 concerning utility patent application contents.</i>	Commissioner for Patents ADDRESS TO: P.O. Box 1450 Alexandria, VA 22313-1450
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1. ☐ Fee Transmittal Form (PTO/SB/17 or equivalent) 2. ☒ Applicant asserts small entity status. See 37 CFR 1.27 3. ☐ Applicant certifies micro entity status. See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent. 4. ☒ Specification [Total Pages <u>42</u>] Both the claims and abstract must start on a new page. (See MPEP § 608.01(a) for information on the preferred arrangement) 5. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets <u>20</u>] 6. Inventor's Oath or Declaration [Total Pages <u>1</u>] (including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e)) a. ☐ Newly executed (original or copy) b. ☐ A copy from a prior application (37 CFR 1.63(d)) 7. ☐ Application Data Sheet * See note below. See 37 CFR 1.76 (PTO/AIA/14 or equivalent) 8. CD-ROM or CD-R in duplicate, large table, or Computer Program (Appendix) ☐ Landscape Table on CD 9. Nucleotide and/or Amino Acid Sequence Submission (if applicable, items a. – c. are required) a. ☐ Computer Readable Form (CRF) b. ☐ Specification Sequence Listing on: i. ☐ CD-ROM or CD-R (2 copies); or ii. ☐ Paper c. ☐ Statements verifying identity of above copies	ACCOMPANYING APPLICATION PAPERS 10. ☐ Assignment Papers (cover sheet & document(s)) Name of Assignee _____ 11. ☐ 37 CFR 3.73(c) Statement ☒ Power of Attorney (when there is an assignee) 12. ☐ English Translation Document (if applicable) 13. ☐ Information Disclosure Statement (PTO/SB/08 or PTO-1449) ☐ Copies of citations attached 14. ☐ Preliminary Amendment 15. ☐ Return Receipt Postcard (MPEP § 503) (Should be specifically itemized) 16. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed) 17. ☐ Nonpublication Request Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent. 18. ☐ Other: _____ _____ _____ _____
--	--

***Note:** (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must** be included in an Application Data Sheet (ADS).
(2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

19. CORRESPONDENCE ADDRESS					
☒ The address associated with Customer Number: <u>25096</u> OR ☐ Correspondence address below					
Name					
Address					
City		State		Zip Code	
Country		Telephone		Email	
Signature	/Matthew S. Williams/			Date	2021-10-11
Name (Print/Type)	Matthew S. Williams			Registration No. (Attorney/Agent)	77,516

This collection of information is required by 37 CFR 1.53(b). 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 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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.

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA/82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	Not Yet Assigned
Filing Date	Concurrently Herewith
First Named Inventor	Richard Quick
Title	SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	111552-8023.US02

SIGNATURE of Applicant or Patent Practitioner

Signature	/Matthew S. Williams/	Date (Optional)	2021-10-11
Name	Matthew S. Williams	Registration Number	77,516
Title (if Applicant is a juristic entity)	Attorney for Applicant		
Applicant Name (if Applicant is a juristic entity)		Inari Medical, Inc.	

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.



*Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. 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 3 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☒ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above:

25096

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☒ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

Firm or Individual Name				
Address				
City		State		Zip
Country				
Telephone		Email		

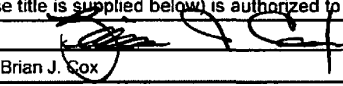
I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Inari Medical, Inc.

- ☐ Inventor or Joint Inventor (title not required below)
- ☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)
- ☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)
- ☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	
Name	Brian J. Cox		
Title	Vice President, Inari Medical, Inc.		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. 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 3 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.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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 ☐ The attached application, or is directed to: ☒ United States application or PCT international application number <u>16/258,344</u> filed on <u>January 25, 2019</u>. 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 willful 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. I hereby state that I have reviewed and understand the contents of the above identified application, including the claims, as amended by any amendment. I acknowledge the duty to disclose information material to patentability as defined in 37 C.F.R. 1.56 including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application. 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: <u>Richard Quick</u> Date: <u>10/21/19</u> Signature: 	
Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.	

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		
	Richard		Quick			
Residence Information (Select One) • US Residency Non US Residency Active US Military Service						
City	Mission Viejo	State/Province	CA	Country of Residence	US	
Mailing Address of Inventor:						
Address 1		c/o Inari Medical, Inc.				
Address 2		9 Parker, Suite #100				
City	Irvine	State/Province	CA			
Postal Code	92618	Country	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.			
Customer Number	25096		
Email Address	patentprocurement@perkinscoie.com	Add Email	Remove Email

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

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		

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		

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

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		
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.			Add

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).

Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ^j (if applicable)	Remove
Additional Foreign Priority Data may be generated within this form by selecting the Add button.				Add

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.

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		

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		Remove
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		
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. Add			

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.

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		

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.				
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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		

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

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application is a continuation of U.S. Patent Application No. 16/258,344, filed on January 25, 2019, and titled "SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," which claims the benefit of U.S. Provisional Patent Application No. 62/622,691, filed on January 26, 2018, and titled "SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," each of which are incorporated herein by reference in their entirety.

TECHNICAL FIELD

[0002] The present technology relates generally to devices and methods for the intravascular treatment of emboli and/or thrombi within a blood vessel of a human patient. In particular, some embodiments of the present technology relate to systems for repeatedly deploying an interventional device at or proximate to a pulmonary embolism within a patient.

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-stenosis 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 of the clot material.

[0010] Moreover, with many devices, it is difficult or not possible to make repeated attempts at removing clot material (e.g., to make multiple passes with a device). In particular, if a first pass with a device does not completely capture and/or collect all of the clot material, the device and an accompanying catheter system must be removed from the patient, cleaned, and subsequently reinserted into the patient in order to make a second pass and remove additional material. This can be time consuming and traumatic for the patient.

[0011] Thus, there exists a need for an improved embolic extraction device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] 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.

[0013] Figures 1A and 1B are perspective views of a retraction and aspiration system shown in a first state and a second state, respectively, in accordance with embodiments of the present technology.

[0014] Figures 2A–2G are schematic illustrations of a distal portion of the retraction and aspiration system during a clot removal procedure in accordance with embodiments of the present technology.

[0015] Figures 3A–3C are a fully-exploded view, an isometric view, and a partially-exploded view of a clot reservoir of the retraction and aspiration system in accordance with embodiments of the present technology.

[0016] Figure 4 is a side view of an attachment member and a fluid control unit of the retraction and aspiration system in accordance with embodiments of the present technology.

[0017] Figure 5 is a side cross-sectional view of the attachment member shown in Figure 4.

[0018] Figure 6 is an isometric view of a first valve insert in accordance with embodiments of the present technology.

[0019] Figures 7A and 7B are a side view and a side cross-sectional view, respectively, of the first valve insert shown in Figure 6 inserted into the attachment member shown in Figure 4 in accordance with embodiments of the present technology.

[0020] Figure 8 is a side view of a second valve insert in accordance with embodiments of the present technology.

[0021] Figure 9 is a side view of the second valve insert shown in Figure 8 inserted into the attachment member shown in Figure 4 in accordance with embodiments of the present technology.

[0022] Figure 10 is a flow diagram of a process or method for operating the retraction and aspiration system in accordance with embodiments of the present technology.

[0023] Figure 11 is a side view of an attachment member and a fluid control unit of the retraction and aspiration system in accordance with embodiments of the present technology.

[0024] Figure 12 is a side view of the fluid control unit shown in Figure 11 in accordance with embodiments of the present technology.

[0025] Figures 13A and 13B are side cross-sectional views of the attachment member shown in Figure 11 in a first configuration and a second configuration, respectively, in accordance with embodiments of the present technology.

[0026] Figure 14 is a flow diagram of a process or method for operating the retraction and aspiration system in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0027] The present technology is generally directed to systems and associated devices and methods for engaging and removing clot material from a blood vessel of a human patient. In some embodiments, an interventional device can be advanced through a guide catheter and deployed within clot material in a blood vessel. The interventional device can subsequently be withdrawn from the patient through the guide catheter to remove clot material captured by the interventional device. In some embodiments of the present technology, the interventional device can be repeatedly deployed in/withdrawn from the blood vessel to capture a desired amount of the clot material—without requiring that the guide catheter be fully withdrawn from the patient after each "pass" (e.g., each repeated deployment/withdrawal of the interventional device). That is, the guide catheter may be inserted only a single time during an intravascular procedure including multiple passes to remove clot material from the patient.

[0028] Although many of the embodiments are described below with respect to devices, systems, and methods for treating a pulmonary embolism, other applications and other embodiments in addition to those described herein are within the scope of the technology (e.g., intravascular procedures other than the treatment of emboli, intravascular procedures for treating cerebral embolism, etc.). Additionally, several other embodiments of the technology can have different configurations, states, components, or procedures than those described herein. Moreover, it will be appreciated that specific elements, substructures, advantages, uses, and/or other features of the embodiments described with reference to Figures 1A–14 can be suitably interchanged, substituted or otherwise configured with one another in accordance with additional embodiments of the present technology. Furthermore, suitable elements of the embodiments described with reference to Figures 1A–14 can be used as standalone and/or self-contained devices. A person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described below with reference to Figures 1A–14.

[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 retraction and aspiration apparatus and/or an associated catheter system with reference to an operator and/or a

location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," etc. are not meant to limit the referenced component to use in a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the retraction and aspiration system of the present technology can be used in any orientation suitable to the user.

I. Selected Embodiments of Retraction/Aspiration Systems and Methods of Use

[0030] Figures 1A and 1B are perspective views of a proximal portion of a clot retrieval system 1 configured in accordance with embodiments of the present technology, shown in a first state and a second state, respectively. Referring to Figures 1A and 1B together, the clot retrieval system 1 includes a retraction and aspiration device 100 ("RA device 100"), a catheter system 200, and a tubing system 300. In some embodiments, the RA device 100 is coupleable to the catheter system 200 and operable to simultaneously (i) retract a portion of the catheter system 200 and (ii) aspirate through the catheter system 200. In certain embodiments, the RA device 100 and catheter system 200 can both be fluidly coupled to the tubing system 300 to enable material (e.g., blood and clot material) aspirated from the catheter system 200 to flow into the tubing system 300. In particular, the RA device 100, the catheter system 200, and the tubing system 300 can be the same as or similar to one or more of the retraction and aspiration devices, catheter systems, and tubing systems disclosed in U.S. Patent 9,526,864, filed June 9, 2015, and titled "RETRACTION AND ASPIRATION DEVICE FOR TREATING EMBOLISM AND ASSOCIATED METHODS," which is incorporated herein by reference in its entirety.

[0031] Figures 2A–2G are schematic illustrations of a distal portion of the clot retrieval system 1 during a clot removal procedure in accordance with embodiments of the present technology. In particular, Figures 2A–2G illustrate a distal portion of the catheter system 200 that is positioned proximate to an embolism or clot material within a blood vessel (e.g., a pulmonary blood vessel). Accordingly, operation of the catheter system 200 is described with references to Figures 2A–2G.

[0032] Figure 2A is a side view of a distal portion of the catheter system 200 positioned adjacent an embolism or clot material PE within a blood vessel BV (e.g., a pulmonary blood vessel). As shown in Figure 2A, the catheter system 200 can include an outer guide catheter 206

defining a lumen 205, a delivery sheath 204 slidably received within the lumen of the guide catheter 206, and an elongated pull (and/or push) member 202 slidably received within a lumen of the delivery sheath 204. The guide catheter 206 and the delivery sheath 204 individually comprise an elongated shaft having a lumen and, in some embodiments, the push member 202 can also define a lumen (e.g., configured to receive a guidewire therethrough). In a particular embodiment, the catheter system 200 does not include a guide catheter 206 and/or a delivery sheath 204. As shown in Figure 2A, a distal portion of the push member 202 can be integral with or coupled to an interventional device ID, such as a clot removal and/or clot treatment device, that is housed within the delivery sheath 204. Accordingly, axial movement of the pull member 202 causes axial movement of the interventional device ID.

[0033] As further shown in Figure 2A, the delivery sheath 204 and the interventional device ID can be positioned at least partially within the clot material PE. Access to the pulmonary vessels can be achieved through the patient's vasculature, for example, via the femoral vein. The catheter system 200 can include an introducer 210 (Figure 1A and 1B; e.g., a Y-connector with a hemostasis valve) that can be partially inserted into the femoral vein. A guidewire (not shown) can be guided into the femoral vein through the introducer 210 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 embolism, the guidewire can be guided to one or more of the branches of the right pulmonary artery and/or the left pulmonary artery. 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 pulmonary embolism.

[0034] As shown in Figures 2B and 2C, the delivery sheath 204 can be withdrawn proximally (e.g., as indicated by arrow A1 in Figure 2B) to allow the interventional device ID to expand within the clot material PE, thereby grabbing the clot material PE that is nearby. Although Figure 2B shows the interventional device ID positioned at the treatment site such that a distal terminus of the

interventional device ID is distal of a distal terminus of the clot material PE, in some procedures the interventional device ID may be positioned such that the distal terminus of the interventional device ID is proximal of the distal terminus of the clot material PE. As shown in Figure 2D, in some embodiments the guide catheter 206 can optionally be advanced distally (e.g., as indicated by arrow A2) until the guide catheter 206 is positioned proximate to a proximal portion of the clot material PE.

[0035] Referring again to Figures 1A and 1B, the RA device 100 includes (i) a housing 102, (ii) an actuation mechanism that includes a lever 104 coupled to and extending from the housing 102, and (iii) a pressure source (obscured in Figures 1A and 1B; e.g., a syringe) positioned within the housing 102, coupled to the actuation mechanism, and configured to generate negative and/or positive pressure. The lever 104 is shown in a first position and second position in Figures 1A and 1B, respectively. The housing 102 can have a proximal portion 100a, a distal portion 100b, and an opening 114 at the distal portion 100b configured to receive a portion of the catheter system 200 and to mechanically couple the catheter system 200 to the housing 102. For example, a proximal portion of the guide catheter 206 can include an attachment/valve member 208 that is configured to be detachably coupled to the RA device 100 (e.g., via a snap-fit arrangement) to secure the catheter 200 to the RA device 100. As described in greater detail below, the attachment/valve member 208 can fluidly couple an aspiration lumen of the catheter system 200 (e.g., the lumen 205 of the guide catheter 206) to the tubing system 300 of the clot retrieval system 1.

[0036] The housing 102 can further include a channel 116 that extends proximally from the opening 114 along approximately the length of the housing 102, as shown in Figures 1A and 1B. The channel 116 can have a height at least as great as the outer diameter of the delivery sheath 204 of the catheter system 200 (and/or another component of the catheter system 200) such that the delivery sheath 204 can fit sideways through the channel 116. In some embodiments, the pull member 202 and the interventional device ID (Figures 2A–2G) can be pre-loaded into the delivery sheath 204, and the delivery sheath 204 can be fed distally through the channel 116 (e.g., either via the proximal end of the channel 116 or first pushed sideways through a portion of the channel 116) and into the guide catheter 206. In other embodiments, the interventional device ID and the

delivery sheath 204 are fed into the guide catheter 206 and the interventional device ID is deployed prior to coupling the guide catheter 206 to the RA device 100.

[0037] When the RA device 100 is coupled to the catheter system 200 (e.g., when the attachment/valve member 208 of the catheter system 200 is positioned within the opening 114 in the housing 102 of the RA device 100), movement of the lever 104 functions to retract a portion of the catheter system 200 positioned in the channel 116 (e.g., the delivery sheath 204 and/or the push member 202). For example, the RA device 100 can include a locking portion that grips the delivery sheath 204 (and, in some embodiments, indirectly the push member 202) to pull the delivery sheath 204 proximally as the lever 104 is moved from the first to the second position.

[0038] The tubing system 300 of the clot retrieval system 1 fluidly couples the pressure source of the RA device 100 to the aspiration lumen of the catheter system 200. When the RA device 100 is coupled to the catheter system 200, movement of the lever 104 functions to simultaneously generate negative pressure in the pressure source and to retract a portion of the catheter system 200, as described above. The tubing system 300 has a first portion 314 coupled to the pressure source, a second portion 316 coupled to the guide catheter 206, and a drainage portion 318 coupled to a reservoir 320 (e.g., a vinyl bag). The first portion 314, second portion 316, and/or drainage portion 318 can include one or more tubing sections 302 (labeled individually as tubing sections 302a–302f) and/or fluid control unit, such as one or more control valves. In certain embodiments, one or more of the tubing sections 302 can have a relatively large diameter (e.g., greater than about 0.1 inch, greater than about 0.210 inch, etc.) to help inhibit clogging of clot material within the tubing system 300.

