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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/342,553	06/27/2023	Ben Merritt	111552.8018.US11	6799

25096 7590 05/07/2024

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

EXAMINER	
RASSAVONG, ERIC	

ART UNIT	PAPER NUMBER
3781	

NOTIFICATION DATE	DELIVERY MODE
05/07/2024	ELECTRONIC

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

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

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

patentprocurement@perkinscoie.com

Imperative Care v. Inari Medical
U.S. Patent 11,974,910
Imperative Care Ex. 1002

APPLICATION NO.	ISSUE DATE	PATENT NO.
18/342,553	07-May-2024	11974910

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

EGRANT NOTIFICATION

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

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

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/342,553	05/07/2024	11974910	111552.8018.US11	6799

25096 7590 04/17/2024

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

ISSUE NOTIFICATION

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

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

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

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

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

Applicant will be able to obtain more detailed information by accessing the Patent Center (https://patentcenter.uspto.gov).

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

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

Ben Merritt, San Clemente, CA;
Jacqueline Macias, Fullerton, CA;
Brian Michael Strauss, San Clemente, CA;
Thomas Tu, Louisville, KY;
John Coleman Thress, Capistrano Beach, CA;

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

Inari Medical, Inc., Irvine, CA;

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

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18/342,553- Conf # 6799
	Filing Date	June 27, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	~~Not Yet Assigned~~ Eric Rassavong
	Attorney Docket Number	111552.8018.US11

U.S. PATENTS AND PUBLICATIONS					
Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	20230233311	07-27-2023	Merritt et al.	
	2.	20070233043	10-04-2007	Dayton et al.	
	3.	8343167 01/2013	~~01-01-2028~~	Henson	
	4.	8568465	10-29-2013	Freudenthal et al.	
	5.	20230241302	08-03-2023	Merritt et al.	
	6.	20230240705	08-03-2023	Rosenbluth et al.	
	7.	20230240706	08-03-2023	Rosenbluth et al.	
	8.	10183159	01-22-2019	Nobles et al.	

Change(s) applied to document,
/J.E./
3/29/2024

FOREIGN PATENT DOCUMENTS						
Examiner Initial*	Cite No	Foreign Document Number[3]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[5]
	1.	WO2023147353	08-03-2023	Inari Medical, Inc.		

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

EXAMINER SIGNATURE			
Examiner Signature /ERIC RASSAVONG/ (10/25/2023)		Date Considered	10/25/2023
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

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

163380412.1

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.R./

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18/342,553	06/27/2023	Ben Merritt	111552.8018.US11	6799

25096 7590 03/28/2024

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EXAMINER	
RASSAVONG, ERIC	

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3781	

NOTIFICATION DATE	DELIVERY MODE
03/28/2024	ELECTRONIC

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

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

patentprocurement@perkinscoie.com

Supplemental ***Notice of Allowability***	**Application No.** 18/342,553	**Applicant(s)** Merritt et al.	
	Examiner ERIC RASSAVONG	**Art Unit** 3781	**AIA (FITF) Status** Yes

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

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

1. ☑ This communication is responsive to Printer Rush filed on 03/19/2024.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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

3. ☑ The allowed claim(s) is/are 1-17,19 and 21-22 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information , please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

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

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

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

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

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

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

Attachment(s)

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

/E.R./ Examiner, Art Unit 3781	/SUSAN S SU/ Primary Examiner, Art Unit 3781

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed
PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18/342,553- Conf # 6799
	Filing Date	June 27, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552.8018.US11

U.S. PATENTS AND PUBLICATIONS

Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	11918244	03-05-2024	Marchand et al.	
	2.	11918243	03-05-2024	Marchand et al.	
	3.	6059745	05-09-2000	Gelbfish	
	4.	20030225379	12-04-2003	Schaffer et al.	
	5.	20050131387	06-16-2005	Pursley	
	6.	5951539	09-14-1999	Nita et al.	
	7.	11213356	01-04-2022	Tanner et al.	
	8.	7905877	03-15-2011	Jilnenez et al.	
	9.	20010041881	11-15-2001	SARGE et al.	
	10.	20110264132	10-27-2011	Strauss et al.	
	11.	20200054861	02-20-2020	Korkuch et al.	
	12.	20190223893	07-25-2019	GILVARRY et al.	
	13.	20190328411	10-31-2019	VALE et al.	
	14.	20240074771	03-07-2024	Quick et al.	
	15.				
	16.				

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[5]
	1.					
	2.					
	3.					
	4.					
	5.					
	6.					

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552.8018.US11

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
		English translation of Japanese Office Action received for JP Application No. 2022-574456, Applicant: Inari Medical, Inc, Date of Mailing: January 23, 2024, 12 pages.	
		Chinese First Office Action received for CN Application No. 201980067623.1, Applicant: Inari Medical, Inc., Date of Mailing: January 31, 2024, 10 pages.	
		International Search Report and Written Opinion for International App. No. PCT/US23/73765; Date of Filing: September 8, 2023, Applicant: Inari Medical, Inc., Date of Mailing: February 28, 2024, 7 pages.	
		International Search Report and Written Opinion for International App. No. PCT/US23/69892; Date of Filing: July 10, 2023, Applicant: Inari Medical, Inc., Date of Mailing: February 29, 2024, 12 pages.	

EXAMINER SIGNATURE			
Examiner Signature	/ERIC RASSAVONG/ (03/25/2024	Date Considered	03/25/2024

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

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

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☐ None

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.R./

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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	Filing Date	June 27, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552.8018.US11

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

COPIES OF REFERENCES

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

SIGNATURE

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

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2024-03-12
Name/Print	Matthew S. Williams	Registration Number	77,516

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

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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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
18/342,553	06/27/2023	3781	1820	111552.8018.US11	20	3

CONFIRMATION NO. 6799

UPDATED FILING RECEIPT

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

OC00000006990291

Date Mailed: 03/20/2024

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)

Ben Merritt, San Clemente, CA;
Jacqueline Macias, Fullerton, CA;
Brian Michael Strauss, San Clemente, CA;
Thomas Tu, Louisville, KY;
John Coleman Thress, Capistrano Beach, CA;
Paul Lubock, Monarch Beach, 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 18/167,757 02/10/2023
which is a CON of 17/976,711 10/28/2022
which is a CON of 17/865,315 07/14/2022 PAT 11,642,209
which is a CON of 16/536,185 08/08/2019 PAT 11,559,382
which claims benefit of 62/718,269 08/13/2018
and claims benefit of 62/718,248 08/13/2018

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: 07/17/2023

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 18/342,553**

Projected Publication Date: 10/26/2023

Non-Publication Request: No

Early Publication Request: No

Title

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES 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).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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

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

NOT GRANTED

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

SelectUSA

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.

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
18/342,553	06/27/2023	Ben Merritt	111552.8018.US11

CONFIRMATION NO. 6799

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

37 CFR 1.48 ACKNOWLEDGEMENT LETTER

OC000000069902918

Date Mailed: 03/20/2024

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

This is in response to the applicant's request under 37 CFR 1.48(a) submitted on 03/14/2024.

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

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

/dtdinh/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Ben Merritt et al.

Application No.: 18/342,553 Confirmation No.: 6799

Filed: June 27, 2023 Art Unit: 3781

For: SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS Examiner: Eric Rassavong

COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

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

Dear Commissioner:

In the Notice of Allowability mailed March 13, 2024, the Examiner allowed claims 1–17, 19, 21, and 22. The Applicant acknowledges the Examiner's statements of Reasons for Allowance of the above-referenced patent application and agrees that the claimed subject matter is patentable. However, the Applicant takes no position regarding the Reasons for Allowance presented by the Examiner other than the positions the Applicant may have previously taken during prosecution. Therefore, the Examiner's Reasons for Allowance should not be attributed to the Applicant as an indication of the basis for the Applicant's belief that the claims are patentable. Furthermore, the Applicant respectfully asserts that there may also be additional reasons for patentability of the claimed subject matter not explicitly stated in this record and the Applicant does not waive its rights to such arguments by not further addressing such reasons herein.

Dated: March 14, 2024

Respectfully submitted,

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

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

Attorneys for Applicant

UNITED STATES
PATENT AND TRADEMARK OFFICE

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

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/342,553	**03/14/2024 05:37:21 PM Z ET**	**111552.8018.US11**

Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	6799	FILED BY	JiYoung Anderson
PATENT CENTER #	64691553	AUTHORIZED BY	Matthew Williams
CUSTOMER #	25096	FILING DATE	06/27/2023
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Ben Merritt

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 5111	**E20243DH37446338**	**JiYoung Anderson**

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

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES
PATENT AND TRADEMARK OFFICE

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

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/342,553	**03/14/2024 05:37:21 PM Z ET**	**111552.8018.US11**

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CUSTOMER #	25096	FIRST NAMED INVENTOR	Ben Merritt
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Matthew Williams

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2024.3.14 Comments - 111552.8018.US11.pdf	2	Miscellaneous Incoming Letter	97 KB
2024-03-14 Issue Fee Transmittal - 111552.8018.US11.pdf	2	Issue Fee Payment (PTO-85B)	237 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2024.3.14 Comments - 111552.8018.US11.pdf	8D2EF88976DCE3C914DE298E8D5F596ACDE0799FA6190067 B30265057341D79B529B583AE558A471AEEB2FFEDCD98F312 5D9A31B79AD3973678E2E7D35E96DBF

2024-03-14 Issue Fee Transmittal - 111552.8018.US11.pdf	A9D9710506F1EA39D08C6A727BE2F1EE1F7C91C82A6DCA2C 1E48FF505BCFF28FB5695793AD581AD6339B172239DEBE4E7 E3B8737B16C83E3DE35C11CBC361593

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.

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PART B – FEE(S) TRANSMITTAL

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

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

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

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

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

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

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

Certificate of Mailing or Transmission

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

JiYoung Anderson	(Typed or printed name)
/JiYoung Anderson/	(Signature)
2024-03-14	(Date)

APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
18/342,553	Jun 27, 2023	Ben Merritt	111552.8018.US11	6799

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

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
UTILITY	LARGE	1200	0	0	1200	2024-06-13

EXAMINER	ART UNIT	CLASS-SUBCLASS
Eric Rassavong	3781	606-127000

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

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

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-09 or more recent) attached. Use of a Customer Number is required.

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

1. Perkins Coie LLP
2.
3.

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

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

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

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

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

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

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

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

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

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

☐ Applicant certifying micro entity status. See 37 CFR 1.29. NOTE: Absent a valid Certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

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

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

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

Authorized Signature /Matthew S. Williams/ Date 2024-03-14

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

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

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

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

Privacy Act Statement

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

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

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

UNITED STATES
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Alexandria, VA 22313 - 1450
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/342,553	**03/14/2024 05:24:07 PM Z ET**	**111552.8018.US11**

Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	6799	FILED BY	JiYoung Anderson
PATENT CENTER #	64691232	FILING DATE	06/27/2023
CUSTOMER #	25096	FIRST NAMED INVENTOR	Ben Merritt
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Matthew Williams

Documents

TOTAL DOCUMENTS: 3

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
Corrected ADS-111552-8018US11.pdf	10	Application Data Sheet	169 KB
Warning: This is not a USPTO supplied ADS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
Declaration signed additional Paul and John - 111552.8018.US11.pdf	2	Oath or Declaration filed	887 KB
2024.3.14 Request for Correction for inventorship - 111552.8018.US11.pdf	3	Request under Rule 48 correcting inventorship	227 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
Corrected ADS-111552-8018US11.pdf	69EA5B097C693508CF0AB2F95E10B12A764C3164BB83223B0BD461A72F8CB5A224D7C431B29F8AAB0BEB6F6CE1437E2FD817C817256430B03D9B9EF5B9724D85
Declaration signed additional Paul and John - 111552.8018.US11.pdf	F53A36BF5B42AB3E8EE3B1C46CF9026D92952C76BF660B973D7062F2C2005318E05315D49A57FA4905B025D00C01F50F50CB591CBD026B6B07271AFE63EBA6AA
2024.3.14 Request for Correction for inventorship - 111552.8018.US11.pdf	5BFD5E63C28F19FE481C65E5F0DA7F79C3C6236D29C3C9E9C26E1F67270C7A37E44C90B7BEA9188E482B2616C6850F266619EE8FAF4C93130B72BDD40EEF59AF

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

New Applications Under 35 U.S.C. 111

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/342,553	**03/14/2024 05:24:07 PM Z ET**	**111552.8018.US11**

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APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
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PATENT CENTER #	64691232	AUTHORIZED BY	Matthew Williams
CUSTOMER #	25096	FILING DATE	06/27/2023
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Ben Merritt

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 5111	**E20243DH24389356**	**JiYoung Anderson**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1830	PROCESSING FEE, EXCEPT IN PROVISIONAL APPLICATIONS	140.00	1	140.00
1819	CORRECTION OF INVENTORSHIP AFTER FIRST ACTION ON MERITS	640.00	1	640.00
			TOTAL AMOUNT:	**$780.00**

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

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Based on USPTO form PTO/AIA/01

Docket No.: 111552.8018.US11

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

As the below named inventor, I hereby declare that:

This declaration is directed to:

[ ] The attached application, or

[X] United States application or PCT international application number 18/342,553

filed on 2023-06-27.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any wilful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms
PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: John Coleman Thress Date: 03/08/2024

Signature: _____

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S.Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

Based on USPTO form PTO/AIA/01

Docket No.: 111552.8018.US11

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 18/342,553

filed on 2023-06-27.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

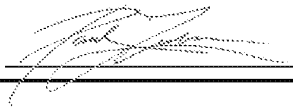
I hereby acknowledge that any wilful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms
PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Paul Lubock Date: March 14, 2024

Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S.Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**
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CORRECTED APPLICATION DATA SHEET

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552.8018.US11
	Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES 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
	Ben		Merritt	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	San Clemente	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o Inari Medical, Inc.
Address 2	6001 Oak Canyon, Suite #100

City	Irvine	State/Province	CA
Postal Code	92618	Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jacqueline		Macias	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Fullerton	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o Inari Medical, Inc.
Address 2	6001 Oak Canyon, Suite #100

City	Irvine	State/Province	CA
Postal Code	92618	Country	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Brian	Michael	Strauss	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552.8018.US11
	Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS	

City	San Clemente	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o Inari Medical, Inc.		
Address 2	6001 Oak Canyon, Suite #100		
City	Irvine	State/Province	CA
Postal Code	92618	Country i	US

Inventor 4 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Thomas		Tu	

Residence Information (Select One) (●) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Louisville	State/Province	KY	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o Inari Medical, Inc.		
Address 2	6001 Oak Canyon, Suite #100		
City	Irvine	State/Province	CA
Postal Code	92618	Country i	US

Inventor 5 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	John	Coleman	Thress	

Residence Information (Select One) (●) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Capistrano Beach	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o Inari Medical, Inc.		
Address 2	6001 Oak Canyon, Suite #100		
City	Irvine	State/Province	CA
Postal Code	92618	Country i	US

Inventor 6 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Paul		Lubock	

Residence Information (Select One) (●) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Monarch Beach	State/Province	CA	Country of Residence	US

PTO/AIA/14 (11-15)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552.8018.US11
	Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS	

Mailing Address of Inventor:			
Address 1	c/o Inari Medical, Inc.		
Address 2	6001 Oak Canyon, Suite #100		
City	Irvine	State/Province	CA
Postal Code	92618	Country i	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	25096		
Email Address	patentprocurement@perkinscoie.com	Add Email	Remove Email

Application Information:

Title of the Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS		
Attorney Docket Number	111552.8018.US11	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	38	Suggested Figure for Publication (if any)	2

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.

PTO/AIA/14 (11-15)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552.8018.US11
	Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS	

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	18/167757	2023-02-10
Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
18/167757	Continuation of	17/976711	2022-10-28
Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
17/976711	Continuation of	17/865315	2022-07-14
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
17/865315	Continuation of	16/536185	2019-08-08	11559382	2023-01-24

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16/536185	Claims benefit of provisional	62/718269	2018-08-13

PTO/AIA/14 (11-15)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552.8018.US11
	Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS	

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16/536185	Claims benefit of provisional	62/718248	2018-08-13
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.			

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

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

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552.8018.US11
	Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

PTO/AIA/14 (11-15)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552.8018.US11
	Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

(●) Assignee	( ) Legal Representative under 35 U.S.C. 117	( ) Joint Inventor
( ) Person to whom the inventor is obligated to assign.	( ) Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	Inari Medical, Inc.

Mailing Address Information For Applicant:

Address 1	6001 Oak Canyon, Suite #100		
Address 2			
City	Irvine	**State/Province**	CA
Country	US	Postal Code	92618
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button.

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552.8018.US11
	Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Matthew S. Williams/			Date (YYYY-MM-DD)	2024-03-14
First Name	Matthew S.	Last Name	Williams	Registration Number	77,516

Additional Signature may be generated within this form by selecting the Add button.

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552.8018.US11
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Privacy Act Statement

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

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

1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Doc Code: R48.REQ
Document Description: Request under Rule 48 correcting inventorship

PTO/AIA/40 (04-18)
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U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE
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REQUEST FOR CORRECTION IN A PATENT APPLICATION RELATING TO INVENTORSHIP OR AN INVENTOR NAME, OR ORDER OF NAMES, OTHER THAN IN A REISSUE APPLICATION (37 CFR 1.48)

Application Number	18/342,553 - Conf. 6799
Filing Date	2023-06-27
First Named Inventor	Ben Merritt
Art Unit	3781
Examiner Name	Eric Rassavong
Practitioner Docket Number	111552.8018.US11

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

Applicant hereby **requests that the inventorship be corrected or changed, or that the name of the inventor or a joint inventor, or the order of the names of joint inventors, be changed,** in the above-identified application. **Note:** 37 CFR 1.48 applies to any request to correct inventorship filed on or after September 16, 2012, regardless of the application filing date. **Do not submit this form after payment of the issue fee or if the application has been patented.** See 37 CFR 1.324 for correction of inventorship in a patent.

Please check the applicable box(es) below.

For a nonprovisional application:

☑ 1. This request is to correct or change the inventorship in a **nonprovisional** application (**under 37 CFR 1.48(a)**) and includes:

☑ An application data sheet (ADS) in accordance with 37 CFR 1.76(c) with the corrected or updated information shown with markings (*e.g.*, underlining for insertions, strikethrough for deletions). See the Manual of Patent Examining Procedure (MPEP) section 601.05(a) for information about filing an ADS in an application filed on/after September 16, 2012. For information about filing a Supplemental ADS in an application filed before September 16, 2012, see MPEP 601.05(b).

☑ The processing fee set forth in 37 CFR 1.17(i). $ 140

☑ An inventor is being added. An inventor's oath or declaration by any actual inventor who has not yet executed an oath or declaration is required (see 37 CFR 1.48(b)). See MPEP 602.01(a) for information about an inventor's oath or declaration for an application filed on/after September 16, 2012 (*e.g.*, form **PTO/AIA/01**). For information about an inventor's oath or declaration for an application filed before September 16, 2012 (*e.g.*, form **PTO/SB/01**), see MPEP 602.01(b).

☑ This request is being filed after the first Office action on the merits has been given or mailed (see 37 CFR 1.48(c) and 1.17(d)). Check one of the following:

☐ This request to correct or change the inventorship is due solely to the cancellation of claims in the application.

OR

☑ The fee set forth in 37 CFR 1.17(d) is due (in addition to the fee set forth in 37 CFR 1.17(i)). $ 640

This collection of information is required by 37 CFR 1.48. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

PTO/AIA/40 (04-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REQUEST FOR CORRECTION IN A PATENT APPLICATION RELATING TO INVENTORSHIP OR AN INVENTOR NAME, OR ORDER OF NAMES, OTHER THAN IN A REISSUE APPLICATION (37 CFR 1.48)

☐ 2. This request is to correct or update the name of the inventor or a joint inventor, or the order of names of joint inventors, in a **nonprovisional** application (**under 37 CFR 1.48(f)**) and includes:

☐ An application data sheet in accordance with 37 CFR 1.76(c) identifying the complete inventive entity, including the corrected or updated name of the inventor, or the new order of names shown with markings (*e.g.*, underlining for insertions, strikethrough for deletions). See the MPEP 601.05(a) for information about filing an ADS in an application filed on/after September 16, 2012. For information about filing a Supplemental ADS in an application filed before September 16, 2012, see MPEP 601.05(b).

☐ The processing fee set forth in 37 CFR 1.17(i). $ _____

For a provisional application:

☐ This request is to change or correct the inventorship, or correct or update the name of the inventor or a joint inventor, in a **provisional** application (**under 37 CFR 1.48(d)**) and includes:

☐ **Attached hereto** is a document that is signed by a party set forth in 37 CFR 1.33(b) and identifies each inventor by his or her legal name, in the preferred order. Note: the document may be an application data sheet in accordance with 37 CFR 1.76(c) that identifies the changes with markings (underlining for insertions, strikethrough for deletions).

☐ The processing fee set forth in 37 CFR 1.17(q). $ _____

Fee Payment Information:

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously

☐ A check in the amount of the fee is enclosed.

☑ Payment by credit card. Form PTO-2038 is attached.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 50-0665.

☑ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ Applicant*

☑ attorney or agent of record
Registration number 77,516

☐ attorney or agent acting under 37 CFR 1.34
Registration number _____

Signature /Matthew S. Williams/

Typed or printed name Matthew S. Williams

Date 2024-03-14

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. *Juristic entities must be represented by a patent practitioner (See 37 CFR 1.31, applicable to any paper filed on or after September 16, 2012 that is presented on behalf of a juristic entity, regardless of application filing date). Submit multiple forms if more than one signature is required, see below**.

☒ ** Total of 1 forms are submitted.

Privacy Act Statement

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

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

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

25096 7590 03/13/2024

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

EXAMINER	
RASSAVONG, ERIC	
ART UNIT	PAPER NUMBER
3781	

DATE MAILED: 03/13/2024

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/342,553	06/27/2023	Ben Merritt	111552.8018.US11	6799

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

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	06/13/2024

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

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

HOW TO REPLY TO THIS NOTICE:

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

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

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

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

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

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

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

PART B - FEE(S) TRANSMITTAL

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

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

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

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

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

25096 7590 03/13/2024
PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

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

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/342,553	06/27/2023	Ben Merritt	111552.8018.US11	6799

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

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	06/13/2024

EXAMINER	ART UNIT	CLASS-SUBCLASS
RASSAVONG, ERIC	3781	606-127000

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

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

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

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

1 _____
2 _____
3 _____

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

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

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

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

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required)

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

❑ Electronic Payment via the USPTO patent electronic filing system ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

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

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

❑ Applicant certifying micro entity status. See 37 CFR 1.29

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

❑ Applicant asserting small entity status. See 37 CFR 1.27

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

❑ Applicant changing to regular undiscounted fee status.

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

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/342,553	06/27/2023	Ben Merritt	111552.8018.US11	6799

25096 7590 03/13/2024

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

EXAMINER	
RASSAVONG, ERIC	
ART UNIT	**PAPER NUMBER**
3781	

DATE MAILED: 03/13/2024

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

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

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

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

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

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

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

Privacy Act Statement

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

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

1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;
2) a federal, state, local, or international agency, in response to its request;
3) a contractor of the USPTO having need for the information in order to perform a contract;
4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;
5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;
6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;
7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;
8) another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c));
9) the Office of Personnel Management (OPM) for personnel research purposes; and
10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

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

Notice of Allowability	Application No. 18/342,553	Applicant(s) Merritt et al.	
	Examiner ERIC RASSAVONG	Art Unit 3781	AIA (FITF) Status Yes

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

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

1. ☑ This communication is responsive to Remarks filed on 02/06/2024.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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

3. ☑ The allowed claim(s) is/are 1-17,19 and 21-22 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information , please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

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

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

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

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

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

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

Attachment(s)

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

/E.R./ Examiner, Art Unit 3781	/SUSAN S SU/ Primary Examiner, Art Unit 3781

EXAMINER'S AMENDMENT / REASONS FOR ALLOWANCE

Notice of Pre-AIA or AIA Status

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

Status of Claims

2. **Claims 1-17, 19, and 21-22** are currently pending. **Claims 18 and 20** are cancelled. **Claims 1, 3, 8, 11-12, and 19** have been amended. **Claims 21 and 22** are newly added. No new subject matter is added.

Examiner's Amendment

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

4. Authorization for this examiner's amendment was given in an interview with Matt Williams on 2/14/2024.

5. The application has been amended as follows:

Claim 1:

In line 1 --- A clot treatment system for treating clot material comprising a pulmonary embolism in ~~the~~ a vasculature of a patient.

Claim 11:

In line 1 --- A clot treatment system for treating clot material comprising a pulmonary embolism in ~~the~~ a vasculature of a patient.

Allowable Claims

6. **Claims 1-17, 19, and 21-22** are allowed.

Reasons for Allowance

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

Claims 1 and 11 are allowable for reciting, *inter alia,* "a clot treatment system for treating clot material comprising a pulmonary embolism in the vasculature of a patient" and "wherein the second catheter has a size of 16 French or greater".

Garrison (US 20150173782 A1) teaches all of the limitations as discussed previously in Non-Final Rejection filed on 11/06/2023. However, Garrison fails to teach a clot treatment system for treating clot material comprising a pulmonary embolism in the vasculature of a patient" and "wherein the second catheter has a size of 16 French or greater". The clot treatment device of Garrison is configured for a neurovascular application and not for larger vasculature such as pulmonary embolism. It would be unreasonable to modify the clot treatment device of Garrison to be used for pulmonary embolisms. There is no prior art that teaches all of the limitations. Therefore, claims 1 and 11 are allowable. **Claims 2-10 and 22** are allowable for depending on claim 1. **Claims 12-17, 19, and 21** are allowable for depending on claim 11.

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

Conclusion

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

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

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

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

/E.R./ (2/27/2024)
Examiner, Art Unit 3781

/SUSAN S SU/
Primary Examiner, Art Unit 3781
28 February 2024

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/342,553	Merritt et al.
	Examiner	**Art Unit**
	ERIC RASSAVONG	3781

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

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

CLAIM		DATE								
Final	Original	10/27/2023	02/27/2024							
	1	=	=							
	2	=	=							
	3	=	=							
	4	=	=							
	5	=	=							
	6	=	=							
	7	=	=							
	8	=	=							
	9	=	=							
	10	=	=							
	11	=	=							
	12	=	=							
	13	=	=							
	14	=	=							
	15	=	=							
	16	=	=							
	17	=	=							
	18	✓	-							
	19	=	=							
	20	=	-							
	21		=							
	22		=							

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/342,553	Merritt et al.
	Examiner	**Art Unit**
	ERIC RASSAVONG	3781

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

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

/ERIC RASSAVONG/ Examiner, Art Unit 3781	27 February 2024	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	1	
/SUSAN S SU/ Primary Examiner, Art Unit 3781	28 February 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	20D

U.S. Patent and Trademark Office — Part of Paper No.: 20240227

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/342,553	Merritt et al.
	Examiner	**Art Unit**
	ERIC RASSAVONG	3781

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

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

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

/ERIC RASSAVONG/ Examiner, Art Unit 3781	27 February 2024	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	1	
/SUSAN S SU/ Primary Examiner, Art Unit 3781	28 February 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	20D

U.S. Patent and Trademark Office — Part of Paper No.: 20240227

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/342,553	Merritt et al.
	Examiner	**Art Unit**
	ERIC RASSAVONG	3781

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

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	10	10	18	19										
2	2	11	11	-	20										
3	3	12	12	19	21										
4	4	13	13	20	22										
5	5	14	14												
6	6	15	15												
7	7	16	16												
8	8	17	17												
9	9	-	18												

/ERIC RASSAVONG/ Examiner, Art Unit 3781	27 February 2024	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	1	
/SUSAN S SU/ Primary Examiner, Art Unit 3781	28 February 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	20D

U.S. Patent and Trademark Office — Part of Paper No.: 20240227

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/342,553	Merritt et al.
	Examiner	Art Unit
	ERIC RASSAVONG	3781

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61F2/01	10/25/2023	/E.R./
A61B17/12109, 17/221, 2017/22034, 2017/22079, 17/005	10/25/2023	/E.R./
A61M1/815, 1/84, 1/79, 25/10	10/25/2023	/E.R./
A61M1/815	02/27/2024	/E.R./
A61F2/01	02/27/2024	/E.R./

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

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

Search Notes		
Search Notes	**Date**	**Examiner**
Inventor Name Search PALM	10/25/2023	/E.R./
CPC and text searching completed.	10/27/2023	/E.R./
Updated Search	02/27/2024	/E.R./

/E.R./ Examiner, Art Unit 3781	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/342,553	Merritt et al.
	Examiner	Art Unit
	ERIC RASSAVONG	3781

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	Keyword search in USPAT	10/27/2023	/E.R./

/E.R./ Examiner, Art Unit 3781	

Bibliographic Data

Application No: 18/342,553

Foreign Priority claimed: ○ Yes ◉ No

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

Verified and Acknowledged: /ERIC RASSAVONG/ Examiner's Signature | Initials

Title: SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
06/27/2023	606	3781	
RULE			

APPLICANTS

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

INVENTORS

Ben Merritt, San Clemente, CA, UNITED STATES

Jacqueline Macias, Fullerton, CA, UNITED STATES

Brian Michael Strauss, San Clemente, CA, UNITED STATES

Thomas Tu, Louisville, KY, UNITED STATES

CONTINUING DATA

This application is a CON of 18167757 02/10/2023

18167757 is a CON of 17976711 10/28/2022

17976711 is a CON of 17865315 07/14/2022 PAT 11642209

17865315 is a CON of 16536185 08/08/2019 PAT 11559382

16536185 has PRO of 62718248 08/13/2018

16536185 has PRO of 62718269 08/13/2018

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

07/17/2023

STATE OR COUNTRY

UNITED STATES

ADDRESS

FILING FEE RECEIVED

$6,160

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L92	57	("10648268" OR "11806033" OR "11832837" OR "11832838" OR "11833023" OR "11839393" OR "11844921" OR "11849963" OR "11890180" OR "20030023263" OR "20030135151" OR "20040039351" OR "20080087853" OR "20080294096" OR "20090312786" OR "20100114017" OR "20110152889" OR "20110309037" OR "20120095448" OR "20130123705" OR "20130190701" OR "20130270161" OR "20140163615" OR "20140180055" OR "20160220795" OR "20170113005" OR "20170143880" OR "20170172591" OR "20200022711" OR "20210128182" OR "20210316127" OR "20230310137" OR "20230310138" OR "20230310751" OR "20230320834" OR "20230329734" OR "20230338130" OR "20230355256" OR "20230355259" OR "20230355938" OR "20230363776" OR "20230363883" OR "20230389932" OR "20230390045" OR "2784717" OR "3438607" OR "3785380" OR "4401107" OR "4634421" OR "5242461" OR "5323514" OR "5484418" OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/27 09:23 AM

		"5911728" OR "6017335" OR "6908455" OR "7837630" OR "9884387").pn.					
L93	518	(embolism clot).clm. AND (tube catheter).clm. AND (suction "neagtive pressure").clm. AND (two second).clm. AND first.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/27 04:13 PM
L94	329	A61F2/01.cpc. AND (embolism clot) AND (tube catheter) AND (suction "neagtive pressure") AND (two second) AND first	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/27 04:13 PM
L95	149	A61M1/815.cpc. AND (embolism clot) AND (tube catheter) AND (suction "neagtive pressure") AND (two second) AND first	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/27 04:13 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N6	788	(embolism clot).clm. AND (tube catheter).clm. AND (suction "neagtive pressure").clm AND (two).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/27 04:13 PM
N7	162	(embolism clot).clm. AND (tube catheter).clm. AND (suction "neagtive pressure").clm. AND (two second).clm. AND first.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/27 04:13 PM
N8	184	(embolism clot).clm. AND (tube catheter).clm. AND (suction "neagtive pressure").clm. AND (two second).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/27 04:13 PM
N9	10429690	(embolism clot).clm. AND (tube	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/27 04:13 PM

		catheter).clm. (two second).clm.					
N10	1506	(embolism clot).clm. AND (tube catheter).clm. AND (two second).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/27 04:13 PM

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed
PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18/342,553- Conf # 6799
	Filing Date	June 27, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552.8018.US11

U.S. PATENTS AND PUBLICATIONS

Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	20110152889	06-23-2011	Ashland	
	2.	20230310138	10-05-2023	Merritt et al.	
	3.	20230310137	10-05-2023	Merritt et al.	
	4.	20230310751	10-05-2023	Merritt et al.	
	5.	20030023263	01-30-2003	Krolik et al.	
	6.	20030135151	07-17-2003	Deng	
	7.	20200022711	01-23-2020	Look et al.	
	8.	6017335	01-25-2000	Burnham	
	9.	20040039351	02-26-2004	Barrett	
	10.	20140180055	06-26-2014	Glynn et al.	
	11.	20230329734	10-19-2023	Marchand et al.	
	12.	5242461	09-07-1993	Kortenbach et al.	
	13.	11806033	11-07-2023	Marchand et al.	
	14.	3438607	04-15-1969	Williams et al.	
	15.	4401107	08-30-1983	Harber et al.	
	16.	4634421	01-06-1987	Hegemann	
	17.	5484418	01-16-1996	Quiachon et al.	
	18.	20080087853	04-17-2008	Kees	
	19.	10648268	05-12-2020	Jaffrey et al.	
	20.	20230320834	10-12-2023	Merritt et al.	
	21.	2784717	03-12-1957	E.O. Thompson	
	22.	9884387	02-06-2018	Plha	
	23.	20230338130	10-26-2023	Merritt et al.	
	24.	2010114017	05-06-2010	Lenker et al.	
	25.	20230355259	11-09-2023	Marchand et al.	
	26.	20230355256	11-09-2023	Dinh	
	27.	20230355938	11-09-2023	Merritt et al.	
	28.	20230363883	11-16-2023	Merritt et al.	
	29.	20230363776	11-16-2023	Quick	
	30.	20170113005	04-27-2017	LINDER et al.	
	31.	20110309037	12-22-2011	LEE	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.R./

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed
PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552.8018.US11

U.S. PATENTS AND PUBLICATIONS					
Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	32.	20080294096	11-27-2008	Uber, III et al.	
	33.	20130270161	10-17-2013	KUMAR et al.	
	34.	20210316127	10-14-2021	Buck et al.	
	35.	20170172591	06-22-2017	Ulm, III	
	36.	11832837	12-05-2023	Hauser	
	37.	11832838	12-05-2023	Hauser	
	38.	11833023	12-05-2023	Hauser	
	39.	20230390045	12-07-2023	Merritt et al.	
	40.	20230389932	12-07-2023	Ozenne et al.	
	41.	11839393	12-12-2023	Hauser	
	42.	11844921	12-19-2023	Merritt et al.	
	43.	11849963	12-26-2023	Quick	
	44.	20130190701	07-25-2013	Kirn	
	45.	20210128182	05-06-2021	Teigen et al.	
	46.	20170143880	05-25-2017	LUXON et al.	
	47.	3785380	01-15-1974	Brumfield	
	48.	6908455	06-21-2005	Hajianpour	
	49.	7837630	11-23-2010	Nieoson et al.	
	50.	20090312786	12-17-2009	Trask et al.	
	51.	20120095448	04-19-2012	KAJII	
	52.	20160220795	08-04-2016	KORKUCH et al.	
	53.	20130123705	05-16-2013	Holm et al.	
	54.	11890180	02-06-2024	Merritt et al.	
	55.	20140163615	06-12-2014	Gadlage et al.	
	56.	5323514	06-28-1994	Masuda et al.	
	57.	5911728	06-15-1999	Sepetka et al.	
	58.				
	59.				
	60.				

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.R./

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552.8018.US11

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[5]
	1.	WO2023192925	10-05-2023	Inari Medical, Inc.		
	2.	WO2019173475	09-12-2019	Innovative Cardiovascular Solutions, LLC		
	3.	WO2023215779	11-09-2023	Inari Medical, Inc.		
	4.					
	5.					
	6.					

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
		Extended European Search Report issued for EP Application No. 20877370.5, Date of Mailing: October 17, 2023, 11 pages.	
		International Search Report and Written Opinion for International App. No. PCT/US23/65128; Date of Filing: March 30, 2023, Applicant: Inari Medical, Inc., Date of Mailing: November 14, 2023, 14 pages.	
		International Search Report and Written Opinion for International App. No. PCT/US23/66538; Date of Filing: May 3, 2023, Applicant: Inari Medical, Inc., Date of Mailing: January 4, 2024, 14 pages.	

EXAMINER SIGNATURE

Examiner Signature	/ERIC RASSAVONG/ (02/27/2024)	Date Considered	02/27/2024

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

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

CERTIFICATION STATEMENT

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

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

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

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	Filing Date	June 27, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552.8018.US11

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

OR

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

☐ See attached certification statement.

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

☐ None

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

COPIES OF REFERENCES

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

SIGNATURE

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

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2024-02-06
Name/Print	Matthew S. Williams	Registration Number	77,516

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.R./

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

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18/342,553- Conf # 6799
	Filing Date	June 27, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552.8018.US11

U.S. PATENTS AND PUBLICATIONS

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

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[5]
	1.	WO2012114633	08-30-2012	TERUMO KABUSHIKI KAISHA		
	2.					
	3.					
	4.					
	5.					
	6.					

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
		English translation of Japanese Office Action received for JP Application No. 2022-574456, Applicant: Inari Medical, Inc, Date of Mailing: January 23, 2024, 12 pages.	
		Chinese First Office Action received for CN Application No. 201980067623.1, Applicant: Inari Medical, Inc., Date of Mailing: January 31, 2024, 10 pages.	

EXAMINER SIGNATURE

Examiner Signature	/ERIC RASSAVONG/ (02/27/2024)	Date Considered	02/27/2024

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

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.R./

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18/342,553- Conf # 6799
	Filing Date	June 27, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552.8018.US11

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☐ None

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

COPIES OF REFERENCES

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

SIGNATURE

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

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

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.R./

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18/342,553- Conf # 6799
	Filing Date	June 27, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552.8018.US11

U.S. PATENTS AND PUBLICATIONS					
Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	11918244	03-05-2024	Marchand et al.	
	2.	11918243	03-05-2024	Marchand et al.	
	3.	6059745	05-09-2000	Gelbfish	
	4.	20030225379	12-04-2003	Schaffer et al.	
	5.	20050131387	06-16-2005	Pursley	
	6.	5951539	09-14-1999	Nita et al.	
	7.	11213356	01-04-2022	Tanner et al.	
	8.	7905877	03-15-2011	Jilnenez et al.	
	9.	20010041881	11-15-2001	SARGE et al.	
	10.	20110264132	10-27-2011	Strauss et al.	
	11.	20200054861	02-20-2020	Korkuch et al.	
	12.	20190223893	07-25-2019	GILVARRY et al.	
	13.	20190328411	10-31-2019	VALE et al.	
	14.	20240074771	03-07-2024	Quick et al.	
	15.				
	16.				

FOREIGN PATENT DOCUMENTS						
Examiner Initial*	Cite No	Foreign Document Number[3]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[5]
	1.					
	2.					
	3.					
	4.					
	5.					
	6.					

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18/342,553- Conf # 6799
	Filing Date	June 27, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552.8018.US11

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
		English translation of Japanese Office Action received for JP Application No. 2022-574456, Applicant: Inari Medical, Inc, Date of Mailing: January 23, 2024, 12 pages.	
		Chinese First Office Action received for CN Application No. 201980067623.1, Applicant: Inari Medical, Inc., Date of Mailing: January 31, 2024, 10 pages.	
		International Search Report and Written Opinion for International App. No. PCT/US23/73765; Date of Filing: September 8, 2023, Applicant: Inari Medical, Inc., Date of Mailing: February 28, 2024, 7 pages.	
		International Search Report and Written Opinion for International App. No. PCT/US23/69892; Date of Filing: July 10, 2023, Applicant: Inari Medical, Inc., Date of Mailing: February 29, 2024, 12 pages.	

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

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

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

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☐ None

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18/342,553- Conf # 6799
	Filing Date	June 27, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552.8018.US11

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

COPIES OF REFERENCES

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

SIGNATURE

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

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2024-03-12
Name/Print	Matthew S. Williams	Registration Number	77,516

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

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 05 2024

PERKINS COIE LLP

PCT

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

(PCT Rule 44.1)

Applicant's or agent's file reference 111552-8040WO00	Date of mailing *(day/month/year)* FEB 28 2024 **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 23/73765	International filing date *(day/month/year)* 08 September 2023 (08.09.2023)
Applicant INARI MEDICAL, INC.	

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

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

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

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

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

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

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

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

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

4. **Reminders**

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

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

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

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

Name and mailing address of the ISA/US 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 Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/220 (revised January 2020)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference		FOR FURTHER ACTION
111552-8040WO00		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 23/73766	08 September 2023 (08.09.2023)	09 September 2022 (09.09.2022)
Applicant INARI MEDICAL, INC.		

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

This international search report consists of a total of 9 sheets.

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

1. **Basis of the report**

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

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

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

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

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

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

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

4. With regard to the **title**,

   ☒ the text is approved as submitted by the applicant.

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

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

   ☒ the text is approved as submitted by the applicant.

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

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

   a. the figure of the drawings to be published with the abstract is Figure No. 3C

   ☒ as suggested by the applicant.

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

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

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 23/79765

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61M 25/00 (2024.01)
ADD. B29C 53/58, B29C 53/60, B29L 31/00 (2024.01)

CPC - INV. A61M 25/005, A61M 25/0012
ADD. A61M 25/0053, B29C 53/58, B29C 53/60, B29L 2031/7542

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 --- Y	US 2005/0131387 A1 (PURSLEY) 16 June 2005 (16.06.2005), entire document	1-21, 23-24, 29-35, 37-39 --- 22, 25-28, 36
Y	US 5,951,539 A (NITA et al.) 14 September 1999 (14.09.1999), entire document, especially Fig. 2A-2F; col 11, ln 8; col 12, ln 6-14, 47	22
Y	US 2022/0151647 A1 (Inari Medical, Inc.) 19 May 2022 (19.05.2022), entire document, especially Fig. 3A; para [0026], [0033]-[0035].	25
Y	US 11,213,356 B2 (Auris Health, Inc) 04 January 2022 (04.01.2022), specifically Fig. 33B; col 51, ln 42-58	26-28, 36
A	US 7,905,877 B1 (JIMENEZ et al.) 15 March 2011 (15.03.2011), entire document	1-39
A	US 2001/0041881 A1 (SARGE et al.) 15 November 2001 (15.11.2001), entire document	1-39

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
26 January 2024	FEB 28 2024
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 Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

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 05 2024

PERKINS COIE LLP

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	FEB 28 2024
Applicant's or agent's file reference 111552-8040WO00	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 23/73765	08 September 2023 (08.09.2023)	09 September 2022 (09.09.2022)

International Patent Classification (IPC) or both national classification and IPC
IPC - INV. A61M 25/00 (2024.01)
ADD. B29C 53/58, B29C 53/60, B29L 31/00 (2024.01)
CPC - INV. A61M 25/005, A61M 25/0012
ADD. A61M 25/0053, B29C 53/58, B29C 53/60, B29L 2031/7542

Applicant INARI MEDICAL, INC.

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

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

2. **FURTHER ACTION**

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

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

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

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	29 January 2024	Kari Rodriquez PCT Help Desk Telephone No. 571-272-4300

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

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 23/73765

Box No. I **Basis of this opinion**

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

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

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

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

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

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

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

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

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

5. Additional comments:

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

1. Statement

Novelty (N)	Claims	1-39	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-39	NO
Industrial applicability (IA)	Claims	1-39	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-21, 23-24, 29-34, 37-39 lack an inventive step under PCT Article 33(3) as being obvious over US 2005/0131387 A1 to Pursley.

As per claim 1, Pursley teaches a catheter (a catheter having fibrous reinforcement, Abstract), comprising:
a longitudinal axis (axis running through center of 41 from left most edge to rightmost edge, Fig. 10);
a plurality of wires (40, Fig. 10; group of filaments 48, para [0043]), wherein the wires are coiled about the longitudinal axis spaced apart from another in a first direction to form a first coil layer (see filaments of 40 spaced apart and wrapped around longitudinal axis of 41 in a the first direction of right to left, Fig. 10; 40 are wound on 41 simultaneously… filament group spacing, para [0043]), Pursley does not specifically teach and wherein the wires are coiled about the longitudinal axis spaced apart from one another in a second direction, opposite the first direction, over the first coil layer to form a second coil layer over the first coil layer; and
an outer sheath over the plurality of wires.
However, in another embodiment, Pursley further teaches a longitudinal axis (longitudinal axis of 11 and 12, Fig. 2 and 4) and a single wire (13, Fig. 3; a single filament 13, para [0036]), wherein the single wire is coiled about the longitudinal axis in a first direction (see 13 coiled around 12 from 14 to 18 to form 19, Fig. 3; proximal end 14… distal end 18… winding 19, para [0036]) to form a first coil layer (20, Fig. 4; a first pass 20, para [0038]), and wherein the single wire is coiled about the longitudinal axis spaced apart from one another in a second direction, opposite the first direction (see 13 coiled around 12 moving away from 18, Fig. 5; when 20 is completed, the filament source reverses its direction, para [0038]), over the first coil layer to form a second coil layer over the first coil layer (see 21 over 20, Fig. 6; a second pass 21 of the filament winding is then applied over 12 and over the first pass 20, para [0038]); and
an outer sheath over the plurality of wires (23, Fig. 7; 20, 21 form a first fibrous layer 22… plastic coating 23 is applied over the first fibrous layer 22, para [0039]). Accordingly, it would have been obvious to a person having ordinary skill in the art to apply the full process of the second pass and the other sheath of the second embodiment of Pursley on the plurality of wires of the first embodiment of Pursley, in order to fully complete the catheter creation process when utilizing a plurality of wires.

As per claim 2, Pursley teaches the catheter of claim 1, further comprising an inner liner (12, Fig. 2; catheter 10 can be formed… on a core substrate 12 that forms an inner liner, para [0035]), wherein the wires are coiled over the inner liner (see 13 coiled over 12, Fig. 5; winding 13 around 12, para [0036]).

As per claim 3, Pursley teaches the catheter of claim 1 wherein the wires in the first coil layer have a helical arrangement (see helical arrangement of first pass 20, Fig. 3) having a first orientation (see first orientation from moving from 14 to 18, Fig. 3), and wherein the wires in the second coil layer have a helical arrangement (see helical arrangement of second pass 21, Fig. 5) having a second orientation opposite the first orientation (see second orientation moving away from 18, Fig. 5; when 20 is completed, the filament source reverses its direction of axial movement… a second pass 21 of the filament winding is then applied over 12… as the filament source moves back to 14, para [0038]).

As per claim 4, Pursley teaches the catheter of claim 1 wherein the wires each include a continuous end portion (see end of wire coiling at distal end of 18, Fig. 5; As a result, the filament winding 19 is continuous from its initial anchor at proximal end 14, to the end of first pass 20 at the distal end 18 of 12, and then back to the end of the second pass 21 at the proximal end 14, para [0039]) at which the wire switches from the first direction to the second direction (see switch in direction from Fig. 3 to Fig. 5) and transitions from the first coil layer to the second coil layer (filament winding 19 is continuous, para [0039]; see 20 above 21 at distal end 18, Fig. 6).

As per claim 5, Pursley teaches the catheter of claim 1 wherein the wires each include a self-terminating end portion (see self-terminating end portion where coiling changes direction, Fig. 5; As a result, the filament winding 19 is continuous from its initial anchor at proximal end 14, to the end of first pass 20 at the distal end 18 of 12, and then back to the end of the second pass 21 at the proximal end 14, para [0039]) at which the wire switches from the first direction to the second direction (see switch in direction from Fig. 3 to Fig. 5) and transitions from the first coil layer to the second coil layer (filament winding 19 is continuous, para [0039]; see 20 above 21 at distal end 18, Fig. 6).

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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:

Regarding claims 26-28, the terms "the inner coil layer" and "the outer coil layer" are confusing and lack proper antecedent basis on claim 1 from which claims 26-28 are dependent. Accordingly, the terms "the inner coil layer" and "the outer coil layer" have been corrected to "the first coil layer" and the "the second coil layer" respectively, for which proper antecedent basis is provided by claim 1.

Regarding claim 32, the terms "the first coil layer" and "the second coil layer" are confusing and lack proper antecedent basis on claim 29 from which claim 32 is dependent. Accordingly, the term "the first coil layer" and "the second coil layer" has been corrected to "the inner coil layer" and "the outer coil layer" respectively, for which proper antecedent basis is provided by claim 29.

