

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No. : 11,744,691 Confirmation No: 1816
Issued : September 5, 2023
Inventors : Ben Merritt
Jacqueline Macias
Brian Michael Strauss
Thomas Tu
John Coleman Thress
Paul Lubock

Application No. : 18/180,016
Filed : March 7, 2023

Title **SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED
DEVICES AND METHODS**

**STATEMENT OF ASSIGNEE UNDER 37 CFR § 1.324 REGARDING
CORRECTION OF INVENTORSHIP**

Commissioner:

Assignee, Inari Medical, Inc., hereby agrees to adding John Coleman Thress and Paul Lubock as inventors of U.S. Patent No. 11,744,691.

A Statement under 37 § C.F.R. 3.73(c) is attached specifying documentary evidence of the chain of title.

Date: 3/20/24

Signature

Authorized Signer

Brian Strauss

Authorized Signer -- Printed Name

Sr. VP, R&D Engineering

Authorized Signer -- Title

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.

STATEMENT UNDER 37 CFR 3.73(c)Applicant/Patent Owner: Inari Medical, Inc.Application No./Patent No.: 18/180,016Filed/Issue Date: 2023-03-07Titled: SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODSInari Medical, Inc., a Corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☒ The assignee of the entire right, title, and interest.
2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):
- ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.
- ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (e.g., bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

- A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.
- B. ☒ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: Merrit, Ben; Macias, Jacqueline; Strauss, Briar To: INARI MEDICAL, INC.The document was recorded in the United States Patent and Trademark Office at
Reel 063292, Frame 0651, or for which a copy thereof is attached.2. From: Tu, Thomas To: INARI MEDICAL, INC.The document was recorded in the United States Patent and Trademark Office at
Reel 063292, Frame 0717, or for which a copy thereof is attached.

[Page 1 of 2]

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

STATEMENT UNDER 37 CFR 3.73(c)

3. From: John Coleman Thress and Paul Lubock To: INARI MEDICAL, INC.

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

4. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☒ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Matthew S. Williams/

2024-04-30

Signature

Date

Matthew S. Williams

77,516

Printed or Typed Name

Title or Registration 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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No. : 11,744,691 Confirmation No: 1816
Issued : September 5, 2023
Inventors : Ben Merritt
Jacqueline Macias
Brian Michael Strauss
Thomas Tu
John Coleman Thress
Paul Lubock

Application No. : 18/180,016
Filed : March 7, 2023

Title **SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED
DEVICES AND METHODS**

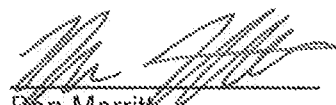
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**STATEMENT UNDER 37 CFR § 1.324 REGARDING
CORRECTION OF INVENTORSHIP**

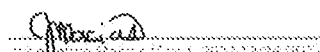
Dear Commissioner:

We, Ben Merritt, Jacqueline Macias, Brian Michael Strauss, and Thomas Tu, are the currently named inventors on U.S. Patent No. 11,744,691. We agree to adding John Coleman Thress and Paul Lubock as inventors to U.S. Patent No. 11,744,691.

Dated: 3/27/24


Ben Merritt

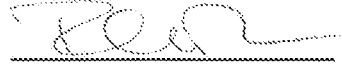
Dated: Apr 1, 2024


U.S. Patent No. 11,744,691, dated 09/05/23
Jacqueline Macias

Dated: 3/27/24


Brian Michael Strauss

Dated: 4/2/24


Thomas Tu



ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
18/180,016

RECEIPT DATE / TIME
04/30/2024 06:02:15 PM Z ET

ATTORNEY DOCKET #
111552.8018.US07

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 # 11744691

CONFIRMATION # 1816

FILED BY JiYoung Anderson

PATENT CENTER # 65323608

FILING DATE 03/07/2023

CUSTOMER # 25096

FIRST NAMED
INVENTOR Ben Merritt

CORRESPONDENCE
ADDRESS -

AUTHORIZED BY Matthew Williams

Documents

TOTAL DOCUMENTS: 7

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2024.4.30 6a Statement Under 37 CFR 3.73 - 111552.8018.US07.pdf	3	Assignee showing of ownership per 37 CFR 3.73	5614 KB
6b Assignment additional all signed - 111552.8018.US07.pdf	4	Assignee showing of ownership per 37 CFR 3.73	1284 KB
1 and 3 Additional Statement by inventor signed John and Paul - 111552.8018.US07.pdf	1	Transmittal Letter	503 KB
2 Statement signed by current inventors - 111552.8018.US07.pdf	2	Transmittal Letter	326 KB

4 Declaration additional signed Paul and John - 111552.8018.US07.pdf	2	Oath or Declaration filed	1441 KB
5 Assignee Statement signed - 111552.8018.US07.pdf	1	Transmittal Letter	1140 KB
2024.4.30 Request to Correct Inventorship - 111552.8018.US07.pdf	3	Request under Rule 48 correcting inventorship	115 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2024.4.30 6a Statement Under 37 CFR 3.73 - 111552.8018.US07.pdf	52D5C775BEF5A63D52976F936BEABC59A1AEBC3DF27F7914 DC238335411E2C94B69BC278337B8C5429387E260511DA4626 DE1EF988A27A6C8E64023E9561A034
6b Assignment additional all signed - 111552.8018.US07.pdf	565BC5A010A311DAAD1284FA63EF4BFFA3FD5AF61892988F2 CB58258328EA19F7C94367268F136D89506766D045FB80D27D 23C13B06F6F0FBF116B66F7390826
1 and 3 Additional Statement by inventor signed John and Paul - 111552.8018.US07.pdf	0421E4FC47E548B8DB95215A8D72724A4F3EA8A5B848736279 6F924BB63F5ACBAFA421F21BE4F1505A40A9BA3A15F55135D 3D151532838A693AB707C92366BF3
2 Statement signed by current inventors - 111552.8018.US07.pdf	FF3C576E06ADBA911BC2A70B0114A7F95801592A4642986EE EE2F842BB0D98073A79F73603498D071E64C3394EB9F1DB8F0 DB95F987B1DF645E6217ABCA1F1B8
4 Declaration additional signed Paul and John - 111552.8018.US07.pdf	D7FEA41F6CAEB9E84C7924948F280977CFFE1CE1E73E01D52 B71AB5897FE2EFE560C18F9978738D6F71D2BA952BE3FA9FA BE0E7B7A39794B7A48E1B02CB50B11
5 Assignee Statement signed - 111552.8018.US07.pdf	F3BE12641BD677D6F8DE6C4D240040534DF2FAAFF509BD309 CA13CDE920B0A56AEB9E439E7B4911842D2EF0C48B0039F2F 473BCF79A0B90399EDE035922C4719

2024.4.30 Request to Correct	7B54D04AA4E9D08ACC58A4FBC0CECAEB121CD68970089C0
Inventorship -	E3F4DDBD3A26E070E7EB361208CB6DFAABA37875348946705
111552.8018.US07.pdf	BE340CEE2B040F3C0744A361142C31B7

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 #
18/180,016

RECEIPT DATE / TIME
04/30/2024 06:02:15 PM Z ET

ATTORNEY DOCKET #
111552.8018.US07

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 # 11744691

CONFIRMATION # 1816

FILED BY JiYoung Anderson

PATENT CENTER # 65323608

AUTHORIZED BY Matthew Williams

CUSTOMER # 25096

FILING DATE 03/07/2023

CORRESPONDENCE
ADDRESS -

FIRST NAMED
INVENTOR Ben Merritt

Payment Information

PAYMENT METHOD
CARD / \$111

PAYMENT TRANSACTION ID
E20244T102378262

PAYMENT AUTHORIZED BY
JiYoung Anderson

FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
1811	CERTIFICATE OF CORRECTION	160.00	1	160.00
TOTAL AMOUNT:				\$160.00

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.

ASSIGNMENT BY INVENTORS

This Assignment is by the following individuals (the "Assignors"):

- John Coleman Thress having a mailing address of 6001 Oak Canyon, Suite 100, Irvine, California 92618, US; and
- Paul Lubock having a mailing address of 6001 Oak Canyon, Suite 100, Irvine, California 92618, US.

The Assignors invented one or more certain inventions (the "Invention(s)") described in an application for Letters Patent of the United States SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS, and filed on March 3, 2023 as U.S. Patent Application No. 18/180,016 (the "Application").

Inari Medical, Inc., a Corporation of California having its principal place of business at 6001 Oak Canyon, Suite 100, Irvine, California 92618 (the "Assignee"), desires to acquire the entire right, title and interest in and to the Invention(s) and the Applications, and in and to any patents (the "Patents") that may be granted for the Invention(s) in the United States and/or in any foreign countries.

For valuable consideration, the receipt and sufficiency of which Assignors acknowledge, Assignors hereby sell, assign, and transfer to Assignee, its successors, legal representatives and assigns, the entire right, title and interest in and to: the Invention(s), the Applications, and any Patents; any divisions, continuations, and continuations-in-part of the Applications and any other application claiming priority rights from the Applications; any reissues, reexaminations, or extensions of any and all Patents; the right to file foreign applications directly in the name of Assignee; and the right to claim priority rights deriving from the Applications (collectively, the "Rights"). Assignors warrant that Assignors own the Rights, and that the Rights are unencumbered. Assignors also agree to not sign any writing or do any act conflicting with this Assignment, and, without further compensation, sign all documents and do such additional acts as Assignee deems necessary or desirable to: perfect Assignee's

enjoyment of the Rights; conduct proceedings regarding the Rights, including any litigation or interference proceedings; or perfect or defend title to the Rights. Assignors request the Commissioner of Patents to issue any Patent of the United States that may be issued on the Invention(s) to Assignee. This Assignment may be executed in counterparts.

For Inari Medical, Inc.:

Date: 1/31/2024

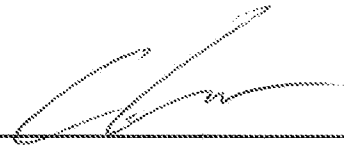
Signature 

Brian Strauss Authorized Signer

Sr. VP, R&D Engineering Authorized Signer – Printed Name

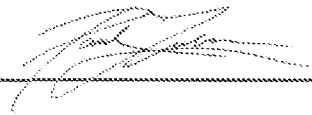
Authorized Signer – Title

Date: 21/10/24



John Coleman Thress

Date: February 21, 2024



Paul Lubock

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No. : 11,744,691 Confirmation No: 1816
Issued : September 5, 2023
Inventors : Ben Merritt
Jacqueline Macias
Brian Michael Strauss
Thomas Tu
John Coleman Thress
Paul Lubock

Application No. : 18/180,016
Filed : March 7, 2023

Title **SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED
DEVICES AND METHODS**

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

REQUEST TO CORRECT INVENTORSHIP UNDER 37 CFR § 1.324

Dear Commissioner:

Inari Medical, Inc., the Assignee of the entire right, title, and interest to U.S. Patent No. 11,744,691 (the '691 patent), hereby requests that the '691 patent be corrected pursuant to 37 C.F.R. § 1.324 to name the actual inventors.

The Office is requested to correct inventorship by **adding** the following omitted inventors:

- John Coleman Thress – Capistrano Beach, California; and
- Paul Lubock – Monarch Beach, California;

Following correction, the '691 patent will list Ben Merritt, Jacqueline Macias, Brian Michael Strauss, Thomas Tu, John Coleman Thress, and Paul Lubock as inventors.

In support of this request under 37 C.F.R. § 1.324, the following is included with this submission:

1. Statement by the individuals identified above that the error in inventorship occurred without deceptive intent on their part and agreeing to this change in inventorship;
2. Statement from currently named inventors, Ben Merritt, Jacqueline Macias, Brian Michael Strauss, and Thomas Tu, agreeing to this change in inventorship;
3. Declarations from the inventors being added, John Coleman Thress and Paul Lubock;
4. Statement from Inari Medical, Inc., agreeing to this change in inventorship;
5. Statement by Inari Medical, Inc. under 37 C.F.R. § 3.73(c), establishing the right to take action as the Assignee; and
6. Processing fee of \$160.00 under 37 C.F.R. § 1.20(b).

Based on the above, applicant respectfully requests the Commissioner to grant this request under 37 CFR § 1.324 and issue a Certificate of Correction naming the actual inventors as listed in this request.

The Commissioner is hereby authorized to charge any additional fees that may be required under 37 C.F.R. 1.324, or credit any overpayment, to Deposit Account No. 50-0665.

Respectfully submitted,

Dated: April 30, 2024

By /Matthew S. Williams/
Matthew S. Williams
Registration No.: 77,516
PERKINS COIE LLP
P.O. Box 1247
Seattle, Washington 98111-1247
(206) 359-3343
(206) 359-9000 (Fax)
Attorneys for Applicant

**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 18/180,016
filed on 2023-03-07.

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.

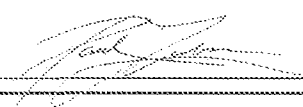
I hereby acknowledge that any wilful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

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: January 25, 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.

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No. : 11,744,691 Confirmation No: 1816

Issued : September 5, 2023

Inventors : Ben Merritt
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Application No. : 18/180,016

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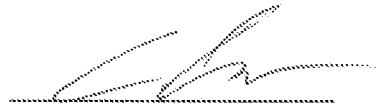
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**STATEMENT UNDER 37 CFR § 1.324 REGARDING
CHANGE OF INVENTORSHIP**

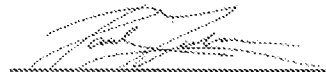
Dear Commissioner:

We, John Coleman Thress and Paul Lubock are being named as joint inventors of the above identified patent and agree to the addition as inventors of U.S. Patent No. 11,744,691. The inventorship error of failing to include John Coleman Thress and Paul Lubock as a joint inventor of the patent occurred without any deceptive intention on the part of John Coleman Thress and Paul Lubock.

Dated: 03/28/2024


John Coleman Thress

Dated: 4/30/24


Paul Lubock



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United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/180,016	03/07/2023	Ben Merritt	111552.8018.US07	1816
25096	7590	09/05/2023	EXAMINER	
PERKINS COIE LLP - SEA General			RASSAVONG, ERIC	
PATENT-SEA			ART UNIT	
P.O. BOX 1247			PAPER NUMBER	
SEATTLE, WA 98111-1247			3781	
			NOTIFICATION DATE	DELIVERY MODE
			09/05/2023	ELECTRONIC

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

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

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

patentprocurement@perkinscoie.com



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APPLICATION NO.	ISSUE DATE	PATENT NO.
18/180,016	05-Sep-2023	11744691

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.
18/180,016	09/05/2023	11744691	111552.8018.US07	1816

25096 7590 08/16/2023
PERKINS COIE LLP - SEA General
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;

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.



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25096	7590	08/10/2023	EXAMINER	
PERKINS COIE LLP - SEA General			RASSAVONG, ERIC	
PATENT-SEA			ART UNIT	PAPER NUMBER
P.O. BOX 1247			3781	
SEATTLE, WA 98111-1247			NOTIFICATION DATE	DELIVERY MODE
			08/10/2023	ELECTRONIC

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patentprocurement@perkinscoie.com

Supplemental Notice of Allowability	Application No. 18/180,016	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 IDS filed on 7/17/2023.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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

3. ☒ The allowed claim(s) is/are 2-14 and 16-33. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

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

Certified copies:

a) ☐ All b) ☐ Some* c) ☐ None of the:

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

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

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

* Certified copies not received: _____.

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

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

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

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

Attachment(s)

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

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

Doc code: IDS

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2012. OMB 0651-0031
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	18/180,016 - Conf# 1816
	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US07

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.	20160038267	02-11-2016	ALLEN et al.	
	2.	20140222070	08-07-2014	BELSON et al.	
	3.	20130204297	08-08-2013	Melsheimer et al.	
	4.	11697012	07-11-2023	Merritt et al.	
	5.	11697011	07-11-2023	Merritt et al.	
	6.	20140324091	10-30-2014	Rosenbluth et al.	
	7.	20150018859	01-15-2015	Quick et al.	
	8.	20150196744	07-16-2015	Aboytes	
	9.	20160367285	12-22-2016	Sos	
	10.	20130144326	06-06-2013	Brady et al.	
	11.	20140005715	01-02-2014	Castella et al.	
	12.	20140180397	06-26-2014	Gerberding et al.	
	13.	20150150672	06-04-2015	Ma	
	14.	20130030460	01-31-2013	Marks et al.	
	15.	20230218310	07-13-2023	Scheinblum et al.	
	16.	20230218313	07-13-2023	Rosenbluth 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.					
	2.					
	3.					
	4.					
	5.					

Doc code: IDS

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US07

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

EXAMINER SIGNATURE			
Examiner Signature	/ERIC RASSAVONG/	Date Considered	08/07/2023
*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.			
<small> 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. </small>			

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	

Doc code: IDS

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

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	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US07

representation that: (i) a search has been made; (ii) additional information that may be material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, Applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

COPIES OF REFERENCES

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

SIGNATURE

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

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2023-07-17
Name/Print	Matthew S. Williams	Registration Number	77,516

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

PTO/SB/08a(04-07)

Approved for use through 7/31/2008. OMB 0851-0031

US Patent & Trademark Office, U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT***Complete if Known*

Application Number	177154,806 - Conf. #9021 18/180,016
Filing Date	January 21, 2021
First Named Inventor	Phil Marchand
Art Unit	3774 3781
Examiner Name	Tuan Van Nguyen Eric Rassavong

(Use as many sheets as necessary)

Sheet	1	of	3	Attorney Docket No: 111552-8015.US03
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US PATENT AND PUBLICATION DOCUMENTS

Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Filing Date If Appropriate
		20160030708	02-04-2016	Casiello et al.	
		20160135829	05-19-2016	Holoehwost et al.	
		20060264905	11-23-2006	Eskridge et al.	
		5244619	09-14-1993	Burnham	
		20170021130	01-26-2017	Dye	
		20160106353	04-21-2016	Schuetz et al.	
		10960114	03-30-2021	Gosis	
		10531883	01-14-2020	Deville et al.	
		9581942	02-28-2017	Shippert	
		5234403	08-10-1993	Yoda et al.	
		20100106081	04-29-2010	Brandeis	
		20100094201	04-15-2010	Mallaby	
		20050004534	01-06-2005	Lockwood et al.	
		20190365395	12-05-2019	Tran et al.	
		20160038267	02-11-2016	ALLEN et al.	
		20140222070	08-07-2014	BELSON et al.	
		20130204297	08-08-2013	Melsheimer et al.	
		11697012	07-11-2023	Merritt et al.	
		11697011	07-11-2023	Merritt et al.	
		20230218310	07-13-2023	Scheinblum et al.	
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		20150018859	01-15-2015	Quick et al.	
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		20140180397	06-26-2014	Gerberding et al.	
		20150150672	06-04-2015	Ma	
		20130030460	01-31-2013	Marks et al.	

EXAMINER /ERIC RASSAVONG/ {08/07/2023}

DATE CONSIDERED 08/07/2023

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

162982736.1

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

Substitute for form 1449A/PTO					
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	177154,806 - Cont. #9021
				Filing Date	January 21, 2021
				First Named Inventor	Phil Marchand
				Art Unit	3771
				Examiner Name	Tuan Van Nguyen
Sheet	2	of	3	Attorney Docket No: 111552-8015.US03	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of cited Document	T ²

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No ¹	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 ²
		International Search Report and Written Opinion for International App. No. PCT/US23/61256; Date of Filing: January 25, 2023, Applicant: Inari Medical, Inc., Date of Mailing: June 7, 2023, 8 pages.	
		Gross et al., "Dump the pump: manual aspiration thrombectomy (MAT) with a syringe is technically effective, expeditious, and cost-efficient," J NeuroIntervent Surg, 2018, 4 pages.	

CERTIFICATION STATEMENT

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

☐

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

OR

☐

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☐

See attached certification statement.

☐

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

EXAMINER

/ERIC RASSAVONG/ (08/07/2023)

DATE CONSIDERED

08/07/2023

Substitute Disclosure Statement Form (PTO-1449)
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162982736.1

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PTO/SB/08a(04-07)

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US Patent & Trademark Office, U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)					
				<i>Complete if Known</i>	
				Application Number	17/154,806 - Conf. #9021
				Filing Date	January 21, 2021
				First Named Inventor	Phil Marchand
				Art Unit	3774
				Examiner Name	Tuan Van Nguyen
Sheet	3	of	3	Attorney Docket No: 111552-8015.US03	

☒

A certification statement is not submitted herewith.

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

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Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2023-07-17
Name/Print	Matthew S. Williams	Registration Number	77,516

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EXAMINER /ERIC RASSAVONG/ {08/07/2023}**DATE CONSIDERED** 08/07/2023

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. † Applicant's unique citation designation number (optional) ‡ Applicant is to place a check mark here if English language Translation is attached

162982736.1

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Doc code: IDS

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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	18/180,016 - Conf# 1816
	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt
	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552.8018.US07

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
	552.	20150209165	07-30-2015	Grandfield et al.	
	553.	20150238207	08-27-2015	Cox et al.	
	554.	20150250578	09-10-2015	Cook et al.	
	555.	20150265299	09-24-2015	Cooper et al.	
	556.	20150305756	10-29-2015	Rosenbluth	
	557.	20150305859	10-29-2015	Eller	
	558.	20150352325	12-10-2015	Quick	
	559.	20150360001	12-17-2015	Quick	
	560.	20150374391	12-31-2015	Quick	
	561.	20160008014	08-09-2016	Rosenbluth	
	562.	20160022293	01-28-2016	Dubrul et al.	
	563.	20160058540	03-03-2016	Don Michael	
	564.	20160074627	03-17-2016	Cottone	
	565.	20160106448	04-21-2016	Brady et al.	
	566.	20160106449	04-21-2016	Brady et al.	
	567.	20160113663	04-28-2016	Brady et al.	
	568.	20160113664	04-28-2016	Brady et al.	
	569.	20160113665	04-28-2016	Brady et al.	
	570.	20160113666	04-28-2016	Quick	
	571.	20160143721	05-26-2016	Rosenbluth	
	572.	20160206344	07-21-2016	Bruzzi et al.	
	573.	20160228134	08-11-2016	Martin et al.	
	574.	20160262790	09-15-2016	Rosenbluth et al.	
	575.	20160287276	10-06-2016	Cox et al.	
	576.	20160367285	05-19-2016	Sos	12/2016
	577.	20170014560	01-19-2017	Minskoff et al.	
	578.	20170037548	02-09-2017	Lee	
	579.	20170042571	02-16-2017	Levi	
	580.	20170058623	03-02-2017	Jaffrey et al.	

Change(s) applied
to document,
/J.T./
7/21/2025

Doc code: IDS

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt
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	Attorney Docket Number	111552.8018.US07

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
	523.	20140243882	08-28-2014	Ma	
	524.	20140257253	09-11-2014	Jemison	
	525.	20140276403	09-18-2014	Follmer et al.	
	526.	20140318354	10-30-2014	Thompson et al.	
	527.	20140324091	05-03-2015	Rosenbluth	10/2014
	528.	20140330286	11-06-2014	Wallace et al.	
	529.	20140336691	11-13-2014	Jones et al.	
	530.	20140343593	11-20-2014	Chin et al.	
	531.	20140364896	12-11-2014	Consigny	
	532.	20140371779	12-18-2014	Vale et al.	
	533.	20150005781	01-01-2015	Lund-Clausen et al.	
	534.	20150005792	01-01-2015	Ahn	
	535.	20150018859	02-16-2016	Quick	
	536.	20150018860	01-15-2015	Quick	
	537.	20150018929	01-15-2015	Martin et al.	
	538.	20150025555	01-22-2015	SOS	
	539.	20150032144	01-29-2015	Holloway	
	540.	20150059908	03-05-2015	Mollen	
	541.	20150088190	03-26-2015	Jensen	
	542.	20150127035	05-07-2015	Trapp et al.	
	543.	20150133990	05-14-2015	Davidson	
	544.	20150150672	08-07-2015	Ma	06/2015
	545.	20150164523	06-18-2015	Brady et al.	
	546.	20150164666	06-18-2015	Johnson et al.	
	547.	20150190155	07-09-2015	Ulm III	
	548.	20150190156	07-09-2015	Ulm III	
	549.	20150196380	07-16-2015	Berrada et al.	
	550.	20150196744	04-03-2016	Aboytes	07/2015
	551.	20150209058	07-30-2015	Ferrera et al.	

Change(s) applied
to document,
/J.T./
7/21/2025

Doc code: IDS

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

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U.S. PATENTS AND PUBLICATIONS					
Examiner Initial*	Cite No.	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	494.	20130046332	02-21-2013	Jones et al.	
	495.	20130066348	03-14-2013	Fiorella et al.	
	496.	20130092012	04-18-2013	Marchand et al.	
	497.	20130096571	04-18-2013	Massicotte et al.	
	498.	20130102996	04-25-2013	Strauss	
	499.	20130116721	05-09-2013	Takagi et al.	
	500.	20130144326	06-02-2013	Brady et al.	06/2013
	501.	20130165871	06-27-2013	Fiorella et al.	
	502.	20130184703	07-18-2013	Shireman et al.	
	503.	20130197567	08-01-2013	Brady et al.	
	504.	20130226196	08-29-2013	Smith	
	505.	20130289608	10-31-2013	Tanaka et al.	
	506.	20130317589	11-28-2013	Martin et al.	
	507.	20130345739	12-26-2013	Brady et al.	
	508.	20140005712	01-02-2014	Martin	
	509.	20140005713	01-02-2014	Bowman	
	510.	20140005715	03-31-2015	Castella et al.	
	511.	20140005717	01-02-2014	Martin et al.	
	512.	20140025048	01-23-2014	Ward	
	513.	20140031856	01-30-2014	Martin	
	514.	20140046133	02-13-2014	Nakamura et al.	
	515.	20140046243	02-13-2014	Ray et al.	
	516.	20140121672	05-01-2014	Folk	
	517.	20140155830	06-05-2014	Bonnette et al.	
	518.	20140155908	07-22-2014	Rosenbluth et al.	
	519.	20140155980	06-05-2014	Turjman	
	520.	20140180397	09-05-2014	Gerberding et al.	06/2014
	521.	20140188143	04-03-2015	Martin et al.	07/2014
	522.	20140236219	08-21-2014	Dubrul et al.	

Change(s) applied
to document,
/J.T./
7/21/2025

Doc code: IDS

PTO/SB/08a (01-10)

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U.S. PATENTS AND PUBLICATIONS					
Examiner Initial*	Cite No.	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	465.	20110196414	08-11-2011	Porter et al.	
	466.	20110213290	09-01-2011	Chin et al.	
	467.	20110213403	09-01-2011	Aboytes	
	468.	20110224707	09-15-2011	Miloslavskiet al.	
	469.	20110245807	10-06-2011	Sakata et al.	
	470.	20110251629	10-13-2011	Galdonik et al.	
	471.	20110264133	10-27-2011	Hanlon et al.	
	472.	20110265681	11-03-2011	Allen et al.	
	473.	20110288529	11-24-2011	Fulton	
	474.	20110288572	11-24-2011	Martin	
	475.	20110319917	12-29-2011	Ferrera et al.	
	476.	20120059309	03-08-2012	di Palma et al.	
	477.	20120059356	03-08-2012	di Palma et al.	
	478.	20120083824	04-05-2012	Berrada et al.	
	479.	20120083868	04-05-2012	Shrivastava	
	480.	20120089216	04-12-2012	Rapaport et al.	
	481.	20120101480	04-26-2012	Ingle et al.	
	482.	20120101510	04-26-2012	Lenker et al.	
	483.	20120138832	06-07-2012	Townsend	
	484.	20120143239	06-07-2012	Aklog et al.	
	485.	20120165919	06-28-2012	Cox et al.	
	486.	20120179181	07-12-2012	Straub et al.	
	487.	20120197277	08-02-2012	Stinis	
	488.	20120232655	09-13-2012	Lorrison et al.	
	489.	20120271105	10-25-2012	Nakamura et al.	
	490.	20120271231	10-25-2012	Agrawal	
	491.	20120277788	11-01-2012	Cattaneo	
	492.	20120310166	12-06-2012	Huff	
	493.	20130030460	04-24-2014	Marks et al.	01/2013

Change(s) applied
to document,

/J.T./

7/21/2023 161789961.1



ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
18/180,016

RECEIPT DATE / TIME
07/18/2023 05:36:07 PM ET

ATTORNEY DOCKET #
111552.8018.US07

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 # 1816

FILED BY J iYoung Anderson

PATENT CENTER # 62463422

FILING DATE 03/07/2023

CUSTOMER # 25096

FIRST NAMED
INVENTOR Ben Merritt

CORRESPONDENCE
ADDRESS -

AUTHORIZED BY Matthew Williams

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-7-18 Comments - 111552-8018US07.PDF	2	Miscellaneous Incoming Letter	75 KB
2023-7-18 Issue Fee Transmittal - 111552- 8018US7.PDF	2	Issue Fee Payment (PTO-85B)	237 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-7-18 Comments - 111552-	D0C75A31AC5227276A08CFF48F24C3BBF25AC1DB703F7D0B

8018US07.PDF

320DACE817690011B49CFB8A0297B333ECE56CD80D8319FDA
8A3ABE78358E096B48AC320124AF4282023-7-18 Issue Fee
Transmittal - 111552-
8018US7.PDFA6D04CC7538C56D696F53E2C93A0A99DE0436905384B5C758
D5ECB98DD08FAD6E4D1F48DCE58B63F472E478861A8166E5
E37D1F6C82BE4734D216FF91FB55C4B

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.



ELECTRONIC PAYMENT RECEIPT

APPLICATION #
18/180,016

RECEIPT DATE / TIME
07/18/2023 05:36:07 PM ET

ATTORNEY DOCKET #
111552.8018.US07

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 # 1816

FILED BY J iYoung Anderson

PATENT CENTER # 62463422

AUTHORIZED BY Matthew Williams

CUSTOMER # 25096

FILING DATE 03/07/2023

CORRESPONDENCE ADDRESS -

FIRST NAMED INVENTOR Ben Merritt

Payment Information

PAYMENT METHOD
CARD / 3369

PAYMENT TRANSACTION ID
E20237HH37127665

PAYMENT AUTHORIZED BY
J iYoung Anderson

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

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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)
2023-07-18	(Date)

APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
18/180,016	Mar 7, 2023	Ben Merritt	111552.8018.US07	1816

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

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
UTILITY	LARGE	1200	0	0	1200	2023-10-18

EXAMINER	ART UNIT	CLASS-SUBCLASS
Eric Rassavong	3781	-

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.

Perkins Coie LLP

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

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

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

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

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

Authorized Signature /Matthew S. Williams/

Date 2023-07-18

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.

AIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Ben Merritt et al.

Application No.: 18/180,016

Confirmation No.: 1816

Filed: March 7, 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 July 18, 2023, the Examiner allowed claims 2–14 and 16–33. The Applicant acknowledges Examiner’s statements of Reasons for Allowance of the above-referenced patent application and agrees that the claimed subject matter is patentable. However, the Applicant takes no position regarding the Reasons for Allowance presented by the Examiner other than the positions the Applicant may have previously taken during prosecution. Therefore, the Examiner’s Reasons for Allowance should not be attributed to the Applicant as an indication of the basis for the Applicant’s belief that the claims are patentable. Furthermore, the Applicant respectfully asserts that there may also be additional reasons for patentability of the claimed subject matter not explicitly stated in this record and the Applicant does not waive its rights to such arguments by not further addressing such reasons herein.

Dated: July 18, 2023

Respectfully submitted,

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

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

Attorney for Applicant



UNITED STATES PATENT AND TRADEMARK OFFICE

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

25096 7590 07/18/2023
PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

EXAMINER	
RASSAVONG, ERIC	
ART UNIT	PAPER NUMBER
3781	

DATE MAILED: 07/18/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/180,016	03/07/2023	Ben Merritt	111552.8018.US07	1816

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	10/18/2023

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

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

HOW TO REPLY TO THIS NOTICE:

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

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

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

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

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

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

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

PART B - FEE(S) TRANSMITTAL

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

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

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

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence 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)

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

25096 7590 07/18/2023
PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/180.016	03/07/2023	Ben Merritt	111552.8018.US07	1816

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nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	10/18/2023

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,

1 _____

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

2 _____

3 _____

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

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

(A) NAME OF ASSIGNEE

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

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

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

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

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

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

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

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

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

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

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

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

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/180,016	03/07/2023	Ben Merritt	111552.8018.US07	1816
25096	7590	07/18/2023	EXAMINER	
PERKINS COIE LLP - SEA General			RASSAVONG, ERIC	
PATENT-SEA				
P.O. BOX 1247			ART UNIT	
SEATTLE, WA 98111-1247			PAPER NUMBER	
			3781	

DATE MAILED: 07/18/2023

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

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

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

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

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

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

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

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 18/180,016	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 07/03/2023.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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

3. ☒ The allowed claim(s) is/are 2-14 and 16-33. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

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

Certified copies:

a) ☐ All b) ☐ Some* c) ☐ None of the:

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

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

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

* Certified copies not received: _____.