[0039] More specifically, the first portion 314 can include the tubing section 302a. The drainage portion 318 can include (i) the tubing section 302b, (ii) a first fluid control unit (e.g., a valve) 304, and (iii) the tubing section 302c. The second portion 316 can include (i) the tubing section 302d, (ii) a clot reservoir 306, (iii) the tubing section 302e, (iv) a second fluid control unit 310, and (v) the tubing section 302f. In some embodiments, the first fluid control unit 304 can be a one-way valve (e.g., a check valve) that only allows fluid flow from the first portion 314 and/or second portion 316 to the drainage portion 318 (and not vice-versa). In certain embodiments, as described in detail with reference to Figures 3A–3C, the clot reservoir 306 can also include a one-

way valve that only allows fluid flow from the second portion 316 to the drainage portion 318 (and not vice-versa). In some embodiments, the second fluid control unit 310 can be a stopcock or a clamp that is externally operated to regulate the flow of liquid through the second portion 316 of the tubing system 300. A Y-connector 308 can fluidly couple the first, second, and drainage portions 314, 316, 318. In other embodiments, the first, second, and/or drainage portions 314, 316, 318 can have more or fewer tubing sections, connectors, and/or fluid control unit and/or other suitable configurations.

[0040] As shown in Figures 1A and 2E, moving the lever 104 from the first position to the second position (indicated by arrow A1 in Figure 1A) simultaneously (1) generates a negative pressure in the lumen 205 of the guide catheter 206 (indicated by arrow F in Figure 1A and F1 in Figure 2E), and (2) retracts the delivery sheath 204 and/or push member 202 proximally, thereby retracting the interventional device ID from the treatment site. During this time, in some embodiments, the guide catheter 206 remains fixed (e.g., by the housing 102) relative to the delivery sheath 204 and pull member 202. In such embodiments, as the lever 104 moves from the first position to the second position, the interventional device ID, delivery sheath 204, pull member 202, and at least a portion of the clot material PE are drawn proximally into the guide catheter 206.

[0041] As shown in Figure 1B, moving the lever 104 from the second position to the first position (indicated by arrow A2 in Figure 1B) creates a positive pressure (e.g., indicated by arrows F in Figure 1B) in the first portion 314 and drainage portion 318 of the tubing system 300. The clot reservoir 306 prevents the positive pressure from affecting the aspiration lumen of the catheter system 200, thereby preventing backflow of fluid into the blood vessel BV at the treatment site. With respect to the catheter system 200, when the lever 104 is actuated from the second position to the first position, the RA device 100 does not engage the delivery sheath 204 or the push member 202 to move these components. Thus, the next time the lever 104 is actuated relative to the housing 102, the RA device 100 engages a new portion of the delivery sheath 204 and push member 202 such that the delivery sheath 204 and push member 202 are incrementally retracted proximally each time the lever 104 is "pumped" (e.g., moved from the first position toward the second position and then back toward the first position).

[0042] Depending on the age and size of the clot material PE, local anatomical and/or physiological conditions, and position of the interventional device ID relative to the clot material PE, the lever 104 can be pumped several times to fully extract the clot material PE and/or interventional device ID from the treatment site. For example, Figures 2D and 2E show the proximal movement of the delivery sheath 204 and pull member 202 after a first pump of the lever 104. Figures 2E and 2F show the proximal movement of the delivery sheath 204, pull member 202, and interventional device ID after a second pump of the lever 104 (e.g., including a second instance of pressure generation indicated by arrows F1 and F2 in Figures 2E and 2F, respectively). In some embodiments, the interventional device ID and the clot material PE can be fully withdrawn into the guide catheter 206 after a single pump of the lever 104. In other embodiments, such as those procedures where the interventional device ID is initially positioned such that a distal terminus of the interventional device ID is proximal of a distal terminus of the clot material PE (the clot material PE often originates in a vein of the patient's leg, and thus is cast into an elongated, worm-like shape), it can take several pumps of the lever 104 to fully withdraw the clot material PE into the guide catheter 206. Thus, in some embodiments, even when the interventional device ID is positioned within the guide catheter 206 such that a distal terminus of the interventional device ID is proximal of the distal terminus of the guide catheter 206, the lever 104 can be pumped several more times to continue to withdraw the clot material PE into the guide catheter 206 and the tubing system 300 (e.g., into the second portion 316, the clot reservoir 306, and/or the drainage portion 318).

[0043] Once the clot material PE is positioned within the guide catheter 206 such that a distal terminus of the clot material PE is proximal from a distal terminus of the guide catheter 206, the catheter system 200 can be withdrawn proximally (e.g., as indicated by arrow A3 in Figure 2G) from the treatment site, and removed from the patient. However, sometimes, as shown in Figure 2G, retracting the interventional device ID and delivery sheath 204 into the guide catheter 206 may not remove all of the clot material PE (or a desired amount of the clot material PE) from the blood vessel BV. That is, a single "pass" (e.g., a deployment of the interventional device ID and subsequent retraction of the interventional device ID into the guide catheter 206) may not adequately remove the clot material PE from the blood vessel BV. In such instances, the operator of the clot retrieval system 1 may wish to make another pass with the

interventional device ID to remove all or a portion of the remaining clot material PE in the blood vessel BV.

[0044] To redeploy the interventional device ID, many conventional systems require that the entire catheter system, including the guide catheter 206, be fully removed from the patient (e.g., including a guide catheter). That is, if the once-deployed interventional device is reintroduced without fully removing and cleaning the catheter system, there is a significant risk that clot material and/or other contaminants from the catheter system will be reintroduced into the blood vessel of the patient during a second pass. As described in further detail below, the present technology advantageously allows for an interventional device to be redeployed without fully removing a guide catheter, and with a significantly reduced risk of reintroducing clot material and/or other contaminants into the blood vessel of the patient.

II. Selected Embodiments of Clot Reservoirs and Associated Methods of Use

[0045] Figures 3A–3C are a fully-exploded view, an isometric view, and a partially-exploded view of the clot reservoir 306 of the clot retrieval system 1. With reference to Figure 3A, the clot reservoir 306 includes a housing 322 defining a chamber 323, a filter 321 configured to be positioned within the housing 322, and a cap assembly 330 configured to be coupled to the housing 322. The housing 322 can include a port 324 configured to be removably, fluidly coupled to the catheter system 200. In some embodiments, a tubing section 326 is coupled to the port 324 during priming of the clot retrieval system 1 and, as described in further detail below with reference to Figures 10 and 14, during flushing of the tubing system 300. In certain embodiments the tubing section 326 is semi-permanently coupled to the housing 322 and can be used to fluidly couple the housing 322 to the tubing system 300 and/or the catheter system 200.

[0046] In the embodiment illustrated in Figure 3A, the cap assembly 330 includes a fluid connector (e.g., a barbed outlet) 332 for connecting to the tubing system 300 (e.g., to the tubing section 302d shown in Figures 1A and 1B), a nut 333 for releasably securing the cap assembly 330 to the housing 322 (e.g., via a threaded coupling), a first cap portion 334, and a second cap portion 338. In some embodiments, the fluid connector 332 is secured to the first cap portion 334 via an adhesive 331a, and the first cap portion 334 is secured to the nut 333 via a second adhesive 331b. In some embodiments, the first and second adhesives 331a, 331b are the same. The

cap assembly 330 can further include a check valve assembly 335 positioned between the first and second cap portions 334, 338 and comprising a piston 336 and a spring 339 (e.g., a passivated compression spring). The check valve assembly 335 provides for one-way fluid flow through the clot reservoir 306, for example, from the catheter system 200 to the reservoir 320 (Figures 1A and 1B). The clot reservoir 306 can further include one or more O-rings 337 for sealing the various components.

[0047] In operation, blood and clot material flow into the clot reservoir 306 via the port 324 as the lever 104 of the RA device 100 is moved from the first position toward the second position. Clot material is captured within the housing 322 and inhibited from exiting through the cap assembly 330 by the filter 321 while blood is allowed to flow from the port 324 to the fluid connector 332. In particular, the filter 321 inhibits clot material from passing into the check valve assembly 335, which could inhibit function of the check valve assembly 335 and/or macerate the clot material and make it indistinguishable from or difficult to distinguish from other fluids (e.g., blood) aspirated and/or removed from the patient. The check valve assembly 335 subsequently inhibits backflow of fluid through the housing 322 via the fluid connector 332 as the lever 104 of the RA device 100 is moved from the second position toward the first position. With reference to Figures 3B and 3C, the cap assembly 330 can be decoupled from the housing 322 to, for example, permit an operator to remove clot material collected in the housing 322. Moreover, as shown, the housing 322 may be made of a transparent material that permits the operator to visualize material within the housing 322. As described in further detail below, in some embodiments, the operator can at least partially determine whether subsequent passes using the interventional device ID are necessary by visualizing the amount of clot material collected in the housing 322.

[0048] Additional details of the clot reservoir 306, and associated devices and methods, are described in Appendix A to this application.

III. Selected Embodiments of Attachment/Valve Members, and Associated Devices and Methods of Use

[0049] Figure 4 is a side view of an attachment/valve member 408 ("attachment member 408") of the catheter system 200 and a second fluid control unit 410 of the tubing system 300 in accordance with embodiments of the present technology. The attachment

member 408 and second fluid control unit 410 can have some features generally similar to the features of the attachment/valve member 208 and second fluid control unit 310, respectively, described above with reference to Figures 1A and 1B. For example, the attachment member 408 can be integral with or coupled to a proximal portion of the guide catheter 206 and configured to be detachably coupled to the RA device 100 (Figures 1A and 1B; e.g., via a snap-fit arrangement) to at least partially secure the catheter system 200 to the RA device 100. When secured to the RA device 100, the attachment member 408 can fluidly couple the lumen 205 (e.g., an aspiration lumen) of the guide catheter 206 to the tubing system 300 of the clot retrieval system 1 via the tubing section 302f. Likewise, the second fluid control unit 410 can be a clamp ("clamp 410") that is externally operable to regulate the flow of liquid through the tubing section 302f. For example, the clamp 410 may be actuated (e.g., compressed or squeezed by the hand of an operator) to partially or fully restrict fluid flow through the tubing section 302f. In some embodiments, the clamp 410 includes features for locking or maintaining the clamp 410 in a position such that it restricts fluid flow through the tubing section 302f. Figure 4 illustrates the clamp 410 in a position that permits fluid flow through the tubing section 302f.

[0050] As further shown in Figure 4, the tubing system 300 can include a connector 417 that, for example, fluidly connects the tubing section 302f to other portions of the tubing system 300 (e.g., those shown in Figures 1A and 1B). In some embodiments, the connector 417 is a quick-release connector that enables rapid coupling/decoupling of the tubing section 302f to the clot reservoir 306 and/or other components of the tubing system 300. In some embodiments, the tubing system 300 can include a flush port adapter that can be removably coupled to the connector 417. The flush port adapter can be configured to, for example, fluidly connect a flushing device (e.g., a syringe) to the catheter system 200 so that the guide catheter 206 can further be flushed with a fluid (e.g., heparinized saline).

[0051] Figure 5 is a side cross-sectional view of the attachment member 408 show in Figure 4. As shown in the embodiment of Figure 5, the attachment member 408 includes a body or housing 440 having a proximal opening 443a, a distal opening 443b, and a first lumen 441 extending between the proximal and distal openings 443a and 443b. The first lumen 441 further comprises a first portion 441a having a first diameter (e.g., a constant first diameter) and a second

portion 441b having a second diameter greater than the first diameter. In some embodiments, the first diameter can be generally the same as the outer diameter of the guide catheter 206. The housing 443 further includes a branch portion 444 configured to be coupled to the tubing section 302f and having a second lumen 442 branching from the first lumen 441. In some embodiments, the second lumen 442 can have a relatively large diameter (e.g., between about 0.098 inch and 0.210 inch, about 0.210 inch, greater than 0.210 inch, etc.) to help inhibit clogging and/or collecting of clot material within the attachment member 408 during, for example, aspiration of the guide catheter 206.

[0052] As illustrated in the embodiment of Figure 5, the attachment member 408 can further include a valve 445 within the second portion 441b of the first lumen 441. The valve 445 can be, for example, a hemostasis valve configured to maintain hemostasis by preventing fluid flow in the proximal direction through the proximal opening 443a of the attachment member 408 as the delivery sheath 204, the pull member 202, the guidewire, the interventional device ID, and/or other components of the catheter system 200 are inserted through the valve 445 for advancement to the treatment site in the blood vessel BV.

[0053] Figure 6 is an isometric view of a first valve insert 650, such as a hub valve insert, in accordance with embodiments of the present technology. The first valve insert 650 is configured to be inserted at least partially into the first lumen 441 of the attachment member 408 (e.g., into the valve 445) through the proximal opening 443a of the attachment member 408. Accordingly, Figures 7A and 7B are a side view and a side cross-sectional view, respectively, of the first valve insert 650 inserted into the attachment member 408 in accordance with embodiments of the present technology.

[0054] Referring to Figure 6, the first valve insert 650 includes a proximal portion 651a, a distal portion 651b extending from the proximal portion 651a, and a lumen 654. As illustrated in the embodiment of Figure 6, the proximal portion 651a can optionally include one or more first engagement features (e.g., flanges, tabs, etc.) 652 configured to engage with the attachment member 408 of the catheter system 200 to securely position (e.g., lock, mate, flush, etc.) the first valve insert 650 within the attachment member 408. For example, in some embodiments, the first engagement features 652 can be configured to "snap" into (e.g., mate with) corresponding

grooves on the attachment member 408. The proximal portion 651a can further include one or more second engagement features 653 (e.g., flanges, tabs, etc.) configured to be gripped by an operator to enable the operator to, for example, easily manipulate and/or position the first valve insert 650 within the attachment member 408.

[0055] Referring to Figures 6–7B together, the distal portion 651b of the first valve insert 650 is configured to be positioned at least partially within the second portion 441b of the first lumen 441 of the attachment member 408. For example, the first valve insert 650 can be advanced distally over the delivery sheath 204 and/or the guidewire of the catheter system 200 to the attachment member 408. Once inserted into the attachment member 408, the first valve insert 650 opens (e.g., exercises) the valve 445. In some embodiments, the lumen 654 of the distal portion 651b of the first valve insert 650 has a generally constant diameter that is generally the same as the first diameter of the first portion 441a of the first lumen 441 of the attachment member 408. In the embodiment illustrated in Figure 7B, when the first valve insert 650 is within the attachment member 408, the distal portion 651b extends substantially or entirely through the second portion 441b of the first lumen 441 such that the lumen 654 of the first valve insert 650 and the second portion 441a of the first lumen 441 of the attachment member 408 together define a generally continuous lumen extending through the attachment member 408 (e.g., between the distal opening 443b of the attachment member 408 and a proximal terminus of the lumen 654).

[0056] In one aspect of the present technology, the continuous lumen formed by inserting the first valve insert 650 into the attachment member 408 can have a generally constant diameter along the length of the lumen configured to accommodate the outer diameter of the guide catheter 206. Accordingly, as described in further detail below, when a clot retaining portion of an interventional device and associated clot material are retracted proximally through the guide catheter 206, the interventional device ID does not greatly change shape (e.g., expand or compress) while passing through the attachment member 408 and the likelihood of clot material being retained within the attachment member 408 is greatly reduced.

[0057] Figure 8 is a side view of a second valve insert 860 (e.g., an aspiration insert) in accordance with embodiments of the present technology. Similar to the first valve insert 650, the second valve insert 860 is configured to be inserted at least partially into the first lumen 441 of the

attachment member 408 (e.g., through the valve 445) through the proximal opening 443a of the attachment member 408. Accordingly, Figure 9 is a side view of the second valve insert 860 inserted into the attachment member 408 in accordance with embodiments of the present technology.