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As per claim 6, Pursley teaches the catheter of claim 1 wherein the wires have a first pitch in the first coil layer (the filament winding 19 can have a variable pitch, para [0038]) and a second pitch in the second coil layer (the second pass 21 of the winding 19 can be applied with a variable pitch, para [0038]), and wherein the first pitch and the second pitch are the same (the second pass 21 of the winding 19 can be applied with a variable pitch similar to the first pass 20, para [0038]; see similar varying pitch between 20 and 21, Fig. 5 and Fig. 6).

As per claim 7, Pursley teaches the catheter of claim 1 wherein the wires have a first pitch in the first coil layer (a first pass 20 of the filament winding 19... can have a constant pitch, para [0038]) and a second pitch in the second coil layer (the second pass 21 of the winding 19 can be applied with a variable pitch, para [0038]), and wherein the first pitch and the second pitch are the different (reasonably assuming the first pitch and the second pitch would be different with the first pitch being constant and second pitch being variable).

As per claim 8, Pursley teaches the catheter of claim 1 wherein the wires have a first pitch in the first coil layer (see pitch of 19 as it is forming the first pass 20, Fig. 3) and a second pitch in the second coil layer (see pitch of 19 as it is forming the second pass 21, Fig. 5), and wherein the first pitch and/or the second pitch varies along the longitudinal axis (see how pitch of 20 and 21 gets larger moving from 18 to 14, Fig. 5 and 6; filament winding 19 can have a variable pitch, para [0038]).

As per claim 9, Pursley teaches the catheter of claim 1 wherein the wires are further (a) coiled about the longitudinal axis in the first direction to form a third coil layer over the second coil layer (the filament for the first additional layer 32 is anchored in the proximal end, and then the filament is wound over the first fibrous layer 31 at the filament source is moved axially along the core member from the proximal end to the distal position, para [0040]; first fibrous layer 31 of the catheter can be formed using the same process used to form the first layer 22 in catheter 10, para [0040]; see first pass of 32 over second pass of 31, Fig. 9) and (b) coiled about the longitudinal axis in the second direction over the third coil layer to form a fourth coil layer over the third coil layer (see second pass of 32 over first pass of 32, Fig. 9; as the filament source is moved axially along the core member from the proximal end to a distal portion and then back to the proximal end, para [0040]).

As per claim 10, Pursley teaches the catheter of claim 9 wherein the wires each include (a) a first self-terminating end portion (see self-terminating end portion where coiling changes direction, Fig. 5; As a result, the filament winding 19 is continuous from its initial anchor at proximal end 14, to the end of first pass 20 at the distal end 18 of 12, and then back to the end of the second pass 21 at the proximal end 14, para [0038]; see analogous end portion near 36, Fig. 8 and 9) at which the wire switches from the first direction to the second direction (see switch in direction from Fig. 3 to Fig. 5; 31 can be formed using the same process used to form 22 in catheter 10, para [0040]) and transitions from the first coil layer to the second coil layer (filament winding 19 is continuous, para [0038]; see 20 above 21 at distal end 18, Fig. 6; 31 can be formed using the same process used to form 22 in catheter 10, para [0040]), but Pursley does not specifically teach (b) a second self-terminating end portion at which the wire switches from the second direction to the first direction and transitions from the second coil layer to the third coil layer. However, Pursley does further teach the filament winding is continuous (para [0038]) and multiple fibrous reinforcement layers can be formed by repeating the process (para [0040]). Accordingly, it would have been obvious to a person having ordinary skill in the art to make four layers continuously instead of two layers (Note: having four layers would mean having two sets of continuous wire layers wherein the first and third coil layers are coiled in a first direction and the second and fourth coil layers are coiled in a second direction, and the wire being continuous would mean there is a second self-terminating connection from the second to the third layer while still following the tapering shape as shown in Fig. 8 and 9).

As per claim 11, Pursley teaches the catheter of claim 10 wherein the first self-terminating end portions are positioned at a distal end portion of the catheter (left most end of 30, Fig. 8 and 9; see transition from first to second layer at left most end of 30, Fig. 8), and wherein the second self-terminating end portions are positioned at a proximal end portion of the catheter (right most end of 30, Fig. 8 and 9; see where right most dot of the second pass of 31 is near and would transition to the right most dot of the right most dot of the first pass of 32 at the right most end of 30, Fig. 9).

As per claim 12, Pursley teaches the catheter of claim 10 wherein the first self-terminating end portions are at a different position along the longitudinal axis relative to the second self-terminating end portions (see first-self terminating end portions at the left most end of the longitudinal axis while the second-self terminating end is at the right most end, Fig. 9).

As per claim 13, Pursley teaches the catheter of claim 9 wherein the third coil layer extends only partially over the second coil layer along the longitudinal axis (see first pass of 32 only partially covering the second pass of 31, Fig. 9; the distal end of the first additional layer 32 can be an intermediate point along the catheter between the proximal and distal ends, para [0041]).

As per claim 14, Pursley teaches the catheter of claim 9, but Pursley does not specifically teach wherein the third coil layer extends entirely over the second coil layer along the longitudinal axis. However, Pursley does teach the distal end end of the first additional layer does not have to be in the middle of the catheter (can be an intermediate point, para [0041]) and that the additional layers can be applied over the first layer to impart different properties (para [0040]). Accordingly, it would have been obvious to a person having ordinary skill in the art to extend the third coil layer entirely over the second coil layer, in order to fully reinforce the entire length of the catheter instead of only a portion when full additional reinforcement is required.

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Box V.2 - Citations and explanations

As per claim 15, Pursley teaches the catheter of claim 1 wherein the wires are first wires, and further comprising a plurality of second wires (see second set of single wire 32, Fig. 8 and 9; can be a plurality of wires as evidenced by a different embodiment of Pursley, Fig. 10; the filament for the first additional layer 32 is anchored in the proximal end, para [0040]; reasonably assuming additional layer 32 is made of a separate wire since it is detailed to be anchored again), wherein the second wires are (a) coiled about the longitudinal axis in the first direction to form a third coil layer over the second coil layer (the filament for the first additional layer 32 is anchored in the proximal end, and then the filament is wound over the first fibrous layer 31 at the filament source is moved axially along the core member from the proximal end to the distal position, para [0040]; first fibrous layer 31 of the catheter can be formed using the same process used to form the first layer 22 in catheter 10, para [0040]; see first pass of 32 over second pass of 31, Fig. 9) and (b) coiled about the longitudinal axis in the second direction over the third coil layer to form a fourth coil layer over the third coil layer (see second pass of 32 over first pass of 32, Fig. 9; as the filament source is moved axially along the core member from the proximal end to a distal portion and then back to the proximal end, para [0040]).

As per claim 16, Pursley teaches the catheter of claim 15 wherein the first wires each include a first self-terminating end portion (see self-terminating end portion where coiling changes direction, Fig. 9; As a result, the filament winding 19 is continuous from its initial anchor at proximal end 14, to the end of first pass 20 at the distal end 16 of 12, and then back to the end of the second pass 21 at the proximal end 14, para [0039]; see analogous end portion near 36, Fig. 8 and 9) at which the wire switches from the first direction to the second direction (see switch in direction from Fig. 3 to Fig. 5; 31 can be formed using the same process used to form 22 in catheter 10, para [0040]) and transitions from the first coil layer to the second coil layer (filament winding 19 is continuous, para [0039]; see 20 above 21 at distal end 16, Fig. 9; 31 can be formed using the same process used to form 22 in catheter 10, para [0040]), and wherein the second wires each include a second self-terminating end portion (see self-terminating end portion near 34 of first additional layer 32 where coiling changes directions, Fig. 8; each additional fibrous layer can be formed in a manner similar to first layer 31, para [0040]) at which the second wire switches from the first direction to the second direction and transitions from the third coil layer to the fourth coil layer (first additional layer 32 is anchored in the proximal end, and then the filament is wound over the first fibrous layer as the filament source is moved axially along the core member from the proximal end to a distal portion and then back to the proximal portion, para [0040]; filament winding is continuous, para [0039]; see second pass of 32 over the first pass of 32, Fig. 9; each additional fibrous layer can be formed in a manner similar to first layer 31, para [0040]).

As per claim 17, Pursley teaches the catheter of claim 16, but Pursley does not specifically teach wherein the first self-terminating end portions are positioned at a same position along the longitudinal axis relative to the second self-terminating end portions. However, Pursley does teach the distal end end of the first additional layer (34, Fig. 8; distal end 34 of the first additional layer 32, para [0041]) does not have to be in the middle of the catheter (can be an intermediate point, para [0041]) and that the additional layers can be applied over the first layer to impart different properties (para [0040]). Accordingly, it would have been obvious to a person having ordinary skill in the art to extend the third coil layer entirely over the second coil layer which would position the first and second self-terminating portions at the same position, in order to fully reinforce the entire length of the catheter instead of only a portion when full additional reinforcement along the entire catheter is required.

As per claim 18, Pursley teaches the catheter of claim 16 wherein the first self-terminating end portions and the second self-terminating end portions are positioned at a distal end portion (see distal end portion between 35 and 36, Fig. 8 and 9; distal end 35 of the second additional layer 33, para [0041]) of the catheter (see first and second self-terminating end portions between 35 and 36 and catheter 30, Fig. 8 and 9).

As per claim 19, Pursley teaches the catheter of claim 16 wherein the first self-terminating end portions are positioned at a different position along the longitudinal axis relative to the second self-terminating end portions (see first self-terminating end portions of 31 further to the left of the longitudinal axis of 30 relative to the second self-terminating end portions, Fig. 8 and 9).

As per claim 20, Pursley teaches the catheter of claim 15 wherein the third coil layer extends only partially over the second coil layer along the longitudinal axis (see first pass of 32 only partially covering the second pass of 31, Fig. 9; the distal end of the first additional layer 32 can be an intermediate point along the catheter between the proximal and distal ends, para [0041]).

As per claim 21, Pursley teaches the catheter of claim 15, but Pursley does not specifically teach wherein the third coil layer extends entirely over the second coil layer along the longitudinal axis. However, Pursley does teach the distal end end of the first additional layer does not have to be in the middle of the catheter (can be an intermediate point, para [0041]) and that the additional layers can be applied over the first layer to impart different properties (para [0040]). Accordingly, it would have been obvious to a person having ordinary skill in the art to extend the third coil layer entirely over the second coil layer, in order to fully reinforce the entire length of the catheter instead of only a portion when full additional reinforcement is required.

As per claim 23, Pursley teaches the catheter of claim 1 wherein the plurality of wires comprises 4 wires (group of filaments 40 can be supplied from a plurality of filament sources 42, 43, 44, and 45, para [0043]; see 4 filaments comprising 40, Fig. 10).

As per claim 24, Pursley teaches the catheter of claim 1, but Pursley does not specifically teach wherein the plurality of wires comprises 12 wires. While Pursley does not specifically teach wherein the plurality of wires comprises 12 wires, it is well known in the art that duplication and elimination of parts could have been used to have arrive at 12 wires. Accordingly, it would have been obvious to a person having ordinary skill in the art to have arrived at 12 wires for Pursley's plurality of wires, in order to have made the creation process faster for a catheter needing more reinforcement that would come with additional wires.

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As per claim 29, Pursley teaches a method of manufacturing a catheter (a method of making a catheter 10, para [0035]), the method comprising:
coiling [a plurality] of wires (13 coils to form 19, Fig. 3; a single filament 13… filament winding 19, para [0036]) about a mandrel (11, Fig. 1; mandrel 11, para [0035]) in a first direction (see 13 coiled around 12 from 14 to 18 to form 19, Fig. 3; proximal end 14… distal end 18, para [0036]; 12… slid over mandrel 11, para [0036]) to form an inner coil layer (20, Fig. 4; a first pass 20, para [0038]);
coiling the wires about the mandrel in a second direction opposite the first direction (see 13 coiled around 12 moving away from 18, Fig. 5; when 20 is completed, the filament source reverses its direction, para [0038]; 12… slid over mandrel 11, para [0038]) to form an outer coil layer over the inner coil layer (see 21 over 20, Fig. 6; a second pass 21 of the filament winding is then applied over 12 and over the first pass 20, para [0038]);
positioning an outer sheath (23, Fig. 7; plastic coating 23, para [0039]) over the inner and outer coil layers (first and second passes 20, 21 of filament winding 19 form a first fibrous layer 22… plastic coating 23 is applied over 22… 23 can be formed by applying a polymer material in a particulate preform over an outer surface of the core member 12 and fibrous layer 22, para [0039]); and
coupling the outer sheath to the inner and outer coil layers (see 23 coupled to 20 and 21, Fig. 7; 23 can be applied by laminating a plastic tube over an outer surface of the core member 12 and the fibrous layer 22, para [0039]), but Pursley does not specifically teach coiling a plurality of wires. In an alternative embodiment, Pursley teaches coiling a plurality of wires (see filaments of 40 spaced apart and wrapped around core member 41, Fig. 10; group of filaments 40, para [0043]). Accordingly, it would have been obvious to a person having ordinary skill in the art to apply the group of filaments of the alternative embodiment of Pursley on method of the first embodiment Pursley, in order to in order to have made the creation process faster for a catheter needing more reinforcement that would come with additional filaments.

As per claim 30, Pursley teaches the method of claim 29 wherein the method further comprises positioning an inner liner (12, Fig. 2; catheter 10 can be formed… on a core substrate 12 that forms an inner liner, para [0035]) over the mandrel (core substrate 12 that forms an inner lining of catheter 10 and is slid over mandrel 11 as shown in Fig. 2, para [0035]), and wherein coiling the wires about the mandrel in the first direction includes coiling the wires over the inner liner in the first direction (see 13 coiled around 12 from 14 to 18 to form 19, Fig. 3; proximal end 14… distal end 18, para [0036]) to form the inner coil layer over the inner liner (see 20 formed over 12, Fig. 4; a first pass 20, para [0038]).

As per claim 31, Pursley teaches the method of claim 30 wherein coupling the outer sheath to the inner and outer coil layers includes fusing the outer sheath and the inner liner together (plastic coating 23 can be applied by laminating a plastic tube over an outer surface of the core member 12, para [0039]; see 23 in direct contact with 12, unlabeled, Fig. 7; reasonably assuming laminating a plastic tube on a core substrate of the inner liner would result in some form of fusing or else the plastic coating would slide and rotate around the inner liner).

As per claim 32, Pursley teaches the method of claim 29 wherein the wires in the inner coil layer (Corrected – see Box VIII) have a helical arrangement (see helical arrangement of first pass 20, Fig. 3) having a first orientation (see first orientation from moving from 14 to 18, Fig. 3), and wherein the wires in the outer coil layer (Corrected – see Box VIII) have a helical arrangement (see helical arrangement of second pass 21, Fig. 5) having a second orientation opposite the first orientation (see second orientation moving away from 18 and the opposing orientations of 20 and 21, Fig. 5; when 20 is completed, the filament source reverses its direction of axial movement… a second pass 21 of the filament winding is then applied over 12… as the filament source moves back to 14, para [0038]).

As per claim 33, Pursley teaches the method of claim 29 wherein coiling the wires about the mandrel in the first direction to form the inner coil layer includes varying a pitch between the wires in the first direction (filament winding 19 can have a variable pitch in which the turns of the winding 19 become closer together near the distal end 18, para [0038]; see pitch of 20 decreasing towards 18, Fig. 3 and 4).

As per claim 34, Pursley teaches the method of claim 29 wherein coiling the wires about the mandrel in the second direction to form the outer coil layer includes varying a pitch between the wires in the second direction (the second pass 21 of the winding 19 can be applied with a variable pitch similar to the first pass 20, para [0038]; see pitch of 21 increasing towards 14, Fig. 5 and 6).

As per claim 37, Pursley teaches the method of claim 29 wherein coiling the wires about the mandrel in the second direction includes forming a continuous end portion (see end of wire coiling at distal end of 18, Fig. 5; As a result, the filament winding 19 is continuous from its initial anchor at proximal end 14, to the end of first pass 20 at the distal end 18 of 12, and then back to the end of the second pass 21 at the proximal end 14, para [0039]) of each of the wires at which the wire switches from the first direction to the second direction (see switch in direction from Fig. 3 to Fig. 5) and transitions from the inner coil layer to the outer coil layer (filament winding 19 is continuous, para [0039]; see 20 above 21 at distal end 18, Fig. 6).

As per claim 38, Pursley teaches the method of claim 29 wherein coiling the wires about the mandrel in the second direction includes forming a self-terminating end portion (see self-terminating end portion where coiling changes direction, Fig. 5; As a result, the filament winding 19 is continuous from its initial anchor at proximal end 14, to the end of first pass 20 at the distal end 18 of 12, and then back to the end of the second pass 21 at the proximal end 14, para [0039]) of each of the wires at which the wire switches from the first direction to the second direction (see switch in direction from Fig. 3 to Fig. 5) and transitions from the inner coil layer to the outer coil layer (filament winding 19 is continuous, para [0039]; see 20 above 21 at distal end 18, Fig. 6).

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As per claim 39, Pursley teaches a catheter (a catheter having fibrous reinforcement, Abstract), comprising:
a longitudinal axis (axis running through center of 41 from left most edge to rightmost edge, Fig. 10);
a plurality of wires (40, Fig. 1; group of filaments 40, para [0043]), wherein—
the wires are coiled about the longitudinal axis in a first direction to form a first coil layer (see filaments of 40 spaced apart and wrapped around longitudinal axis of 41 in a the first direction of right to left, Fig. 10; 40 are wound on 41 simultaneously... filament group spacing, para [0043]), but Pursley does not specifically teach the wires are coiled about the longitudinal axis in a second direction, opposite the first direction, over the first coil layer to form a second coil layer over the first coil layer, and the wires each include a self-terminating end portion at which the wire switches from the first direction to the second direction and transitions from the first coil layer to the second coil layer; and
an outer sheath over the wires. However, in another embodiment, Pursley further teaches a longitudinal axis (longitudinal axis of 11 and 12, Fig. 2 and 4) and a single wire (13, Fig. 3; a single filament 13, para [0036]), wherein the single wire is coiled about the longitudinal axis in a first direction (see 13 coiled around 12 from 14 to 18 to form 19, Fig. 3; proximal end 14 ... distal end 18..., winding 19, para [0036]) to form a first coil layer (20, Fig. 4; a first pass 20, para [0036]), and wherein the single wire is coiled about the longitudinal axis spaced apart from one another in a second direction, opposite the first direction (see 13 coiled around 12 moving away from 18, Fig. 5; when 20 is completed, the filament source reverses its direction, para [0038]), over the first coil layer to form a second coil layer over the first coil layer (see 21 over 20, Fig. 5; a second pass 21 of the filament winding is then applied over 12 and over the first pass 20, para [0038]), and the wires each include a self-terminating end portion (see self-terminating end portion where coiling changes direction, Fig. 5; As a result, the filament winding 19 is continuous from its initial anchor at proximal end 14, to the end of first pass 20 at the distal end 18 of 12, and then back to the end of the second pass 21 at the proximal end 14, para [0039]) at which the wire switches from the first direction to the second direction (see switch in direction from Fig. 3 to Fig. 5) and transitions from the first coil layer to the second coil layer (filament winding 19 is continuous, para [0039]; see 20 above 21 at distal end 18, Fig. 5); and
an outer sheath over the plurality of wires (23, Fig. 7, 20, 21 form a first fibrous layer 22... plastic coating 23 is applied over the first fibrous layer 22, para [0039]). Accordingly, it would have been obvious to a person having ordinary skill in the art to apply the full process of the second pass and the other sheath of the second embodiment of Pursley on the plurality of wires of the first embodiment of Pursley, in order to fully complete the catheter creation process when utilizing a plurality of wires.

Claims 29, and 35 lack an inventive step under PCT Article 33(3) as being obvious over Pursley (Second Treatment).

As per claim 29, Pursley teaches a method of manufacturing a catheter (a method of making a catheter 10, para [0035]), the method comprising:
coiling [a plurality] of wires (13 coils to form 19, Fig. 3; a single filament 13. ., filament winding 19, para [0036]) about a mandrel (11, Fig. 1; mandrel 11, para [0035]) in a first direction (see 13 coiled around 12 from 14 to 18 to form 19, Fig. 3; proximal end 14.... distal end 18, para [0036]; 12... slid over mandrel 11, para [0035]) to form an inner coil layer (20, Fig. 4; a first pass 20, para [0036]; see bottom layer of 31 in Fig. 9 created using same method, para [0040]);
coiling the wires about the mandrel in a second direction opposite the first direction (each additional fibrous layer 32, 33 can be formed in a manner similar to first layer 31..., as the filament source is moved axially... to a distal position and then back to the proximal position, para [0040]) to
form an outer coil layer over the inner coil layer (see top layer of 32 over the bottom layer of 31, Fig. 9);
positioning an outer sheath over the inner and outer coil layers (a plastic coating can be applied over all of the fibrous layers 31-33 simultaneously, para [0041]); and
coupling the outer sheath to the inner and outer coil layers (the plastic coating can be applied by laminating a plastic tube over an outer surface of the core member and the fibrous layer, para [0039]), but Pursley does not specifically teach coiling a plurality of wires. In an alternative embodiment, Pursley teaches coiling a plurality of wires (see filaments of 40 spaced apart and wrapped around core member 41, Fig. 10; group of filaments 40, para [0043]). Accordingly, it would have been obvious to a person having ordinary skill in the art to apply the group of filaments of the alternative embodiment of Pursley on method of the first embodiment Pursley, in order to in order to have made the creation process faster for a catheter needing more reinforcement that would come with additional filaments.

As per claim 38, Pursley teaches the method of claim 29 wherein the method further comprises positioning an elongate component (see layer created by elongate member between 32 and 31, Fig. 8) over the inner coil layer (see elongate member over bottom layer of 31, Fig. 8), and wherein coiling the wires about the mandrel in the second direction to form the outer coil layer includes coiling the wires over the elongate component (see top layer of 32 coiled over the elongate member layer, Fig. 8) to secure the elongate component between the inner and outer coil layers (reasonably assuming elongate member is secured between 31 and 32 as the member would have to be placed before creation of 32 for it to be between 31 and 32).

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Continuation of:
Box V.2 - Citations and explanations

Claim 22 lacks an inventive step under PCT Article 33(3) as being obvious over Pursley in view of US 5,951,539 A to Nita et al. (hereinafter 'Nita').

As per claim 22, Pursley teaches the catheter of claim 1, but Pursley does not specifically teach wherein the wires have a rectangular cross-sectional shape. In similar art, Nita teaches a ribbon (206, Fig. 2C; ribbon 206, col 11, ln 8) for wrapping in a first and second direction (see 206 wrapped in a first and second direction, Fig. 2C and 2D) within an outer sheath (212/214/216/218, Fig. 2F; outer polymeric coverings 212, 214, 216, 218, col 12, ln 47), analogous to the filament, wrapping, and outer sheath of Pursley (Fig. 6 and 7), wherein the wires have a rectangular cross-sectional shape (see rectangular cross-section of 206, Fig. 2C; 206 that are suitable for use in this invention are desirably... include elongated shape, the cross-section of which are... rectangular, col 12, ln 8-14). Accordingly, it would have been obvious to a person having ordinary skill in the art to apply the rectangular cross-section of Nita on the wires of Pursley, in order to increase the surface area of the wires contacting the inner liner to reduce any chance of the wire slipping during the winding process.

Claim 25 lacks an inventive step under PCT Article 33(3) as being obvious over Pursley in view of US 2022/0151647 A1 to Inari Medical, Inc. (hereinafter 'Inari Medical').

As per claim 25, Pursley teaches the catheter of claim 1, further comprising an inner liner (12, Fig. 2; catheter 10 can be formed... on a core substrate 12 that forms an inner liner, para [0035]) defining an inner lumen (see inner lumen of 12 currently filled by 11, Fig. 2; 12 forms an inner lining of the catheter, para [0035]), wherein the wires are coiled over the inner liner (see 13 coiled over 12, Fig. 5; winding 13 around 12, para [0036]), but Pursley does not specifically teach wherein the lumen has a diameter of 20 French or greater. In similar art, Inari Medical teaches a catheter (126, Fig. 3A; catheter 126 includes... a distal region 126, para [0026]) with a coil (336, Fig. 3A; a coil 336, para [0033]) wrapped around the inner liner (see 336 wrapped around 232, Fig. 3A; inner liner 232, para [0033]) defining a lumen (121, Fig. 3A; lumen 121, para [0026]; 232 defines 121, para [0035]), analogous to the coil and liner of Pursley (Fig. 4 and 5), wherein the lumen has a diameter of 20 French or greater (the inner liner 232 can have a diameter D of... greater than about 20 French, para [0035]). Accordingly, it would have been obvious to a person having ordinary skill in the art to apply the inner liner diameter of Inari Medical on the inner liner of Pursley, in order to create a catheter with a diameter large enough to facilitate movement of various components through the lumen, such as aspiration catheters or delivery sheaths.

Claims 26-28 and 36 lack an inventive step under PCT Article 33(3) as being obvious over Pursley in view of US 11,213,356 B2 in view of Auris Health, Inc. (hereinafter 'Auris Health').

As per claim 26, Pursley (Second Treatment) teaches the catheter of claim 1, but Pursley does not specifically teach further comprising a lumen extending between the first coil layer and the second coil layer (Corrected -- see Box VIII). However, Pursley does further teach an elongate member between the first coil layer and the second coil layer (see layer created by elongate member between 32 and 31, Fig. 8). Additionally, in similar art, Auris Health teaches a catheter (300, Fig. 33B; elongate instrument or catheter 300, col 51, ln 41-21) with an inner layer (312, Fig. 33B; inner layer of material... 312, col 51, ln 45) and an outer layer (302, Fig. 33B; outer layer of material... 302, col 51, ln 44, analogous to the inner coil layer and outer coil layer of Pursley (31 and 32, Fig. 8), wherein an elongate component (components of the elongate instrument 300, e.g.,... support tubes 310,... one or more pull wires 314 may be disposed within lumens of 310, col 51, ln 51-59; 310, Fig. 33B) is positioned between the inner layer and the outer layer (see 310 between 302 and 312, Fig. 33B; components of the elongate instrument 300 may be contained within or between 302 and 312, col 51, ln 42-45). Accordingly, it would have been obvious to a person having ordinary skill in the art to apply the elongate members of Auris Health on the elongate member of Pursley, in order to provide the elongate member with a space for a pull wire to allow for increased control of the catheter by making it steerable.

As per claim 27, Pursley teaches the catheter of claim 1, but Pursley does not specifically teach further comprising a lumen extending between the second coil layer (Corrected -- see Box VIII) and the outer sheath. In similar art, Auris Health teaches a catheter (300, Fig. 33B; catheter 300, col 51, ln 42) with a first layer (312, Fig. 33B; inner layer of material... 312, col 51, ln 45) and a second layer (302, Fig. 33B; outer tube... 302, col 51, ln 44), wherein a lumen extends between the first layer and second layer (the components of 300 may be contained with or between 302 and 312... operational tubes 304, flexible tubes 306, push tubes 308, and support tubes 310 are disposed within the minor, secondary, or peripheral lumens in the body structure of the elongate structure,... one or more pull wires 314 may be disposed with lumens of the support tubes 310, col 51, ln 42-56; see 314 within lumen of 310 within lumen of 306 within lumen of 304, Fig. 33B). Accordingly, it would have been obvious to a person having ordinary skill in the art to apply the intra-layer lumen of Auris Health on the second coil layer and outer sheath of Pursley, in order to allow for a space between the second coil layer and outer sheath for a pull wire to allow for increased control of the catheter by making it steerable.

--- See continuation box ---

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 23/73785

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 28, Pursley teaches the catheter of claim 1, further comprising:
an inner liner (12, Fig. 2; catheter 10 can be formed... on a core substrate 12 that forms an inner liner, para [0035]), wherein the wires are coiled over the inner liner (see 13 coiled over 12, Fig. 5; winding 13 around 12, para [0038]), but Pursley does not specifically teach and a lumen extending between the first coil layer (Corrected – see Box VIII) and the inner liner. In similar art, Auris Health teaches a catheter (300, Fig. 33B; catheter 300, col 51, ln 42) with a first layer (312, Fig. 33B; inner tube 312, col 51, ln 45) and a second layer (302, Fig. 33B; outer layer of material... 302, col 51, ln 44), where a lumen extends between the first layer and second layer (the components of 300 may be contained with or between 302 and 312... operational tubes 304, flexible tubes 306, push tubes 308, and support tubes 310 are disposed within the minor, secondary, or peripheral lumens in the body structure of the elongate structure... one or more pull wires 314 may be disposed with lumens of the support tubes 310, col 51, ln 42-58; see 314 within lumen of 310 within lumen of 306 within lumen of 304, Fig. 33B). Accordingly, it would have been obvious to a person having ordinary skill in the art to apply the intra-layer lumen of Auris Health on the inner liner before the coiling of the first coil layer of Pursley, in order to allow for a space between the inner liner and first coil for a pull wire to allow for increased control of the catheter by making it steerable.

As per claim 36, Pursley teaches the method of claim 35, but Pursley does not specifically teach wherein the elongate component comprises a lumen. In similar art, Auris Health teaches a catheter (300, Fig. 33B, elongate instrument or catheter 300, col 51, ln 41-21) with an inner layer (312, Fig. 33B; inner layer of material... 312, col 51, ln 45) and an outer layer (302, Fig. 33B; outer layer of material... 302, col 51, ln 44, analogous to the inner coil layer and outer coil layer of Pursley (31 and 32, Fig. 8), wherein an elongate component (components of the elongate instrument 300, e.g... . support tubes 310... one or more pull wires 314 may be disposed within lumens of 310, col 51, ln 51-58; 310, Fig. 33B) comprises a lumen (see 314 within the lumen of 310, Fig. 33B; 314 may be disposed within lumens of the support tubes 310, col 51, ln 57-58). Accordingly, it would have been obvious to a person having ordinary skill in the art to apply the elongate members of Auris Health on the elongate member of Pursley, in order to provide the elongate member with a space for a pull wire to allow for increased control of the catheter by making it steerable.

Claims 1-39 have industrial applicability as defined by PCT Article 33(4) because the subject can be made or used in industry.

1. SEARCH HISTORY

Application Number	PCT/US 23/73765
Search Conducted By	JJH
Search Approved By	AD

CPC/IPC Classifications Searched	CPC - INV- A61M 25/0012; A61M25/005 ADD- A61M25/0053; B29C53/58; B29C53/60; B29L2031/7542 IPC(8) – INV- A61M25/00 (2024.01) ADD- B29C53/58; B29C53/60; B29L31/00 (2024.01)
Date Conducted	26 January 2024 (26.01.2024)

Documentation Searched	CPC - INV- A61M 25/0012; A61M25/005 ADD- A61M25/0053; B29C53/58; B29C53/60; B29L2031/7542 IPC(8) – INV- A61M25/00 (2024.01) ADD- B29C53/58; B29C53/60; B29L31/00 (2024.01) USPC - 604/526; 156/172
Search Terms Used	Catheter, first, second, coil*, layers, lumen%, between, wall, multilayer, secondary, making, plurality, continuously, continuous, wound, wire%, spiral, helical, shape, cord%, double, helix, oppos*, medical, tube, back, wounded, 20, French, winding, method, manufacturing, self-terminating, double-back, double back, different, orientation, direction%, sheets, inner, outer, liner, sheath, filament%, pitch, angle, 22, 24, 26, 28, 30, 32, 34, mandrel, core, making, fuse, coupl*, vary*,
Date Conducted	26 January 2024 (26.01.2024)

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

	ZA ZM ZW
Date Conducted	26 January 2024 (26.01.2024)

Search Logic:

1 PN=(US20050131387A1 OR US6152912A OR US5951539A OR US7905877B1 OR US10799688B2) 4
2 IPC=(A61M25/00 OR B29C53/58 OR B29C53/60 OR B29L31/00) 63,337
3 CPC=(A61M25/0012 OR A61M25/005 OR A61M25/0053 OR B29C53/58 OR B29C53/60 OR B29L2031/7542) 4,510
4 UC=(604/526 OR 156/172) 1,203
5 2 OR 3 OR 4 64,859
6 5 AND FT=(self-terminating OR continuous OR double-back OR double back) 15,120
7 6 AND FT=((oppos* OR different)NEAR(orientation% OR wind* OR direction%)) 4,450
8 7 AND FT=(layers OR sheets) 2,349
9 8 AND FT=((inner AND outer)W3(liner OR sheath OR layer)) 347
10 9 AND FT=(plurality NEAR (wire% OR cord% OR filament%)) 97
11 10 AND FT=(pitch OR angle) 88
12 11 NOT 1 88
13 9 AND FT=(20 French OR 22 French OR 24 French OR 26 French OR 28 French OR 30 French OR 32 French OR 34 French) 16
14 13 NOT (11 OR 1) 10
15 5 AND FT=(mandrel OR core) 14,285
16 15 AND FT=(coil OR helix OR helical OR spiral) 6,572
17 16 AND FT=(plurality NEAR (wire% OR cord% OR filament%)) 1,090
18 17 AND FT=(pitch OR angle) 754
19 18 AND FT=(catheter) 559
20 19 AND FT=((oppos* OR different)NEAR(orientation% OR wind* OR direction%)) 330
21 20 AND FT=(self-terminating OR continuous OR double-back OR double back) 234
22 21 AND FT=((method of manufacturing) OR (method of making)) 69
23 22 NOT (13 OR 11 OR 1) 50
24 19 AND FT=(fuse OR coupl*)433
25 24 AND FT=(((first AND second)OR(inner AND outer))NEAR(layer OR sheet)) 124
26 25 AND FT=(lumen) 119
27 26 NOT (22 OR 13 OR 11 OR 1) 82
28 FT=(plurality NEAR (wire% OR cord% OR filament%)) 256,872
29 28 AND FT=(self-terminating OR continuous OR double-back OR double back) 53,086
30 29 AND FT=((oppos* OR different)NEAR(orientation% OR wind* OR direction%)) 17,265
31 30 AND FT=(((first AND second)OR(inner AND outer))NEAR(layer OR sheet)) 2,877
32 31 AND FT=(catheter) 335
33 32 AND FT=(vary*)NEAR(pitch OR angle) 40
34 33 NOT (26 OR 22 OR 13 OR 11 OR 1) 19
35 32 AND FT=(mandrel OR core) 251
36 35 AND FT=(coiling OR winding) 141
37 36 AND FT=(French) 39
38 37 NOT (34 OR 26 OR 22 OR 13 OR 11 OR 1) 17
39 FT=(coiling OR winding) 1,759,221
40 39 AND FT=(((first AND second)OR(inner AND outer))NEAR(layer OR sheet)) 36,085
41 40 AND FT=(pitch OR angle) 15,514
42 41 AND FT=((oppos* OR different)NEAR(orientation% OR wind* OR direction%))

	7,509	
43	42 AND FT=(self-terminating OR continuous OR double-back OR double back)	4,321
44	43 AND FT=((method of manufacturing) OR (method of making))	1,258
45	44 AND FT=(plurality NEAR (wire% OR cord% OR filament%))	292
46	45 AND FT=(catheter)	66
47	46 NOT (37 OR 34 OR 26 OR 22 OR 13 OR 11 OR 1)	33
48	43 AND FT=(catheter)	409
49	48 AND FT=(mandrel OR core)	348
50	49 AND FT=(fuse)	54
51	50 NOT (46 OR 37 OR 34 OR 26 OR 22 OR 13 OR 11 OR 1)	30
52	PN=(US20050131387A1 OR US2005137519A1 OR US5951539A OR US10799688B2)	
4		
53	CTB 52 OR CTF 52	664
54	53 AND FT=(plurality NEAR (wire% OR cord% OR filament%))	127
55	54 AND FT=((oppos* OR different)NEAR(orientation% OR wind* OR direction%))	60
56	55 NOT (52 OR 50 OR 46 OR 37 OR 34 OR 26 OR 22 OR 13 OR 11 OR 1)	39

Electronic Database Searched	Google
Files Searched	Scholar (Articles excluding patents)
Date Conducted	26 January 2024 (26.01.2024)

Search Logic:

catheter with first and second coiling layers (About 3,930,000 results)
catheter with a lumen between first and second coiling layers (About 1,530,000 results)
catheter with a lumen between layers (About 1,400,000 results)
catheter with lumens in catheter wall (About 2,910,000 results)
multilayer catheter wall with lumens in the catheter wall (About 92,100 results)
catheter with a second lumen in between layers of the catheter wall (About 2,580,000 results)
making a catheter with a secondary lumen in between layers (About 2,620,000 results)
catheter with plurality of continuously wound wires in a spiral or helical shape (About 2,570,000 results)
catheter with plurality of continuously wound cords in a spiral or helical shape (About 2,680,000 results)
medical tube with first and second coiling layers (About 9,790,000 results)

Electronic Database Searched	Google
Files Searched	Patents (US Patents/Published Applications, EPO publications, International, China, Germany, Canada)
Date Conducted	26 January 2024 (26.01.2024)

Search Logic:

medical tube with double helix layer (More than 100,000 results)

medical tube with opposing coils (More than 100,000 results)
catheter opposing coils (More than 100,000 results)
catheter with first coil layer that continuously coils back to make a second coil layer (About 31,500 results)
catheter with first and second wounded wire layers (More than 100,000 results)
20 French catheter (More than 100,000 results)
(20 French catheter) AND (winding) (About 9,937 results)
(20 French catheter) AND (coiling layer) (About 19,209 results)
catheter with lumen between coiling layers (About 58,901 results)
method of manufacturing a catheter with a secondary lumen between wall layers (More than 100,000 results)

UNITED STATES
PATENT AND TRADEMARK OFFICE

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

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/342,553	**03/12/2024 12:04:26 PM Z ET**	**111552.8018.US11**

Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	6799	FILED BY	JiYoung Anderson
PATENT CENTER #	64646972	FILING DATE	06/27/2023
CUSTOMER #	25096	FIRST NAMED INVENTOR	Ben Merritt
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Matthew Williams

Documents

TOTAL DOCUMENTS: 5

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2024-3-12 IDS SB08 - fee - 111552-8018US11.pdf	3	Information Disclosure Statement (IDS) Form (SB08)	128 KB
Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
NPL_JP_OA_EN_translation_2022_574456_Jan_23_2024_12pages.pdf	12	Non Patent Literature	90 KB
NPL_CN_OA_201980067623_1-Jan-31-2024_10pages.pdf	10	Non Patent Literature	4167 KB
NPL_ International Search Report and Written Opinion for PCTUS23_69892 Feb 29 2024 - 12 pages.pdf	12	Non Patent Literature	2385 KB

NPL_ ISR-PCTUS23_73765 mailed Feb 28 2024 - 17 pages.pdf	17	Non Patent Literature	4062 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2024-3-12 IDS SB08 - fee - 111552-8018US11.pdf	155312116703D3F2D435277F31910BB93FAE12C8C85391E9AF B0A0ADD22448E05678B792B9897DB55850B0C987B35DB7A7C 4FB581260151515F35D36D052E962
NPL_JP_OA_EN_translation_2 022_574456_Jan_23_2024_12 pages.pdf	E0BF4FF27D4EEEBB71BADC1AD30A9B577E0EB1EEE2E1C85 202503E8D603F7738A0635294E4CB8A8BC3B69E0933747C1F8 13ABBC9E8209B6CA6CDD318E79A8A2B
NPL_CN_OA_201980067623_ 1-Jan-31-2024_10pages.pdf	D36442307760D7AA0218DDEDF940C7677E44D4096160D2063 2D68F8CA4724B1004BC9A1ADC81D006F7042DB9C272D5833 AEEDEA99A3217C8C65E4108F8A849A8
NPL_ International Search Report and Written Opinion for PCTUS23_69892 Feb 29 2024 - 12 pages.pdf	78069CC55D7E42BF80642DC2834B924BD8469B20A995C38ED 382E9349B42263243476EC6F3751AA1EB465BA03215B45260A 55AB2CB46F55D6FCC0FFAE315F879
NPL_ ISR-PCTUS23_73765 mailed Feb 28 2024 - 17 pages.pdf	0608EB456C09173F5255952BFFC0F2C30796A469D59CC27A7 2D81BD147DBDD53826F66AD4C1C4D9AADF71113DA4A25B0 FC1C4D9AEEB0EF77E987F959A4524C1D

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES
PATENT AND TRADEMARK OFFICE

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

ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/342,553	**03/12/2024 12:04:26 PM Z ET**	**111552.8018.US11**

Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	6799	FILED BY	JiYoung Anderson
PATENT CENTER #	64646972	AUTHORIZED BY	Matthew Williams
CUSTOMER #	25096	FILING DATE	06/27/2023
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Ben Merritt

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 5111	**E20243BC04569761**	**JiYoung Anderson**

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

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

New Applications Under 35 U.S.C. 111

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

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

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C.

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

New International Application Filed with the USPTO as a Receiving Office

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

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: Benjamin D. Cashdollar
Perkins Coie LLP
P.O. Box 1247
Seattle, WA 98111-1247
United States Of America

RECEIVED
PATENT DOCKETING

MAR 05 2024

PERKINS COIE LLP

PCT

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

(PCT Rule 44.1)

Applicant's or agent's file reference 111552-8044WO00	Date of mailing *(day/month/year)* FEB 29 2024 **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US23/69892	International filing date *(day/month/year)* 10 July 2023 (10.07.2023)

Applicant INARI MEDICAL, INC.

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

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

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

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

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

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

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

4. **Reminders**

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

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

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

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

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

Form PCT/ISA/220 (revised January 2020)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION
111552-8044WO00	see Form PCT/ISA/220 as well as, where applicable, item 5 below.

International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US23/69892	10 July 2023 (10.07.2023)	

Applicant
INARI MEDICAL, INC.

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

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

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

1. **Basis of the report**

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

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

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

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

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

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

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

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

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

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

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

6. With regard to the drawings,

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

☒ 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 2022)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US23/69392

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:
-***-Please See Supplemental Page-***-

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.:
1-20

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 2022)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US23/69692

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61F 2/01; A61B 17/00; A61B 17/22; A61B 17/221; A61M 1/00; A61M 25/01 (2023.01)
ADD.
CPC - INV. A61F 2/011; A61B 17/221; A61F 2/01; A61M 25/0097

ADD. A61B 17/22032; A61B 2017/00778; A61B 2017/22051; A61B 2017/320716; A61B 2217/005; A61F 2/013; A61M 1/79

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2011/0264132 A1 (STRAUSS BRIAN M) 27 October 2011; Figure 11c; Paragraphs 0003, 0005, 0012, 0018, 0045, 0092; Abstract	1, 2, 4-6, 13-16, 18, 19 --- 3, 7-9, 17, 20
X --- Y	US 2016/0143721 A1 (INCEPTUS MEDICAL LLC) 26 May 2016; Figures 12, 13, 15a; Paragraphs 0054, 0077, 0080; Abstract	1, 2, 4-6, 10, 13-16, 19 --- 3, 7-9, 11, 12, 17, 20
Y	US 2012/0143239 A1 (AKLOG LISHAN) 07 June 2012; Paragraphs 0027, 0046	3, 7-9, 17, 20
Y	US 2020/0054861 A1 (ABIOMED INC.) 20 February 2020; Paragraphs 0266-0268	11, 12
A	US 2019/0223883 A1 (NEURAVI LIMITED) 25 July 2019; entire document	1-20
A	US 2019/0328411 A1 (NEURAVI LIMITED) 31 October 2019; entire document	1-20

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
12 January 2024 (12.01.2024)	FEB 29 2024
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2022)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US23/69892

-***-Continued From Box No. III: Observations where unity of invention is lacking-***-

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

Group I: Claims 1-20 are directed toward a system and method for removing clot material from a blood vessel of patient.

Group II: Claims 21-45 are directed toward a method of removing clot material from a blood vessel of a patient using a clot treatment system and a system for removing clot material from a vasculature of patient.

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:

Group I include an intermediate catheter configured to extend through the delivery catheter; an embolic protection device coupled to a distal portion of the intermediate catheter, wherein the delivery catheter and intermediate catheter are movable relative to one another to move the embolic protection device between (a) a first embolic protection device position in which the embolic protection device is constrained within the delivery catheter and (b) a second embolic protection device position in which the embolic protection device is unconstrained by the delivery catheter and configured to expand within the blood vessel; a deployment catheter configured to extend through the intermediate catheter; wherein the deployment catheter and the intermediate catheter are movable relative to one another to move the embolic protection device between (a) a first clot treatment device position in which the clot treatment device is constrained within the deployment catheter and (b) a second clot treatment device position in which the clot treatment device is unconstrained by the deployment catheter and configured to expand within the blood vessel; retracting the delivery catheter to allow the embolic protection device to expand within the blood vessel at least partially proximal to the clot material; advancing a clot treatment assembly through the intermediate catheter and at least partially through the clot material; retracting a deployment catheter of the clot treatment assembly relative to a clot treatment device of the clot treatment assembly to allow the clot treatment device to expand within the blood vessel at least partially distal to the clot material; and withdrawing the clot treatment device proximally though the clot material and into the embolic protection device, which are not present in Group II.

Group II include radially constraining a clot treatment device and an embolic protection device within the catheter; moving the catheter proximally to deploy the clot treatment device at least partially distal to clot material within the blood vessel; and moving the catheter further proximally to deploy the embolic protection device at least partially proximal to the clot material; a clot treatment device coupled to the second shaft and positioned distal of the embolic protection device. wherein, in response to proximal movement of the catheter relative to the mechanical thrombectomy assembly, the clot treatment device and the embolic protection device are configured to transition between an undeployed configuration and a deployed configuration; wherein the intermediate deployment shaft is positioned radially outward of the first shaft, which are not present in Group I.

The common technical features of Groups I and II are a system for removing clot material from a blood vessel of patient, the system comprising: a catheter; an embolic protection device; a clot treatment device coupled to the elongate shaft; a method of removing clot material from a blood vessel of a patient, the method comprising: advancing a catheter through the blood vessel such that a distal portion of the catheter is proximate to the clot material.

These common technical features are disclosed by US 2020/0155293 A1 to Morrison et al. (hereinafter 'Morrison'). Morrison discloses a system for removing clot material from a blood vessel of patient (An intravascular emboli capture and retrieval system for intravascular embolism protection and embolism removal or maceration; paragraph [0104]), the system comprising: a catheter (capture/delivery sheath 12, figure 1; paragraph [0104]); an embolic protection device (capture sleeve 14; figure 1; paragraph 0104]); a clot treatment device coupled to the elongate shaft (filter 26 coupled to the shaft and used for maceration of the clot; figure 2; paragraph [0109]); a method of removing clot material from a blood vessel of a patient (method of removing a clot from the blood vessel; paragraph [0113]), the method comprising: advancing a catheter through the blood vessel such that a distal portion of the catheter is proximate to the clot material (advancing delivery sheath 12 (catheter) through the blood vessel such that a distal portion is proximate the clot as shown; figure 6; paragraph [0113]).

Since the common technical features are previously disclosed by the Morrison reference, the common features are not special and so Groups I and II lack unity.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: Benjamin D. Cashdollar
Perkins Coie LLP
P.O. Box 1247
Seattle, WA 98111-1247
United States Of America

RECEIVED
PATENT DOCKETING

MAR 05 2024

PERKINS COIE LLP

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	FEB 29 2024
Applicant's or agent's file reference 111552-8044WO00	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US23/69692	10 July 2023 (10.07.2023)	

International Patent Classification (IPC) or both national classification and IPC
IPC - INV. A61F 2/01; A61B 17/00; A61B 17/22; A61B 17/221; A61M 1/00; A61M 25/01 (2023.01)
ADD.
CPC - INV. A61F 2/011; A61B 17/221; A61F 2/01; A61M 25/0097

ADD. A61B 17/22032; A61B 2017/00778; A61B 2017/22051; A61B 2017/320716; A61B 2217/005

Applicant INARI MEDICAL, INC.

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

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

2. **FURTHER ACTION**

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

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

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

Name and mailing address of the ISA/	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	12 January 2024 (12.01.2024)	Shane Thomas PCT Help Desk Telephone No. 571-272-4300

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

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US23/69892

Box No. I Basis of this opinion

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

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

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

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

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

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

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

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

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

5. Additional comments:

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

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US23/69692

Box No. IV Lack of unity of invention

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

   ☐ paid additional fees.

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

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

   ☒ not paid additional fees.

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

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

   ☐ complied with.

   ☒ not complied with for the following reasons:

-***-Please See Supplemental Page-***-

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. 1-20

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

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US23/69892

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

1. Statement

Novelty (N)	Claims	3, 7-9, 11, 12, 17, 20	YES
	Claims	1, 2, 4-6, 10, 13-16, 18, 19	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1, 2, 4-6, 13-16, 18, and 19 lack novelty under PCT Article 33(2) as being anticipated by STRAUSS US 2011/0264132 A1 (STRAUSS).