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

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

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

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

Attachment(s)

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

Notice of Pre-AIA or AIA Status

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

Status of Claims

2. **Claims 2-14 and 16-33** are currently pending. **Claims 2, 6, 10, 11, 14, and 16-20** are currently amended. **Claims 1 and 15** are cancelled. No new subject matter is added.

Allowable Claims

3. **Claims 2-14 and 16-33** are allowed.

Allowable Subject Matter

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

Claim 6 and 17 would be allowable for reciting, *inter alia*, "a coupled assembly including: the second chamber; the aspiration catheter; and a hemostasis valve".

Heaton teaches all of the limitations as discussed in the Non-Final Rejection filed 03/07/2023. However, Heaton fails to teach a coupled assembly including: the second chamber; the aspiration catheter; and a hemostasis valve. As described in the Non-Final Rejection having the second chamber be part of another assembly that includes the aspiration catheter and a hemostasis valve would destroy the function of how Heaton operates. Also, there is no hemostasis valve mentioned in Heaton. There is no prior art that disclose these limitations. Therefore the combination of limitations on claim 6 would be considered allowable. **Claims 7-9 and 21-29** would be allowable for depending on claim 6. **Claims 30-33** are allowable for depending on claim 17.

Claim 10 and 18 would be allowable for reciting, *inter alia*, “wherein the second chamber is removably coupled between the aspiration pump and the catheter”.

Heaton teaches all of the limitations in the Non-Final Rejection filed 03/07/2023. However, Heaton fails to teach wherein the second chamber is removably coupled between the aspiration pump and the catheter. The second chamber of Heaton comprises a variable volume such as a bellows that generates negative pressure within the chamber. Therefore it would be impossible for the second chamber, i.e. the bellows pump itself, to be removably coupled between the pump and the catheter. For this reason the limitations of claim 10 would be considered allowable. **Claims 2-5 and 11-14** would be allowable for depending on claim 10. **Claims 16 and 19-20** would be allowable for depending on claim 18.

5. 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

6. 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>.

Art Unit: 3781

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./ (7/7/2023)

Examiner, Art Unit 3781

/SUSAN S SU/

Primary Examiner, Art Unit 3781

9 July 2023

<i>Index of Claims</i> 	Application/Control No. 18/180,016	Applicant(s)/Patent Under Reexamination Merritt et al.
	Examiner ERIC RASSAVONG	Art Unit 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	06/14/2023	07/07/2023						
	1	✓	-						
	2	✓	=						
	3	✓	=						
	4	✓	=						
	5	✓	=						
	6	✓	=						
	7	✓	=						
	8	✓	=						
	9	✓	=						
	10	✓	=						
	11	✓	=						
	12	✓	=						
	13	✓	=						
	14	✓	=						
	15	✓	-						
	16	✓	=						
	17	✓	=						
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	26		=						
	27		=						
	28		=						
	29		=						
	30		=						
	31		=						
	32		=						
	33		=						

Issue Classification 	Application/Control No. 18/180,016	Applicant(s)/Patent Under Reexamination Merritt et al.
	Examiner ERIC RASSAVONG	Art Unit 3781

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

CPC Combination Sets					
Symbol				Type	Set

/ERIC RASSAVONG/ Examiner, Art Unit 3781 (Assistant Examiner)	07 July 2023 (Date)	Total Claims Allowed: 31	
/SUSAN S SU/ Primary Examiner, Art Unit 3781 (Primary Examiner)	09 July 2023 (Date)	O.G. Print Claim(s) 6	O.G. Print Figure 20E

Issue Classification 	Application/Control No. 18/180,016	Applicant(s)/Patent Under Reexamination Merritt et al.
	Examiner ERIC RASSAVONG	Art Unit 3781

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

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

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

/ERIC RASSAVONG/ Examiner, Art Unit 3781 (Assistant Examiner)	07 July 2023 (Date)	Total Claims Allowed: 31	
/SUSAN S SU/ Primary Examiner, Art Unit 3781 (Primary Examiner)	09 July 2023 (Date)	O.G. Print Claim(s) 6	O.G. Print Figure 20E

Issue Classification 	Application/Control No. 18/180,016	Applicant(s)/Patent Under Reexamination Merritt et al.
	Examiner ERIC RASSAVONG	Art Unit 3781

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47
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CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
-	1	14	10	29	19	12	28								
19	2	15	11	30	20	13	29								
20	3	16	12	5	21	24	30								
21	4	17	13	6	22	25	31								
22	5	18	14	7	23	26	32								
1	6	-	15	8	24	27	33								
2	7	31	16	9	25										
3	8	23	17	10	26										
4	9	28	18	11	27										

/ERIC RASSAVONG/ Examiner, Art Unit 3781 (Assistant Examiner)	07 July 2023 (Date)	Total Claims Allowed: 31	
/SUSAN S SU/ Primary Examiner, Art Unit 3781 (Primary Examiner)	09 July 2023 (Date)	O.G. Print Claim(s) 6	O.G. Print Figure 20E

<i>Search Notes</i> 	Application/Control No. 18/180,016	Applicant(s)/Patent Under Reexamination Merritt et al.
	Examiner ERIC RASSAVONG	Art Unit 3781

CPC - Searched*		
Symbol	Date	Examiner
A61B17/12109, 17/221, 2017/22034, 2017/22079, 2217/005	06/12/2023	/E.R./
A61F2/01	06/12/2023	/E.R./
A61M1/815, 1/84, 1/79, 25/10	06/12/2023	/E.R./
A61B17/12109, 17/221, 2017/22034, 2017/22079, 2217/005	07/07/2023	/E.R./
A61F2/01	07/07/2023	/E.R./
A61M1/815, 1/84, 1/79, 25/10	07/07/2023	/E.R./

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

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

Search Notes		
Search Notes	Date	Examiner
Inventor Name Search in PALM	06/12/2023	/E.R./
CPC and text searching completed	06/12/2023	/E.R./
Consulted Primary Examiner Susan Su on Prior art	06/12/2023	/E.R./
Updated Search	07/07/2023	/E.R./

/E.R./ Examiner, Art Unit 3781	
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<i>Search Notes</i> 	Application/Control No. 18/180,016	Applicant(s)/Patent Under Reexamination Merritt et al.
	Examiner ERIC RASSAVONG	Art Unit 3781

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	Keyword search in USPAT	06/12/2023	/E.R./

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

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2012. OMB 0651-0031
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	18/180,016 - Conf# 1816
	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US07

U.S. PATENTS AND PUBLICATIONS					
Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	11648028	05-16-2023	Rosenbluth et al.	
	2.	5030201	07-09-1991	Palestrant	
	3.	11642209	05-09-2023	Merritt et al.	
	4.	6540722	04-01-2003	Boyle et al.	
	5.	7678131	03-16-2010	Muller	
	6.	9301769	04-05-2016	Brady et al.	
	7.	20210393278	12-23-2021	O'MALLEY et al.	
	8.	20210038385	02-11-2021	Popp et al.	
	9.	20050203605	09-15-2005	Dolan	
	10.	6152144	11-28-2000	Lesh et al.	
	11.	9011551	04-21-2015	Oral et al.	
	12.	8647367	02-11-2014	Kassab et al.	
	13.	11166703	11-09-2021	Kassab et al.	
	14.	8834519	09-16-2014	van der Burg et al.	
	15.	7713282	05-11-2010	Frazier et al.	
	16.	8080032	12-20-2011	van der Burg et al.	
	17.	7722641	05-25-2010	van der Burg et al.	
	18.	8523897	09-03-2013	van der Burg et al.	
	19.	8535343	09-17-2013	van der Burg et al.	
	20.	7152605	12-26-2006	Khairkahan et al.	
	21.	9168043	10-27-2015	van der Burg et al.	
	22.	7128073	10-31-2006	van der Burg et al.	
	23.	10772636	09-15-2020	Kassab et al.	
	24.	8480708	07-09-2013	Kassab et al.	
	25.	9717488	08-01-2017	Kassab et al.	
	26.	8784469	07-22-2014	Kassab	
	27.	9566073	02-14-2017	Kassab et al.	
	28.	20160192912	07-07-2016	Kassab et al.	
	29.	20160030708	02-04-2016	Casiello et al.	
	30.	20160135829	05-19-2016	Holoehwost et al.	
	31.	20060264905	11-23-2006	Eskridge et al.	

Doc code: IDS

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

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	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US07

U.S. PATENTS AND PUBLICATIONS					
Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	32.	5244619	09-14-1993	Burnham	
	33.	20170021130	01-26-2017	Dye	
	34.	20160106353	04-21-2016	Schuetz et al.	
	35.	10960114	03-30-2021	Goisis	
	36.	10531883	01-14-2020	Deville et al.	
	37.	9581942	02-28-2017	Shippert	
	38.	5234403	08-10-1993	Yoda et al.	
	39.	20190365395	12-05-2019	Tran et al.	
	40.				
	41.				

FOREIGN PATENT DOCUMENTS						
Examiner Initial*	Cite No	Foreign Document Number ³	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
	1.	WO2016014955	01-28-2016	OSTEOMEDIX, INC.		
	2.	EP2942624	11-11-2015	Kim, Hong		
	3.	WO2006029270	03-16-2006	SMITH & NEPHEW, INC.		

NON-PATENT LITERATURE DOCUMENTS					T ⁵
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.			
		International Search Report and Written Opinion for International App. No. PCT/US23/60502; Date of Filing: January 11, 2023, Applicant: Inari Medical, Inc., Date of Mailing: May 25, 2023, 9 pages.			
		International Search Report and Written Opinion for International App. No. PCT/US23/61256; Date of Filing: January 25, 2023, Applicant: Inari Medical, Inc., Date of Mailing: June 7, 2023, 8 pages.			
		Gross et al., "Dump the pump: manual aspiration thrombectomy (MAT) with a syringe is technically effective, expeditious, and cost-efficient," J NeuroIntervent Surg, 2018, 4 pages.			

Doc code: IDS

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

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

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	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US07

EXAMINER SIGNATURE	
Examiner Signature/ERIC RASSAVONG/ (07/07/2023)	Date Considered 07/07/2023
*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.	
<small> 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. </small>	

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

Doc code: IDS

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18/180,016 - Conf# 1816
	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US07

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

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2023-07-05
Name/Print	Matthew S. Williams	Registration Number	77,516

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

Bibliographic Data

Application No: 18/180,016

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.
03/07/2023	606	3781	111552.8018.US07
RULE			

APPLICANTS

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

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Jacqueline Macias, Fullerton, CA, UNITED STATES

Brian Michael Strauss,

Thomas Tu,

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

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PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L77	375	A61M1/79.cpc. AND pump AND removable	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/07/07 09:23 PM
L78	34288	A61M25/10.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:23 PM
L79	1126	A61F2/01.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:23 PM
L80	22	A61M1/815.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:23 PM
L81	159	A61M1/84.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:23 PM
L82	1058	A61B17/221.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:23 PM
L83	531	A61B2017/22034.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:23 PM
L84	420	A61B2017/22079.cpc.	(US-PGPUB; USPAT;	OR	ON	ON	2023/07/07

		AND A61B17/12109.cpc.	USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				09:23 PM
L85	459	A61B2217/005.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:24 PM
L86	21	A61M1/79.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:24 PM
L87	1310	A61M25/10.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:24 PM
L88	23	A61M1/84.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:24 PM
L89	721	A61B17/221.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:24 PM
L90	220	A61B2017/22034.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:24 PM
L91	104	A61B2017/22079.cpc.	(US-PGPUB; USPAT;	OR	ON	ON	2023/07/07

		AND A61F2/01.cpc.	USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				09:24 PM
L92	104	A61B2217/005.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:24 PM
L93	26	A61M1/79.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:24 PM
L94	121	A61M25/10.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:24 PM
L95	194	A61M1/84.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:24 PM
L96	21	A61B17/221.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:24 PM
L97	22	A61B2017/22034.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:24 PM
L98	52	A61B2017/22079.cpc.	(US-PGPUB; USPAT;	OR	ON	ON	2023/07/07

		AND A61M1/815.cpc.	USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				09:24 PM
L99	58	A61B2217/005.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:24 PM
L100	90	A61M1/79.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:24 PM
L101	21	A61M25/10.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:24 PM
L102	194	A61M1/84.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:24 PM
L103	21	A61B17/221.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:24 PM
L104	229	catheter AND "deep vein thrombus" AND "pulmonary embolism"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 09:24 PM
L105	1110	A61M1/79.cpc. AND	(US-PGPUB; USPAT;	OR	ON	ON	2023/07/07

		removable	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)				09:24 PM
L106	492	A61M1/79.cpc. AND removable	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/07/07 09:24 PM
L107	375	A61M1/79.cpc. AND pump AND removable	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/07/07 09:24 PM
L108	375	A61M1/79.cpc. AND pump AND removable	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/07/07 09:24 PM
L109	39	("10531883" OR "10772636" OR "10960114" OR "11166703" OR "11642209" OR "11648028" OR "20050203605" OR "20060264905" OR "20160030708" OR "20160106353" OR "20160135829" OR "20160192912" OR "20170021130" OR "20190365395" OR "20210038385" OR "20210393278" OR "5030201" OR "5234403" OR "5244619" OR "6152144" OR "6540722" OR "7128073" OR "7152605" OR "7678131" OR "7713282" OR "7722641" OR "8080032" OR "8480708" OR "8523897" OR "8535343" OR "8647367" OR "8784469" OR "8834519" OR "9011551" OR "9168043" OR "9301769" OR "9566073" OR "9581942" OR "9717488").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/07 09:26 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
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07/07/2023 09:29:25 PM

Workspace: SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS VII

Page 5 of 6
ER

N9	1	(rapid quick fast accelerated speedy).clm. AND (aspiration suction).clm. AND (catheter).clm. AND (syringe).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/07 09:24 PM
N10	29	(rapid quick fast accelerated speedy).clm. AND (aspiration suction).clm. AND (catheter).clm. AND (syringe).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/07 09:24 PM
N11	114	(catheter).clm. AND (syringe).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/07 09:24 PM
N12	29	(rapid quick fast accelerated speedy).clm. AND (aspiration suction).clm. AND (catheter).clm. AND (syringe).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/07 09:24 PM
N13	6	(rapid quick fast accelerated speedy).clm. AND (aspiration suction).clm. AND (catheter).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/07 09:24 PM
N14	2	(rapid quick fast accelerated speedy).clm. AND (catheter).clm. AND (syringe).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/07 09:24 PM
N15	7	(aspiration suction).clm. AND (catheter).clm. AND (syringe).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/07 09:24 PM
N16	2849	(catheter).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/07 09:24 PM

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td>17/154,806 - Conf. #9021</td> </tr> <tr> <td>Filing Date</td> <td>January 21, 2021</td> </tr> <tr> <td>First Named Inventor</td> <td>Phil Marchand</td> </tr> <tr> <td>Art Unit</td> <td>3771</td> </tr> <tr> <td>Examiner Name</td> <td>Tuan Van Nguyen</td> </tr> </table>		Application Number	17/154,806 - Conf. #9021	Filing Date	January 21, 2021	First Named Inventor	Phil Marchand	Art Unit	3771	Examiner Name	Tuan Van Nguyen
Application Number	17/154,806 - Conf. #9021														
Filing Date	January 21, 2021														
First Named Inventor	Phil Marchand														
Art Unit	3771														
Examiner Name	Tuan Van Nguyen														
Sheet	1	of	3	Attorney Docket No: 111552-8015.US03											

US PATENT AND PUBLICATION DOCUMENTS					
Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Filing Date If Appropriate
		20160030708	02-04-2016	Casiello et al.	
		20160135829	05-19-2016	Holoehwost et al.	
		20060264905	11-23-2006	Eskridge et al.	
		5244619	09-14-1993	Burnham	
		20170021130	01-26-2017	Dye	
		20160106353	04-21-2016	Schuetz et al.	
		10960114	03-30-2021	Goisis	
		10531883	01-14-2020	Deville et al.	
		9581942	02-28-2017	Shippert	
		5234403	08-10-1993	Yoda et al.	
		20100106081	04-29-2010	Brandeis	
		20100094201	04-15-2010	Mallaby	
		20050004534	01-06-2005	Lockwood et al.	
		20190365395	12-05-2019	Tran et al.	
		20160038267	02-11-2016	ALLEN et al.	
		20140222070	08-07-2014	BELSON et al.	
		20130204297	08-08-2013	Melsheimer et al.	
		11697012	07-11-2023	Merritt et al.	
		11697011	07-11-2023	Merritt et al.	
		20230218310	07-13-2023	Scheinblum et al.	
		20230218383	07-13-2023	Merritt et al.	
		20230218313	07-13-2023	Rosenbluth et al.	
		20230200970	06-29-2023	Merritt et al.	
		20140324091	10-30-2014	Rosenbluth et al.	
		20150018859	01-15-2015	Quick et al.	
		20150196744	07-16-2015	Aboytes	
		20160367285	12-22-2016	Sos	
		20130144326	06-06-2013	Brady et al.	
		20140005715	01-02-2014	Castella et al.	
		20140180397	06-26-2014	Gerberding et al.	
		20150150672	06-04-2015	Ma	
		20130030460	01-31-2013	Marks et al.	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				<i>Complete if Known</i> Application Number 17/154,806 - Conf. #9021 Filing Date January 21, 2021 First Named Inventor Phil Marchand Art Unit 3771 Examiner Name Tuan Van Nguyen	
Sheet	2	of	3	Attorney Docket No: 111552-8015.US03	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of cited Document	T ²

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No ¹	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 ²
		International Search Report and Written Opinion for International App. No. PCT/US23/61256; Date of Filing: January 25, 2023, Applicant: Inari Medical, Inc., Date of Mailing: June 7, 2023, 8 pages.	
		Gross et al., "Dump the pump: manual aspiration thrombectomy (MAT) with a syringe is technically effective, expeditious, and cost-efficient," J NeuroIntervent Surg, 2018, 4 pages.	

CERTIFICATION STATEMENT	
Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):	
☐	That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).
OR	
☐	That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).
☐	See attached certification statement.
☐	The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i> Application Number 17/154,806 - Conf. #9021 Filing Date January 21, 2021 First Named Inventor Phil Marchand Art Unit 3771 Examiner Name Tuan Van Nguyen	
Sheet	3	of	3	Attorney Docket No: 111552-8015.US03	

☒ A certification statement is not submitted herewith.

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

COPIES OF REFERENCES

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

SIGNATURE

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

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2023-07-17
Name/Print	Matthew S. Williams	Registration Number	77,516

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

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. † Applicant's unique citation designation number (optional) ‡ Applicant is to place a check mark here if English language Translation is attached



ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
18/180,016

RECEIPT DATE / TIME
07/17/2023 05:52:05 PM ET

ATTORNEY DOCKET #
111552.8018.US07

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 # 1816

FILED BY J iYoung Anderson

PATENT CENTER # 62455207

FILING DATE 03/07/2023

CUSTOMER # 25096

FIRST NAMED
INVENTOR Ben Merritt

CORRESPONDENCE
ADDRESS -

AUTHORIZED BY Matthew Williams

Documents

TOTAL DOCUMENTS: 3

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-7-17 IDS SB08 - 111552-8015US3.PDF	3	Information Disclosure Statement (IDS) Form (SB08)	252 KB

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

NPL_ISR_PCT_2023-61256- June-7-2023-8-pages.PDF	8	Non Patent Literature	1063 KB
NPL-Gross-Dump the Pump.PDF	4	Non Patent Literature	870 KB

Digest

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

2023-7-17 IDS SB08 - 111552-8015US3.PDF	7597340E6091B39BFC2A6A0ED52D25B3C1BE083FE76704EFE143FEA8DF7E7FB808E6DC4CF90A3D34BA0DF5663CE328D9CFBCAC5BDD2A2A2E97D7084024CFDBCA
NPL_ISR_PCT_2023-61256-June-7-2023-8-pages.PDF	E29F558402CAA5ECA7B480DBF767FC910107364FF8EB3919C86E39BC20664311EDA23D81B18626667115B85F0FF8707387E626478C646A16AA39EB2CD5DE7AAA
NPL-Gross-Dump the Pump.PDF	D44985D30C015BE8DA101967568EDF70598C9DCC517B882F1524CC5F8D5C8C53620135568E11D3A8E76C94DABDD42BADCF78DE5603483BF94B00DA3679A300F1D

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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



ELECTRONIC PAYMENT RECEIPT

APPLICATION #
18/180,016

RECEIPT DATE / TIME
07/17/2023 05:13:28 PM ET

ATTORNEY DOCKET #
111552.8018.US07

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 # 1816

FILED BY J iYoung Anderson

PATENT CENTER # 62454762

AUTHORIZED BY Matthew Williams

CUSTOMER # 25096

FILING DATE 03/07/2023

CORRESPONDENCE ADDRESS -

FIRST NAMED INVENTOR Ben Merritt

Payment Information

PAYMENT METHOD
CARD / 3369

PAYMENT TRANSACTION ID
E20237GH14309450

PAYMENT AUTHORIZED BY
J iYoung Anderson

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

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FIRST NAMED
INVENTOR Ben Merritt

CORRESPONDENCE
ADDRESS -

AUTHORIZED BY Matthew Williams

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
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Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-7-17 IDS SB08 - 111552- 8018US7.PDF	68917CDEDB0B11FD9A11AC4884546F4AC844F4F5D767CEB79 95924C088AA0A74669A157CB036FE577E36E180D06F6A3D12F

DC92F6A2A9B72A0B585E5A004E9FD

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18/180,016 - Conf# 1816
	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US07

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.	20160038267	02-11-2016	ALLEN et al.	
	2.	20140222070	08-07-2014	BELSON et al.	
	3.	20130204297	08-08-2013	Melsheimer et al.	
	4.	11697012	07-11-2023	Merritt et al.	
	5.	11697011	07-11-2023	Merritt et al.	
	6.	20140324091	10-30-2014	Rosenbluth et al.	
	7.	20150018859	01-15-2015	Quick et al.	
	8.	20150196744	07-16-2015	Aboytes	
	9.	20160367285	12-22-2016	Sos	
	10.	20130144326	06-06-2013	Brady et al.	
	11.	20140005715	01-02-2014	Castella et al.	
	12.	20140180397	06-26-2014	Gerberding et al.	
	13.	20150150672	06-04-2015	Ma	
	14.	20130030460	01-31-2013	Marks et al.	
	15.	20230218310	07-13-2023	Scheinblum et al.	
	16.	20230218313	07-13-2023	Rosenbluth 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.					
	2.					
	3.					
	4.					
	5.					

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18/180,016 - Conf# 1816
	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US07

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

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	
<p>*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.</p>			
<p>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.</p>			

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).	
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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).	
☐ See attached certification statement.	
☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.	
☐ None	
<p>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</p>	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18/180,016 - Conf# 1816
	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US07

representation that: (i) a search has been made; (ii) additional information that may be material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, Applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

COPIES OF REFERENCES

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

SIGNATURE

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

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2023-07-17
Name/Print	Matthew S. Williams	Registration Number	77,516

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



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
18/180,016	03/07/2023	Ben Merritt	111552.8018.US07

CONFIRMATION NO. 1816

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

PUBLICATION NOTICE



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Title:SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Publication No.US-2023-0218383-A1

Publication Date:07/13/2023

NOTICE OF PUBLICATION OF APPLICATION

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

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PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To: MATTHEW S. WILLIAMS PERKINS COIE LLP P.O. BOX 1247 SEATTLE, WA 98111-1247
RECEIVED PATENT DOCKETING MAY 31 2023 PERKINS COIE LLP

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

(PCT Rule 44.1)

Applicant's or agent's file reference 111552-8034WO00	Date of mailing <i>(day/month/year)</i> <div style="text-align: center; font-size: 1.2em; font-weight: bold;">MAY 25 2023</div>
International application No. PCT/US 23/60502	International filing date <i>(day/month/year)</i> 11 January 2023 (11.01.2023)
Applicant INARI MEDICAL, INC.	

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

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

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

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

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

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

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

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

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

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

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

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

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8366	Authorized officer <div style="text-align: center; font-weight: bold;">Kari Rodriguez</div> Telephone No. PCT Helpdesk: 571-272-4300
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Form PCT/ISA/220 (revised January 2020)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 111552-8034WO00		FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 23/60502	International filing date (day/month/year) 11 January 2023 (11.01.2023)	(Earliest) Priority Date (day/month/year) 11 January 2022 (11.01.2022)
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 2 sheets.

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

1. Basis of the report

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

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

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

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

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

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

4. With regard to the title,

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

5. With regard to the abstract,

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

6. With regard to the drawings,

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

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 23/60502

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61B 17/22, A61B 17/221 (2023.01)
- ADD.

CPC - INV. A61B 17/221

ADD. A61B 2017/2212

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

See Search History document

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 9,301,769 B2 (Brady et al.) 05 April 2016 (05.04.2016), entire document	1-13, 15-20
Y		14
Y	US 2021/0393278 A1 (O'Malley et al.) 23 December 2021 (23.12.2021), entire document	14
A	US 2021/0038385 A1 (Popp et al.) 11 February 2021 (11.02.2021), entire document	1-20
A	US 2005/0203605 A1 (Dolan) 15 September 2005 (15.09.2005), entire document	1-20

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

☐ See patent family annex.

* Special categories of cited documents:

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

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

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

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

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

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

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

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

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

"Z" document member of the same patent family

Date of the actual completion of the international search

22 March 2023

Date of mailing of the international search report

MAY 25 2023

Name and mailing address of the ISA/US

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

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

Facsimile No. 571-273-8300

Authorized officer

Kari Rodriguez

Telephone No. PCT Helpdesk: 571-272-4300

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: MATTHEW S. WILLIAMS PERKINS COIE LLP P.O. BOX 1247 SEATTLE, WA 98111-1247			RECEIVED PATENT DOCKETING MAY 31 2023 PERKINS COIE LLP			Date of mailing <i>(day/month/year)</i> MAY 25 2023		
Applicant's or agent's file reference 111552-8034WO00			FOR FURTHER ACTION See paragraph 2 below					
International application No. PCT/US 23/60502		International filing date <i>(day/month/year)</i> 11 January 2023 (11.01.2023)		Priority date <i>(day/month/year)</i> 11 January 2022 (11.01.2022)				
International Patent Classification (IPC) or both national classification and IPC IPC - INV. A61B 17/22, A61B 17/221 (2023.01) ADD. INV. A61B 17/221 CPC - ADD. A61B 2017/2212								
Applicant INARI MEDICAL, INC.								

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

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

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 65.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/226 or before the expiration of 22 months from the priority date, whichever expires later.

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

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Date of completion of this opinion 22 March 2023	Authorized officer Kari Rodriguez PCT Help Desk Telephone No. 571-272-4300
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Form PCT/ISA/237 (cover sheet) (revised July 2022)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 23/60502

Box No. 1 Basis of this opinion

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



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



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

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

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

a. ☐

forming part of the international application as filed.

b. ☐

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



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

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

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 23/60502

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

1. Statement

Novelty (N)	Claims	14	YES
	Claims	1-13, 15-20	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 1-13 and 15-20 lack novelty under PCT Article 33(2) as being anticipated by US 9,301,769 B2 to Brady et al. (hereinafter "Brady")

Regarding claim 1, Brady teaches a system for removing clot material from an implant positioned within a body vessel (Fig 1a; col 1, in 31-36), comprising:

a clot treatment device (device 1, Fig 1a; col 44, in 23-39) configured to be deployed within the implant,

wherein the clot treatment device includes a first end portion (see collar 885 at proximal end 893, Fig 35a; col 56, in 3-9), a second end portion (see end at distal collar 887, Fig 35b; col 56, in 23-26), and a plurality of struts (882, 883, Fig 35a; col 56, in 9-10) extending between the first end portion and the second end portion (see Fig 35a);

a handle including an actuator (11, Fig 1a; col 44, in 39-43, see discussion wherein physician is able to manually control the device via the handle);

a first elongate member (shaft distal end 890, Fig 56a; col 56, in 3-9), coupling the first end portion of the clot treatment device to the handle (see Fig 1a); and

a second elongate member (see elongate shaft 9 in Fig 1a and at distal stop 888, Fig 56a; col 56, in 3-9) coupling the second end portion of the clot treatment device to the handle (see Fig 1a).

wherein actuation of the actuator is configured to move the second elongate member relative to the first elongate member to reduce a distance between the first end portion and the second end portion to radially expand the struts (see first position of device in Fig 35b and second position of device in Fig 35a; col 44, in 39-46, see discussion wherein the handle is used to control and move the capture net).

Regarding claim 2, Brady teaches the system of claim 1. Brady further teaches wherein the implant is a stent (col 3, in 31-36; col 3, in 29-38).

Regarding claim 3, Brady teaches the system of claim 1. Brady further teaches wherein the first end portion is a proximal end portion of the clot treatment device (see where 885 is at end 890 and 893, Fig 35a; col 56, in 3-9), and

wherein the second end portion is a distal end portion of the clot treatment device (see end at distal collar 887, Fig 35b; col 56, in 23-26).

Regarding claim 4, Brady teaches the system of claim 3. Brady further teaches wherein the second elongate member (see elongate shaft 9 in Fig 1a and at distal stop 888, Fig 56a; col 56, in 3-9) extends through a lumen (col 13, in 43-49) of the first elongate member (shaft distal end 890, Fig 56a; col 56, in 3-9).

Regarding claim 5, Brady teaches the system of claim 1. Brady further teaches wherein the first end portion is a distal end portion of the clot treatment device, and wherein the second end portion is a proximal end portion of the clot treatment device (see Figs 1a and 35a, wherein the positioning of the end portions 893 and 887 is reflective about the perpendicular axis to the longitudinal axis of the elongate shaft 9 that coupled to the handle 11).

Regarding claim 6, Brady teaches the system of claim 1. Brady further teaches wherein actuation of the actuator is configured to move both the first elongate member and the second elongate member relative to the handle (see first position at 35b and second position at 35a; col 56, in 10-14; col 44, in 39-44).

Regarding claim 7, Brady teaches the system of claim 1. Brady further teaches wherein the handle is rotatable to rotate the clot treatment device relative to the implant (see flexibility of elongate shaft 9 relative to handle 11 shown as rotatable in Fig 1a).

Regarding claim 8, Brady teaches the system of claim 1. Brady further teaches wherein the handle is longitudinally movable to move the clot treatment device longitudinally relative to the implant (see handle in Fig 1a; col 44, in 39-43; col 56, in 10-14).

- Continued in Supplemental Box -

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 23/00502

Box No. VIII Certain observations on the international application

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

Claim 15. Lack of antecedent basis for "the second elongate member" and "the first elongate member"

Claim 18. Semantics... "compressing" should be "comprising"

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AUS 23/60502

Supplemental Box

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

Continuation of:

- Box V.2. Citations and explanations -

Regarding claim 9, Brady teaches the system of claim 1. Brady also teaches wherein the handle is rotatable and longitudinally movable to rotate and longitudinally move the clot treatment device relative to the implant (see flexibility of elongate shaft 9 relative to handle 11 shown as rotatable in Fig 1a; col 44, in 39-43; col 56, in 10-14).

Regarding claim 10, Brady teaches the system of claim 1. Brady further teaches comprising a guide catheter (889, Fig 35b; col 7, in 13-21; col 26, in 8-31).

wherein the clot treatment device is configured to be

(a) covered within the guide catheter in a first state (889, Fig 35b; col 26, in 8-31) and

(b) uncovered from the guide catheter and expanded to a second state (Fig 35a; col 26, in 8-31).

Regarding claim 11, Brady teaches the system of claim 1. Brady further teaches wherein the struts extend generally axially between the first and second end portions and each have an undulating shape (882 and 883, Fig 35a; col 56, in 3-16).

Regarding claim 12, Brady teaches the system of claim 1. Brady further teaches

wherein the struts each extend axially between the first and second end portions (882 and 883, Fig 35a; col 56, in 3-16), and

wherein the clot treatment device does not include any crossmembers interconnecting the struts (Fig 35a).

Regarding claim 13, Brady teaches the system of claim 1. Brady further teaches wherein the actuator is a rotatable knob or a slider (handle 11, Fig 1a; col 12, in 3-42, wherein the handle actuates the expandable body to slide through a micro lumen).

Regarding claim 15, Brady teaches a method of removing clot material from an implant positioned within a body vessel (Fig 1a; col 1, in 31-36), the method comprising:

positioning a clot treatment device (device 1, Fig 1a; col 44, in 23-39) at least partially within the implant,

wherein the clot treatment device has

(a) a first end portion (see collar 885 at proximal end 893, Fig 35a; col 56, in 3-9),

(b) a second end portion (see end at distal collar 887, Fig 35b; col 56, in 23-28), and

(c) a plurality of struts (882 and 883, Fig 35a; col 56, in 9-10) extending between the first end portion and the second end portion (see Fig 35a)

moving the second elongate member (see elongate shaft 9 in Fig 1a and at distal stop 888, Fig 56a; col 56, in 3-9) relative to the first elongate member (shaft distal end 890, Fig 56a; col 56, in 3-9) to reduce a distance between the first end portion and the second end portion to radially expand the struts (see first position of device in Fig 35b and second position of device in Fig 35a; col 44, in 39-46, see discussion wherein the handle is used to control and move the capture net); and

after radially expanding the struts, rotating and/or translating the clot treatment device within the implant to materially engage the clot material with at least a portion of the struts (col 26, in 8-31).