[0058] Referring to Figure 8, the second valve insert 860 includes a proximal portion 861a, a distal portion 861b extending from the proximal portion 861a, and a lumen 864 extending through the second valve insert 860. As illustrated in the embodiment of Figure 8, the distal portion 861b can optionally include one or more first engagement features (e.g., flanges, tabs, etc.) 862 configured to engage with the attachment member 408 to securely position (e.g., lock) the second valve insert 860 within the attachment member 408. For example, in some embodiments, the first engagement features 862 can be configured to "snap" into (e.g., mate with) corresponding grooves on the attachment member 408. The proximal portion 861a can further include one or more second engagement features 865a (e.g., flanges, tabs, etc.) configured to be gripped by an operator to enable the operator to, for example, easily manipulate and/or position the second valve insert 860 within the attachment member 408.

[0059] The proximal portion 861a can include one or more adjustment features 865 (labeled individually as adjustment features 865a and 865b) for adjusting a diameter of the lumen 864. For example, in some embodiments the second valve insert 860 is a Tuohy Borst Adapter that can be adjusted, via the one or more adjustment features 865, to seal the proximal opening 443a of the attachment member 408 by sealing the lumen 864 against a component of the catheter system 200 inserted therethrough. More particularly, referring to Figures 8 and 9 together, the distal portion 861b of the second valve insert 860 is configured to be positioned at least partially within the attachment member 408 (e.g., within the second portion 441b of the first lumen 441). For example, the second valve insert 860 can be advanced distally over the guidewire of the catheter system 200 to the attachment member 408. Once inserted into the attachment member 408, the second valve insert 860 opens (e.g., exercises) the valve 445. By tightening at least one of the adjustment features 865, at least a portion of the lumen 864 can be narrowed until a seal is formed between the second valve insert 860 and the guidewire or other component of the catheter system 200 positioned therein.

[0060] As described in further detail below, in some embodiments, the second valve insert 860 may more completely seal against components of the catheter system 200 than the valve 445 of the attachment member 408. Accordingly, use of the second valve insert 860 can improve the efficiency of aspiration of the guide catheter 206 using the RA device 100 (Figures 1A and 1B).

[0061] Figure 10 is a flow diagram of a process or method 1000 for operating the clot retrieval system 1 including the attachment member 408 and the first and second valve inserts 650, 860 to remove clot material from within a blood vessel (e.g., a pulmonary blood vessel) of a human patient in accordance with embodiments of the present technology. Although some features of the method 1000 are described in the context of the embodiments shown in Figures 1A–9 for sake of illustration, one skilled in the art will readily understand that the method 1000 can be carried out using other suitable systems and/or devices.

[0062] The method 1000 includes engaging the interventional device ID of the catheter system 200 with the clot material PE in the blood vessel BV as, for example, described above with reference to Figures 2A–2D (block 1001). In particular, the attachment member 408 (Figures 4 and 5) of the catheter system 200 can be attached to the RA device 100, and the interventional device ID can be deployed within at least a portion of the clot material PE by proximally retracting the delivery sheath 204.

[0063] The method 1000 continues by proximally retracting the interventional device ID and associated clot material PE into the guide catheter 206 of the catheter system 200 until a distal terminus of the clot material PE is proximal from a distal terminus of the guide catheter 206 as, for example, described above with reference to Figures 2E–2G (block 1002). In particular, the RA device 100 can be pumped or cycled one or more times (e.g., one time, three times, five times, etc.) to retract the interventional device ID and/or delivery sheath 204 into the guide catheter 206 while simultaneously aspirating the lumen 205 of the guide catheter 206 to remove clot material PE and blood, which are drawn through the attachment member 408 and into the tubing system 300 (e.g., through the clot reservoir 306 to the reservoir 320).

[0064] In some embodiments, the interventional device ID can be retracted proximally into the guide catheter 206 without use of the RA device 100. For example, the operator can manually retract the interventional device ID and associated clot material PE into the guide catheter 206.

[0065] After initial deployment of the interventional device ID in blocks 1001 and 1002, the operator can determine whether it is necessary or desirable to redeploy the interventional device ID within the blood vessel BV of the patient in order to remove additional clot material PE that was not removed during a previous pass with the interventional device ID (block 1003). In some embodiments, the operator can visualize the amount of clot material PE collected in the clot reservoir 306 to at least partially determine whether another pass is needed. In other embodiments, the operator can rely on imaging (e.g., fluoroscopic imaging) of the blood vessel BV or other techniques known in the art to determine whether an additional pass is necessary. If another pass is not needed (e.g., the clot material PE was adequately removed), the operator can elect to withdraw the catheter system 200 from the patient (block 1004). If clot material PE remains in the vessel, the operator can prepare to redeploy the interventional device ID.

[0066] To redeploy the interventional device ID, the method 1000 includes positioning the first valve insert 650 (Figure 6) and withdrawing the interventional device ID from the patient (block 1005). In particular, before positioning the first valve insert 650, the catheter system 200 can be decoupled from the RA device by (i) decoupling the attachment member 408 from the distal portion 100b of the RA device 100 and (ii) removing the delivery sheath 204 and/or guidewire from the channel 116. Additionally, in some embodiments, the clamp 410 can be actuated (e.g., closed) to prevent fluid flow from the guide catheter 206 into the tubing system 300 during withdrawal of the interventional device ID.

[0067] The first valve insert 650 can be advanced over the delivery sheath 204 and/or guidewire of the catheter system 200 until it is positioned (e.g., seated) at least partially within the attachment member 408 (Figures 7A and 7B). Once the first valve insert 650 is positioned within the attachment member 408, the interventional device ID and delivery sheath can be fully withdrawn from the patient. For example, in some embodiments, the operator may grip a portion of the delivery sheath 204 that is exposed proximally from the RA device 100 and pull the delivery sheath 204 and interventional device ID proximally through the guide catheter 206. In some

embodiments, the first valve insert 650 is only positioned within the attachment member 408 when the interventional device ID is proximate the attachment member 408. That is, the operator may partially withdraw the delivery sheath 204 and interventional device ID within the guide catheter 206 before advancing the first valve insert 650 into position. In some embodiments, the delivery sheath 204 includes a marking (e.g., a specific color pattern) configured to indicate to the operator that the distal end of the delivery sheath 204 and/or the interventional device ID is near (e.g., proximally approaching) the attachment member 408. In certain embodiments, the guidewire of the catheter system 200 is pinned during withdrawal of the interventional device ID and the delivery sheath 204 such that the guidewire does not move relative to the interventional device ID and the delivery sheath 204. Therefore, in such embodiments, the guidewire does not need to be re-advanced to the treatment site prior to an additional pass.

[0068] In operation, the first valve insert 650 helps create a lumen of constant diameter through the attachment member 408 such that a diameter of the interventional device ID does not substantially change (e.g., expand and/or contract) as the interventional device ID is withdrawn proximally through the attachment member 408. In particular, the first valve insert 650 can effectively shield the interventional device ID from the valve 445 of the attachment member 408. Without the first valve insert 650, as the interventional device ID is withdrawn proximally it can expand within the attachment member 408 (e.g., as the interventional device ID passes through the second portion 441b of the first lumen 441) before being squeezed (e.g., radially collapsed) as it passes through the valve 445. Without the first valve insert 650, the valve 445 may strip (e.g., break off, shear, etc.) clot material PE that held by the interventional device ID. This can cause clot material PE to remain in the attachment member 408 after the interventional device ID is fully withdrawn from the patient, which presents a significant risk that remaining clot material PE will be reintroduced into the blood vessel BV of the patient if a second pass is made with the interventional device ID without fully removing the guide catheter 206 from the patient to enable cleaning of the guide catheter 206 and the attachment member 408. The first valve insert 650 of the present technology inhibits clot material PE engaged with the interventional device ID from being stripped by the valve 445 within the attachment member 408 and, therefore, enables a second pass with the interventional device ID to be made without removing the guide catheter 206 from the patient.

[0069] The method 1000 includes removing the first valve insert 650 and positioning the second valve insert 860 (Figure 9) (block 1006). For example, the first valve insert 650 can be withdrawn proximally over the guidewire of the catheter system 200 and the second valve insert 860 can then be advanced distally over the guidewire until it is positioned within the attachment member 408. In some embodiments, the first valve insert 650 is removed and the second valve insert 860 is inserted into the attachment member 408 immediately after the delivery sheath 204 and interventional device ID are withdrawn from the patient. Prompt removal of the first valve insert 650 can restore function of the valve 445 and prevent excess blood from leaking through the lumen 654 of the first valve insert 650 once the delivery sheath 204 and interventional device ID are removed.

[0070] Positioning the second valve insert 860 further includes adjusting (tightening) the second valve insert 860 over the guidewire to seal the proximal opening 443a of the attachment member 408. In some embodiments, the method 1000 need not include positioning of the second valve insert 860. Instead, the valve 445 of the attachment member 408 may provide a suitable seal for subsequent aspiration steps. However, in some embodiments, use of the second valve insert 860 can provide a better seal between the guidewire of the catheter system 200 and the attachment member 408, and thus improve the efficiency of aspiration using the RA device 100.

[0071] The method 1000 includes aspirating the guide catheter 206 by, for example, pumping or cycling the lever 104 of the RA device 100 one or more times (block 1007). In embodiments where the clamp 410 was previously closed (e.g., at block 1005), prior to pumping the lever 104, the operator can actuate (e.g., open) the clamp 410 to permit fluid flow from the guide catheter 206 into the tubing system 300. Aspirating the guide catheter 206 removes any residual clot material PE remaining in the guide catheter 206. Accordingly, the residual clot material PE is not reintroduced into the blood vessel BV of the patient when the interventional device ID and delivery sheath 204 are subsequently advanced through the guide catheter 206 during another pass. In certain embodiments, the guide catheter 206 can further be flushed with a fluid (e.g., heparinized saline). For example, the connector 417 can be decoupled from the tubing system 300 and the fluid can be introduced from a flushing device (e.g., a syringe) through a flush port adapter coupled (e.g., semi-permanently coupled) to the connector 417.

[0072] In some embodiments, the guide catheter 206 can be aspirated without use of the RA device 100. For example, a syringe or other pressure source can be fluidly coupled directly to the connector 417 and used to aspirate the guide catheter 206. In such embodiments, opening of the clamp 410 fluidly connects the syringe to the lumen 205 of the guide catheter 206 and closing of the clamp 410 fluidly disconnects the syringe from the lumen 205 of the guide catheter 206. In some embodiments, the syringe or other pressure source can be pre-charged with a vacuum—such as by drawing a plunger of the syringe with the clamp 410 closed. The clamp 410 can then be opened to instantaneously or nearly instantaneously (e.g., immediately) apply the stored vacuum pressure to the tubing system 300 and to the lumen 205 of the guide catheter 206, thereby generating suction throughout the guide catheter 206. In particular, suction can be generated at a distal portion of the guide catheter 206. In one aspect of the present technology, pre-charging or storing the vacuum before applying the vacuum to the lumen 205 of the guide catheter 206 is expected to generate greater suction forces with a faster ramp time (and correspondingly greater fluid flow velocities) at and/or near a distal portion of the guide catheter 206 as compared to, for example, simply activating the pressure source of the RA device 100 by cycling the lever 104 of the RA device 100. These suction forces generated by application of the stored vacuum can be used to not only aspirate the guide catheter 206, but also to aspirate or otherwise remove some or all of the clot material PE remaining in the blood vessel BV after retraction of the interventional device ID.

[0073] The method 1000 includes flushing the tubing system 300 (block 1008). In some embodiments, flushing the tubing system 300 includes (i) actuating (e.g., closing) the clamp 410 to inhibit fluid flow from the guide catheter 206 into the tubing system 300, (ii) disconnecting the tubing section 326 of the clot reservoir 306 from the tubing section 302e and the connector 417 of the tubing system 300, (iii) placing the tubing section 326 into a container of fluid (e.g., saline), and (iv) pumping the lever 104 of the RA device 100 to draw the fluid through the tubing system 300. In some embodiments, the housing 322 of the clot reservoir 306 can be temporarily disconnected (e.g., unscrewed) from the cap assembly 330 so that the clot material PE in the clot reservoir 306 can be removed. In certain embodiments, the tubing system 300 need not be flushed prior to a second pass with the interventional device ID or another interventional device. In some embodiments, flushing the tubing system 300 can include attaching a syringe to the fluid connector 332 of the clot reservoir 306 and/or to the tubing section 302a of the tubing system 300

and using the syringe to generate a negative pressure to draw the fluid through the clot reservoir 306.

[0074] After the tubing system 300 has been flushed, the method 1000 can return to block 1001. In particular, the same interventional device ID and delivery sheath 204 can be cleaned and subsequently advanced through the guide catheter 206 and to the remaining clot material PE in the blood vessel BV. In some embodiments, a new interventional device and delivery sheath can be used for each pass to reduce the likelihood of contamination (e.g., reintroduction of clot material PE into the patient). Once the desired amount of clot material PE has been removed from the patient, the catheter system 200 may be fully withdrawn from the patient (block 1004).

[0075] In one aspect of the present technology, the method 1000 provides for multiple passes of an interventional device without requiring that the entire guide catheter be removed after each pass. Accordingly, the present technology allows for only a single insertion of a guide catheter during a procedure including multiple passes to remove clot material—increasing the speed of the procedure and reducing trauma to the patient since the guide catheter does not need to be reintroduced (e.g., advanced through the vasculature and past the heart) before each pass.

[0076] Moreover, in certain embodiments, the present technology can enable the guide catheter 206 to be relocated to an alternate treatment site within the patient without removing the guide catheter 206 from the patient and, therefore, without reintroducing the guide catheter 206 through the heart. For example, the guide catheter 206 can be relocated to another treatment site within the lungs including a treatment site in the opposite lung. More specifically, (i) a dilator can be reintroduced into the guide catheter 206, (ii) the guide catheter 206 can be withdrawn into the main pulmonary artery, (iii) the guidewire can be redirected to the new treatment site, (iv) the guide catheter 206 can be advanced over the guidewire to the new treatment site, and (v) the dilator can be removed.

[0077] Additional details of the systems, devices, and methods described above with reference to Figures 4–9 are provided in Appendix B to this application.

IV. Other Selected Embodiments of Attachment/Valve Members, and Associated Devices and Methods of Use

[0078] Figure 11 is a side view of an attachment/valve member 1108 ("attachment member 1108") of the catheter system 200 and a second fluid control unit 1110 of the tubing system 300 in accordance with embodiments of the present technology. The attachment member 1108 and the second fluid control unit 1110 can have some features generally similar to the features of the attachment members 208, 408 and the second fluid control unit 310, 410, respectively, described above with reference to Figures 1A–10. For example, the attachment member 1108 can be integral with or coupled to a proximal portion of the guide catheter 206 and configured to be detachably coupled to the RA device 100 (Figures 1A and 1B; e.g., via a snap-fit arrangement) to at least partially secure the catheter system 200 to the RA device 100. When secured to the RA Device 100, the attachment member 1108 can fluidly connect the lumen 205 (e.g., an aspiration lumen) of the guide catheter 206 to the tubing system 300 of the clot retrieval system 1 via the tubing section 302f. Likewise, the second fluid control unit 1110 can be a stopcock ("stopcock 1110") that is externally operable to regulate the flow of fluid through the tubing section 302f.

[0079] As further shown in Figure 11, the tubing system 300 can include a connector 1117 for, for example, fluidly connecting the tubing section 302f and the stopcock 1110 to other portions of the tubing system 300 (e.g., those shown in Figures 1A and 1B). In some embodiments, the connector 1117 is a quick-release connector that enables rapid coupling/decoupling of the tubing section 302f and stopcock 1110 to other components of the tubing system 300.

[0080] Figure 12 is a side view of the stopcock 1110 in accordance with embodiments of the present technology. In the embodiment illustrated in Figure 12, the stopcock 1110 includes a grip member (e.g., a handle, a knob, etc.) 1211 that can be actuated (e.g., twisted by the hand of an operator) to partially or fully restrict fluid flow through the tubing section 302f. In some embodiments, the stopcock 1110 also includes an injection port 1212 (e.g., a needleless injection port) configured to receive a syringe or other fluid delivery member therethrough. In some embodiments, the injection port 1212 permits fluid to be introduced into the attachment member 1108 and the guide catheter 206 without requiring that a connector 1117 be decoupled from

the tubing system 300. For example, in some embodiments, an operator can actuate the stopcock 1110 (e.g., twist the grip member 1211) to close the stopcock 1110 and subsequently introduce a syringe at the injection port 1212 to flush the guide catheter 206 with a fluid (e.g., saline) introduced via the syringe.