As to claims 1 and 14, STRAUSS teaches a system and method for removing clot material from a blood vessel of patient, the system comprising: a delivery catheter (sheath, shroud, jacket; para [0092]); an intermediate catheter (guide catheter 1120) configured to extend through the delivery catheter (para [0092]); an embolic protection device (flared distal end 1122) coupled to a distal portion of the intermediate catheter (fig. 11c), wherein the delivery catheter and intermediate catheter are movable relative to one another to move the embolic protection device between (a) a first embolic protection device position in which the embolic protection device is constrained within the delivery catheter (within the sheath, shroud, jacket; para [0092]) and (b) a second embolic protection device position in which the embolic protection device is unconstrained by the delivery catheter and configured to expand within the blood vessel (removal of the sheath, shroud, jacket; para [0092]); a deployment catheter (proximal shaft 1102) configured to extend through the intermediate catheter (fig. 11c); an elongate shaft (snare 1118) configured to extend through the deployment catheter (fig. 11c); and a clot treatment device (expandable region 1104) coupled to the elongate shaft (fig. 11c), wherein the deployment catheter and the intermediate catheter are movable relative to one another to move the embolic protection device between (a) a first clot treatment device position in which the clot treatment device is constrained within the deployment catheter (recovery, para [0093]; best seen in fig. 4b; fig. 12, para [0045]) and (b) a second clot treatment device position in which the clot treatment device is unconstrained by the deployment catheter and configured to expand within the blood vessel (figs. 11c).

As to claims 2 and 16, STRAUSS teaches the system/method of claims 1 and 14 wherein, in the second embolic protection device position, the embolic protection device is configured to expand to a diameter of the blood vessel (fig. 11c).

As to claims 4 and 15, STRAUSS teaches the system/method of claims 2 and 14 wherein, in the second embolic protection device position, the embolic protection device is configured to substantially prevent blood flow through the blood vessel (fig. 11c).

As to claims 5 and 18, STRAUSS teaches the system/method of claims 1 and 14 wherein the blood vessel is a periphery artery (para [0003], [0005]).

As to claims 6 and 19, STRAUSS teaches the system/method of claims 1 and 14 wherein the embolic protection device is a funnel having a tapered shape (fig. 11c).

As to claim 13, STRAUSS teaches the system of claim 1, further comprising an aspiration source fluidly coupled to the delivery catheter (para [0012], [0018]).

Claims 1, 2, 4-6, 10, 13-16, and 19 lack novelty under PCT Article 33(2) as being anticipated by INCEPTUS US 2016/0143721 A1 (INCEPTUS).

As to claims 1 and 14, INCEPTUS teaches a system and method for removing clot material from a blood vessel of patient, the system comprising: a delivery catheter (guide catheter 1404); an intermediate catheter (funnel catheter 1412) configured to extend through the delivery catheter (fig. 15a); an embolic protection device (expandable portion 1414) coupled to a distal portion of the intermediate catheter (fig. 15a), wherein the delivery catheter and intermediate catheter are movable relative to one another to move the embolic protection device between (a) a first embolic protection device position in which the embolic protection device is constrained within the delivery catheter (within guide catheter; para [0080]) and (b) a second embolic protection device position in which the embolic protection device is unconstrained by the delivery catheter and configured to expand within the blood vessel (removal from guide catheter, fig. 15a; para [0077]); a deployment catheter (pusher member 1201) configured to extend through the intermediate catheter (fig. 15a); an elongate shaft (see shaft connected to 1202, fig. 15a) configured to extend through the deployment catheter (fig. 15a); and a clot treatment device (1202) coupled to the elongate shaft (fig. 15a), wherein the deployment catheter and the intermediate catheter are movable relative to one another to move the embolic protection device between (a) a first clot treatment device position in which the clot treatment device is constrained within the deployment catheter (fig. 12) and (b) a second clot treatment device position in which the clot treatment device is unconstrained by the deployment catheter and configured to expand within the blood vessel (fig. 13).

-***-Continued in Supplemental Box-***-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US23/69892

Supplemental Box

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

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 1-20 are directed toward a system and method for removing clot material from a blood vessel of patient.

Group II: Claims 21-45 are directed toward a method of removing clot material from a blood vessel of a patient using a clot treatment system and a system for removing clot material from a vasculature of patient.

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:

Group I include an intermediate catheter configured to extend through the delivery catheter; an embolic protection device coupled to a distal portion of the intermediate catheter, wherein the delivery catheter and intermediate catheter are movable relative to one another to move the embolic protection device between (a) a first embolic protection device position in which the embolic protection device is constrained within the delivery catheter and (b) a second embolic protection device position in which the embolic protection device is unconstrained by the delivery catheter and configured to expand within the blood vessel; a deployment catheter configured to extend through the intermediate catheter; wherein the deployment catheter and the intermediate catheter are movable relative to one another to move the embolic protection device between (a) a first clot treatment device position in which the clot treatment device is constrained within the deployment catheter and (b) a second clot treatment device position in which the clot treatment device is unconstrained by the deployment catheter and configured to expand within the blood vessel; retracting the delivery catheter to allow the embolic protection device to expand within the blood vessel at least partially proximal to the clot material; advancing a clot treatment assembly through the intermediate catheter and at least partially through the clot material; retracting a deployment catheter of the clot treatment assembly relative to a clot treatment device of the clot treatment assembly to allow the clot treatment device to expand within the blood vessel at least partially distal to the clot material; and withdrawing the clot treatment device proximally though the clot material and into the embolic protection device, which are not present in Group II.

Group II include radially constraining a clot treatment device and an embolic protection device within the catheter; moving the catheter proximally to deploy the clot treatment device at least partially distal to clot material within the blood vessel; and moving the catheter further proximally to deploy the embolic protection device at least partially proximal to the clot material; a clot treatment device coupled to the second shaft and positioned distal of the embolic protection device; wherein, in response to proximal movement of the catheter relative to the mechanical thrombectomy assembly, the clot treatment device and the embolic protection device are configured to transition between an undeployed configuration and a deployed configuration; wherein the intermediate deployment shaft is positioned radially outward of the first shaft, which are not present in Group I.

The common technical features of Groups I and II are a system for removing clot material from a blood vessel of patient, the system comprising: a catheter; an embolic protection device; a clot treatment device coupled to the elongate shaft; a method of removing clot material from a blood vessel of a patient, the method comprising: advancing a catheter through the blood vessel such that a distal portion of the catheter is proximate to the clot material.

These common technical features are disclosed by US 2020/0155293 A1 to Morrison et al. (hereinafter 'Morrison'). Morrison discloses a system for removing clot material from a blood vessel of patient (An intravascular emboli capture and retrieval system for intravascular embolism protection and embolism removal or maceration; paragraph [0104]), the system comprising: a catheter (capture/delivery sheath 12; figure 1; paragraph [0104]); an embolic protection device (capture sleeve 14; figure 1; paragraph 0104]); a clot treatment device coupled to the elongate shaft (filter 26 coupled to the shaft and used for maceration of the clot; figure 2; paragraph [0109]); a method of removing clot material from a blood vessel of a patient (method of removing a clot from the blood vessel; paragraph [0113]), the method comprising: advancing a catheter through the blood vessel such that a distal portion of the catheter is proximate to the clot material (advancing delivery sheath 12 (catheter) through the blood vessel such that a distal portion is proximate the clot as shown; figure 6; paragraph [0113]).

Since the common technical features are previously disclosed by the Morrison reference, the common features are not special and so Groups I and II lack unity.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US23/69892

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-***-Continued From Box V. 2: Citations and Explanations-***-

As to claims 2 and 16, INCEPTUS teaches the system/method of claims 1 and 14, wherein in the second embolic protection device position, the embolic protection device is configured to expand to a diameter of the blood vessel (fig. 15a).

As to claims 4 and 15, INCEPTUS teaches the system/method of claims 2 and 14, wherein, in the second embolic protection device position, the embolic protection device is configured to substantially prevent blood flow through the blood vessel (fig. 15a).

As to claim 5, INCEPTUS teaches the system of claim 1 is fully capable of being used in a periphery artery.

As to claims 6 and 19, INCEPTUS teaches the system/method of claims 1 and 14, wherein the embolic protection device is a funnel having a tapered shape (fig. 15a).

As to claim 10, INCEPTUS teaches the system of claim 1, further comprising: a valve assembly fixedly coupled to a proximal portion of the deployment catheter (para [0054]); and a hub fixedly coupled to a proximal portion of the elongate shaft, wherein the valve assembly is movable relative to the hub to retract the deployment catheter relative to the elongate shaft to move the clot treatment device between the first clot treatment position and the second clot treatment position (para [0054]).

As to claim 13, INCEPTUS teaches the system of claim 1, further comprising an aspiration source fluidly coupled to the delivery catheter (para [0054]).

Claims 3, 7-9, 17, and 20 lack an inventive step under PCT Article 33(3) as being obvious over STRAUSS in view of AKLOG et al. US 2012/0143239 A1 (AKLOG).

As to claims 3 and 17, STRAUSS teaches the system/method of claims 2 and 14. It should be noted that STRAUSS fails to specifically teach wherein the embolic protection device is impermeable to blood. STRAUSS teaches treating a thrombous/clot (abstract).

AKLOG teaches a system/method with a common embolic protection device that is impermeable to blood (para [0046]). The impermeable embolic protection device preventing a clot/emboli from leaking through into the vasculature (para [0046]). Therefore, it would have been obvious to one having ordinary skill in the art before the relevant date to modify embolic protection device of STRAUSS to be impermeable in view of AKLOG to prevent a clot/emboli from entering the bloodsteam thereby preventing a stroke (para [0027]).

As to claim 7, STRAUSS teaches the system of claim 6. It should be noted that STRAUSS fails to teach wherein the embolic protection device is impermeable to blood. STRAUSS teaches treating a thrombous/clot (abstract).

AKLOG teaches a system with a common embolic protection device that is impermeable to blood (para [0046]). The impermeable embolic protection device preventing a clot/emboli from leaking through into the vasculature (para [0046]). Therefore, it would have been obvious to one having ordinary skill in the art before the relevant date to modify embolic protection device of STRAUSS to be impermeable in view of AKLOG to prevent a clot/emboli from entering the bloodsteam thereby preventing a stroke (para [0027]).

As to claims 8 and 20, STRAUSS teaches the system/method of claims 1 and 14. It should be noted that STRAUSS fails to teach wherein the embolic protection device is a balloon. STRAUSS teaches an embolic protection device that is expandable (para [0079])

AKLOG teaches a system/method with a common embolic protection device that is a balloon (inflatable body 30). It would have been obvious to one having ordinary skill in the art before the relevant date to modify the system/method of STRAUSS to make use of a balloon to expand the embolic protection device in view of AKLOG as an obvious alternative for expanding the embolic protection device

As to claim 9, STRAUSS in view of AKLOG teaches the system of claim 8. Modified STRAUSS further teaches wherein in the second embolic protection device position, the balloon is configured to expand to a diameter of the blood vessel to substantially prevent blood flow through the blood vessel (fig. 11c, STRAUSS).

Claims 3, 7-9, 17, and 20 lack an inventive step under PCT Article 33(3) as being obvious over INCEPTUS in view of AKLOG.

As to claims 3 and 17, INCEPTUS teaches the system/method of claims 2 and 14. It should be noted that INCEPTUS fails to specifically teach wherein the embolic protection device is impermeable to blood. INCEPTUS teaches treating an emolism/clot (abstract).

AKLOG teaches a system/method with a common embolic protection device that is impermeable to blood (para [0046]). The impermeable embolic protection device preventing a clot/emboli from leaking through into the vasculature (para [0046]). Therefore, it would have been obvious to one having ordinary skill in the art before the relevant date to modify embolic protection device of INCEPTUS to be impermeable in view of AKLOG to prevent a clot/emboli from entering the bloodsteam thereby preventing a stroke (para [0027]).

As to claim 7, INCEPTUS teaches the system of claim 6. It should be noted that INCEPTUS fails to teach wherein the embolic protection device is impermeable to blood. INCEPTUS teaches treating an emolism/clot (abstract).

AKLOG teaches a system with a common embolic protection device that is impermeable to blood (para [0046]). The impermeable embolic protection device preventing a clot/emboli from leaking through into the vasculature (para [0046]). Therefore, it would have been obvious to one having ordinary skill in the art before the relevant date to modify embolic protection device of INCEPTUS to be impermeable in view of AKLOG to prevent a clot/emboli from entering the bloodsteam thereby preventing a stroke (para [0027]).

-***-Continued Within the Next Supplemental Box-***-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US23/69892

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-***-Continued from previous Supplemental Box-***-

As to claims 8 and 20, INCEPTUS teaches the system/method of claims 1 and 14. It should be noted that INCEPTUS fails to teach wherein the embolic protection device is a balloon. INCEPTUS teaches an embolic protection device that is expandable (para [0077])

AKLOG teaches a system/method with a common embolic protection device that is a balloon (inflatable body 30). It would have been obvious to one having ordinary skill in the art before the relevant date to modify the system/method of INCEPTUS to make use of a balloon to expand the embolic protection device in view of AKLOG as an obvious alternative for expanding the embolic protection device

As to claim 9, INCEPTUS in view of AKLOG teaches the system of claim 8. Modified INCEPTUS further teaches wherein in the second embolic protection device position, the balloon is configured to expand to a diameter of the blood vessel to substantially prevent blood flow through the blood vessel (fig. 15a, INCEPTUS).

Claims 11 and 12 lack an inventive step under PCT Article 33(3) as being obvious over INCEPTUS in view of ABIOMED, INC. US2020/0054861 (ABIOMED)

As to claim 11, INCEPTUS teaches the system of claim 1. It should be noted that INCEPTUS fails to teach a handle having a housing and a trigger movable relative to the housing, wherein the deployment catheter is fixedly coupled to the trigger, and wherein the trigger is movable relative to housing to retract the deployment catheter relative to the elongate shaft to move the clot treatment device between the first clot treatment position and the second clot treatment position. INCEPTUS teaches a system that manually operated.

ABIOMED teaches a system that includes a housing and a trigger movable relative to the housing, wherein the deployment catheter is fixedly coupled to the trigger, and wherein the trigger is movable relative to housing to retract the deployment catheter relative to the elongate shaft to move the clot treatment device between the first clot treatment position and the second clot treatment position (para [0264]-[0268]). Therefore, it would have been obvious to one having ordinary skill in the art before the relevant date to modify the system of INCEPTUS to include a housing and trigger in view of ABIOMED as an alternative to manually operating the catheters by hand.

As to claim 12, INCEPTUS in view of ABIOMED teaches the system of claim 11. Modified INCEPTUS further teaches a hub fixedly coupled to a proximal portion of the elongate shaft, wherein the hub is coupled to the housing (para [0266]-[0268], ABIOMED).

Claims 1-20 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/342,553	**02/26/2024 10:33:14 PM Z ET**	**111552.8018.US11**

Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	6799	FILED BY	JiYoung Anderson
PATENT CENTER #	64455357	AUTHORIZED BY	Matthew Williams
CUSTOMER #	25096	FILING DATE	06/27/2023
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Ben Merritt

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 5111	**E20242PM33406601**	**JiYoung Anderson**

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

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

New Applications Under 35 U.S.C. 111

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

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

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C.

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

New International Application Filed with the USPTO as a Receiving Office

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18/342,553- Conf # 6799
	Filing Date	June 27, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552.8018.US11

U.S. PATENTS AND PUBLICATIONS

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

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[5]
	1.	WO2012114633	08-30-2012	TERUMO KABUSHIKI KAISHA		
	2.					
	3.					
	4.					
	5.					
	6.					

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
		English translation of Japanese Office Action received for JP Application No. 2022-574456, Applicant: Inari Medical, Inc, Date of Mailing: January 23, 2024, 12 pages.	
		Chinese First Office Action received for CN Application No. 201980067623.1, Applicant: Inari Medical, Inc., Date of Mailing: January 31, 2024, 10 pages.	

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18/342,553- Conf # 6799
	Filing Date	June 27, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552.8018.US11

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☐ None

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

COPIES OF REFERENCES

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

SIGNATURE

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

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

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

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(81) 指定国 (表示のない限り、全ての種類の国内保護が可能): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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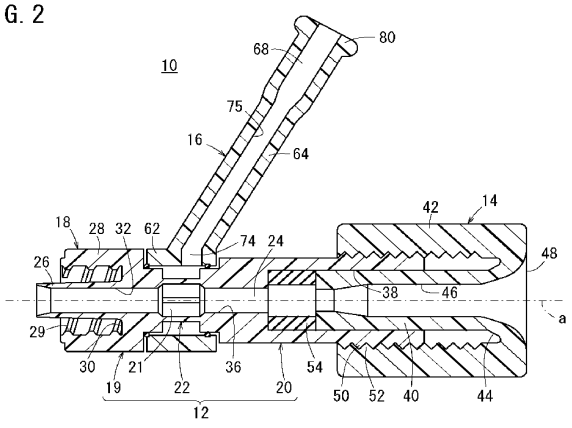
添付公開書類:
— 国際調査報告（条約第 21 条(3)）

WO 2012/114633 A1

(54) **Title**: MEDICAL CONNECTOR

(54) 発明の名称 : 医療用コネクタ

FIG. 2



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

(57) 要約:

[続葉有]

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

明　細　書

発明の名称 ： 医療用コネクタ

技術分野

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

背景技術

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

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

発明の概要

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

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

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

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

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

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

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

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

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

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

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

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

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

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

図面の簡単な説明

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

[図2]図１に示した医療用コネクタの軸線方向に沿った縦断面図である。

[図3]図１に示した医療用コネクタの使用状態を示す縦断面図である。

[図4]図１に示した医療用コネクタの部分拡大断面図である。

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

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

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

発明を実施するための形態

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

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

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

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

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

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

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

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

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

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

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

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

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

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

段差と、内筒部４０の先端面との間に挟持されている。

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

前後に反転させた構成を設けてもよい。

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

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

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

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

請求の範囲

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

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

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

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

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

ことを特徴とする医療用コネクタ（１０）。

［請求項2］ 請求項１記載の医療用コネクタ（１０）において、

前記連通路（２１）は、前記コネクタ本体（１２）の周方向に複数設けられる、

ことを特徴とする医療用コネクタ（１０）。

［請求項3］ 請求項１記載の医療用コネクタ（１０）において、

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

ことを特徴とする医療用コネクタ（１０）。

［請求項4］ 請求項１記載の医療用コネクタ（１０）において、

前記コネクタ本体（１２）は、前記接続部（１８）を含む第１要素

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

ことを特徴とする医療用コネクタ（１０）。

［請求項5］ 請求項４項記載の医療用コネクタ（１０）において、

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

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

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

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

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

ことを特徴とする医療用コネクタ（１０）。

[図1]

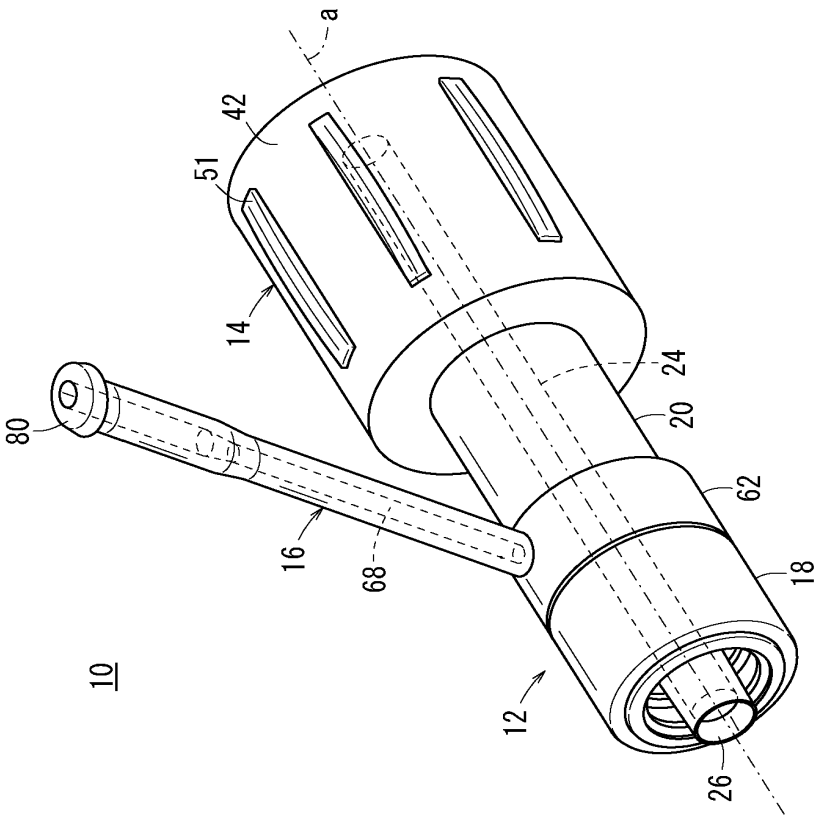


FIG. 1

[図2]

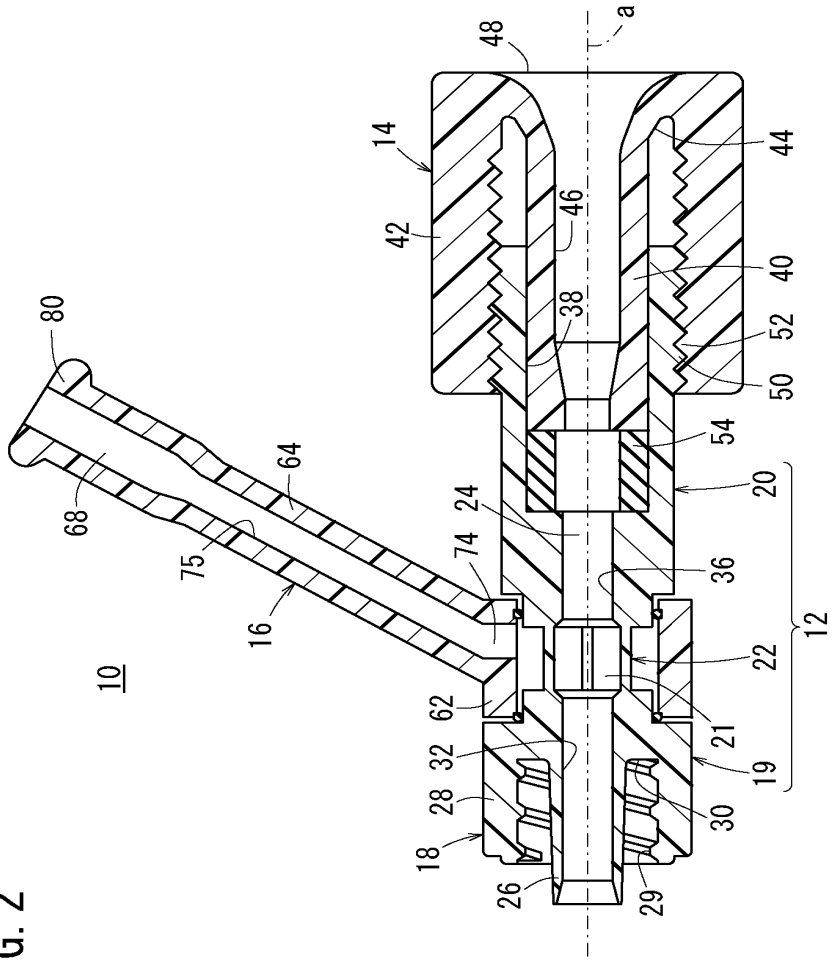

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FIG. 2

[図3]

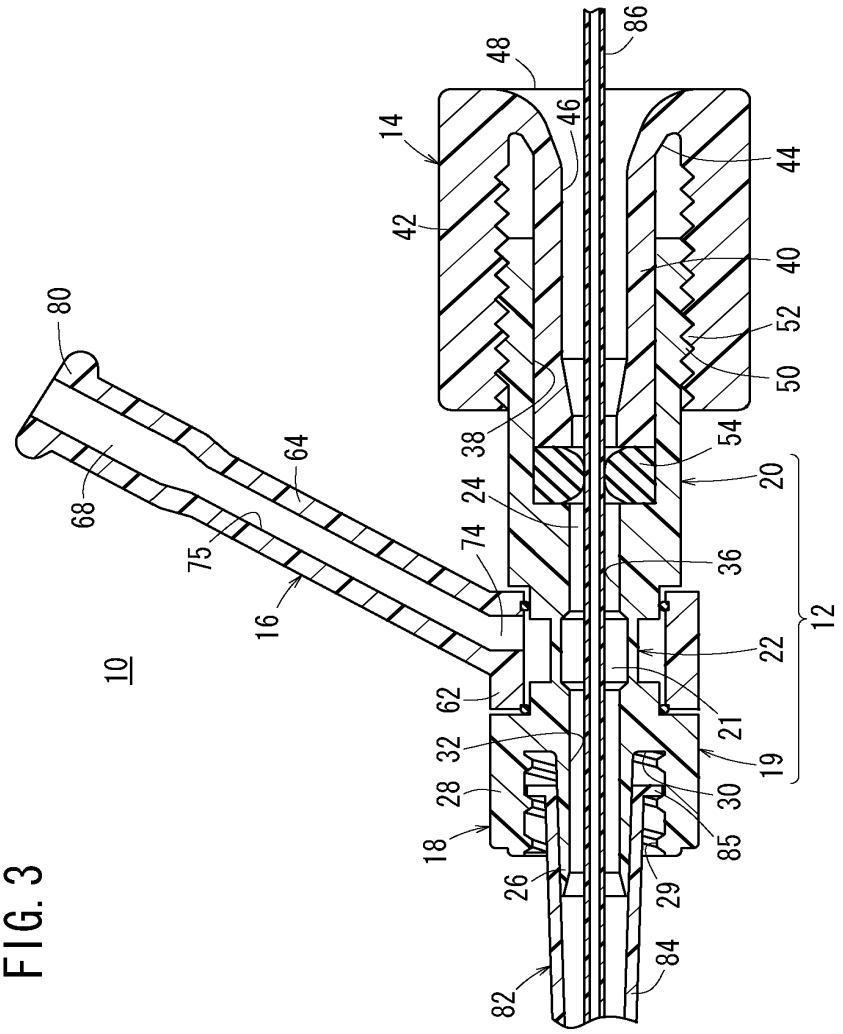
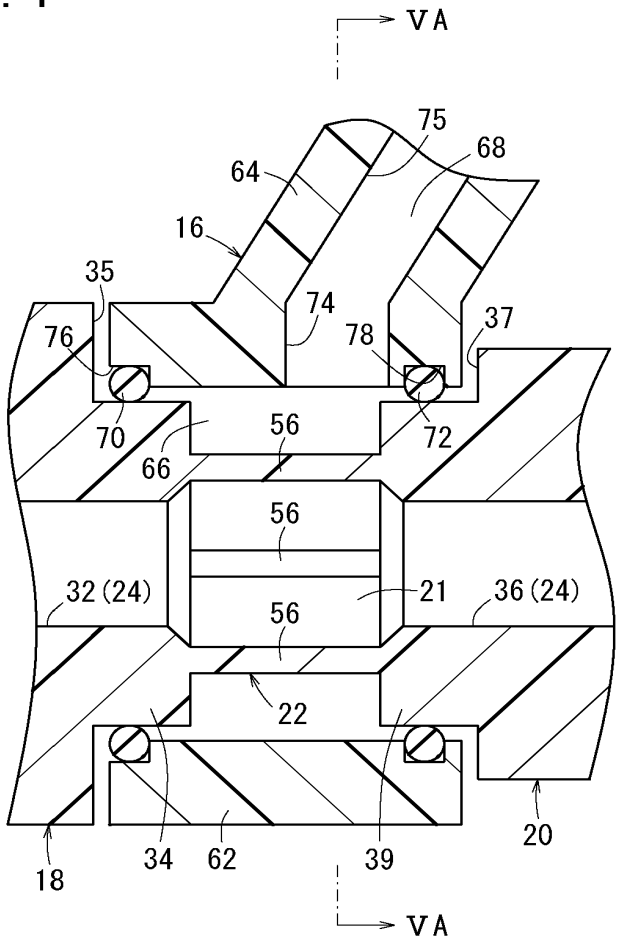

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FIG. 3

[図4]

FIG. 4


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VA

[図5]

FIG. 5A

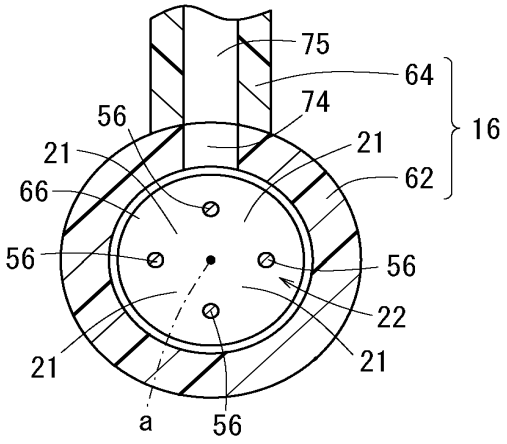


FIG. 5B

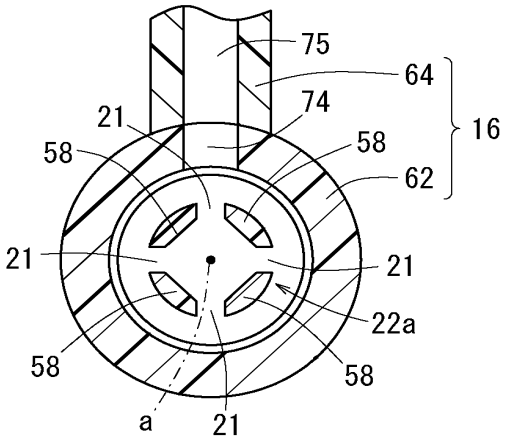
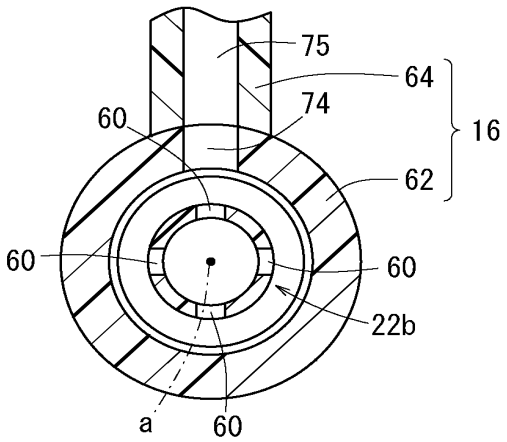


FIG. 5C



[図6]

FIG. 6B

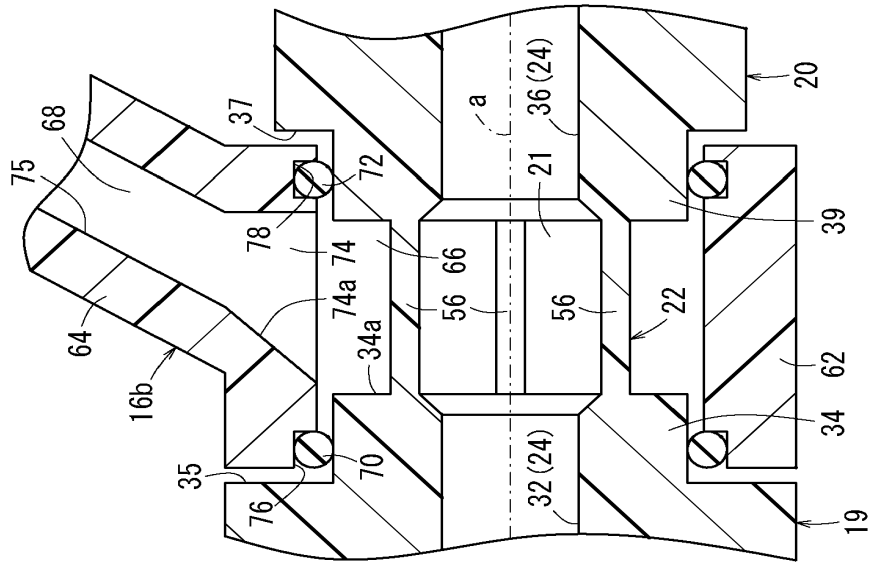
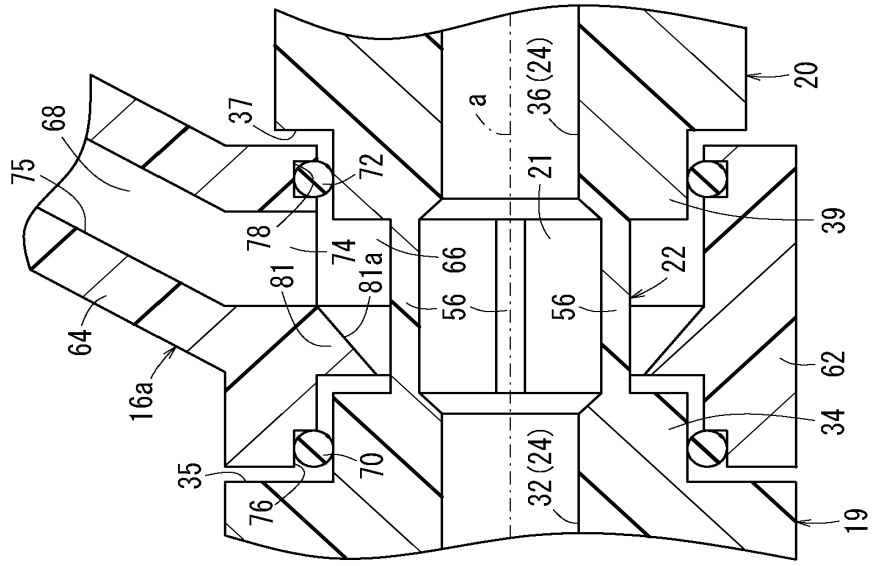


FIG. 6A



[図7]

FIG. 7C

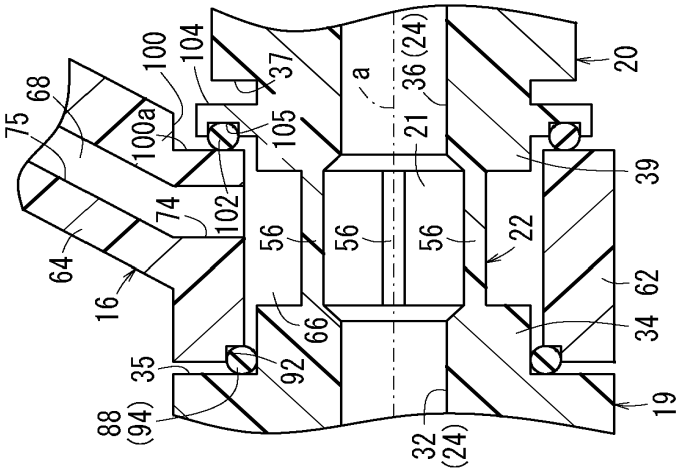


FIG. 7B

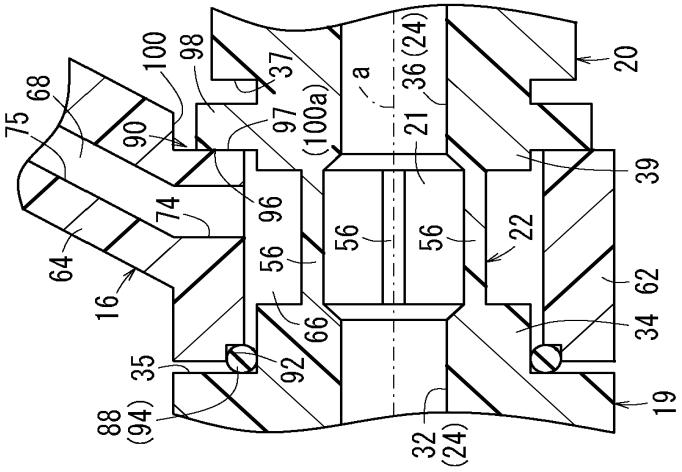
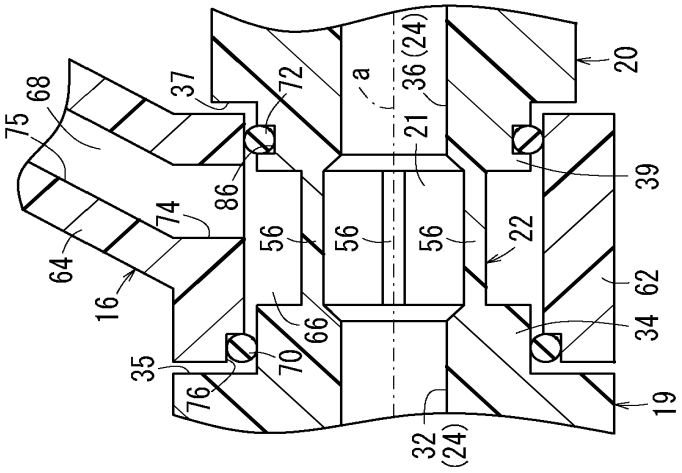


FIG. 7A



INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2011/079651

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

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

B. FIELDS SEARCHED

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

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"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 22 March, 2012 (22.03.12)	Date of mailing of the international search report 03 April, 2012 (03.04.12)
Name and mailing address of the ISA/ Japanese Patent Office Facsimile No.	Authorized officer Telephone No.

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

国際調査報告

国際出願番号　ＰＣＴ／ＪＰ２０１１／０７９６５１

Ａ．　発明の属する分野の分類（国際特許分類（ＩＰＣ））

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

Ｂ．　調査を行った分野

調査を行った最小限資料（国際特許分類（ＩＰＣ））

Int.Cl.　A61M39/00, A61M25/02

最小限資料以外の資料で調査を行った分野に含まれるもの

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

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

Ｃ．　関連すると認められる文献

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

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

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

国際調査を完了した日	国際調査報告の発送日
２２．０３．２０１２	０３．０４．２０１２

国際調査機関の名称及びあて先
日本国特許庁（ＩＳＡ／ＪＰ）
郵便番号１００－８９１５
東京都千代田区霞が関三丁目４番３号

特許庁審査官（権限のある職員）　３Ｅ　９３３４
鈴木　洋昭
電話番号　０３－３５８１－１１０１　内線　３３４４

様式ＰＣＴ／ＩＳＡ／２１０（第２ページ）（２００９年７月）

Ｃ（続き）．　関連すると認められる文献

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

様式ＰＣＴ／ＩＳＡ／２１０（第２ページの続き）（２００９年７月）

UNITED STATES
PATENT AND TRADEMARK OFFICE

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

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/342,553	**02/26/2024 10:33:14 PM Z ET**	**111552.8018.US11**

Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	6799	FILED BY	JiYoung Anderson
PATENT CENTER #	64455357	FILING DATE	06/27/2023
CUSTOMER #	25096	FIRST NAMED INVENTOR	Ben Merritt
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Matthew Williams

Documents

TOTAL DOCUMENTS: 4

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2024-2-26 - IDS SB08 - fee - 111552-8018US11.pdf	2	Information Disclosure Statement (IDS) Form (SB08)	122 KB
Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
NPL_EN Translation of JP Official Action JP 2022-574456 mailed Jan 23 2023 12 pages.pdf	12	Non Patent Literature	91 KB
NPL_CN-Office Action 201980067623.1 mailed Jan. 31 2024 -10 pages.pdf	10	Non Patent Literature	371 KB
FOR_WO2012114633.pdf	30	Foreign Reference	1051 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2024-2-26 - IDS SB08 - fee - 111552-8018US11.pdf	F62B74E13CDFF09B6A6451CD555E38B2ABECF581C84A01BE D0E2AEC98072BDD01404C4E4CFECAB8EA334C9E37A039950 C3DAE7F371796AD0C13E400F2DDB55E5
NPL_EN Translation of JP Official Action JP 2022-574456 mailed Jan 23 2023 12 pages.pdf	8FE5FDE20C13A1EAB315826C2B2E39B7E0E6CE2AEF62BDE2 0DFD8B716DA495C3D7BAC423879A9611348E4CB1C4613B7E E01F8D54BE1580CE6E5F9E3C436302C9
NPL_CN-Office Action 201980067623.1 mailed Jan. 31 2024 -10 pages.pdf	67A4EFF504AA331CEC2C9D259CD544739D92C7C66DC4824A 0FC1237FB36FC905AA26A95EF95F26FED5E827B5C61B45BB D219D6ACB245089061913101DC669601
FOR_WO2012114633.pdf	686B21251DE173EEDE1A69F56BB0D3888962CBEF494AD6AE 574FAFDA438BFCDCABAA90DE7E1EC169DB112EDF154EFF4 7F1D1D803B115ADD1652AAB0A55BCF2EF

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES
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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/342,553	**02/06/2024 07:50:43 PM Z ET**	**111552.8018.US11**

Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	6799	FILED BY	JiYoung Anderson
PATENT CENTER #	64234160	AUTHORIZED BY	Matthew Williams
CUSTOMER #	25096	FILING DATE	06/27/2023
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Ben Merritt

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 5111	**E202426J51177608**	**JiYoung Anderson**

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

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

New Applications Under 35 U.S.C. 111

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

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

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C.

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

New International Application Filed with the USPTO as a Receiving Office

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

Docket No.: 111552.8018.US11
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Ben Merritt et al.

Application No.: 18/342,553

Filed: June 27, 2023

For: SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Conf. No.: 6799

Art Unit: 3781

Examiner: Eric Rassavong

Customer No. 25096

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

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

Dear Commissioner:

In response to the Office Action mailed on November 6, 2023, please amend and consider the above-identified application as follows:

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

Remarks begin on page 7.

AMENDMENTS TO THE CLAIMS

Please amend claims 1, 3, 8, 11, 12, and 19; cancel claims 18 and 20; and add new claims 21 and 22. Following is a complete listing of the claims pending in the application, as amended:

1. (Currently Amended) A clot treatment system for treating clot material comprising a pulmonary embolism in the vasculature of a patient, comprising:

a first clot aspiration assembly, including:

a first catheter;

a first pressure source; and

a first fluid control device between the first catheter and the first pressure source, wherein the first fluid control device is movable between (a) ~~an open~~a first position in which the first pressure source is fluidly ~~connected to~~ disconnected from the first catheter and (b) a ~~closed~~ second position~~ed~~ in which the first pressure source is fluidly ~~disconnected from~~connected to the first catheter,

wherein the first pressure source is configured to generate vacuum pressure while the first fluid control device is in the ~~closed~~first position, and

wherein, upon movement of the first fluid control device from the ~~open~~ first position to the ~~closed~~ second position, the vacuum pressure is applied to the first catheter to generate suction at a distal portion of the first catheter; and

a second clot aspiration assembly, including:

a second catheter advanceable through the first catheter, wherein the second catheter has a distal portion, wherein the second catheter has a size of 16 French or greater, and wherein the second catheter is shaped to be intravascularly advanced through the vasculature of the patient such that the distal portion of the second catheter is positioned proximate to the pulmonary embolism;

a second pressure source; and

a second fluid control device between the second catheter and the second pressure source, wherein the second fluid control device is movable between (a) ~~an open~~a first position in which the second pressure source is fluidly ~~connected to~~disconnected from the second catheter and (b) a ~~closed~~ second position~~ed~~ in which the second pressure source is fluidly ~~disconnected from~~connected to the second catheter,

wherein the second pressure source is configured to generate vacuum pressure while the second fluid control device is in the ~~closed~~ first position, and

wherein, upon movement of the second fluid control device from the ~~open~~ first position to the ~~closed~~ second position, the vacuum pressure is applied to the second catheter to generate suction at ~~a~~ the distal portion of the second catheter to aspirate blood and at least a portion of the pulmonary embolism into the second catheter.

2. (Original) The clot system of claim 1 wherein the first catheter has a first length, and wherein the second catheter has a second length longer than the first length.

3. (Currently Amended) The clot treatment system of claim 1 wherein the first catheter has a size of 24 French, and wherein the size of the the second catheter has ~~a size of~~is 16 French.

4. (Original) The clot treatment system of claim 1 wherein the first pressure source is the same as the second pressure source.

5. (Original) The clot treatment system of claim 1 wherein the first pressure source and the second pressure source comprise an electric pump.

6. (Original) The clot treatment system of claim 1 wherein the first clot aspiration assembly further includes a hemostasis valve configured to receive the second catheter.

7. (Original) The clot treatment system of claim 6 wherein the hemostasis valve comprises:

a tubular member defining a lumen configured to slidably receive the second catheter; and

a filament extending at least partially around the tubular member, wherein the filament is moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal around the second catheter and (b) a second position wherein the filament is moved to at least partially open the lumen.

8. (Currently Amended) The clot treatment system of claim 1 wherein the first fluid control device is user actuatable to move between the ~~open~~ first position and ~~closed~~ the second position~~s~~ of the first fluid control device, and wherein the second fluid control device is user actuatable to move between the ~~open~~ first positoin and ~~closed~~ the second position~~s~~ of the second fluid control device.

9. (Original) The clot treatment system of claim 1 wherein the first pressure source is a first syringe, and wherein the second pressure source is a second syringe.

10. (Original) The clot treatment system of claim 1 wherein the first pressure source is a first vacuum-pressure locking syringe, and wherein the second pressure source is a second vacuum-pressure locking syringe.

11. (Currently Amended) A clot treatment system for treating clot material comprising a pulmonary embolism in the vasculature of a patient, comprising:

a first clot aspiration assembly, including:

a first catheter; and

a first pressure source configured to be fluidly coupled to the first catheter and to generate suction at a distal portion of the first catheter; and

a second clot aspiration assembly, including:

a second catheter advanceable through the first catheter, wherein the second catheter has a distal portion, wherein the second catheter has a size of 16

French or greater, and wherein the second catheter is shaped to be intravascularly advanced through the vasculature of the patient such that the distal portion of the second catheter is positioned proximate to the pulmonary embolism;

a second pressure source; and

a fluid control device between the second catheter and the second pressure source, wherein the fluid control device is movable between (a) ~~an open~~a first position in which the second pressure source is fluidly ~~connected to~~disconnected from the second catheter and (b) a ~~closed~~ second position~~ed~~ in which the second pressure source is fluidly ~~disconnected from~~connected to the second catheter,

wherein the second pressure source is configured to generate vacuum pressure while the fluid control device is in the ~~closed~~ first position, and

wherein, upon movement of the fluid control device from the ~~open~~ first position to the ~~closed~~ second position, the vacuum pressure is applied to the second catheter to generate suction at ~~a~~ the distal portion of the second catheter to aspirate blood and at least a portion of the pulmonary embolism into the second catheter.

12. (Currently Amended) The clot treatment system of claim 11 wherein the first catheter has a size of 24 French, and wherein the size of the the second catheter ~~has a size of~~is 16 French.

13. (Original) The clot treatment system of claim 11 wherein the first pressure source is the same as the second pressure source.

14. (Original) The clot treatment system of claim 11 wherein the first pressure source and the second pressure source comprise an electric pump.

15. (Original) The clot treatment system of claim 11 wherein the first clot aspiration assembly further includes a hemostasis valve configured to receive the second catheter.

16. (Original) The clot treatment system of claim 15 wherein the hemostasis valve is fluidly coupled to a proximal end portion of the first catheter, and wherein the first pressure source is fluidly coupled to the first catheter via a tube branching from the first catheter distal to the proximal end portion of the first catheter.

17. (Original) The clot treatment system of claim 16 wherein the hemostasis valve is a first hemostasis valve, wherein the tube is a first tube, and wherein the second clot aspiration assembly further includes a second hemostasis valve fluidly coupled to a proximal end portion of the second catheter, and wherein the second pressure source is fluidly coupled to the second catheter via a second tube branching from the second catheter distal to the proximal end portion of the second catheter.

18. (Canceled)

19. (Currently Amended) The clot treatment system of claim 11 wherein the first catheter has a size of 24 French, wherein the size of the second catheter ~~has a size of~~is 16 French, and wherein the first pressure source and the second pressure source comprise an electric pump.

20. (Canceled)

21. (New) The clot treatment systme of claim 15 wherein the first pressure source is the same as the second pressure source.

22. (New) The clot treatment systme of claim 7 wherein the first pressure source is the same as the second pressure source.

REMARKS

Claims 1–20 were pending when the present Office Action was mailed on November 6, 2023. In this response, claims 18 and 20 have been canceled and claims 1, 3, 8, 11, 12, and 19 have been amended to further clarify certain features of these claims and to expedite prosecution of this application. The foregoing amendments and cancelations are made without commenting on or conceding the merits of any rejections of these claims and without prejudice to or disclaimer of pursuing the subject matter of these claims in a continuation or other related application. New claims 21 and 22 have been added in this response. Accordingly, claims 1–17, 19, 20, and 21 are currently pending.

The status of the application in light of the November 6, 2023, Office Action is as follows:

(A) Claim 18 was rejected under 35 U.S.C. § 102(a)(1) over U.S. Patent Application Publication No. 2015/0173782 to Garrison et al. ("Garrison"); and

(B) Claims 1–17, 19, and 20 were allowed.