Regarding claim 16, Brady teaches the method of claim 15. Brady further teaches

wherein the first end portion (see collar 885 at proximal end 893, Fig 35a; col 56, in 3-9) of the clot treatment device is coupled to a first elongate member (shaft distal end 890, Fig 56a; col 56, in 3-9),

wherein the second end portion (see end at distal collar 887, Fig 35b; col 56, in 23-28) of the clot treatment device is coupled to a second elongate member (see elongate shaft 9 in Fig 1a and at distal stop 888, Fig 56a; col 56, in 3-9), and

wherein moving the second elongate relative to the first elongate member comprises

actuating an actuator on a handle (11, Fig 1a; col 44, in 39-43, see discussion wherein physician is able to manually control the device via the handle) coupled to the first elongate member and the second elongate member (Figs 1a and 35a) to move the second elongate member relative to the first elongate member (see first position at 35b and second position at 35a; col 56, in 10-14; col 44, in 39-44; col 26, in 8-31).

Regarding claim 17, Brady teaches the method of claim 15. Brady further teaches wherein the struts each extend axially between the first and second end portions (882 and 883, Fig 35a; col 56, in 3-16), and

wherein the clot treatment device does not include any crossmembers interconnecting the struts (Fig 35a).

Regarding claim 18, Brady teaches the method of claim 15. Brady further teaches wherein the implant is a stent (col 3, in 31-36; col 3, in 28-36).

- Continued in Supplemental Box -

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 23/60502

Supplemental Box

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

Continuation of:

- Preceding Supplemental Box for V.2. Citations and explanations -

Regarding claim 19, Brady teaches a clot treatment device (device 1, Fig. 1a; col 44, in 23-38) comprising:

a proximal end portion (see collar 885 at proximal end 890 and 893, Fig. 35a; col 56, in 3-8);

a distal end portion (see end at distal collar 887, Fig. 35b; col 56, in 23-28; and

a plurality of struts extending generally axially along a longitudinal axis between the proximal end portion and the distal end portion (882 and 883, Fig. 35a; col 56, in 9-10);

wherein movement of the first end portion toward the second end portion is configured to radially expand the struts (see first position of device in Fig. 35b and second position of device in Fig. 35a; col 56, in 3-12);

individual ones of the struts include

a proximal portion extending from the proximal end portion (see struts 882 and 883 at proximal end 890, Fig. 35a);

a distal portion extending from the distal end portion (see struts at distal end near 887, Fig. 35a); and

a middle portion (see additional embodiment Figs. 6 and 7)

(a) extending between the proximal portion and the distal portion (Figs. 6 and 7) and

(b) having a hook-like shape in a direction about the longitudinal axis (Figs. 6 and 7; col 45, in 53-56); and

individual ones of the struts have an undulating shape in a direction along the longitudinal axis (see struts 882 and 883, Fig. 35a).

Regarding claim 20, Brady teaches the clot treatment device of claim 19. Brady further teaches wherein the clot treatment device does not include any cross-members interconnecting the struts (Figs. 6, 7, and 35a).

Claim 14 lacks an inventive step under PCT Article 33(3) as being obvious over Brady in view of US 2021/0393278 A1 to O'Malley et al. (hereinafter "O'Malley").

Regarding claim 14, Brady teaches the system of claim 1. Brady does not specifically teach wherein the handle includes an indicator configured to indicate an amount that the struts are radially expanded. However, Brady teaches the handle operating an activation cable from the shaft to advance the radial struts that expand in operation (Figs. 1a and 35a; col 56, in 3-14). Further, O'Malley teaches wherein the handle (shaft 106, Fig. 1A; para [0097]) includes an indicator configured to indicate an amount that the struts are radially expanded (see indicator bands 107, Fig. 1A; para [0097]). Accordingly, it would have been obvious to a person of ordinary skill in the art to combine a system for removing clot material as in Brady with a handle including an indicator configured to indicate an amount that the struts are radially expanded as in O'Malley so as to provide for an indication of advancement of the system into a patient.

Claims 1-20 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.



(51) International Patent Classification:

A61B 17/16 (2006.01) *A61M 1/00* (2006.01)
A61B 10/02 (2006.01) *A61B 17/32* (2006.01)

(21) International Application Number:

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62/030,882 30 July 2014 (30.07.2014) US

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(54) Title: ANATOMICAL SPECIMEN COLLECTION DEVICE AND SYSTEM

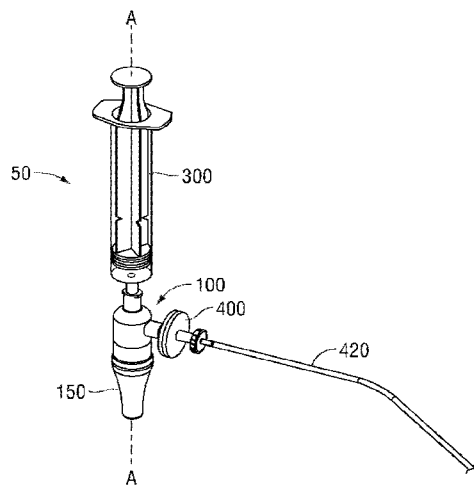


FIG. 1

(57) Abstract: A bone dust collection device includes a bone dust collection structure defining a longitudinal axis and having a proximal end and a distal end. The bone dust collection structure has a transverse plate member connected at or in the vicinity of the proximal end to a cylindrical wall defining an aperture at the distal end for receiving and collecting bone dust. The aperture extends proximally and includes a filtration member disposed therein. The filtration member causes at least partial separation of fluid from the bone dust via the fluid passing proximally through the filtration member. The bone dust collection structure enables removal of bone dust collected therein. A method of collecting an anatomical specimen includes generating an anatomical specimen in particulate form at a surgical site of a subject; collecting the particulate accumulated in the collection device; and packing the collected particulate into a region of interest in the subject.

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ANATOMICAL SPECIMEN COLLECTION DEVICE AND SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to, and benefit of, U.S. Provisional Patent Application No. 62/028,552 filed on July 24, 2015, entitled "ANATOMICAL SPECIMEN COLLECTION DEVICE AND SYSTEM", by John M. Abrahams and to U.S. Provisional Patent Application No. 62/030,882 filed on July 30, 2015 of the same title, by John M. Abrahams et al., the entire contents of both of which are incorporated herein by reference.

BACKGROUND

[0002] 1. Technical Field

[0003] The present disclosure relates to anatomical specimen collectors.

[0004] 2. Discussion of Related Art

[0005] During orthopaedic surgery, bone is drilled and bone dust is formed. During the surgical procedure, bone replacement is performed by harvesting bone dust from a subject other than the patient or subject in the form of allograft. In addition to the expense of supplying bone replacement from a source other than the patient or subject, the equipment used for such procedures is bulky and difficult to work with.

SUMMARY

[0006] The present disclosure relates to novel and non-obvious device, system and method for harvesting an anatomical specimen such as bone dust from a subject and replacing the anatomical specimen in the subject.

[0007] More particularly, the present disclosure relates to a bone dust collection device that includes a bone dust collection structure defining a longitudinal axis and having a proximal end and a distal end. The bone dust collection structure has a transverse plate member connected at or in the vicinity of the proximal end to a cylindrical wall defining an aperture at the distal end for receiving and collecting bone dust, the aperture extending proximally and including a filtration member disposed therein. The filtration member is configured and disposed wherein the filtration member causes at least partial separation of fluid from the

bone dust via the fluid passing proximally through the filtration member. The bone dust collection structure is configured to enable removal of bone dust collected therein.

[0008] In one embodiment, at least one aperture may be defined in the transverse plate member that enables the fluid at least partially separated from the bone dust by the filtration member to pass therethrough. A flow interruption member may be configured and disposed with respect to the bone dust collection structure wherein flow of fluid through the at least one aperture of the bone dust collection structure occurs by suction pressure induced on the flow interruption member causing the flow interruption member to change position to enable flow through the at least one aperture defined in the transverse plate member.

[0009] In one embodiment, least another aperture may be defined in the transverse plate member wherein the flow interruption member includes a shaft member disposed through the at least another aperture wherein the change of position of the flow interruption member occurs via the suction pressure induced on the flow interruption member to enable flow through the at least one aperture defined in the transverse plate member.

[00010] In one embodiment, the bone dust collection device may further include a syringe including a plunger in fluid communication with the bone dust collection structure wherein the suction pressure is caused by retraction of the plunger away from the bone dust collection structure to enable flow through the at least one aperture defined in the transverse plate member.

[00011] In one embodiment, advancement of the plunger may cause the flow interruption member to interrupt flow from the bone dust collection structure. The bone dust collection device may further include a conduit in fluid communication with the bone dust collection structure, wherein advancement of the plunger causes the fluid received through the at least one aperture defined in the transverse plate member to discharge through the conduit away from the bone dust collection device.

- [00012] In one embodiment, the conduit may be structured such that the conduit discharges the fluid in a direction generally perpendicular to the direction of fluid flow through the filtration member.
- [00013] In still a further embodiment, the bone dust collection device may further include another flow interruption device configured and disposed with respect to the flow interruption device and with respect to the bone dust collection structure wherein suction pressure induced on the another flow interruption device causes the another flow interruption device to be in a closed position and causes the flow interruption member to change position to enable flow through the at least one aperture defined in the transverse plate member.
- [00014] In a further embodiment, the bone dust collection device may further include another flow interruption device configured and disposed with respect to the flow interruption device and with respect to the bone dust collection structure wherein the another flow interruption device is a plug member to seal off flow therethrough during connection of the bone dust collection device to a continuous vacuum system. and suction pressure induced on the flow interruption device causes the flow interruption member to change position to enable flow through the at least one aperture defined in the transverse plate member.
- [00015] In yet another embodiment, the bone dust collection device may further include a bone dust removal structure defining an aperture having a proximal end and a distal end. The aperture may be configured and disposed for facilitating transport of bone dust from the distal end of the bone dust removal structure to the bone dust collection structure.
- [00016] In a still further embodiment, the bone dust removal structure may include a nozzle that defines the aperture of the bone dust removal structure, the nozzle defining a proximal end and a distal end, wherein the nozzle facilitates transport of the bone dust to the bone dust collection structure. In yet another embodiment, the nozzle may be removably attached to the bone dust collection structure, wherein removal of the nozzle from the bone dust collection structure enables removal of bone dust collected within the bone dust collection structure.

- [00017] In one embodiment, the bone dust collection device may further include a guide member configured and disposed with respect to the suction source and the bone dust collection structure for enabling a user to manually control the location of the bone dust removal structure during a surgical procedure.
- [00018] In one embodiment, the flow interruption member may be an umbrella valve. In yet another embodiment, the another flow interruption member is a check valve.
- [00019] The present disclosure relates also to a bone dust collection device that includes a bone dust collection structure defining a proximal end and a distal end, the bone dust collection structure including a filtration member at the proximal end and defining an aperture at the distal end for receiving and collecting bone dust, the filtration member causing at least partial separation of fluid from the bone dust via the fluid passing proximally through the filtration member; and a bone dust removal structure defining an aperture having a proximal end and a distal end, the aperture configured and disposed for facilitating transport of bone dust from the distal end of the bone dust removal structure to the bone dust collection structure, the bone dust removal structure removably attached to the bone dust collection structure, wherein removal of the bone dust removal structure from the bone dust collection structure enables removal of bone dust collected within the bone dust collection structure.
- [00020] The present disclosure relates also to an anatomical collection system that includes an anatomical specimen collection structure defining a proximal end and a distal end, the anatomical specimen collection structure including a filtration member at the proximal end and defining an aperture at the distal end for receiving and collecting an anatomical specimen, the filtration member causing at least partial separation of fluid from the anatomical specimen via the fluid passing proximally through the filtration member; and an anatomical specimen removal structure defining an aperture having a proximal end and a distal end, the aperture configured and disposed for facilitating transport of the anatomical specimen from the distal end of the anatomical specimen removal structure to the anatomical specimen collection structure. The anatomical specimen removal

structure is removably attached to the anatomical specimen collection structure wherein detachment of the anatomical specimen removal structure from the anatomical specimen collection structure enables removal of the anatomical specimen collected within the anatomical specimen collection structure.

[00021] In one embodiment, the anatomical specimen is bone dust.

[00022] The present disclosure relates also to a method of collecting an anatomical specimen that includes generating an anatomical specimen in particulate form at a surgical site of a subject; irrigating the surgical site to suspend the particulate in a particulate fluid mixture; disposing a tip of a collection device in the particulate fluid mixture; aspirating the collection device to filter and separate the particulate from the particulate fluid mixture therein accumulating the particulate in the collection device; and collecting the particulate accumulated in the collection device.

[00023] The method may further include packing the collected particulate into a region of interest in the subject.

[00024] In one embodiment, the collecting the particulate accumulated in the collection device is preceded by disassembling the collection device, and the method may further include reassembling the collection device; generating additional anatomical specimen in particulate form at a surgical site of the subject; irrigating the surgical site to suspend the particulate in a particulate fluid mixture; disposing the tip of the collection device in the particulate fluid mixture; aspirating the collection device to filter and separate the particulate from the particulate fluid mixture therein accumulating the particulate in the collection device; and collecting the particulate accumulated in the collection device.

[00025] The method may further include packing the additionally collected particulate into a region of interest in the subject.

[00026] In one embodiment, the aspirating of the collection device may include connecting the collection device to a vacuum source, which in one embodiment, may be in an operating room, wherein the vacuum source is in fluid communication with the fluid in the particulate fluid mixture to filter and separate the particulate from the particulate fluid mixture.

[00027] In one embodiment, the aspirating of the collection device may include actuating a syringe in fluid communication with the collection device and in fluid communication with the particulate fluid mixture wherein the actuating of the syringe effects filtering and separating the particulate from the particulate fluid mixture.

BRIEF DESCRIPTION OF THE DRAWINGS

[00028] The advantages of the embodiments of the present disclosure will become apparent from the following detailed description of the various embodiments of the present disclosure with reference to the drawings wherein:

[00029] FIG. 1 is a transparent perspective view of a bone dust collection system according to one embodiment of the present disclosure;

[00030] FIG. 2 is an exploded view of a bone dust collection device that is included within the bone dust collection system of FIG. 1;

[00031] FIG. 3 is a profile view of one embodiment of a bone dust collection device that may be included within the bone dust collection system of FIG. 1;

[00032] FIG. 4 is a partial profile cross-sectional view of the bone dust collection system of FIGS. 1 and 2 having one embodiment of a filtration member according to the present disclosure;

[00033] FIG. 5 is a cross-sectional enlarged view of the bone dust collection housing and valve support structure of the bone dust collection device of FIG. 3 having an embodiment of a filtration member according to the present disclosure;

[00034] FIG. 6A is an end view of a filter that is included within the bone dust collection device of FIGS. 1-5;

[00035] FIG. 6B is a side view of the filter of FIG. 6A;

[00036] FIG. 6C is a view of Detail 6C of FIG. 6B;

[00037] FIG. 6D is a proximal perspective view of the filter of FIGS. 6A-6C;

[00038] FIG. 7A is an end view of one embodiment of a nozzle that may be included within the bone dust collection device of the bone dust collection system of FIGS. 1-5;

[00039] FIG. 7B is a cross-sectional view of the nozzle of FIG. 7A taken along cross-section line 7B-7B;

- [00040] FIG. 8A is an end view of another embodiment of a nozzle that may be included within the bone dust collection device of the bone dust collection system of FIGS. 1-5;
- [00041] FIG. 8B is a cross-sectional view of the nozzle of FIG. 8A taken along cross-section line 8B-8B;
- [00042] FIG. 9A is an end view of one embodiment of a valve cap that that may be included with the bone dust collection device of the bone dust collection system of FIGS. 1-5;
- [00043] FIG. 9B is a cross-sectional view of the valve cap of FIG. 9A taken along section line 9B-9B;
- [00044] FIG. 10 is an exploded partially transparent view of a handle assembly that may be included as part of the bone dust collection device of the bone dust collection system of FIGS. 1-5;
- [00045] FIG. 10A is a cross-sectional view of the handle assembly of FIG. 10;
- [00046] FIG. 11 is a perspective, partially transparent view of the handle assembly of FIGS. 10 and 10A and the bone dust collection device of FIG. 3 that includes a plug seal;
- [00047] FIG. 12 is a perspective, partially transparent view of the handle assembly of FIG. 11 and the bone dust collection device of FIGS. 1-2 and 4-5 that includes a check valve seal;
- [00048] FIG. 13 is a partially transparent view of one embodiment of a self-contained bone dust collection device according to the present disclosure that includes a check valve and a flow diversion member for diverting fluid flow from the bone dust collection device;
- [00049] FIG. 13A is a partially transparent view of another embodiment of the self-contained bone collection device of FIG. 13;
- [00050] FIG. 14 is a zoomed out partial profile cross-sectional view of the bone dust collection system of FIG. 1-3;
- [00051] FIG. 15A is a detailed view of an extraction flow interruption member illustrated in the form of an umbrella valve that is positioned on an upper surface of the housing in a closed position;

- [00052] FIG. 15B is a detailed view of the umbrella valve positioned on the upper surface of the housing in an open position to enable flow of fluid past the umbrella valve;
- [00053] FIG. 16 is a cross-sectional view of the bone dust collection device when the umbrella valve is in the closed position as illustrated in FIG. 15A;
- [00054] FIG. 17 is a cross-sectional view of the bone dust collection device when the umbrella valve is in the open position for permitting passage of fluid past the umbrella valve;
- [00055] FIG. 18 is a cross-sectional view of the bone dust collection device when the umbrella valve is in the closed position for discharging and diverting fluid which has been collected by syringe;
- [00056] FIG. 19 is a cross-sectional view of another embodiment of the bone dust collection device having the alternate filtration member shown in FIG. 4 and wherein the umbrella valve is in the open position;
- [00057] FIG. 20 is cross-sectional view of the bone dust collection device of FIG. 19 wherein the umbrella valve is in the closed position and fluid is diverted through a check valve;
- [00058] FIG. 21 is a cross-sectional view of the bone dust collection device having the filtration member of FIG. 5 in an inverted position to allow removal of collected bone dust;
- [00059] FIG. 22 is a cross-sectional view of the bone dust collection device of FIG. 19 in an inverted position to allow removal of collected bone dust;
- [00060] FIG. 23 is a perspective transparent view of a kit package that houses bone dust collection devices according to embodiments of the present disclosure;
- [00061] FIG. 24 is a perspective view of the bone dust collection device of FIG. 3 having a plug member to seal off flow during connection of the bone dust collection device to a continuous vacuum system;
- [00062] FIG. 25 is a perspective view of the bone dust collection device of FIGS. 1-2 and 4-5 having a fluid flow diversion member and a check valve wherein fluid flow is directed vertically downward;

- [00063] FIG. 26 is a cross-sectional view of the bone dust collection device of FIG. 25;
- [00064] FIG. 27 is a perspective view of the bone dust collection device of FIGS. 25 and 26 wherein the fluid flow is directed horizontally;
- [00065] FIG. 28 is a perspective view of the bone dust collection device of FIG. 24 wherein the plug member is replaced by a flow diversion member to enable diversion of fluid back to a surgical site;
- [00066] FIG. 29 is a transparent elevation view of the bone dust collection device of FIG. 28;
- [00067] FIG. 30 is a perspective view of the bone dust collection device of FIG. 28 wherein a tubular portion of the flow diversion member has been removed;
- [00068] FIG. 31 is a perspective view of the bone dust collection device of FIG. 30 wherein the flow diversion member is oriented at an angle to enable diversion of fluid in an alternative direction with respect to a surgical site; and
- [00069] FIG. 32 is a perspective view of the bone dust collection device of FIG. 30 wherein the flow diversion member is oriented at an angle to enable diversion of fluid in yet another alternative direction with respect to a surgical site.

DETAILED DESCRIPTION

- [00070] To advance the state of the art of bone dust collection, the present disclosure relates to a bone dust collection system where a user, e.g., a surgeon or other medical professional, is able to simply collect bone dust using a hand-held device during aspiration from a surgical site.
- [00071] As defined herein, a bone dust collection device refers to an assembly of components which may either be employed independently or in a self-contained manner to collect bone dust while a bone dust collection system refers to utilization of the device and its assembly of components in conjunction with an external suction source such as via fluid communication with an operating room suction or vacuum system. The suction or vacuum system may also be located outside of an operating room under appropriately certified conditions. The device can be used to collect other anatomical specimen besides bone dust, such as, for example, bone marrow or other biological cells.

- [00072] The bone dust collection device enables collection of bone dust, defined herein as generally in the range of about 25 micron to about 600 micron cross-section bone particles, during a surgical procedure in order to harvest and use the bone dust for bone fusion mass in orthopedic surgery of the same patient. In actuality, the bone dust collection device enables collection of bone dust of sizes generally known to be created during surgical procedures.
- [00073] The device generally may be applied to one or more medical procedures performed on a single patient. The device may be utilized as a stand-alone bone collection device that includes a syringe or the device may be adapted as a bone collection system by fluidically coupling the device to a vacuum source such as commonly found in an operating room environment. The device may be used multiple times on the same patient during the same operating procedure but is discarded after completion of usage.
- [00074] The output of the device may be a “plug” of bone that can be held with forceps and placed into an intervertebral cage or used for any other procedure that requires bone or fusion construct. The output of the device may also be bone dust that is concentrated and can be manually placed into an intervertebral cage or construct or placed therein using instruments.
- [00075] The device is configured to allow fluids, e.g., blood and saline, to pass through a separator or filtration member, .e.g., a filter or a valve mechanism, thus separating bone dust from fluids. The bone dust collection device aspirates surgical fluid and filters out bone dust for use during a surgical procedure.
- [00076] The bone dust so collected may be processed by the user during the procedure wherein the processing of the bone dust may include cleaning, compacting, and transfer of the bone dust.
- [00077] As described above, the bone dust collection device may be disposed of, and in most cases is intended to be discarded, following usage.
- [00078] After using a surgical drill, the user aspirates surgical fluid to filter and then harvest bone dust; Fluid is discarded and bone dust is removed from a collection chamber defined within the bone dust collection device. Bone dust may be used for fusion or reconstruction procedures. Procedures include, but are not limited

to, e.g., spinal fusion, long bone fusion, cranial reconstruction, craniofacial reconstruction, orthopaedic reconstruction, or dental reconstruction.

[00079] Turning now to FIGS. 1, 2 and 3, there is illustrated a bone dust collection system 50 that includes a bone dust collection device according to one embodiment of the present disclosure. More particularly, bone dust collection device 100 includes a cylindrically-shaped bone dust collection structure 110 that extends from a proximal end 114a to a distal end 114b of the bone dust collection structure 110. The proximal end 114a of the bone dust collection structure 110 is configured as a valve support plate 116 such that the bone dust collection structure 110 also serves as a valve support structure. Cylindrical wall 118 extends distally from the valve support plate 116 to define a central aperture and volume 120 for receiving and collecting bone dust (see FIG. 3).

[00080] As best illustrated in FIG. 2 and FIG. 3, the valve support structure or bone dust collection structure 110 includes a valve supporting surface or plate 116 near the proximal end 114a.

[00081] The central aperture 120 extends proximally towards proximal end 114a of the bone dust collection structure 110 and includes a filtration member 122 disposed therein that may be part of a filter assembly 124. The filter assembly 124 may include a ring-shaped filter mounting member 126 that is configured to be disposed within the central aperture 120.

[00082] As explained in more detail below, the filtration member 122 and the filter assembly 124 are configured and disposed wherein the filtration member 122 causes at least partial separation of fluid from the bone dust via the fluid passing proximally through the filtration member 122. Thus, the bone dust collection structure 110 is configured to enable removal of bone dust collected therein.

[00083] As best shown in FIG. 2, the bone dust collection device 100 defines a central longitudinal axis **A-A** that extends from a proximal end 100a to a distal end 100b. At least one fluid flow aperture 116a is defined in the transverse plate member 116 that enables the fluid at least partially separated from the bone dust by the filtration member 122 to pass therethrough. A fluid extraction valve shaft aperture 116' is also defined in the transverse plate member 116 generally

through the center **C** of the transverse plate member 116 through which longitudinal axis **A-A** passes. A second fluid flow aperture 116b may also be defined in the transverse plate member 116 on a side of the longitudinal axis **A-A** opposite to the first fluid flow, e.g., at a position 180° from the first fluid flow aperture 116a, which is at position 0°. Additional fluid flow apertures (not shown) may also be positioned at 90° or 270° or other suitable locations if desired. It should be noted also that the bone dust collection structure 110 may be oriented such that the first and second fluid flow apertures 116a and 116b may coincide with the 90° and 270° positions, respectively, or vice versa. Such interchangeability of the orientation of the first and second fluid flow apertures 116a and 116b is taken advantage of throughout the description which follows where necessary or desirable to explain the operation of the bone dust collection device 100.

[00084] The bone dust collection device 100 further includes a fluid extraction flow interruption member 130 that is configured and disposed with respect to the bone dust collection structure 110 wherein, as explained in more detail below, flow of fluid through at least one aperture or, for example, fluid flow apertures 116a and 116b, of the bone dust collection structure 110 occurs by suction pressure induced on the fluid extraction flow interruption member 130 causing the flow interruption member 130 to change position to enable flow through fluid flow apertures 116a and 116b.

[00085] As indicated above, fluid extraction valve shaft aperture 116' is defined in the transverse plate member 116. As shown in FIG. 3, the extraction flow interruption member 130 may be an umbrella valve as shown and which includes a shaft member 132 that is disposed through the fluid extraction valve shaft aperture 116'. The extraction flow interruption member 130 includes a diaphragm 134 that is formed with the shaft member 132. The diaphragm 134 is made from an elastomeric and flexible material and which overlays the fluid flow apertures 116a and 116b on the proximal side of transverse plate member 116 such that the change of position of the extraction flow interruption member 130 occurs via the suction pressure induced on the flow interruption member, and

more particularly on the diaphragm 134, such that the diaphragm 134 flips away from the transverse plate member 116 to expose the fluid flow apertures 116a and 116b, thereby enabling flow through the apertures 116a and 116b. The shaft member 132 includes a proximal portion 132a and a distal portion 132b wherein the distal portion 132b defines a diameter that is greater than the diameter of the proximal portion 132a. The fluid extraction valve shaft aperture 116' is thus shaped accordingly to define a proximal narrow diameter portion and a distal wide diameter portion to match the proximal and distal portions 132a and 132b of the shaft member 132.

[00086] In the embodiment of the housing 110 illustrated in FIG. 3, a portion 1161 of the transverse plate member 116 extends distally into the central aperture 120 to define a circumferential channel 136 between inner surface 118a of the housing wall 118 and the distally extending portion 1161 of the transverse plate member 116. The filter assembly 124 is configured and disposed wherein the ring-shaped filter mounting member 126 is received in the circumferential channel 136 such that the filtration member 122 overlays the distal ends of the fluid flow apertures 116a and 116b.

[00087] The bone dust collection device 100 may further include a bone dust removal structure 150 that defines an aperture 152 having a proximal end 152a and a distal end 152b. In one embodiment, the bone dust removal structure 150 may include, or be formed in the shape of, a nozzle wherein proximal end 154a of the nozzle 150 may engage with outer surface 118b of housing wall 118 for structural stability of the nozzle 150 during usage for collecting bone dust. The aperture 152 of the nozzle 150 is configured and disposed for facilitating transport of bone dust, or a mixture of bone dust and irrigating fluid such as saline solution, as represented by arrow **B**, from the distal end 152b of the bone dust removal structure or nozzle 150 to the central aperture 120 of the bone dust collection structure 110. When in the form of a nozzle, the nozzle thus defines the aperture 152 of the bone dust removal structure 150. The nozzle defines the proximal end 152a and distal end 152b, wherein the nozzle facilitates transport of the bone dust **B**, which includes fluid from the surgical site, to the bone dust

collection structure 110. The nozzle may be removably attached to the bone dust collection structure 110 by disengaging from outer surface 118b of housing wall 118. Removal of the nozzle 150 from the bone dust collection structure 110 enables removal of bone dust collected within the bone dust collection structure 110, as described in more detail below. The nozzle 150 may be made from flexible, elastomeric materials, such as, but not limited to, silicone or urethane.

[00088] The bone dust collection device 100 may further include a tee-shaped port member or cap 160 that defines a bone dust collection interface aperture 162b at a distal portion 160b of the tee-shaped port member or cap 160. The tee-shaped port member or cap 160 may further define a suction device interface aperture 162a at a proximal portion 160a. Additionally, tee-shaped port member or cap 160 defines a fluid diversion aperture 162c at branch connection 160c. As described in more detail below, when in operation, the bone dust collection device 100 in FIG. 3 is connected to a continuous suction source, such as an operating room suction system, at suction device interface aperture 162a. When in this mode of operation for collecting bone dust, the fluid diversion aperture 162c is sealed via a plug 164 inserted therethrough. Fluid from the surgical site is separated from the bone dust (arrow **B**) by the filtration member 122 and passes through to the suction device interface aperture 162a. Suction is maintained by the presence of the plug 164.

[00089] FIG. 4 is a cross-sectional view of the bone dust collection system of FIGS. 1 and 2 having another embodiment of a bone dust collection device according to the present disclosure. More particularly, bone dust collection system 50' is identical to bone dust collection system 50 except that bone dust collection structure 110 is replaced by bone dust collection structure 210 which differs from bone dust collection structure 110. For simplicity, only those features of bone dust collection structure 210 which differ from the corresponding features of bone dust collection structure 110 are described. Additionally, those features are numbered as 210 instead of 110, 216 instead of 116, etc. Reference to FIG. 3 is implied where features not explicitly shown in FIG. 4 are described.

[00090] Bone dust collection device 200 includes cylindrically-shaped bone dust collection structure 210 that extends from proximal end 214a to distal end 214b of the bone dust collection structure 210. The proximal end 214a of the bone dust collection structure 210 is also configured as a valve support plate 216 such that the bone dust collection structure 210 also serves as a valve support structure in the same manner as described above with respect to bone dust collection device 100. Cylindrical wall 118 extends distally from the valve support plate 216 to define a central aperture and volume 220 for receiving and collecting bone dust.

[00091] Valve support structure or bone dust collection structure 210 includes valve supporting surface or plate 216 near the proximal end 214a.

[00092] The central aperture 220 extends proximally towards proximal end 214a of the bone dust collection structure 210 and includes filtration member 122 disposed therein that may be part of filter assembly 224. The filter assembly 224 may now include ring-shaped filter mounting member 226 that is configured to be disposed within the central aperture 220.

[00093] Again, as explained in more detail below, the filtration member 122 and the filter assembly 224 are configured and disposed wherein the filtration member 122 causes at least partial separation of fluid from the bone dust via the fluid passing proximally through the filtration member 122. The filter assembly 224 and filtration member 122 are mounted within the central aperture 220 wherein the ring-shaped filter mounting member 226 has an outside diameter approximately corresponding to the inside diameter of the cylindrical wall 118 such that the ring-shaped filter mounting member 226 may be disposed in a snug fit within the bone dust collection structure 210. Thus, the bone dust collection structure 210 is also configured to enable removal of bone dust collected therein.

[00094] Although illustrated as an assembly of filtration member 122 and the filter mounting member 226, the filter assembly 224 may be a molded construction. In either case, the filtration member 122 may be a mesh with an over-under weave knit material or be a molded membrane with small holes or apertures formed therein, on the order of 100 microns (μm) in cross-sectional distance. The

filtration member 122 may be made from, but not limited to, materials such as fiberglass, copper or stainless steel. The ring-shaped filter mounting member 226 may be made from a thermoplastic elastomer such as polyvinyl chloride and urethane.

[00095] Bone dust collection device 200 also defines a central longitudinal axis **A'-A'** that extends from proximal end 100a to distal end 100b. At least one fluid flow aperture 216a is defined in transverse plate member 216 that enables the fluid at least partially separated from the bone dust by the filtration member 122 to pass therethrough. Fluid extraction valve shaft aperture 216' is also defined in the transverse plate member 216 generally through the center **C** of the transverse plate member 216 through which longitudinal axis **A'-A'** passes. Second fluid flow aperture 216b may also be defined in the transverse plate member 216 again on a side of the longitudinal axis **A'-A'** opposite to the first fluid flow, e.g., at a position 180° from the first fluid flow aperture 216a, which is at position 0°. Additional fluid flow apertures (not shown) may also be positioned at 90° or 270° or other suitable locations if desired. It should be noted again that the bone dust collection structure 210 may also be oriented such that the first and second fluid flow apertures 216a and 216b may coincide with the 90° and 270° positions, respectively, or vice versa. Such interchangeability of the orientation of the first and second fluid flow apertures 216a and 216b is taken advantage of throughout the description which follows where necessary or desirable to explain the operation of the bone dust collection device 200.

[00096] The bone dust collection device 200 further includes also fluid extraction flow interruption member 130 that is configured and disposed with respect to the bone dust collection structure 210 wherein, as explained in more detail below, flow of fluid through at least one aperture or, for example, fluid flow apertures 216a and 216b, of the bone dust collection structure 210 occurs by suction pressure induced on the fluid extraction flow interruption member 130 causing the flow interruption member 130 to change position to enable flow through fluid flow apertures 216a and 216b.