[0081] Figures 13A and 13B are side cross-sectional views of the attachment member 1108 in a first configuration and a second configuration, respectively, in accordance with embodiments of the present technology. The attachment member 1108 can be, for example, a garrote valve (e.g., a hemostasis valve) as disclosed in provisional U.S. Patent Application No. 62/554,931, filed September 6, 2017, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is reproduced in Appendix D to this application, and which is incorporated herein by reference in its entirety.

[0082] In particular, referring to Figures 13A and 13B together, the attachment member 1108 can include a housing 1370 having a proximal opening 1373a and a distal opening 1373b, and defining a first lumen (e.g., an interior channel) 1371 extending between the proximal and distal openings 1373a, 1373b. The housing 1370 further includes a branch portion 1380 configured to be coupled to the tubing section 302f and defining a second lumen 1381 branching from the first lumen 1371. In some embodiments, the second lumen 1381 can have a relatively large diameter (e.g., between about 0.098 inch and 0.210 inch, about 0.210 inch, greater than 0.210 inch, etc.) to help inhibit clogging and/or collection of clot material within the attachment member 1108 during, for example, aspiration of the guide catheter 206. In one aspect of the present technology, the first lumen 1371 can have a generally constant diameter along its length.

[0083] As shown, a tubular member (e.g., an elongate member) 1372 can extend at least partially through the first lumen 1371 to define a central lumen 1374 that is generally coaxial with the first lumen 1371. In some embodiments, the tubular member 1372 can comprise a compliant tubular structure (e.g., a silicon tube) that can be, for example, a thin-walled compliant tubular structure. The thin-walled structure of the tubular member 1372 can facilitate the collapse, and specifically the uniform collapse of the tubular member 1372 and sealing of the tubular member 1372. For example, the attachment member 1108 can further include an actuation mechanism 1375 coupled to the tubular member 1372 and configured to collapse and seal the

tubular member 1372 via compression and/or constriction of one or more filaments 1376 coupled to the tubular member 1372.

[0084] More specifically, in some embodiments, the actuation mechanism 1375 can be a manual actuator such as one or more buttons 1378. Depression or release of the buttons can, in some embodiments, facilitate sealing of the tubular member 1372 around tools or instruments of a wide range of sizes and/or diameters that fit through the tubular member 1372. For example, Figure 13A illustrates the attachment member 1108 with the actuation mechanism 1375 in the first configuration in which the tubular member 1372 is in a collapsed and/or sealed state having a minimum diameter (e.g., conformed to a diameter of a portion of a catheter system inserted therethrough). In the embodiment shown in Figure 13A, the actuation mechanism 1375 is biased (e.g., by one or more springs 1377) to maintain the tubular member 1372 in the collapsed state. Specifically, in the first configuration, the actuation mechanism 1375 can tighten the filament 1376 to constrict or compress the tubular member 1372 to seal the central lumen 1374 of the tubular member 1372. Thus, when the buttons 1378 are not depressed, the attachment member 1108 can provide a hemostatic seal.

[0085] As shown in the embodiment of Figure 13B, the attachment member 1108 is in an expanded (e.g., open) and/or unsealed state having a maximum diameter (e.g., a diameter generally the same as the first lumen 1371). More particularly, one or more of the buttons 1378 may be depressed to, for example, loosen the filament 1376 and allow expansion of the tubular member 1372 to unseal the central lumen 1374 of the tubular member 1372.

[0086] Accordingly, the actuation mechanism 1375 and tubular member 1372 of the attachment member 1108 provide for sealing of the attachment member 1108 around, for example, various components of the catheter system 200 (e.g., the delivery sheath 204, the pull member 202, the guidewire, the interventional device ID, etc.) that are inserted through the attachment member 1108 for advancement to the treatment site in the blood vessel BV. Moreover, in the second configuration, the central lumen 1374 of the tubular member 1372 and the first lumen 1371 of the housing 1370 can together provide a continuous lumen of generally constant diameter. As described above, such a constant diameter can prevent clot material PE associated with the interventional device ID from getting stuck in (e.g., remaining in) the attachment member 1108 as

the interventional device ID is retracted through the attachment member 1108—thus minimizing the risk of reintroducing clot material to the patient upon a second pass using the interventional device ID (or another interventional device).

[0087] Figure 14 is a flow diagram of a process or method 1400 for operating the clot retrieval system 1 including the attachment member 1108 to remove clot material from within a blood vessel (e.g., a pulmonary blood vessel) of a human patient in accordance with embodiments of the present technology. Although some features of the method 1400 are described in the context of the embodiments shown in Figures 1A, 1B, and 11–13 for sake of illustration, one skilled in the art will readily understand that the method 1400 can be carried out using other suitable systems and/or devices.

[0088] The method 1400 includes engaging the interventional device ID of the catheter system 200 with the clot material PE in the blood vessel BV as, for example, described above with reference to Figures 2A–2D (block 1401). In particular, the attachment member 1108 of the catheter system 200 can be coupled to the RA device 100, and the interventional device ID can be deployed within at least a portion of the clot material PE by proximally retracting the delivery sheath 204 relative to the interventional device ID.

[0089] The method 1400 continues by proximally retracting the interventional device ID and associated clot material PE into the guide catheter 206 of the catheter system 200 until a distal terminus of the clot material PE is proximal from a distal terminus of the guide catheter 206 as, for example, described above with reference to Figures 2E–2G (block 1402). In particular, the RA device 100 can be pumped or cycled one or more times (e.g., one time, three times, five times, etc.) to retract the interventional device ID and/or delivery sheath 204 into the guide catheter 206 while simultaneously aspirating the lumen 205 of the guide catheter 206 to remove clot material PE and blood, which are drawn through the attachment member 1108 of the catheter system 200 and into the tubing system 300 (e.g., through the clot reservoir 306 to the reservoir 320).

[0090] In some embodiments, the interventional device ID can be retracted proximally into the guide catheter 206 without use of the RA device 100. For example, the operator can manually retract the interventional device ID and associated clot material PE into the guide catheter 206.

[0091] After the initial deployment of the interventional device ID in blocks 1401 and 1402, the operator can determine whether it is necessary or desirable to redeploy the interventional device ID within the blood vessel BV of the patient in order to remove additional clot material PE that was not removed during a previous pass with the interventional device ID (block 1403). In some embodiments, the operator can visualize the amount of clot material PE collected in the clot reservoir 306 to at least partially determine whether another pass is needed. In other embodiments, the operator can rely on imaging (e.g., fluoroscopic imaging) of the blood vessel BV or other techniques known in the art to determine whether an additional pass is necessary. If another pass is not needed (e.g., the clot material PE was adequately removed), the operator can elect to withdraw the catheter system 200 from the patient at block 1404. If clot material PE remains in the vessel, the operator can prepare to redeploy the interventional device ID.

[0092] To redeploy the interventional device ID, the method 1400 includes withdrawing the interventional device ID from the patient (block 1405). In particular, before withdrawing the interventional device ID, the catheter system 200 can be decoupled from the RA device by (i) decoupling the attachment member 1108 from the distal portion 100b of the RA device 100 and (ii) removing the delivery sheath 204 and/or guidewire from the channel 116 of the RA device 100. Additionally, in some embodiments, the stopcock 1110 can be actuated (e.g., twisted closed) to prevent fluid flow from the guide catheter 206 into the tubing system 300 during withdrawal of the interventional device ID.

[0093] The delivery sheath 204 and/or another component of the catheter system 200 may then be manually (e.g., by the operator) or automatically pulled proximally to withdraw the interventional device ID from the patient. Before the interventional device ID and associated clot material PE are withdrawn through the attachment member 1108, the actuation mechanism 1375 of the attachment member 1108 can be actuated (e.g., by depressing the buttons 1378) to move the tubular member 1372 to the second configuration (e.g., to open the tubular member 1372) such that the central lumen 1374 of the tubular member 1372 and the first lumen 1371 of the housing 1370 together provide a continuous lumen of generally constant diameter. Accordingly, the interventional device ID can be fully withdrawn (e.g., retracted proximally) through the attachment member 1108 without causing a significant amount of clot material PE associated with the

interventional device ID to remain in the attachment member 1108—thus minimizing the risk of reintroducing clot material to the patient upon an additional pass using the interventional device ID (or another interventional device). Moreover, in certain embodiments, the guidewire of the catheter system 200 is pinned during withdrawal of the interventional device ID and the delivery sheath 204 such that the guidewire does not move relative to the interventional device ID and the delivery sheath 204. Therefore, in such embodiments, the guidewire does not need to be re-advanced to the treatment site prior to an additional pass.

[0094] Once the interventional device ID has been fully removed from the guide catheter 206 and the attachment member 1108, the attachment member 1108 can be returned to the first (e.g., sealed) configuration by, for example, releasing the buttons 1378. Next, the method includes aspirating the guide catheter 206 by, for example, pumping or cycling the lever 104 of the RA device 100 one or more times (block 1406). In embodiments where the stopcock 1110 was previously closed (e.g., at block 1405), prior to pumping the lever 104, the stopcock 1110 can be opened to permit fluid flow from the guide catheter 206 into the tubing system 300. Aspirating the guide catheter 206 removes any residual clot material PE remaining in the guide catheter 206. Accordingly, the residual clot material PE is not reintroduced into the blood vessel BV of the patient when the interventional device ID and delivery sheath 204 (or another interventional device ID) are subsequently advanced through the guide catheter 206 during another pass. In certain embodiments, the guide catheter 206 can further be flushed with a fluid (e.g., heparinized saline). For example, the fluid can be introduced through the injection port 1212 while simultaneously pressing the buttons 1378 of the attachment member 1108. In certain embodiments, the stopcock 1110 can be closed (e.g., at block 1406), and a syringe can be connected to the injection port 1212 and used to generate a negative pressure prior to opening the stopcock 1110 to permit fluid flow from the guide catheter 206 into the syringe.

[0095] In some embodiments, the guide catheter 206 can be aspirated without use of the RA device 100. For example, a syringe or other pressure source can be fluidly coupled directly to the connector 1117 and used to aspirate the guide catheter 206. In such embodiments, opening of the stopcock 1110 fluidly connects the syringe to the lumen 205 of the guide catheter 206 and closing of the stopcock 1110 fluidly disconnects the syringe from the lumen 205 of the guide catheter 206.

In some embodiments, the syringe or other pressure source can be pre-charged with a vacuum—such as by drawing a plunger of the syringe with the stopcock 1110 closed. The stopcock 1110 can then be opened to instantaneously or nearly instantaneously (e.g., immediately) apply the stored vacuum pressure to the tubing system 300 and to the lumen 205 of the guide catheter 206, thereby generating suction throughout the guide catheter 206. In particular, suction can be generated at a distal portion of the guide catheter 206. In one aspect of the present technology, pre-charging or storing the vacuum before applying the vacuum to the lumen 205 of the guide catheter 206 is expected to generate greater suction forces with a faster ramp time (and correspondingly greater fluid flow velocities) at and/or near a distal portion of the guide catheter 206 as compared to, for example, simply activating the pressure source of the RA device 100 by cycling the lever 104 of the RA device 100. These suction forces generated by application of the stored vacuum can be used to not only aspirate the guide catheter 206, but also to aspirate or otherwise remove some or all of the clot material PE remaining in the blood vessel BV after retraction of the interventional device ID.

[0096] The method 1400 includes flushing the tubing system 300 (block 1407). In some embodiments, flushing the tubing system 300 includes (i) closing the stopcock 1110 to inhibit fluid flow from the guide catheter 206 into the tubing system 300, (ii) disconnecting the tubing section 326 of the clot reservoir 306 from the tubing section 300e of the tubing system 300, (iii) placing the tubing section 326 into a container of fluid (e.g., saline), and (iv) pumping the lever 104 of the RA device 100 to draw the fluid through the tubing system 300. In some embodiments, the housing 322 of the clot reservoir 306 can be temporarily decoupled (e.g., unscrewed) from the cap assembly 330 so that the clot material PE in the clot reservoir 306 can be removed. In certain embodiments, the tubing system 300 need not be flushed prior to an additional pass with the interventional device ID. In some embodiments, flushing the tubing system 300 can include attaching a syringe to the fluid connector 332 of the clot reservoir 306 and/or to the tubing section 302a of the tubing system 300 and using the syringe to generate a negative pressure to draw the fluid through the clot reservoir 306.

[0097] After the tubing system 300 has been flushed, the method 1400 can return to block 1401. In particular, the same interventional device ID and delivery sheath 204 can be cleaned and subsequently advanced through the guide catheter 206 and to the remaining clot material PE in

the blood vessel. In some embodiments, a new interventional device ID and delivery sheath 204 can be used for each pass to reduce the likelihood of contamination (e.g., reintroduction of clot material PE). Once the desired amount of clot material PE has been removed from the patient, the catheter system 200 may be fully withdrawn from the patient (block 1404).

[0098] In one aspect of the present technology, the method 1400 provides for multiple passes of an interventional device without requiring that the entire guide catheter be removed after each pass. Accordingly, the present technology allows for only a single insertion of a guide catheter during a procedure including multiple passes to remove clot material—increasing the speed of the procedure and reducing trauma to the patient since the guide catheter does not need to be reintroduced (e.g., advanced through the vasculature and past the heart) before each pass.

[0099] Moreover, in certain embodiments, the present technology can enable the guide catheter 206 to be relocated to an alternate treatment site within the patient without removing the guide catheter 206 from the patient and, therefore, without reintroducing the guide catheter 206 through the heart. For example, the guide catheter 206 can be relocated to another treatment site within the lungs including a treatment site in the opposite lung. More specifically, (i) a dilator can be reintroduced into the guide catheter 206, (ii) the guide catheter 206 can be withdrawn into the main pulmonary artery, (iii) the guidewire can be redirected to the new treatment site, (iv) the guide catheter 206 can be advanced over the guidewire to the new treatment site, and (v) the dilator can be removed.

[0100] Additional details of the systems, devices, and methods described above with reference to Figures 11–14 are provided in Appendix C to this application.

V. Examples

1. A method for the intravascular treatment of clot material from a treatment site within a blood vessel of a human patient, the method comprising:
 - engaging a first interventional device with the clot material at the treatment site in the blood vessel;
 - retracting the first interventional device and a portion of the clot material into a distal portion of an elongated shaft;

inserting a first valve insert into an attachment member coupled to a proximal portion of the elongated shaft;
withdrawing the first interventional device and the portion of the clot material proximally through (a) the elongated shaft, (b) the attachment member, and (c) the first valve insert;
inserting a second valve insert into the attachment member instead of the first valve insert;
aspirating the elongated shaft; and
advancing a second interventional device distally through the elongated shaft to the treatment site.

2. The method of example 1 wherein, after inserting the first valve insert into the attachment member, the first valve insert and the attachment member together define a lumen having a generally constant diameter.

3. The method of example 2 wherein the diameter of the lumen is generally the same as the diameter of the elongated shaft.

4. The method of any one of examples 1–3 wherein inserting the first valve insert into the attachment member includes exercising a valve of the attachment member.

5. The method of any one of examples 1–4, further comprising actuating the second valve insert to seal the attachment member.

6. The method of any one of examples 1–5 wherein the first interventional device and the second interventional device are the same interventional device, and wherein the method further comprises cleaning the interventional device to remove the portion of the clot material.

7. The method of any one of examples 1–6, further comprising engaging the second interventional device with remaining clot material at the treatment site in the blood vessel.

8. The method of any one of examples 1–7 wherein aspirating the elongated shaft includes aspirating, into the elongated shaft, at least a portion of clot material remaining at the treatment site in the blood vessel.

9. The method of example 8 wherein aspirating the elongated shaft includes—
coupling a syringe to the elongated shaft via a fluid control unit, wherein opening of the fluid control unit fluidly connects the syringe to the elongated shaft, and wherein closing of the fluid control device fluidly disconnects the syringe from the elongated shaft;
drawing a plunger of the syringe to generate a vacuum while the fluid control unit is closed;
and
opening the fluid control unit to apply the vacuum to the elongated shaft to thereby aspirate the portion of the remaining clot material into the elongated shaft.