(A) Response to the Section 102 Rejection of Claim 18 (Garrison)

Claim 18 was rejected under Section 102 over Garrison. Without commenting on or conceding the merits of the rejection of claim 18, claim 18 has been canceled in this response. Accordingly, the rejection of claim 18 is now moot.

(B) Allowed Claims 1–17, 19, and 20

Claims 1–17, 19, and 20 were allowed. The Applicant thanks the Examiner for indicating that claims 1–17, 19, and 20 are allowable. The undersigned attorney notes that claims 1–17, 19, and 20 may be allowable for reasons other than those identified by the Examiner and does not concede that the Examiner's characterization of the terms of these claims and the prior art are correct. For example, independent claims 1 and 11, as amended, are further patentable over Garrison for at least the reasons discussed during the January 25th videoconference interview with the Examiner and his supervisor in related U.S. Patent Application No. 18/329,450, and specifically the Examiner's comments in the Applicant-Initiated Interview Summary mailed

January 31, 2024 that "Attorney and Examiner agree that incorporating more structural claim language, i.e. diameter of the catheter, would make the claim 1 allowable over the prior art Garrison."

New Claims 21 and 22

New claims 21 and 22 have been added in this response. New claims 21 and 22 depend from independent claims 11 and 1, respectively. Accordingly, new claims 21 and 22 are patentable over Garrison and the other art of record for at least the same reasons as allowable claims 1 and 11, and for the additional features of these dependent claims.

Conclusion

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

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

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

Please charge any underpayment or credit any overpayment to Deposit Account No. 50-0665, under Order No. 111552.8018.US11 from which the undersigned is authorized to draw.

Respectfully submitted,

Dated: February 6, 2024

By: /Matthew S. Williams/

Matthew S. Williams
Registration No.: 77,516

PERKINS COIE LLP
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Seattle, WA 98111-1247
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Facsimile: (206) 359-7198

Attorney for Applicant

UNITED STATES
PATENT AND TRADEMARK OFFICE

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

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/342,553	**02/06/2024 07:50:43 PM Z ET**	**111552.8018.US11**

Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
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2024-2-6 - IDS SB08 - 111552-8018US11.pdf		4	Information Disclosure Statement (IDS) Form (SB08)	140 KB
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2024-2-6 Response to NFOA 2023-11-06 - 111552.8018.US11-REM.pdf	(7-9)	3	Applicant Arguments/Remarks Made in an Amendment	36 KB
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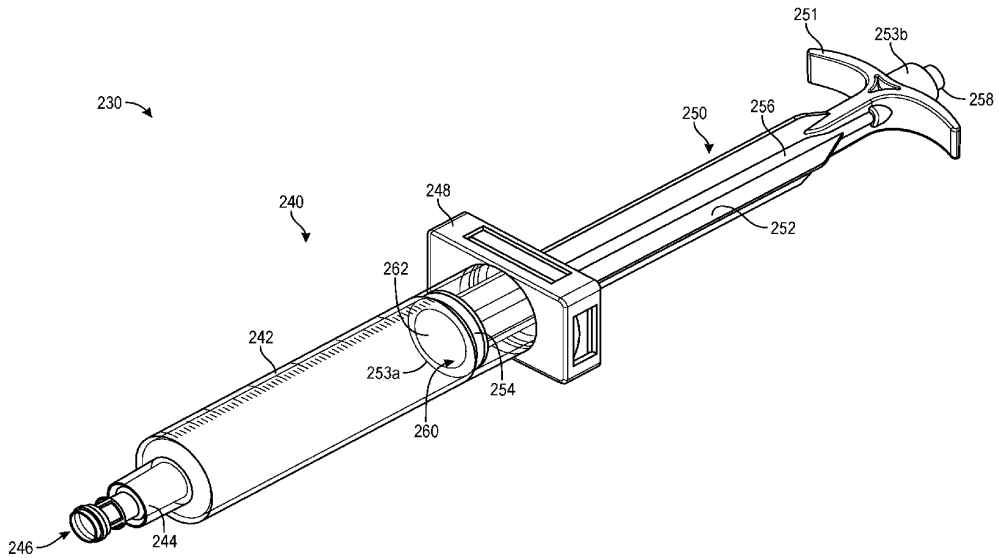


FIG. 2A

(57) Abstract: Disclosed herein are clot treatment systems with filtering syringes, and associated devices and methods. The filtering syringe can be coupled to a catheter subsystem insertable within a patient. The filtering syringe can aspirate material (e.g., clot material, blood, etc.) from a patient via the catheter subsystem. The filtering syringe can include a plunger assembly, and the plunger assembly can include one or more filters. Each of the filters can be configured to (i) allow at least a first portion of aspirated material (e.g., blood) to pass through at least one of the filters, and (ii) prevent at least a second portion of the aspirated material (e.g., clot material) from passing through at least one of the filters. In some embodiments, the filtering syringe is fluidly coupled to a filtered material subsystem that can fluidly couple the filtering syringe to the patient or another suitable fluid outflow location.

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BLOOD-FILTERING DEVICES FOR USE WITH CLOT TREATMENT SYSTEMS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims benefit of U.S. Provisional Application No. 63/326,196, filed March 31, 2022, entitled BLOOD-FILTERING DEVICES FOR USE WITH CLOT TREATMENT SYSTEMS, which is incorporated by reference herein in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to blood-filtering devices for use with clot treatment systems, and associated methods.

BACKGROUND

[0003] Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

[0004] When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. However, infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can accordingly lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

[0005] In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT commonly occurs where there is a propensity for stagnated blood (e.g., long-distance air travel, immobility, etc.) and clotting (e.g., cancer; recent surgery, such as orthopedic surgery, etc.). DVT can obstruct drainage of venous blood from the legs, leading to swelling, ulcers, pain, and infection. DVT can also create a reservoir in which blood clots can collect and then travel to other parts of the body, including the heart, lungs, brain (which may cause a stroke), abdominal organs, and/or extremities.

[0006] Various devices exist for performing a thrombectomy or removing clot material to reestablish blood flow within a patient. Such devices can remove the target clot material and often additionally remove one or more fluids (e.g., blood) along with the clot material. These

devices are often designed to make it difficult to return removed fluids (e.g., blood) to the patient, even when doing so may be advantageous. For example, some existing devices include bypass circuits that can be cumbersome to set up and may require a specially trained user (e.g., a perfusionist) present to operate correctly.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0008] Figure 1 is a partially schematic side view of a clot treatment or clot removal system comprising an aspiration assembly configured in accordance with embodiments of the present technology.

[0009] Figure 2A is a perspective view of a pressure source comprising a vacuum-pressure locking syringe configured in accordance with embodiments of the present technology.

[0010] Figure 2B is a perspective view of a plunger assembly of the vacuum-pressure locking syringe of Figure 2A in accordance with embodiments of the present technology.

[0011] Figure 2C is an exploded perspective view of the plunger assembly of Figure 2A in accordance with embodiments of the present technology.

[0012] Figures 3–7B illustrate various embodiments of filtered material subsystems coupled to the syringe of Figure 2A and configured in accordance with embodiments of the present technology.

[0013] Figure 8A is a perspective view of another plunger assembly configured in accordance with embodiments of the present technology.

[0014] Figure 8B is a perspective view of a filter assembly configured in accordance with embodiments of the present technology.

[0015] Figures 9A and 9B are perspective views of another filtering syringe configured in accordance with embodiments of the present technology.

[0016] Figure 10 is a perspective view of another filtering syringe configured in accordance with embodiments of the present technology.

[0017] Figure 11A is a perspective view of another filtering syringe configured in accordance with embodiments of the present technology

[0018] Figure 11B is an enlarged perspective view of a distal portion of the filtering syringe of Figure 11A, with other portions of the filtering syringe omitted for illustrative clarity.

[0019] Figure 11C is a perspective view of a filter assembly of the filtering syringe of Figure 11A, configured in accordance with embodiments of the present technology.

[0020] Figure 11D is an enlarged side cross-sectional view of the filtering syringe of Figure 11A taken along section line 11D–11D in Figure 11B.

[0021] Figure 12A is a perspective view of a filter assembly of another filtering syringe configured in accordance with embodiments of the present technology.

[0022] Figure 12B is a cross-sectional view of the filter assembly of Figure 12A taken along section line 12B–12B in Figure 11B in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0023] The present technology is generally directed to clot treatment systems with filters, and associated devices and methods. In some of the embodiments described in detail below, the filters can be part of a filtering syringe. The filtering syringe can be coupled to a catheter subsystem insertable within a patient, such that the filtering syringe can remove (e.g., aspirate) material (e.g., clot material, blood) from a patient via the catheter subsystem. The filtering syringe can include a plunger assembly, and the plunger assembly can include one or more filters. The filters can be configured to (i) allow at least a first portion of material removed from the patient to pass through at least one of the filters, and (ii) prevent at least a second portion of the removed material from passing through at least one of the filters. In some embodiments, for example, the one or more filters are configured to (i) allow blood to pass through at least one of the filters, and (ii) prevent clot material from passing through at least one of the filters, such that the at least one filter can "filter" blood from the material removed from the patient.

[0024] In some embodiments, the clot treatment systems further include a filtered material subsystem. The filtered material subsystem can include one or more valves and/or tubing sections that can fluidly couple the filtering syringe and the patient. Additionally, in at least some embodiments, the filtered material subsystem includes a fluid drive element fluidly coupled to the filtering syringe and operable to draw fluid through one or more of the filters, for example,

to filter the blood from the clot material within the filtering syringe and/or to otherwise drive flow of the blood through at least part of the filtered material subsystem. In operation, the filtered material subsystem can be configured to (i) capture/receive all or part of the blood within the filtering syringe, and/or (ii) return/reintroduce all or part of the blood within the filtering syringe back to the patient.

[0025] In some aspects of the present technology, the filtering syringe can be used to perform multiple material removal (e.g., aspiration) cycles while remaining coupled to the filtered material subsystem and/or the catheter subsystem such that, during one or more of the material removal cycles, at least part of the aspirated material (e.g., blood) removed from the patient can be filtered and/or reintroduced into the patient without disconnecting the filtering syringe from the filtered material subsystem and/or the catheter subsystem, and/or while maintain a generally consistent (e.g., optimal) vacuum power/pressure and/or volumetric flowrate throughout the one or more material removal cycles. In some embodiments, the filtering syringe can be used to perform multiple material removal cycles while remaining fluidly coupled to the catheter system via a single fluid control device. In some aspects, having multiple fluid control devices (e.g., check-valves, Y-connectors, and the like) between a catheter system and a pressure source can reduce the pressure/aspiration power applied by the pressure source to the catheter system. In some embodiments, the filtering syringe can be used to perform one or more material removal cycles while remaining fluidly coupled to catheter and returning at least part of the filtered blood to the patient without using any fluid control devices to control/direct fluid flow between the filtering syringe and the patient. Additionally, or alternatively, at least some of the filtered material subsystems are expected to be safer and/or reduce the likelihood that clot material removed from the patient is accidentally/inadvertently reintroduced into the patient. For example, at least some of the filtered material subsystems can define one or more flow paths configured to direct the flow of the aspirated material to inhibit or prevent the filtered material (e.g., blood) from being reintroduced into the filtering syringe and/or the clot material in the filtering syringe from being driven back into the patient P. In these and other embodiments, at least some of the filtering syringes and/or filtered material subsystems can be configured such that a user can more easily perform one or more tests or other analyses on at least part of the filtered material before or instead of returning the filtered material to the patient.

[0026] Certain details are set forth in the following description and in Figures 1–12B to provide a thorough understanding of various embodiments of the present technology. In other instances, well-known structures, materials, operations, and/or systems often associated with

intravascular procedures, blood filtering, clot removal procedures, catheters, and the like are not shown or described in detail in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. Those of ordinary skill in the art will recognize, however, that the present technology can be practiced without one or more of the details set forth herein and/or with other structures, methods, components, and so forth. Moreover, although many of the devices and systems are described herein in the context of removing and/or treating aspirated material and/or clot material, the present technology can be used to remove and/or treat other unwanted material in addition or alternatively to clot material, such as thrombi, emboli, plaque, intimal hyperplasia, post-thrombotic scar tissue, etc. Accordingly, the terms "clot," "clot material," and "aspirated material" as used herein can refer to any of the foregoing materials and/or the like.

[0027] The terminology used below is to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain examples of embodiments of the technology. Indeed, certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

[0028] The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope unless expressly indicated. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as the position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles, and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles, and features without departing from the present technology. In addition, those of ordinary skill in the art will appreciate that further embodiments of the present technology can be practiced without several of the details described below.

[0029] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to a specific orientation. It will be appreciated that such

designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

[0030] Figure 1 is a partially schematic side view of a clot treatment or clot removal system comprising an aspiration assembly 10 ("assembly 10") configured in accordance with embodiments of the present technology. In the illustrated embodiment, the assembly 10 includes a catheter subsystem 100, a tubing subsystem 120, a pressure source 130, and a filtered material subsystem 170. The catheter subsystem 100 includes a catheter 102 (e.g., an aspiration catheter) comprising an elongated shaft defining a lumen 104 and having a distal portion 103a and a proximal portion 103b. The catheter 102 can be intravascularly advanced to a treatment site within a blood vessel of a patient P such that, for example, the distal portion 103a is positioned in and/or proximate to clot material within the blood vessel. The catheter subsystem 100 further includes a valve 106 that can be integral with or coupled to the proximal portion 103b of the catheter 102.

[0031] In general, the clot removal system (i) can include features generally similar or identical to those of the clot removal systems described in detail in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety, and/or (ii) can be used to treat/remove clot material from a patient (e.g., a human patient) using any of the methods described in detail therein. In some embodiments, the catheter subsystem 100 can include some features that are at least generally similar in structure and function, or identical in structure and function, to those of the catheters disclosed in (i) U.S. Patent Application Publication No. 17/529,018, titled "CATHETERS HAVING SHAPED DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS," and filed November 17, 2021, and/or (ii) U.S. Patent Application Publication No. 17/529,064, titled "CATHETERS HAVING STEERABLE DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS," and filed November 17, 2021, each of which is incorporated herein by reference in its entirety.

[0032] In the illustrated embodiment, the valve 106 includes a distal portion 107a, a proximal portion 107b, and a lumen 109 extending therethrough from the distal portion 107a to the proximal portion 107b. In some embodiments, the valve 106 is a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in the proximal direction through the valve 106 as various components, such as delivery sheaths,

pull members, guidewires, interventional devices, other aspiration catheters, etc., are inserted through the valve 106 to be delivered through the catheter 102 to a treatment site in a blood vessel. The valve 106 further includes one or more branches or side ports 108 configured to fluidly couple the lumen 104 of the catheter 102 to the tubing subsystem 120. In the illustrated embodiment, the valve 106 includes buttons 101 that can be actuated (e.g., depressed) to open a conduit within the lumen 109. In some embodiments, the valve 106 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety. In some embodiments, the proximal portion 107b of the valve 106 is further configured to be detachably coupled (e.g., via a snap-fit arrangement) to a filtering device, such as one or more of the filtering syringes described in greater detail below with reference to Figures 2A-2C.

[0033] The tubing subsystem 120 fluidly couples the catheter subsystem 100 to the pressure source 130. More specifically, the tubing subsystem 120 can include one or more tubing sections 124 (individually labeled as a first tubing section 124a and a second tubing section 124b), at least one fluid control device 126 (e.g., a valve), and at least one connector 128 for fluidly coupling the tubing subsystem 120 to the pressure source 130 and/or other suitable components. More specifically, in the illustrated embodiment, the fluid control device 126 is a stopcock that is fluidly coupled to (i) the side port 108 of the valve 106 via the first tubing section 124a and (ii) the connector 128 via the second tubing section 124b. In at least some embodiments, the fluid control device 126 is a three-way stopcock, and includes a free port or inlet configured to allow a user to fluidly couple additional devices to the catheter subsystem 100 while the pressure source 130 is also fluidly coupled to the catheter subsystem 100, for example, to reintroduced filtered blood into a patient as described in detail below with reference to Figure 3. The fluid control device 126 is externally operable by a user to regulate the flow of fluid therethrough and, specifically, from the lumen 104 of the catheter 102 to the pressure source 130. In other embodiments, the fluid control device 126 can be a clamp that can be actuated (e.g., compressed or squeezed by the hand of a user) to partially or fully restrict fluid flow through the first tubing section 124a and/or the second tubing section 124b. In yet other embodiments, the fluid control device 126 can be omitted and its functionality incorporated into the pressure source 130.

[0034] The pressure source 130 is configured to generate (e.g., form, create, charge, build up) a vacuum (e.g., negative relative pressure) and store the vacuum for subsequent application

to the catheter subsystem 100. Further details of suitable pressure sources are described in detail below with reference to Figures 2A–2C and 9A–12B. In some embodiments, the pressure source 130 aspirates fluid (e.g., blood), clot material, and/or other material from the patient P during a clot removal process. In the illustrated embodiment, the pressure source 130 is fluidly coupled to the filtered material subsystem 170. The filtered material subsystem 170 can receive the aspirated fluid, clot material, and/or other material from the pressure source 130 and filter the fluid from the other material. In some embodiments, the filtered material subsystem 170 can be fluidly coupled to the patient P and configured to reintroduce the aspirated fluid (e.g., blood) into the patient. Additional details regarding suitable filtered material subsystems are described in greater detail below with reference to Figures 3-7B. Additionally, in at least some embodiments, the filtered material subsystem 170 can be omitted and the pressure source 130 can be used to transfer the aspirated fluid (e.g., blood) to the patient (e.g., intravenously, via the fluid control device 126, via one of the side ports 108, and the like) or any other suitable location.

[0035] During operation of the assembly 10, a user can first close the fluid control device 126 before activating the pressure source 130 to build up vacuum pressure within the pressure source 130 (e.g., a vacuum chamber of the pressure source 130). In some embodiments, the user can control or select the volume of the generated vacuum. In this manner, a vacuum is charged within the pressure source 130 before the pressure source 130 is fluidly connected to the catheter subsystem 100. To aspirate the lumen 104 of the catheter 102, the user can open the fluid control device 126 to fluidly connect the pressure source 130 to the catheter subsystem 100 and thereby apply or release the vacuum stored in the pressure source 130 to the lumen 104 of the catheter 102. Opening of the fluid control device 126 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing subsystem 120 and the catheter 102, thereby generating suction throughout the catheter 102. In particular, the suction is applied at the distal portion 103a of the catheter 102. In one aspect of the present technology, pre-charging or storing the vacuum before applying the vacuum to the lumen 104 of the catheter 102 is expected to generate greater suction forces (and corresponding fluid flow velocities) at and/or near the distal portion 103a of the catheter 102 compared to simply activating the pressure source 130 while it is fluidly connected to the catheter 102. The suction forces generated by application of the stored vacuum can be used to aspirate or otherwise remove aspirated material from within a blood vessel of a human patient. The aspirated material can be received by the pressure source 130, and at least a portion of the aspirated material can be filtered, transferred to the filtered material subsystem 170, and/or returned to/reintroduced into the patient P or another suitable outflow location.

[0036] Figure 2A is a perspective view of a pressure source 230 comprising a vacuum-pressure locking and/or filtering syringe ("filtering syringe 230") configured in accordance with embodiments of the present technology. In some embodiments, the filtering syringe 230 can include some features generally similar or identical to those of any one of the syringes described in detail in U.S. Patent Application No. 17/396,426, filed August 6, 2021, and titled "AUTOMATICALLY LOCKING VACUUM SYRINGES, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

[0037] In the illustrated embodiment, the filtering syringe 230 includes a barrel assembly 240 and a filtering plunger assembly 250 ("the plunger assembly 250"). The barrel assembly 240 includes a chamber or barrel 242, a tip 244 extending distally from the barrel 242, and a lumen or bore 246 extending through the tip 244 and the barrel 242. In some embodiments, the barrel assembly 240 includes a locking component 248. The barrel 242 is shown as transparent in Figure 2A for clarity.

[0038] The plunger assembly 250 can include a body or plunger 252 having a first (e.g., distal) end portion 253a defining a distal end terminus of the plunger 252, and a second (e.g., proximal) end portion 253b opposite the first end portion 253a and defining a proximal end terminus of the plunger 252. The plunger assembly 250 can further include a seal 254, a port or valve 258 (such as a Luer-activated valve or any other suitable valve), and a lumen 256 (partially obscured in Figure 2A) extending at least partially or fully through the plunger 252 between the first end portion 253a and the second end portion 253b. Additionally, the plunger assembly 250 can include a handle 251 to improve user handling of the plunger assembly 250. In the illustrated embodiment, the seal 254 is positioned proximate to the first end portion 253a, and the valve 258 and the handle 251 are positioned proximate to the second end portion 253b. The lumen 256 can be fluidly coupled to the valve 258, and the valve 258 can be fluidly coupled to the filtered material subsystem 170 and/or the patient P (Figure 1), such that fluid within the lumen 256 can flow to and/or toward the filtered material subsystem 170 and/or the patient P via the valve 258.

[0039] The plunger assembly 250 further includes a filter assembly 260. In the illustrated embodiment, the filter assembly 260 is positioned at the first end portion 253a of the plunger 252 and at a distal end portion of the lumen 256. In other embodiments, the filter assembly 260 can be positioned proximate to the second end portion 253b, proximally from the lumen 256, and/or at any other suitable position relative to the lumen 256 and/or within the filtering syringe 230. The filter assembly 260 can include one or more filters 262 (which can also be referred to

as "filtering elements," "filtering stages," or the like). As described in detail below, fluid (e.g., blood) can be pulled through the filters 262 into the lumen 256 and out of the valve 258.

[0040] At least a portion of the plunger assembly 250 is advanceable distally and proximally through the barrel 242. In the illustrated embodiment, the seal 254 sealably engages an interior surface of the barrel 242 and forms a substantially fluid impermeable seal therewith. Referring to both Figures 1 and 2A together, the tip 244 can be configured to detachably couple the filtering syringe 230 to the tubing subsystem 120. In the illustrated embodiment, the tip 244 is a Luer connector that can be coupled to the connector 128 and/or the proximal portion 107b of the valve 106 via one or more suitable adaptors. In some embodiments, the barrel 242 can be made of a transparent material that permits a user to visualize material (e.g., aspirated material) within the barrel 242.

[0041] With continued reference to Figures 1 and 2A together, during operation of the assembly 10, a user can first close the fluid control device 126 and then grip the plunger assembly 250 and/or the barrel assembly 240 to withdraw (e.g., retract) the plunger 252 at least partially out of the barrel 242 to thereby generate a vacuum in the barrel 242. In some embodiments, once the user has withdrawn the plunger 252 to a predetermined volume, the locking component 248 can automatically engage the plunger 252 to lock the plunger 252 relative to the barrel 242. In other embodiments, the plunger 252 can be locked by rotating the plunger 252 relative to the barrel 242 to engage the locking component 248. In some such embodiments, the user can control the volume of the vacuum—by withdrawing the plunger 252 more or less—to provide a desired amount or level of suction/aspiration upon opening of the fluid control device 126. In other embodiments, the filtering syringe 230 may not be a locking syringe, and the user can instead hold the plunger 252 in position relative to the barrel 242. In some embodiments, the syringe has a volume of about 60 cc or less than about 60 cc. With the plunger 252 withdrawn, the user can open the fluid control device 126 to aspirate material (e.g., clot material, bodily fluid(s), and the like) through the lumen 104 and into the barrel 242. The filters 262 of the filter assembly 260 can be selected to allow select material(s) and/or fluid(s) (e.g., one or more vascular fluids, blood, plasma, water, hemoglobin, white blood cells, and the like) aspirated from the patient to pass therethrough. For example, one or more of the filters 262 can (i) allow a first portion of the aspirated material (e.g., blood, blood plasma, and the like) to pass through the filter assembly 260, and (ii) prevent at least a second portion of the aspirated material (e.g., clot material, thrombi, emboli, and the like) from passing through the filter assembly 260. Accordingly, when pressure is applied to the lumen 256, the filter assembly 260 can "filter" or otherwise separate

the first portion of the aspirated material (e.g., blood) from the second portion of the aspirated material (e.g., clot material).

[0042] Figure 2B is a perspective view of the plunger assembly 250 of Figure 2A. Figure 2C is an exploded perspective view of the plunger assembly 250 of Figure 2A. Referring to Figures 2B and 2C together, in the illustrated embodiment, the filter assembly 260 includes a first filter 262a and a second filter 262b. Each of the filters 262a-b can be formed from a polyester, a polyamide, a hemocompatible material, a combination thereof, and/or any other suitable material. The first and second filters 262a-b can provide multiple stages of filtration to, for example, prolong the life of the filter assembly 260 and/or provide an increased filtering surface area. The first and second filters 262a-b can have the same, generally similar, or different sizes, thicknesses, porosities, and the like. In at least some embodiments, for example, the first filter 262a has a relatively large/coarse porosity of about 200 microns, and the second filter 262b has a relatively small/fine porosity of about 40 microns. In such embodiments, the first filter 262a can be configured to be relatively resilient to negative pressure, large aspirated thrombi, and/or cleaning, and the second filter 262b can be configured to filter blood, microemboli, and the like. In other embodiments, the first filter 262a and/or the second filter 262b can have any other suitable porosity, such as less than 40 microns, more than 200 microns, and/or any porosity therebetween. In these and other embodiments, the first and second filters 262a-b can have any other suitable configuration.

[0043] In some embodiments, one or more of the filters 262 can be detachably coupled to the plunger assembly 250 (to, e.g., form the filter assembly 260), such that one or more of the filters 262 can be removed from the plunger assembly 250, such as for cleaning, reuse, and/or disposal. Alternatively or additionally, one or more of the filters 262 can be coupled to, integrally formed with, or otherwise form a single-piece assembly with the plunger 252, such that the plunger 252 can be removed from the barrel 242 to clean, reuse, and/or dispose of the plunger 252 and/or the filter after use. Although the first and second filters 262a-b have a circular shape in the embodiment illustrated in Figure 2C, in other embodiments one or both of the filters 262a-b can have a disc, pleated, conical, cylindrical, or any other suitable shape. Although in first and second filters 262a-b are positioned adjacent to each other in the embodiment illustrated in Figure 2C, in other embodiments the first and second filters 262a-b can be spaced apart from each other. In at least some embodiments, for example, the first filter 262a can be positioned proximate the distal end portion 253a of the plunger assembly 250 and the second filter 262b can be positioned proximate the proximal end portion 253b of the plunger assembly 250 opposite

the first filter 262a. Although the filter assembly 260 includes two filters in the embodiment illustrated in Figure 2C, in other embodiments the filter assembly 260 can include more or fewer of the filters 262, such as one, more than two, or any other suitable number of filters 262.

[0044] Referring to Figure 2C, the lumen 256 has a first (e.g., distal) aperture or opening 257a and a second (e.g., proximal) aperture or opening 257b opposite the first opening 257a. In the illustrated embodiment, the first opening 257a is positioned to receive fluid from the barrel 242 (Figure 2A) through the filter assembly 260, and the second opening 257b is fluidly coupled to the valve 258. In some aspects of the present technology, it is expected that the lumen 256 will be unlikely to substantially clog during use because it receives fluid filtered by the filter assembly 260.

[0045] Figures 3–7B illustrate embodiments of filtered material subsystems 370–770, respectively, configured in accordance with embodiments of the present technology. Each of the various filtered material subsystems 370–770 can include some features that are generally similar in structure and function, or identical in structure and function, to one another and/or to the corresponding features of the filtered material subsystem 170 described in detail above with reference to Figure 1 and can operate in a generally similar or identical manner to one another and/or to the filtered material subsystem 170. Moreover, one or more of the different features of the filtered material subsystems 370–770 of the present technology can be combined or omitted.

[0046] Figure 3 is a perspective view of the filtering syringe 230 of Figure 2A coupled to the assembly 10 of Figure 1 in accordance with embodiments of the present technology. In the illustrated embodiment, the tip 244 of the barrel assembly 240 is fluidly coupled to the connector 128, and the valve 258 of the plunger assembly 250 is fluidly coupled to a filtered material subsystem 370 generally similar in structure and/or function to the filtered material subsystem 170 of Figure 1. In the illustrated embodiment, the filtered material subsystem 370 comprises a syringe ("the syringe 370"). In other embodiments, the filtered material subsystem 370 can include a blood bag, a container, and/or any other suitable fluid reservoir.

[0047] During a procedure involving the assembly 10, such as a clot treatment and/or a clot removal procedure, a user can open the fluid control device 126 after withdrawing the plunger 252 to charge a vacuum in the barrel 242 to aspirate aspirated material AM into the barrel 242, as described in detail with reference to Figures 1 and 2A. The aspirated material AM can include a first (e.g., filterable) portion FM ("the first material FM," "the filterable material FM," and the like) and a second (e.g., unfilterable) portion UFM ("the second material UFM,"

"the unfilterable material UFM," and the like). For example, the first material FM can comprise blood and the second material UFM can comprise clot material.

[0048] After aspirating the aspirated material AM, the user can close the fluid control device 126 to inhibit the aspirated material AM from flowing back through the fluid control device 126, into the assembly 10, and/or otherwise toward the patient P (Figure 1). When the aspirated material AM is within the barrel 242, the user can filter the aspirated material AM using the filter assembly 260 to separate all or part of the first material FM from the second material UFM. More specifically, the user can apply a force/pressure to the valve 258 with the syringe 370 to draw the aspirated material AM against the filter assembly 260 and cause at least part of the first material FM to flow through the filter assembly 260 toward the syringe 370. To apply the force/pressure to the valve 258, the user can (i) move the syringe 370 in a first (e.g., distal) direction D1 toward the plunger assembly 250 to depress the plunger 252 through the barrel 242 to drive the aspirated material AM against the filter assembly 260 and the through the lumen 256 to the syringe 370 and/or (ii) actuate the syringe 370 (e.g., by withdrawing a plunger thereof in a second direction D2) to draw the first material FM through the filter assembly 260 without depressing the plunger 252.

[0049] Once all or part of the first material FM is within the syringe 370, the user can (i) disconnect the syringe 370 from the valve 258, and/or (ii) return at least a portion of the first material FM (e.g., blood) to the patient. For example, the user can connect the syringe 370 to the fluid control device 126 (e.g., the free port or inlet, described above with reference to Figure 1) and actuate the syringe 370 to inject all or part of the first material FM within the syringe 370 into the catheter 102 (Figure 1) and the patient. As another example, the user can use the syringe 370 to inject all or part of the first filtered material FM into the patient intravenously, via one or more of the side ports 108 (Figure 1), and/or using any other suitable method or technique. Additionally, or alternatively, the user can (i) disconnect the filtering syringe 230 from the assembly 10, (ii) remove all or part of the remaining aspirated material AM and/or the second material UFM from the barrel 242, and/or (iii) use the filtering syringe 230 to perform one or more subsequent aspirations to remove additional material from the patient. In some embodiments, for example, the user can flush all or part of the aspirated material AM from the filtering syringe 230 via the valve 258 by, for example, fluidly coupling the valve 258 to a fluid source and flowing fluid at least partially through the filtering syringe 230 and toward and/or out of the tip 244. In other embodiments, the user can place the tip 244 of the filtering syringe 230 into a bowl containing a saline solution, or any other suitable washing/flushing solution,

withdraw the plunger 252 to pull at least a portion of the saline solution into the barrel 242 (e.g., to mix with any aspirated material AM contained therein), and then depress the plunger 252 to expel all or part of the aspirated material AM and/or the saline solution from the barrel 242. In these and other embodiments, the user can de-air the filtering syringe 230 before aspirating material from the patient. For example, the user can use the syringe 370 to (i) inject liquid (e.g., saline) into the filtering syringe 230 and/or (ii) draw fluid (e.g., air, liquid, etc.) from within the filtering syringe via, for example, the valve 258 on the filtering syringe 230. Additionally, or alternatively, the user can de-air the syringe 370 before reintroducing the first filtered material FM into the patient, for example, by actuating the plunger of the syringe 370 to remove air bubbles from the syringe's barrel.

[0050] Figure 4 is an enlarged side view of the filtering syringe 230 of Figure 2A coupled to a filtered material subsystem 470 in accordance with embodiments of the present technology. In the illustrated embodiment, the filtered material subsystem 470 includes a fluid control device 472 and a tubing section 474. The tubing section 474 can fluidly couple the filtering syringe 230, via the fluid control device 472, to the patient P or another suitable outflow location. The fluid control device 472 can include a one-way valve, a check valve, or any other suitable fluid control device. A first (e.g., distal) end of the fluid control device 472 is fluidly coupled to the valve 258 of the filtering syringe 230, and a second (e.g., proximal) end of the fluid control device 472 is fluidly coupled to the tubing section 474. In the illustrated embodiment, the fluid control device 472 is configured to allow fluid (e.g., the first material FM, Figure 3) to flow in the second direction D2 (e.g., through the fluid control device 472 to and/or toward the patient P), and to substantially or fully prevent fluid from flowing in the first direction D1 (e.g., opposite the second direction D2, from the patient P toward the filtering syringe 230).

[0051] In operation, the user can couple the filtering syringe 230 to the assembly 10 (e.g., via the connector 128, Figure 1) and actuate the assembly 10 to aspirate the aspirated material AM from the patient P, as described previously herein. Then, the user can close the fluid control device 126 (Figure 1) and move the plunger 252 in the first direction D1 to filter the aspirated material AM. Specifically, movement of the plunger 252 in the first direction D1 drives the first material FM in the second direction D2, through the filter assembly 260, the lumen 256, and the valve 258 and into the filtered material subsystem 470. In some embodiments, at least a portion of the first material FM can be returned to/reintroduced into the patient P via the tubing 474.

[0052] In some aspects of the present technology, the filtering syringe 230 can remain coupled to the filtered material subsystem 470 for one or more aspiration cycles, e.g., unless or until the filtering syringe 230 is filled with the second material UFM (Figure 3) and/or the user determines that the filtering syringe 230 should be cleaned/flushed. Accordingly, in at least some aspects of the present technology, the filtering syringe 230 and the filtered material subsystem 470 are expected to form a generally or substantially closed-loop system operable to remove aspirated material from the patient and return at least a portion of the aspirated material (e.g., the first material FM) to the patient P.

[0053] Figure 5 is a side view of the filtering syringe 230 of Figure 2A coupled to a filtered material subsystem 570 in accordance with embodiments of the present technology. In the illustrated embodiment, the filtered material subsystem 570 includes two fluid control devices 572a-b (i.e., a first fluid control device 572a and a second fluid control device 572b), two tubing sections 574a-b (i.e., a first tubing section 574a and a second tubing section 574b), and a fluid drive component 576. Each of the fluid control devices 572a-b can be generally similar or identical in structure and/or function to the fluid control device 472 of Figure 4. The fluid drive component 576 can include a syringe (e.g., "the drive syringe 576"), which can be generally similar or identical in structure and/or function to the syringe 370 of Figure 3. The first fluid control device 572a can be coupled to the valve 258 of the filtering syringe 230; the first tubing section 574a can be (i) positioned between the first fluid control device 572a and the second fluid control device 572b, and (ii) fluidly coupled to the drive syringe 576; and the second tubing section 574b can be fluidly coupled to the second fluid control device 572b opposite the first tubing section 574a. In the illustrated embodiment, the first tubing section 574a is a "T-shaped" tubing section and the drive syringe 576 has a plunger 578 that can be withdrawn/depressed to drive fluid in/out of the drive syringe 576.

[0054] The first and second fluid control devices 572a-b are each one-way valves positioned to allow fluid (e.g., the first material FM, Figure 3) to flow in the second direction D2 (e.g., from the filtering syringe 230 toward the patient P), and to substantially or fully prevent the fluid from flowing in a direction opposite the second direction D2 (e.g., from the patient P toward the filtering syringe 230). Accordingly, the first and second fluid control devices 572a-b can define one or more flow paths FP (i.e., a first flow path FP1 and a second flow path FP2) through the filtered material subsystem 570. The drive syringe 576 is configured to control the flow of fluid through the filtered material subsystem 570, e.g., through the first and second flow paths FP1, FP2. In the illustrated embodiment, for example, the user can withdraw the plunger

578 to drive fluid along the first flow path FP1 from the filtering syringe 230, through the first fluid control device 572a, and into the drive syringe 576. As the user withdraws the plunger 578, the second fluid control device 572b can substantially or fully prevent the drive syringe 576 from drawing fluid from the patient P, (e.g., because the force/pressure applied to the second fluid control device 572b when the plunger 578 is withdrawn in a direction opposite the second direction D2).

[0055] After the user has withdrawn the plunger 578, the user can depress the plunger 578 to drive fluid along the second flow path FP2 from the drive syringe 576, through the second fluid control device 572b, into the second tubing section 574b, and toward the patient P. As the user depresses the plunger 578, the first fluid control device 572a can substantially or fully prevent the drive syringe 576 from driving fluid flow into the filtering syringe 230 (e.g., because the force/pressure applied to the first fluid control device 572a when the user depresses the plunger 578 is in a direction opposite the second direction D2). In some aspects of the present technology, this can inhibit or prevent filtered material (e.g., the first material FM) from being reintroduced into the filtering syringe 230 and/or the aspirated material AM in the filtering syringe 230 from being driven back into the patient P (e.g., through the catheter 102; Figure 1).

[0056] In some aspects of the present technology, the user can operate the drive syringe 576 to de-air the filtered material subsystem 570 and/or the filtering syringe 230. De-airing the filtering syringe 230 can be generally similar to the filtering process described above, but with the drive syringe 576 drawing air and/or other fluid(s) from the filtering syringe 230 instead of the first material FM. In further aspects of the present technology, after the user has withdrawn the plunger 578 but before or instead of depressing the plunger 578, the user can (i) decouple the drive syringe 576 from the first tubing section 574a, (ii) perform one or more tests on the material within the drive syringe 576, (iii) transfer all or part of the material within the drive syringe 576 to another site and/or patient, (iv) take one or more images of the material within the drive syringe 576, and/or flush the filtering syringe 230 and/or the drive syringe 576.

[0057] Figure 6 is a side view of the filtering syringe 230 of Figure 2A coupled to a filtered material subsystem 670 in accordance with embodiments of the present technology. The filtered material subsystem 670 can include aspects generally similar in structure and/or function to the filtered material subsystem 570 of Figure 5, with like reference numbers (e.g., first tubing section 674a versus the first tubing section 574a of Figure 5) indicating like elements. Additionally, the filtered material subsystem 670 includes a second locking syringe 630 ("second

syringe 630") that can be generally similar in structure and/or function to the filtering syringe 230 ("first filtering syringe 230") of Figure 2A. In some embodiments, the second syringe 630 may not include a filtering assembly or filters.

[0058] In operation, a plunger 652 of the second syringe 630 can be withdrawn and then locked to generate and store vacuum within the second syringe 630. Once material is aspirated into the filtering syringe 230, the vacuum pressure in the second syringe 630 can automatically draw some of the aspirated material toward and through the filter assembly 260 along the first flow path FP1 such that some of the filtered blood can be drawn into the second syringe 630. To fully filter the material from the filtering syringe 230 into the filtered material subsystem 670, the locking component 248 can be unlocked to allow the plunger 252 to move in the first direction D1 to equalize the pressures between the filtering syringe 230 and the second syringe 630. After the filtered material FM is drawn into the second syringe 630, the second plunger 652 can be unlocked (via, e.g., locking component 648) and depressed to drive fluid from the second syringe 630 along the second flow path FP2 from the second syringe 630 to and/or toward the patient P.

[0059] Figure 7A is a side view of the filtering syringe 230 of Figure 2A coupled to a filtered material subsystem 770 in accordance with embodiments of the present technology. The filtered material subsystem 770 can include aspects that are generally similar in structure and/or function to the filtered material subsystem 570 of Figure 5, with like reference numbers (e.g., drive syringe 776 versus the drive syringe 576 of Figure 5) indicating like elements. Additionally, the filtered material subsystem 770 includes a fluid control device 780. The fluid control device 780 can include a three-way valve, a stopcock, or any other suitable fluid control device. Each of the filtering syringe 230, the drive syringe 776, and tubing section 774 can be fluidly coupled to the fluid control device 780. The fluid control device 780 can be configured to selectively control the flow of fluid through one or more of the flow paths FP1, FP2 within the filtered material subsystem 770. In the illustrated embodiment, for example, the fluid control device 780 includes an actuation element or lever 782 operable to transition the fluid control device 780 between (i) a first configuration (shown in Figure 7A) in which the first flow path FP1 is open (e.g., the fluid control device 780 allows fluid to flow from the filtering syringe 230 toward and/or to the drive syringe 776) and the second flow path FP2 is closed (e.g., the fluid control device 780 partially or fully prevents fluid from entering the tubing section 774), and (ii) a second configuration (not shown) in which the first flow path FP1 is closed (e.g., the fluid control device 780 partially or fully prevents fluid from entering the filtering syringe 230) and

the second flow path FP2 is open (e.g., the fluid control device 780 allows fluid to flow from the drive syringe 776 toward and/or into the tubing section 774).

[0060] In operation, the user can transition the fluid control device 780 to the first configuration and withdraw the plunger 778 to drive fluid along the first flow path FP1, e.g., from the filtering syringe 230, through the fluid control device 780, and into the drive syringe 776. As the user withdraws the plunger 778, the fluid control device 780 can substantially or fully prevent the drive syringe 776 from drawing fluid from the patient P when the tubing section 774 is fluidly coupled to the patient P (e.g., because the second flow path FP2 is closed when the fluid control device 780 is in the first configuration). After the user has withdrawn the plunger 778, the user can transition the fluid control device 780 from the first configuration toward and/or to the second configuration and depress the plunger 778 to drive fluid along the second flow path FP2 from the drive syringe 776, through the fluid control device 780, into the tubing section 774, and toward the patient P. As the user depresses the plunger 778, the fluid control device 780 can substantially or fully prevent the drive syringe 776 from driving fluid into the filtering syringe 230 because the first flow path FP1 is closed when the stopcock is in the second configuration. In some embodiments, after depressing the plunger 778, the user can perform one or more additional aspiration cycles with the filtered material subsystem 770 without disconnecting the filtering syringe 230 or the drive syringe 776 from the fluid control device 780.

[0061] Figure 7B illustrates the filtering syringe 230 of Figure 2A coupled to the filtered material subsystem 770 in accordance with additional embodiments of the present technology. In Figure 7B, the drive syringe 776 (Figure 7A) has been disconnected from the fluid control device 780 such that the fluid control device 780 has a free aperture or port 784. Additionally, the fluid control device 780 has been transitioned to a third configuration in which fluid can flow along a third flow path FP3, from the filtering syringe 230, through the fluid control device 780, and toward the patient P. Accordingly, when the fluid control device 780 is in the third configuration, the user can drive fluid through the filtered material subsystem 770 by moving the plunger 252 in the first direction D1, as described in detail above with reference to Figure 4. In some aspects of the present technology, the user can de-air/flush the filtering syringe 230 and/or the tubing section 774 via the free port 784. For example, the user can transition the fluid control device 780 to the first configuration (Figure 7A) to de-air/flush the filtering syringe 230 along the first flow path FP1 (Figure 7A) and/or transition the fluid control device 780 to the second configuration (not shown) to de-air/flush the tubing section 774 along the second flow path FP2 (Figure 7A).

[0062] Figure 8A is a perspective view of another plunger assembly 850 configured in accordance with embodiments of the present technology. The plunger assembly 850 can include at least some aspects that are generally similar or identical in structure and/or function to the plunger assembly 250 of Figures 2A–2C, with like reference numbers (e.g., lumen 856 versus the lumen 256 of Figures 2A–2C) indicating generally similar or identical aspects. Additionally, in the illustrated embodiment, the plunger assembly 250 further includes a pleated filter assembly 860. Referring to Figure 8B, in the illustrated embodiment the pleated filter assembly 860 includes a first filter 862a and a second filter 862b. In other embodiments, the pleated filter assembly 860 can include more or fewer filters. In these and other embodiments, the pleated filter assembly 860 can have a greater filtering surface area compared to the generally flat or planar filters/filter assemblies. Accordingly, in some aspects of the present technology, the pleated filter assembly 860 can have an increased filtering surface area compared to the filter assembly 260 of Figures 2A–2C while having a generally similar or identical cross-sectional area as the filter assembly 260.

[0063] Figures 9A and 9B are perspective views of another filtering syringe 930 configured in accordance with embodiments of the present technology. The filtering syringe 930 can include at least some aspects that are generally similar or identical in structure and/or function to the filtering syringe 230 of Figures 2A–2C, with like reference numbers (e.g., lumen 946 versus the lumen 246 of Figure 2A) indicating generally similar or identical aspects. In the illustrated embodiment, the filtering syringe 930 includes the plunger assembly 850 of Figure 8A. In other embodiments, the filtering syringe 930 can include the plunger assembly 250 of Figures 2A–2C, or any other suitable plunger assembly. Additionally, the filtering syringe 930 includes a detachable cap 943 (which can also be referred to as a "locking cap," a "twist cap," a "removable cap," and the like). The detachable cap 943 can be releasably coupled to the barrel 242. Referring to Figure 9B, the detachable cap 943 can be configured to matingly engage with a coupling portion 945 of the barrel 242. In the illustrated embodiment, the coupling portion 945 includes one or more coupling slots or grooves 947, the detachable cap 943 includes one or more tabs or protrusions 949 (which can extend radially from an inner surface of the cap 943, as shown in Figure 9B), and each coupling slot 947 is configured to slidably receive a corresponding tab 949 to couple the detachable cap 943 to the barrel 942. In at least some embodiments, the detachable cap 943 can include an O-ring or other sealing element (not visible in Figure 9B) that forms a substantially fluid-impermeable seal with the barrel 942 when the detachable cap 943 is coupled to the barrel 942, for example, to maintain a vacuum pressure generated/stored within

the barrel 942, and/or to inhibit or prevent fluid and/or other aspirated material within the barrel 942 from leaking out the barrel 942.

[0064] In operation, a user can rotate the detachable cap 943 relative to the barrel 942 (e.g., in the direction shown by the arrow R) to couple and/or uncouple the detachable cap 943 and the barrel 942. The user can uncouple the detachable cap 943 from the barrel 942 after performing one or more material removal cycles to, for example, flush or remove any fluid, clot material, or other aspirated material collected within the barrel 942. After flushing/removing material collected within the barrel 942, the user can recouple the detachable cap 943 to the barrel 942 and use the filtering syringe 930 to perform one or more additional material removal cycles, alone or in combination with any of the filtered material systems described in detail with reference to Figures 3–7B.

[0065] Figure 10 is a perspective view of another filtering syringe 1030 configured in accordance with embodiments of the present technology. The filtering syringe 1030 can include at least some aspects that are generally similar or identical in structure and/or function to the filtering syringe 230 of Figure 2A–2C and/or the filtering syringe 930 of Figures 9A–9B, with like numbers (e.g., barrel 1042 versus the barrel 242 of Figure 2A and/or the barrel 942 of Figures 9A and 9B) indicating generally similar or identical aspects. The filtering syringe 1030 can include a plunger assembly 1050 having a first (e.g., distal) body portion 1052a and a second (e.g., proximal) body portion 1052b. The first body portion 1052a can include the filter assembly 860 of Figures 8A and 8B, a seal or sealing element 1054, a valve 1058 (e.g., a luer-activated valve, a one-way valve, or the like), and/or a locking feature 1059 configured to engage a locking component 1048 of the filtering syringe 1030. In other embodiments, the first body portion 1052a can include the filter assembly 260 of Figures 2A–2C, or any other suitable filter and/or filter assembly. The second body portion 1052b can include a handle 1051, a plunger $1052b_1$, and/or a tip 1055. The tip 1055 can be configured to couple (e.g., fluidly coupled) to the valve 1058, such that the second body portion 1052b can be coupled/connected to the first body portion 1052a.