[00097] As indicated above, fluid extraction valve shaft aperture 216' is defined in the transverse plate member 216. As shown in FIG. 3, the extraction flow interruption member 130 may be an umbrella valve as shown and which includes shaft member 132 that is disposed through the fluid extraction valve shaft aperture 216'. The extraction flow interruption member 130 again includes diaphragm 134 that is formed with the shaft member 132. The diaphragm 134 is again made from an elastomeric and flexible material and which overlays the fluid flow apertures 216a and 216b on the proximal side of transverse plate member 216. Again, the change of position of the extraction flow interruption member 130 occurs via the suction pressure induced on the flow interruption member, and more particularly on the diaphragm 134, such that the diaphragm 134 flips away from the transverse plate member 216 to expose the fluid flow apertures 216a and 216b, thereby enabling flow through the apertures 216a and 216b. The shaft member 132 includes again proximal portion 132a and distal portion 132b wherein the distal portion 132b defines a diameter that is greater than the diameter of the proximal portion 132a. However, in contrast to fluid extraction valve shaft aperture 116', fluid extraction valve shaft aperture 216' is thus shaped accordingly to define a narrow diameter portion to match the proximal portion 132a of the shaft member 132. The transverse plate member 216 is not characterized by the portion 1161 of the transverse plate member 116 that extends distally into the central aperture 120. Thus there is no circumferential channel 136 between inner surface 118a of the housing wall 118 and the distally extending portion 1161 of the transverse plate member 116.

[00098] The bone dust collection device 200 also includes the bone dust removal structure 150 mounted on cylindrical wall 118 and tee-shaped port member or cap 160 mounted to bone dust collection structure 210 at proximal end 214a in a similar manner as described above with respect to FIG. 3. However, a suction device 300 is now inserted into the suction device interface aperture 162a while a fluid flow diversion interruption device 400 is in fluid communication with fluid diversion aperture 162c at branch connection 160c.

- [00099] Fluid flow diversion interruption device 400 is configured and disposed with respect to the flow interruption member 130 and with respect to the bone dust collection structure 210 wherein suction pressure induced on the flow interruption member 130 causes the flow interruption member 130 to change position to enable flow through the apertures 216a and 216b defined in the transverse plate member 216 while fluid flow diversion interruption device 400 is in a closed position.
- [000100] In one embodiment, suction device 300 may be a syringe 302 including a plunger 304 in fluid communication with the bone dust collection structure 210 via distal port 302b of the syringe 302 inserted into the suction device interface aperture 162a of tee-shaped port member or cap 160. Suction pressure is caused by retraction of the plunger 304 in the proximal direction away from the bone dust collection structure 210 to enable flow through the apertures 216a and 216b defined in the transverse plate member 216.
- [000101] Conversely, advancement of the plunger 304 distally causes the flow interruption member 130 to interrupt flow from the bone dust collection structure 210 while fluid is diverted through the fluid flow diversion interruption device 400 which includes an upstream port 400a that is inserted in fluid diversion aperture 162c of the tee-shaped port member or cap 160.
- [000102] On downstream side 400b of fluid flow diversion interruption device 400, there is disposed a conduit 410 in fluid communication with the bone dust collection structure 210, wherein advancement of the plunger 304 causes the fluid (as represented by arrow **F**) received through the apertures 216a and 216b defined in the transverse plate member 216 to discharge through the fluid conduit 410 away from the bone dust collection device 200 in the direction of arrow **F**. Fluid communication between the fluid conduit 410 and the fluid flow diversion interruption device 400 may be established via a luer valve 412 connecting the fluid conduit 410 to the downstream side 400b. In one embodiment, the fluid flow diversion interruption device 400 may be a check valve installed so as to enable flow of fluid in the direction of arrow **F** and to prevent flow in the direction opposite to arrow **F**. In one embodiment, the conduit 410 is structured such that

the conduit 410 discharges the fluid in a direction generally perpendicular, e.g., in the direction of arrow **F**, to the direction of fluid flow through the filtration member 122.

[000103] FIG. 5 is a cross-sectional enlarged view of the bone dust collection housing and valve support structure 110 of the bone dust collection device of FIG. 3 having an embodiment of the filtration member 122 and transverse plate member 116 with circumferential channel 136 described above with respect to FIG. 3.

[000104] FIG. 6A is an end view of the filter assembly 124 that is included within the bone dust collection device 200 of FIGS. 1-3 and 5. FIG. 6B is a side view of the filter assembly 124 of FIG. 6B illustrating wherein ring-shaped filter mounting member 126 includes a cylindrical wall 128 which is configured and disposed to be received within the circumferential channel 136 illustrated in FIGS. 3 and 5. The cylindrical wall 128 has a height dimension **H** above the filtration member 122. The cylindrical wall 128 may be characterized by a partially contoured profile at the proximal end having a radius of curvature **R**. The ring-shaped filter mounting member 126 may define an inner diameter **D1** and an outer diameter **D2**.

[000105] FIG. 6C is a view of Detail 6C of FIG. 6B wherein ring-shaped filter mounting member 126 includes cylindrical wall 128.

[000106] FIG. 6D is a proximal perspective view of the filter assembly 124 of FIGS. 6A-6C.

[000107] FIG. 7A is an end view of the bone dust removal structure 150 in the form of a nozzle that may be included within the bone dust collection device 100 or 200 of the bone dust collection systems 50 or 50' of FIGS. 1-5.

[000108] FIG. 7B is a cross-sectional view of the nozzle 150 of FIG. 7A taken along cross-section line 7B-7B. The diameter **D3** of central aperture 152 at proximal end 152a tapers in the distal direction to diameter **D4** at distal end 152b such that diameter **D3** is greater than diameter **D4**. Having the tapered configuration such that the diameter of the central aperture 152 increases from the distal end 152b

to the proximal end 152a tends to minimize flow obstruction during operation of the bone collection device 100.

[000109] FIG. 8A is an end view of another embodiment of bone dust removal structure in the form of a nozzle 250 that may be included within the bone dust collection device 100 or 200 of the bone dust collection systems 50 or 50' of FIGS. 1-5.

[000110] FIG. 8B is a cross-sectional view of the nozzle of FIG. 8A taken along cross-section line 8B-8B. More particularly, nozzle 250 defines a generally constant diameter D5 circular aperture 251 at proximal end 250a wherein the circular aperture 251 is configured and disposed to receive the filter assembly 124 (see FIG. 1-5). Nozzle 250 further defines another generally constant diameter D6 circular aperture 252 that extends distally from an interface 254 with circular aperture 251 wherein bone dust B is suctioned from distal end 250b. In a similar manner as with respect to nozzle 150, nozzle 250 may be made from flexible, elastomeric materials, such as, but not limited to, silicone.

[000111] FIG. 9A is an end view of one embodiment of valve tee-shaped port member or cap 160 that that may be included with the bone dust collection device 100 or 200 of the bone dust collection systems 50 or 50' of FIGS. 1-5.

[000112] FIG. 9B is a cross-sectional view of the valve cap tee-shaped port member or cap 160 of FIG. 9A taken along section line 9B-9B.

[000113] As described above with respect to FIG. 4, tee-shaped port member or cap 160 that defines bone dust collection interface aperture 162b at distal portion 160b of the tee-shaped port member or cap 160. The tee-shaped port member or cap 160 may further define suction device interface aperture 162a at proximal portion 160a. Additionally, tee-shaped port member or cap 160 defines fluid diversion aperture 162c at branch connection 160c at generally a right angle with respect to interface apertures 162a and 162b.

[000114] FIG. 10 is an exploded partially transparent view of a handle assembly 500 that may be included as part of the bone dust collection devices 100 or 200 of the bone dust collection systems 50 or 50' of FIGS. 1-5. The handle assembly 500 includes a central handle member 502 having a generally cylindrical

configuration with a knurled outer surface 502a having a series of ridges to assist a user in gripping the handle member 502. The central handle member 502 also defines a central bore or aperture 504 that extends from proximal end 506a of the handle member 502 to distal end 506b of the handle member 502.

[000115] The handle assembly 502 may further include a connector member 510 at proximal end 506a. The connector member 510 defines a barbed proximal end 512a and a barbed distal end 512b and a central bore 514 extending through each end. Distal barbed end 512b of connector member 510 is configured and disposed to engage with proximal end 506a of the central handle member 502 and be received within the central bore or aperture 504.

[000116] Additionally, the handle assembly 500 may include at distal end 506a of central handle member 502 a luer fitting 516 having a proximal barbed end 518a. The luer fitting 516 defines a central bore 520 such that the proximal barbed end 518a is configured to be received within the central bore or aperture 504.

[000117] FIG. 10A is a cross-sectional view of the handle assembly 500 of FIG. 10.

[000118] FIG. 11 is a perspective, partially transparent view of the handle assembly of FIGS. 10 and 10A and the bone dust collection device of FIG. 3 that includes a plug seal forming a bone dust collection system 600. As can be appreciated by the foregoing description of FIGS. 110 and 10A, when the handle assembly 500 is assembled as shown wherein the luer fitting 516, the central handle member 502 and the connector member 510 are connected in series, fluid communication is established from the luer fitting 516 to the connector member 510 via the central bore 520 of the luer fitting 516, the central bore 504 of the central handle member 502 and the central bore 514 of the connector member 510. In this configuration, suction is established through the handle assembly 500 in the proximal direction of arrow **S** by connection to a continuous suction source such as an operating room such system (not shown). Bone dust as represented by arrow **B** at bone dust removal structure 150 is collected by the bone dust collection device 100 or 200 by the establishment of the suction condition **S**. The fluid extraction flow interruption member 130 (see FIG. 3) is now in an open position to permit the passage of fluid through the handle assembly 500 while

fluid flow through the fluid diversion aperture 162c at branch connection 160c is sealed via the plug member 164. Bone dust is collected in the bone dust collection device 100 or 200.

[000119] FIG. 12 is a transparent view of the handle assembly 500 of FIG. 11 and the bone dust collection device 100 or 200 of FIGS. 1-5 forming bone dust collection system 600'. As can be appreciated by the foregoing description of FIG. 11, when the handle assembly 500 is assembled as shown wherein the luer fitting 516, the central handle member 502 and the connector member 510 are connected in series, fluid communication is again established from the luer fitting 516 to the connector member 510 via the central bore 520 of the luer fitting 516, the central bore 504 of the central handle member 502 and the central bore 514 of the connector member 510. In this configuration, suction is again established through the handle assembly 500 in the proximal direction of arrow **S** by connection to a continuous suction source such as an operating room such system (not shown). Bone dust as represented by arrow **B** at bone dust removal structure 150 is collected by the bone dust collection device 100 or 200 by the establishment of the suction condition **S**. The fluid extraction flow interruption member 130 (see FIG. 3) again is now in an open position to permit the passage of fluid through the handle assembly 500 while, in contrast to the sealing provided by plug member 164, the fluid flow diversion interruption device 400 is in a closed position. Bone dust is collected in the bone dust collection device 110 or 210.

[000120] FIG. 13 is a partially transparent view of one embodiment of a self-contained bone dust collection device according to the present disclosure. More particularly, referring to FIG. 4 above, self-contained bone dust collection device 700 includes the suction device 300 which may be a syringe 302 including a plunger 304 in fluid communication with the bone dust collection structure 110 (see FIG. 3) or bone dust collection structure 210. However, as described above with respect to FIG. 5, in lieu of fluid conduit 410, self-contained bone collection device 700 includes flow diversion member 420 that is in fluid communication with the fluid flow diversion interruption device 400 on the downstream side 400b.

[000121] Again, flow diversion member 420 may be a right angle or 90 degree luer valve and is further described below. When the plunger 304 is advanced distally following retraction and accumulation of fluid within the syringe 302, fluid flow diversion interruption device 400 shifts to the open position (while fluid extraction flow interruption member 130 shifts to the closed position) to divert fluid through flow diversion member 420. Flow diversion member 420 may be utilized to divert fluid back to a surgical site by directing the fluid vertically downward as shown by arrow **F1**.

[000122] FIG. 13A is a partially transparent view of another embodiment of the self-contained bone collection device of FIG. 13. More particularly, bone dust collection device 700' differs from bone dust collection device 700 in that fluid flow diversion interruption device 400 is now downstream of flow diversion member 420.

[000123] FIG. 14 is a zoomed out partial profile cross-sectional view of the bone dust collection systems 50 or 50' that includes fluid conduit 410 of FIG. 1-3. FIG. 15A is a detailed view of extraction flow interruption member 130 illustrated in the form of umbrella valve 130 that is positioned on upper surface 115 of the housing in a closed position. The extraction flow interruption member 130 again includes diaphragm 134 that is formed with the shaft member 132. The diaphragm 134 is again made from an elastomeric and flexible material and which overlays the fluid flow apertures 116a and 116b on the proximal side or upper surface 115 of transverse plate member 116. FIG. 15B is a detailed view of the umbrella valve positioned on the upper surface 115 of the housing in an open position to enable flow of fluid past the umbrella valve. Again, the change of position of the extraction flow interruption member 130 occurs via the suction pressure induced on the flow interruption member, and more particularly on the diaphragm 134, such that the diaphragm 134 flips away from the transverse plate member 116 to expose the fluid flow apertures 116a and 116b, thereby enabling flow of fluid through the apertures 116a and 116b, as indicated by arrows F2A and F2B, respectively. Those skilled in the art will recognize that the actual flexing and flipping of the diaphragm 134 to establish the open position is a very

small rise away from the transverse plate member 116. That is, the diaphragm 134 must flex upwardly sufficiently to enable passage of the fluid, such as blood and/or saline solution, with any particulates including bone dust or other anatomical specimens contained therein that have passed through the filtration member 124 (see FIG. 3) while the anatomical specimen is being collected. The umbrella valve may be made from thermoplastic elastomers such as, but not limited to, polyvinyl chloride or urethane or the like.

[000124] FIG. 16 is a cross-sectional view of the bone dust collection device 100 or 200 when the umbrella valve 130 is in the closed position as described above with respect to FIG. 15A.

[000125] FIG. 17 is a cross-sectional view of the bone dust collection device 100 or 200 when the umbrella valve 130 is in the open position for permitting passage of fluid past the umbrella valve 130 as shown by arrows **F2A** and **F2B** and then through suction device interface aperture 162a at proximal portion 160a as shown by arrow **F3**. In this configuration, the suction device 300 which may be in the form of syringe 302 as described above draws suction on the interface aperture 162a to enable the fluid to be drawn into the syringe. During this operation, the plunger 304 is retracted proximally through the syringe 302.

[000126] FIG. 18 is a cross-sectional view of the bone dust collection device 100 or 200 when the umbrella valve 130 is in the closed position for discharging and diverting fluid which has been collected by syringe 302 in the direction of arrow **F4** through fluid diversion aperture 162c at branch connection 160c. During this operation, the plunger 304 is advanced distally through the syringe 302.

[000127] FIG. 19 is a cross-sectional view of another embodiment of the bone dust collection device 200 having the alternate filtration member 224 shown in FIG. 4. During this operation, the fluid flow diversion interruption device 400 is in the closed position and the umbrella valve 130 is in the open position. for permitting passage of fluid past the umbrella valve 130 as shown by arrows **F2A** and **F2B** and then through suction device interface aperture 162a at proximal portion 160a as shown by arrow **F3**.

[000128] FIG. 20 is cross-sectional view of the bone dust collection device 200 of FIG. 19 wherein the umbrella valve 130 is in the closed position and fluid is diverted through fluid diversion aperture 162c and the fluid flow diversion interruption device 400 in the direction of arrow **F4**.

[000129] Although the flow interruption member 130 has been illustrated as an umbrella valve, other flow interruption members may be employed such as a miter valve or duck bill valve, a check or flapper valve, or a disk valve or the like. In such cases, the tee-shaped port member or cap 160 and/or the filtration assembly 224 may be reconfigured if or as necessary to accommodate the design, operation and configuration of the particular flow interruption member being employed.

[000130] FIG. 21 is a cross-sectional view of the bone dust collection device 100 having the filtration member 124 of FIG. 5 in an inverted position to allow removal of collected bone dust 180. The collected bone dust 180 may be removed manually with a flat instrument or spatula or by a power-assisted instrument including a suction source.

[000131] FIG. 22 is a cross-sectional view of the bone dust collection device 200 of FIG. 19 in an inverted position to allow removal of collected bone dust 180. Similarly, the collected bone dust 180 may be removed manually with a flat instrument or spatula or by a power-assisted instrument including a suction source.

[000132] FIG. 23 is a perspective transparent view of a kit package 800 that houses the bone dust collection devices 100 or 200 and associated components according to embodiments of the present disclosure.

[000133] More particularly, kit 800 includes a support tray 802 that defines a first depression 804a and an adjacent second depression 804b which are interconnected via a central depression 804c. As illustrated, suction device 300 is received in first depression 804a, handle assembly 500 is received in second depression 804b together with plug member 164 while bone dust collection device 100 or 200 may be received in central depression 804c. When provided

with a covering (not shown), the kit package and contents may be provided to the user in a sterile condition via means known in the art.

[000134] Alternatively, the contents may also be provided in a sterile condition in a taped banded bag such as, for example, a Sklar banded bag product no. 96-5582 or equivalent as necessary due to the size of the contents (not shown – by Sklar Instruments, West Chester, Pennsylvania, USA) or Tyvek® (DuPont de Nemours, Inc.) pouch or equivalent as known in the art.

[000135] FIG. 24 is a perspective view of the bone dust collection device 100 of FIG. 3 having plug member 164 to seal off flow through fluid diversion aperture 162c at branch connection 160c during connection of the bone dust collection device to a continuous vacuum system.

[000136] FIG. 25 is a perspective view of the bone dust collection device 100 or 200 of FIG. 24 wherein the plug member 164 is replaced by flow diversion member 420 in the form of a 90 degree elbow and fluid flow diversion interruption device 400 to enable diversion of fluid in a vertically downward direction back to a surgical site.

[000137] FIG. 26 is a cross-sectional view of the bone dust collection device 100 of FIG. 25 with fluid flow diversion member 420 in the form of a 90 degree elbow and fluid flow diversion interruption device 400 to enable diversion of fluid in a vertically downward direction back to a surgical site.

[000138] FIG. 27 is a perspective view of the bone dust collection device 100 or 200 of FIGS. 25 and 26 wherein the fluid flow is directed horizontally.

[000139] FIG. 28 is a perspective view of the bone dust collection device 100 or 200 of FIG. 25-27 wherein the fluid flow diversion interruption device 400 is replaced by a fluid port connection fitting member 430 and a tubular member 440 to enable diversion in a vertically downward direction of fluid back to a surgical site.

[000140] FIG. 29 is a cross-sectional elevation view of the bone dust collection device 100 or 200 of FIG. 28 wherein fluid port connection fitting member 430 and tubular member 440 enable diversion of fluid in a vertically downward direction.

[000141] FIG. 30 is a perspective view of the bone dust collection device 100 or 200 of FIG. 29 wherein tubular member 440 of the fluid port connection fitting member 430 has been removed.

[000142] FIG. 31 is a perspective view of the bone dust collection device 100 or 200 of FIG. 30 wherein the flow diversion member 430 is oriented at an angle of 45 degrees below the horizontal to enable diversion of fluid in an alternative direction with respect to a surgical site.

[000143] FIG. 32 is a perspective view of the bone dust collection device 100 or 200 of FIG. 28 wherein the flow diversion member 430 is oriented horizontally to enable diversion of fluid in yet another alternative direction with respect to a surgical site.

[000144] From the foregoing description, it can be appreciated that the harvested or collected bone may be used during:

[000145] (1) Fusion construct - spine or long bone - to promote fusion healing.

[000146] (2) Bone fusion wherein placement of bone dust into a fusion device such as a cage implant may be utilized to promote bone fusion.

[000147] (3) Replacement of bone after craniotomy or any skull base procedure where bone is removed.

[000148] (4) Dental reconstruction/fusion procedure.

[000149] Between the bone dust collection structure and the syringe, the one-way valve or check valve allows for continued suction and expulsion of air without disconnecting the syringe from the bone dust collection device.

[000150] The size of the central aperture and volume 120 (see FIG. 3) and 220 (see FIG. 4) for receiving and collecting bone dust can be altered depending on use of the device. The size of the bone collection devices 110 and 210 (see FIGS. 3 and 4, respectively) and respective central apertures and volumes 120 and 220 can be made smaller for cervical surgery or made larger for lumbar surgery or long bone repair.

[000151] Embodiments of the bone dust collection device may include a mechanism to include or mix bone marrow aspirate or also other biological cells.

- [000152] Since bone marrow is flexible tissue, embodiments of the bone dust collection device may be used to filter bone marrow alone as a separate device and without the need for drilling. In such embodiments, the filter design parameters may be adjusted accordingly to suit collection of bone marrow or other biological cells.
- [000153] The bone dust collecting structures 110 or 210 may be centrifuged to spin down bone products and separate blood products.
- [000154] The harvesting or bone dust collection system or self-contained device generally is provided via a sterile cartridge, adaptable to a standard luer fitting. The harvesting system may be provided sterile by the medical device manufacturer.
- [000155] The filter assembly allows blood and fluids to pass, but generally retains bone particles between about 75 to about 300 microns. Filter mesh size may be optimized, such as by empirical testing of various filter sizes and types, to result in minimal fluid flow restriction and clogging during the procedure and to result in maximal bone fragment collection. Consideration must also be given to optimization and alternate particle size ranges when collecting other anatomical specimens such as bone marrow or other biological cells.
- [000156] The bone dust collection volume generally is about 0.5 cc (cubic centimeters) minimum.
- [000157] The device may be designed to allow a clinician to cycle the syringe multiple times while harvesting bone dust, while dispensing blood/saline out of the side port.
- [000158] The bone dust harvesting system allows easy removal of the bone dust from the device. The device allows cleaning of the bone dust using a sterile saline flush. The harvesting system allows easy consolidation and removal of the bone dust. Removal methods include utilizing a scoop (spatula, spoon or similar). Prior to removal of the bone dust, aspiration of the bone dust via air flow may assist in drying the bone dust to result in a more cohesive bone plug when removing the bone dust.

[000159] The device is generally provided sterile in a double Tyvek® pouch in order to comply with sterile transfer protocol in the sterile OR field.

[000160] Sterilization methods may include exposure to Gamma radiation.

[000161] The bone dust collection device may be reused on the same patient during the same surgical procedure. The device generally should not be re-sterilized. It is intended for use in the collection of bone dust created during a surgical procedure when using any high-speed drill that creates bone dust (cutting burrs, diamond burrs, etc.).

[000162] The device generally does not contain latex.

[000163] Bone dust collected by the surgeon is used for the procedure at his or her discretion. As indicated above, bone dust can be packed into an interbody cage device to augment a fusion construct. In conjunction with FIG. 11 or FIG. 12 and the foregoing disclosure.

[000164] TABLE 1 below indicates detailed method steps for “Using the Bone Dust Collection System with Operating Room Suction.”

TABLE 1
USING THE BONE DUST COLLECTION SYSTEM WITH OPERATING ROOM
SUCTION

Step No.	Description
1.	Open the single-pouch in a sterile fashion onto the operating room surgical field.
2.	Insert side plug into valve body of the device.
3.	Attach handle assembly to the luer lock of the device.
4.	Attach operating room suction tubing to universal connector on handle assembly.
5.	Using a high-speed drill, create bone dust based on the procedure.

6.	Irrigate surgical site with saline to suspend the bone dust.
7.	Place the tip of the collection device into the saline/bone dust mixture and aspirate using suction system.
8.	Collect bone dust in the chamber and saline with blood products in the suction canister.
9.	Upon completely filling the collection chamber with bone dust, remove the tip and collect the bone dust with a flat instrument or spatula.
10.	Pack the collected bone dust into the region of interest in the subject – interbody cage, bone defect, etc.
11.	If necessary, replace tip and collect additional bone dust.
12.	If necessary, repeat usage of the bone dust collection system until enough bone for the procedure has been collected.

[000165] In conjunction with FIG. 13 or FIG. 13A, and the foregoing disclosure, TABLE 2 below indicates detailed method steps for “Using the Self-Contained Bone Dust Collection Device with Syringe Suction.”

TABLE 2
USING THE SELF-CONTAINED DEVICE WITH SYRINGE SUCTION

Step No.	Description
1.	Open the single-pouch in a sterile fashion onto the operating room surgical field.
2.	Attach a 30 cc syringe to the luer lock of the device.

3.	Attach the right angle check valve assembly to the valve body.
4.	Using a high-speed drill, create bone dust based on the procedure.
5.	Suspend the bone dust using a small amount of saline irrigation.
6.	Place the tip of the collection device into the saline/bone dust mixture and aspirate by pulling back the syringe piston. Bone dust is collected in the chamber while saline and blood products are collected within the syringe.
7.	Recycle excess saline and blood collected within the syringe by pushing in the syringe piston allowing the excess fluid to be expelled through the side port back into the surgical wound.
8.	When the collection chamber is filled with bone dust, remove the tip and collect bone dust with a flat instrument or spatula.
9.	Pack the collected bone dust into the region of interest in the subject – interbody cage, bone defect, etc.
10.	If necessary, replace tip and collect additional bone dust.
11.	If necessary, repeat usage of the bone dust collection system until enough bone for the procedure has been collected.

[000166] In view of the foregoing, the embodiments of the present disclosure relate to a general method of collecting an anatomical specimen that includes the following steps.

[000167] With reference particularly to FIGS. 11, 12, 13 and 13A, the method includes generating an anatomical specimen, e.g., bone dust 180 (see FIG. 21) in particulate form at a surgical site of a subject (not shown).

[000168] The method includes irrigating the surgical site to suspend the particulate in a particulate fluid mixture (not shown). Upon irrigating the surgical site, the method includes disposing a tip of a collection device, e.g., the collection device 100 in FIG. 1, in the particulate fluid mixture (e.g., represented in FIG. 15B by arrows **F2A** and **F2B** internally within the collection device 100 in FIG. 1); aspirating the collection device, e.g., collection device 100, to filter and separate the particulate from the particulate fluid mixture therein accumulating the particulate, e.g., bone dust 180 in FIG. 17, in the collection device, e.g., collection device 100; and collecting the particulate, e.g., bone dust 180, accumulated in the collection device 100.

[000169] The method may further include packing the collected particulate, e.g., bone dust 180, into a region of interest in the subject (not shown).

[000170] The step of collecting the particulate accumulated in the collection device may be preceded by disassembling the collection device. The method may further include reassembling the collection device and repeating the foregoing steps of generating additional anatomical specimen in particulate form at a surgical site of the subject; irrigating the surgical site to suspend the particulate in a particulate fluid mixture; disposing the tip of the collection device in the particulate fluid mixture; aspirating the collection device to filter and separate the particulate from the particulate fluid mixture therein accumulating the particulate in the collection device; and collecting the particulate accumulated in the collection device.

[000171] The method may then include again packing the additionally collected particulate, e.g., bone dust 180, into a region of interest in the subject.

[000172] As shown in FIGS. 11 and 12, the aspirating of the collection device 100 may include connecting the collection device 100 to a vacuum source, that

establishes suction through the handle assembly 500 in the proximal direction of arrow **S** in an operating room (not shown) wherein the vacuum source is in fluid communication with the fluid in the particulate fluid mixture, shown by arrow B, to filter and separate the particulate, bone dust 180 from the particulate fluid mixture, shown by arrow B.

[000173] Alternatively, as shown in FIGS. 13 and 13A, the aspirating of the collection device 100 may include actuating a syringe, e.g., syringe 300, in fluid communication with the collection device 100 and in fluid communication with the particulate fluid mixture, shown by arrow B, wherein the actuating of the syringe effects filtering and separating the particulate, e.g., bone dust 180, from the particulate fluid mixture.

[000174] In conjunction with the foregoing disclosure and FIGS. 1-32, TABLE 3 indicates "Consideration for Using the Bone Dust Collection System or Device".

TABLE 3
CONSIDERATIONS FOR USING THE BONE DUST COLLECTION SYSTEM OR
DEVICE

Consideration No.	Description
1.	The device functions better with saline and bone dust mixture while minimizing the amount of blood.
2.	If there is too much blood in the field, the tip or filter may become clogged making it difficult to aspirate bone dust. The surgeon should irrigate the field, stop bleeding as much as possible, and try the procedure for bone dust collection at this point with a dry field.
3.	The tip may detach with excessive force while pushing into the wound to collect bone dust. Simply re-attach.

4.	Occasionally, the tip can become clogged with minimal saline. Irrigate further and simply put gentle pressure on the tip to dislodge stuck bone dust.
5.	The device is not a fusion device; it is intended to assist the surgeon in collecting bone dust.
6.	It is not expected that the device promotes better fusion rates.

[000175] The detailed description of exemplary embodiments herein makes reference to the accompanying drawings, which show the exemplary embodiments by way of illustration and their best mode. While these exemplary embodiments are described in sufficient detail to enable those skilled in the art to practice the disclosure, it should be understood that other embodiments may be realized and that logical and mechanical changes may be made without departing from the spirit and scope of the disclosure. Thus, the detailed description herein is presented for purposes of illustration only and not of limitation. For example, the steps recited in any of the method or process descriptions may be executed in any order and are not limited to the order presented. Moreover, any of the functions or steps may be outsourced to or performed by one or more third parties. Furthermore, any reference to singular includes plural embodiments, and any reference to more than one component may include a singular embodiment.

CLAIMS:

What is claimed is:

1. A bone dust collection device comprising:
a bone dust collection structure defining a longitudinal axis and having a proximal end and a distal end,
the bone dust collection structure having a transverse plate member connected at or in the vicinity of the proximal end to a cylindrical wall defining an aperture at the distal end for receiving and collecting bone dust, the aperture extending proximally and including a filtration member disposed therein, the filtration member configured and disposed wherein the filtration member causes at least partial separation of fluid from the bone dust via the fluid passing proximally through the filtration member, the bone dust collection structure configured to enable removal of bone dust collected therein.
2. The bone dust collection device according to claim 1, wherein at least one aperture is defined in the transverse plate member that enables the fluid at least partially separated from the bone dust by the filtration member to pass therethrough.
3. The bone dust collection device according to claim 2, further comprising a flow interruption member configured and disposed with respect to the bone dust collection structure wherein flow of fluid through the at least one aperture of the bone dust collection structure occurs by suction pressure induced on the flow interruption member causing the flow interruption member to change position to enable flow through the at least one aperture defined in the transverse plate member.
4. The bone dust collection device according to claim 3, wherein at least another aperture is defined in the transverse plate member wherein the flow interruption member includes a shaft member disposed through the at least another aperture wherein the change of position of the flow interruption member occurs via the suction pressure induced on the flow interruption member to enable flow through the at least one aperture defined in the transverse plate member.

5. The bone dust collection device according to claim 3, further comprising a syringe including a plunger in fluid communication with the bone dust collection structure wherein the suction pressure is caused by retraction of the plunger away from the bone dust collection structure to enable flow through the at least one aperture defined in the transverse plate member.
6. The bone dust collection device according to claim 5, wherein advancement of the plunger causes the flow interruption member to interrupt flow from the bone dust collection structure.
7. The bone dust collection device according to claim 6, further comprising a conduit in fluid communication with the bone dust collection structure, wherein advancement of the plunger causes the fluid received through the at least one aperture defined in the transverse plate member to discharge through the conduit away from the bone dust collection device.
8. The bone dust collection device according to claim 7, wherein the conduit is structured such that the conduit discharges the fluid in a direction generally perpendicular to the direction of fluid flow through the filtration member.
9. The bone dust collection device according to claim 3, further comprising another flow interruption device configured and disposed with respect to the flow interruption device and with respect to the bone dust collection structure wherein suction pressure induced on the another flow interruption device causes the another flow interruption device to be in a closed position and causes the flow interruption member to change position to enable flow through the at least one aperture defined in the transverse plate member.
10. The bone dust collection device according to claim 3, further comprising another flow interruption device configured and disposed with respect to the flow interruption device and with respect to the bone dust collection structure wherein the another flow

interruption device is a plug member to seal off flow therethrough during connection of the bone dust collection device to a continuous vacuum system and suction pressure induced on the flow interruption device causes the flow interruption member to change position to enable flow through the at least one aperture defined in the transverse plate member.

11. The bone dust collection device according to claim 1, further comprising:

a bone dust removal structure defining an aperture having a proximal end and a distal end, the aperture configured and disposed for facilitating transport of bone dust from the distal end of the bone dust removal structure to the bone dust collection structure.

12. The bone dust collection device according to claim 11, wherein the bone dust removal structure includes a nozzle that defines the aperture of the bone dust removal structure, the nozzle defining a proximal end and a distal end, wherein the nozzle facilitates transport of the bone dust to the bone dust collection structure.

13. The bone dust collection device according to claim 12, wherein the nozzle is removably attached to the bone dust collection structure, wherein removal of the nozzle from the bone dust collection structure enables removal of bone dust collected within the bone dust collection structure.

14. The bone dust collection device according to claim 3, further comprising a guide member configured and disposed with respect to the suction source and the bone dust collection structure for enabling a user to manually control the location of the bone dust removal structure during a surgical procedure.