10. The method of example 9 wherein the fluid control unit is a clamp.

11. A method for the intravascular treatment of clot material from a treatment site within a blood vessel of a human patient, the method comprising:
engaging a first interventional device with the clot material at the treatment site in the blood vessel;
retracting the first interventional device and a portion of the clot material into a distal portion of an elongated shaft;
withdrawing the interventional device and the portion of the clot material from the blood vessel through the elongated shaft and an attachment member coupled thereto, including—
before withdrawing the interventional device through the attachment member, actuating the attachment member to move the attachment member from a first configuration in which a lumen of the attachment member is sealed to a second configuration in which the lumen of the attachment member is open;

after withdrawing the interventional device through the attachment member,
actuating the attachment member to return the attachment member to the first
configuration from the second configuration;
aspirating the elongated shaft; and
advancing a second interventional device distally through the elongated shaft to the
treatment site.

12. The method of example 11 wherein actuating the attachment member includes
pressing one or more buttons on the attachment member.

13. The method of example 11 or 12 wherein in the second configuration, the lumen of
the attachment member has a generally constant diameter.

14. The method of example 13 wherein the diameter of the lumen is generally the same
as a diameter of the elongated shaft.

15. The method of any one of examples 11–14 wherein the first interventional device
and the second interventional device are the same interventional device, and wherein the method
further comprises cleaning the interventional device to remove the portion of the clot material.

16. The method of any one of examples 11–15, further comprising engaging the second
interventional device with remaining clot material in the blood vessel.

17. The method of one of examples 11–16 wherein aspirating the elongated shaft
includes—

coupling a syringe to the elongated shaft via a stopcock, wherein opening of the stopcock
fluidly connects the syringe to the elongated shaft, and wherein closing of the
stopcock fluidly disconnects the syringe from the elongated shaft;
drawing a plunger of the syringe to generate a vacuum while the stopcock is closed; and

opening the stopcock to apply the vacuum to the elongated shaft to thereby aspirate, into the elongated shaft, at least a portion of clot material remaining at the treatment site in the blood vessel.

18. A method for the intravascular treatment of clot material from a treatment site within a blood vessel of a human patient, the method comprising:

engaging an interventional device with the clot material at the treatment site in the blood vessel;

retracting the interventional device and a portion of the clot material into a distal portion of a lumen of an elongated shaft;

unsealing an attachment member coupled to a proximal portion of the elongated shaft;

withdrawing the interventional device and the portion of the clot material through the lumen of the elongated shaft and through the attachment member;

sealing the attachment member;

aspirating the elongated shaft; and

advancing the same or a different interventional device distally through the lumen of the elongated shaft to the treatment site.

19. The method of example 18 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 a diameter of the lumen of the elongated shaft.

20. The method of example 18 or 19, further comprising:

engaging the same or the different interventional device with clot material remaining in the blood vessel; and

retracting the same or the different interventional device and a portion of the remaining clot material into the distal portion of the lumen of the elongated shaft;

unsealing the attachment member; and

withdrawing the same or the different interventional device and the portion of the remaining clot material through the lumen of the elongated shaft and through the attachment member.

VI. Conclusion

[0101] 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.

[0102] 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.

[0103] 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 method for the intravascular treatment of clot material from a treatment site within a blood vessel of a human patient, the method comprising:
 - engaging a first interventional device with the clot material at the treatment site in the blood vessel;
 - retracting the first interventional device and a portion of the clot material into a distal portion of an elongated shaft;
 - inserting a first valve insert into an attachment member coupled to a proximal portion of the elongated shaft;
 - withdrawing the first interventional device and the portion of the clot material proximally through (a) the elongated shaft, (b) the attachment member, and (c) the first valve insert;
 - inserting a second valve insert into the attachment member instead of the first valve insert;
 - aspirating the elongated shaft; and
 - advancing a second interventional device distally through the elongated shaft to the treatment site.
2. The method of claim 1 wherein, after inserting the first valve insert into the attachment member, the first valve insert and the attachment member together define a lumen having a generally constant diameter.
3. The method of claim 2 wherein the diameter of the lumen is generally the same as the diameter of the elongated shaft.
4. The method of claim 1 wherein inserting the first valve insert into the attachment member includes exercising a valve of the attachment member.

5. The method of claim 1, further comprising actuating the second valve insert to seal the attachment member.

6. The method of claim 1 wherein the first interventional device and the second interventional device are the same interventional device, and wherein the method further comprises cleaning the interventional device to remove the portion of the clot material.

7. The method of claim 1, further comprising engaging the second interventional device with remaining clot material at the treatment site in the blood vessel.

8. The method of claim 1 wherein aspirating the elongated shaft includes aspirating, into the elongated shaft, at least a portion of clot material remaining at the treatment site in the blood vessel.

9. The method of claim 8 wherein aspirating the elongated shaft includes—
coupling a syringe to the elongated shaft via a fluid control unit, wherein opening of the fluid control unit fluidly connects the syringe to the elongated shaft, and wherein closing of the fluid control device fluidly disconnects the syringe from the elongated shaft;
drawing a plunger of the syringe to generate a vacuum while the fluid control unit is closed;
and
opening the fluid control unit to apply the vacuum to the elongated shaft to thereby aspirate the portion of the remaining clot material into the elongated shaft.

10. The method of claim 9 wherein the fluid control unit is a clamp.

11. A method for the intravascular treatment of clot material from a treatment site within a blood vessel of a human patient, the method comprising:
engaging a first interventional device with the clot material at the treatment site in the blood vessel;

retracting the first interventional device and a portion of the clot material into a distal portion of an elongated shaft;

withdrawing the interventional device and the portion of the clot material from the blood vessel through the elongated shaft and an attachment member coupled thereto, including—

before withdrawing the interventional device through the attachment member, actuating the attachment member to move the attachment member from a first configuration in which a lumen of the attachment member is sealed to a second configuration in which the lumen of the attachment member is open;

after withdrawing the interventional device through the attachment member, actuating the attachment member to return the attachment member to the first configuration from the second configuration;

aspirating the elongated shaft; and

advancing a second interventional device distally through the elongated shaft to the treatment site.

12. The method of claim 11 wherein actuating the attachment member includes pressing one or more buttons on the attachment member.

13. The method of claim 11 wherein in the second configuration, the lumen of the attachment member has a generally constant diameter.

14. The method of claim 13 wherein the diameter of the lumen is generally the same as a diameter of the elongated shaft.

15. The method of claim 11 wherein the first interventional device and the second interventional device are the same interventional device, and wherein the method further comprises cleaning the interventional device to remove the portion of the clot material.

16. The method of claim 11, further comprising engaging the second interventional device with remaining clot material in the blood vessel.

17. The method of claim 11 wherein aspirating the elongated shaft includes—
coupling a syringe to the elongated shaft via a stopcock, wherein opening of the stopcock fluidly connects the syringe to the elongated shaft, and wherein closing of the stopcock fluidly disconnects the syringe from the elongated shaft;
drawing a plunger of the syringe to generate a vacuum while the stopcock is closed; and
opening the stopcock to apply the vacuum to the elongated shaft to thereby aspirate, into the elongated shaft, at least a portion of clot material remaining at the treatment site in the blood vessel.

18. A method for the intravascular treatment of clot material from a treatment site within a blood vessel of a human patient, the method comprising:

engaging an interventional device with the clot material at the treatment site in the blood vessel;
retracting the interventional device and a portion of the clot material into a distal portion of a lumen of an elongated shaft;
unsealing an attachment member coupled to a proximal portion of the elongated shaft;
withdrawing the interventional device and the portion of the clot material through the lumen of the elongated shaft and through the attachment member;
sealing the attachment member;
aspirating the elongated shaft; and
advancing the same or a different interventional device distally through the lumen of the elongated shaft to the treatment site.

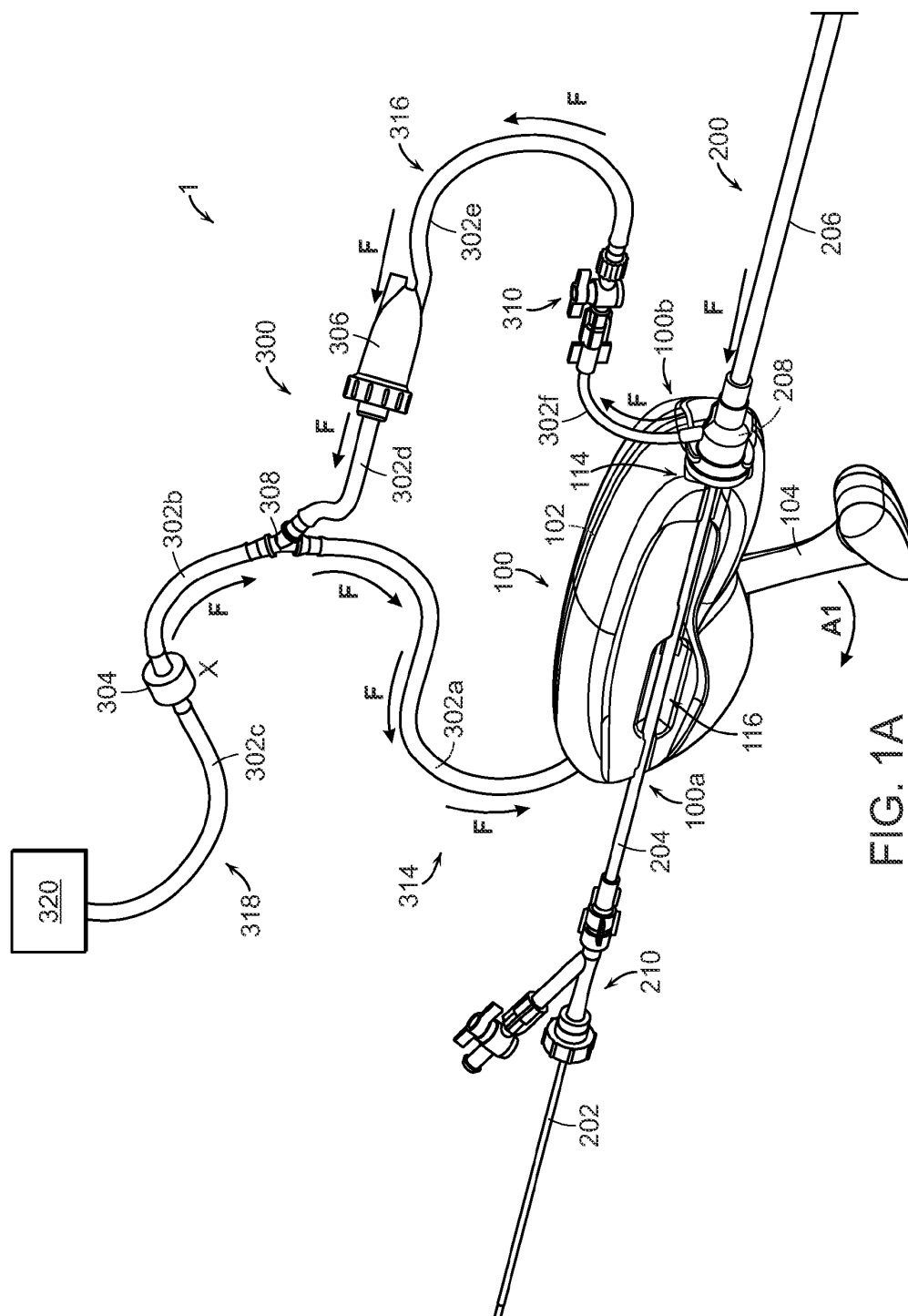
19. The method of claim 18 wherein unsealing the attachment member includes exercising a valve of the attachment member such that a lumen of the attachment member has a diameter that is about equal to a diameter of the lumen of the elongated shaft.

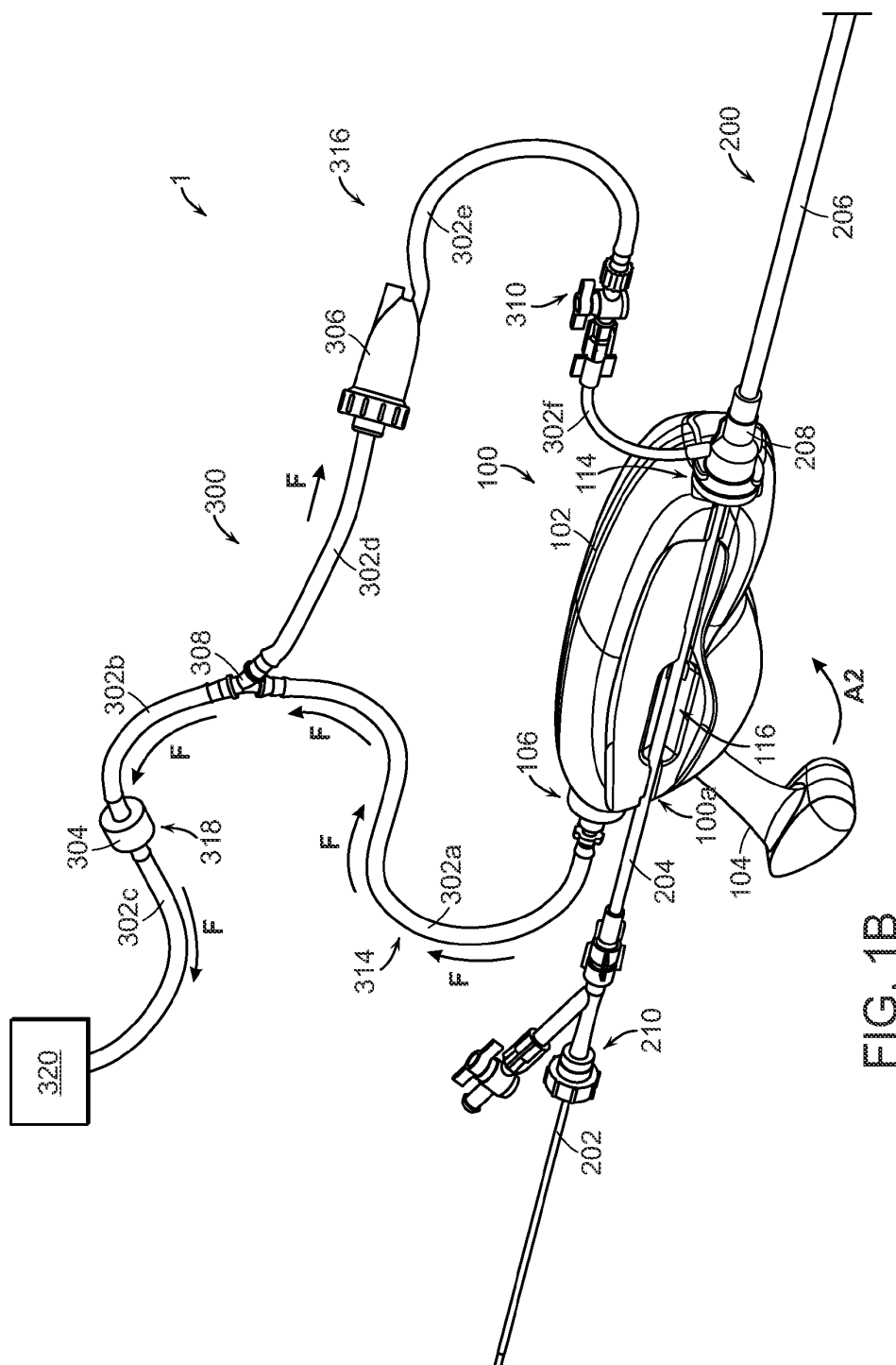
20. The method of claim 18, further comprising:
engaging the same or the different interventional device with clot material remaining in the
blood vessel; and
retracting the same or the different interventional device interventional device and a portion
of the remaining clot material into the distal portion of the lumen of the elongated
shaft;
unsealing the attachment member; and
withdrawing the same or the different interventional device and the portion of the remaining
clot material through the lumen of the elongated shaft and through the attachment
member.