[0066] In the illustrated embodiment, the second body portion 1052b includes a syringe ("syringe 1052b"), such as a 30cc luer-lock syringe, or any other suitable syringe, including any of the filtering syringes described herein. In these and other embodiments, the syringe 1052b can have an internal volume less than, equal to, or greater than an internal volume of the barrel 1042. The tip 1055 of the syringe 1052b can be coupled to the first body portion 1052a, such that

movement of the syringe 1052b can cause corresponding movement of the first body portion 1052a. In operation, for example, the plunger assembly 1050 (e.g., the syringe 1052b) can be drawn (e.g., proximally, by a user) relative to the barrel 1042 to generate and/or store a vacuum within the filtering syringe 1030, as described previously with reference to Figures 1–2C. Continuing to move the plunger assembly 1050 can cause the locking component 1048 to engage the locking feature 1059 of the first body portion 1052a, for example, to lock the plunger assembly 1050 relative to the barrel assembly 1040 and store a vacuum within the barrel 1042, as described previously regarding Figures 2A–2C. Once a vacuum has been generated and/or stored within the filtering syringe 1030, the filtering syringe 1030 can be used to perform one or more material removal cycles, for example, as described previously with reference to Figures 1–2C, and/or alone or in combination with any of the filtered material systems described in detail with reference to Figures 3–7B. After the filtering syringe 1030 has been used to perform a material removal cycle, at least a portion of the aspirated material within the barrel 1042 can be filtered by actuating the plunger $1052b_1$ of the syringe 1052b to draw material (e.g., blood) through the filter assembly 860 and into the syringe 1052b via the valve 1058. In at least some embodiments, the syringe 1052b can be configured such that all or substantially all of the aspirated blood within the barrel 1042 can be filtered and drawn into the syringe 1052b. Additionally, or alternatively, the syringe 1052b can be advanced toward the aspirated material within the barrel 1042 to filter material within the barrel 1042. In these and other embodiments, because the first body portion 1052a sealingly engages the barrel 1042, withdrawing the plunger $1052b_1$ proximally can cause a corresponding distal movement of the syringe 1052b and the first body portion 1052a within the barrel 1042 as blood is filtered and drawn into the syringe 1052b. Similarly, moving the syringe 1052b distally can cause a corresponding proximal movement of the plunger $1052b_1$. Once at least a portion of the filtered material is drawn into the syringe 1052b, the syringe 1052b can then be disconnected from the first body portion 1052a and the filtered material (e.g., blood) within the syringe 1052b can be, for example, returned to the patient.

[0067] Figure 11A is a perspective view of another filtering syringe 1130 configured in accordance with embodiments of the present technology. Figure 11B is an enlarged perspective view of a distal portion 11B of the filtering syringe 1130 in accordance with embodiments of the present technology. Referring to Figures 11A and 11B together, the filtering syringe 1130 can include at least some aspects that are generally similar or identical in structure and/or function to the filtering syringe 230 of Figure 2A–2C, the filtering syringe 930 of Figures 9A–9B, and/or

the filtering syringe 1030 of Figure 10, with like numbers (e.g., barrel assembly 1140 versus the barrel assembly 240 of Figure 2A, the barrel assembly 940 of Figures 9A and 9B, and/or the barrel assembly 1040 of Figure 10) indicating generally similar or identical aspects. The filtering syringe 1130 can include the barrel assembly 1140, a plunger assembly 1150, and a filtered material subsystem 1170. The filtered material subsystem 1170 can be fluidly coupled to the plunger assembly 1150. The plunger assembly 1150 can include a plunger 1152 that can be slidably received within the barrel assembly 1140. The plunger 1152 can include a filter assembly 1160 and a seal 1154. In the illustrated embodiment, the filter assembly 1160 is seated at least partially within the plunger 1152 proximal to a first or distal end portion 1153a of the plunger 1152 and distal from the seal 1154. In other embodiments, the filter assembly 1160 can have another suitable position.

[0068] Figure 11C is a perspective view of the filter assembly 1160 in accordance with embodiments of the present technology. The filter assembly 1160 can include an annular filter 1162 defining a central space 1164. The annular filter 1162 can be configured to allow flow of select fluids (e.g., blood) across the annular filter 1162 toward and/or away from the central space 1164, such as radially outwardly or inwardly relative to a longitudinal axis X of the annular filter 1162. In the illustrated embodiment, the annular filter 1162 includes one or more folds or pleats 1166, each of which can increase a surface area of the annular filter 1162 while maintaining a generally compact formfactor. In some aspects of the present technology, the pleats 1166 and/or the increased surface area of the annular filter 1162 associated therewith are expected to reduce or prevent blockages, clogs, and/or other reductions of fluid flow through the annular filter 1162, which can increase the number of filtrations performed before replacement of the annular filter 1162.

[0069] Figure 11D is an enlarged side cross-sectional view of the filtering syringe 1130 taken along section line 11D–11D in Figure 11B in accordance with embodiments of the present technology. The first end portion 1153a of the plunger 1152 can at least partially define a first or distal chamber portion 1141a on a first (e.g., distal) side of the first end portion 1153a and a second or proximal portion chamber portion 1141b on a second (e.g., proximal) side of the first end portion 1153a opposite the first side. A lateral-most edge 1168 of the first end portion 1153a can have a dimension (e.g., a diameter) less than a corresponding dimension (e.g., a dimeter) of an inner surface 1190 of the barrel 1142, such that the lateral-most edge 1168 can be spaced apart from an inner surface 1190 of the barrel 1142 to define a gap or fluid passage 1192 that fluidly couples the first chamber portion 1141a and the second chamber portion 1141b. The

annular filter 1162 can be carried by the plunger 1152 and can be positioned at least partially within the second chamber portion 1141b, such as with the central space 1164 of the annular filter 1162 at least partially aligned with a lumen 1156 of the plunger 1152, and/or such that all or substantially all fluid within the barrel 1142 that enters the lumen 1156 must pass through the annular filter 1162. In the illustrated embodiment, the annular filter 1162 is radially inward from the lateral-most edge 1168, such that the lateral-most edge 1168 overhangs or otherwise extends radially outward relative to the annular filter 1162.

[0070] During a procedure, aspirated material AM including blood and/or clot material can be drawn into the first chamber portion 1141a of the barrel 1142. The plunger 1152 can be advanced in the first direction D1 and/or a vacuum can be applied to the lumen 1156 to cause at least some material (e.g., blood) within the first chamber portion 1141a to flow through the gap 1192, into the second chamber portion 1141b, at least partially through the annular filter 1162, into the central space 1164 of the annular filter 1162, and/or into the lumen 1156, such as shown by flow path arrow FP in Figure 11D. The material (e.g., blood) within the lumen 1156 can flow into the filtered material subsystem 1170 and/or be returned to the patient P, including via any of the techniques described previously herein. The first end portion 1153a and/or the gap 1192 between the first chamber portion 1141a and the second chamber portion 1141b are expected to prevent at least a portion of the aspirated material AM (e.g., at least some aspirated clot material) from entering the second chamber portion 1141b and/or otherwise reduce or prevent contact between the aspirated material AM and the annular filter 1162, without or substantially without inhibiting the flow of other material (e.g., blood) between the first chamber portion 1141a and the second chamber portion 1141b. This, in turn, is expected to reduce or prevent clogs or other obstructions to fluid flow through the annular filter 1162. Accordingly, the first end portion 1153a and/or the gap 1192 can be configured to provide a first filtering stage that inhibits or prevents relatively large material from entering the second chamber portion 1141b while the annular filter 1162 can provide a second filtering stage that inhibits or prevents relatively smaller material from entering the lumen 1156.

[0071] Figure 12A is a perspective view of a plunger assembly 1250 of another filtering syringe configured in accordance with embodiments of the present technology. At least some aspects of the plunger assembly 1250 can be at least generally similar or identical in structure and/or function to one or more of the plunger assemblies 250, 850, 1050, 1150 described previously herein. For example, the plunger assembly 1250 includes a plunger 1252 configured

to carry one or more filters 1162 (Figure 12B). However, a first or distal end portion 1253a of the plunger 1252 includes one or more holes or apertures 1292.

[0072] Figure 12B is a cross-sectional view of the plunger assembly 1250 of Figure 12A taken along section line 12B–12B in Figure 11B. In Figure 12B, the plunger assembly 1250 is shown positioned within a barrel 1242 of a filtering syringe 1230, in accordance with embodiments of the present technology. As best seen in Figure 12B, the plunger 1252 defines a filter chamber 1294 configured to receive the annular filter 1162 and a lumen 1256 that can be fluidly coupled to the filtered material subsystem 1170 and/or the patient. The holes 1292 formed in the first end portion 1253a of the plunger 1252 can be configured to allow fluid communication between the filter chamber 1294 (e.g., the central space 1164 of the annular filter 1162) and the exterior of the plunger 1252 (e.g., the interior of the barrel 1242). More specifically, when the annular filter 1162 is positioned within the filter chamber 1294, individual ones of the holes 1292 can allow at least some of the aspirated material AM within the barrel 1242 (including, e.g., blood and/or other fluids) to flow into the central space 1164 of the annular filter 1162. A proximal end portion 1263 of the filter 1162 can be sealed so that at least some of the aspirated material AM that passes through the holes 1292 is caught within the central space 1164, e.g., and does not pass through the filter 1162 into the filter chamber 1294 and/or the lumen 1256. A distal end portion 1265 of the filter 1162 can be coupled to at least part of the first end portion 1253a, e.g., to prevent, or at least partially prevent, the aspirated material AM from entering the filter chamber 1294 without passing through the central space 1164 of the annular filter 1162.

[0073] During a procedure, the plunger 1252 can be moved the first direction D1 relative to the barrel 1242 to force at least some of the aspirated material AM through individual ones of the holes 1292 and/or into the central space 1164. As the aspirated material AM collects within the central space 1164, the filter 1162 can separate blood and/or other fluids contained within the aspirated material AM from the aspirated material AM. Because the proximal and distal end portions 1263, 1265 of the annular filter 1162 are sealed, the blood and/or other fluids can be separated by causing the blood and/or other fluids to flow outwardly from the central space 1164 across the filter 1162. For example, moving the plunger 1252 in the first direction D1 relative to the barrel 1242 can force the blood and/or other fluids across the filter 1162, into a space between the filter 1162 and the filter chamber 1294, and into and/or through at least a portion of the lumen 1256. The blood and/or other fluids within the lumen 1256 can flow to the filtered material subsystem 1170 and/or be returned to the patient P.

[0074] Accordingly, in some aspects of the present technology, a filtering syringe can be coupled to a catheter subsystem insertable within a patient. The filtering syringe can aspirate material (e.g., clot material, blood, etc.) from a patient via the catheter subsystem. The filtering syringe can include a plunger assembly, and the plunger assembly can include one or more filters. Individual ones of the filters can be configured to (i) allow at least a first portion of aspirated material to pass through at least one of the filters, and (ii) prevent at least a second portion of the aspirated material from passing through at least one of the filters. In some embodiments, for example, the filters are configured to (i) allow blood to pass through the filters, and (ii) prevent clot material from passing through the filters, such that the filters can "filter" blood from the other material aspirated from the patient. In some embodiments, the filtering syringe is fluidly coupled to a filtered material subsystem. The filtered material subsystem can include one or more valves and/or tubing sections that can fluidly couple the filtering syringe to the patient or another suitable fluid (e.g., blood) outflow location. The filtered material subsystem can (i) capture/receive all or part of the first portion of the aspirated material filtered by the filtering syringe, and/or (ii) return/reintroduce all or part of the first portion of the aspirated material into the patient.

[0075] Several aspects of the present technology are set forth in the following examples:

1. A filtering syringe for treatment of clot material from within a blood vessel of a patient, the filtering syringe comprising:

a barrel defining a chamber configured to receive at least a portion of the clot material and blood from the human patient;

a plunger assembly having a first end portion and a second end portion opposite the first end portion, wherein the plunger assembly includes a filter proximate to the first end portion, a port proximate to the second end portion, and a lumen therebetween and fluidly coupling the filter and the port;

wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel; and

wherein the filter is configured to allow at least part of the blood received within the chamber to separate from the portion of the clot material and enter the lumen of the plunger assembly.

2. The filtering syringe of example 1, further comprising a tip configured to fluidly couple the filtering syringe to a clot treatment system.

3. The filtering syringe of example 1 or example 2 wherein the filter has a circular, annular, cylindrical, and/or pleated shape.

4. The filtering syringe of any of examples 1-3 wherein the filter has a porosity between about 40 microns and about 200 microns.

5. The filtering syringe of any of examples 1-4 wherein the filter includes at least one of a polyester, a polyamide, and/or a hemocompatible material.

6. The filtering syringe of any of examples 1-5 wherein the filter is a first filter having a first porosity, the filtering syringe further comprising a second filter having a second porosity.

7. The filtering syringe of example 6 wherein the first porosity is different than the first porosity.

8. The filtering syringe of example 6 wherein the first porosity is the same as the second porosity.

9. The filtering syringe of any of examples 6-8 wherein the second filter is positioned proximate the first end portion of the plunger assembly.

10. The filtering syringe of any of examples 6-9 wherein the second filter is spaced apart from the first filter.

11. The filtering syringe of any of examples 1-10 wherein the port includes a luer-activated valve.

12. The filtering syringe of any of examples 1-11 wherein the first end portion of the plunger assembly is a distal end portion of the plunger assembly and the second end portion is a

proximal end portion of the plunger assembly, wherein the filter is positioned proximally from the distal end portion.

13. The filtering syringe of any of examples 1-12 wherein the chamber includes an inner surface, and wherein first end portion of the plunger assembly is radially spaced apart from chamber such that the barrel assembly and the plunger assembly at least partially define (i) a first chamber portion positioned on a first side of the first end portion of the plunger assembly, (ii) a second chamber portion positioned on a second side of the first end portion of the plunger assembly, the second side opposite the first side, and (iii) a gap fluidly coupling the first chamber portion and the second chamber portion.

14. The filtering syringe of example 13 wherein the filter is positioned in the second chamber portion, wherein the first chamber portion is configured to receive at least the portion of the clot material from the patient, wherein the gap is configured to at least partially prevent the portion of the clot material from entering the second chamber portion, and wherein the filter is configured to allow blood within the second chamber portion to enter the lumen.

15. The filtering syringe of any of examples 1-14 wherein the first end portion of the plunger assembly is configured to at least partially prevent contact between the filter and the portion of the clot material.

16. The filtering syringe of any of examples 1-15 wherein the plunger assembly defines a filter chamber configured to receive the filter, and wherein the first end portion of the plunger assembly includes one or more holes in fluid communication with the filter chamber.

17. The filtering syringe of example 16 wherein the filter is an annular filter defining a central space, and wherein individual ones of the one or more holes are positioned to direct at least a portion of the clot material and/or the blood received from the patient into the central space.

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

a catheter configured to be intravascularly positioned at a treatment site proximate to the clot material within the blood vessel;

a filtering syringe configured to generate negative pressure, wherein the filtering syringe includes—

a tip configured to be fluidly coupled to the catheter to receive at least a portion of the clot material and blood from within the blood vessel via the catheter, and

a filter assembly including one or more filters configured to filter the blood from the portion of the clot material.

19. The system of example 18, further comprising a filtered material system fluidly coupled to the filtering syringe and configured to receive at least a portion of the filtered blood.

20. The system of example 19, wherein the filtered material system includes a fluid drive component operable to drive flow of the filtered blood through at least part of the filtered material system.

21. The system of example 20 wherein the filtered material system includes at least one flow path, and wherein fluid drive component is operable to drive the flow of the filtered blood through the at least one flow path.

22. The system of example 21 wherein the at least one flow path is configured to direct fluid flow away from the filtering syringe.

23. The system of any of examples 19-22 wherein the filtering syringe further includes a valve opposite the tip, wherein the filtered material system includes (i) a fluid control device fluidly coupled to the valve and (ii) tubing fluidly coupled to the fluid control device, and wherein the fluid control device is configured to at least partially prevent filtered blood within the tubing from entering the filtering syringe.

24. A method for removing clot material from within a blood vessel of a human patient, the method comprising:

positioning a distal portion of a catheter proximate to the clot material within the blood vessel;

coupling a filtering and pressure-generating syringe to the catheter via a fluid control device, wherein (i) opening of the fluid control device fluidly connects the filtering and pressure-generating syringe to the catheter, and (ii) closing the fluid control device fluidly disconnects the filtering and pressure-generating syringe from the catheter;

activating the syringe to generate a vacuum while the fluid control device is closed;

opening the fluid control device to apply the vacuum to the catheter to thereby aspirate at least a portion of the clot material into the catheter; and

filtering blood from the portion of the clot material via a filter of the syringe.

25. The method of example 24 wherein filtering the blood includes moving a plunger of the syringe to cause the filter to move toward the portion of the clot material.

26. The method of example 24 or example 25 wherein filtering the blood includes actuating a fluid drive component of a filtered material system to cause the blood to flow through the filter proximally toward the fluid drive component.

27. A filtering syringe for removing target material from within a human patient, the filtering syringe comprising:

a barrel defining a chamber configured to receive at least a portion of the target material and fluid from the human patient;

a plunger assembly having a first end portion and a second end portion opposite the first end portion, wherein the plunger assembly includes a filter proximate to the first end portion, a valve proximate to the second end portion, and a lumen therebetween and fluidly coupling the filter and the valve;

wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel; and

wherein the filter is configured to allow at least part of the fluid received within the chamber to pass through the filter and enter the lumen of the plunger assembly.

28. The filtering syringe of example 27 wherein the fluid includes blood.

29. The filtering syringe of example 27 or example 28 wherein the target material includes clot material.

30. A filtering syringe for treating a human patient, comprising:

a barrel defining a chamber configured to receive first material and second material from within the human patient;

a plunger assembly having a first end portion and a second end portion opposite the first end portion, wherein the plunger assembly includes a filter proximate to the first end portion, a valve proximate to the second end portion, and a lumen therebetween and fluidly coupling the filter and the valve;

wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel; and

wherein the filter is configured to (i) allow at least part of the first material received within the chamber to pass through the filter and enter the lumen of the plunger assembly, and (ii) prevent at least part of the second material received within the chamber from passing through the filter.

31. The filtering syringe of example 30 wherein the first material includes blood.

32. The filtering syringe of example 30 or example 31 wherein the second material includes clot material.

33. A filtering syringe for treating a human patient, comprising:

a barrel defining a chamber configured to receive first material and second material from within the human patient; and

a plunger assembly including a first body portion and a second body portion, wherein the first body portion includes a filter and a valve, and wherein the second body portion defines an interior chamber and is detachably couplable to the first body portion via the valve;

wherein at least part of the first body portion and the second body portion are insertable within the chamber and slidable relative to the barrel; and

wherein the filter is configured to allow at least part of the first material received within the chamber to pass through the filter and into the interior chamber of the second body portion.

34. The filtering syringe of example 33 wherein the second body portion comprises a syringe including a plunger operable to draw at least part of the first material within the chamber through the filter and into the interior chamber of the syringe.

35. The filtering syringe of example 34 wherein the syringe includes a tip, and wherein the valve of the first body portion is configured to matingly engage the tip of the syringe to fluidly couple the chamber of the barrel to the interior chamber of the syringe.

36. The filtering syringe of any of examples 33-35 wherein the first material includes blood.

37. The filtering syringe of any of examples 33-36 wherein the second material includes clot material.

[0076] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology, as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0077] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0078] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in

the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A filtering syringe for treatment of clot material from within a blood vessel of a patient, the filtering syringe comprising:

a barrel defining a chamber configured to receive at least a portion of the clot material and blood from the patient; and

a plunger assembly having a first end portion and a second end portion opposite the first end portion, wherein the plunger assembly includes a filter proximate to the first end portion, a port proximate to the second end portion, and a lumen therebetween and fluidly coupling the filter and the port;

wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel; and

wherein the filter is configured to allow at least part of the blood received within the chamber to separate from the portion of the clot material and enter the lumen of the plunger assembly.

2. The filtering syringe of claim 1, further comprising a tip configured to fluidly couple the filtering syringe to a clot treatment system.

3. The filtering syringe of claim 1 wherein the filter has a circular, annular, cylindrical, and/or pleated shape.

4. The filtering syringe of claim 1 wherein the filter has a porosity between about 40 microns and about 200 microns.

5. The filtering syringe of claim 1 wherein the filter includes at least one of a polyester, a polyamide, and/or a hemocompatible material.

6. The filtering syringe of claim 1 wherein the filter is a first filter having a first porosity, the filtering syringe further comprising a second filter having a second porosity.

7. The filtering syringe of claim 6 wherein the first porosity is different than the first porosity.

8. The filtering syringe of claim 6 wherein the first porosity is the same as the second porosity.

9. The filtering syringe of claim 6 wherein the second filter is positioned proximate the first end portion of the plunger assembly.

10. The filtering syringe of claim 6 wherein the second filter is spaced apart from the first filter.

11. The filtering syringe of claim 1 wherein the port includes a luer-activated valve.

12. The filtering syringe of claim 1 wherein the first end portion of the plunger assembly is a distal end portion of the plunger assembly and the second end portion is a proximal end portion of the plunger assembly, wherein the filter is positioned proximally from the distal end portion.

13. The filtering syringe of claim 1 wherein the chamber includes an inner surface, and wherein first end portion of the plunger assembly is radially spaced apart from chamber such that the barrel assembly and the plunger assembly at least partially define (i) a first chamber portion positioned on a first side of the first end portion of the plunger assembly, (ii) a second chamber portion positioned on a second side of the first end portion of the plunger assembly, the second side opposite the first side, and (iii) a gap fluidly coupling the first chamber portion and the second chamber portion.

14. The filtering syringe of claim 13 wherein the filter is positioned in the second chamber portion, wherein the first chamber portion is configured to receive at least the portion of the clot material from the patient, wherein the gap is configured to at least partially prevent the portion of the clot material from entering the second chamber portion, and wherein the filter is configured to allow blood within the second chamber portion to enter the lumen.

15. The filtering syringe of claim 1 wherein the first end portion of the plunger assembly is configured to at least partially prevent contact between the filter and the portion of the clot material.

16. The filtering syringe of claim 1 wherein the plunger assembly defines a filter chamber configured to receive the filter, and wherein the first end portion of the plunger assembly includes one or more holes in fluid communication with the filter chamber.

17. The filtering syringe of claim 16 wherein the filter is an annular filter defining a central space, and wherein individual ones of the one or more holes are positioned to direct at least a portion of the clot material and/or the blood received from the patient into the central space.

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

a catheter configured to be intravascularly positioned at a treatment site proximate to the clot material within the blood vessel; and

a filtering syringe configured to generate negative pressure, wherein the filtering syringe includes—

a tip configured to be fluidly coupled to the catheter to receive at least a portion of the clot material and blood from within the blood vessel via the catheter, and

a filter assembly including one or more filters configured to filter the blood from the portion of the clot material.

19. The system of claim 18, further comprising a filtered material system fluidly coupled to the filtering syringe and configured to receive at least a portion of the filtered blood.

20. The system of claim 19, wherein the filtered material system includes a fluid drive component operable to drive flow of the filtered blood through at least part of the filtered material system.

21. The system of claim 20 wherein the filtered material system includes at least one flow path, and wherein fluid drive component is operable to drive the flow of the filtered blood through the at least one flow path.

22. The system of claim 21 wherein the at least one flow path is configured to direct fluid flow away from the filtering syringe.

23. The system of claim 19 wherein the filtering syringe further includes a valve opposite the tip, wherein the filtered material system includes (i) a fluid control device fluidly coupled to the valve and (ii) tubing fluidly coupled to the fluid control device, and wherein the fluid control device is configured to at least partially prevent filtered blood within the tubing from entering the filtering syringe.

24. A method for removing clot material from within a blood vessel of a human patient, the method comprising:

positioning a distal portion of a catheter proximate to the clot material within the blood vessel;

coupling a filtering and pressure-generating syringe to the catheter via a fluid control device, wherein (i) opening of the fluid control device fluidly connects the filtering and pressure-generating syringe to the catheter, and (ii) closing the fluid control device fluidly disconnects the filtering and pressure-generating syringe from the catheter;

activating the syringe to generate a vacuum while the fluid control device is closed;

opening the fluid control device to apply the vacuum to the catheter to thereby aspirate at least a portion of the clot material into the catheter; and

filtering blood from the portion of the clot material via a filter of the syringe.

25. The method of claim 24 wherein filtering the blood includes moving a plunger of the syringe to cause the filter to move toward the portion of the clot material.

26. The method of claim 24 wherein filtering the blood includes actuating a fluid drive component of a filtered material system to cause the blood to flow through the filter proximally toward the fluid drive component.

27. A filtering syringe for removing target material from within a human patient, the filtering syringe comprising:

a barrel defining a chamber configured to receive at least a portion of the target material and fluid from the human patient; and

a plunger assembly having a first end portion and a second end portion opposite the first end portion, wherein the plunger assembly includes a filter proximate to the first end portion, a valve proximate to the second end portion, and a lumen therebetween and fluidly coupling the filter and the valve;

wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel; and

wherein the filter is configured to allow at least part of the fluid received within the chamber to pass through the filter and enter the lumen of the plunger assembly.

28. The filtering syringe of claim 27 wherein the fluid includes blood.

29. The filtering syringe of claim 27 wherein the target material includes clot material.

30. A filtering syringe for treating a human patient, comprising:

a barrel defining a chamber configured to receive first material and second material from within the human patient; and

a plunger assembly having a first end portion and a second end portion opposite the first end portion, wherein the plunger assembly includes a filter proximate to the first end portion, a valve proximate to the second end portion, and a lumen therebetween and fluidly coupling the filter and the valve;

wherein at least the first end portion of the plunger assembly is insertable within the chamber and slidable relative to the barrel; and

wherein the filter is configured to (i) allow at least part of the first material received within the chamber to pass through the filter and enter the lumen of the plunger

assembly, and (ii) prevent at least part of the second material received within the chamber from passing through the filter.

31. The filtering syringe of claim 30 wherein the first material includes blood.

32. The filtering syringe of claim 30 wherein the second material includes clot material.

33. A filtering syringe for treating a human patient, comprising:

a barrel defining a chamber configured to receive first material and second material from within the human patient; and

a plunger assembly including a first body portion and a second body portion, wherein the first body portion includes a filter and a valve, and wherein the second body portion defines an interior chamber and is detachably couplable to the first body portion via the valve;

wherein at least part of the first body portion and the second body portion are insertable within the chamber and slidable relative to the barrel; and

wherein the filter is configured to allow at least part of the first material received within the chamber to pass through the filter and into the interior chamber of the second body portion.

34. The filtering syringe of claim 33 wherein the second body portion comprises a syringe including a plunger operable to draw at least part of the first material within the chamber through the filter and into the interior chamber of the syringe.

35. The filtering syringe of claim 34 wherein the syringe includes a tip, and wherein the valve of the first body portion is configured to matingly engage the tip of the syringe to fluidly couple the chamber of the barrel to the interior chamber of the syringe.

36. The filtering syringe of claim 33 wherein the first material includes blood.

37. The filtering syringe of claim 33 wherein the second material includes clot.

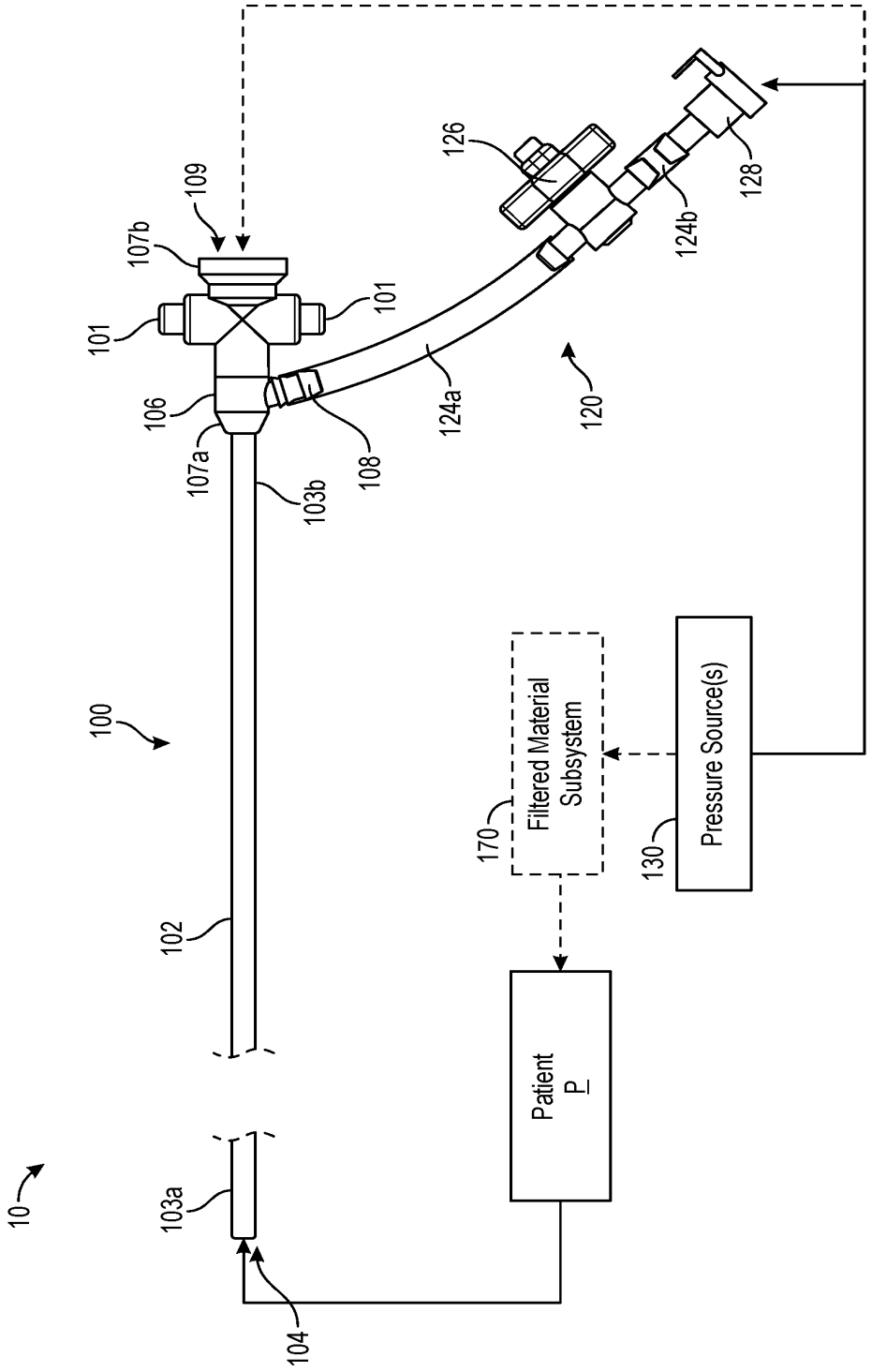

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100
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103a
103b
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107a
107b
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109
120
124a
124b
126
128
130
170
Filtered Material Subsystem
Pressure Source(s)
Patient P

FIG. 1

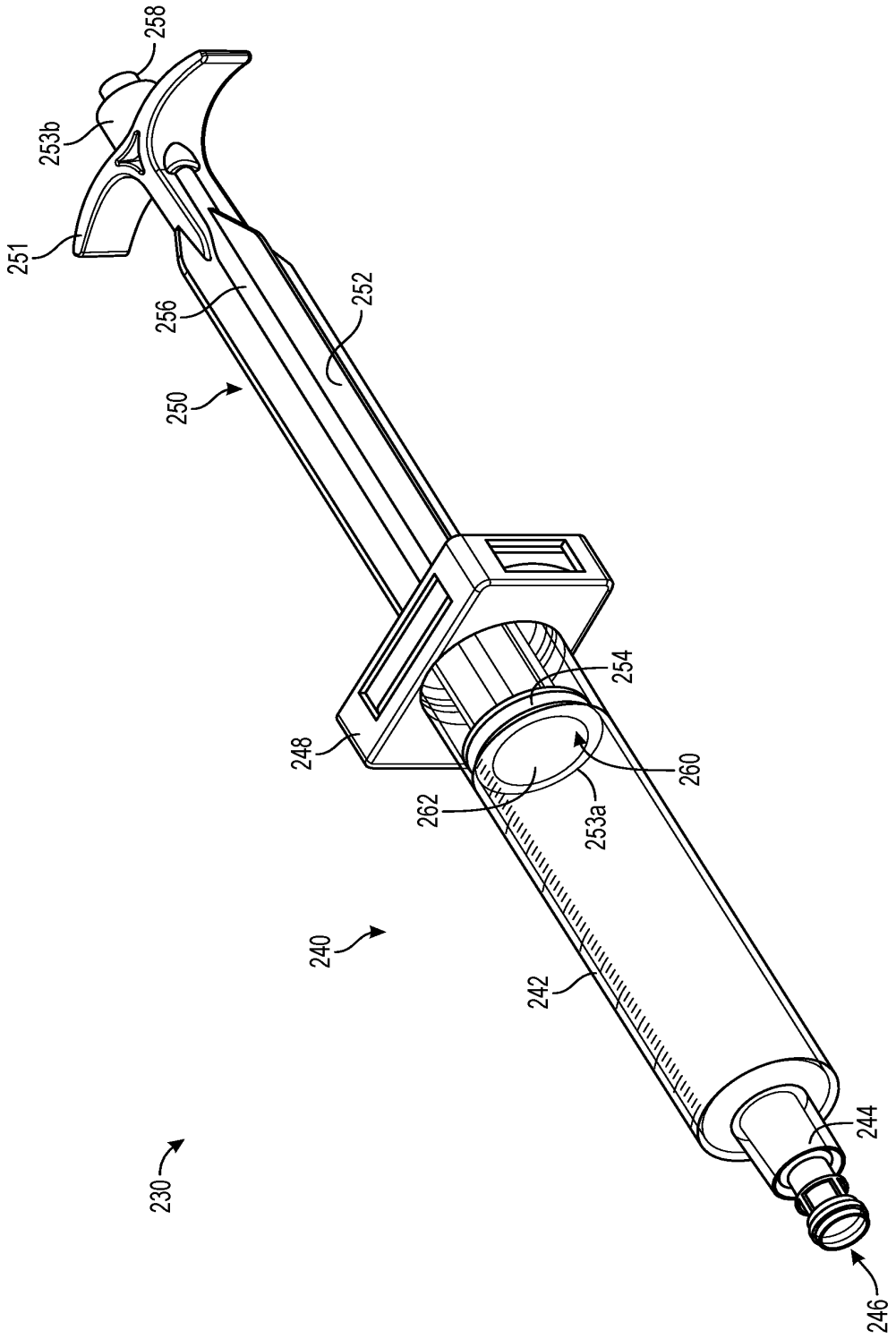

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253b
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253a
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230
246

FIG. 2A

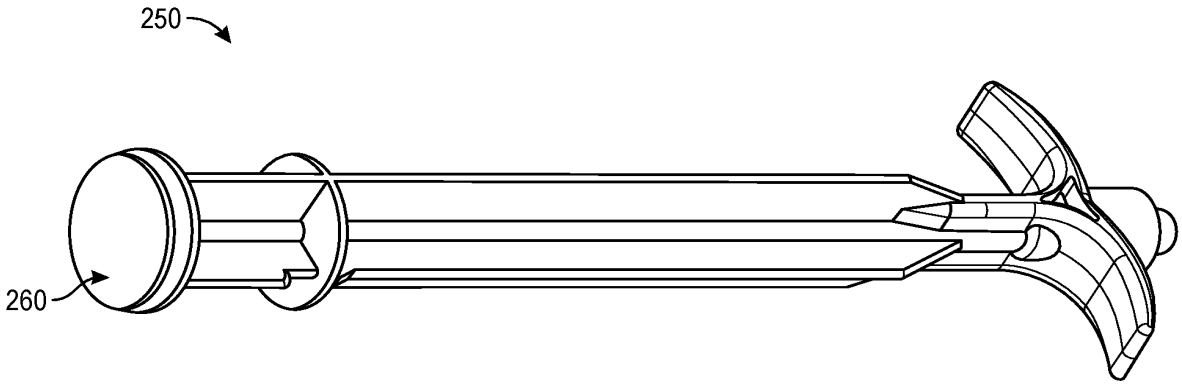


FIG. 2B

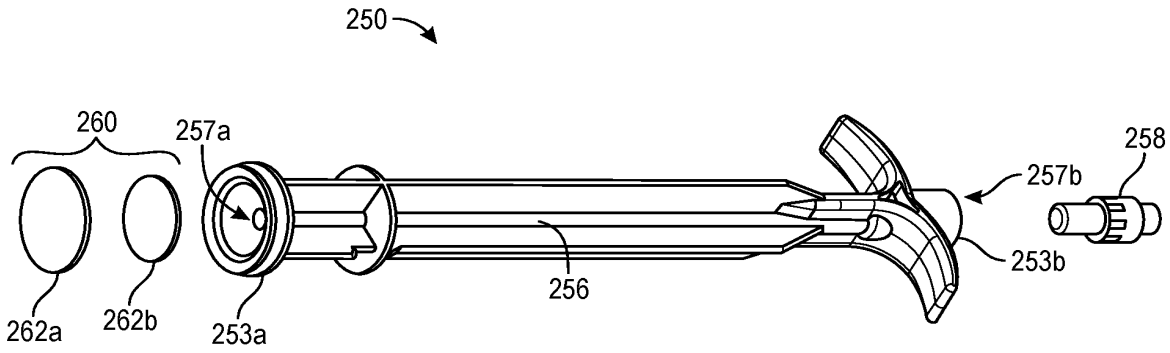


FIG. 2C

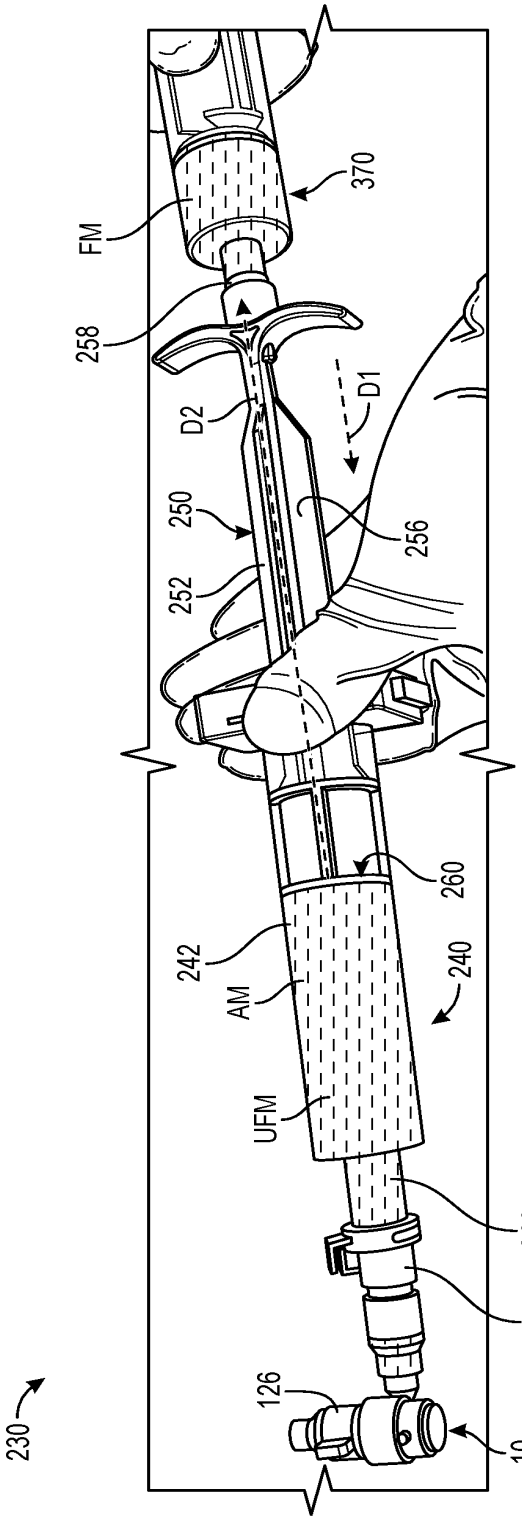


FIG. 3

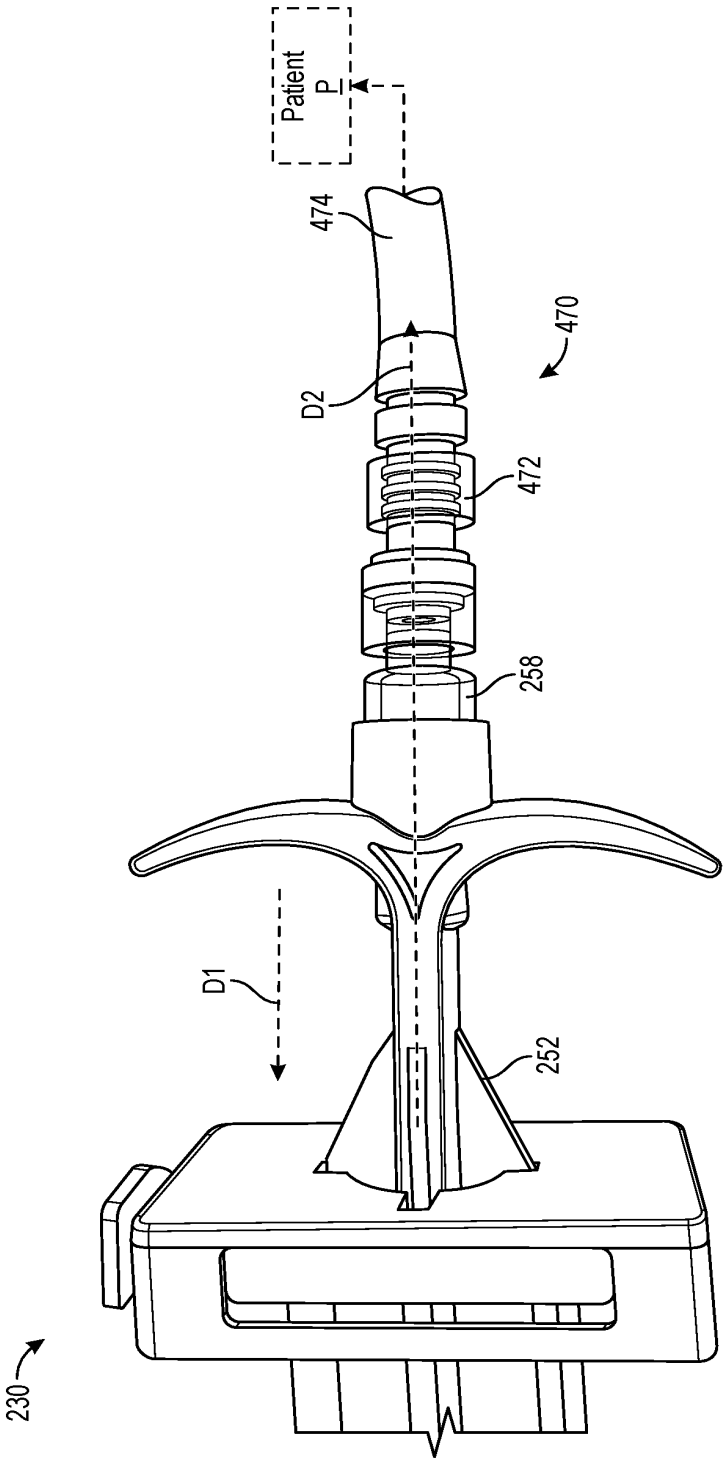


FIG. 4

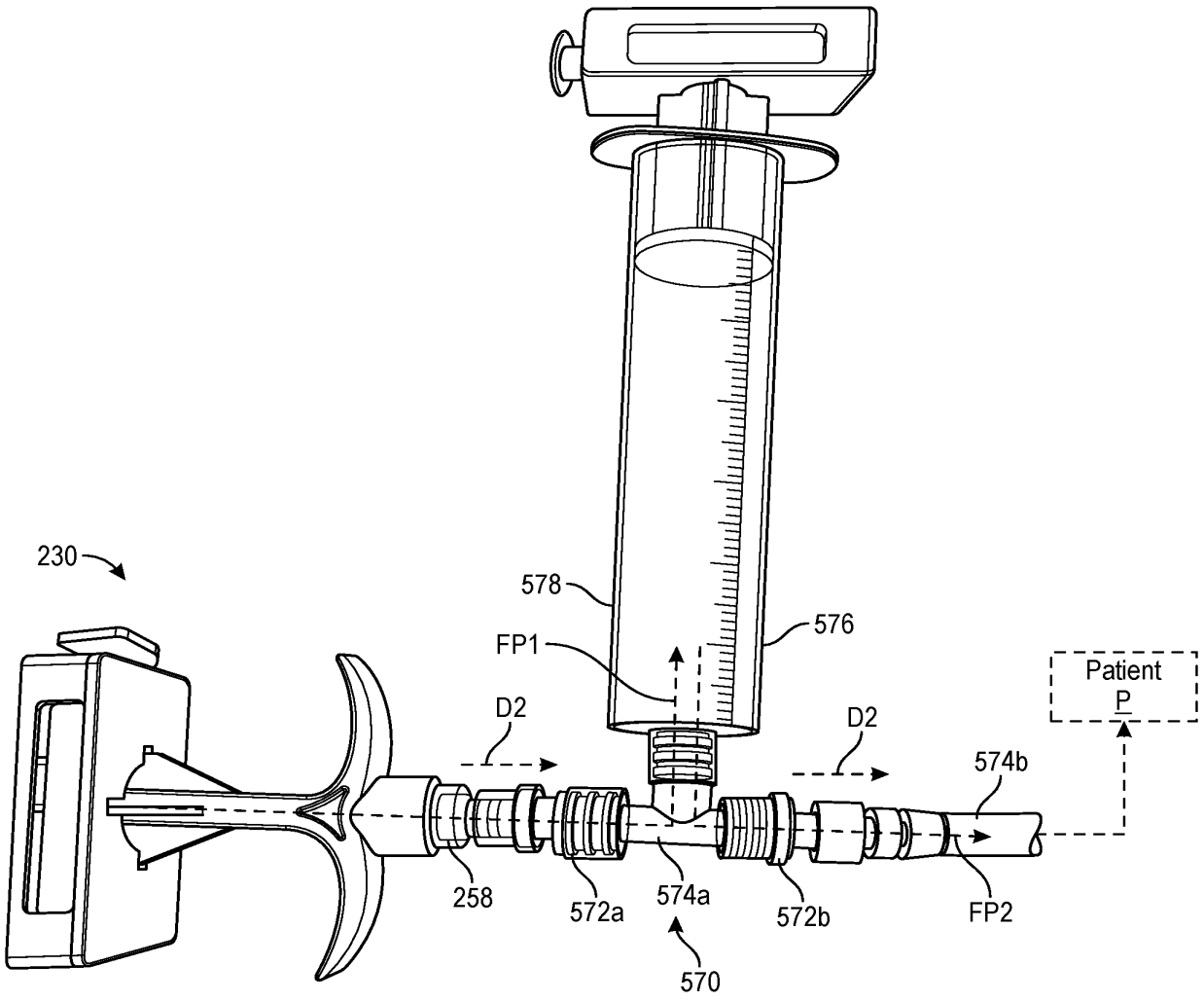


FIG. 5

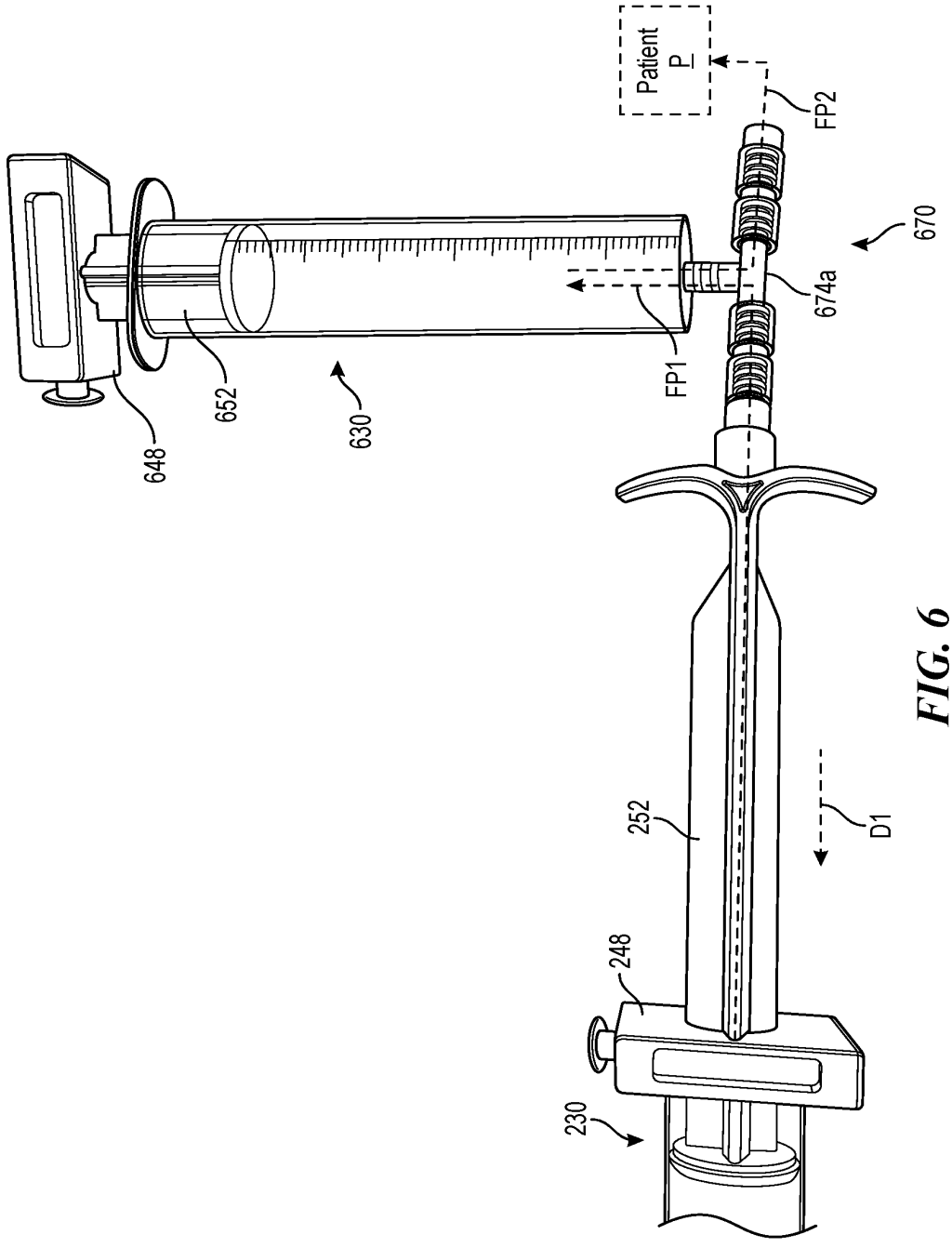


FIG. 6

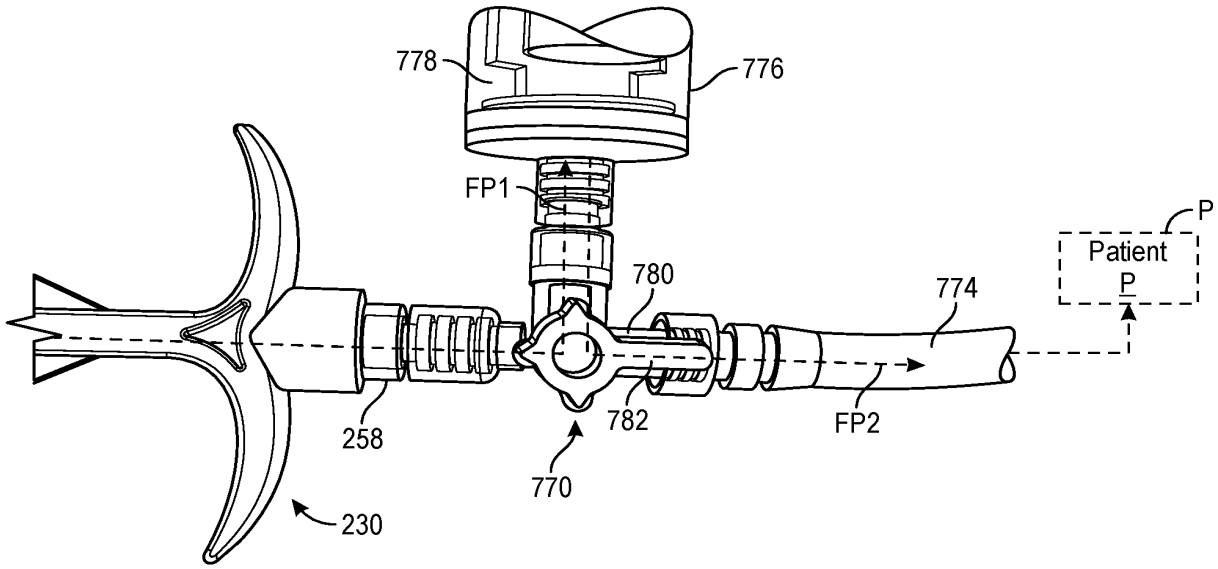

778
776
FP1
P
Patient
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FP2
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230