15. The bone dust collection device according to claim 3, wherein the flow interruption member is an umbrella valve.

16. The bone dust collection device according to claim 9, wherein the another flow interruption member is a check valve.

17. A bone dust collection device comprising:

a bone dust collection structure defining a proximal end and a distal end, the bone dust collection structure including a filtration member at the proximal end and defining an aperture at the distal end for receiving and collecting bone dust, the filtration member causing at least partial separation of fluid from the bone dust via the fluid passing proximally through the filtration member; and

a bone dust removal structure defining an aperture having a proximal end and a distal end, the aperture configured and disposed for facilitating transport of bone dust from the distal end of the bone dust removal structure to the bone dust collection structure, the bone dust removal structure removably attached to the bone dust collection structure, wherein removal of the bone dust removal structure from the bone dust collection structure enables removal of bone dust collected within the bone dust collection structure.

18. An anatomical collection system comprising:

an anatomical specimen collection structure defining a proximal end and a distal end, the anatomical specimen collection structure including a filtration member at the proximal end and defining an aperture at the distal end for receiving and collecting an anatomical specimen, the filtration member causing at least partial separation of fluid from the anatomical specimen via the fluid passing proximally through the filtration member; and

an anatomical specimen removal structure defining an aperture having a proximal end and a distal end, the aperture configured and disposed for facilitating transport of the anatomical specimen from the distal end of the anatomical specimen removal structure to the anatomical specimen collection structure, the anatomical specimen removal structure removably attached to the anatomical specimen collection structure wherein detachment of the anatomical specimen removal structure from the

anatomical specimen collection structure enables removal of the anatomical specimen collected within the anatomical specimen collection structure.

19. The anatomical collection system according to claim 18, wherein the anatomical specimen is bone dust.

20. A method of collecting an anatomical specimen comprising:

generating an anatomical specimen in particulate form at a surgical site of a subject;

irrigating the surgical site to suspend the particulate in a particulate fluid mixture;

disposing a tip of a collection device in the particulate fluid mixture;

aspirating the collection device to filter and separate the particulate from the particulate fluid mixture therein accumulating the particulate in the collection device; and collecting the particulate accumulated in the collection device.

21. The method according to claim 20, further comprising:

packing the collected particulate into a region of interest in the subject.

22. The method according to claim 20, wherein the collecting the particulate accumulated in the collection device is preceded by disassembling the collection device, the method further comprising:

reassembling the collection device;

generating additional anatomical specimen in particulate form at a surgical site of the subject;

irrigating the surgical site to suspend the particulate in a particulate fluid mixture;

disposing the tip of the collection device in the particulate fluid mixture;

aspirating the collection device to filter and separate the particulate from the particulate fluid mixture therein accumulating the particulate in the collection device; and collecting the particulate accumulated in the collection device.

23. The method according to claim 22, further comprising:

packing the additionally collected particulate into a region of interest in the subject.

24. The method according to claim 20, wherein the aspirating of the collection device includes connecting the collection device to a vacuum source wherein the vacuum source is in fluid communication with the fluid in the particulate fluid mixture to filter and separate the particulate from the particulate fluid mixture.

25. The method according to claim 24, wherein the connecting the collection device to a vacuum source includes connecting the collection device to a vacuum source in an operating room.

26. The method according to claim 20, wherein the aspirating of the collection device includes actuating a syringe in fluid communication with the collection device and in fluid communication with the particulate fluid mixture wherein the actuating of the syringe effects filtering and separating the particulate from the particulate fluid mixture.

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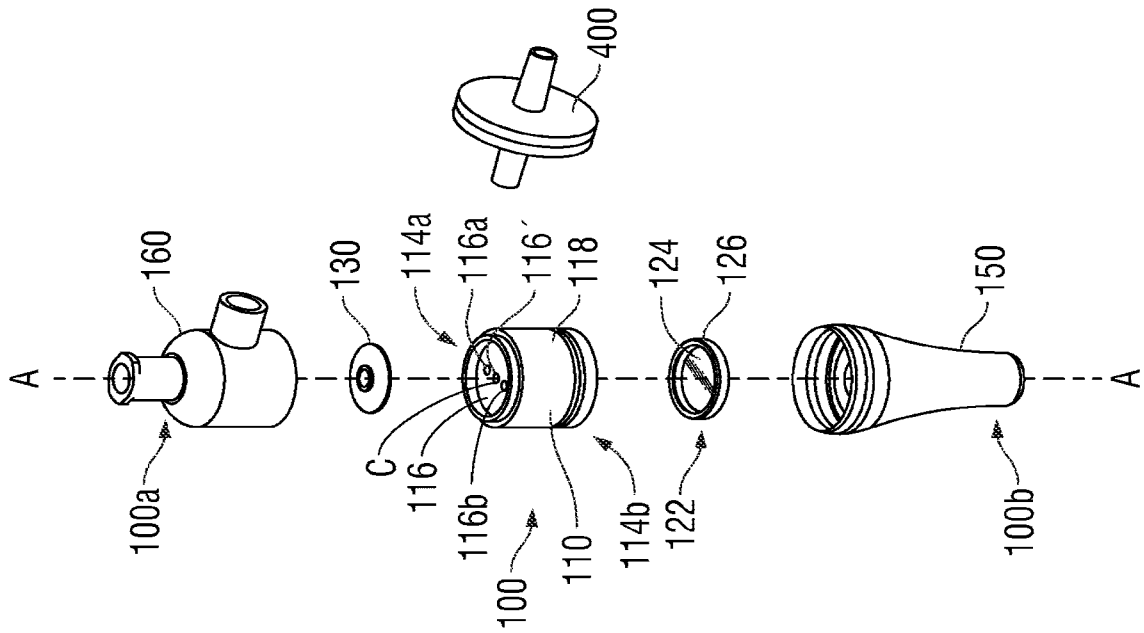


FIG. 2

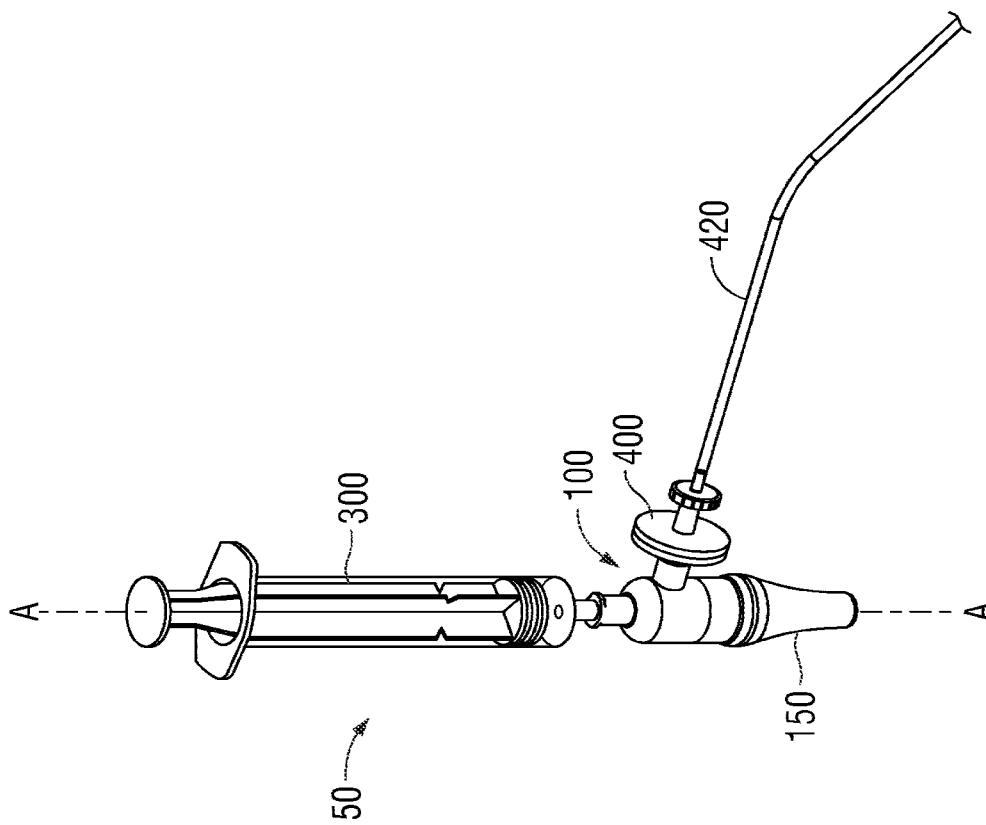


FIG. 1

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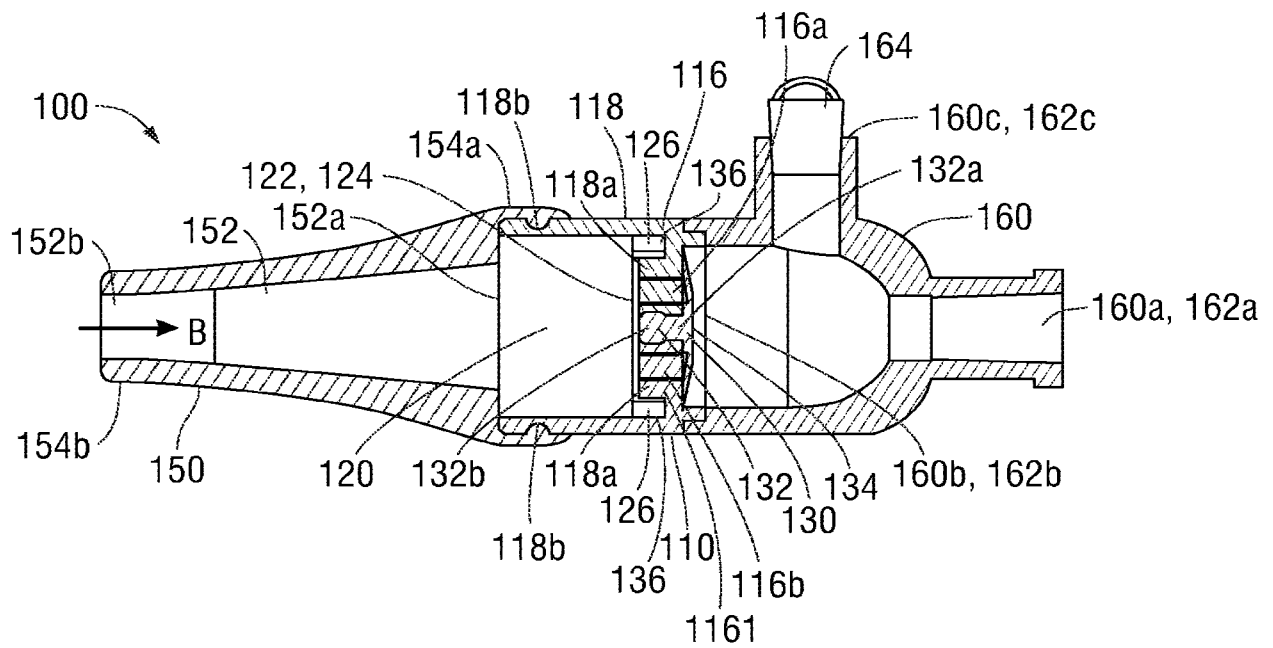


FIG. 3

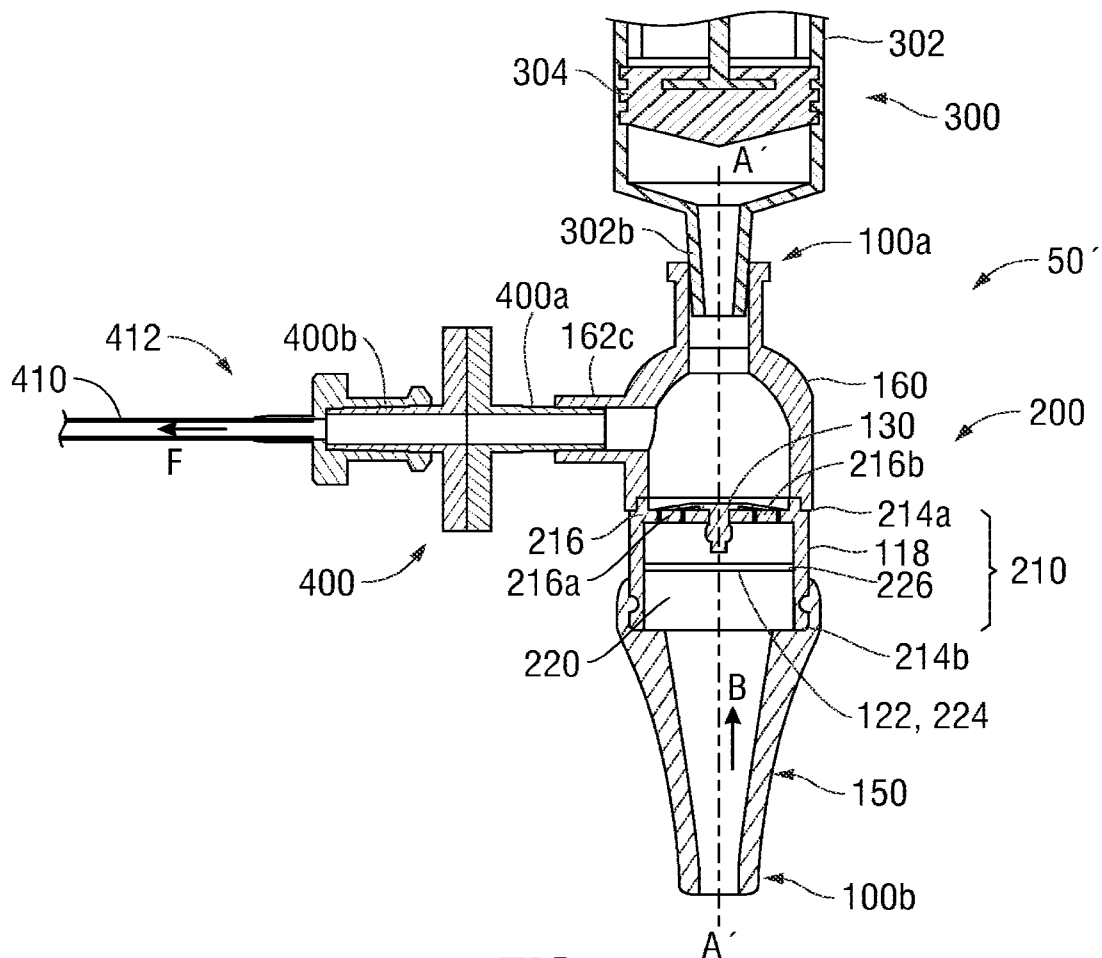


FIG. 4

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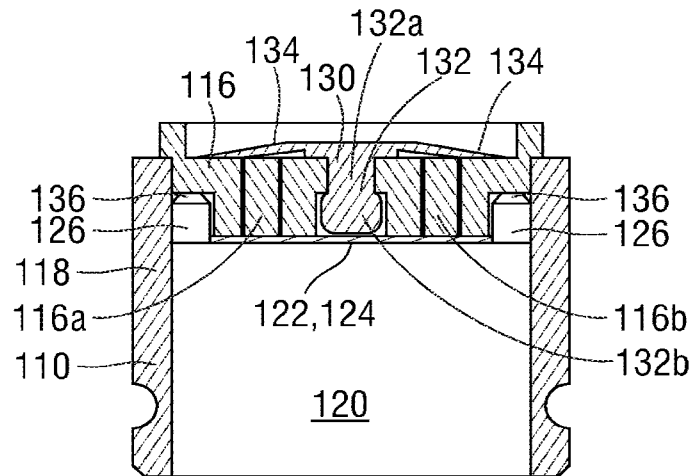


FIG. 5

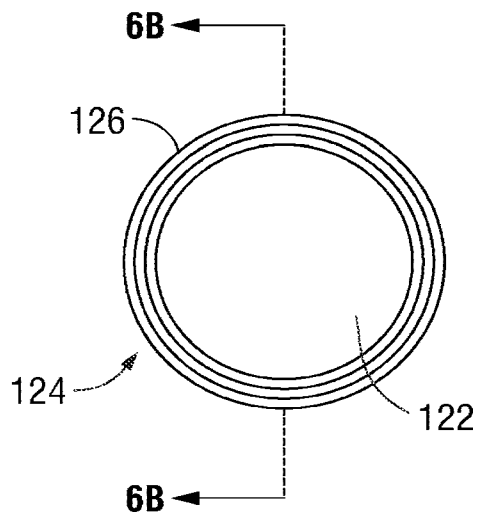


FIG. 6A

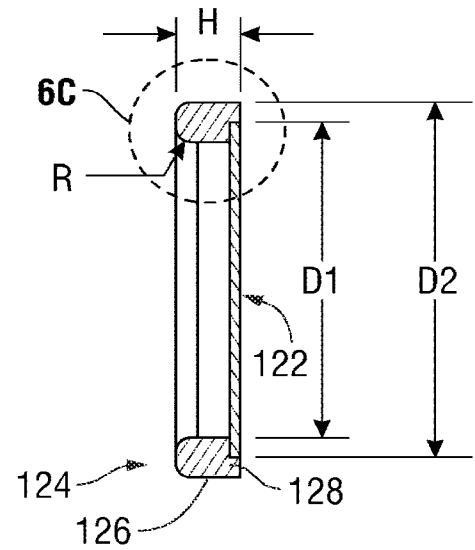


FIG. 6B

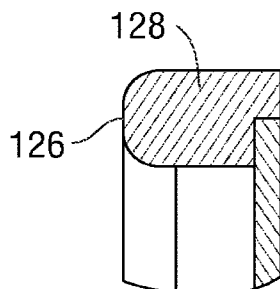


FIG. 6C

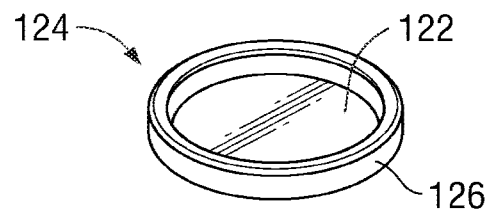


FIG. 6D

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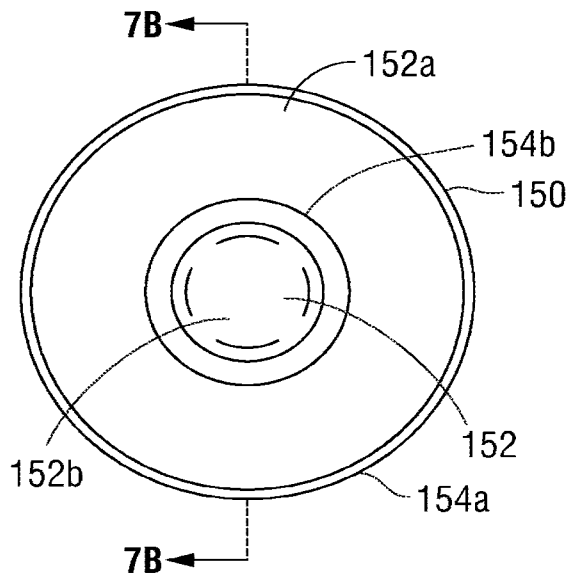


FIG. 7A

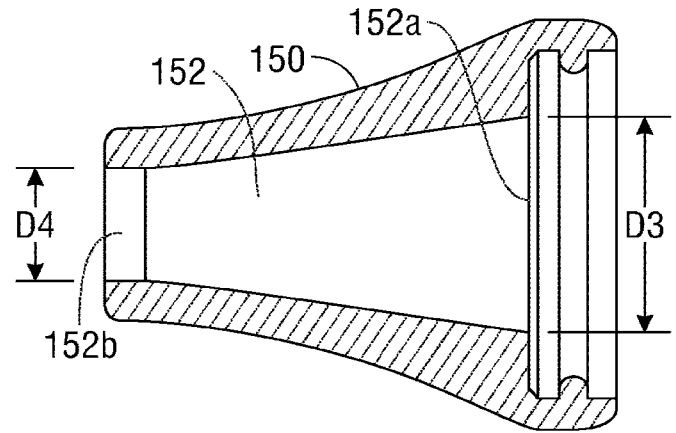


FIG. 7B

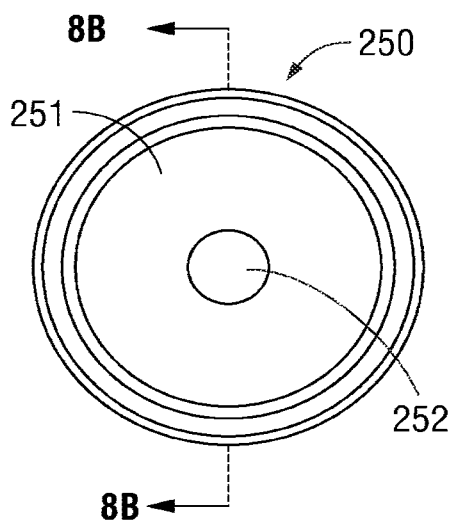


FIG. 8A

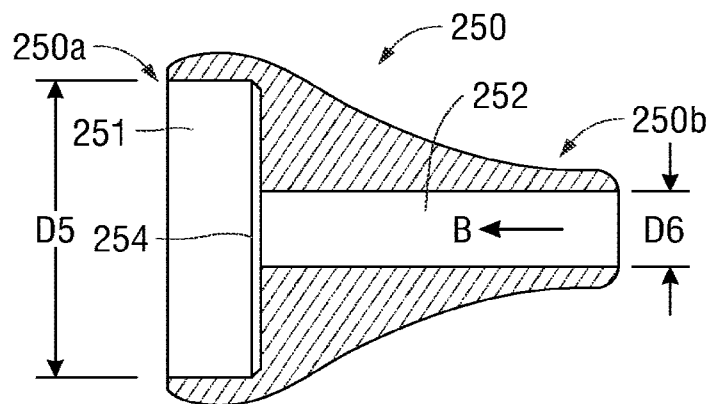


FIG. 8B

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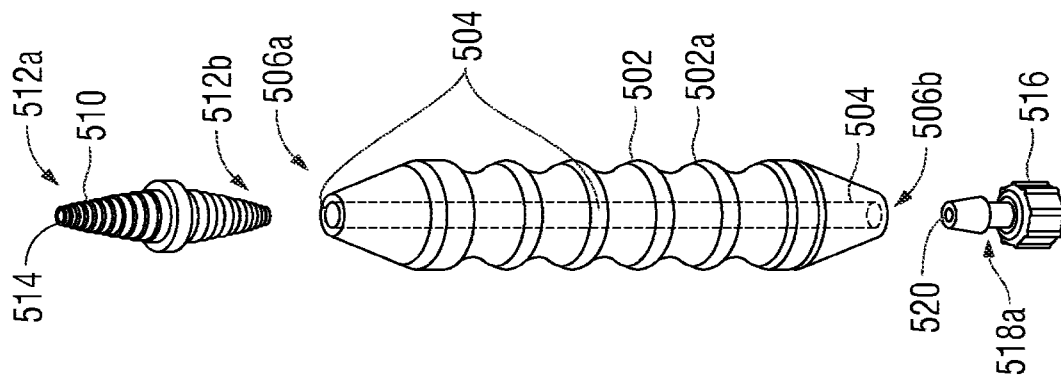


FIG. 10

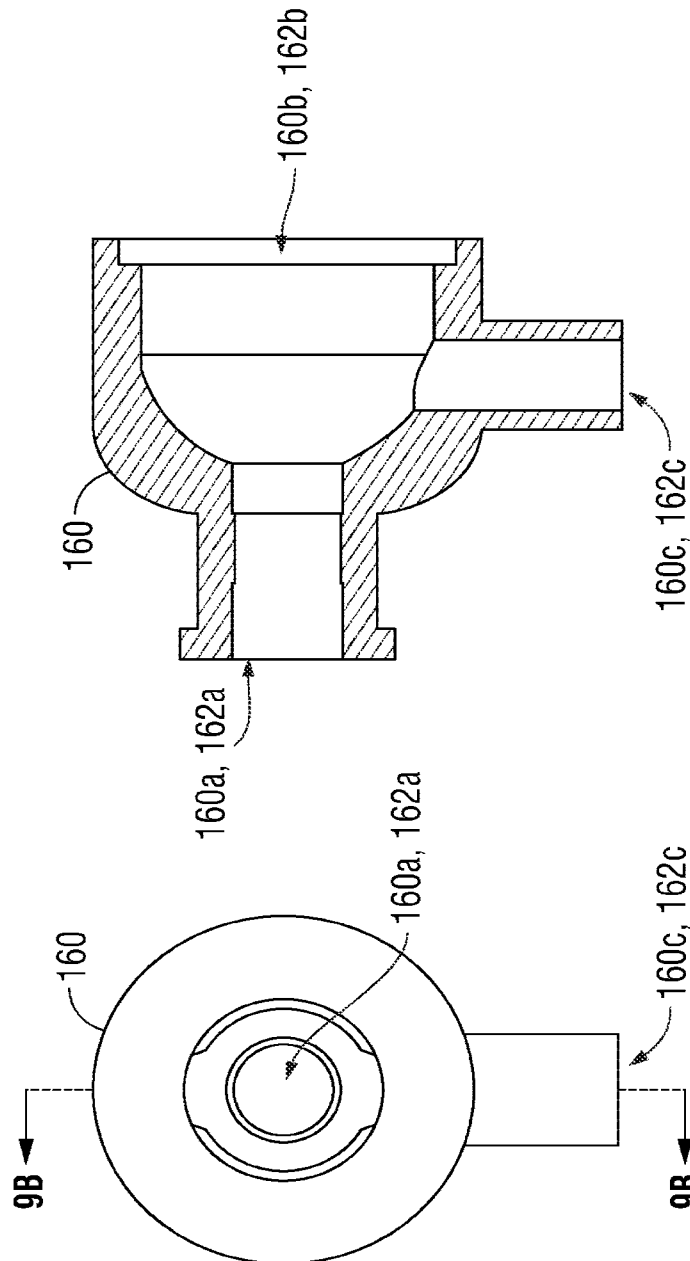


FIG. 9B

FIG. 9A

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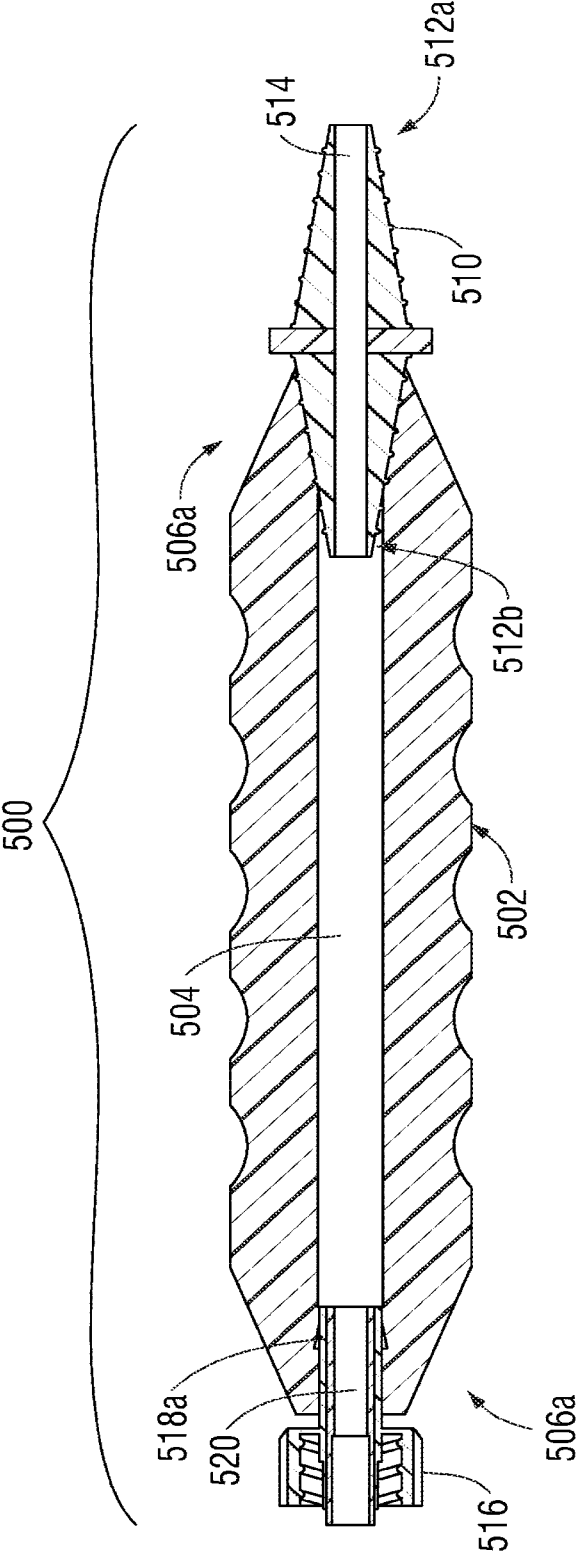


FIG. 10A

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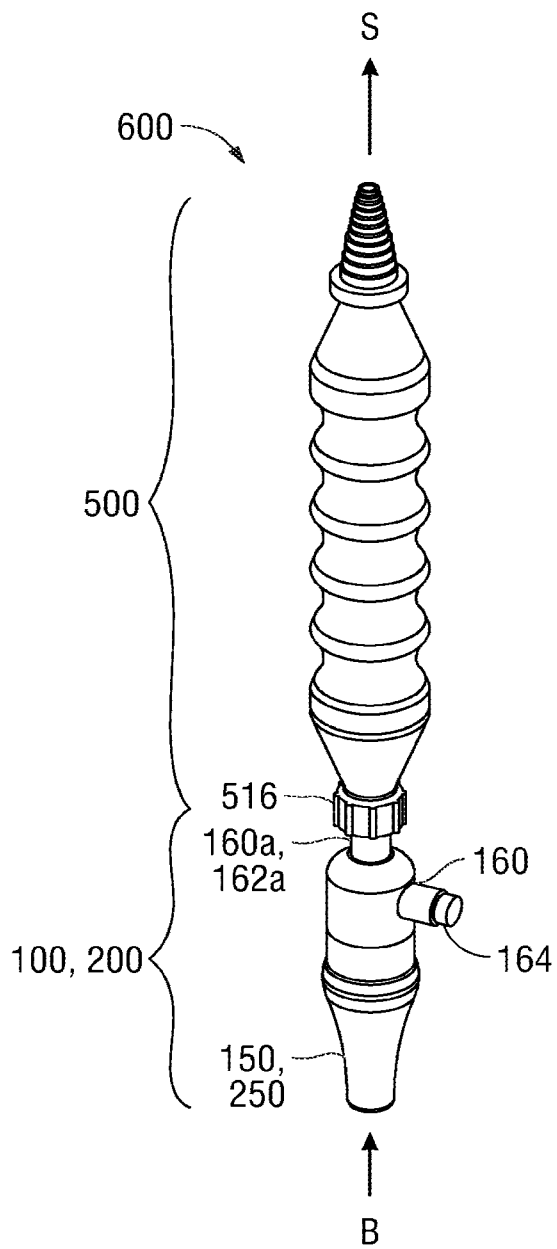