ABSTRACT OF THE DISCLOSURE

Systems and methods for the intravascular treatment of clot material within a blood vessel of a human patient are disclosed herein. A method in accordance with embodiments of the present technology can include, for example, engaging an interventional device of a catheter system with clot material in a blood vessel and withdrawing the interventional device and the portion of the clot material through a guide catheter. In some embodiments, the catheter system can include an attachment/valve member coupled to a proximal portion of the guide catheter, and the method can include unsealing the attachment/valve member to facilitate withdrawing the interventional device through the attachment/valve member without significant retention of clot material within the attachment/valve member. The method can further include resealing and aspirating the guide catheter before advancing another interventional device to the clot material to again engage and remove clot material from the blood vessel.

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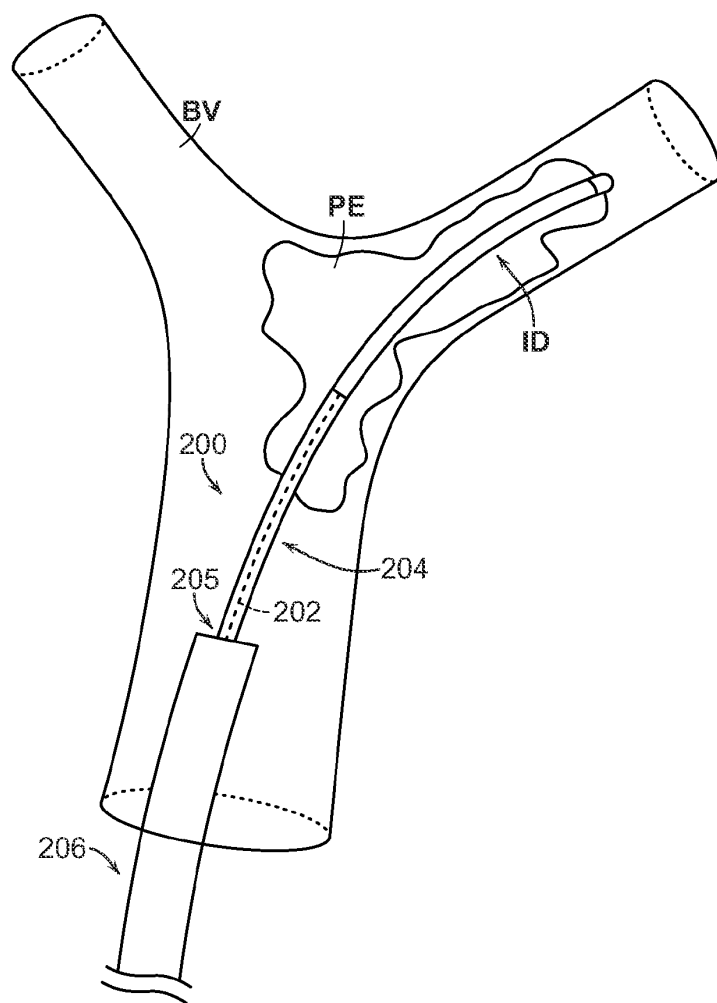


FIG. 2A

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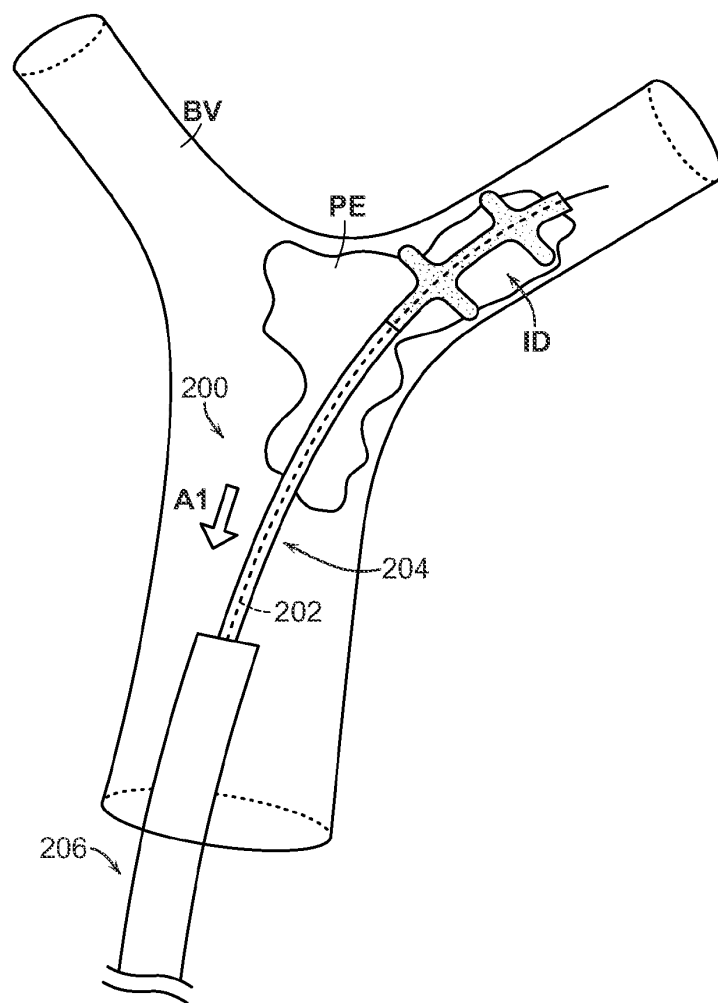


FIG. 2B

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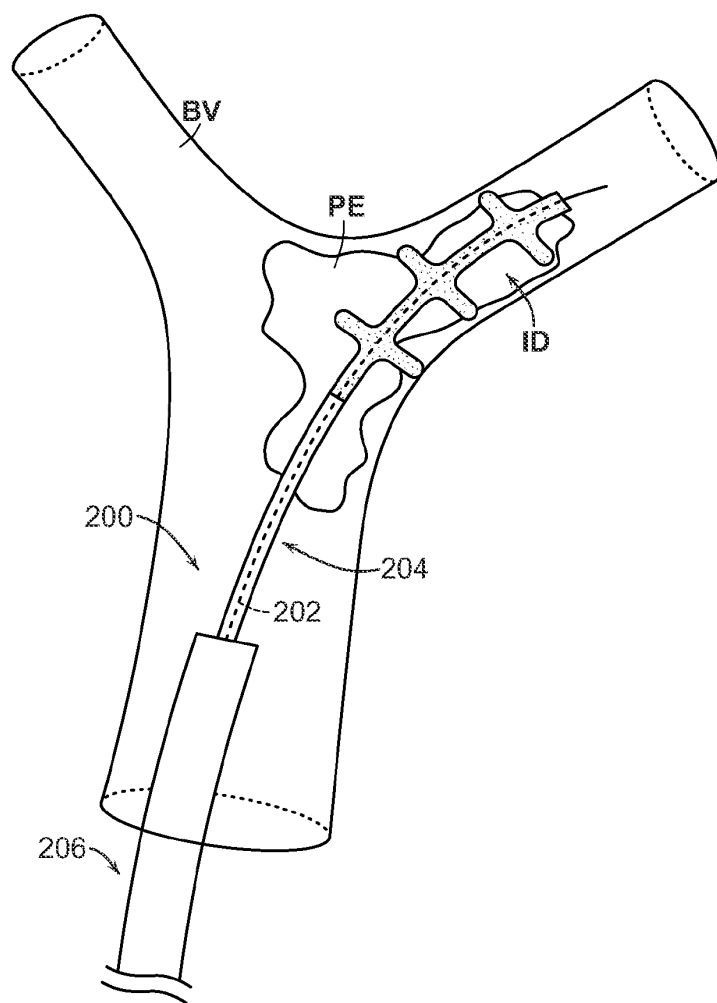


FIG. 2C

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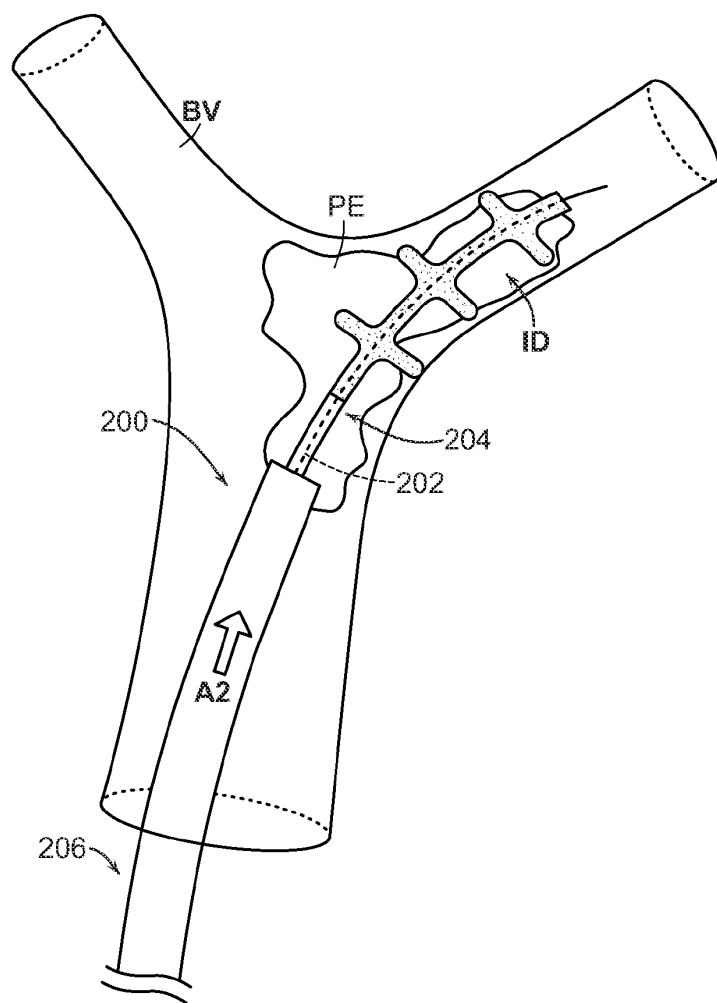


FIG. 2D

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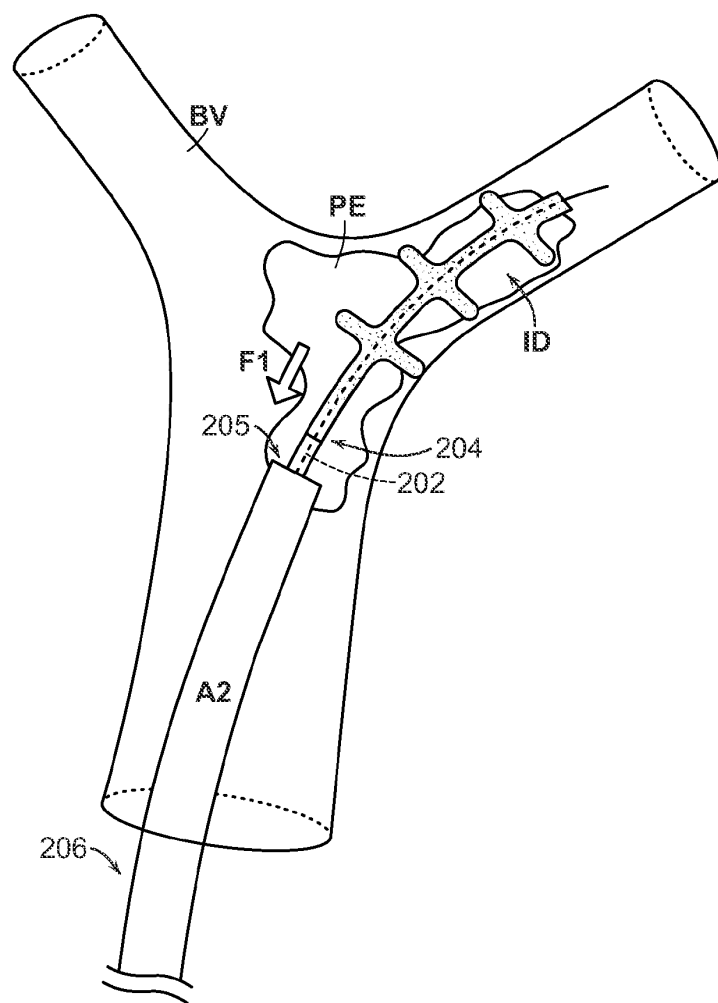


FIG. 2E

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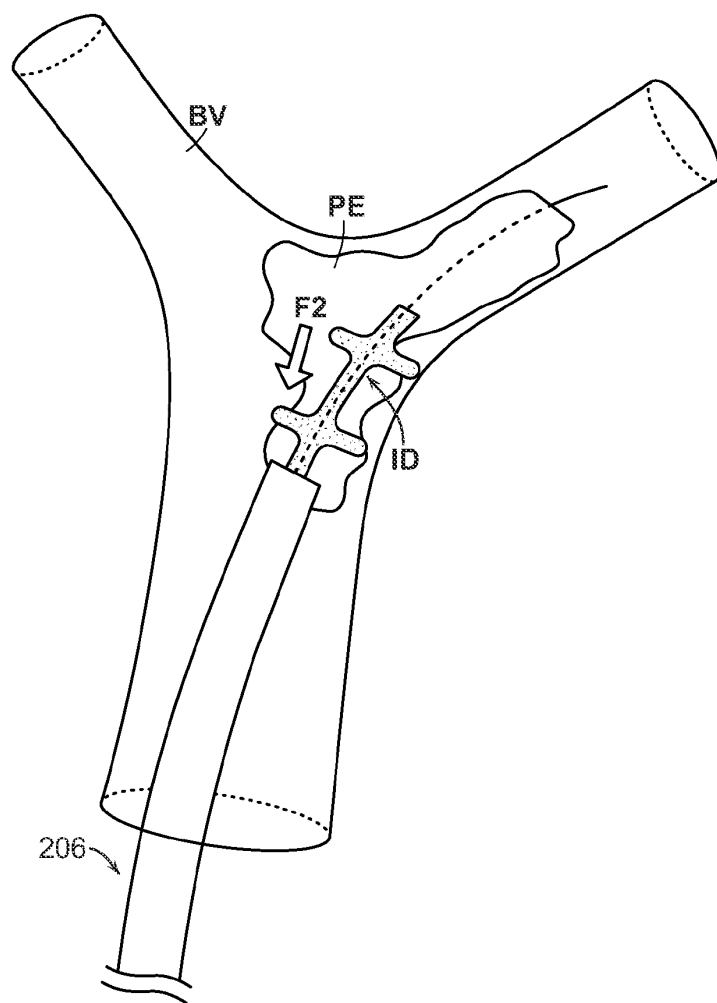


FIG. 2F

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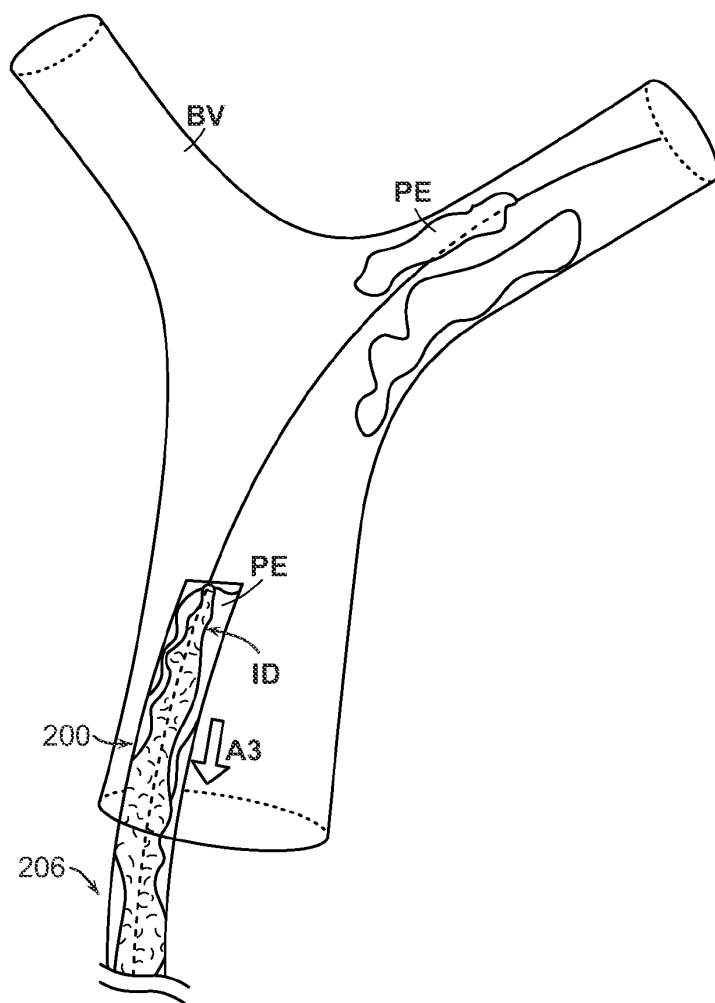