FIG. 7A

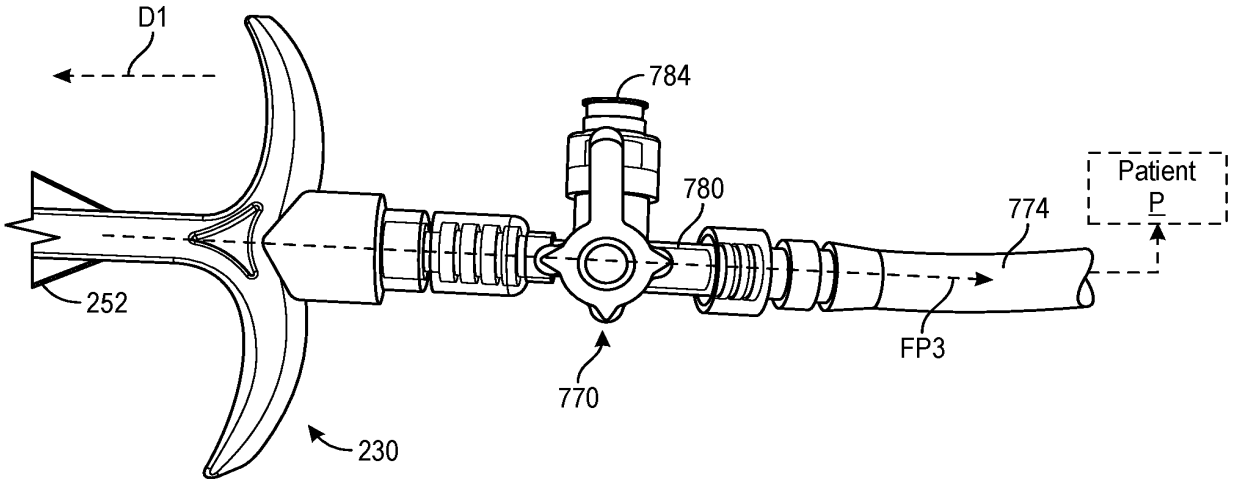

D1
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Patient
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252
FP3
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FIG. 7B

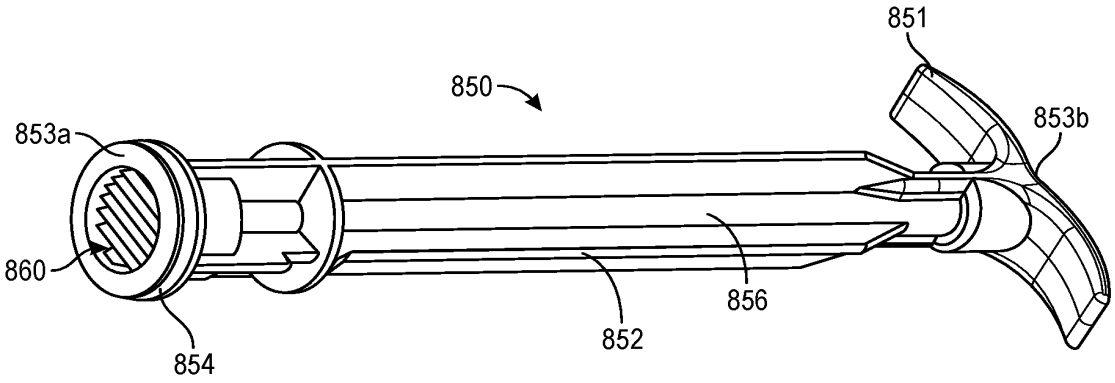


FIG. 8A

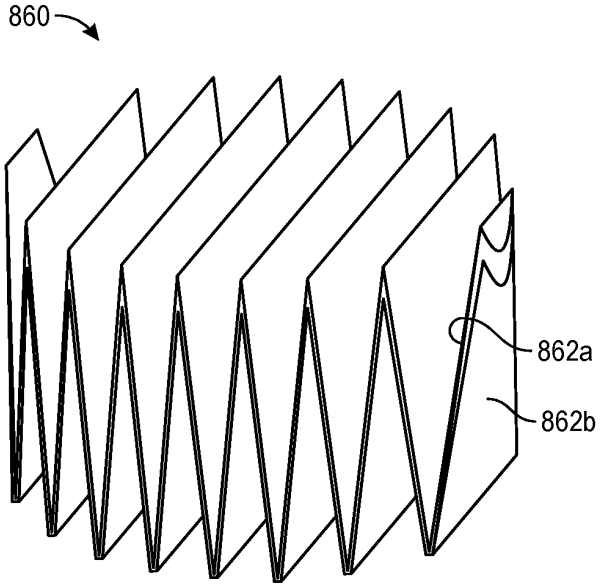


FIG. 8B

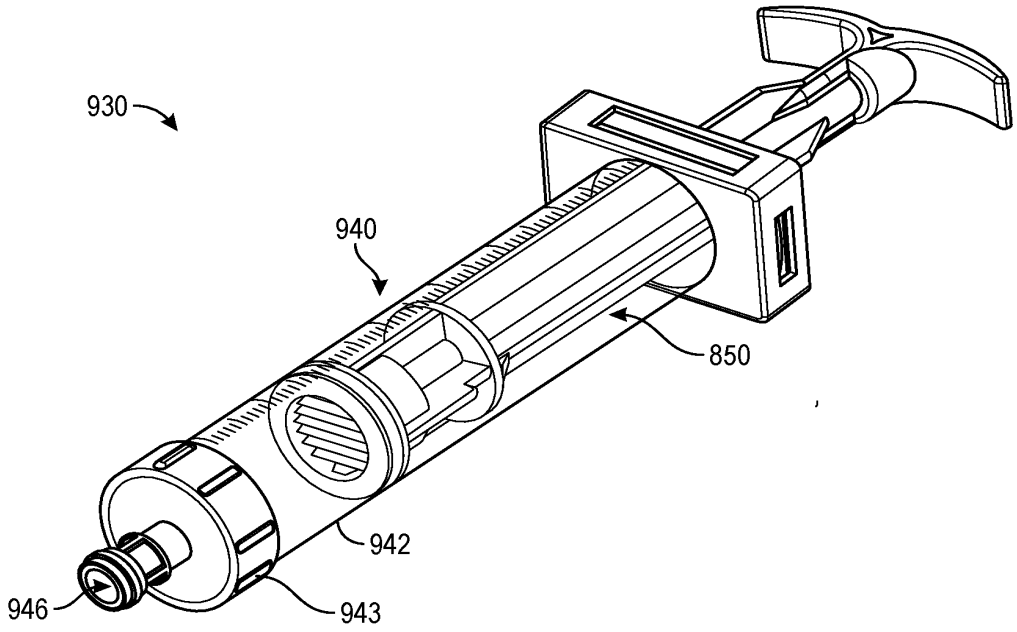


FIG. 9A

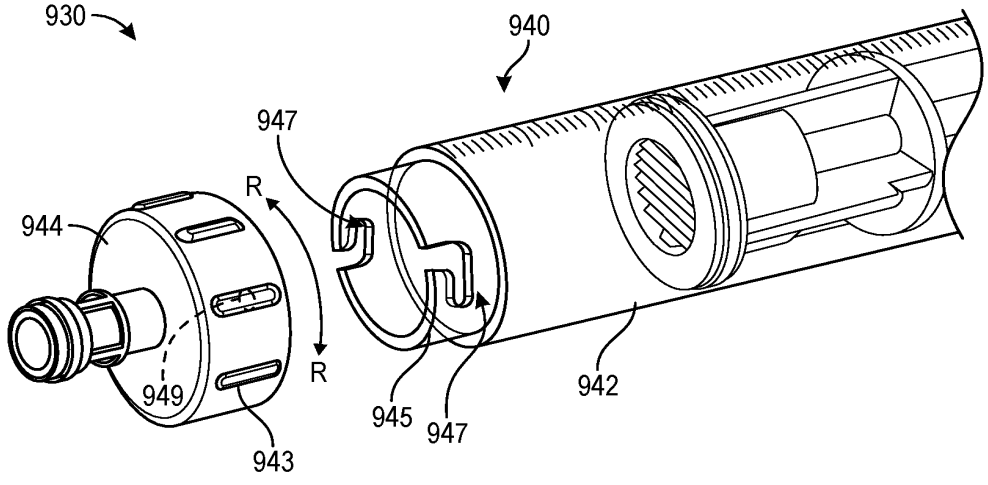


FIG. 9B

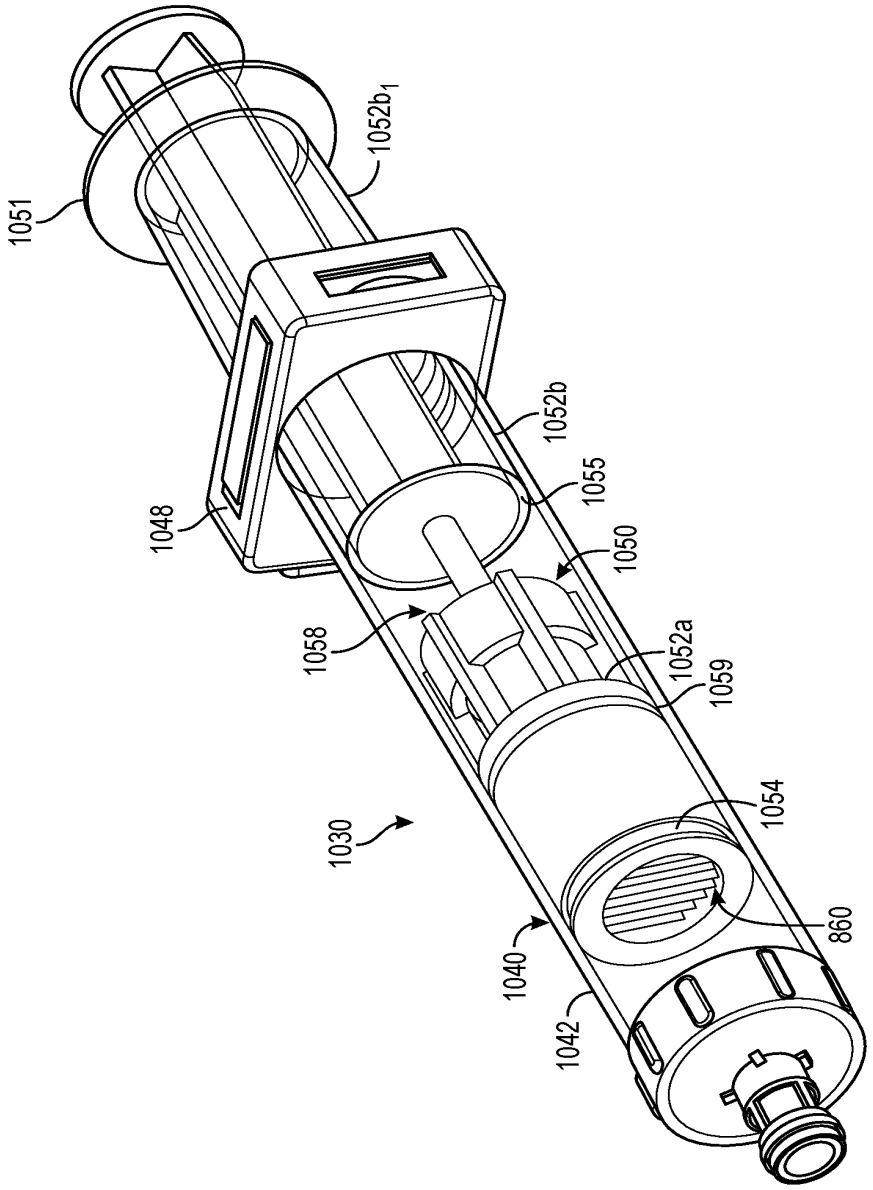

1051
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1042

FIG. 10

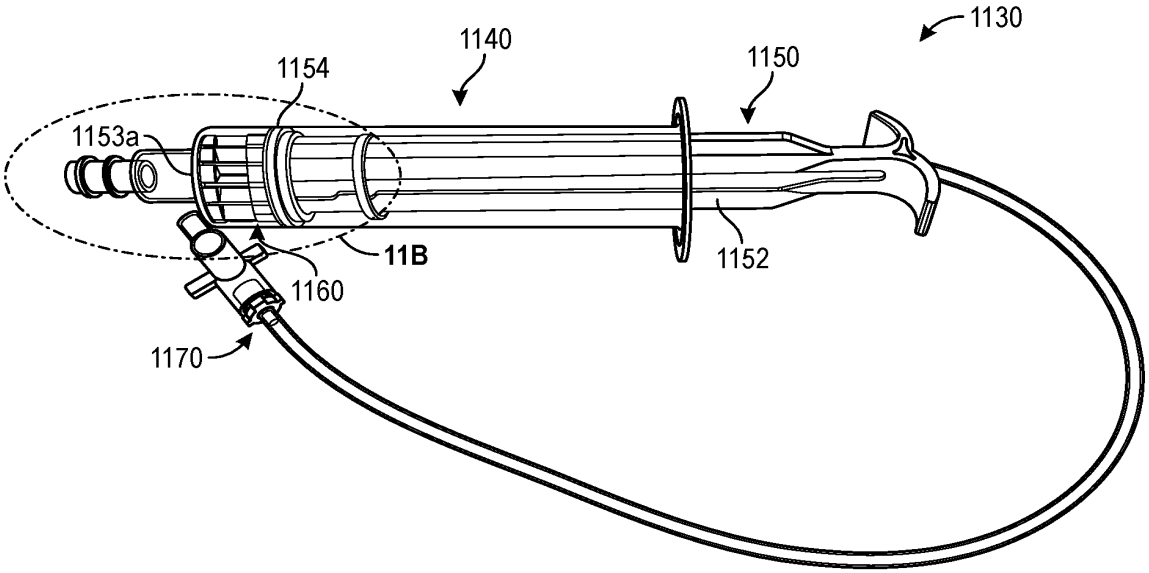


FIG. 11A

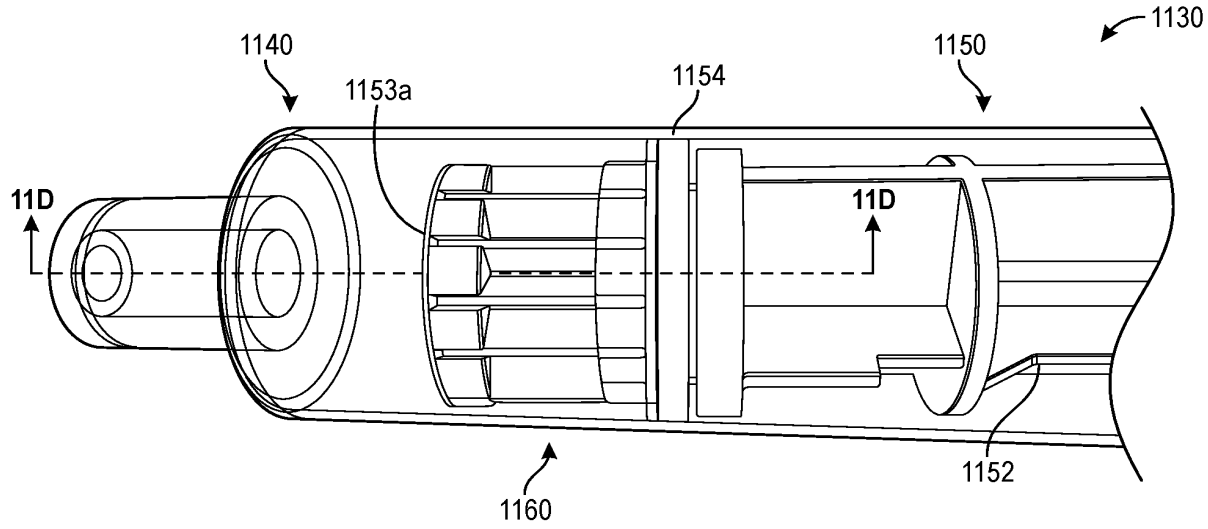


FIG. 11B

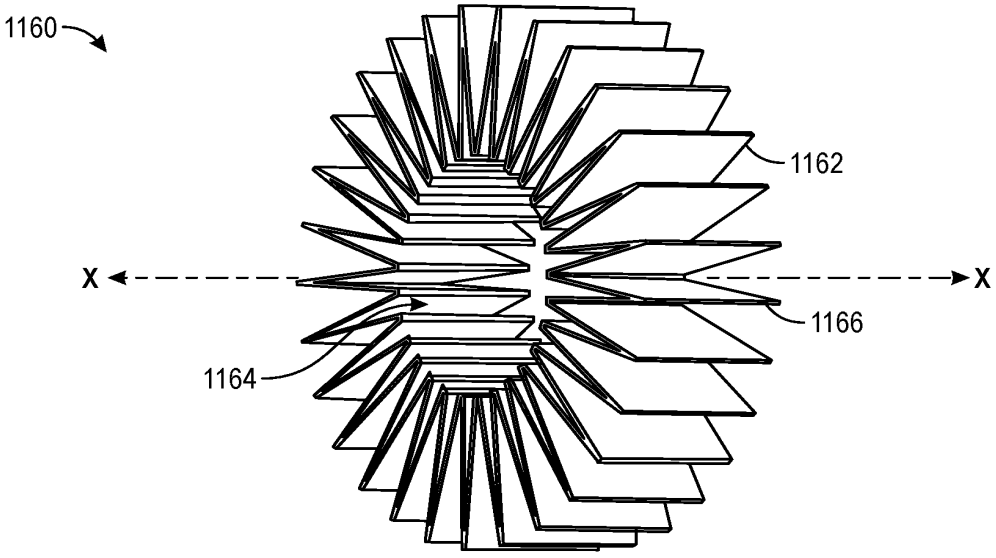


FIG. 11C

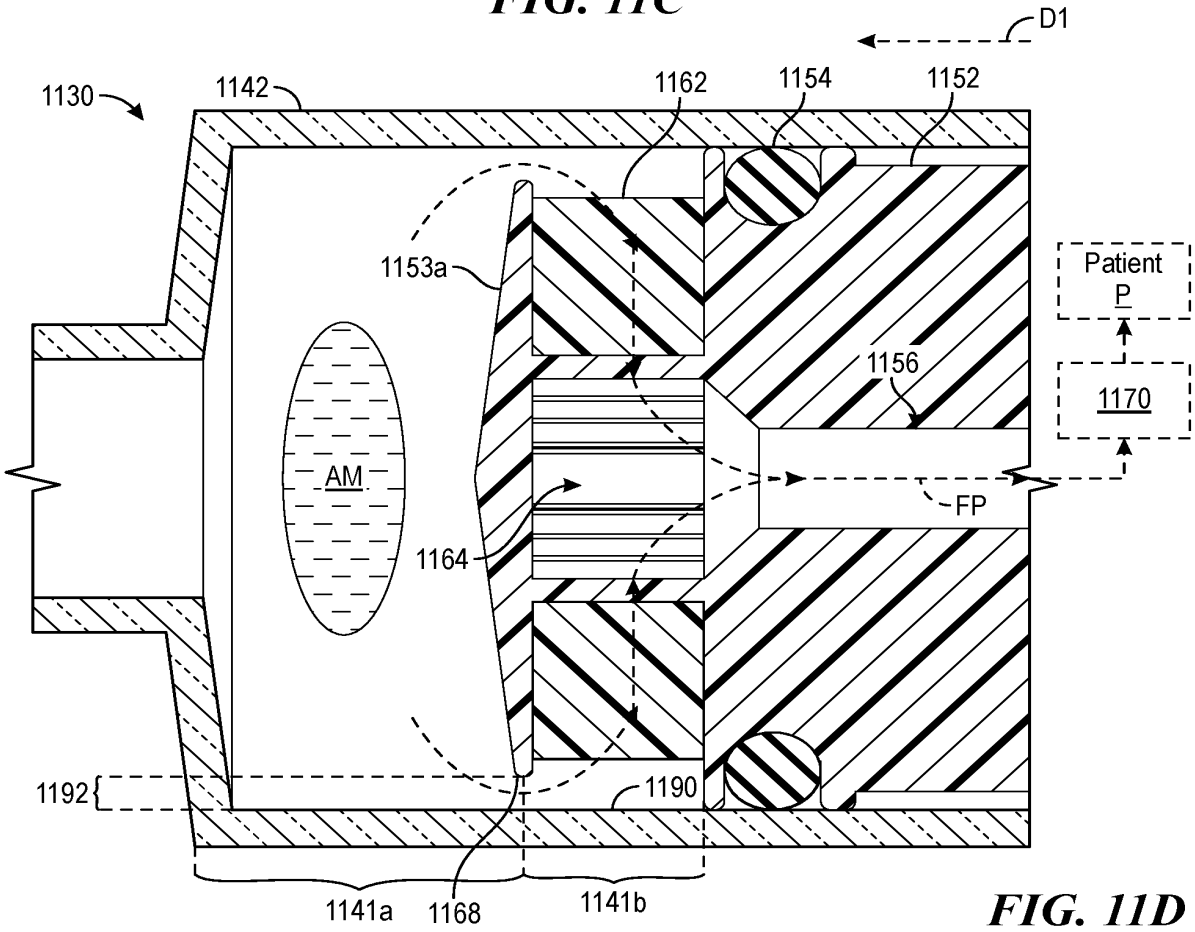


FIG. 11D

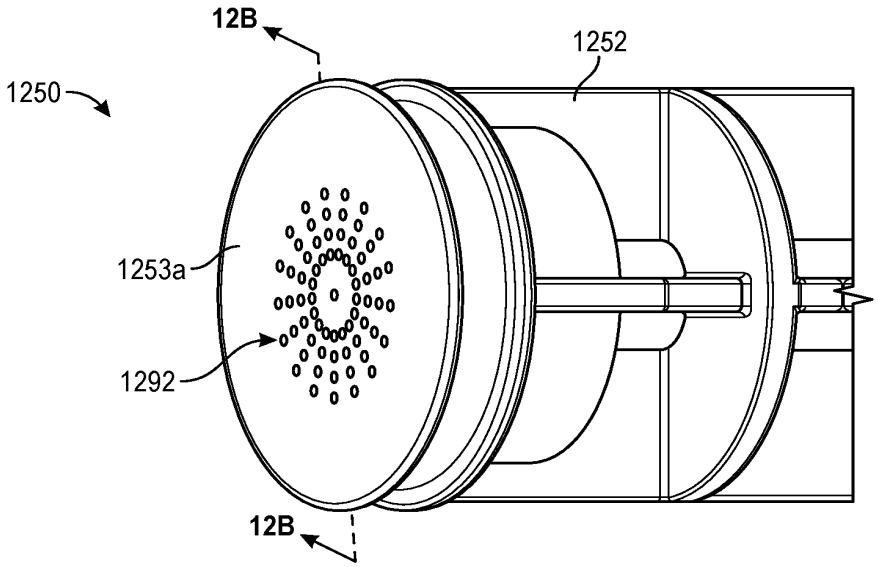


FIG. 12A

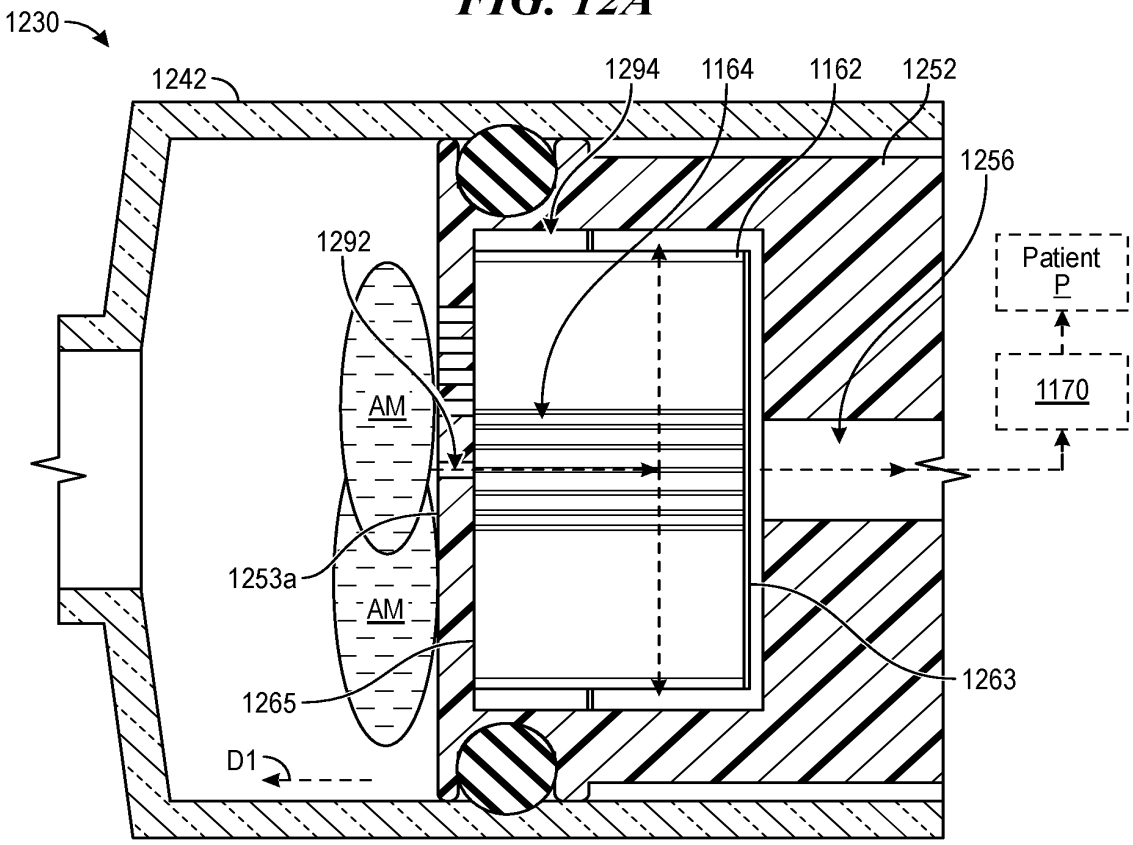


FIG. 12B

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

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

RECEIVED
PATENT DOCKETING

JAN 11 2024

PERKINS COIE LLP

PCT

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

(PCT Rule 44.1)

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

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

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

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

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

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

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

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

4. **Reminders**

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

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

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

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

Name and mailing address of the ISA/US 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 Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/220 (revised January 2020)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

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

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

Applicant
INARI MEDICAL, INC.

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

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

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

1. **Basis of the report**

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

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

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

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

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

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

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

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

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

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

☒ the text is approved as submitted by the applicant.

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

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

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

☒ as suggested by the applicant.

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

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

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 23/86538

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

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

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

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

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

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

This International Searching Authority found multiple inventions in this international application, as follows:
-*- see extra sheet -*-

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

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

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

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-8

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 23/66538

A. CLASSIFICATION OF SUBJECT MATTER

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

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
07 September 2023 (07.09.2023)	JAN 04 2024
Name and mailing address of the ISA/US 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 Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 23/66538

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

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

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

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

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

SPECIAL TECHNICAL FEATURES

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

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

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

COMMON TECHNICAL FEATURES

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

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

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

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

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

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

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

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

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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

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JAN 11 2024

PERKINS COIE LLP

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	JAN 04 2024
Applicant's or agent's file reference 111562-8042WO00	FOR FURTHER ACTION See paragraph 2 below

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

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

Applicant INARI MEDICAL, INC.

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

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

2. FURTHER ACTION

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

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

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

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

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

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 23/66536

Box No. I Basis of this opinion

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

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

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

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

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

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

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

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

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

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 23/66538

Box No. IV Lack of unity of invention

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

   ☐ paid additional fees.

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

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

   ☒ not paid additional fees.

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

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

   ☐ complied with.

   ☒ not complied with for the following reasons:

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

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

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

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

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

SPECIAL TECHNICAL FEATURES

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

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

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

COMMON TECHNICAL FEATURES

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

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

-*- Continued in Supplemental Box -*-

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

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-8

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 23/66538

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

1. Statement

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

2. Citations and explanations:

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

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

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

As to claim 3, Trask discloses the dilator of claim 1 wherein the first body region has a first durometer (the proximal end hence 32a has a durometer of 60-80 shore D, para [0034]), wherein the second body region has a second durometer (the distal end hence 32b has a durometer of 30-70 shore D, para [0034]), and wherein the second durometer is less than the first durometer (see how the distal end has a lower durometer than the proximal end, para [0034]).

As to claim 4, Trask discloses the dilator of claim 1 wherein the first body region comprises a first material (the first section 32a has a first material blend, para [0036]), and wherein the second body region comprises a second material different than the first material (the second section 32b has a second different material blend, para [0036]).

As to claim 5, Trask discloses the dilator of claim 1, further comprising a third body region between the tip and the coupling component (the dilator may have at least two stiffness sections between the proximal and distal ends hence including a third stiffness section, para [0009]), wherein the third body region has a third flexibility profile different than the first flexibility profile or the second flexibility profile (multiple stiffness sections that become less rigid toward's the distal end hence the third region has a different flexibility than the other regions, para [0009]).

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

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

-*-Continued in Supplemental Box-*-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 23/86538

Supplemental Box

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

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

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

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

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

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

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

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

As to claim 6, Route discloses the dilator of claim 1, further comprising a notch positioned between the tip and the coupling component (the distal dilator portion can include detents on an outer surface configured to lock with corresponding features on an inner surface of a lumen, para [0016]; see additional views of a dilator 1340 including distal region 1360 between the tip 1346 and proximal coupling component, Fig 12A; dilator 1340 as described elsewhere, para [0094]; the entire dilator 1340 can be tubular and portion 1360 can include detents on an outer surface to lock with correspondingly shaped features of a catheter, para [0095], para [0016]).

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

As to claim 8, Route discloses the dilator of claim 6 wherein the notch is a first notch, the dilator further comprising a second notch positioned on a proximal or a distal side of the first notch (multiple detents to provide multiple points of locking connection hence further comprising a second notch either proximal or distal to the first notch, para [0017], para [0095]).

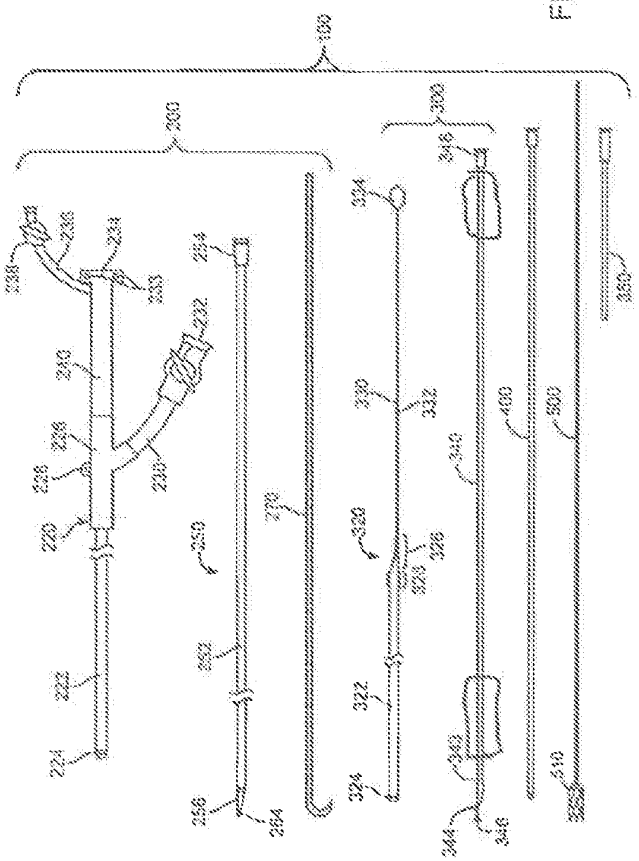
Claims 1-8 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

Supplemental Box

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

Supplemental Fig 1

FIG. 1



SEARCH HISTORY

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

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

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

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

Search Logic:

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

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

Electronic Database Searched	Google
Files Searched	Google Web
Date Conducted	07 September 2023 (07.09.2023)
Search Logic:	

variable stiffness vascular access dilator
About 126,000 results

inari medical vascular access dilator

About 34,100 results

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

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

dilator with varying flexibility
About 8,770 results

vascular catheter and dilator
About 7,410 results

dilator to lock to valve
About 4,020 results

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18/342,553- Conf # 6799
	Filing Date	June 27, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552.8018.US11

U.S. PATENTS AND PUBLICATIONS					
Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	20110152889	06-23-2011	Ashland	
	2.	20230310138	10-05-2023	Merritt et al.	
	3.	20230310137	10-05-2023	Merritt et al.	
	4.	20230310751	10-05-2023	Merritt et al.	
	5.	20030023263	01-30-2003	Krolik et al.	
	6.	20030135151	07-17-2003	Deng	
	7.	20200022711	01-23-2020	Look et al.	
	8.	6017335	01-25-2000	Burnham	
	9.	20040039351	02-26-2004	Barrett	
	10.	20140180055	06-26-2014	Glynn et al.	
	11.	20230329734	10-19-2023	Marchand et al.	
	12.	5242461	09-07-1993	Kortenbach et al.	
	13.	11806033	11-07-2023	Marchand et al.	
	14.	3438607	04-15-1969	Williams et al.	
	15.	4401107	08-30-1983	Harber et al.	
	16.	4634421	01-06-1987	Hegemann	
	17.	5484418	01-16-1996	Quiachon et al.	
	18.	20080087853	04-17-2008	Kees	
	19.	10648268	05-12-2020	Jaffrey et al.	
	20.	20230320834	10-12-2023	Merritt et al.	
	21.	2784717	03-12-1957	E.O. Thompson	
	22.	9884387	02-06-2018	Plha	
	23.	20230338130	10-26-2023	Merritt et al.	
	24.	2010114017	05-06-2010	Lenker et al.	
	25.	20230355259	11-09-2023	Marchand et al.	
	26.	20230355256	11-09-2023	Dinh	
	27.	20230355938	11-09-2023	Merritt et al.	
	28.	20230363883	11-16-2023	Merritt et al.	
	29.	20230363776	11-16-2023	Quick	
	30.	20170113005	04-27-2017	LINDER et al.	
	31.	20110309037	12-22-2011	LEE	

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

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	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552.8018.US11

U.S. PATENTS AND PUBLICATIONS					
Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	32.	20080294096	11-27-2008	Uber, III et al.	
	33.	20130270161	10-17-2013	KUMAR et al.	
	34.	20210316127	10-14-2021	Buck et al.	
	35.	20170172591	06-22-2017	Ulm, III	
	36.	11832837	12-05-2023	Hauser	
	37.	11832838	12-05-2023	Hauser	
	38.	11833023	12-05-2023	Hauser	
	39.	20230390045	12-07-2023	Merritt et al.	
	40.	20230389932	12-07-2023	Ozenne et al.	
	41.	11839393	12-12-2023	Hauser	
	42.	11844921	12-19-2023	Merritt et al.	
	43.	11849963	12-26-2023	Quick	
	44.	20130190701	07-25-2013	Kirn	
	45.	20210128182	05-06-2021	Teigen et al.	
	46.	20170143880	05-25-2017	LUXON et al.	
	47.	3785380	01-15-1974	Brumfield	
	48.	6908455	06-21-2005	Hajianpour	
	49.	7837630	11-23-2010	Nieoson et al.	
	50.	20090312786	12-17-2009	Trask et al.	
	51.	20120095448	04-19-2012	KAJII	
	52.	20160220795	08-04-2016	KORKUCH et al.	
	53.	20130123705	05-16-2013	Holm et al.	
	54.	11890180	02-06-2024	Merritt et al.	
	55.	20140163615	06-12-2014	Gadlage et al.	
	56.	5323514	06-28-1994	Masuda et al.	
	57.	5911728	06-15-1999	Sepetka et al.	
	58.				
	59.				
	60.				

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

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	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552.8018.US11

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[5]
	1.	WO2023192925	10-05-2023	Inari Medical, Inc.		
	2.	WO2019173475	09-12-2019	Innovative Cardiovascular Solutions, LLC		
	3.	WO2023215779	11-09-2023	Inari Medical, Inc.		
	4.					
	5.					
	6.					

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
		Extended European Search Report issued for EP Application No. 20877370.5, Date of Mailing: October 17, 2023, 11 pages.	
		International Search Report and Written Opinion for International App. No. PCT/US23/65128; Date of Filing: March 30, 2023, Applicant: Inari Medical, Inc., Date of Mailing: November 14, 2023, 14 pages.	
		International Search Report and Written Opinion for International App. No. PCT/US23/66538; Date of Filing: May 3, 2023, Applicant: Inari Medical, Inc., Date of Mailing: January 4, 2024, 14 pages.	

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

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

CERTIFICATION STATEMENT

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

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

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

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

SIGNATURE

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

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2024-02-06
Name/Print	Matthew S. Williams	Registration Number	77,516

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(54) Title: EMBOLIC PROTECTION DEVICE

(57) Abstract: The present invention includes an embolic protection device comprising a catheter having a self-expanding embolic filter that is disposed around the catheter proximal to a distal portion, wherein the embolic filter comprises a frame, and the frame defines an opening of the embolic filter that faces the distal end of the catheter; a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon the longitudinal retraction of the deployment mechanism; and a wire coupled to the frame for expanding the size or diameter of the embolic filter opening.

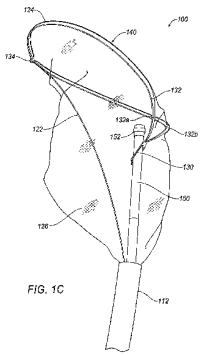


FIG. 1C

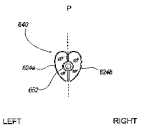


FIG. 6C

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[Continued on next page]

TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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EMBOLIC PROTECTION DEVICE

CROSS REFERENCE TO RELATED APPLICATION

[0001] This PCT application claims the benefit of U.S. provisional application no. 62/639,618, filed on March 7, 2018, and U.S. provisional application no. 62/812,391, filed on March 1, 2019. Each of these documents is hereby incorporated by reference in its entirety.

TECHNICAL FIELD

[0002] This application relates to embolic protection devices including a catheter and methods of using such embolic protection devices in medical procedures (e.g., closed-heart surgical procedures).

BACKGROUND

[0003] Traditional pigtail catheters are used during percutaneous cardiac procedures where the positioning of various instruments and devices within the vasculature of a patient is important. These pigtail catheters comprise a curved distal end that can rest within the patient's anatomy (e.g., an artery (e.g., aorta)) and hold the catheter in place while other instrumentation and devices are delivered into the patient's vasculature. Some traditional pigtail catheters include a lumen and small apertures at their distal ends through which a contrast agent can be injected into a patient's vasculature for imaging the relevant portion of the patient's anatomy and identifying anatomical landmarks.

[0004] However, the use of traditional pigtail catheters in percutaneous cardiac procedures often results in serious and life-threatening complications for the patient. For example, cerebral embolism is a common complication in cardiac procedures, such as valve replacement and repair, where a traditional pigtail catheter is deployed. During such procedures, plaque, calcium, thrombi, or any combination thereof, in the vessels, valves, and/or cardiac chambers can be dislodged by the catheter or other medical devices introduced into the patient's vasculature. The dislodged plaque, calcium, thrombi or any combination thereof can be carried into the patient's brain via blood flow from the aorta and can cause blockages therein leading to an embolic event such as stroke. Approximately 2.9%-6.7% of patients undergoing transfemoral transcatheter aortic-valve implantation (TAVI) have a stroke within 30 days, and even more (4.5%-10.6%) have a stroke within a year, often leading to death. Furthermore, up to 85% of patients undergoing TAVI have evidence of embolic phenomenon to the brain based on neuroimaging studies. Although clinically silent, such embolic phenomena are associated with cognitive decline (Astraci 2011; Ghanem 2010; Kahlert 2010; Rodes-Caban 2011).

[0005] Presently, there are a few devices on the market designed to protect the brain, abdominal organs, and carotid arteries from emboli, and these devices suffer from various significant drawbacks. For instance, the Embrella Embolic Deflector®, available from Edwards Lifesciences of Irvine, California, employs a deflector that deflects emboli from the carotid arteries into the descending aorta, but the device does not trap the emboli, so emboli are free to travel to other areas of the body and cause deleterious complications. The EMBOL-X®, also available from Edwards Lifesciences, employs a filtering screen, but this device is designed for use in open heart procedures, which present additional medical risks and increased morbidity. Additionally, the use of multiple devices, for example a catheter for visualization and a separate filter device, lengthens the procedure time and increases the risk of complications to the patient.

SUMMARY

[0006] These and other needs are met by the present invention, which presents an embolic protection device comprising a deployable embolic filter that is disposed around a catheter having a distal portion that can assume an arcuate configuration being at least a semi-circle, and having a wire that is operable to manipulate the embolic filter into a configuration that more fully engages a body lumen.

[0007] The combination of the catheter and the embolic filter in the same device may provide the benefits of both devices individually, as well as provide a synergistic effect. For example, the integration of the catheter and the embolic filter can decrease the duration of the medical procedure and reduce the occurrence of complications (e.g., complications caused by dislodged emboli). In other examples, the expansion of the embolic filter may help to anchor the catheter into position to provide a more accurate position of the catheter than if the position of the catheter is susceptible to the influences of blood flow, tissue movement, and the like. In a valve replacement procedure, anchoring of the catheter and more accurate positioning of the catheter may help ensure that the valve prosthesis is properly positioned and stabilized. In another example, the position of the catheter may ensure that the filter is being properly positioned.

[0008] In some aspects, the embolic protection device comprises a catheter, a self-expanding embolic filter coupled to the catheter, a pull wire for reorienting the filter by bending a frame of the filter, and an outer sheath movable with respect to the embolic filter and the catheter. The outer sheath holds the embolic filter in a collapsed configuration when surrounding the embolic filter and is proximally retracted to deploy the embolic filter. The outer sheath may recapture the embolic filter and any debris captured therein by being distally advanced. The filter and outer sheath might both be movable with respect to the catheter, for example to be

able to move the embolic filter longitudinally without having to move the entire catheter longitudinally. The pull wire is advantageous due to its ability to bend the frame, thereby facing the filter opening towards the distal end of the device and causing the embolic filter to more fully engage the body lumen.

[0009] In some aspects, the catheter has a proximal end and a distal end. A lumen extends from the proximal end of the catheter to the distal end of the catheter. In some embodiments, the lumen may be configured to house a guidewire.

[0010] In some aspects, the catheter is a pigtail catheter. A pigtail catheter is configured to curl at the distal end of the catheter, forming a generally arcuate shape that is at least a semi-circle. The pigtail may have a radiopaque marker viewable on x-rays or other medical imaging devices. The radiopaque marker is on the distal section of the curled pigtail in the form of a longitudinal marker, circumferential bands, or the like. The pigtail may additionally have one or more apertures to dispense drugs and/or contrast agents through the lumen.

[0011] In some aspects, a guidewire is inserted through the patient's skin and into a body lumen such as a femoral, radial, or brachial artery and steered near a target site. The guidewire is inserted into a lumen of the embolic protection device, and the embolic protection device is pushed or tracked over the guidewire to the target site. When the guidewire is retracted from at least the distal portion of the catheter, the catheter assumes a generally arcuate shape. The radiopaque marker on the catheter is used to visualize and position the catheter. Once the catheter is in position, the outer sheath is retracted to deploy the embolic filter and the pull wire is retracted to bend the frame of the filter to position the distal opening of the filter across the vessel. The user can then perform a procedure such as valve replacement, valve repair, radio frequency ablation, and the like. When the procedure is completed, the pull wire is advanced and the outer sheath is advanced to recapture the embolic filter and any debris trapped in the embolic filter. The device is then retracted from the vessel, with the catheter being atraumatic to vessels during retraction.

[0012] Another aspect is a method of capturing embolic debris during a closed-heart surgical procedure comprising inserting the distal end of the catheter of the embolic protection device into a body lumen. The method further comprises allowing the embolic filter to assume an expanded, deployed configuration and retracting the pull wire to bend the frame of the filter, so that a distal opening of the filter spans the body lumen.

[0013] In some aspects, the embolic protection device comprises a catheter, a self-expanding embolic filter coupled to the catheter, a push wire for reorienting the filter by bending a frame of the filter in a longitudinal direction and extending the frame in a radial direction, and an

outer sheath movable with respect to the embolic filter and the catheter. The outer sheath holds the embolic filter in a collapsed configuration when surrounding the embolic filter and is proximally retracted to deploy the embolic filter. The outer sheath may recapture the embolic filter and any debris captured therein by being distally advanced. The push wire is advantageous due to its ability to bend and extend the frame, thereby facing the filter opening towards the distal end of the device and causing the embolic filter to more fully engage the body lumen.

[0014] In some aspects, the catheter has a proximal end and a distal end. A lumen extends from the proximal end to the distal end along a longitudinal axis of the catheter. In some embodiments, the lumen may be configured to house a guidewire.

[0015] In some aspects, the catheter is a pigtail catheter. A pigtail catheter is configured to curl at the distal end of the catheter, forming a generally arcuate shape that is at least a semi-circle. The pigtail may have a radiopaque marker viewable on x-rays or other medical imaging devices. The radiopaque marker is on the distal section of the curled pigtail in the form of a longitudinal marker, circumferential bands, or the like. The pigtail may additionally have one or more apertures to dispense drugs and/or contrast agents through the lumen.