FIG. 11

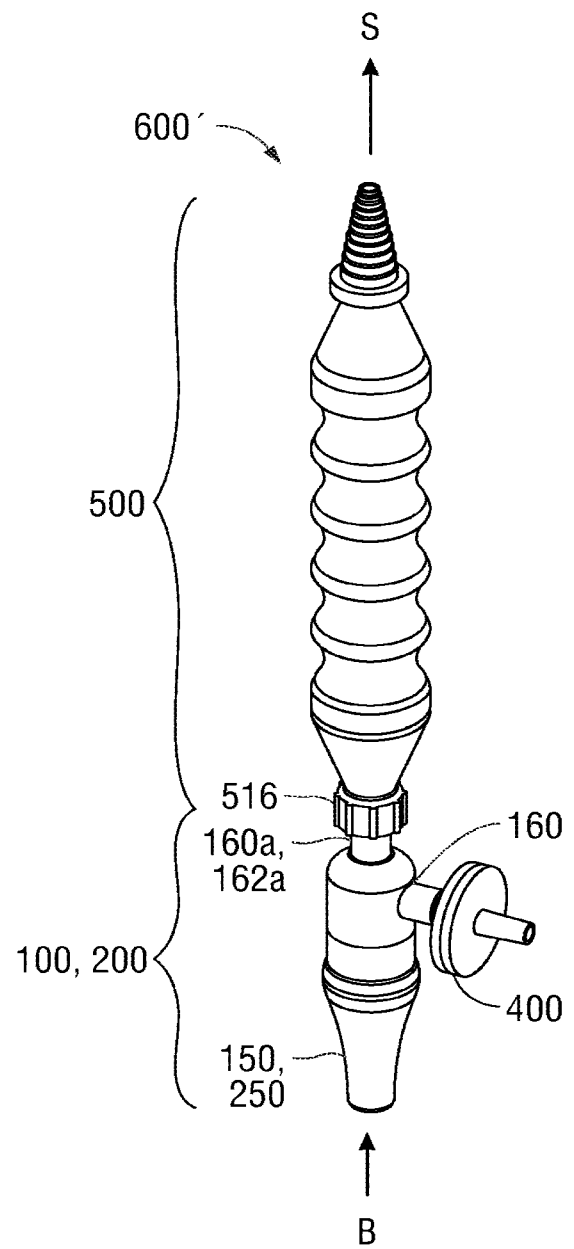


FIG. 12

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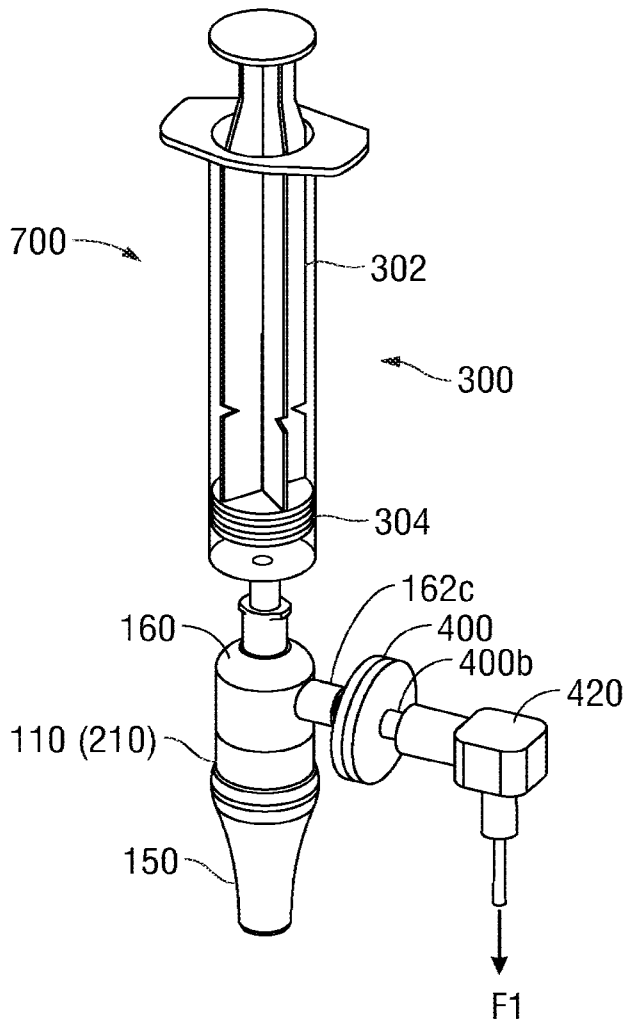


FIG. 13

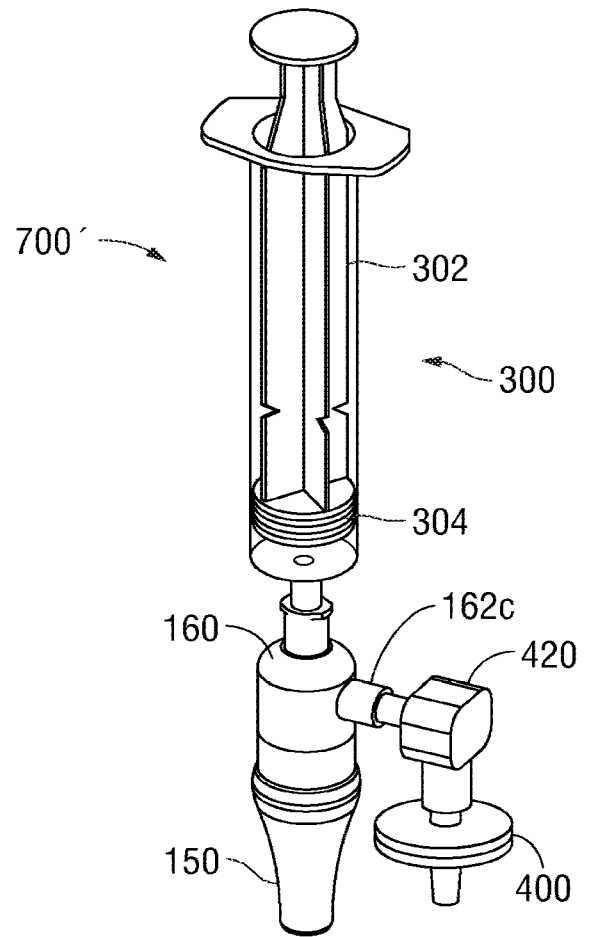


FIG. 13A

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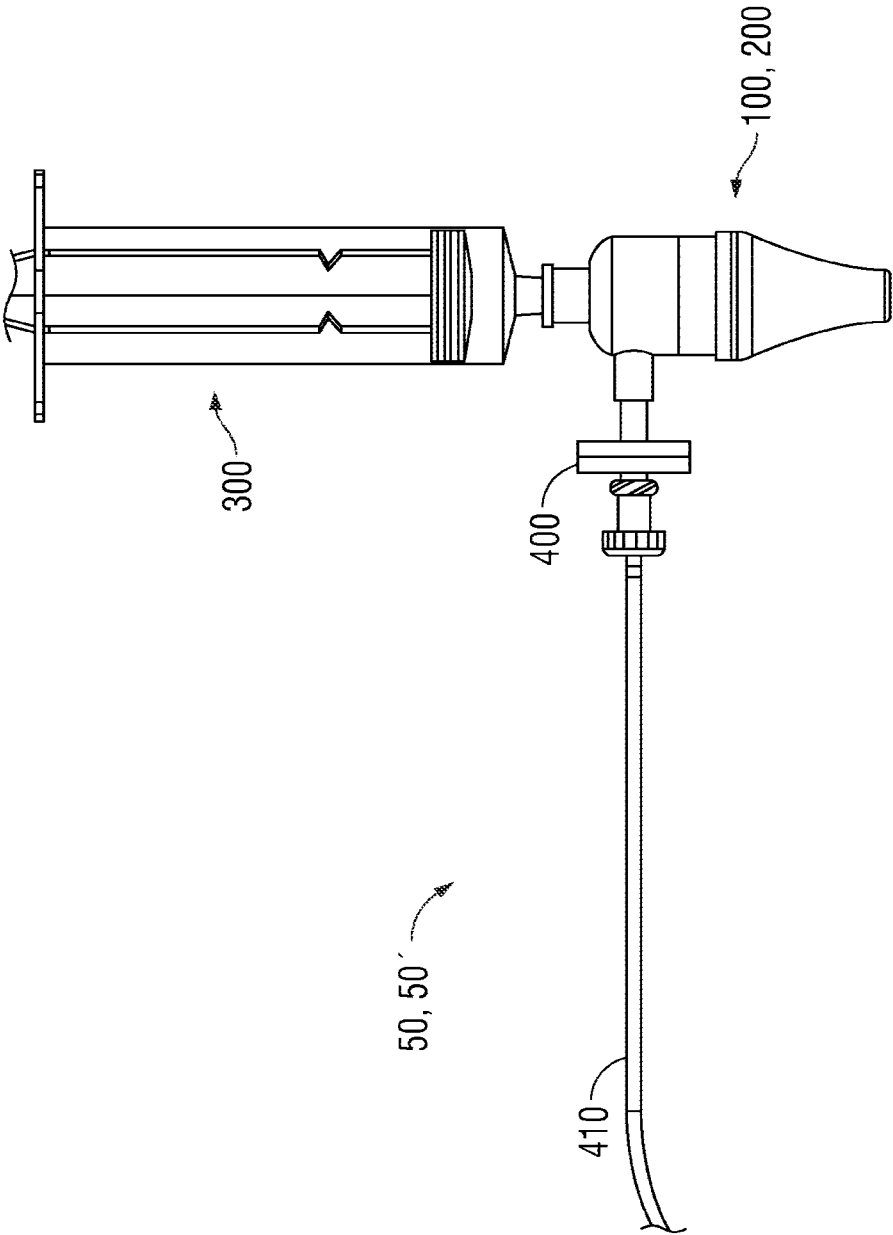


FIG. 14

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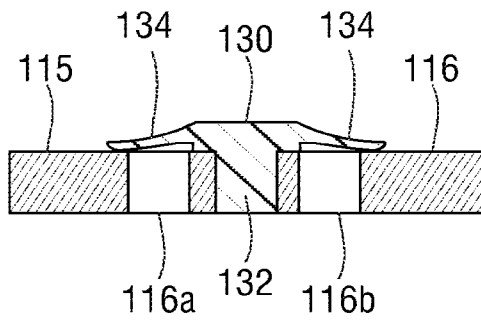


FIG. 15A

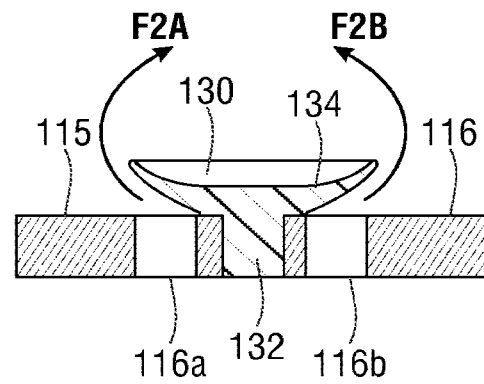


FIG. 15B

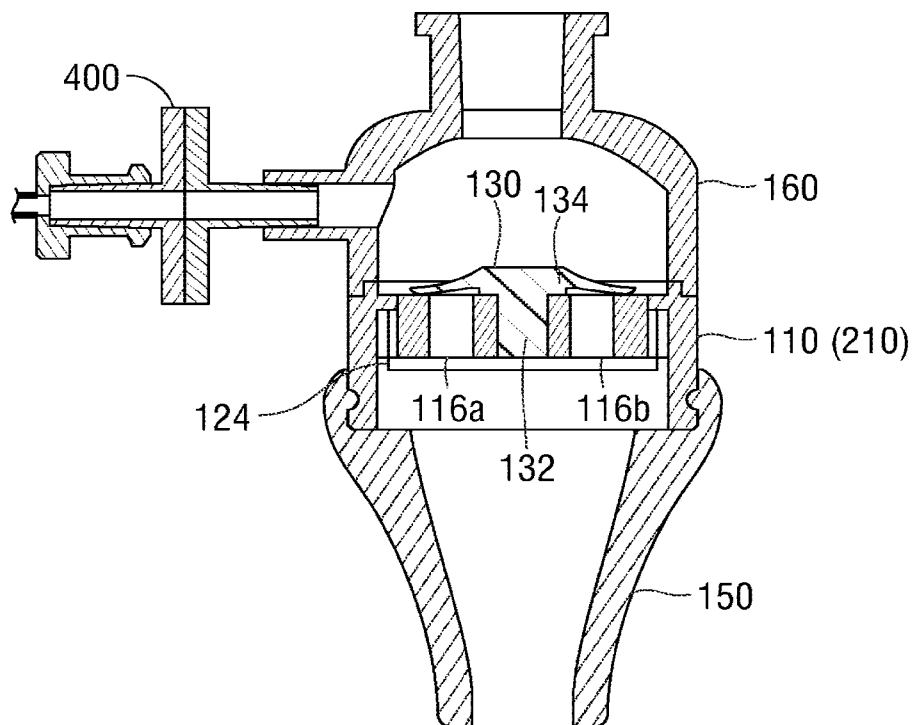


FIG. 16

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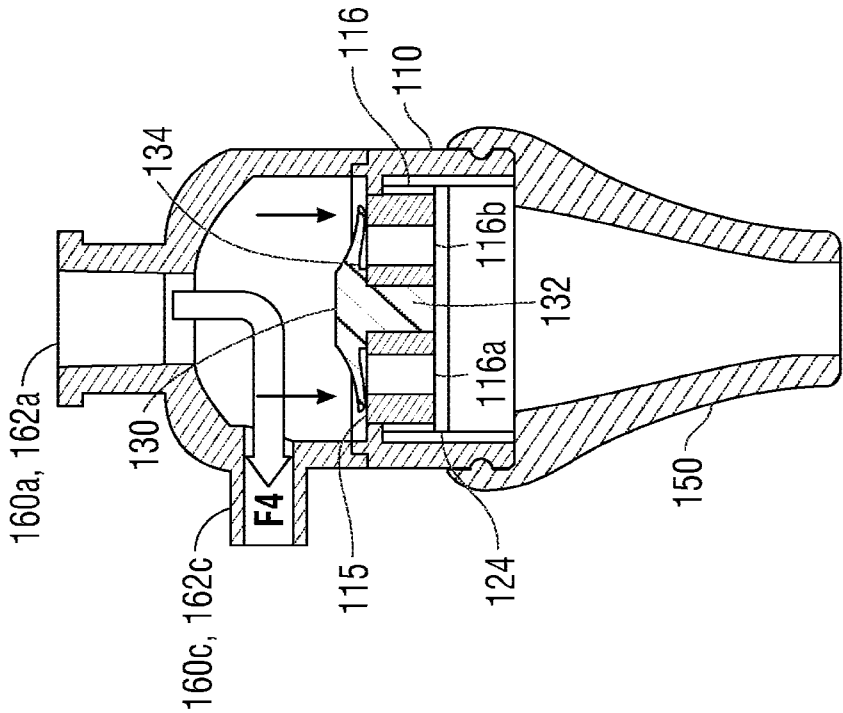


FIG. 17

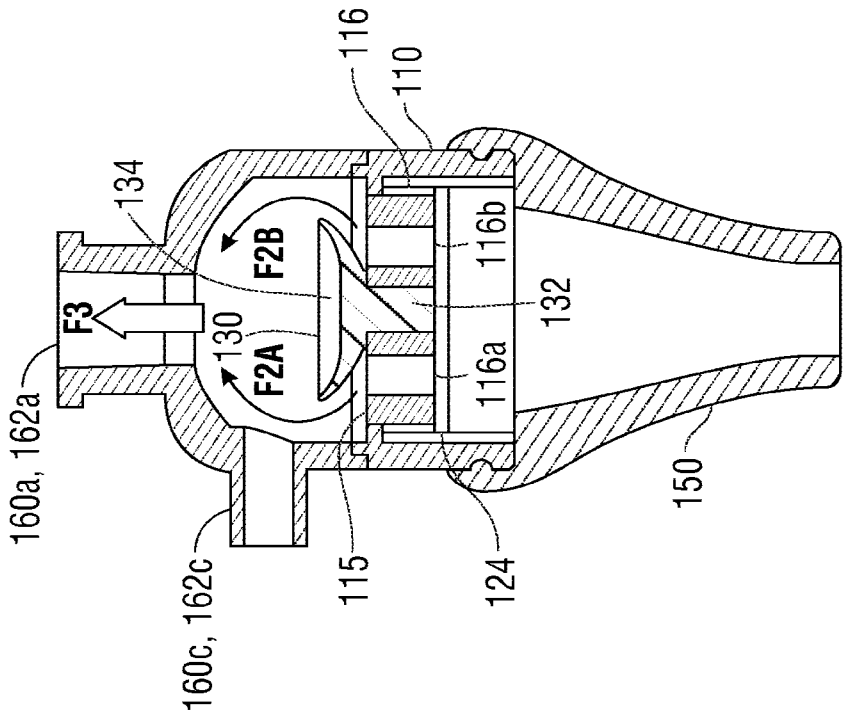


FIG. 18

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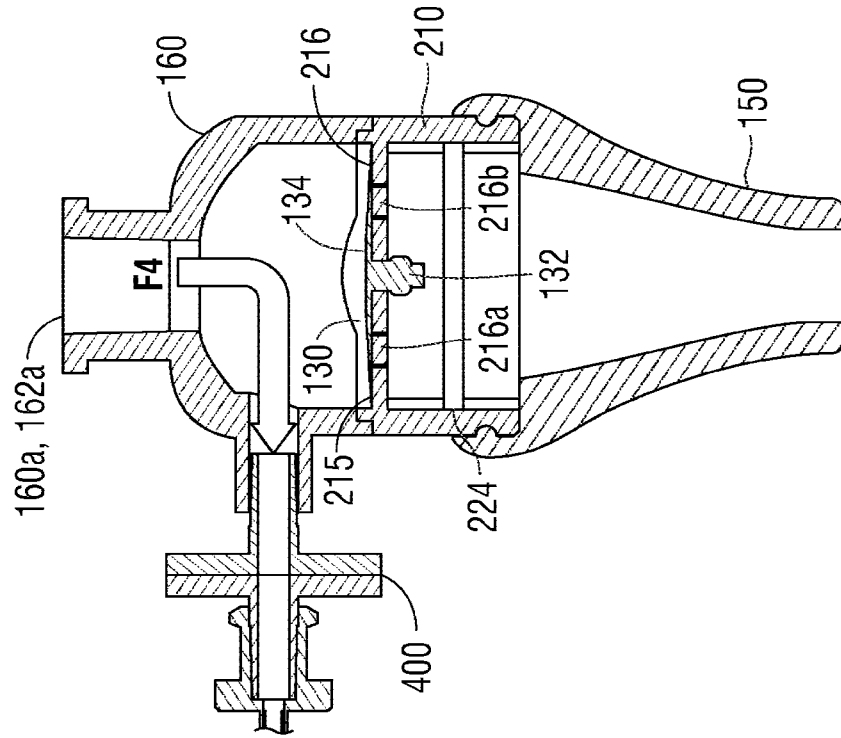


FIG. 20

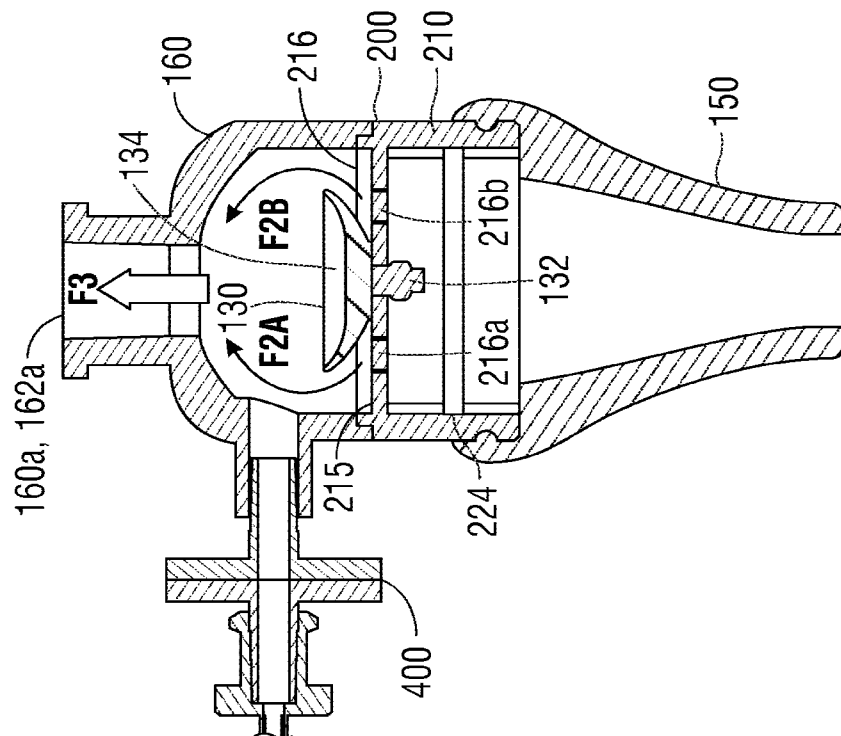


FIG. 19

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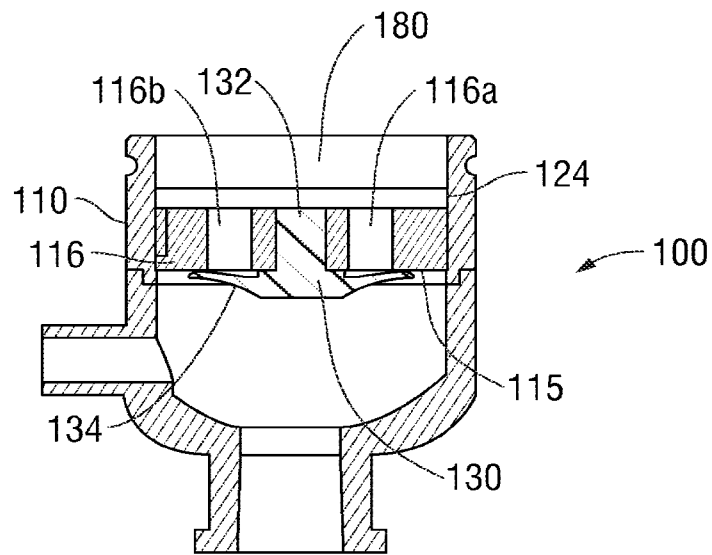


FIG. 21

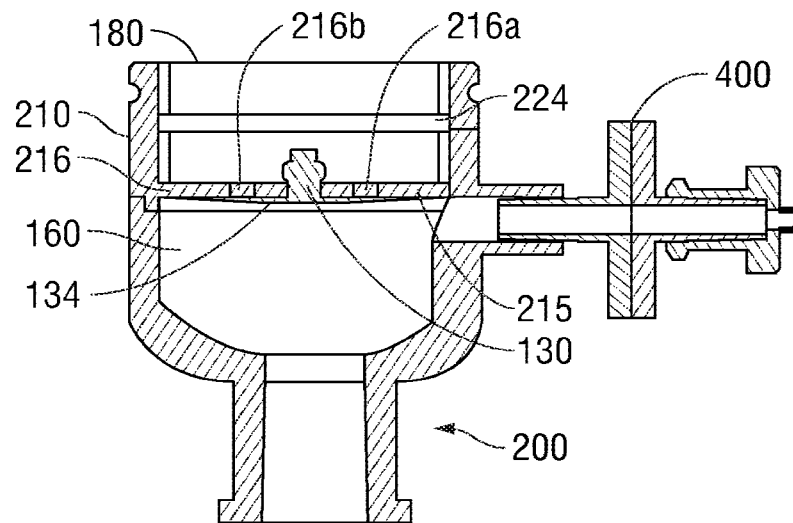


FIG. 22

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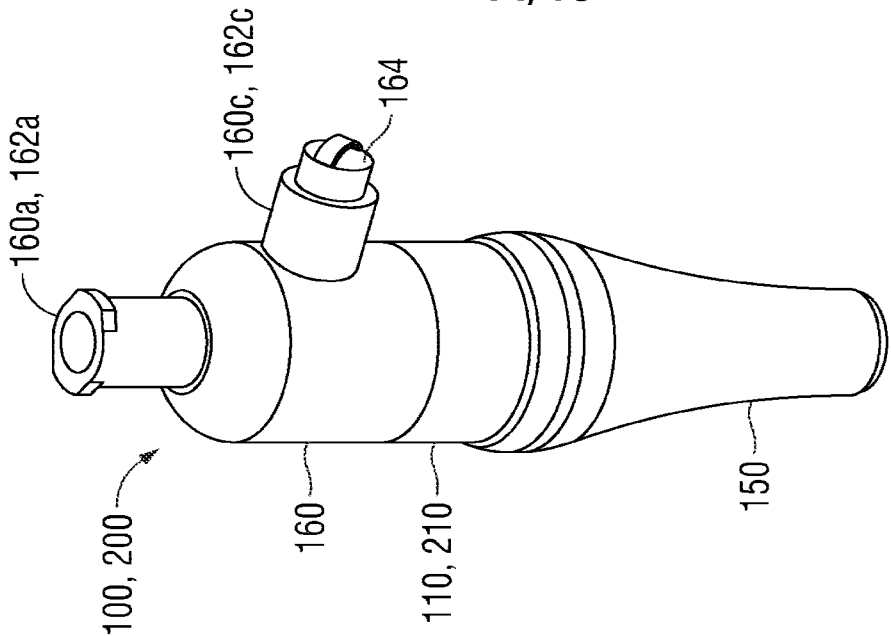


FIG. 24

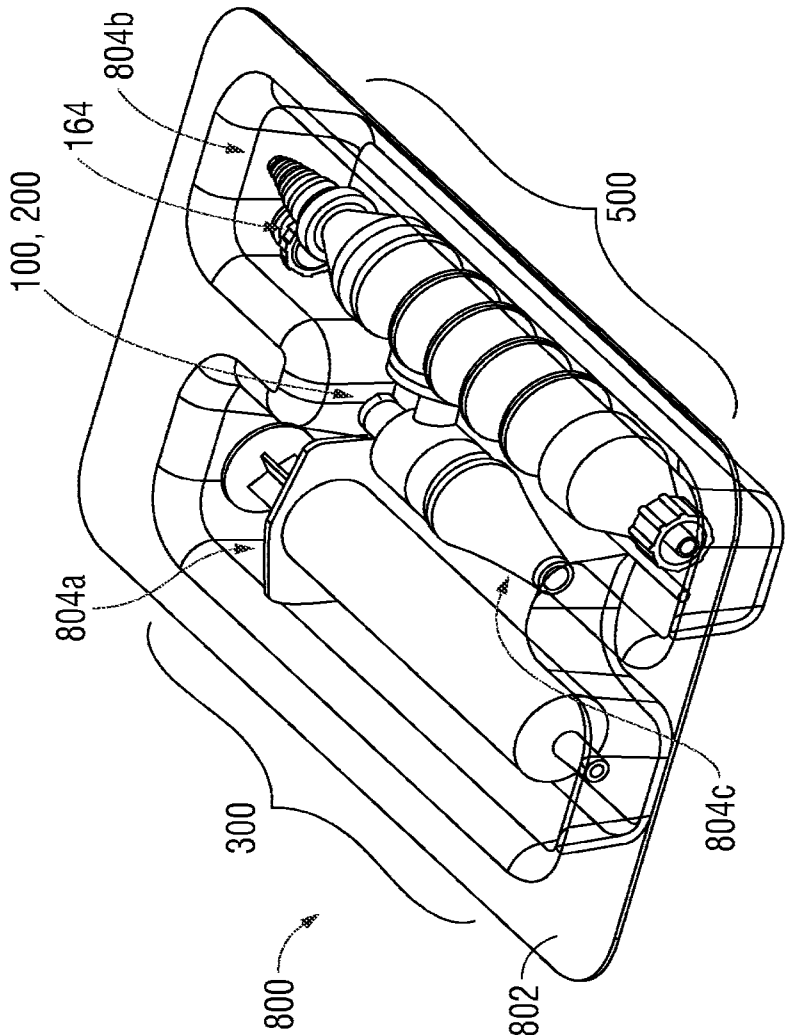


FIG. 23

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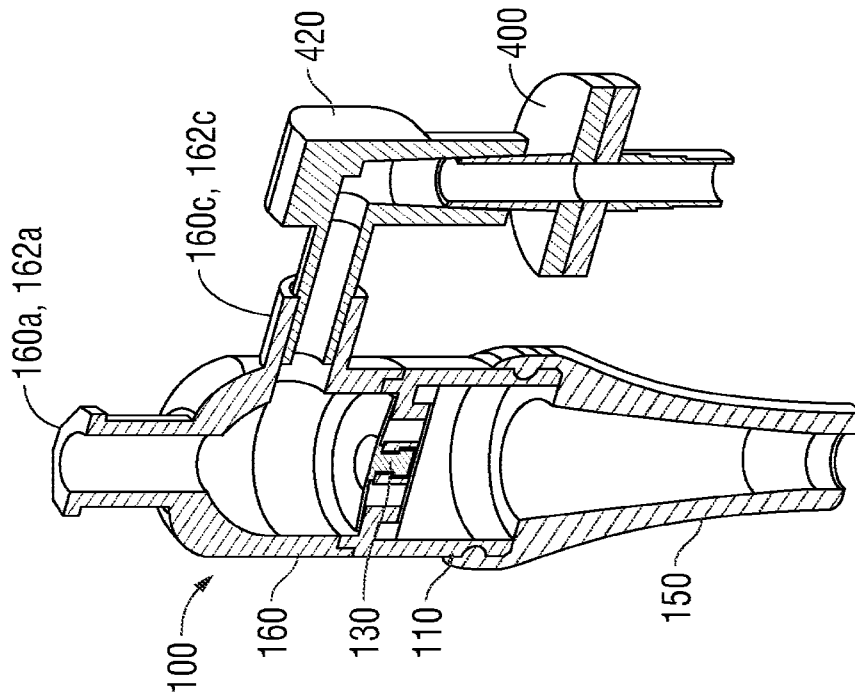


FIG. 26

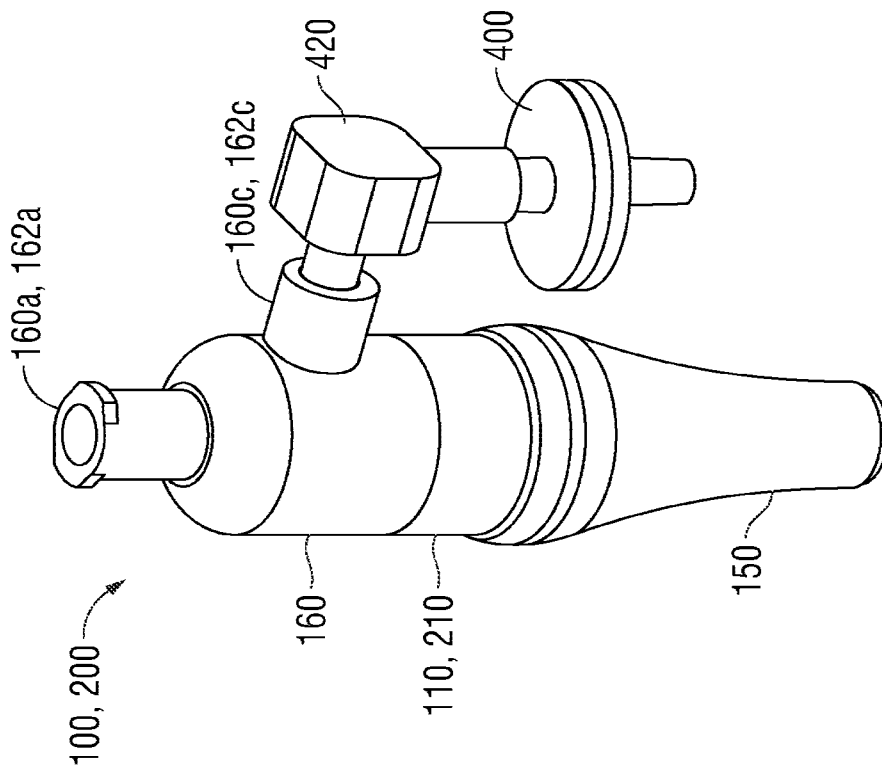


FIG. 25

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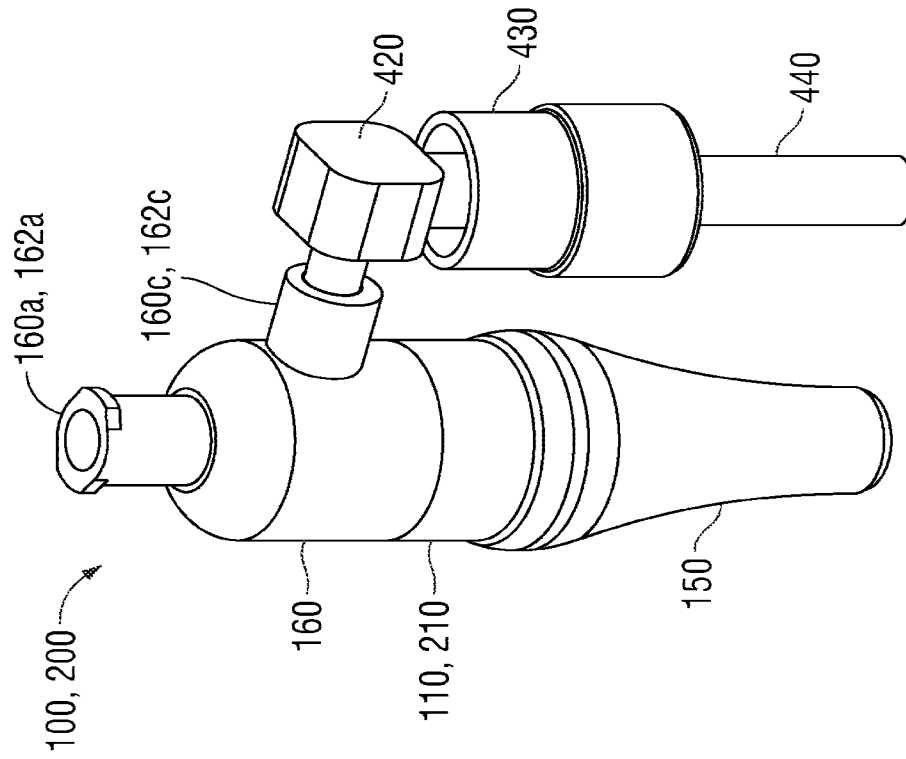