FIG. 2G

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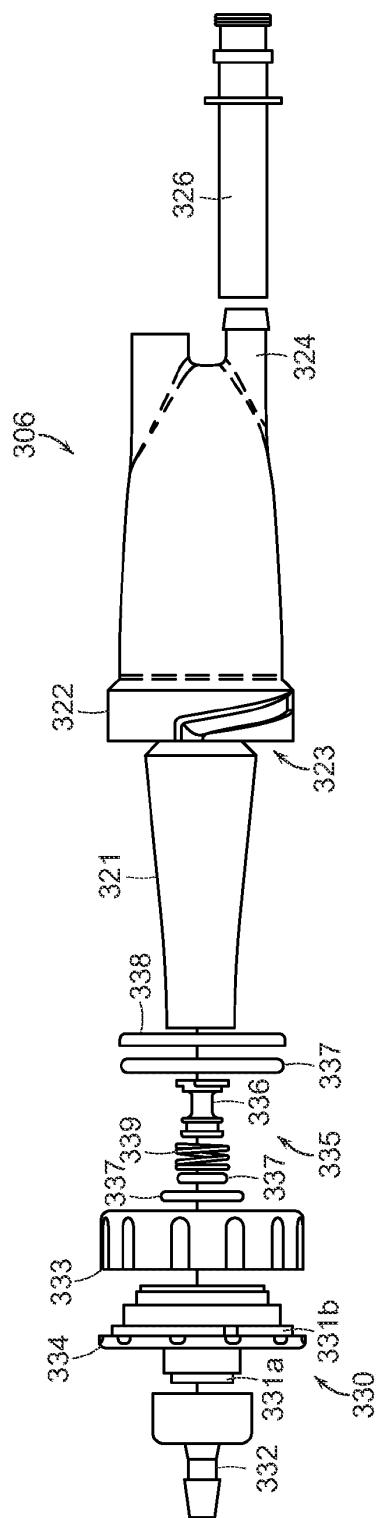


FIG. 3A

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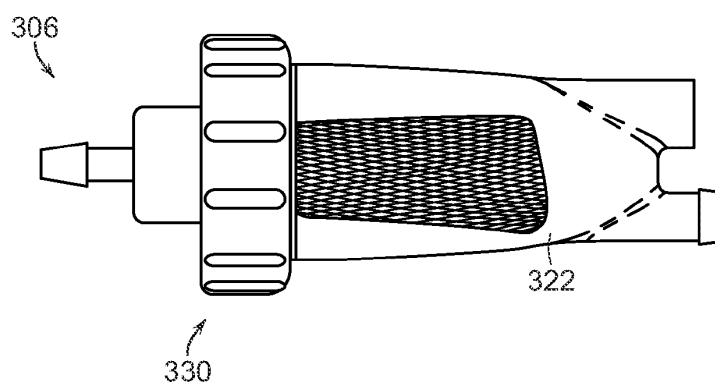


FIG. 3B

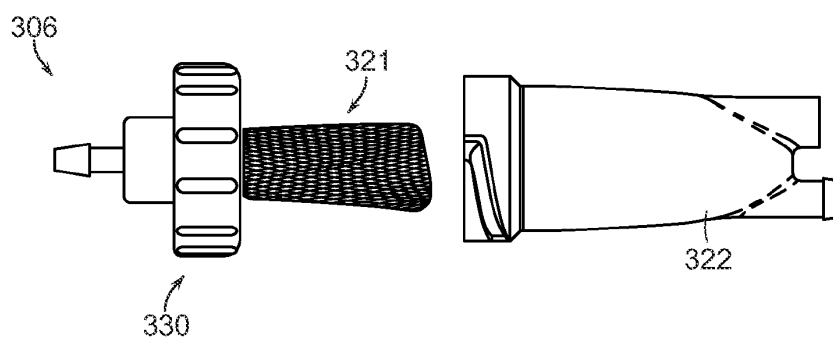


FIG. 3C

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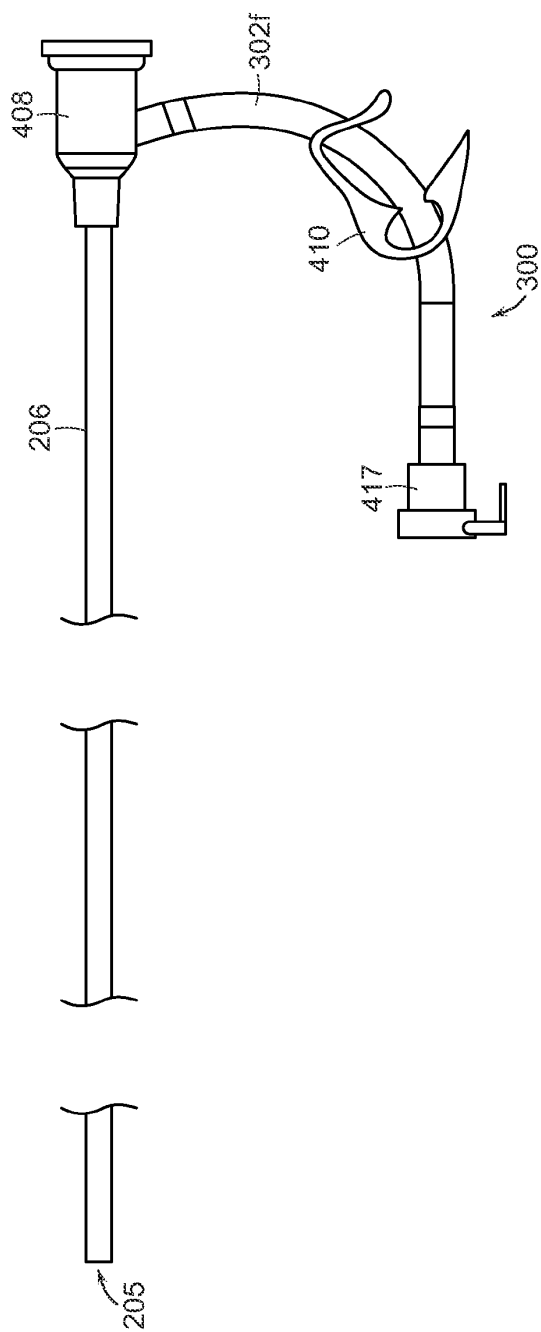


FIG. 4

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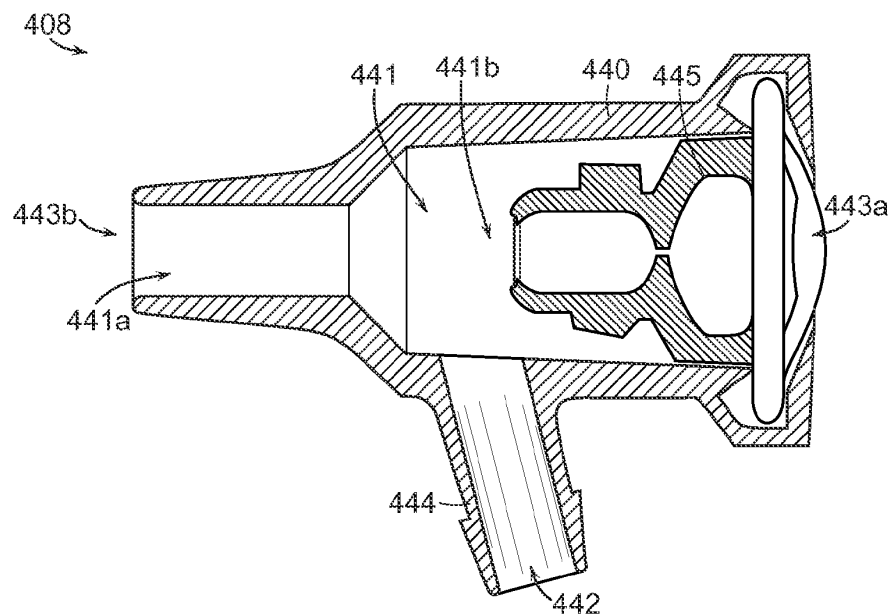


FIG. 5

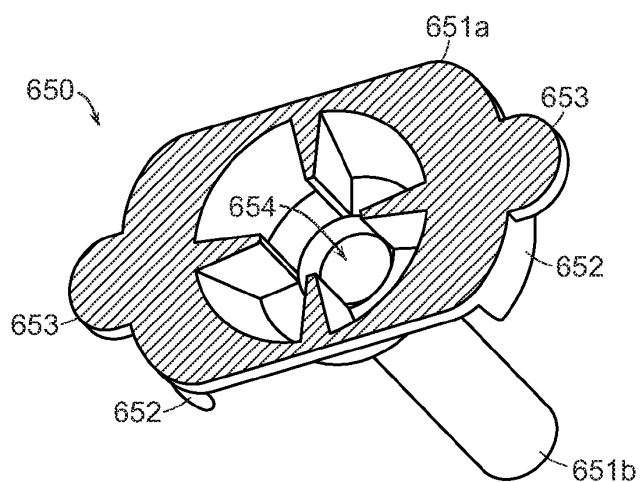


FIG. 6

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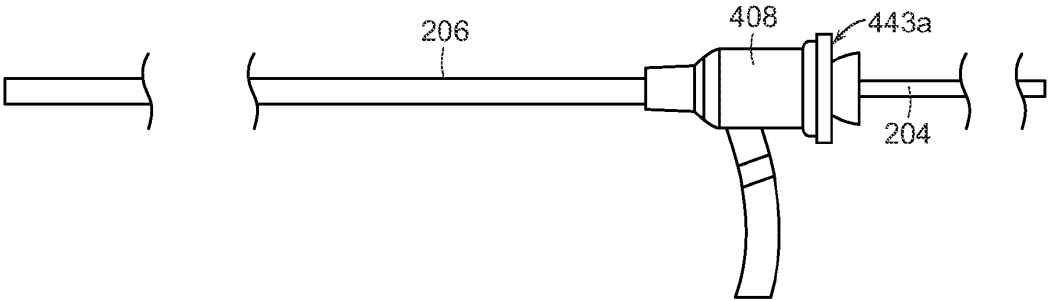


FIG. 7A

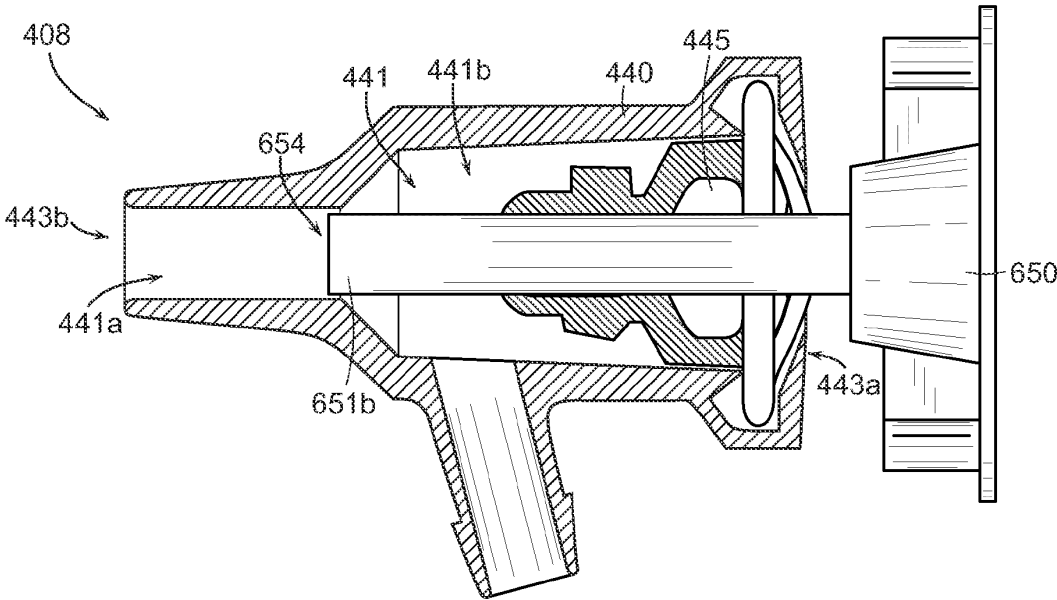


FIG. 7B

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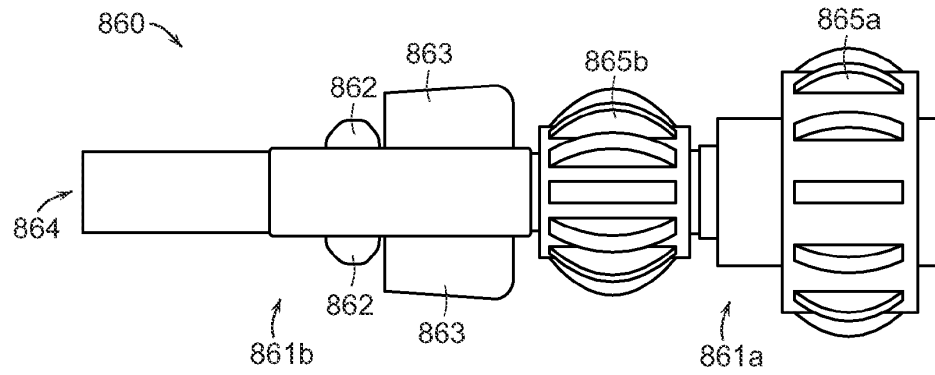


FIG. 8

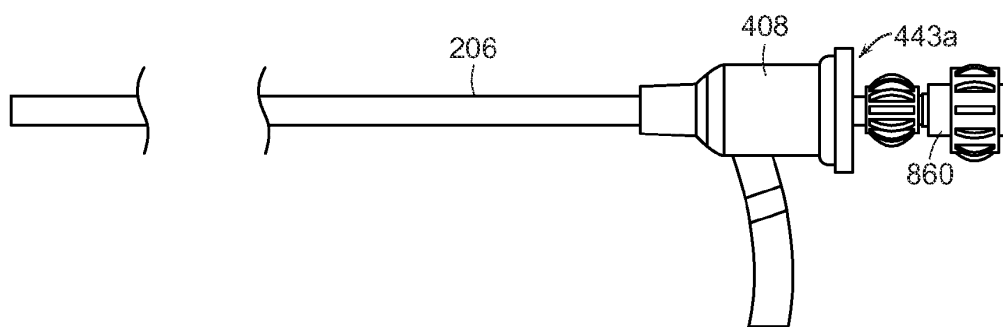


FIG. 9

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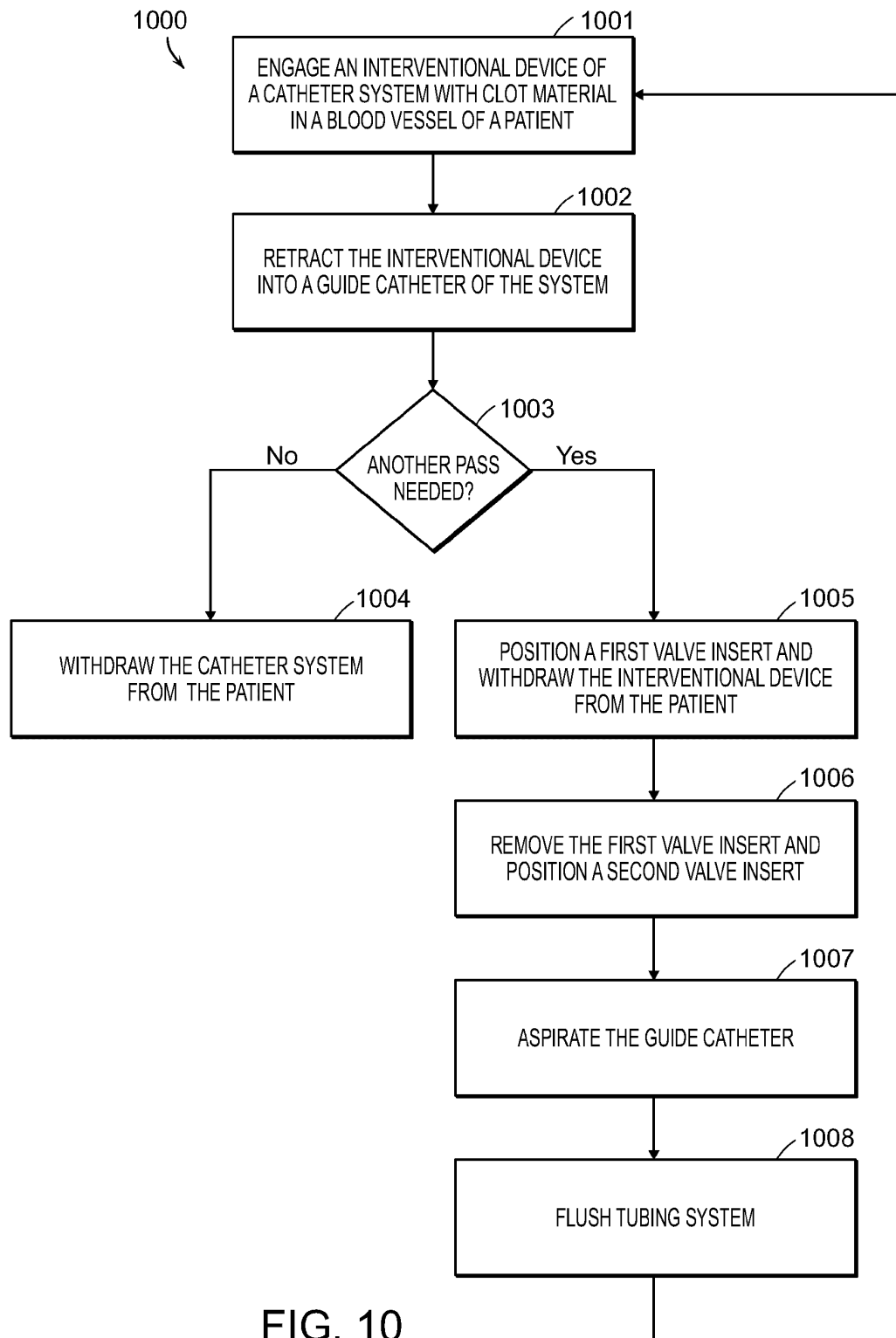