[0016] In some aspects, a guidewire is inserted through the patient's skin and into a body lumen such as a femoral, radial, or brachial artery and steered near a target site. The guidewire is inserted into a lumen of the embolic protection device, and the embolic protection device is pushed or tracked over the guidewire to the target site. When the guidewire is retracted from at least the distal portion of the catheter, the catheter assumes a generally arcuate shape. The radiopaque marker on the catheter is used to visualize and position the catheter. Once the catheter is in position, the outer sheath is retracted to deploy the embolic filter and the push wire is advanced to bend and extend the frame of the filter to position the distal opening of the embolic filter across the vessel. The user can then perform a procedure such as valve replacement, valve repair, radio frequency ablation, and the like. When the procedure is completed, the push wire is retracted and the outer sheath is advanced to recapture the embolic filter and any debris trapped in the embolic filter. The device is then retracted from the vessel, with the catheter being atraumatic to vessels during retraction.

[0017] Another aspect is a method of capturing embolic debris during a closed-heart surgical procedure comprising inserting the distal end of the catheter of the embolic protection device into a body lumen. The method further comprises allowing the embolic filter to assume an expanded, deployed configuration and advancing the push wire to bend and extend the frame of the filter, so that a distal opening of the filter spans the body lumen.

BREF DESCRIPTION OF THE FIGURES

[0018] The following figures are provided by way of example and are not intended to limit the scope of the claimed invention.

[0019] FIGS. 1A and 1B illustrate partial side views of an embodiment of an embolic protection device of the present invention. In FIG. 1A, an embolic filter of the embolic protection device is illustrated in a collapsed (undeployed) configuration. In FIG. 1B, the embolic filter is illustrated in an expanded (deployed) configuration wherein a pull wire affixed to a frame of the embolic filter is advanced to a distal position so that the frame assumes it's self-expanded and undeflected (i.e., unbent) configuration.

[0020] FIG. 1C illustrates a side perspective view of an embodiment of an embolic filter of the present invention assuming a partially deflected (i.e., partially bent) configuration wherein the pull wire affixed to the frame of the embolic filter is partially longitudinally retracted to a proximal position.

[0021] FIG. 1D illustrates a transverse cross-sectional view of an embodiment of an embolic filter of the present invention assuming a fully deflected (e.g., fully bent) configuration wherein the pull wire is fully longitudinally retracted thereby deflecting the filter.

[0022] FIGS. 1E and 1F illustrate front views of an embodiment of an embolic filter frame of the present invention. In FIG. 1E, the filter frame is undeployed wherein the frame is collapsed and enclosed by an outer sheath. In FIG. 1F, the outer sheath is longitudinally retracted and the filter frame is deployed to its self-expanded configuration.

[0023] FIGS. 2A – 2B illustrate partial side views of an embodiment of an embolic protection device of the present invention comprising a shoulder.

[0024] FIGS. 3A – 3D illustrate partial side views of an embodiment of an embolic protection device of the present invention comprising an intermediate tube.

[0025] FIGS. 4A – 4C illustrate partial side views of an embodiment of an embolic protection device of the present invention comprising a deflector.

[0026] FIG. 5A illustrates an embodiment of an embolic protection device comprising a handle. FIG. 5B illustrates a distal portion of the embolic protection device comprising the embolic filter and pigtail catheter.

[0027] FIG. 6A illustrates a partial side view of an embodiment of an embolic protection device of the present invention with an embolic filter in a collapsed (undeployed) configuration.

[0028] FIGS. 6B and 6C illustrate a side view and a front end view of the embolic filter in an self-expanded (deployed) configuration, respectively, wherein a push wire coupled to a frame

of the embolic filter is retracted to a proximal position so that the frame assumes an undeflected (i.e., unbent) configuration.

[0029] FIGS. 6D and 6E illustrate a side view and a front end view of the embolic filter in an partially expanded configuration, respectively, wherein the push wire coupled to the frame of the embolic filter is longitudinally advanced to a first distal position so that the frame assumes a deflected (i.e., bent) configuration.

[0030] FIGS. 6E and 6F illustrate a side view and a front end view of the embolic filter in an fully expanded configuration, respectively, wherein the push wire coupled to the frame of the embolic filter is longitudinally advanced to a second distal position farther than the first distal position shown in FIG. 6C so that the frame assumes an extended configuration.

[0031] FIGS. 7A – 7C illustrate partial side views of an embodiment of an embolic protection device of the present invention having an actuating mechanism for operating an embolic filter.

[0032] FIGS. 8A and 8B illustrate an embodiment of an embolic protection device of the present invention having a handle for manually operating an embolic filter.

[0033] FIGS. 8C – 8F illustrate an example of the handle.

[0034] FIGS. 9A – 9E illustrate a stepwise method of using an embolic protection device of the present invention.

[0035] FIG. 10 illustrates the deflection and capture of embolic debris by an embolic protection device of the present invention comprising a deflector.

[0036] FIG. 11 illustrates the deflection and capture of embolic debris by an embolic protection device of the present invention wherein a second catheter device is present.

[0037] FIGS. 12A – 12D illustrate a stepwise method of using an embolic protection device of the present invention operating an embolic filter.

[0038] FIGS. 13A and 13B are photographs of distal portions of embolic protection devices of the present invention situated within a cadaver's vasculature according to Example 1. In FIG. 13A, the embolic protection device comprises a longitudinal groove in which a second catheter is inserted alongside the embolic protection device. In FIG. 13B, the second catheter is situated adjacent to the embolic protection device that lacks a longitudinal groove.

[0039] FIG. 14 is a bar graph of performance data of an embolic protection device of the present invention (the EPD-1 device) according to Example 2.

[0040] FIGS. 15A – 15J are images generated from diffusion-weighted magnetic resonance imaging (DW-MRI) of representative subjects according to Example 2.

[0041] FIG. 16A is a photograph of thrombi captured by an embolic protection device of the present invention (the EPD-1 device) according to Example 2.

[0042] FIG. 16B is a photograph of a collagenous fragment captured within the filter of the embolic protection device (the EPD-1 device) according to Example 2.

[0043] Like reference numerals in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0044] The present invention provides an embolic protection device and methods of using the embolic protection device for capturing embolic debris during surgical procedures.

[0045] I. DEFINITIONS

[0046] As used herein, the term "self-expanding" means to increase, spread out, or unfold from a collapsed state upon the withdrawal or removal of a restricting or confining force.

[0047] As used herein, the term "closed-heart" refers to any surgical procedure involving the heart, wherein the chest cavity is not opened.

[0048] As used herein, the term "woven" refers to any material that comprises a plurality of strands, wherein the strands are interlaced to form a net, mesh, or screen. Without limitation, examples of woven materials include netting or mesh comprising a polymer, metal, or metal alloy.

[0049] As used herein, the term "non-woven" refers to any material that comprises a continuous film. Non-woven material may be permeable, semi-permeable, or non-permeable. For example, permeable or semi-permeable non-woven material may optionally include one or more pores through which a fluid may pass.

[0050] As used herein, the term "alloy" refers to a homogenous mixture or solid solution produced by combining two or more metallic elements, for example, to give greater strength or resistance to corrosion. For example, alloys include brass, bronze, steel, nitinol, chromium cobalt, MP35N, 35NLT, elgiloy, and the like.

[0051] As used herein, "nitinol" and "nickel titanium" are used interchangeably to refer to an alloy of nickel and titanium.

[0052] As used herein, "chromium cobalt" refers to an alloy of chromium and cobalt.

[0053] As used herein, "MP35N" refers to an alloy of nickel and cobalt.

[0054] As used herein, "35NLT" refers to a cobalt-based alloy that may also comprise chromium, nickel, molybdenum, carbon, manganese, silicon, phosphorus, sulphur, titanium, iron, and boron.

[0055] As used herein, "elgiloy" refers to an alloy of cobalt, chromium, nickel, iron, molybdenum, and manganese.

[0056] As used herein, a "body lumen" refers to the inside space of a tubular structure in the body, such as an artery, intestine, vein, gastrointestinal tract, bronchi, renal tubules, and urinary collecting ducts. In some instances, a body lumen refers to the aorta.

[0057] II. EMBOLIC PROTECTION DEVICES

[0058] Although certain embodiments and examples are described below, those skilled in the art will recognize that the disclosure extends beyond the specifically disclosed embodiments and/or uses and obvious modifications and equivalents thereof. Thus, it is intended that the scope of the disclosure herein presented should not be limited by any particular embodiments described below.

[0059] For purposes of this disclosure, the terms "upper," "lower," "right," "left," "rear," "front," "vertical," "horizontal," and derivatives thereof shall relate to the invention as oriented in FIGS. 1B and 1F (or in FIGS. 6B and 6C). However, it is to be understood that the invention may assume various alternative orientations, except where expressly specified to the contrary. Also, for purposes of this disclosure, the term "coupled" (in all of its forms, couple, coupling, coupled, etc.) generally means the joining of two components (electrical or mechanical) directly or indirectly to one another. Such joining may be stationary in nature or movable in nature; may be achieved with the two components (electrical or mechanical) and any additional intermediate members being integrally formed as a single unitary body with one another or with the two components; and may be permanent in nature or may be removable or releasable in nature, unless otherwise stated.

[0060] FIGS. 1A and 1B illustrate embodiments of an embolic protection device 100. In these embodiments, the device 100 comprises a catheter 102 (e.g., a pigtail catheter) having a proximal end 114, a distal end 116, and a lumen 118 extending from the proximal end 114 to the distal end 116. The lumen 118 may be configured to house a guidewire 990 (see FIGS. 9A and 9B) that is longitudinally moveable through this lumen to coil or straighten the distal portion 104 of the catheter 102 depending on whether the guidewire is retracted (to coil the distal portion) or extended (to straighten the distal portion). In some embodiments, the catheter 102 includes a distal portion 104 configured to assume a generally arcuate shape being at least a semi-circle. A side wall of the catheter 102 may optionally include one or more apertures 108 in the distal portion 104 that are configured to deliver one or more fluids (e.g., imaging dye, contrast agent, oxygenated blood, saline, any combination thereof, or the like) to a body lumen 992 (see FIG. 9A). The apertures 108 (the plural intended to include embodiments in which the distal portion includes one aperture 108) are in fluid communication with the lumen 118. In some embodiments, the distal portion 104 of the catheter 102 includes one or more radiopaque markers 106. In some embodiments, the radiopaque markers 106 are wrapped around the circumference of the distal portion of the catheter and can have the same or different widths. In other embodiments, the radiopaque markers are co-linear with the lumen and extend to the distal end of the catheter. The device

100 further comprises a self-expanding embolic filter 110 defined by a frame 124 and a filter medium 126, and a deployment mechanism 112 (e.g., a longitudinally retractable outer sheath or a longitudinally retractable ring). The embolic filter 110 is disposed around the catheter 102.

[0061] As illustrated in FIG. 1B, in its deployed configuration, the embolic filter 110 includes a distal opening 140 that is defined by the frame 124, faces the distal end 116 of the catheter 102, and extends proximally from the distal opening 140 to a closed proximal end 142. The device 100 further comprises a pull wire 122 that is coupled to the frame 124 and can be retracted to deflect or bend the frame 124 and change the orientation and shape of the distal opening 140.

[0062] In some embodiments, retracting the pull wire 122 may cause the distal opening 140 of the embolic filter 110 to engage at least a portion of the interior body lumen 992 (see FIG. 9D) wall. FIG. 1B illustrates the pull wire 122 in an advanced, i.e., un-retracted or self-expanded, configuration with the frame oriented generally to extend in a distal longitudinal direction, albeit angled back somewhat (e.g., less than about 45 degrees) in a lateral direction. The catheter 102 may be partially surrounded towards its proximal end 114 by a support catheter 150 that terminates at a head 152, proximal to the distal portion 104 of the catheter 102. The support catheter 150 may be made of a thicker, stiffer material to add rigidity and provide a protective or supporting layer surrounding the catheter 102.

[0063] FIG. 1C illustrates the embolic filter 110 deployed (e.g., self-expanded) by retraction of the deployment mechanism (e.g., outer sheath) 112 with the frame 124 partially deflected, i.e., partially bent, by retraction of the pull wire 122. The pull wire 122 is coupled to the frame 124 at a distal coupling 134. The distal opening 140 is primarily defined by a first portion 132 of the frame 124. The first portion 132 of the frame 124 defines a shape of the distal opening 140 that is substantially elliptical (i.e., shaped like an ellipse), or alternatively, substantially oval-shaped or circular. In this embodiment, the portion 132 of the frame 124 may be substantially elliptical and may terminate a V-shaped point at its proximal end, i.e., the portion 132 of the frame 124 may invert its curvature at one end of its substantially elliptical shape (e.g., at its distal end) and come to a point at its proximal end. The distal opening 140 may substantially be defined by the frame 124, but may span across the frame 124 adjacent to the section of the frame 124 that comes to a point. The filter medium 126 may define a portion of the distal opening 140 where the filter medium 126 spans across the frame 124, i.e., adjacent to a point of attachment of the frame 124 to the catheter 102 or support catheter 150.

[0064] The attachment of the frame 124 to the support catheter 150 (or alternatively, directly to the catheter 102) is accomplished via a second portion 130 of the frame 124, which encircles the support catheter 150 (or catheter 102) and is at an angle with respect to the longitudinal axis of the catheter 102. The second portion 130 of the frame 124 may be fixed in its position by friction and by tension of the embolic filter 110 in the lateral and/or longitudinal directions. In other embodiments, the fixed attachment of the second portion 130 of the frame 124 to the support catheter 150 (or catheter 102) may also be accomplished via adhesives, welding, or the like.

[0065] The first portion 132 of the frame 124 may extend in a first lateral direction away from the catheter 102 and away from the second portion 130 of the catheter 102 and loop back across the catheter 102 and extend in the opposite lateral direction. In this embodiment, the first portion 132 of the frame 124 comprises two sides (132a, 132b) that each extend generally in a first lateral direction away from the catheter 102 and then loop back on opposite sides around the catheter 102 and extend generally in the opposite lateral direction before converging and meeting to form the substantially elliptical shape. As shown in FIG. 1F, the embolic filter 110 is symmetrical about the pull wire 122. For ease of discussion, the embolic filter 110 is referred as having a left side and a right side. Elements on the left side of the embolic filter 110 are mirrored by elements on the right side of the embolic filter 110.

[0066] When the pull wire 122 is in its advanced state (or partially, but not fully, retracted state), the frame 124 extends in a distal longitudinal direction as it extends from its attachment to the catheter 102 (or support catheter 150). When the pull wire 122 is in its retracted state (i.e., fully retracted) (see FIG. 1D and FIG. 9E), the frame 124 extends in a distal longitudinal direction near its point of attachment to the catheter 102, but then is bent such that it extends substantially perpendicular to the longitudinal axis of the catheter 102.

[0067] FIG. 1D presents a cross-sectional view of the distal opening 140 of the embolic filter 110 when the embolic filter 110 assumes an expanded configuration and when the pull wire 122 is in a fully retracted state, fully deflecting (or bending) the frame 124. The pull wire 122 deflects or bends the frame 124 in a proximal longitudinal direction and laterally outward. In a fully deflected configuration (i.e., when the pull wire 122 is fully retracted), the distal opening 140 of the embolic filter 110 may be substantially perpendicular to the longitudinal axis of the catheter 102 and may span laterally across the body lumen 992 (see FIGS. 9D and 9E), substantially perpendicular to the longitudinal axis of the body lumen 992. The fully deflected (or bent) configuration may allow the embolic filter 110 to more fully engage the body lumen 992. In this fully deflected configuration, the distal opening 140 is substantially perpendicular to the longitudinal axis of the catheter 102. In the fully deflected

configuration, the width, x, across the distal opening 140 may be increased compared to the corresponding dimension in the undeflected configuration. Likewise, in the fully deflected configuration, the length, y, across the distal opening 140 may be decreased compared to the corresponding dimension in the undeflected configuration. By increasing the width, x, in the bent configuration, the frame 124 defining the distal opening 140 may more fully engage the body lumen 992.

[0068] In the embodiments illustrated in each of FIGS. 1A – 1D, the catheter 102 extends through the distal opening 140 of the embolic filter 110, and the frame 124 extends away from the catheter 102 in a first lateral direction and then curves back around the catheter 102 in the opposite direction.

[0069] The embolic protection device 100, with the embolic filter 110 deployed, i.e., the deployment mechanism 112 is retracted), may assume an undeflected (FIG. 1B), partially deflected (FIG. 1C), or fully deflected (FIGS. 1D and 5E) configuration. These configurations are achieved by engaging the pull wire 122 to a fully advanced, partially retracted (or partially advanced), or fully retracted state. In the fully advanced state, the pull wire 122 is in a distal position. In the fully retracted state, the pull wire 122 is in a proximal position. When longitudinally retracted to a proximal position, the pull wire 122 is configured to deflect (or bend) the frame 124 so that the distal opening 140 of the filter 110 is substantially perpendicular to the longitudinal direction of the catheter 102 and the distal opening 140 faces the distal end 116 of the catheter 102. When longitudinally advanced to a distal position, the pull wire 122 is configured to position the frame 124 so that the distal opening 140 of the filter 110 defined by the frame 124 is substantially parallel or angled less than about 45 degrees with respect to longitudinal direction of the catheter 102.

[0070] In some embodiments, the distal opening 140 of the embolic filter 110 has a diameter of from about 2 cm to about 6 cm (e.g., from about 2.5 cm to about 5 cm or about 4.5 cm). The embolic filter 110 can comprise any suitable size or diameter to accommodate anatomic variability in patients' body lumens 992 (see FIG. 9C). In some embodiments, the embolic filter 110 is coupled to the catheter 102 at the proximal and/or distal ends of the embolic filter 110 and/or at any other points there between. For example, the embolic filter 110 may be coupled to the catheter 102 via the frame 124, specifically the second portion 130 of the frame 124 (distal attachment) and also coupled to the catheter 102 via the filter medium 126 at an attachment point within the sheath 112.

[0071] FIGS. 1E and 1F illustrate the frame 124 of the embolic filter 110. In the embodiment illustrated in FIG. 1E, the frame 124 is collapsed within the outer sheath 112, i.e., with the sheath 112 advanced over the frame 124. In the embodiment illustrated in FIG. 1F, the frame

124 is deployed outside the sheath 112, i.e., with the sheath 112 retracted. The pull wire 122 is coupled to the frame 124 at a distal coupling 134. The pull wire 122 may be coupled to the frame 124 at the distal coupling 134 by a variety of methods, including by means of a hole in the frame 124 through which the pull wire 122 is threaded and crimped to hold it in place. The distal coupling 134 may also include a variation in the curvature of the frame 124, i.e., by inverting the curvature of the frame 124 and coming to a point. This curvature, along with the curvature of the frame 124 adjacent to the point of attachment of the frame 124 to the catheter 102, may aid in collapsing the frame 124 in order to advance the sheath 112 over the embolic filter 110. In some embodiments, the frame 124 comprises a shape memory material (e.g., a metal alloy or polymer). Examples of shape memory materials include, without limitation, nitinol, chromium cobalt, and/or other metal alloys such as MP35N, 35NLT, elgiloy, and the like. In some embodiments, the frame 124 is laser cut from a tube or a sheet.

[0072] FIGS. 2A and 2B illustrate embodiments of an alternative deployment mechanism for an embolic protection device 200 comprising a catheter 202, an embolic filter 210, and a movable outer sheath 212. In some embodiments, the outer sheath 212 can include an optional lip 260 protruding inwardly from the distal end of the outer sheath 212. The catheter 202 can include one or more shoulders 262 (e.g., a distal shoulder 262a and a proximal shoulder 262b) protruding outwardly from an outer wall of the catheter 202. The lip 260 of the outer sheath 212 is configured to engage the shoulder or shoulders 262 of the catheter 202 to inhibit or prevent the outer sheath 212 from moving excessively in either the proximal or distal direction. The lip 260 and shoulder 262 may be arcuate, pronged, and combinations thereof, and the like.

[0073] In some embodiments, the outer sheath 212 and/or the catheter 202 comprise nubs and/or detents configured to provide information to the user about the longitudinal position of the outer sheath without inhibiting further movement. In some embodiments, the outer sheath 212 and the catheter 202 comprise lips 260, shoulders 262, and detents and nubs (e.g., to inhibit longitudinal movement of the outer sheath 212 excessively in either direction, and to provide information about the extent of movement of the outer sheath 212 relative to the catheter 202 (e.g., 1/2 retracted, 1/4 retracted, etc.)).

[0074] Benefits of the outer sheath 212 deployment mechanism may include its simplicity, ease of operation, and small number of moving parts. The embolic protection device 200 is well-suited for use in conjunction with delicate cardiac procedures having serious risks. As the duration of the procedure increases, the risk of complications typically increases as well. Therefore, it can be advantageous that the user be able to quickly and easily deploy and recapture the embolic filter 210. A more complicated device could be more difficult to

operate and could be more likely to malfunction or cause adverse effects. The ability to move the outer sheath 212 relative to the embolic filter 210 can advantageously allow the user to partially recapture the embolic filter 210, for example to adjust the width of the distal opening 140. In some embodiments, narrowing the distal opening 140 allows the user to introduce a second catheter or instrument to the patient's body lumen 992 (see FIG. 9D) and maneuver the second catheter or instrument around and past the catheter 202 and embolic filter 210, as described herein. In some embodiments, an embolic protection device as described herein may have a longitudinally extending groove (not shown) along its surface, e.g., along the catheter 102, along the support catheter 150 or along the deployment mechanism (e.g. outer sheath) 112. In such embodiments, a second catheter or instrument may be inserted while engaging the groove to guide the second device alongside the embolic protection device.

[0075] FIGS. 3A – 3D illustrate embodiments of an embolic protection device 300 in which an embolic filter 310 is movably coupled to a catheter 302 by way of a frame 324 and is longitudinally movable with respect to the catheter 302. In some embodiments, the embolic filter 310 is coupled to an intermediate tube 330 that at least partially circumferentially surrounds the catheter 302. The intermediate tube 330 is longitudinally movable with respect to the catheter 302. An outer sheath 312 is configured to at least partially circumferentially surround both the catheter 302 and the intermediate tube 330. The intermediate tube 330 and the outer sheath 312 can be moved simultaneously and independently. The longitudinal position of the embolic filter 310 with respect to the catheter 302 can be adjusted while the embolic filter 310 is in the collapsed configuration or in a deployed or partially deployed, expanded configuration. In some embodiments, the perimeter of the distal opening of the embolic filter 310 comprises one or more radiopaque markers to allow the user to visualize the position of the distal opening, for example, with respect to various anatomical landmarks. For example, if the user is performing a procedure on a patient's aortic valve and wants to prevent emboli from entering the cerebral arteries, the radiopaque markers can be used to ensure the distal opening of the embolic filter 310 is positioned in the ascending aorta upstream from the carotid arteries.

[0076] FIG. 3A illustrates the embolic filter 310 confined in a closed configuration by the outer sheath 312 and a distal end of intermediate tube 330 at position (a). If the intermediate tube 330 is held stationary at position (a), the outer sheath 312 can be retracted to deploy the embolic filter 310, as shown in FIG. 3C. If the intermediate tube 330 and outer sheath 312 are instead moved simultaneously, the embolic filter 310 remains confined by the outer sheath 312 while the longitudinal position of the embolic filter 310 is adjusted. For example,

FIG. 3B illustrates the embolic filter 310 still confined by outer sheath 312, while the intermediate tube 330 has been retracted so that the distal end of the intermediate tube 330 is at position (b). If the intermediate tube 330 is then held stationary at position (b), the outer sheath 312 can be retracted to deploy the embolic filter 310, as shown in FIG. 3D. The intermediate tube 330 and outer sheath 312 can be moved to adjust the longitudinal position of the embolic filter 310 in a deployed or partially deployed configuration. For example, the intermediate tube 330 and outer sheath 312 can be moved simultaneously to retract the intermediate tube 330 from the position as shown in FIG. 3C to position (b) as shown in FIG. 3D.

[0077] In addition to those described in detail herein, a wide variety of deployment mechanisms for embolic filters are possible. For example, a deployment system may comprise a portion of an annular sheath including inward end protrusions that are guided in tracks along the catheter body. Certain such embodiments may advantageously reduce the profile of the catheter. For another example, a deployment system may comprise a threaded sheath that longitudinally moves upon twisting by the user. For yet another example, a deployment system may comprise a plurality of annular bands that can capture the embolic filter longitudinally and/or circumferentially. Combinations of the deployment systems described herein and other deployment systems are also possible.

[0078] FIGS. 4A – 4C illustrate another embodiment of an embolic protection device 400 comprising a catheter 402, a deflector 460, an embolic filter 410, and a movable outer sheath 412. In some embodiments, the embolic protection device 400 is similar to embolic protection device 100 with the addition of the deflector 460.

[0079] Various types and designs of deflectors can be used with an embolic protection device such as embolic protection device 400. Such deflectors can have different shapes and/or sizes and can vary in where and how they are coupled to the catheter. For example, deflectors can be made in various sizes, for example to accommodate differences in patient anatomy. In some embodiments, the deflector comprises a shape memory material, for example including nitinol, chromium cobalt, and/or alloys such as MP35N, 35NLT, elgiloy, and the like. In some embodiments, the deflector comprises a porous membrane, for example a semi-permeable polyurethane membrane/material, mounted to a self-expanding frame, for example a frame comprising a shape memory material.

[0080] An example of the deflector 460 shown in FIGS. 4A – 4C has a generally butterfly or elliptical shape with two wings or petals 460a and 460b extending to either side of a central axis 464. The wings or petals 460a and 460b may be the same or different in size shape, material, and the like. The deflector 460 is coupled to a side of the catheter 402 via an

elongate member 462 that is coupled (e.g., by adhering, welding, soldering, coupling using a separate component, combinations thereof, and the like) at one end to the central axis 464 of the deflector 460 and at the other end to the catheter 402. In some embodiments, the elongate member 462 comprises a shape memory material, for example including nitinol, chromium cobalt, and/or alloys such as MP35N, 35NLT, elgiloy, and the like that is configured (e.g., shape set) to bias the deflector away from the catheter 402. The deflector 460 is configured to release to an open configuration, shown in FIGS. 4B and 4C, when not confined by, for example, an outer sheath 412. In some embodiments, the deflector 460 is configured to fold along the central axis 464 away from the elongate member 462 so that the wings or petals 460a and 460b come together and the deflector 460 can be contained in, for example, an outer sheath 412, as shown in FIG. 4A. As shown in FIG. 4A, the deflector 460 can initially be folded and contained in the outer sheath 412 such that the wings or petals 460a and 460b are positioned distal to the central axis 464. In some embodiments, the deflector 460 can initially be folded in the opposite direction such that the wings or petals 460a and 460b are positioned proximal to the central axis 464.

[0081] In some embodiments, the catheter 402 is a pigtail-type catheter as shown in FIGS. 4A and 4B and described herein. The catheter 402 includes a distal portion 404 configured to assume a generally arcuate shape being at least a semi-circle. In some embodiments, the distal portion 404 of the catheter 402 includes one or more radiopaque markers 406. A side wall of the catheter 402 may optionally include one or more apertures 408 in the distal portion 404 that are configured to deliver one or more fluids (e.g., imaging dye, contrast agent, oxygenated blood, saline, any combination thereof, or the like) to a body lumen.

[0082] The catheter 402 has a proximal end 414 and a distal end 416. As shown in the FIG. 4B, an example of the catheter 402 is partially surrounded towards its proximal end 414 by a support catheter 450 that terminates at a head 452, proximal to the distal portion 404 of the catheter 402. The support catheter 450 may be made of a thicker, stiffer material to add rigidity and provide a protective or supporting layer surrounding the catheter 402.

[0083] As illustrated in FIG. 4B, the embolic filter 410 comprises a frame 424 and a filter medium 426. In its deployed configuration, the embolic filter 410 includes a distal opening 440 defined by the frame 424, faces the distal end 416 of the catheter 402, and extends proximally from the distal opening 440 to a closed proximal end 442. The device 400 further comprises a pull wire 422 that is coupled to the frame 424 and can be retracted to deflect or bend the frame 424 and change the orientation and shape of the distal opening 440, in manner similar to that described above with reference to FIGS. 1B – 1D.

[0084] In some embodiments, the deflector 460 and embolic filter 410 can be coupled to another type of catheter, for example a catheter without a distal portion configured to assume an arcuate shape. The embolic filter 410 can be similar to the embolic filters 110 and 210 shown in FIGS. 1A – 1D; FIGS. 2A and 2B; and described herein. In some embodiments, the embolic filter 410 is coupled to the catheter 402 proximal to the deflector 460, for example as shown in FIGS. 4A – 4B. In some embodiments, the embolic filter 410 is coupled to the catheter 402 distal to the deflector 460. The embolic filter 410 is coupled so that it is disposed around the catheter 402. This configuration advantageously allows the embolic filter 410 to engage the interior body lumen 992 (see FIG. 9D) wall, as the position of the catheter 402 within the body lumen 992 (see FIG. 9D) may be affected by the deployed deflector 460.

[0085] The combination of the deflector 460 and the embolic filter 410 can advantageously provide additional protection against potential complications resulting from thrombi in the blood stream. For example, if the embolic filter 410 (e.g., the distal end of the embolic filter 410) is distal to the deflector 460, the embolic filter 410 can serve as the primary means of embolic protection and the deflector 460 can serve as the secondary means of embolic protection. If some blood is able to flow around the embolic filter 410 rather than through it, the deflector 460 serves as a secondary (or back-up) protection device and prevents any debris not captured by the embolic filter 410 from entering the cerebral arteries and traveling to the brain. If the embolic filter 410 is proximal to the deflector 460, the deflector 460 can serve as the primary means of embolic protection and the embolic filter 410 can serve as the secondary means of embolic protection. The deflector 460 first deflects debris away from the carotid arteries, then the embolic filter 410 captures debris (e.g., including deflected debris) as blood flows through the descending aorta.

[0086] In some embodiments, the catheter 402 and outer sheath 412 can have lips, shoulders, nubs, and/or detents, for example similar to those shown in FIGS. 2A and 2B and described herein. For example, lips, shoulders, nubs, and/or detents can be positioned on the catheter 402 distal to the deflector 460, between the deflector 460 and embolic filter 410, and proximal to the embolic filter 410 to engage corresponding lips, shoulders, nubs, and/or detents on the outer sheath 412. The lips, shoulders, nubs, and/or detents can advantageously provide the user with information about the longitudinal position of the outer sheath 412 so that the user knows when neither, one, or both of the deflector 460 and embolic filter 410 are deployed. In some embodiments, either or both of the deflector 460 and embolic filter 410 can be movably coupled to the catheter 402 via an intermediate tube similar to that shown in FIGS. 3A – 3D and described herein.

[0087] An embodiment of an embolic protection device 500, similar to the embolic protection device 100 in FIGS. 1A – 1E, is shown in FIGS. 5A and 5B. The embolic protection device 500 comprises a catheter 502, an embolic filter 510, a movable outer sheath 512, and a handle 570. In some embodiments, the catheter 502 is a pigtail-type catheter as shown in the close up view of FIG. 5B and described herein. The catheter 502 includes a distal portion 504 configured to assume a generally arcuate shape being at least a semi-circle. In some embodiments, the distal portion 504 of the catheter 502 includes one or more radiopaque markers 506. A side wall of the catheter 502 may optionally include one or more apertures 508 in the distal portion 504 that are configured to deliver one or more fluids (e.g., imaging dye, contrast agent, oxygenated blood, saline, any combination thereof, or the like) to a body lumen.

[0088] As illustrated in FIG. 5B, the embolic filter 510 comprises a frame 524 and a filter medium 526. In its deployed configuration, the embolic filter 510 opens towards a distal end 516 of the catheter 502. The device 500 further comprises a pull wire 522 that is coupled to the frame 524 and can be retracted to deflect or bend the frame 524 and change the orientation and shape of the embolic filter 510, in manner similar to that described above with reference to FIGS. 1B – 1D.

[0089] Returning to FIG. 5A, the handle 570 has a wire-engagement mechanism 574 configured to advance or retract the pull wire 522 by movement of a first slider 572. The handle 570 also has a sheath-engagement mechanism 578 configured to advance or retract the deployment mechanism (e.g. outer sheath) 512 by movement of a second slider 576.

[0090] FIGS. 6A – 6G illustrate embodiments of an embolic protection device 600. In these embodiments, the embolic protection device 600 comprises a catheter 602 (e.g., a pigtail catheter) having a proximal end 614, a distal end 616, and a lumen 618 extending from the proximal end 614 to the distal end 616 along a longitudinal axis of catheter 602. The lumen 618 may be configured to house a guidewire 1290 (see FIG. 12A) that is longitudinally movable through this lumen to coil or straighten the distal portion 604 of the catheter depending on whether the guidewire is retracted (to coil the distal portion) or extended (to straighten the distal portion). In some embodiments, the catheter 602 includes a distal portion 604 configured to assume a generally arcuate shape being at least a semi-circle. A side wall of the catheter 602 may optionally include one or more apertures 608 in the distal portion 604 that are configured to deliver one or more fluids (e.g., imaging dye, contrast agent, oxygenated blood, saline, any combination thereof, or the like) to a body lumen 1292 (see FIG. 12A). The apertures 608 (the plural intended to include embodiments in which the distal portion 604 includes one aperture 608) are in fluid communication with the lumen 618.

In some embodiments, the distal portion 604 of the catheter 602 includes one or more radiopaque markers 606. In some embodiments, the radiopaque markers 606 are wrapped around the circumference of the distal portion 604 of the catheter 602 and can have the same or different widths. The embolic protection device 600 further comprises a self-expanding embolic filter 610 defined by a frame 624 and a filter medium 626, and a deployment mechanism 612 (e.g., a longitudinally retractable outer sheath or a longitudinally retractable ring). The embolic filter 610 is disposed around the catheter 602.

[0091] FIG. 6B illustrates the embolic filter 610 deployed in a self-expanded configuration by retraction of the deployment mechanism (e.g., outer sheath) 612. The embolic filter 610 includes a distal opening 640 that is defined by the frame 624, faces the distal end 616 of the catheter 602, and extends proximally from the distal opening 640 to a closed proximal end 642. The embolic protection device 600 further comprises a push wire 622 that is coupled to the frame 624. The push wire 622 can be advanced, in the distal direction, to deflect (or bend) and extend the frame 624; and, in turn, change the configuration of the embolic filter 610 between self-expanded, partially expanded, and fully expanded. In some embodiments, advancing the push wire 622 may cause the distal opening 640 of the embolic filter 610 to change orientation, shape, and/or size to engage at least a portion of the interior body lumen 1292 (see FIG. 12D) wall. FIG. 6B illustrates the push wire 622 in a retracted, i.e., un-advanced, state with the frame 624 extending in a distal, longitudinal direction, albeit angled back somewhat (e.g., less than about 45 degrees) in a lateral direction toward the proximal end 614. The catheter 602 may be partially surrounded towards its proximal end 614 by a support catheter 650 that terminates at a head 652, proximal to the distal portion 604 of the catheter 602. The support catheter 650 may be made of a thicker, stiffer material to add rigidity and provide a protective or supporting layer surrounding the catheter 602.

[0092] FIGS. 6C, 6E, and 6G show front-end views of the embolic filter 610, as viewed from the distal opening 640, in the self-expanded, partially expanded, and fully expanded configurations, respectively. The catheter 602 is removed from these views for clarity. The frame 624 comprises two sides (624a, 624b) that each extend generally in a first lateral direction away from the catheter 602/support catheter 650 and then loop back on opposite sides around the catheter 602/support catheter 650 and extend generally in the opposite lateral direction before converging and meeting to form a substantially elliptical (i.e., shaped like an ellipse), or alternatively, a substantially ovular (i.e. shaped like an oval), or circular shape. As shown, the embolic filter 610 is symmetrical about a plane (identified in the figure as a dotted line labeled "P"). For ease of discussion, the embolic filter 610 is referred to as having

a left side and a right side. Elements on the left side of the embolic filter 610 are mirrored by elements on the right side of the embolic filter 610.

[0093] FIGS. 6D and 6E illustrate the embolic filter 610 in the partially expanded configuration with the frame 624 deflected (i.e., bent) by advancement of the push wire 622 in the distal direction. The frame 624 comprises a movable portion 630 and a fixed portion 632. The movable portion 630 of the frame 624 can move, longitudinally, with respect to the catheter 602/support catheter 650. With respect to the catheter 602/support catheter 650, the movable portion 630 can move, longitudinally, while the fixed portion 632 cannot. The frame 624 is coupled to the push wire 622 at the movable portion 630. In a convenient embodiment, the push wire 622 and movable portion 630 are joined by a crimp. In other embodiments, the push wire 622 and movable portion 630 are joined by a weld, adhesive, or threads. The frame 624 is attached to the support catheter 650 (or alternatively, directly to the catheter 602) by the fixed portion 632. The fixed portion 632 of the frame 624 may be attached to the catheter 602/support catheter 650 by a weld, an adhesive, or the like.

[0094] Starting at the fixed portion 632, the frame 624 extends in a distal, longitudinal direction and then bends at an angle with respect to the longitudinal axis of the catheter 602/support catheter 650. When the push wire 622 is in its retracted state, the frame 624 bends at an acute angle and extends in a proximal, longitudinal direction such that the frame 624 folds onto itself (see FIG. 6B). Advantageously, in this configuration, the embolic filter 610 may more effectively retain embolic debris captured during a procedure. The curvature of the frame 624 adjacent the movable portion 630 may aid in collapsing the frame 624 in order to advance the outer sheath 612 over the embolic filter 610.

[0095] FIG. 6E shows the front-end view of the embolic filter 610, as viewed from the distal opening 640, when the push wire 622 is advanced and the embolic filter 610 assumes a partially expanded configuration. The advancing push wire 622 urges the movable portion 630 forward relative to the catheter 602/support catheter 650. (Shown in FIG. 6D as an arrow pointing away from the support catheter 650.) This in turn deflects or bends the frame 624 longitudinally in the distal direction and laterally outward. In a deflected configuration (i.e., when the push wire 622 is advanced), the distal opening 640 of the embolic filter 610 may be substantially perpendicular to the longitudinal axis of the catheter 602/support catheter 650 and may span laterally across the body lumen 1292 (see FIG. 12D), substantially perpendicular to the longitudinal axis of the body lumen 1292. In the deflected configuration, the width, X_{bent}, across the distal opening 640 is increased compared to the corresponding dimension in the non-deflected configuration. By increasing the width, X_{bent}, in the bent configuration, the frame 624 defining the distal opening 640 engages the body lumen 1292.

[0096] FIGS. 6F and 6G illustrate the embolic filter 610 in the fully expanded configuration with the frame 624 extended by the further advancement of the push wire 622 in the distal direction. Moving the push wire 622 further, distally, urges the movable portion 630 sideways relative to the catheter 602/support catheter 650. This in turn extends the frame 624 radially outward, away from the catheter 602/support catheter 650. (Shown in FIG. 6G as a left directional arrow and right directional arrow pointing away from the support catheter 650.) In some embodiments, in addition to extending the frame 624 in the radial direction, the advancing push wire 622 moves the movable portion 630 forward relative to the catheter 602/support catheter 650; which, in turn, bends the frame 624, further, in the longitudinal direction. In one embodiment, the movable portion 630 is formed with a curve or bend to aid in extending the frame 624 in the radial direction.

[0097] In an extended configuration, the width, $X_{extended}$, across the distal opening 640 is increased compared to the corresponding dimension (X_{bent}) in the partially expanded configuration of the embolic filter 610. By increasing the width, $X_{extended}$, in the extended configuration, the frame 624 defining the distal opening 640 engages the body lumen 1292. The increase in the width across the distal opening 640 between the partially expanded configuration (X_{bent}) and the fully expanded configuration ($X_{extended}$) of the embolic filter 610 (and intermediate configurations in between) may represent a range of filter sizes or diameters, e.g., 25 millimeters (mm) to 40 mm. The range of filter sizes accommodates variations in patient vasculature. Advantageously, instead of a one-size-fits-all device or multiple devices of different sizes, certain embodiments of the embolic protection device 600 provide a single device that can be tailored to a particular patient and/or a particular surgical procedure. For example, a surgeon can expand the embolic filter 610 to a first size and then adjust the embolic filter 610 to a second size to achieve a better fit within a patient's vasculature.

[0098] In some embodiments, the distal opening 640 of the embolic filter 610 has a diameter of from about 2 centimeters (cm) to about 6 cm (e.g., from about 2.5 cm to about 4 cm or to about 4.5 cm). The embolic filter 610 can comprise any suitable size or diameter to accommodate anatomic variability in patients' body lumens 1292 (see FIG. 12A).

[0099] FIGS. 7A – 7C illustrate another embodiment of an embolic protection device 700 comprising a catheter 702, an embolic filter 710, a movable outer sheath 712, and an actuating mechanism for operating the embolic filter 710. A portion of the catheter 702 is slidably received and supported by a fixed inner catheter 750 that terminates at a head 752. The fixed inner catheter 750 may be made of a thicker, stiffer material to add rigidity and provide a protective or supporting layer surrounding the catheter 702. The embolic filter 710

is disposed around the fixed inner catheter 750 and is configured to self-expand to a radially expanded configuration, as shown in FIG. 7A, when not confined or restrained by the outer sheath 712.

[00100] The embolic filter 710 includes a frame 724 and a filter medium 726. The frame 724 defines a distal opening 740 of the embolic filter 710 and includes a movable portion 730 for controlling the size or diameter of the distal opening 740. The embolic filter 710 extends proximally from the distal opening 740 to a closed proximal end 742. The frame 724 further includes a fixed portion 732 for attaching the frame 724 to the fixed inner catheter 750 at a location adjacent to the closed proximal end 742 of the embolic filter 710. In some embodiments, the embolic protection device 700 is similar to the embolic protection device 600 of FIGS. 6A – 6G with the addition of the actuating mechanism.

[00101] The actuating mechanism comprises an inner catheter 756 and an outer catheter 758. The inner catheter 756 slides over the fixed inner catheter 750. The outer catheter 758 slides over the inner catheter 756. The movement of the inner catheter 756 and outer catheter 758 relative to the fixed inner catheter 750 controls the size or diameter of the embolic filter 710, as will be described in greater detail below.

[00102] The embolic protection device 700 further includes a push wire 722 coupled to a distal portion 764 of the outer catheter 758. The push wire 722 is longitudinally movable between a fully retracted state, a partially advanced (or partially retracted) state, and a fully advanced state by the outer catheter 758. The push wire 722 is further coupled to the movable portion 730 of the frame 724. Moving the outer catheter 758, relative to the fixed inner catheter 750, translates into moving the push wire 722 between the fully retracted, partially advanced, and fully advanced states. This in turn urges the movable portion 730, causing the frame 724 to deflect (or bend) or extend.

[00103] In various embodiments of the embolic protection device 700, the foregoing device components may be coupled to each other, as described above, by any number of means and techniques. For example, in a convenient embodiment, sleeves made from polyether block amide (PEBAX®) or other similar biocompatible material attach the push wire 722 to the distal portion 764 of the outer catheter 758, attach the top guide 760 to the distal portion 766 of the inner catheter 756, and attach the bottom guide 762 to the fixed inner catheter 750. Additionally or alternatively, the device components may be joined together with a biocompatible adhesive(s).

[00104] The actuating mechanism further comprises a top guide 760 and a bottom guide 762 for directing the deflection and extension of the frame 724 so that the distal opening 740 of the embolic filter 710 faces towards a distal end (or working end) of the

device 220 as it expands. In some embodiments, the top guide 760 and the bottom guide 762 keep the movable portion 730 and the fixed portion 732 of the frame 724 straight, respectively. The top guide 760 and the bottom guide 762 are arranged at opposite points around the fixed inner catheter 750 with portions disposed along the fixed inner catheter 750. The top guide 760 is coupled at one end to a distal portion 766 of the inner catheter 756. A portion of the top guide 760, distal to the distal portion 766, is in slidable engagement with the fixed inner catheter 750 at or otherwise adjacent to the closed proximal end 742 of the embolic filter 710. For example, a portion of the top guide 760 slides under the filter medium 726 along the fixed inner catheter 750 and passes through the closed proximal end 742 of the embolic filter 710. The bottom guide 762 is fixedly attached to the fixed inner catheter 750 at or otherwise adjacent to the closed proximal end 742 of the embolic filter 710.

[00105] At the distal opening 740 of the embolic filter 710, the top guide 760 and the bottom guide 762 are movable away from the fixed inner catheter 750. The top guide 760 slidably receives the movable portion 730 of the frame 724 and the bottom guide 762 receives the fixed portion 732. The arrangement causes the top guide 760 and bottom guide 762 to flare or flex outward away from the fixed inner catheter 750 (as one moves from the closed proximal end 742 of the embolic filter 710 to the distal opening 740), thereby, giving the embolic filter 710 a general funnel-like appearance. The top guide 760 and the bottom guide 762 may also support the filter medium 726, in the longitudinal and lateral directions, between the distal opening 740 and the closed proximal end 742 of the embolic filter 710. In a convenient embodiment, the top guide 760 and the bottom guide 762 are hypotubes made from stainless steel, polyetheretherketone (PEEK), or other biocompatible material.

[00106] FIG. 7A further illustrates the outer sheath 712 fully retracted over the embolic filter 710 and the embolic filter 710 exposed. The inner catheter 756 and outer catheter 758 are in their initial positions (labeled "A" in the figure) relative to the fixed inner catheter 750. With the embolic filter 710 unsheathed, the movable portion 730 and the fixed portion 732 of the frame 724, with the top guide 760 and bottom guide 762, flex outwardly away from the fixed inner catheter 750. This causes the distal opening 740 of the embolic filter 710 to lie at an angle with respect to the fixed inner catheter 750. For example, the frame 724 and the fixed inner catheter 750 are at an angle of 45 degrees or less. At this stage in deployment, the embolic filter 710 is in a self-expanded configuration with the frame 724 unbent.

[00107] FIG. 7B illustrates the distal opening 740 partial expanded to a first size or diameter. The inner catheter 756 and outer catheter 758 are advanced in unison, distally, over the fixed inner catheter 750. The inner catheter 756 and outer catheter 758 are moved from their initial positions (labeled "A" in the figure) to their intermediate positons (labeled "B" in

the figure), relative to the fixed inner catheter 750. The concerted movement of the inner catheter 756 and the outer catheter 758 advances the push wire 722 and the top guide 760 together; and, in turn, urges the movable portion 730 of the frame 724, longitudinally, in the distal direction (forward direction). This rotates the distal opening 740 of the embolic filter 710 into an orientation substantially perpendicular to the longitudinal axis of the fixed inner catheter 750 and expands the distal opening 740 to the first size (e.g., a diameter of about 25 mm).

[00108] FIG. 7C illustrates the distal opening 740 fully expanded to a second size larger than the first size. In FIG. 7E, the outer catheter 758 is distally advanced over the inner catheter 756 and the fixed inner catheter 750. Without the inner catheter 756 moving, the outer catheter 758 moves from its intermediate positon (labeled "B" in the figure) to its final position (labeled "C" in the figure), relative to the fixed inner catheter 750. The continued distal movement of the outer catheter 758 moves the push wire 722 without moving the top guide 760. A length of the movable portion 730 of the frame 724 is radially played out from the top guide 760 (i.e., out of the plane of the page), extending the frame 724 and further expanding the distal opening 740 of the embolic filter 710 to the second size (e.g., a diameter of about 40 mm).

[00109] FIGS. 8A – 8F illustrate embodiments of an embolic protection device 800 comprising a catheter 802, an embolic filter 810, a movable outer sheath 812, and a handle 870 for manually operating the embolic filter 810. In FIG. 8B, the embolic protection device 800 further comprises a push wire 822, a filter frame 824, a filter media 826, a movable portion 830, a fixed portion 832, a fixed inner catheter 850, an inner catheter 856, an outer catheter 858, a top guide 860, and a bottom guide 862 arranged in a configuration similar to the configuration described above with reference to FIGS. 7A – 7C. For example, the push wire 822 is coupled to a distal portion 864 of the outer catheter 858, and the top guide 860 is coupled at one end to a distal portion 866 of the inner catheter 856. In some embodiments, the embolic protection device 800 is similar to the embolic protection device 700 of FIGS. 7A – 7C with the addition of the handle 870.