FIG. 28

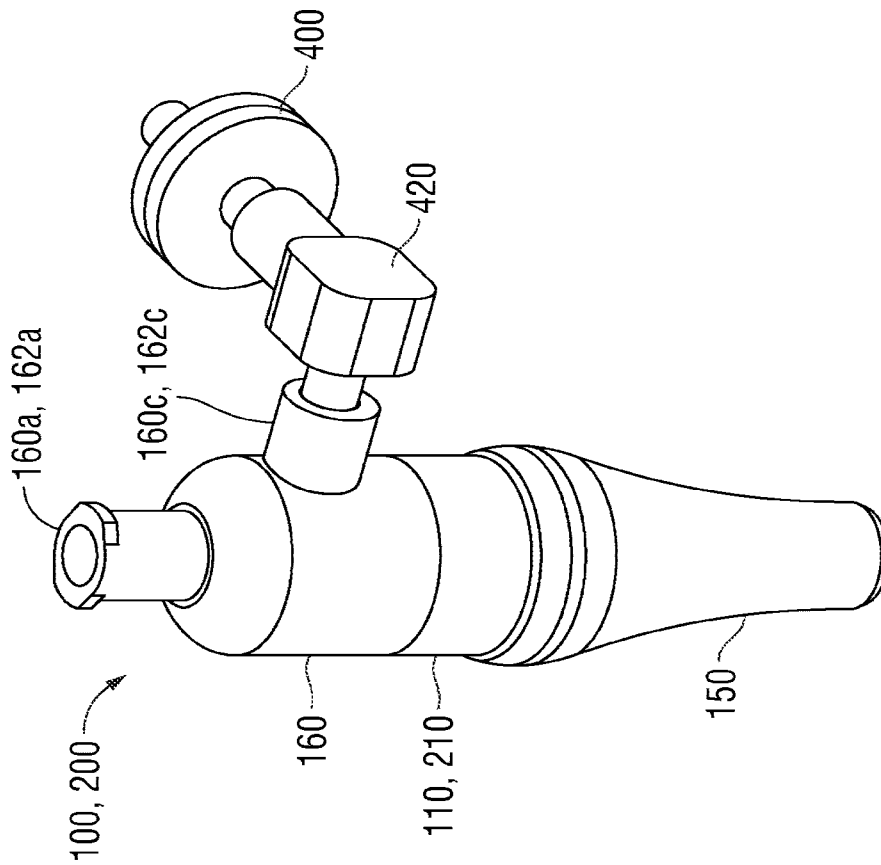


FIG. 27

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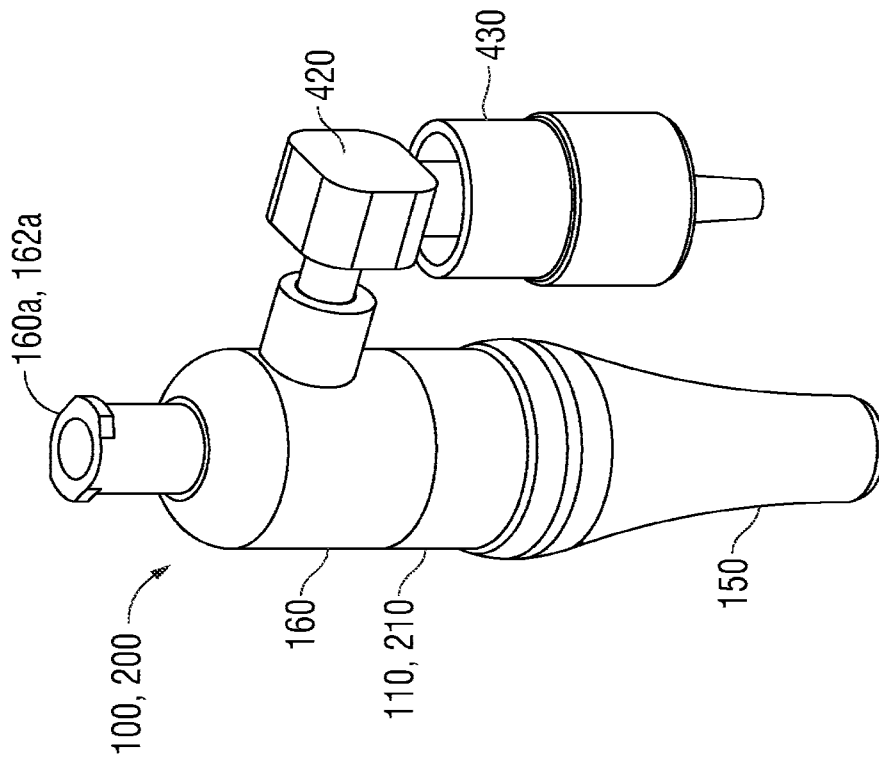


FIG. 30

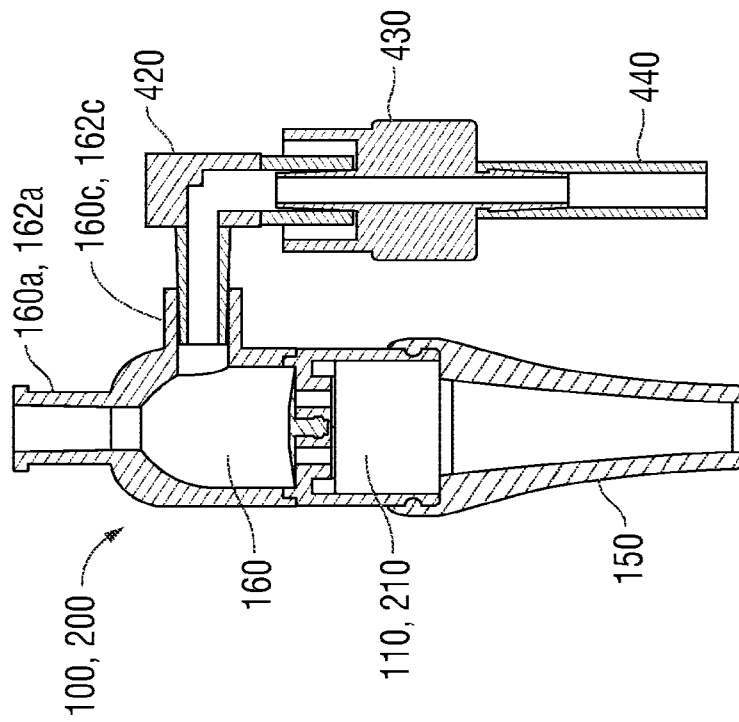


FIG. 29

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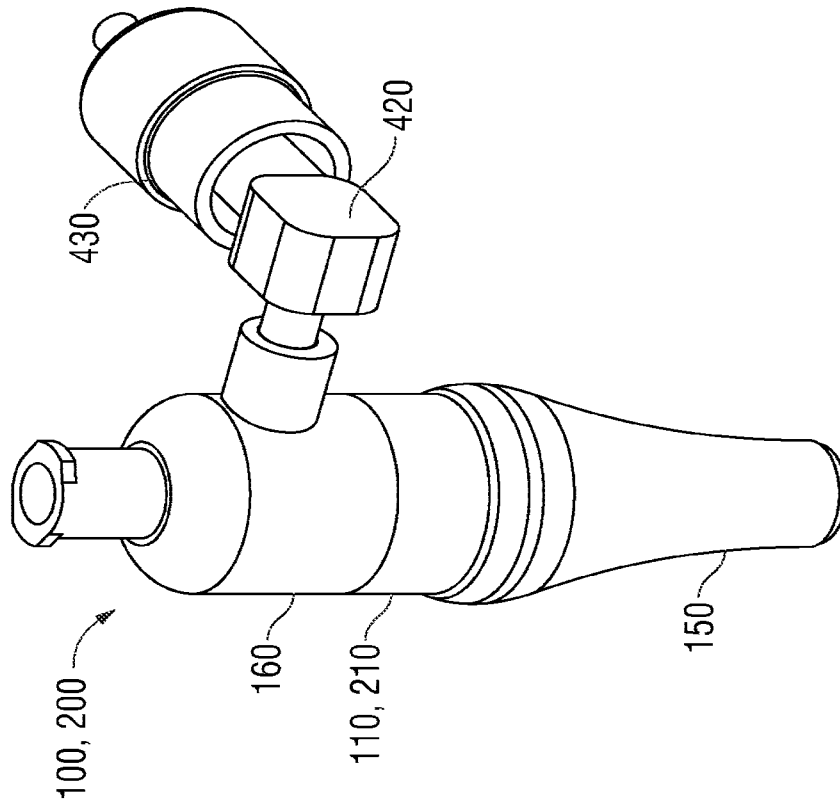


FIG. 32

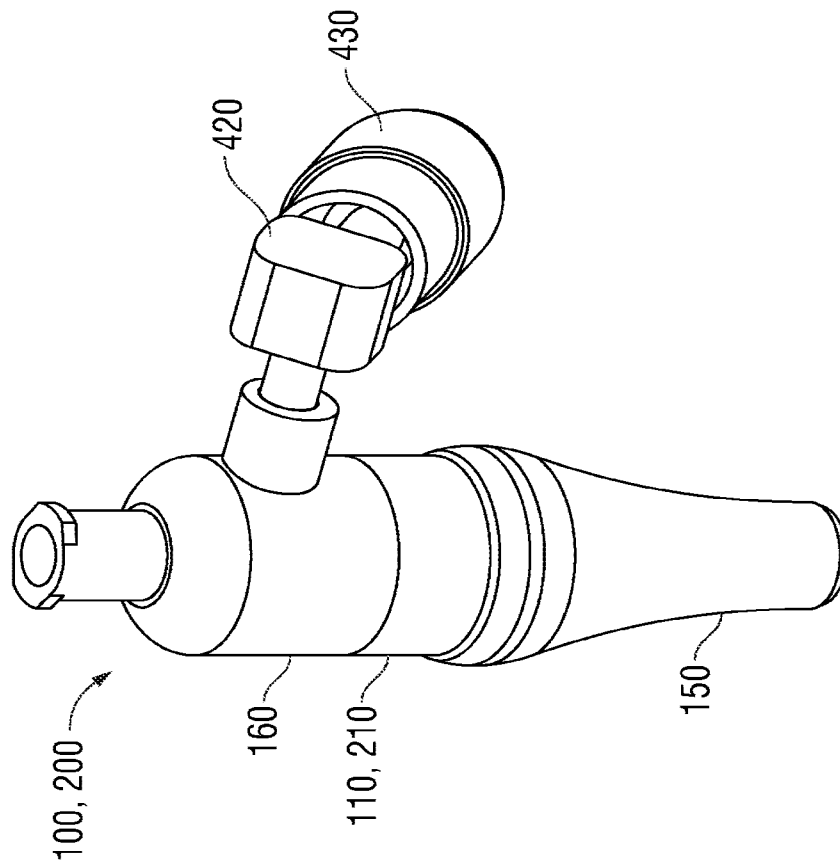


FIG. 31

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2015/042017

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/16 A61B10/02 A61M1/00
 ADD. A61B17/32

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CN 202 427 033 U (YONGTUAN LI) 12 September 2012 (2012-09-12) figure 1	1,2, 11-13, 17-19
X	----- CN 203 724 605 U (NANJING STOMATOLOGICAL HOSPITAL) 23 July 2014 (2014-07-23) figure 1	1,2, 11-13, 17-19
X	----- JP H07 79997 A (KOMIYAMA YATARO; HATTORI MORIHIRO) 28 March 1995 (1995-03-28) figures 1,3	1,2, 11-13, 17-19



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

2 November 2015

Date of mailing of the international search report

09/11/2015

Name and mailing address of the ISA/

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

Authorized officer

Hamann, Joachim

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/042017

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

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

1. ☒ Claims Nos.: 20-26
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

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

Remark on Protest

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

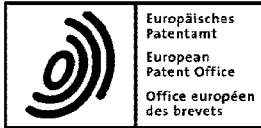
PCT/US2015/042017

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
CN 202427033	U	12-09-2012	NONE		

CN 203724605	U	23-07-2014	NONE		

JP H0779997	A	28-03-1995	JP	2563237 B2	11-12-1996
			JP	H0779997 A	28-03-1995

(19)



(11)

EP 2 942 624 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:
11.11.2015 Bulletin 2015/46

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G01N 33/49 (2006.01) **A61M 1/34** (2006.01)
B01D 61/14 (2006.01)

(21) Application number: **14176323.5**

(22) Date of filing: **09.07.2014**

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR
Designated Extension States:
BA ME

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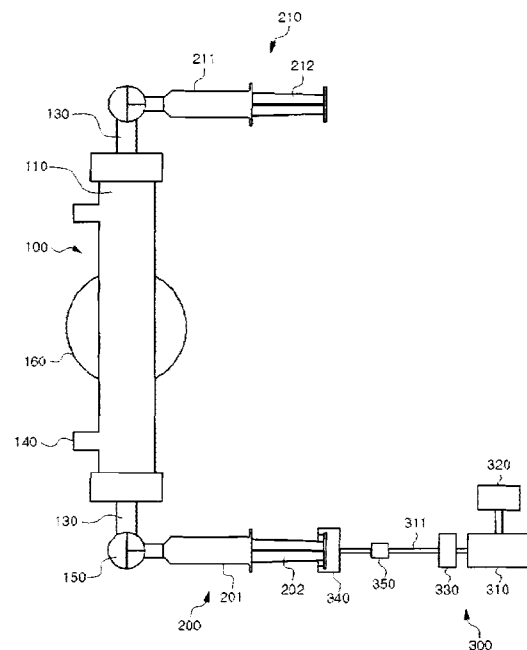
(30) Priority: **09.05.2014 KR 20140055596**

(54) Device and method for extracting concentrated plasma

(57) The present invention relates to a device and method for extracting concentrated plasma that includes a membrane filter unit for isolating a component based on a predetermined particle diameter from blood plasma, a first receiving member for providing a predetermined injection rate and a predetermined injection pressure to inject the blood plasma into the membrane filter unit and thereby to settle down platelets in the blood plasma, a pressurizing means mounted in connection to the first receiving member so as to provide an injection rate and an injection pressure for the blood plasma, and a second receiving member mounted on the membrane filter unit at a predetermined distance from the first receiving member and open into a second space to hold air, where the second receiving member is allowed to open or close. This can pass the blood plasma through the membrane filter unit for a sufficient period of time using a predetermined pressure, gravity and vacuum, thereby maximizing the settlement of the platelets in the blood plasma flowing into the membrane filter unit, achieving filtration while the platelets settle down, minimizing the contact area between the platelets and a filter built in the membrane filter unit, and finally reducing the quantity of the platelets adsorbed onto the membrane to obtain platelet rich plasma containing a maximum quantity of platelets.

In addition, the concentrated plasma can be readily gelled simply by repeating the filtration or adding calcium.

FIG. 2



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Description

TECHNICAL FIELD

[0001] The present invention relates to a device and method for extracting concentrated plasma. More particularly, the present invention relates to a device and method for extracting concentrated plasma that is designed to extract concentrated plasma from the blood plasma removed of red blood cells.

BACKGROUND ART

[0002] In general, whole blood can be separated into blood corpuscles and blood plasma. The blood corpuscles fall into three general categories: red blood cells, white blood cells, and platelets. The blood plasma is mostly water, and contains clotting factors, electrolytes, and so forth.

[0003] To explain the blood plasma in further detail, the blood plasma consists of 60 to 85 % of water, 7 % of proteins, 1 % of fat, 0.1 % of sugar, and 0.9 % of other mineral ions. In this regard, the proteins in blood plasma can be classified into albumin and globulin, which are determined by using the difference in solubility in ammonium sulfate and individually consist of a combination of several proteins. The albumin constitutes about 55 % of the plasma protein and plays an important role in supplying proteins and maintaining the plasma colloid osmotic pressure. The globulin makes up about 38 % of the plasma protein and falls into one of the three categories: alpha globulin, beta globulin and gamma globulin. The alpha globulin contains lipoproteins and glycoproteins including fibrinogen and helps transport of vitamins, hormones, and so forth. The beta globulin performs a function as a carrier of prothrombin, plasma thromboplastin, iron, copper, or the like. The gamma globulin mostly contains immune antibodies.

[0004] The blood plasma, which plays a major role in the blood, can be injected into the human body to promote the transport of nutrient substances and thereby maximize its function such as inhibition of toxic substances.

[0005] Therefore, as illustrated in FIG. 1, the whole blood (Wb) is separated into red blood cells (RBCs), platelet rich plasma (PRP) and platelet poor plasma (PPP). Generally, the red blood cells are separated from the whole blood, and platelet rich plasma (PRP) and platelet poor plasma (PPP) are extracted. The platelet rich plasma (PRP) and the platelet poor plasma (PPP) are used in various treatment and cosmetic applications, including the treatment of wounds including sinus elevation surgery for dental implant, heart surgery, orthopedic surgery, dermatological treatment, and so forth.

[0006] In addition, the platelet poor plasma (PPP) is separated from the whole blood and contains proteins and a small quantity of platelets not isolated yet. Therefore, a reisolation process for the platelet poor plasma (PPP) is performed to re-extract the proteins and plate-

lets from the platelet poor plasma (PPP). For this purpose, the conventional method involves a repetition of centrifugal isolation and filtration on the platelet poor plasma (PPP).

[0007] However, even after the process of centrifugal isolation and filtration is done again on the platelet poor plasma (PPP) remaining after extraction of platelet rich plasma (PRP) from the blood plasma, the concentrated plasma re-extracted from the platelet poor plasma (PPP) has such a low content that it hardly contains a large quantity of proteins having a low molecular weight and not separated in the conventional process of centrifugal isolation and filtration. And, there is also a problem suggested in regards to the low efficiency of the conventional device and method that obtains concentrated plasma with low content.

Prior Documents

Patent Documents

[0008]

(Patent Document 1) KR20100116160 10

(Patent Document 2) KR20100041436 10

DISCLOSURE OF INVENTION

[0009] For solving the problems aforementioned, it is an object of the present invention to provide a device and method for extracting concentrated plasma that is designed to extract concentrated plasma with high concentration containing a maximum quantity of platelets while filtering the blood plasma out by passing the blood plasma removed of red blood cells through a filter by using a defined principle of pressure, gravity and vacuum.

[0010] To achieve the object of the present invention, there is provided a device for extracting concentrated plasma that includes: a membrane filter unit for isolating a component based on a predetermined particle diameter from blood plasma; and a first receiving member for providing a predetermined injection rate and a predetermined injection pressure to inject the blood plasma into the membrane filter unit and thereby to settle down platelets in the blood plasma.

[0011] The device further includes a pressurizing means mounted in connection to the first receiving member to provide the injection rate and the injection pressure of the blood plasma.

[0012] In this regard, the pressurizing means includes: a piston moving in connection to the membrane filter unit to inject the blood plasma in the first receiving member into the membrane filter unit; and a power source mounted to induce the movement of the piston.

[0013] The power source limits the moving distance of the piston to remain part of the blood plasma in the first receiving member for a predetermined period of time after the time that the blood plasma is completely injected

into the membrane filter unit.

[0014] The power source maintains the piston at a moved position for a predetermined period of time after the time that the movement of the piston is completed.

[0015] The power source moves the piston in a reverse direction at a predetermined speed in order to separate platelets, fibrinogens, proteins, and so forth filled in the filter after completion of the filtration.

[0016] The pressurizing means further includes: an adaptor for intermediating a coupling of a first plunger mounted in the first receiving member and the piston to inject the blood plasma in the first receiving member into the membrane filter unit; and a controller for controlling the operation of the power source to regulate the injection rate and the injection pressure of the blood plasma according to the moving distance and the moving rate of the piston and the first plunger.

[0017] The pressurizing means further includes a direction-diverting switch for diverting the moving direction of the piston.

[0018] The membrane filter unit includes: a body having the first receiving membrane mounted thereon and including an inlet portion provided on either side portion of the membrane filter unit to exhaust air from the membrane filter unit when the blood plasma of the first receiving member flows in, and an outlet portion for exhausting a component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the membrane filter unit; a hollow filter being mounted in the body and having a second space for receiving a component having a particle diameter equal to or smaller than the predetermined particle diameter which is filtered when the blood plasma of the first receiving member flows in through the inlet portion; and a first space formed between the hollow filter and the body to open into the outlet portion to temporarily receive a component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter and to exhaust the same through the outlet portion.

[0019] In addition, the membrane filter unit further includes a fixing member mounted on the body for arranging the membrane filter unit in the upright position to settle down platelets of the blood plasma flowing into the membrane filter unit under the effect of gravity.

[0020] The device for extracting concentrated plasma according to the present invention further includes a second receiving member mounted on the membrane filter unit at a predetermined distance from the first receiving member to open into the second space 180 and receive air.

[0021] In this regard, the membrane filter unit further includes a valve mounted as an intermediate on a coupling portion between the inlet portion and the first and second receiving members. The valve is arranged to have the second space and the first receiving member open into each other at normal times. And, the valve is arranged to close the second space and the second re-

ceiving member when blood plasma is injected into the second space, and to open the second space into the second receiving member and inject air in the second receiving member into the second space when a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space is to flow into the first receiving member.

[0022] On the other hand, according to the present invention, there is provided a method for extracting concentrated plasma that includes: a step S20 of injecting blood plasma into a membrane filter unit to settle down platelets in the blood plasma and thereby remaining a component having a particle diameter equal to or larger than the predetermined particle diameter which has not passed through a filter built in the membrane filter unit; and a step S40 of collecting a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the membrane filter unit.

[0023] The method for extracting concentrated plasma according to the present invention further includes a step S10 of arranging the membrane filter unit in the upright position to reduce the contact area between the filter in the membrane filter unit and the platelets, before the filtering step S20.

[0024] The method for extracting concentrated plasma according to the present invention further includes a step S30 of waiting for a predetermined period of time after the blood plasma is completely injected and reducing pressure in the membrane filter unit to exhaust a component having a particle diameter equal to or smaller than the predetermined particle diameter.

[0025] The filtering step S20 includes injecting part of the blood plasma into the membrane filter unit. The first collecting step S40 includes collecting both a component having a particle diameter equal to or larger than the predetermined particle diameter which has passed through the filter and the remaining the blood plasma in one position.

[0026] The method for extracting concentrated plasma according to the present invention further includes a second collecting step S50 of injecting air into the membrane filter unit to collect again both the remaining component having a particle diameter equal to or larger than the predetermined particle diameter and the remaining blood plasma in one position.

[0027] In all the steps other than the collecting step, first and second spaces are formed by mounting a filter in a body of the membrane filter, where the second space holds a component having a particle diameter equal to or larger than the predetermined particle diameter which is filtered out from the filter when the blood plasma flows in, and the second space momentarily collecting a component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter to exhaust the component through an outlet portion formed in the body of the membrane filter unit.

[0028] In addition, the filtering step S20 further includes a step S23 of injecting the blood plasma into the second space at a predetermined injection rate and a predetermined pressure to settle down the platelets. Here, the injection pressure of the blood plasma is determined to have the range of a load internal pressure imposed on the filter mounted in the membrane filter unit during the filtration is equal to or lower than the permissible internal pressure of the filter.

[0029] The injecting step S23 includes using a pressurizing means to move a first plunger mounted on a first receiving member holding the blood plasma and push the blood plasma. As a power source of the pressurizing means moves a piston to move the first plunger mounted on the piston, thereby injecting the blood plasma into the second space at a predetermined injection rate and a predetermined pressure. When part of the blood plasma is injected into the second space, the remainder of the blood plasma remains in the first receiving member. After filtration, the first plunger is moved back to collect a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space into the first receiving member holding the remaining blood plasma.

[0030] Further, air in a second receiving member mounted on the membrane filter unit is injected into the second space to collect a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space into the first receiving member holding the remaining blood plasma.

[0031] The first receiving member and the second receiving member are connected to the second space. Before the second collecting step S50, a valve is manipulated to have the second space open into the first receiving member and disconnect the second space from the second receiving member. In the second collecting step S50, the valve is manipulated to have the second space open into the first receiving member and the second receiving member.

[0032] In the filtering step S20, a valve 150 mounted on the opposite side of a first receiving member is closed to open into the membrane filter unit.

[0033] Therefore, in the filtering step S20, when the blood plasma is injected, an air layer is formed in part of the space of the membrane filter unit to limit the injection height of the blood plasma to a predetermined height or below.

[0034] The method for extracting concentrated plasma according to the present invention further includes a step S31 of completely closing the membrane filter unit and forming a vacuum pressure in the membrane filter, after the pressure-reducing step S30.

[0035] The collecting step S40 includes opening the valve to momentarily supply external air into the membrane filter unit and thereby collecting a component having a particle diameter equal to or larger than the predetermined particle diameter using the air.

[0036] In addition, the platelet rich plasma becomes gel by repeatedly filtering the blood plasma injected into the membrane filter unit or adding calcium and then repeatedly filtering the blood plasma.

EFFECTS OF THE INVENTION

[0037] As described above, according to the present invention, the conventional process of separating platelet rich plasma and platelet poor plasma from the blood plasma can be omitted to simplify the process of extracting concentrated plasma which contains high concentration of platelets by passing the blood plasma removed of red blood cells through the membrane filter unit.

[0038] Further, the blood plasma can be passed through the membrane filter unit using a predetermined pressure and gravity for a sufficiently long period of time. This can allow the platelets in the blood plasma flowing into the membrane filter unit to settle down to the maximum, making it possible to perform the filtration while the platelets settle down, and minimize the contact area between the platelets and the filter built in the membrane filter unit. As a result, the quantity of the platelets adsorbed onto the membrane can be minimized, and the concentrated plasma can contain the maximum quantity of the platelets.

[0039] Furthermore, after the blood plasma is partly or completely injected into the membrane filter unit, the injection pressure is maintained for a predetermined period of time until the pressure in the membrane filter is sufficiently reduced. This can completely exhaust the component having a particle diameter equal to or smaller than the predetermined particle diameter and remaining in the membrane filter unit.

[0040] Moreover, the blood plasma is injected while the membrane filter unit is closed, so the injection height of the blood plasma can be limited to a predetermined height or below to prevent the contact between the blood plasma and the filter. This can minimize adsorption of the component in the blood plasma onto the filter.

[0041] In addition, the closed membrane filter unit is suddenly opened. This can flow away the component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the membrane filter unit momentarily, thereby readily releasing part of the components adsorbed onto the filter.

[0042] Further, the platelet rich plasma can be gelled by repeatedly filtering the blood plasma collected in the membrane filter unit or adding calcium to the blood plasma and then repeatedly filtering it.

BRIEF DESCRIPTION OF DRAWINGS

[0043] The accompanying drawings, which are incorporated the specification, illustrate a preferred embodiment of the present invention and serve to explain the principles of the invention. It should be apparent that the accompanying drawings are not construed to limit the

scope of the present invention. In the drawings:

FIG. 1 is a side diagram showing the whole blood under centrifugal separation.

FIG. 2 is a schematic constructional diagram showing a device for extracting concentrated plasma according to a preferred embodiment of the present invention.

FIG. 3 is a cross-sectional diagram showing the inside of the membrane filter unit shown in FIG. 2.

FIGS. 4a and 4b are operational diagrams of FIG. 2. FIG. 4c is a constructional diagram showing that a second receiving member is excluded in the membrane filter unit of FIG. 2.

FIG. 5 is a flow chart showing a first extraction method for concentrated plasma using the extracting device of FIG. 2.

FIG. 6 is a flow chart showing a second extraction method for concentrated plasma using the extracting device of FIG. 2.

BEST MODES FOR CARRYING OUT THE INVENTION

[0044] Hereinafter, a detailed description will be given as to the preferred embodiments of the present invention with reference to the accompanying drawings so as for those skilled in the art to readily carry out the present invention. But, in the detailed description of the operational principles regarding the preferred embodiments of the present invention, the specific description as to the known functions or constructions is to be excluded when it is considered to unnecessarily depart from the conception of the present invention.

<Construction>

[0045] FIG. 2 is a schematic constructional diagram showing a device for extracting concentrated plasma according to a preferred embodiment of the present invention. FIG. 3 is a cross-sectional diagram showing the inside of the membrane filter unit shown in FIG. 2. FIGS. 4a and 4b are operational diagrams of FIG. 2.

[0046] The device for extracting concentrated plasma according to the present invention includes, as shown in FIG. 2, a membrane filter unit 100, a first receiving member 200, a second receiving member 210, and a pressurizing means 300.

[0047] The membrane filter unit 100 is a member for filtering blood plasma in order to exhaust a component having a particle diameter equal to or smaller than a predetermined particle diameter which is contained in the blood plasma. In this regard, the blood plasma used to extract platelet rich plasma in the present invention is preferably a blood plasma obtained by removing the whole blood of red blood cells through centrifugal separation, or it may be a platelet poor plasma generally available.

[0048] The membrane filter unit 100 includes a body

110, a filter 120 mounted in the body 110 and designed to have a component of a particle diameter equal to or smaller than the predetermined particle diameter which has passed through, an inlet portion 130 formed on either side portion of the body 110 and individually having the first and second receiving members 200 and 210, an outlet portion 140 mounted in the body 110 to exhaust the component of a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter 120, a three-way valve 150 mounted to open/close the inlet portion 130, and a fixing member 160 for maintaining the body 110 in the upright position.

[0049] In this regard, the membrane filter unit 100 is to separate platelets, proteins, albumins, etc. from water, uric acid, potassium, phosphates, etc. as contained in the blood plasma. For separation, the cross-sectional area of the filter 120 is preferably about 0.04 m² to 0.08 m², more preferably about 0.06 m².

[0050] The membrane filter unit 100 may be an example of membrane filter unit, which is preferably used for blood osmosis. Of course, the membrane filter unit 100 may be a general filter capable of filtering out a component having a particle diameter equal to or larger than the predetermined particle diameter, such as platelets, proteins, albumins, etc. of the blood plasma, in addition to the membrane filter unit.

[0051] On the other hand, the filter 120 is built in the body 110, and the inlet portion 130 and the outlet portion 140 are formed on either side portion of the body 110. The body 110 preferably has a cylindrical shape, or it may have a polygonal pillar shape such as a rectangular pillar shape.

[0052] Between the inner wall of the body 100 and the filter 120 is formed a defined first space 170, which temporarily receives a component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter 120. In other words, the first space 170 is an independent space disconnected from the inlet portion 130.

[0053] The filter 120 is a member through which a component having a particle diameter equal to or smaller than the predetermined particle diameter in the blood plasma is passed. The filter 120 has a hollow cylindrical shape or a hollow polygonal pillar shape that forms a second space 180 into which the blood plasma flows. In this regard, the second space 180 directly opens into the inlet portion 130 to have the blood plasma enter from the inlet portion 130. Accordingly, when the blood plasma flows into the second space 180, a component having a particle diameter equal to or smaller than the predetermined particle diameter in the blood plasma is passed through the filter 120 and flows into the first space 170, and a component having a particle diameter equal to or larger than the predetermined particle diameter in the blood plasma remains in the second space 180.

[0054] In this regard, there can be a modification of the embodiment in such a manner that the filter 120 has a panel shape and divides the inside of the body 110 into

the first and second spaces 170 and 180, where the first space 170 opens into the outlet portion 140 and the second space 180 opens into the inlet portion 130.

[0055] In addition, the inlet portion 130 is formed on either side portion of the body 110. The first receiving member 200 receiving the blood plasma is mounted on the inlet portion 130 formed on the one side of the body 110, and the second receiving member 210 receiving air is mounted on the inlet portion 130 formed on the other side of the body 110. The inlet portion 130 is formed in direct connection to the second space 180 of the filter 120. This is not only to have the blood plasma of the first receiving member 200 flow directly into the second space 180 but also to have a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180 flow into the first receiving member 200 by the pressure applied by the second receiving member 210. Other details in regards to the inlet portion 130 will be described later in association with the three-way valve 150.

[0056] In addition, the outlet portion 140 is formed on the one side of the body 100 or on either side of the body 100 to open into the first space 170. This is to exhaust a component having a particle diameter equal to or smaller than the predetermined particle diameter and flowing into the first space 170 through the filter 120.

[0057] The three-way valve 150 is mounted on either coupling portion of the inlet portion 130 and the first and second receiving members 200 and 210. The three-way valve 150 is operated to disconnect the first receiving member 200 and the second space 180 from the second receiving member 210 while the blood plasma of the first receiving member 200 is flowing into the second space 180 of the filter 100. Further, the three-way valve 150 is operated to have the second receiving member 210 open into the second space 180 and the first receiving member 200 so that, after the filtration of the blood plasma is completed, the air in the second receiving member 210 enters the second space 180 to flow a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180 into the first receiving member 200.

[0058] The fixing member 160 is a member for maintaining the membrane filter unit 100 in the upright position, and it may be any general member designed so that the body 110 can be put in it, suspended from it, inserted into it or picked up from it. The fixing member 160 is excluded when the membrane filter unit 100 is used in a position other than the upright position. For this purpose, the membrane filter unit 100 is formed to have a wider bottom portion or to have a varied shape designed not to let off the blood plasma from the inlet portion 130 when the membrane filter unit having a cylindrical shape is laid on the side. In this case, there is no need of using the membrane filter unit in the upright position, if the platelets in the blood plasma settle down and have a minimum contact area with the filter 120.

[0059] In this regard, the purpose of using the fixing

member 160 to fix the membrane filter unit 100 in the upright position is having the blood plasma flow in from the bottom portion of the body 110 and carrying out the filtration while the platelets in the blood plasma settle down under the effect of gravity. The settlement of the platelets minimizes the contact area between the platelets and the filter 120 to reduce the adsorption of the platelets onto the filter 120 to the minimum. This can minimize a loss of the platelets caused by the adsorption onto the filter 120 and render a maximum amount of platelets contained in the platelet rich plasma that is going to be extracted later.