FIG. 10

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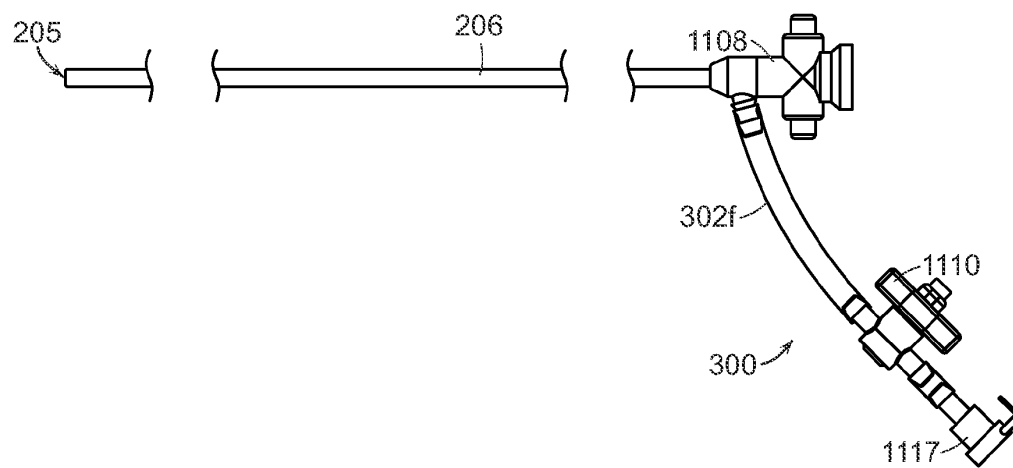


FIG. 11

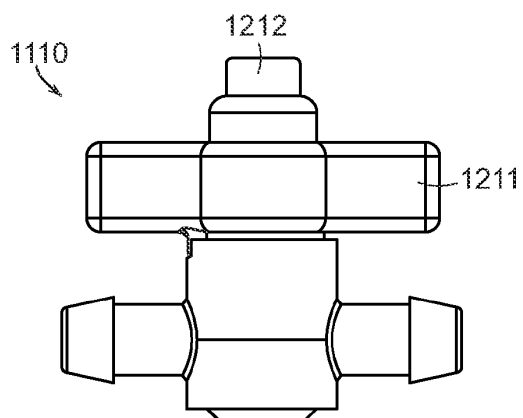


FIG. 12

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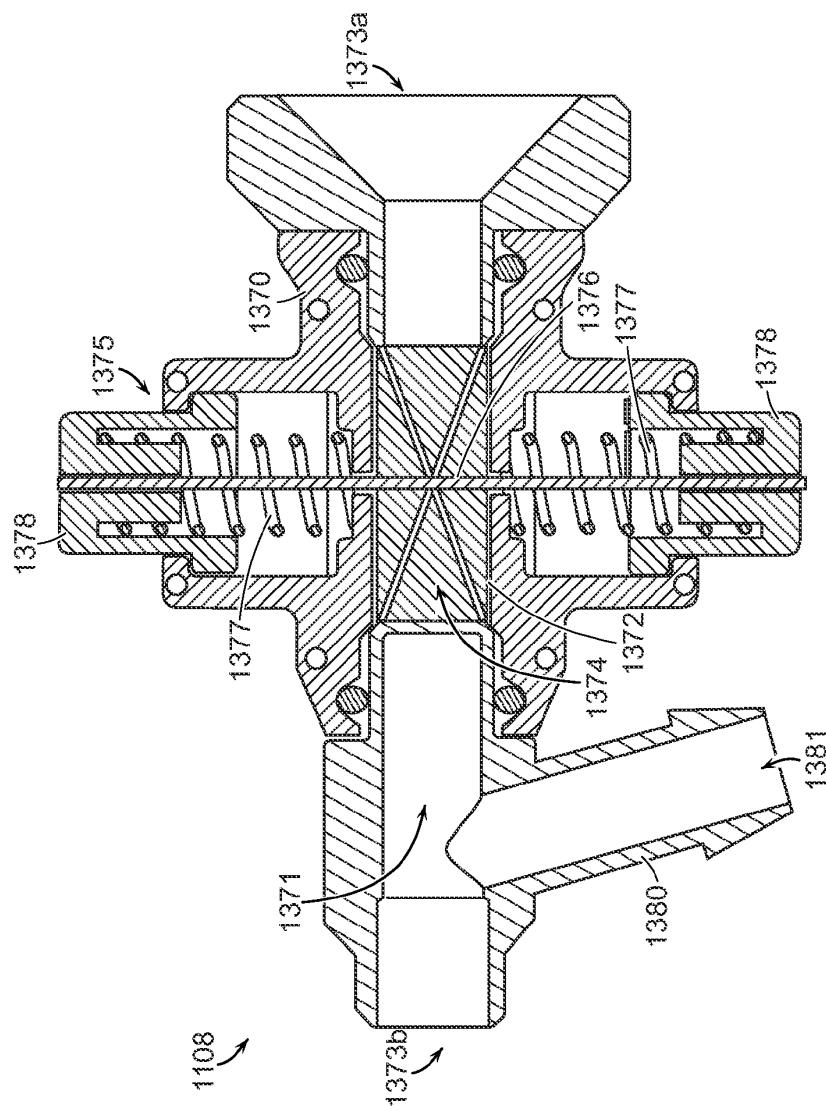


FIG. 13A

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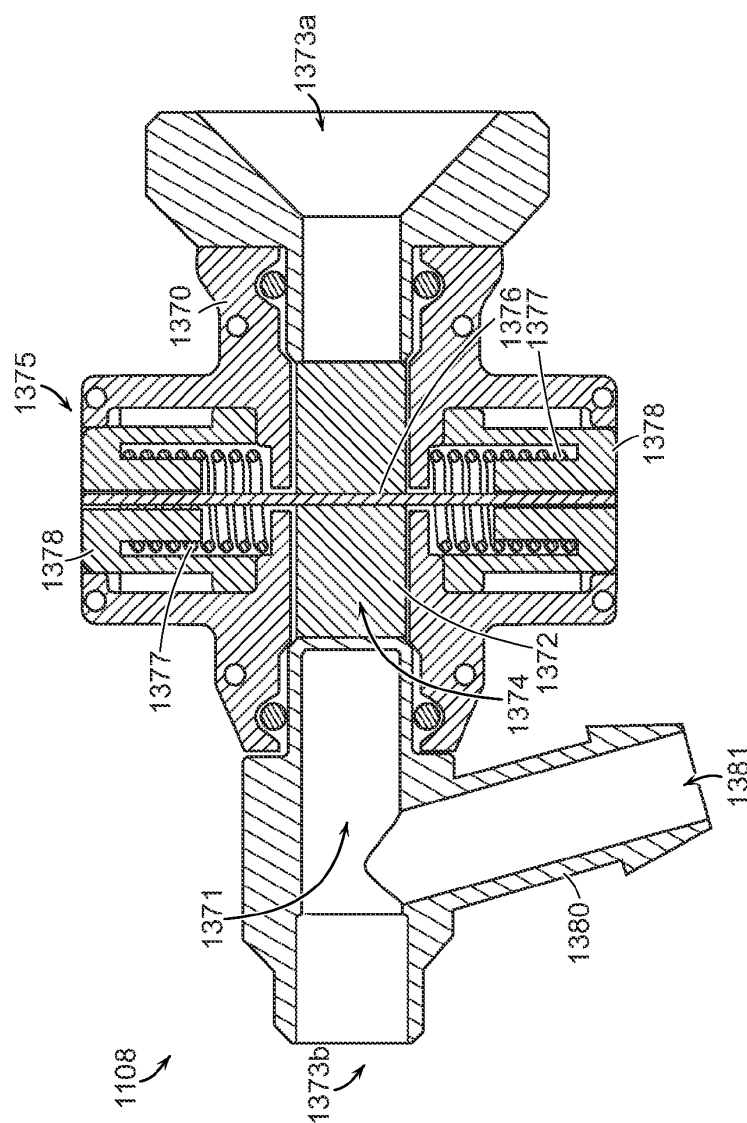


FIG. 13B

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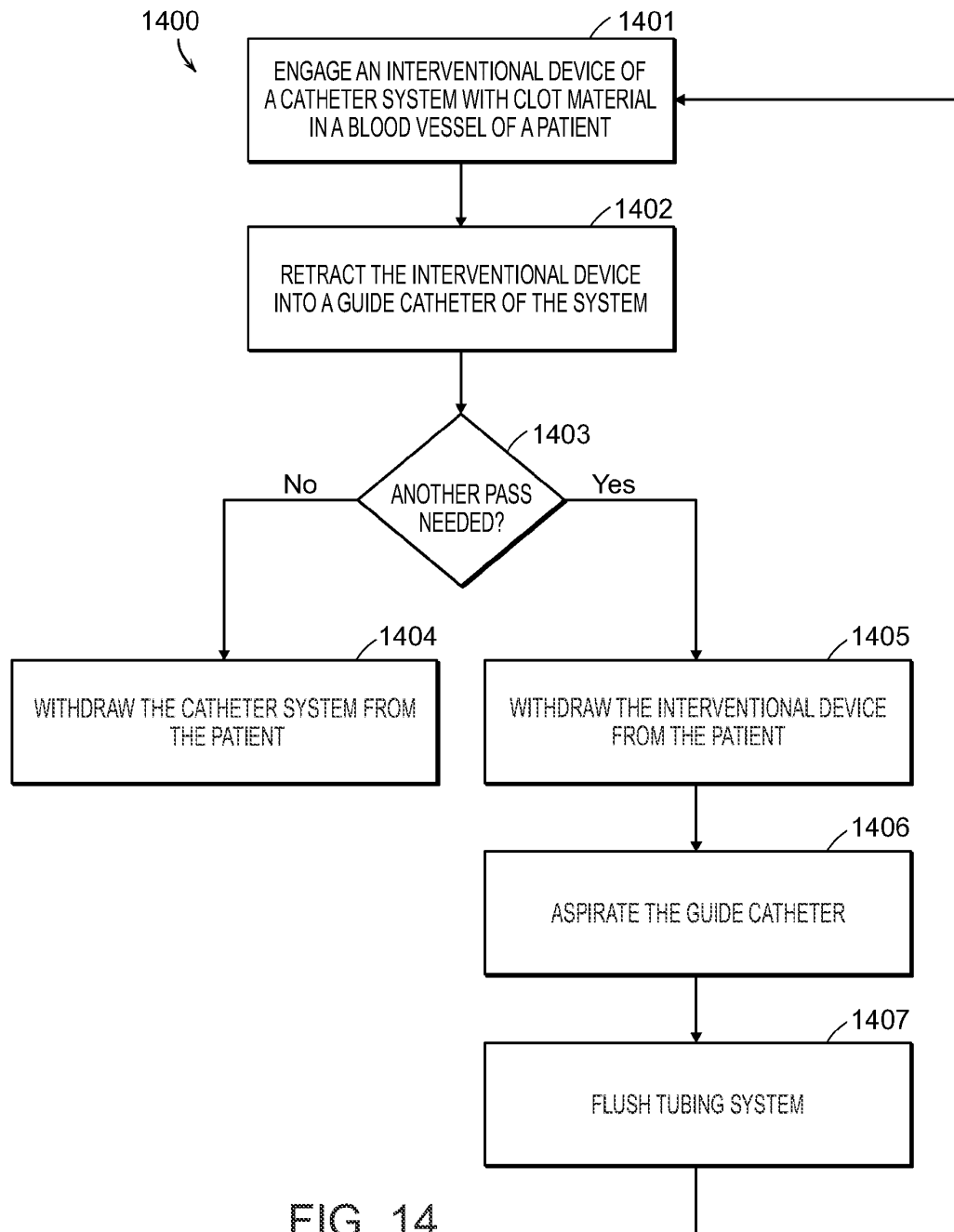


FIG. 14

Electronic Acknowledgement Receipt	
EFS ID:	44000541
Application Number:	17498642
International Application Number:	
Confirmation Number:	1040
Title of Invention:	SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS
First Named Inventor/Applicant Name:	Richard Quick
Customer Number:	25096
Filer:	Matthew S. Williams/JiYoung Anderson
Filer Authorized By:	Matthew S. Williams
Attorney Docket Number:	111552-8023.US02
Receipt Date:	11-OCT-2021
Filing Date:	
Time Stamp:	19:37:33
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no				
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal of New Application	New_App_Transmittal-111552-8023US2.PDF	1407812 f59c177c0b3749a70ae42496c4e1158e227d886d	no	2
Warnings:					

Information:					
2	Transmittal Letter	POA_Transmittal-111552-8023 US2.PDF	624285	no	1
			eaaf6f70a310cbfd7a15fd7f8af3b82bca318a a75		
Warnings:					
Information:					
3	Power of Attorney	Inari-US-signed_POA-111552. PDF	108078	no	1
			39206a0021f30d1946eeba1bb59abf4340b 95b53		
Warnings:					
Information:					
4	Oath or Declaration filed	Signed_declaration- parent-111552-8023US2.PDF	293374	no	1
			894af5271b025fb42475bf64e79eeec65b3ba 3800		
Warnings:					
Information:					
5	Application Data Sheet	Application_Data_Sheet-11155 2-8023US2.PDF	1823035	no	8
			1b7934a43c6229a5f5f90202ceb846329211 6de5		
Warnings:					
Information:					
6		CON_Application-111552-8023 US2.PDF	203025	yes	42
			f32c4d3f8b373cd173dabe5fc9f01777821c 6f48		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Specification		1	36	
	Claims		37	41	
	Abstract		42	42	
Warnings:					
Information:					
7	Drawings-only black and white line drawings	Drawings-111552-8023US2- uspto.PDF	260130	no	20
			883d19df35878f48f3b03f12ecf21a3e889b0 dc1		

Warnings:	
Information:	
Total Files Size (in bytes):	4719739
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