[00110] FIG. 8A illustrates the handle 870 having a first slider 872 operable for manually retracting the outer sheath 812 over the catheter 802 and the embolic filter 810 to deploy the embolic filter 810 in a self-expanded configuration. The first slider 872 is further used to manually advance the outer sheath 812 over the catheter 802 and the embolic filter 810, and collapse/recover the embolic filter 810. The handle 870 further includes a second slider 874 operable for manually increasing and decreasing the size or diameter of a distal opening 840

of the embolic filter 810. (The embolic filter 810 extends proximally from the distal opening 840 to a closed proximal end 842.)

[00111] In some embodiments, the catheter 802 is a pigtail-type catheter as shown in FIG. 8B and described herein. The catheter 802 includes a distal portion 804 configured to assume a generally arcuate shape being at least a semi-circle. In some embodiments, the distal portion 804 of the catheter 802 includes one or more radiopaque markers 806. A side wall of the catheter 802 may optionally include one or more apertures 808 in the distal portion 804 that are configured to deliver one or more fluids (e.g., imaging dye, contrast agent, oxygenated blood, saline, any combination thereof, or the like) to a body lumen.

[00112] The catheter 802 has a proximal end, a distal end 816, and a lumen 818 extending between the proximal end and the distal end 816. The lumen 818 may be configured to house a guidewire 1290 (see FIGS. 12A and 12B) that is longitudinally moveable through this lumen to coil or straighten the distal portion 804 of the catheter 802 depending on whether the guidewire is retracted (to coil the distal portion) or extended (to straighten the distal portion). The apertures 808 and the lumen 818 may in fluid communication with each other in order to deliver one or more fluids to a body lumen as described above.

[00113] As shown in the FIG. 8B, an example of the catheter 802 is partially surrounded towards its proximal end by the fixed inner catheter 850 that terminates at a head 852, proximal to the distal portion 804 of the catheter 802. The fixed inner catheter 850 may be made of a thicker, stiffer material to add rigidity and provide a protective or supporting layer surrounding the catheter 802.

[00114] FIG. 8C illustrates an example of the handle 870 (with the handle cover removed for clarity) including a sheath-engagement mechanism 876 configured to advance or retract the outer sheath 812 by movement of the first slider 872. The outer sheath 812 is joined to the sheath-engagement mechanism 876. Any number of suitable means, (e.g., fastener and/or adhesive) or techniques (e.g., sonic welding, solvent welding, and overmolding) can be used to join the outer sheath 812 and sheath-engagement mechanism 876.

[00115] The sheath-engagement mechanism 876 is movable within the handle 870 between a distal, initial position (shown in FIG. 8C) and a proximal, final position (shown in FIG. 8D). The initial position of the sheath-engagement mechanism 876 corresponds with the outer sheath 812 circumferentially disposed around at least a portion of embolic filter 810 and the embolic filter 810 housed in the collapsed configuration. The final position of the sheath-engagement mechanism 876 corresponds with the outer sheath 812 longitudinally retracted over the embolic filter 810 and the embolic filter 810 deployed in the self-expanded configuration.

[00116] The sheath-engagement mechanism 876 is selectively operable by the first slider 872. For example, an operator presses down on the first slider 872 with their thumb to unlock the sheath-engagement mechanism 876 from the handle 870 in order to move the sheath-engagement mechanism 876 from the initial position (shown in FIG. 8C) to the final position (shown in FIG. 8D). The operator moves the first slider 872, proximally, using their thumb to retract the outer sheath 812 and expose the embolic filter 810. To collapse/recover the embolic filter 810, the operator moves the first slider 872, distally, and advances the outer sheath 812 over the embolic filter 810.

[00117] The example of the handle 870 shown in FIG. 8C further includes an engagement mechanism 878 configured to change the size or diameter of the distal opening 840 of the embolic filter 810 by movement of the second slider 874. The engagement mechanism 878 comprises a top pull 880 and a bottom pull 882. The top pull 880 is coupled to a proximal portion of the outer catheter 858 and the bottom pull 882 is coupled to a proximal portion of the inner catheter 856 (shown in FIG. 8F).

[00118] The engagement mechanism 878 is movable within the handle 870 between an initial (proximal) position (shown in FIGS. 8C and 8D), an intermediate position (shown in FIG. 8E), and a final (distal) position (shown in FIG. 8F). The initial position of the engagement mechanism 878 corresponds with the embolic filter 810 in the self-expanded configuration with the filter frame 824 undeflected (or unbent). The intermediate position of the engagement mechanism 878 corresponds with the embolic filter 810 in a partially expanded configuration with the filter frame 824 deflected (or bent) in the longitudinal direction. The final position of the engagement mechanism 878 corresponds with the embolic filter 810 in a fully expanded configuration with the filter frame 824 extended in the radial direction.

[00119] The engagement mechanism 878 is selectively operable by the second slider 874. For example, with the engagement mechanism 878 at the initial position (shown in FIG. 8D), a user presses the second slider 874 down. The applied force causes a projection (not shown) extending from the second slider 874 to move downward through a hole (not shown) in the top pull 880 and into a recess (not shown) in the bottom pull 882.

[00120] In FIG. 8E, with combined reference to FIG. 8B, with the second slider 874 depressed and engaged with both the top pull 880 and the bottom pull 882, the operator moves the second slider 874, distally, using their thumb to advance the outer catheter 858 and the inner catheter (hidden from view) together. The concerted movement of the outer catheter 858 and the inner catheter moves the push wire 822 and the top guide 860 together (i.e., moved in unison). This in turn, advances the movable portion 830, longitudinally, in the

distal direction (forward direction), and expands the distal opening 840 of the embolic filter 810.

[00121] The distal opening 840 continues to expand with the distal movement of the second slider 874 until the engagement mechanism 878 reaches the intermediate position shown in FIG. 8E. At the intermediate position, the distal opening 840 is at a first size (e.g., a diameter of about 25 mm) and the second slider 874 partially disengages from the engagement mechanism 878. For example, a spring and ball plunger (not shown), located within the handle 870, lifts the projection out of the recess in the bottom pull 882. The second slider 874 disengages from the bottom pull 882 but remains engaged with the top pull 880. It may be convenient to refer to the engagement between the top pull 880 and the bottom pull 882 as temporary.

[00122] In FIG. 8F, with combined reference to FIG. 8B, the operator continues to move the second slider 874, distally, to advance the outer catheter 858 farther in the distal direction. With the bottom pull 882 disengaged, the inner catheter 856 and the top guide 860 are fixed in position, while the push wire 822 advances farther in the distal direction. As a result, a length of the movable portion 830 is radially played out from the top guide 860 (i.e., out of the plane of the page) and further expands the distal opening 840 of the embolic filter 810 to a next size (e.g., a diameter of about 30 mm). The distal opening 840 expands to its maximum size (e.g., a diameter of about 40 mm) when the engagement mechanism 878 is at the final position as shown in FIG. 8F. To recover the embolic filter 810, the process described above with reference to FIGS. 8C – 8F is carried out in reverse.

[00123] In some embodiments, a wire of an embolic protection device as described herein, e.g., the pull wire 122 of the embolic protection device 100 of FIG. 1B or the push wire 622 of the embolic protection device 600 of FIG. 6B, comprises a metal material, for example, stainless steel. Alternatively, the wire may comprise a plastic material or other suitable material. In some embodiments, the wire is stainless steel coated in polytetrafluoroethylene (PTFE). In the case of the wire being a pull wire, similar to the pull wire 122 of FIG. 1B, the pull wire is flexible but may have sufficient rigidity to deflect (or bend) a frame of an embolic filter in a proximal direction when the pull wire is retracted in a manner similar to that described above with reference to FIGS. 1C and 1D. In the case of the wire being a push wire, similar to the push wire 622 of FIG. 6B, the push wire is flexible but may have sufficient rigidity to deflect/bend a frame of an embolic filter in a distal direction when the pull wire is advanced; and to extend the frame in a radial direction when the pull wire is father advanced in a manner similar to that described above with reference to FIGS. 6D – 6F.

[00124] In some embodiments, a filter medium (e.g., the filter medium 126 of FIG. 1A or the filter medium 626 of FIG. 6B) comprises a braided mesh, for example braided nitinol mesh. In some embodiments, the filter medium comprises a porous membrane, for example a semi-permeable polyurethane membrane. In other embodiments, the filter medium has a pore size of from about 100 microns to about 150 microns (e.g., about 125 microns).

[00125] In some embodiments, an embolic filter (e.g., the embolic filter 110 of FIG. 1B or the embolic filter 610 of FIG. 6B) comprises an anti-thrombogenic coating (e.g., a heparin coating or other coating comprising a thrombin or platelet inhibitor) to advantageously reduce thrombogenicity.

[00126] The embolic filter is configured to self-expand to a radially expanded configuration illustrated in, for example FIGS. 1B and 1C, and FIGS. 6B and 6C, when not confined or restrained by an deployment device, such as the outer sheath 112 of FIG. 1A or the outer sheath 612 of FIG. 6A.

[00127] In some embodiments wherein the deployment mechanism comprises an outer sheath (e.g., the movable outer sheath 112 of FIG. 1A or the movable outer sheath 612 of FIG. 6A), the outer sheath is configured to be circumferentially disposed around at least a portion of a catheter and a embolic filter (e.g., the catheter 102 and the embolic filter 110 of FIG. 1A; or the catheter 602 and the embolic filter 610 of FIG. 6A). The outer sheath is configured to contain or house the embolic filter in a collapsed configuration. The outer sheath is longitudinally movable with respect to the catheter, and can be longitudinally retracted (i.e., moved longitudinally in a proximal direction) to deploy the embolic filter and longitudinally advanced (i.e., moved longitudinally in a distal direction) to recapture the embolic filter and any embolic material collected by the embolic filter. The embolic filter is configured to self-expand upon longitudinal retraction of the outer sheath.

[00128] In some embodiments, an embolic filter of an embolic protection device as described herein (e.g., the embolic filter 110 of FIG. 1A and the embolic filter 610 of FIG. 6A) is configured to at least partially collapse upon longitudinal extension of an outer sheath (e.g., the outer sheath 112 of FIG. 1A and the outer sheath 612 of FIG. 6A). In these embodiments, a distal opening of the embolic filter (e.g., the distal opening 140 of FIG. 1B and the distal opening 640 of FIG. 6B) assumes a substantially closed configuration thereby sequestering or substantially sequestering the filtered material.

[00129] In some embodiments, a catheter of an embolic protection device as described herein (e.g., the catheter 102 of FIG. 1A and the catheter 602 of FIG. 6A) may comprise a flexible material so as to be maneuverable within a body lumen (e.g., the body lumen 992 of FIG. 9A and the body lumen 1292 of FIG. 12A) as further described herein. For example, in

some embodiments, the catheter comprises a metal or metal alloy. In other embodiments, the catheter comprises a polymer (e.g., polyurethane, silicone, latex, polytetrafluoroethylene (PTFE), a plastic material, any combination thereof, or the like). In some embodiments, the catheter comprises a metal-reinforced plastic (e.g., including nitinol, stainless steel, and the like). Other materials are also possible. In some embodiments, the catheter is substantially free of latex (natural or synthetic), which may cause allergic reactions in some patients. In some embodiments, the catheter comprises braid-reinforced tubing to advantageously increase the strength of the catheter. In some embodiments, the catheter comprises a braided catheter shaft including a layer of braided wire between two layers of catheter tubing, which may increase the strength of the catheter. In some embodiments, the catheter does not include a braided layer, which may increase the flexibility of the catheter. In some embodiments, the catheter comprises a lubricious coating, for example a coating having a low friction coefficient, to advantageously allow for smoother navigation through tortuous vasculature. In some embodiments, the catheter coating has anti-thrombotic properties to advantageously inhibit thrombus formation. In some embodiments, the catheter has a size (i.e., outside diameter) between about 3 French and about 5 French (between about 2 mm and about 3 mm). Other sizes are also possible, for example depending on the size of the target body lumen of a particular patient. In some embodiments, the catheter has a length between about 65 centimeters (cm) and about 135 cm. Other lengths are also possible, for example to allow for insertion of the catheter in the femoral, radial, brachial, or subclavian artery. The catheter can be manufactured, for example, by extrusion, injection molding, or another suitable process.

[00130] In some embodiments, an embolic protection device as described herein may include one or more radiopaque marker bands located at a distal portion of a catheter. For example, the embolic protection device 100 of FIGS. 1A and 1B with the radiopaque markers 106 located at the distal portion 104 of the catheter 102. As another example, the embolic protection device 600 of FIGS. 6A and 6B with the radiopaque markers 606 located at the distal portion 604 of the catheter 602. When the distal portion assumes a generally arcuate shape, the circumferential radiopaque marker bands may be visualized to confirm that the distal portion is generally arcuate. In some embodiments, the radiopaque marker bands are located so that when the distal portion assumes its generally arcuate configuration, the marker bands are at the distal most point of the catheter, i.e., actually beyond a distal end of the catheter (e.g., beyond the distal end 116 of the catheter 102 shown in FIGS. 1A and 1B; or beyond the distal end 616 of the catheter 602 shown in FIGS. 6A and 6B).

[00131] The radiopaque markers comprise a radiopaque material, for example platinum, tantalum, tungsten, palladium, and/or iridium. Other radiopaque materials are also possible. In some embodiments, a material may be considered radiopaque, for example, if the average atomic number is greater than 24 or if the density is greater than about 9.9 g/cm^3. In some embodiments a distal portion of the catheter (e.g., the distal portion 104 of the catheter 102 of FIGS. 1A and 1B; and the distal portion 604 of the catheter 602 of FIGS. 6A and 6B) may be infused with a radiopaque material so that the entire distal portion is visible using imaging techniques.

[00132] In some embodiments, an outer sheath of an embolic protection device as described herein comprises a hollow tube configured to circumferentially surround at least a portion of the catheter. For example, the outer sheath 112 of the embolic protection device 100 of FIGS. 1A – 1F or the outer sheath 612 of the embolic protection device 600 of FIGS. 6A – 6G. The outer sheath is longitudinally movable with respect to the catheter and is configured to at least partially contain or house the embolic filter in a collapsed configuration when circumferentially surrounding the embolic filter, for example, as shown in FIG. 1A and FIG. 6A. The outer sheath is longitudinally proximally retractable to release the embolic filter to the expanded, open configuration when not contained by the outer sheath.

[00133] In some embodiments, the outer sheath extends proximally to a proximal end of the catheter (e.g., the proximal end 114 of the catheter 102 shown in FIG. 1A or the proximal end 614 of the catheter 602 shown in FIG. 6A) so that the user can grasp and manipulate the outer sheath directly. In some embodiments, the outer sheath extends proximally over only a portion of the catheter, and a secondary device (e.g., a push-rod such as found in stent deployment systems) is coupled to the outer sheath (e.g., to the proximal end of the outer sheath) to allow for indirect manipulation of the outer sheath. Manipulation of the outer sheath may be mechanical, electronic, manual, combinations thereof, and the like.

[00134] In some embodiments, an embolic protection device as described herein may have a longitudinally extending groove (not shown) along its outer surface. For example, the embolic protection device 100 of FIG. 1B includes a longitudinally extending groove along the catheter 102, along the support catheter 150, or along the deployment mechanism (e.g. outer sheath) 112. In another example, the embolic protection device 600 of FIG. 6B includes a longitudinally extending groove along the catheter 602, along the support catheter 650, or along the deployment mechanism/outer sheath 612. In some embodiments, the groove may extend substantially from the proximal end to the distal end of the embolic protection device. The groove may be useful for guiding another catheter device alongside the embolic protection device. For example, the groove may be useful for guiding a valve

delivery device alongside and beyond the distal end of the embolic protection device. Advantageously, the second device may be tracked along the groove and pass beyond the embolic protection device while the embolic filter is deployed as shown, for example, in FIG. 13A.

[00135] A device according to the disclosure herein can comprise some or all of the features of the embolic protection device 100, 200, 300, 400, 500, 600, 700, and 800 as shown in FIGS. 1A – 1F; FIGS. 2A and 2B; FIGS. 3A – 3D; FIGS. 4A – 4C; FIGS. 5A and 5B; FIGS. 6A – 6G; FIGS. 7A – 7C; and FIGS. 8A – 8F; and is described herein in various combinations.

[00136] III. METHODS OF CAPTURING EMBOLIC DEBRIS

[00137] Another aspect of the present invention provides a method 900 of capturing embolic debris during a closed-heart medical procedure (e.g., an aortic valve replacement procedure), as illustrated in a stepwise fashion in FIGS. 9A – 9E, using an embolic protection device of the present invention (e.g., the embolic protection device 100, 200, 300, 400, or 500 as described herein).

[00138] Referring to FIG. 9A, in one embodiment, a guidewire 990 is percutaneously inserted into a body lumen 992 of a patient, for example a femoral, radial, brachial, or subclavian artery, and navigated to the desired anatomical location, for example, the ascending aorta. The guidewire 990 can be a J-tipped wire having a diameter of about 0.035 in. (approx. 0.089 cm). Other types and dimensions of guidewires 990 useful for this method are also possible.

[00139] In some embodiments, the proximal end of the guidewire 990 is inserted into the opening at the distal end 116 of the catheter 102. When the guidewire 990 is in the lumen 118 of the catheter 102 at the distal portion 104 of the catheter 102, the distal portion 104 of the catheter is straightened or assumes the curvature of the guidewire 990. The distal end 116 of the catheter 102 is inserted into the body lumen 992 by tracking the lumen 118 of the catheter 102 over the guidewire 990, as shown in FIG. 9A. The outer diameter of the guidewire 990 is smaller than the inner diameter of the embolic protection device 100 such that the embolic protection device 100 may be tracked over the guidewire 990. The inner surface of the lumen 118 and/or the outer surface of the guidewire 990 may include a lubricious coating to reduce friction during tracking. The guidewire 990 keeps the distal portion 104 of the catheter 102 substantially straight (e.g., from being in the generally arcuate state) as the catheter 102 is inserted into and navigated within the patient's body.

[00140] The radiopaque marker(s) 106 are used to visualize and position the distal portion 104 of the catheter 102 during tracking. The guidewire 990 is retracted, i.e., moved

longitudinally in a proximal direction, a sufficient distance to allow the distal portion 104 of the catheter 102 to assume the generally arcuate shape, as shown in FIG. 9B. The distal portion 104 of the catheter 102 is positioned at the desired anatomical landmark, for example, the lower border of the noncoronary cusp of the aortic valve. The radiopaque marker(s) 106 are on the distal-most section of the distal portion 104 when the distal portion 104 assumes its generally arcuate shape. In some embodiments the distal portion 104 of the catheter 102 may be infused with a radiopaque material so that the entire distal portion 104 is visible using imaging techniques.

[00141] In some embodiments of the method, the proximal end 114 of the catheter 102 is connected to a contrast material injector, and contrast material is injected into the lumen 118 of the catheter 102, for example to visualize the anatomy around the device 100. The contrast material exits the catheter 102 lumen 118 through the opening at the distal end 116 of the catheter 102 and/or through one or more apertures 108 in the side wall of the catheter 102. Injecting contrast material can aid in visualizing and positioning the catheter 102.

[00142] In some embodiments, a second guidewire is percutaneously inserted into a second body lumen, for example the other femoral artery, and a second catheter is tracked over the second guidewire. The second catheter can carry a medical device or instrument, for example, a replacement valve, a valve repair system, or a radio frequency ablation system. Once the second catheter and associated device or instrument are properly positioned, the outer sheath 112 of the catheter 102 is longitudinally proximally retracted, allowing the embolic filter 110 to assume the expanded, deployed configuration, as shown in FIG. 9C.

[00143] Next, the pull wire 122 can be retracted to bend the frame 124 of the embolic filter 110. The pull wire 122 bends the frame 124 in a proximal longitudinal direction and laterally outward. In a fully bent configuration (i.e., with pull wire fully retracted), as shown in FIGS. 9D and 9E, the distal opening 140 of the embolic filter 110 may be substantially perpendicular to the catheter 102 and may span laterally across the body lumen 992, substantially perpendicular to the longitudinal axis of the body lumen 992. The fully bent configuration may engage the body lumen 992, thereby capturing embolic debris 994 in the embolic filter 110 without allowing embolic debris to travel around the outside of the embolic filter 110. The second guidewire and/or the second catheter can also be positioned after the embolic filter 110 is deployed. The distal opening 140 of the embolic filter 110 is located in the ascending aorta so that blood flows through the filter before flowing into the carotid arteries or descending aorta. In some embodiments, when the embolic filter 110 is deployed, the catheter 102 rests against the interior lumen wall, thereby stabilizing the catheter 102.

The procedure can then be performed, and embolic debris dislodged or otherwise in the blood stream during the procedure is captured by the embolic filter 110.

[00144] After the procedure, the pull wire 122 is advanced and the outer sheath 112 is longitudinally distally advanced to recapture the embolic filter 110, returning the frame to the unbent configuration and returning the embolic filter 110 to the collapsed configuration and capturing any embolic debris 994 (see FIG. 9E) contained within the embolic filter 110. The second catheter and catheter 102 can then be withdrawn from the patient's body. The catheter 102 can be retracted over the guidewire 990 or without straightening the distal portion 104 of the catheter 102 because the arcuate shape of the distal portion 104 is atraumatic to the blood vessels.

[00145] In some embodiments, the procedure performed is a cardiac valve replacement procedure, for example an aortic valve replacement procedure. The embolic protection device 100 is introduced into the patient and navigated to the aortic valve as described herein and shown in FIGS. 9A-9E. The radiopaque marker(s) 106 assist in delineating the lower border of the noncoronary cusp to assist in proper positioning of a percutaneously implanted replacement aortic valve. Once the catheter 102 is positioned, a second guidewire can be percutaneously inserted into a second body lumen and navigated to the level of the ascending aorta or left ventricle. A balloon can be tracked over the second guidewire to the aortic valve. The outer sheath 112 is then retracted to deploy the embolic filter 110 and the pull wire 122 is retracted to bend the frame 124 to a bent configuration. Balloon inflation of the valve can then be performed, and the embolic filter 110 captures embolic debris 994 dislodged during the procedure or otherwise in the blood stream. After balloon pre-dilation, the pull wire 122 is advanced and the outer sheath 112 is advanced to recapture the embolic filter 110 and any embolic debris 994 contained within the embolic filter 110. The balloon is removed, and a second catheter carrying a valvular prosthesis is advanced to the level of the ascending aorta by tracking the catheter over the second guidewire. The outer sheath 112 is again retracted to redeploy the embolic filter 110 and the pull wire 122 is again retracted. The radiopaque marker(s) 106 allow the user to properly position the valve prosthesis, for example about 4 mm to about 6 mm below the lower border of the noncoronary cusp. After the procedure is completed, the pull wire 122 is advanced and the outer sheath 112 is advanced to recapture the embolic filter 110 and any captured embolic debris 994, and the catheters are removed from the body. In some embodiments, the second catheter can be removed prior to recapturing the embolic filter 110 and embolic debris 994.

[00146] In some embodiments, the procedure is a cardiac valve repair procedure. The method described herein can also be adapted for a mitral valve repair or replacement

procedure. In some embodiments, the procedure is a radio frequency ablation procedure, for example to treat atrial fibrillation. In some embodiments, the procedure is a catheterization procedure or structural heart procedure.

[00147] In some embodiments, a method of capturing embolic debris as described herein may include inserting a second catheter device through the same vessel as the embolic protection device. The second catheter device may be inserted after the embolic protection device and may be tracked along a longitudinal groove in the outer surface of the embolic protection device. For example, a valve delivery catheter device may be guided alongside the embolic protection device and beyond the distal end of the embolic protection device by tracking the valve delivery device along the groove. Advantageously, the second device may be tracked along the groove and pass beyond the embolic protection device while the embolic filter is deployed as shown, for example, in FIG. 13A.

[00148] FIG. 10 illustrates another embodiment of a method 1000 of deflecting and capturing embolic debris during a medical procedure using an embolic protection device 1001. The embolic protection device 1001 is similar to the embolic protection device 300 that is described in FIGS. 3A – 3D, in that it has an intermediate tube 1030. The embolic protection device 1001 further comprises an embolic filter 1010 that is movably coupled to a catheter 1002 by way of a frame 1024 and is longitudinally movable with respect to the catheter 1002. As shown in the figure, the catheter 1002 is at least partially surrounded by a support catheter 1050 that terminates at a head 1052, proximal to a distal portion 1004 of the catheter 1002. The embolic filter 1010 is coupled to the intermediate tube 1030 that at least partially circumferentially surrounds the support catheter 1050. The intermediate tube 1030 is longitudinally movable with respect to the catheter 1002.

[00149] The embolic protection device 1001 further comprises an outer sheath (not shown) configured to at least partially circumferentially surround both the catheter 1002/support catheter 1050 and the intermediate tube 1030. The intermediate tube 1030 and the outer sheath can be moved simultaneously and independently. The longitudinal position of the embolic filter 1010 with respect to the catheter 1002 can be adjusted while the embolic filter 1010 is in the collapsed configuration or in a deployed or partially deployed, expanded configuration.

[00150] The method 1000 includes capturing emboli using the embolic protection device 1001 in a manner similar to the method 900 described above with reference to FIGS. 9A – 9E. For example, a distal end 1016 of the catheter 1002 is inserted into a body lumen 1080 of a patient by tracking a lumen 1018 of the catheter 1002 over a guidewire, which was previously percutaneously inserted into the body lumen 1080. The guidewire keeps a distal

portion 1004 of the catheter 1002 substantially straight (e.g., from being in the generally arcuate state) as the catheter 1002 is inserted into and navigated within the patient's body. The radiopaque marker 1006 is used to visualize and position the distal portion 1004 of the catheter 1002 during tracking. Visualization may also be accomplished by perfusing imaging dye or contrast agent through apertures 1008 in the distal portion 1004 of the catheter 1002. Once positioned at the desired anatomical landmark (e.g., the lower border of the noncoronary cusp of the aortic valve), the guidewire is retracted a sufficient distance to allow the distal portion 1004 of the catheter 1002 to assume the generally arcuate shape, as shown in FIG. 10.

[00151] The longitudinal position of the embolic filter 1010 within the body lumen 1080 can be adjusted by simultaneously moving the intermediate tube 1030 and the outer sheath. When the embolic filter 1010 is in the desired longitudinal position within the body lumen 1080, the intermediate tube 1030 is held stationary while the outer sheath is retracted to deploy the embolic filter 1010. Next, the pull wire 1022 is retracted to bend the frame 1024 and open the embolic filter 1010 to capture emboli.

[00152] The method 1000 further includes deflecting emboli. The embolic protection device 1001 also comprises a deflector 1060 similar to that shown in FIGS. 4A – C. Once the embolic protection device 1001 is in position (as described above), the deflector 1060 is deployed from the outer sheath to cover the brachiocephalic and left common carotid artery. In some patients, the deflector 1060 might also cover the left subclavian artery. During a subsequent medical procedure, the deflector 1060 can prevent emboli from entering the carotid arteries, and the embolic filter 1010 can capture emboli deflected by the deflector 1060 before it travels to other parts of the patient's body. The method 1000 can also be performed with various other embolic protection devices, for example as described herein, and deflector devices that may vary in configuration and how they are introduced into the body and navigated to the aortic arch.

[00153] FIG. 11 illustrates another embodiment of a method 1100 of deflecting and capturing embolic debris. An embolic protection device 1101 comprises a catheter 1102 (e.g., a pigtail catheter) with a radiopaque marker 1106 and an embolic filter 1110 disposed around the catheter 1102 similar to the embolic filter 110 illustrated in FIGS. 1A – 1F and described herein. As shown in the figure, the catheter 1102 is partially surrounded by a support catheter 1150 that terminates at a head 1152, proximal to a distal portion 1104 of the catheter 1102.

[00154] The method 1100 includes capturing emboli using the embolic protection device 1101 in a manner similar to the method 900 described above with reference to FIGS. 9A –

9E. For example, a distal end 1116 of the catheter 1102 is inserted into a body lumen 1180 of a patient by tracking a lumen 1118 of the catheter 1102 over a guidewire, which was previously percutaneously inserted into the body lumen 1180. The guidewire keeps a distal portion 1104 of the catheter 1102 substantially straight (e.g., from being in the generally arcuate state) as the catheter 1102 is inserted into and navigated within the patient's body. The radiopaque marker 1106 is used to visualize and position the distal portion 1104 of the catheter 1102 during tracking. Visualization may also be accomplished by perfusing imaging dye or contrast agent through apertures 1108 in the distal portion 1104 of the catheter 1102.

[00155] Once positioned at the desired anatomical landmark (e.g., the lower border of the noncoronary cusp of the aortic valve), the guidewire is retracted a sufficient distance to allow the distal portion 1104 of the catheter 1102 to assume the generally arcuate shape, as shown in FIG. 11. An outer sheath (not shown) of the catheter 1102 is longitudinally, proximally retracted, allowing the embolic filter 1110 to assume the expanded, deployed configuration, as shown in FIG. 11. Next, the pull wire 1122 is retracted to bend the frame 1124 and open the embolic filter 1110 to capture emboli.

[00156] The method 1100 further includes deflecting emboli with a deflector 1160. As shown, the deflector 1160 is mounted to a shaft 1162 and contained in an introducer 1168 during insertion. The introducer 1168 is introduced into the patient's body through the artery (e.g., right radial artery) and navigated to the aortic arch via the brachiocephalic artery. Once in position, the deflector 1160 is deployed from the introducer 1168 and pulled back to cover the brachiocephalic and left common carotid artery. In some patients, the deflector 1160 might also cover the left subclavian artery. In some embodiments, the deflector 1160 can be introduced and deployed before the catheter 1102 is navigated to the aortic arch. During a subsequent medical procedure, the deflector 1160 can prevent emboli from entering the carotid arteries, and the embolic filter 1110 can capture emboli deflected by the deflector 1160 before it travels to other parts of the patient's body. The method 1100 can also be performed with various other embolic protection devices, for example as described herein, and deflector devices that may vary in configuration and how they are introduced into the body and navigated to the aortic arch.

[00157] Another aspect of the present invention provides a method of capturing embolic debris during a closed-heart procedure, comprising inserting a distal end of a embolic protection device into a body lumen, the embolic protection device comprising a catheter having a proximal end, a distal end, and a lumen extending from the proximal end of the catheter to the distal end of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter that assumes a generally arcuate shape being at

least a semi-circle when the guidewire is at least partially longitudinally retracted; a self-expanding embolic filter that is disposed around the catheter proximal to the distal portion, wherein the embolic filter comprises a frame, and the frame defines an opening of the embolic filter; a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism; and a pull wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable, and when longitudinally retracted, bends the frame longitudinally toward the proximal end of the catheter and laterally outward from the catheter, such that the opening of the embolic filter generally faces the distal end of the catheter. The method further includes tracking the lumen of the catheter over the guidewire that is percutaneously inserted into the body lumen.

[00158] Some embodiments further comprise at least partially longitudinally retracting the guidewire from the lumen of the catheter, so that the distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle.

[00159] In some embodiments, the distal portion of the catheter comprises a radiopaque marker; and the method further comprises positioning the catheter by visualizing the radiopaque marker using an imaging technique.

[00160] Some embodiments comprise at least partially longitudinally retracting the deployment mechanism and allowing the self-expanding embolic filter to assume an expanded, deployed configuration.

[00161] Some embodiments comprise longitudinally retracting the wire, thereby bending the frame longitudinally toward the proximal end of the catheter and laterally outward from the catheter, wherein the opening defined by the frame substantially spans the body lumen.

[00162] Some embodiments comprise longitudinally retracting the wire to a proximal position, thereby bending the frame so that the opening of the filter defined by the frame is substantially perpendicular to the longitudinal direction of the catheter, wherein the opening defined by the frame substantially spans the body lumen.

[00163] In some embodiments, the embolic filter is movably coupled to the catheter and is longitudinally moveable with respect to the catheter, and the method comprises longitudinally moving the embolic filter with respect to the catheter.

[00164] In some embodiments, the embolic protection device comprises a self-expanding deflector coupled to the catheter proximal to the distal portion, and the method comprises deploying the self-expanding deflector to direct embolic debris toward the embolic filter.

[00165] In some embodiments, the deployment mechanism is a sheath that is circumferentially disposed around at least a portion of the catheter.

[00166] In some embodiments, the distal portion of the catheter comprises one or more apertures that communicate with the lumen of the catheter; the method further comprising perfusing a fluid into the body lumen through the one or more apertures.

[00167] In some embodiments, the embolic protection device comprises a longitudinal groove along an outer surface of the embolic protection device; the method further comprising inserting a second catheter device alongside the embolic protection device by tracking the second catheter device along the groove.

[00168] In some embodiments, the second catheter device is advanced past the embolic filter of the embolic protection device while the embolic filter is in a deployed configuration.

[00169] Another aspect of the present invention provides a method of capturing embolic debris during a closed-heart procedure, the method comprising inserting a distal end of a embolic protection device into a body lumen, the embolic protection device comprising a catheter having a proximal end, a distal end, and a lumen extending from the proximal end of the catheter to the distal end of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted; a self-expanding embolic filter that is disposed around the catheter proximal to the distal portion, wherein the embolic filter comprises a frame, and the frame defines an opening of the embolic filter; a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism; a wire coupled to the frame of the self-expanding filter, wherein the wire is longitudinally movable, and when longitudinally retracted, bends the frame longitudinally toward the proximal end of the catheter and laterally outward from the catheter, such that the opening of the embolic filter generally faces the distal end of the catheter

[00170] The method further includes tracking a lumen of the catheter over a guidewire that is percutaneously inserted into the body lumen and at least partially longitudinally retracting the guidewire from the lumen of the catheter, so that the distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle upon retracting the guidewire from the distal portion of the catheter. The method further includes longitudinally retracting the deployment mechanism and deploying the self-expanding embolic filter. The method further

includes longitudinally retracting the wire and bending the frame of the embolic filter longitudinally toward the proximal end of the catheter and laterally outward from the catheter.

[00171] Yet another aspect of the present invention provides a method 1200 of capturing embolic debris during a closed-heart medical procedure (e.g., an aortic valve replacement procedure), as illustrated in a stepwise fashion in FIGS. 12A – 12D, using an embolic protection device of the present invention (e.g., the embolic protection device 600, 700, or 800 as described herein).

[00172] Referring to FIG. 12A, in one embodiment, a guidewire 1290 is percutaneously inserted into a body lumen 1292 of a patient, for example a femoral, radial, brachial, or subclavian artery, and navigated to the desired anatomical location, for example, the ascending aorta. The guidewire 1290 can be a J-tipped wire having a diameter of about 0.035 in. (approx. 0.089 cm). Other types and dimensions of guidewires useful for this method are also possible.

[00173] In other embodiments, the proximal end of the guidewire 1290 is inserted into the opening at the distal end 616 of the catheter 602. When the guidewire 1290 is in the lumen 618 of the catheter 602 at the distal portion 604 of the catheter 602, the distal portion 604 of the catheter is straightened or assumes the curvature of the guidewire 1290. The distal end 616 of the catheter 602 is inserted into the body lumen 1292 by tracking the lumen 618 of the catheter 602 over the guidewire 1290, as shown in FIG. 12A. The outer diameter of the guidewire 1290 is smaller than the inner diameter of the embolic protection device 600 such that the embolic protection device 600 may be tracked over the guidewire 1290. The inner surface of the lumen 618 and/or the outer surface of the guidewire 1290 may include a lubricious coating to reduce friction during tracking. The guidewire 1290 keeps the distal portion 604 of the catheter 602 substantially straight (e.g., from being in the generally arcuate state) as the catheter 602 is inserted into and navigated within the patient's body.

[00174] The radiopaque marker(s) 606 are used to visualize and position the distal portion 604 of the catheter 602 during tracking. The guidewire 1290 is retracted, i.e., moved longitudinally in a proximal direction, a sufficient distance to allow the distal portion 604 of the catheter 602 to assume the generally arcuate shape, as shown in FIG. 12B. The distal portion 604 of the catheter 602 is positioned at the desired anatomical landmark, for example, the lower border of the noncoronary cusp of the aortic valve. The radiopaque marker(s) 606 are on the distal-most section of the distal portion 604 when the distal portion 604 assumes its generally arcuate shape. In some embodiments, the distal portion 604 of the catheter 602

may be infused with a radiopaque material so that the entire distal portion 604 is visible using imaging techniques.

[00175] In other embodiments of the method, the proximal end 614 of the catheter 602 is connected to a contrast material injector, and contrast material is injected into the lumen 618 of the catheter 602, for example to visualize the anatomy around the embolic protection device 600. The contrast material exits the lumen 618 through the opening at the distal end 616 of the catheter 602 and/or through one or more apertures 608 in the side wall of the catheter 602. Injecting contrast material can aid in visualizing and positioning the catheter 602.

[00176] In other embodiments, a second guidewire is percutaneously inserted into a second body lumen, for example the other femoral artery, and a second catheter is tracked over the second guidewire. The second catheter can carry a medical device or instrument, for example, a replacement valve, a valve repair system, or a radio frequency ablation system. Once the second catheter and associated device or instrument are properly positioned, the outer sheath 612 is longitudinally retracted in the proximal direction, allowing the embolic filter 610 to assume the self-expanded, deployed configuration, as shown in FIG. 12C.

[00177] Next, the push wire 622 can be advanced to bend the filter frame of the embolic filter 610. The push wire and the filter frame are not shown in FIGS. 12A – 12D, but can be seen in FIGS. 6B – 6F as the push wire 622 and the frame 624, respectively. The push wire bends the filter frame in a distal longitudinal direction and laterally outward. In the bent configuration (i.e., with the pull wire advanced in the distal direction), as shown in FIG. 12D, the distal opening 640 of the embolic filter 610 may be substantially perpendicular to the catheter 602 and may span laterally across the body lumen 1292, substantially perpendicular to the longitudinal axis of the body lumen 1292. To accommodate the size of the body lumen 1292, the push wire can be advanced farther to extend the frame in the radial direction and further expand the embolic filter 610.

[00178] The bent configuration may engage the body lumen 1292, thereby capturing embolic debris 1294 in the embolic filter 610 without allowing embolic debris to travel around the outside of the embolic filter 610. The second guidewire and/or the second catheter can also be positioned after the embolic filter 610 is deployed. The distal opening 640 of the embolic filter 610 is located in the ascending aorta so that blood flows through the embolic filter 610 before flowing into the carotid arteries or descending aorta. In some embodiments, when the embolic filter 610 is deployed, the catheter 602 rests against the interior lumen wall, thereby stabilizing the catheter 602. The procedure can then be

performed and embolic debris 1294 dislodged or otherwise in the blood stream during the procedure is captured by the embolic filter 610.

[00179] After the procedure, the push wire 622 is retracted and the outer sheath 612 is longitudinally and distally advanced to recapture the embolic filter 610, returning the filter frame to the unbent configuration and returning the embolic filter 610 to the collapsed configuration. And in turn capturing any embolic debris 1294 (see FIG. 12D) contained within the embolic filter 610. The second catheter and catheter 602 can then be withdrawn from the patient's body. The catheter 602 can be retracted over the guidewire 1290 or without straightening the distal portion 604 of the catheter 602 because the arcuate shape of the distal portion 604 is atraumatic to the blood vessels.

[00180] In other embodiments, the procedure performed is a cardiac valve replacement procedure, for example an aortic valve replacement procedure. The embolic protection device 600 is introduced into the patient and navigated to the aortic valve as described herein and shown in FIGS. 12A – 12D. The radiopaque marker(s) 606 assist in delineating the lower border of the noncoronary cusp to assist in proper positioning of a percutaneously implanted replacement aortic valve. Once the catheter 602 is positioned, a second guidewire can be percutaneously inserted into a second body lumen and navigated to the level of the ascending aorta or left ventricle. A balloon can be tracked over the second guidewire to the aortic valve. The outer sheath 612 is then retracted to deploy the embolic filter 610 and the push wire 622 is advanced to bend the frame 624 to a bent configuration. And if needed to engage the interior body lumen 1292, the push wire 622 may be advanced even farther to extend the frame 624 to an extended configuration. Balloon inflation of the valve can then be performed, and the embolic filter 610 captures embolic debris 1294 dislodged during the procedure or otherwise in the blood stream. After balloon pre-dilation, the push wire 622 is retracted and the outer sheath 612 is advanced to recapture the embolic filter 610 and any embolic debris 1294 contained within the embolic filter 610. The balloon is removed, and a second catheter carrying a valvular prosthesis is advanced to the level of the ascending aorta by tracking the catheter over the second guidewire. The outer sheath 612 is again retracted to redeploy the embolic filter 610 and the push wire 622 is again advanced. The radiopaque marker(s) 606 allow the user to properly position the valve prosthesis, for example about 4 mm to about 6 mm below the lower border of the noncoronary cusp. After the procedure is completed, the push wire 622 is retracted and the outer sheath 612 is advanced to recapture the embolic filter 610 and any captured embolic debris 1294, and the catheters are removed from the body. In some embodiments, the second catheter can be removed prior to recapturing the embolic filter 610 and embolic debris 1294.

[00181] In other embodiments, the procedure is a cardiac valve repair procedure. The method described herein can also be adapted for a mitral valve repair or replacement procedure. In some embodiments, the procedure is a radio frequency ablation procedure, for example to treat atrial fibrillation. In some embodiments, the procedure is a catheterization procedure or structural heart procedure.

[00182] In other embodiments, a method of capturing embolic debris as described herein may include inserting a second catheter device through the same vessel as the embolic protection device. The second catheter device may be inserted after the embolic protection device and may be tracked along a longitudinal groove in the outer surface of the embolic protection device. For example, a valve delivery catheter device may be guided alongside the embolic protection device and beyond the distal end of the embolic protection device by tracking the valve delivery device along the groove. Advantageously, the second device may be tracked along the groove and pass beyond the embolic protection device while the embolic filter is deployed as shown, for example, in FIG. 13A.

[00183] Another aspect of the present invention provides a method of capturing embolic debris during a closed-heart procedure, comprising inserting a distal end of a embolic protection device into a body lumen, the embolic protection device comprising a catheter having a proximal end, a distal end, and a lumen extending from the proximal end of the catheter to the distal end of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter that assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted; a self-expanding embolic filter that is disposed around the catheter proximal to the distal portion, wherein the embolic filter comprises a frame, and the frame defines an opening of the embolic filter; a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism; and a wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable with respect to the catheter; when the wire is longitudinally advanced, in a distal direction, to a first position, the wire is configured to bend the frame longitudinally towards the distal end of the catheter and laterally outward from the catheter, such that the opening of the embolic filter generally faces the distal end of the catheter and expands to a first diameter; and when the wire is longitudinally advanced, in the distal direction, to a second position distally farther than the first position, the wire is configured to extend the frame radially outward from the catheter, such that the opening of

the embolic filter expands to a second diameter larger than the first diameter. The method further includes tracking the lumen of the catheter over the guidewire that is percutaneously inserted into the body lumen.

[00184] Other embodiments further comprise at least partially longitudinally retracting the guidewire from the lumen of the catheter, so that the distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle.

[00185] In other embodiments, the distal portion of the catheter comprises a radiopaque marker; and the method further comprises positioning the catheter by visualizing the radiopaque marker using an imaging technique.

[00186] Other embodiments comprise at least partially longitudinally retracting the deployment mechanism and allowing the self-expanding embolic filter to assume an expanded, deployed configuration.

[00187] Other embodiments comprise longitudinally advancing the wire, thereby bending the frame longitudinally toward the proximal end of the catheter and laterally outward from the catheter, wherein the opening defined by the frame substantially spans the body lumen.

[00188] Other embodiments comprise longitudinally advancing the wire to the first position, thereby bending the frame longitudinally towards the distal end of the catheter and laterally outward from the catheter, and expanding the opening of the embolic filter to the first diameter, which substantially spans the body lumen.

[00189] Other embodiments comprise longitudinally advancing the wire to the second position distally farther than the first position, thereby extending the frame radially outward from the catheter and expanding the opening of the embolic filter to the second diameter larger than the first diameter, which substantially spans the body lumen.

[00190] In other embodiments, the deployment mechanism is a sheath that is circumferentially disposed around at least a portion of the catheter.

[00191] In other embodiments, the distal portion of the catheter comprises one or more apertures that communicate with the lumen of the catheter; the method further comprising perfusing a fluid into the body lumen through the one or more apertures.

[00192] In other embodiments, the embolic protection device comprises a longitudinal groove along an outer surface of the embolic protection device; the method further comprising inserting a second catheter device alongside the embolic protection device by tracking the second catheter device along the groove.

[00193] In other embodiments, the second catheter device is advanced past the embolic filter of the embolic protection device while the embolic filter is in a deployed configuration.

[00194] Another aspect of the present invention provides a method of capturing embolic debris during a closed-heart procedure, the method comprising inserting a distal end of a embolic protection device into a body lumen, the embolic protection device comprising a catheter having a proximal end, a distal end, and a lumen extending from the proximal end of the catheter to the distal end of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted; a self-expanding embolic filter that is disposed around the catheter proximal to the distal portion, wherein the embolic filter comprises a frame, and the frame defines an opening of the embolic filter; a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism; a wire coupled to the frame of the self-expanding filter, wherein the wire is longitudinally movable.

[00195] The method further includes tracking the lumen of the catheter over the guidewire that is percutaneously inserted into the body lumen and at least partially longitudinally retracting the guidewire from the lumen of the catheter, so that the distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle upon retracting the guidewire from the distal portion of the catheter. The method further includes longitudinally retracting the deployment mechanism and deploying the self-expanding embolic filter. The method further includes longitudinally advancing the wire, in a distal direction, to a first position, thereby bending the frame longitudinally towards the distal end of the catheter and laterally outward from the catheter, and expanding the opening of the embolic filter to a first diameter.

[00196] IV. EXAMPLES

[00197] Example 1: Cadaver Model

[00198] Referring to FIGS. 13A and 13B, an embolic protection device of the present invention (EPD-1) was tested in a human cadaver model to visually assess the device's ability to cover all cerebral vessels with an embolic filter while an endovascular device was passed through the aorta and alongside the EPD-1. In the photographs of FIGS. 13A and 13B, the EPD-1 is deployed and covering the opening of cerebral vessels of the cadaver while at the same time, a TAVR delivery system passes above the filter. In FIG. 13A, the TAVR delivery system is tracked along a longitudinal groove on the outer surface of the EPD-1 catheter. In FIG. 13B, the TAVR delivery system is tracked outside the groove of the EPD-1 catheter.

[00199] Example 2: Clinical Study

[00200] Referring to FIG. 14 and FIGS. 15A – 15J, the safety and performance of an embolic protection device according to the present invention ("EPD-1") was assessed during transcatheter aortic valve replacement (TAVR) procedures on human subjects. The primary objective was to evaluate the performance and the treatment of effect of the use of the EPD-1 during TAVR with respect to procedure-related cerebral embolic burden as determined by diffusion-weighted magnetic resonance imaging (DW-MRI). A secondary objective was to analyze the safety profile and type of captured debris from the EPD-1 filter after TAVR.

[00201] The study was designed as a multi-center non-randomized trial including up to 5 clinical sites to evaluate the performance and the treatment effect of the use of the EPD-1 during TAVR with respect to procedure-related silent ischemic damage and cerebral embolic burden, as determined by DW-MRI studies performed before and after the procedure. A secondary objective was to analyze the safety profile and the type of captured debris from the EPD-1 filter after TAVR. The potential risk of neurological compromise and stroke was assessed based on neurological evaluations pre and post procedure. The study population was comprised of up to thirty (30) subjects with severe native aortic valve stenosis who meet the commercially approved indications for TAVR and complied with the inclusion/exclusion criteria.

[00202] Primary Endpoints: 1) Device performance: defined as the successful insertion, placement, and removal of the EPD-1. Device performance was evaluated during and after completion of the TAVR index procedure. 2) Acute cerebral embolic burden reduction after TAVR, defined as number and volume of brain lesions detected with DW MRI at Day 2-5 post TAVR procedure compared with baseline.

[00203] Secondary Endpoints: 1) Rate of major adverse cardiac and cerebrovascular events at 30-days post TAVR index procedure compared to historical data. Major Adverse Cardiac and Cerebrovascular Events (MACCE) are defined as: All-cause mortality; All stroke (major, minor, TIA); Acute Kidney Injury (Class 3). 2) Clinical assessment of subject's neurological status pre- and post-index procedure using the NIH stroke scale.

[00204] Eleven subjects were enrolled in a multi-center, non-randomized, prospective pilot study. The performance characteristics of the EPD-1 were evaluated post-procedurally and scored on a 5-point score (1, unacceptable to 5, excellent). The average performance across all patients of all characteristics for the EPD-1 was 4.8 at clinical site 1 and 3.4 at clinical site 2. Average performance scores (at each of the clinical sites) for each assessed characteristic EPD-1 performance are illustrated in the bar graphs of FIG. 14. The characteristics scored were: vessel access, tracking, use of sheath and deployment buttons, positioning, re-