[0060] The first receiving member 200 is a member for receiving the blood plasma, injecting it into the membrane filter unit 100 and collecting the filtered blood plasma, that is, platelet rich plasma. The first receiving member 200 includes a first receiving portion 201 for receiving the blood plasma or the platelet rich plasma obtained after the filtration and a first plunger 202 mounted to push the blood plasma in the first receiving portion 201 into the second space 180 of the membrane filter unit 100. The first receiving member 200 is preferably, for example, a syringe without a needle, and it may be constructed to include at least two separate members for receiving or pushing the blood plasma or receiving the concentrated plasma after the filtration.

[0061] On the other hand, the second receiving member 210 is a member for receiving air and injecting it into the second space 180 of the membrane 100 after the filtration to push a component having a predetermined particle diameter or a larger particle diameter remaining in the second space 180 into the first receiving member 200. The second receiving member 210 includes a second receiving portion 211 for receiving air and a second plunger 212 mounted to inject the air in the second receiving portion 211 into the second space 180 of the membrane filter unit 100. The second receiving member 210 is preferably, for example, a syringe without a needle, and it may be constructed to include at least two separate members for receiving or pushing air. In this regard, the mounting positions of the first and second receiving members 200 and 210 are the bottom portion and the top portion, respectively, and exchangeable with each other.

[0062] The pressurizing means 300 is a means for injecting the blood plasma in the first receiving member 200 into the second space 180 under a predetermined pressure, and includes a power source 310 having a piston 311 mounted to push or pull the first plunger 202. In addition to the power source 310, the pressurizing means 300 may further include a controller 320 mounted to control the operation of the power source 310, a decelerator 330 mounted on the power source 310, an adaptor 340 mounted to intermediate a coupling of the first plunger 202 and the piston 311, and a direction-diverting switch 350 mounted to divert the moving direction of the piston 311. In this regard, the piston 311 without the first plunger 202 may move by directly sliding inside the first receiving

member 200.

[0063] First of all, the power source 310 is a device that enables the piston 311 coupled to the first plunger 202 of the first receiving member 200 to make a reciprocating movement in order to push or pull the first plunger 202. The power source 310 is preferably, for example, a motor. Otherwise, the power source 310 may also be a device with a separate piston 311 that enables the piston 311 to make a reciprocating movement.

[0064] In this regard, the pressure applied to inject the blood plasma into the membrane filter unit 100, that is, the pressure provided by the power source 310 may be equal to the permissible internal pressure of the filter 120 or below. For example, when the permissible internal pressure of the filter 120 is 500 mmHg, the load internal pressure of the filter 120 during the filtration is preferably in the range of about 300 to 450 mmHg.

[0065] In addition, the power source 310 provides an injection rate that allows the platelets in the blood plasma to settle down under the effect of gravity while the blood plasma is injected into the second space 180.

[0066] The controller 320 controls all the functions of the power source 310, including determination on whether to operate the power source 310 or not, the torque, that is, the magnitude of the pressure to inject the blood pressure into the second space 180, the running time, the moving distance of the piston 311, the moving direction of the piston 311, the injection pressure and the injection rate of the blood plasma, and so forth.

[0067] In one embodiment for extracting concentrated plasma from blood plasma, 5 portions of platelet-rich plasma can be obtained by combining 3 portions of a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180 and 2 portions of a blood plasma remaining in the first receiving member 200. For this purpose, the first plunger 202 in the first receiving member 200 moves only to the scale of 2 in the first receiving member 200 and then stops until a component having a particle diameter equal to or smaller than the predetermined particle diameter is completely exhausted through the outlet portion 140. The movement of the piston 311 in association with the movement of the first plunger 202 is under the control by the controller 320. It is of course possible to obtain 5 portions of the platelet rich plasma by injecting all the blood plasma of the receiving member 200 into the membrane filter unit 100 and filtering out a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180.

[0068] In another embodiment for extracting concentrated plasma from blood plasma, 6 or 7 portions of platelet rich plasma can be obtained by combining 3 portions of the component having particle diameter equal to or larger than a predetermined particle diameter and remaining in the second space 180 and 3 or 4 portions of blood plasma remaining in the first receiving member

200. For this, the first plunger 202 moves only to the scale of 3 or 4 in the first receiving member 200 and then stops. The movement of the piston 311 is also under the control by the controller 320.

[0069] In other words, the controller 320 controls the movement of the piston 311 so that the quantity of the blood plasma remaining in the first receiving member 200 is regulated according to a desired amount of the component having a particle diameter equal to or larger than the predetermined particle diameter in the membrane filter unit 100.

[0070] Contrarily, the controller 320 can simply set the torque range of the power source 310 and control the power source 310 to operate within the range of the predetermined torque. In this case, each of the other functions of the power source 310 aforementioned can be activated independently or at least two of the other functions can be activated simultaneously, by way of separate switches or control buttons.

[0071] The decelerator 330 enhances the torque of the power source 310 and enables the stable occurrence of the torque.

[0072] The adaptor 340 is an intermediate for a stable coupling of the piston 311 and the first plunger 202. The one side of the adaptor 340 is firmly coupled to the first plunger 202, and the other side of the adaptor 340 is fixed to the piston 311.

[0073] The direction-diverting switch 350 is mounted to divert the moving direction of the piston 311 for injecting the blood plasma into the second space 180 or collecting a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180 into the first receiving member 200 after the filtration. The direction-diverting switch 350 may be excluded, in which case the power source 310 can directly divert the moving direction of the piston 311. For example, when the power source 310 is a motor, it can divert the moving direction of the piston 311 by changing its rotational direction.

<Examples>

[0074] FIG. 4c is a constructional diagram showing the membrane filter unit of FIG. 2 without the second receiving member.

[0075] FIG. 4c is almost the same in construction as FIG. 2, excepting that the second receiving member 210 is excluded. Such a construction of FIG. 4c is to carry out a second method mentioned later, and its detailed description will be given in association with the description of the second method.

<First Method>

[0076] FIG. 5 is a flow chart showing a method for extracting concentrated plasma using the extracting device of FIG. 2.

[0077] Firstly, the membrane filter unit 100 is fixed in

the upright position, in step S10. The arrangement is to make the platelets in the blood plasma settle down under the effect of gravity and then to filter the blood plasma. This can minimize the contact area between the platelets and the filter 120 and thereby reduce a loss of the platelets caused by the adsorption onto the filter 120.

[0078] Subsequently, the blood plasma is injected into the membrane filter unit 100 to undergo filtration, while allowing the platelets to settle down, in step S20. For this purpose, there is included a step S21 of receiving the blood plasma in the first receiving member 200 and then mounting the first receiving member 200 on the membrane filter unit 100. In this regard, the first receiving member 200 is mounted on the inlet portion 130 formed on the one side of the body 110 of the membrane filter unit 100, so it opens to the second space in the body 110. In this construction, the first receiving member 200 and the inlet portion 130 are coupled together via the three-way valve 150, which is manipulated to open or close the first receiving member 200 and the second space 180. For injecting the blood plasma into the second space 180, the three-way valve 150 can be manipulated to open the first receiving member 200 and the second space 180. Also, the first receiving member 200 and the second space 180 is kept open in order to collect the platelet rich plasma remaining in the second space into the first receiving member 200 after the subsequent filtration. Ultimately, a two-way valve 150 may be used in place of the three-way valve 150, and the first receiving member 200 may be mounted on the inlet portion 130 without using a valve.

[0079] For obtaining blood plasma, for example, 9 portions of whole blood is mixed with 1 portion of an anticoagulant, and the mixture is removed of red blood cells through centrifugal separation to extract about 4 to 5.5 portions of blood plasma. It is of course possible to extract a larger amount of the blood plasma by mixing a larger quantity of whole blood and a larger quantity of an anticoagulant and then performing extraction of the blood plasma through centrifugal separation and removal of red blood cells.

[0080] Also, this step S20 may further include a step S22 of receiving air in the second receiving member 210 and then mounting the second receiving member 210 on the membrane filter unit 100. In this regard, the second receiving member 210 may be mounted on the inlet portion 130 formed on the other side of the body 110 via the three-way valve 150, which can be manipulated to open or close the second space 180. The mounting step S22 may be carried out right before the second collecting step S50 described later, or the second collecting step S50 may involve injecting external air into the second space 180, while the mounting step S22 is excluded.

[0081] When the blood plasma is injected into the second space 180, the three-way valve 150 is manipulated to open the inlet portion 130 of the second receiving member 210 to the exterior and thereby to exhaust the air of the membrane filter unit 100. In addition, when a com-

ponent having a particle diameter equal to or larger than the predetermined particle diameter in the second space 180 is collected into the first receiving member 200 after the filtration, the second receiving member 210 is mounted on the inlet portion 130 and the three-way valve 150 is manipulated to close the second space 180 of the membrane filter unit 100 from the exterior and allow the second space 180 to open into the second receiving member 210. It is therefore possible to mount the second receiving member 210 and the inlet portion 130 without a two-way valve or another valve other than the three-way valve 150.

[0082] The step S20 may further include a step S23 of moving the piston 311 in one direction by using the pressurizing means 300, that is the power source 310 to move the first plunger 202 of the first receiving member 200 and thereby injecting the blood plasma into the second space 180. In this regard, the pressure that the pressurizing means 300 applies to inject the blood plasma into the second space 180 is in a predetermined pressure range equal to the permissible internal pressure of the filter 120 of the membrane filter unit 100 or below. In the case when the permissible internal pressure of the filter 120 is 500 mmHg, the load internal pressure of the filter 120 during the filtration is in the range of 300 mmHg to 450 mmHg, that is, approximately 60 to 90 %. And, the injection rate for the pressurizing means 300 injecting the blood plasma into the second space 180 is within the range that allows the platelets to settle down in the blood plasma injected in to the second space 180 and enables the continuous injection of the blood plasma while the platelets settle down. The injection pressure and the injection rate can be regulated under the control of the power source 310 and the decelerator 330. When the power source 310 is a motor, the decelerator 330 controls the motor velocity (rpm) of the motor to adjust the injection pressure and the injection rate.

[0083] When the injection pressure is 1,200 kg, for example, the pressure per unit area of the filter 120 in consideration of the gravity is $1,200\text{kg/s}^2 = 0.5\text{kg/cm}^2$, which can be applied to calculate the injection pressure and the injection rate.

[0084] As the blood plasma is injected, the air in the membrane filter unit 100 is exhausted through the three-way valve 150 on the side of the second receiving member 210.

[0085] When the blood plasma is completely injected, the pressure in the membrane filter unit 100 is dropped in a predetermined period of time after the completion of the injection, in step S30. This can activate the settlement of the platelets more by reducing the pressure in the filter 120 of the membrane filter unit 100 and completely exhaust the component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter 120 in the second space 180 and temporarily held in the first space 170 through the outlet portion 140.

[0086] In this regard, as a predetermined quantity of

the blood plasma remains in the first receiving member 200 at the time when the injection of the blood plasma is completed, the first plunger 202 stops at a specific position. This is to remain a predetermined quantity of the blood plasma in the first receiving member 200. For extracting 5 portions of platelet rich plasma, for example, about 3 portions of the component having a particle diameter equal to or larger than the predetermined particle diameter which is obtained through filtration with the membrane filter unit 100 is mixed with about 2 portions of the blood plasma remaining in the first receiving member 200. Accordingly, a defined amount of the platelet rich plasma can be obtained by mixing a defined amount of the component having a particle diameter equal to or greater than the predetermined particle diameter which is obtained through filtration with the membrane filter unit 100 and a defined amount of the blood plasma remaining in the first receiving member 200. The amount of the blood plasma remaining in the first receiving member 200 can be determined based on the amount of the component obtained through the membrane filter unit 100, or the amount of the component obtained through the membrane filter unit 100 can be determined based on the amount of the blood plasma remaining in the first receiving member 200.

[0087] Contrarily, it is possible to obtain no more than the platelet rich plasma filtered through the membrane filter unit 100 by moving the first plunger 202 to a threshold moving position, stopping it and then injecting all the blood plasma of the first receiving member 200 into the membrane filter unit 100.

[0088] Of course, the moving and stop motions of the first plunger 202 are carried out by the movement of the piston 311 mounted on the first plunger 202, and the piston 311 is moved by the power source 310.

[0089] Subsequently, a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the membrane filter unit 100 is first collected into the first receiving member 200, in step S40. In this regard, when the power source 310 forces the piston 311 to make a back motion and the first plunger 202 makes a back motion, most of the component having a particle diameter equal to or larger than the predetermined particle diameter in the second space 180 of the membrane filter unit 100 flows into the first receiving member 200. Here, the direction-diverting switch 350 is manipulated for the back motion of the piston 311.

[0090] Finally, air is injected into the membrane filter unit 100 to collect the remaining component having a particle diameter equal to or larger than the predetermined particle diameter into the first receiving member 200, in step S50. For this purpose, the three-way valve 150 of the second receiving member 210 is manipulated to make the second receiving member 210 open into the second space 180, and then the second plunger 212 is moved to inject the air in the second receiving member 210 into the second space 180, thereby forcing all the

component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180 to flow into the first receiving member 200. It is of course possible to repeat the step S50 in order to completely flow the component having a particle diameter equal to or greater than the predetermined particle diameter into the first receiving member 200.

<Second Method>

[0091] FIG. 6 is a flow chart showing a second extraction method for concentrated plasma using the extracting device of FIG. 2. The second method according to the present invention is a method of collecting a component having a particle diameter equal to or larger than the predetermined particle diameter without using the second receiving member 210. The second method is similar to the first method on the whole, except for a little difference in the steps. The steps of the second method the same as or similar to the steps of the first method are mentioned as the common content and described briefly under necessity.

[0092] Firstly, the membrane filter unit 100 is fixed in the upright position, in step S10. The step S10 is as defined in the first method.

[0093] Subsequently, the valve 150 mounted in the opposing side of the first receiving member 200 and open into the second space 180 is closed, and the blood plasma is injected into the membrane filter unit 100 and passed through the filter while the platelets are allowed to settle down, in step S20. As the valve 150 is closed, the second space 180 opens into the exterior through the outlet portion 140, so that the first plunger 202 of the first receiving member 200 is pressurized under the same pressure of the first method or the stronger pressure to inject the blood plasma into the second space 180. The valve 150 may be a three-way valve, but preferably a two-way valve because the second receiving member 210 is excluded.

[0094] Accordingly, the step S20 includes the step S21 of mounting the first receiving member 200 on the membrane filter unit 100 and the step S23 of moving the piston 311 in one direction by the power source 310 to move the first plunger 202 of the first receiving member 200 and thereby to inject the blood plasma into the second space 180, but it excludes the step S22 of mounting the second receiving member 210 on the membrane filter unit 100.

[0095] As the second space 180 is mostly closed, an air layer is formed on the opposite side to the first receiving member 200 in the second space 180 while the blood plasma is injected, and the air layer prevents the blood plasma from penetrating above a predetermined height. This can force the component having a relatively high force of adhesion such as platelets to remain below a predetermined height and limit the range of adsorbing the components of the blood plasma onto the filter 120

to the maximum.

[0096] Of course, the component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter 120 is exhausted through the outlet portion 140 during the filtration.

[0097] Subsequently, it waits for a predetermined period of time after completion of the injection of the blood plasma and then the pressure in the membrane filter unit 100 is dropped, in step S30. The step S120 is also the same as defined in the first method.

[0098] Subsequently, the outlet portion 140 is blocked to close the second space 180 and then move the first plunger 202 of the first receiving member 200 back, thereby forming a vacuum pressure in the membrane filter unit 100, in step S31. In other words, when the outlet portion 140 is blocked, the second space 180 is completely closed, with the valve 150 closed. At this time, the power source 310 forces the piston 311 to make a back motion and moves the first plunger 202 back, so a strong vacuum pressure is formed in the membrane filter unit 100.

[0099] Finally, the valve 150 is momentarily opened to collect a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180 into the first receiving member 200 all at once, in step S40. By part of the air momentarily introduced, the components adsorbed onto the filter 120 are released from the filter 120 and flow into the first receiving member 200.

[0100] This decompression method has an advantage that the components adsorbed onto the filter 120 during the filtration can be released from the filter 120 to the maximum. It is of course possible to repeat the steps S31 and S40 in a manual, semi-automatic, or automatic manner, in which case the operation of the valve 150 can be controlled through the controller in such a manner of controlling a solenoid valve.

[0101] The above-described first and second methods are applied to extract concentrated plasma from the blood plasma. In this regard, the concentrated plasma extracted according to the present invention has a platelet count about 4 to 5 times higher than the platelet rich plasma obtained by the conventional method using the centrifugal separation. A comparison between the concentrated plasma of the present invention and the whole blood is given in Table 1.

[Table 1]

Whole blood	Platelet rich plasma
Platelet count	4 to 11-fold
Protein count	2 to 4-fold
Fibrinogen count	3 to 5-fold
White blood cell count	3 to 5-fold
Red blood cell count	0.2 to 0.4-fold

[0102] Particularly, the blood plasma is changed into a gel and used for many applications. In the conventional method of making the blood plasma containing an anti-coagulant into a gel, bovine thrombin or collagen is added to the blood plasma. But, the bovine thrombin is a substance extracted from livestock and thus possibly contains a component harmful to the human body (e.g., mad cow disease factor, etc.).

[0103] Accordingly, the present invention repeats the filtration of the blood plasma using a membrane filter, more preferably adds calcium to promote the conversion of prothrombin into thrombin as the first step of the blood coagulation mechanism and thereby to form a large quantity of thrombin from the prothrombin in the blood plasma. Such a large quantity of thrombin serves as a factor to convert fibrinogens into fibrin monomers and is enough to form a large quantity of fibrin monomers. Finally, the fibrin monomers form fibrin clots and the platelet rich plasma is extracted in the form of a gel and thus can be used for various use purposes instead of fibrin glue.

[0104] As described above, those skilled in the art will appreciate that the present invention described herein is susceptible to variation other than those specifically described without changing its technical conception and essential features. Therefore, it should be understood that the foregoing description of preferred embodiments of the present invention has been presented for purposes of illustration and not intended to limit the scope of the present invention.

[0105] It should also be understood that the scope of the present invention is defined by the scope of the following claims other than the detailed description and construed to include all the variations and modifications derived from the meanings and scope of the claims and their equivalents.

100: membrane filter unit
 110: body
 120: filter
 130: inlet portion
 140: outlet portion
 150: valve
 160: fixing member
 170: first space
 180: second space
 200: first receiving member
 201: first receiving portion
 202: first plunger
 210: second receiving member
 211: second receiving portion
 212: second plunger
 300: pressurizing means
 310: power source
 311: piston
 320: controller
 330: decelerator
 340: adaptor
 350: direction-diverting switch

Claims

1. A device for extracting concentrated plasma, which is to extract concentrated plasma, the device comprising:

a membrane filter unit (100) for isolating a component based on a predetermined particle diameter from blood plasma; and
a first receiving member (200) for providing a predetermined injection rate and a predetermined injection pressure to inject the blood plasma into the membrane filter unit (100) and let thereby platelets in the blood plasma settle down by gravity.

2. The device for extracting concentrated plasma as claimed in claim 1, further comprising:

a pressurizing means (300) mounted in connection to the first receiving member (200) to provide the injection rate and the injection pressure of the blood plasma.

3. The device for extracting concentrated plasma as claimed in claim 2, wherein the pressurizing means (300) comprises:

a piston 311 moving relative to the membrane filter unit (100) to inject the blood plasma in the first receiving member (200) into the membrane filter unit (100); and
a power source (310) mounted to induce the movement of the piston (311).

4. The device for extracting concentrated plasma as claimed in claim 3, wherein the power source (310) limits the moving distance of the piston (311) to remain part of the blood plasma in the first receiving member (200) for a predetermined period of time after the time that the injection of the blood plasma into the membrane filter unit (100) is completed.

5. The device for extracting concentrated plasma as claimed in claim 3 or 4, wherein the power source (310) maintains the piston (311) at a position for the predetermined period of time after the time that the movement of the piston (311) is completed.

6. The device for extracting concentrated plasma as claimed in claim 3, wherein the pressurizing means (300) further comprises:

an adaptor (340) for intermediating a coupling of a first plunger (202) mounted in the first receiving member (200) and the piston (311) to inject the blood plasma in the first receiving member (200) into the membrane filter unit

(100); and

a controller (320) for controlling the operation of the power source (310) to regulate the injection rate and the injection pressure of the blood plasma according to the moving distance and the moving rate of the piston (311) and the first plunger (202).

7. The device for extracting concentrated plasma as claimed in claim 3 or 6, wherein the pressurizing means (300) further comprises:

a direction-diverting switch (350) for diverting the moving direction of the piston (311).

8. The device for extracting concentrated plasma as claimed in claim 1, wherein the membrane filter unit (100) comprises:

a body 110 having the first receiving member (200) mounted thereon, the body comprising a first and a second inlet portion (130), wherein the air is exhausted through the second inlet portion (130) at one end of the membrane filter unit 100 when the blood plasma flows in through the first inlet portion (130) at the other end of the membrane filter unit (100), and an outlet portion (140) for exhausting a component having a particle diameter equal to or smaller than the predetermined particle diameter passed through the membrane filter unit (100);
a hollow filter (120) being mounted in the body (110) and having a second space (180) for receiving the component having a particle diameter equal to or smaller than the predetermined particle diameter which was filtered when the blood plasma of the first receiving member (200) flows in through the first inlet portion (130); and
a first space (170) formed between the hollow filter (120) and the body (110) to open into the outlet portion (140) to temporarily receive the component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter (120) and exhaust the same through the outlet portion (140).

9. The device for extracting concentrated plasma as claimed in claim 1 or 8, wherein the membrane filter unit further comprises:

a fixing member (160) mounted on the body (110) for arranging the membrane filter unit in the upright position to settle down platelets of the blood plasma flowing into the membrane filter unit under the effect of gravity.

10. The device for extracting concentrated plasma as

claimed in claim 8, further comprising:

a second receiving member (210) being mounted on the membrane filter unit (100) at a predetermined distance from the first receiving member (200) to open into the second space (180) and receiving air.

11. The device for extracting concentrated plasma as claimed in claim 10, wherein the membrane filter unit (100) further comprises a first valve (150) being mounted as an intermediate on a coupling portion between the first inlet portion (130) and the first receiving member (200) and a second valve (150) being mounted as an intermediate on a coupling portion between the second inlet portion (130) and the second receiving member (210), the first valve being arranged to have the second space (180) and the first receiving member (200) open into each other at normal times, and the second valve being arranged to close the second space (180) and the second receiving member (210) when blood plasma is injected into the second space (180), and to open the second space (180) into the second receiving member (210) and inject air in the second receiving member (210) into the second space (180) when a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space (180) is to flow into the first receiving member (200).
12. A method for extracting concentrated plasma, which is to extract concentrated plasma, the method comprising:

a filtering step (S20) of injecting blood plasma into a membrane filter unit (100) to let the platelets settle down by gravity in the blood plasma and thereby remaining a component having a particle diameter equal to or larger than the predetermined particle diameter which has not passed through a filter (120) built in the membrane filter unit (100); and
a step (S40) of collecting the component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the membrane filter unit (100).

13. The method for extracting concentrated plasma as claimed in claim 12, further comprising:
a step (S10) of arranging the membrane filter unit (100) in the upright position to reduce the contact area between the filter (120) in the membrane filter unit (100) and the platelets, before the filtering step (S20).

14. The method for extracting concentrated plasma as

claimed in claim 12, further comprising:

a step (S30) of waiting for a predetermined period of time after the blood plasma is completely injected and reducing pressure in the membrane filter unit (100) after the predetermined period of time to exhaust a component having a particle diameter equal to or smaller than the predetermined particle diameter.

15. The method for extracting concentrated plasma as claimed in claim 12, wherein the filtering step (S20) includes injecting part of the blood plasma into the membrane filter unit (100), wherein the first collecting step (S40) includes collecting both a component, having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the filter, and the remaining blood plasma in one position.

16. The method for extracting concentrated plasma as claimed in claim 15, further comprising:

a second collecting step (S50) of injecting air into the membrane filter unit (100) to collect again both the remaining component having a particle diameter equal to or larger than the predetermined particle diameter and the remaining blood plasma in one position.

17. The method for extracting concentrated plasma as claimed in claim 12, 14, 15, or 16, wherein in all the steps other than the collecting step, first and second spaces (170) and (180) are formed by mounting a filter (120) in a body (110) of the membrane filter (100), wherein the second space (180) holds a component having a particle diameter equal to or larger than the predetermined particle diameter which is filtered out from the filter (120) when the blood plasma flows in, the first space (170) temporarily collecting a component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter (120) to exhaust the component through an outlet portion (140) formed in the body (110) of the membrane filter unit (100).

18. The method for extracting concentrated plasma as claimed in claim 17, wherein the filtering step (S20) further includes a step (S23) of injecting the blood plasma into the second space (180) at a predetermined injection rate and a predetermined pressure to let the platelets settle down by gravity, wherein the injection pressure of the blood plasma is determined to have the range of a load internal pressure imposed on the filter (120) mounted in the membrane filter unit (100) during the filtration is equal to or lower than the permissible internal pres-

sure of the filter (120).

19. The method for extracting concentrated plasma as claimed in claim 18, wherein the injecting step (S23) includes using a pressurizing means (300) to move a first plunger (202) mounted on a first receiving member (200) holding the blood plasma and push the blood plasma, wherein as a power source (310) of the pressurizing means (300) moves a piston (311) to move the first plunger (202) mounted on the piston (311), thereby injecting the blood plasma into the second space 180 at a predetermined injection rate and a predetermined pressure, wherein when part of the blood plasma is injected into the second space (180), the remainder of the blood plasma remains in the first receiving member (200), wherein after filtration, the first plunger (202) is moved back to collect a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space into the first receiving member (200) holding the remaining blood plasma.
20. The method for extracting concentrated plasma as claimed in claim 19, wherein air in a second receiving member (210) mounted on the membrane filter unit (100) is injected into the second space (180) to collect a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space (180) into the first receiving member (200) holding the remaining blood plasma.
21. The method for extracting concentrated plasma as claimed in claim 20, wherein the first receiving member (200) and the second receiving member (210) are connected to the second space (180), wherein before the second collecting step (S50), a first valve (150) is manipulated to have the second space (180) open into the first receiving member (200) and a second valve (150) is manipulated to disconnect the second space (180) from the second receiving member (210), wherein in the second collecting step (S50), the first valve (150) is manipulated to have the second space (180) open into the first receiving member (200) and the second valve (150) is manipulated to have the second space (180) open into the second receiving member (210).
22. The method for extracting concentrated plasma as claimed in claim 14, wherein the filtering step (S20) includes opening a first valve (150) at a side of a receiving member (200) to have the second space (180) open into the first receiving member (200) and closing a second valve (150) mounted on the oppo-

site side of the first receiving member (200).

23. The method for extracting concentrated plasma as claimed in claim 22, wherein in the filtering step (S20), when the blood plasma is injected, an air layer is formed in part of the space of the membrane filter unit (100) to limit the injection height of the blood plasma to a predetermined height or below.
24. The method for extracting concentrated plasma as claimed in claim 22, further comprising:
a step S31 of completely closing the membrane filter unit and forming a vacuum pressure in the membrane filter (100), after the pressure-reducing step (S30).
25. The method for extracting concentrated plasma as claimed in claim 24, wherein the collecting step S40 includes opening the second valve (150) to momentarily supply external air into the membrane filter unit (100) and thereby collecting a component having a particle diameter equal to or larger than the predetermined particle diameter using the air.
26. The method for extracting concentrated plasma as claimed in claim 12, wherein the concentrated plasma becomes gel by repeatedly filtering the blood plasma injected into the membrane filter unit (100) or adding calcium and then repeatedly filtering the blood plasma.

FIG. 1

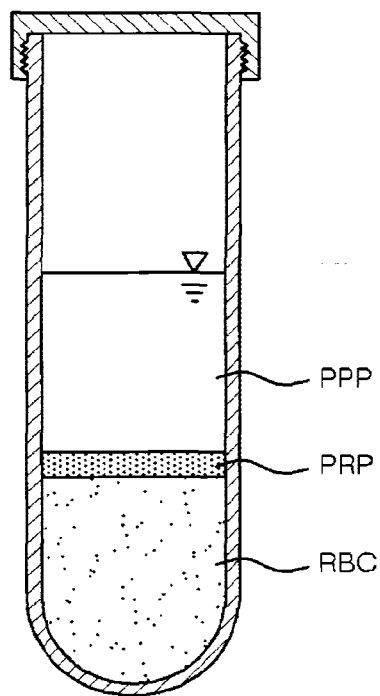


FIG. 2

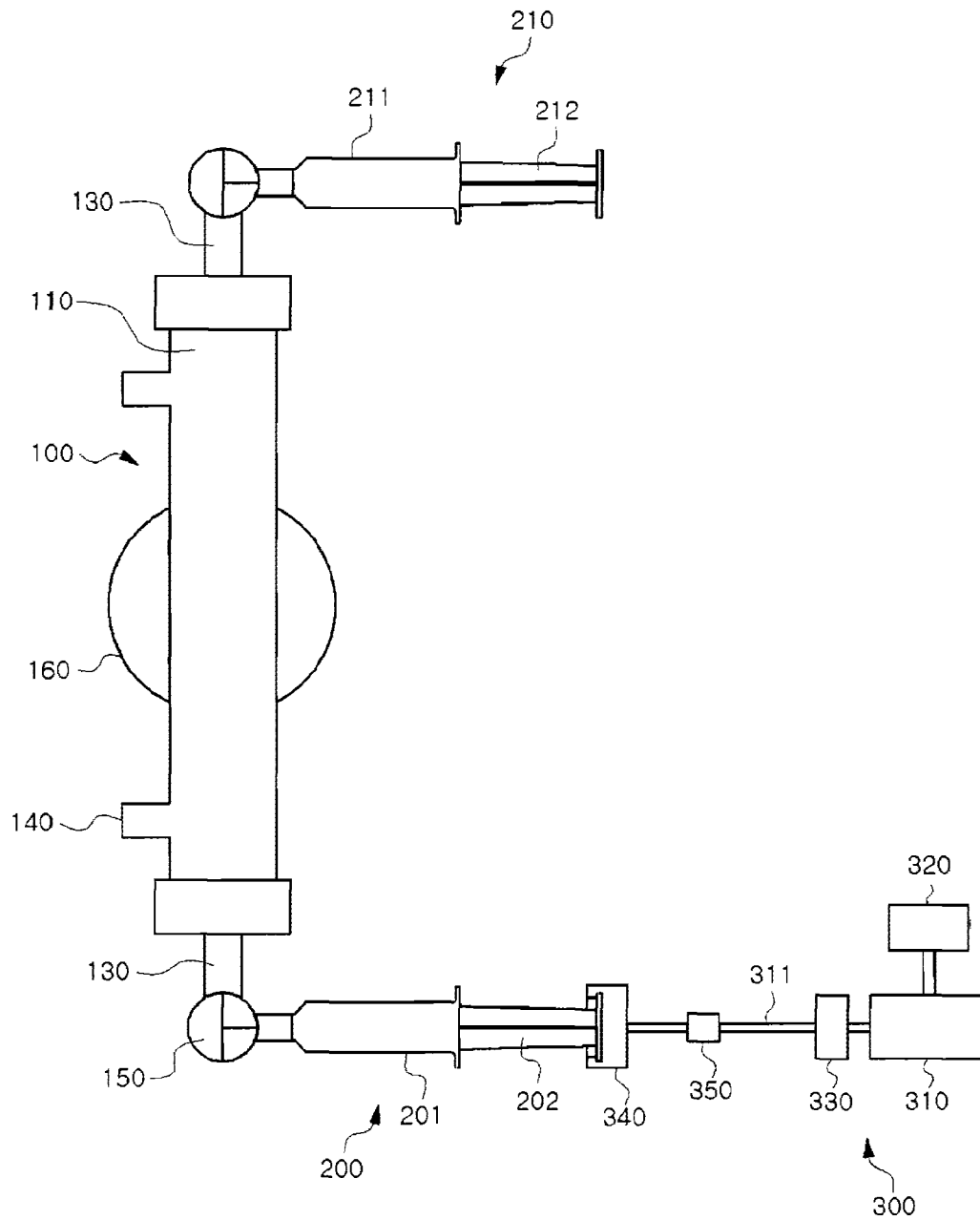


FIG. 3

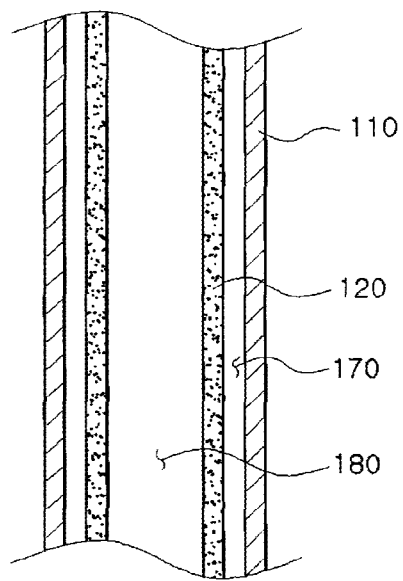


FIG. 4a

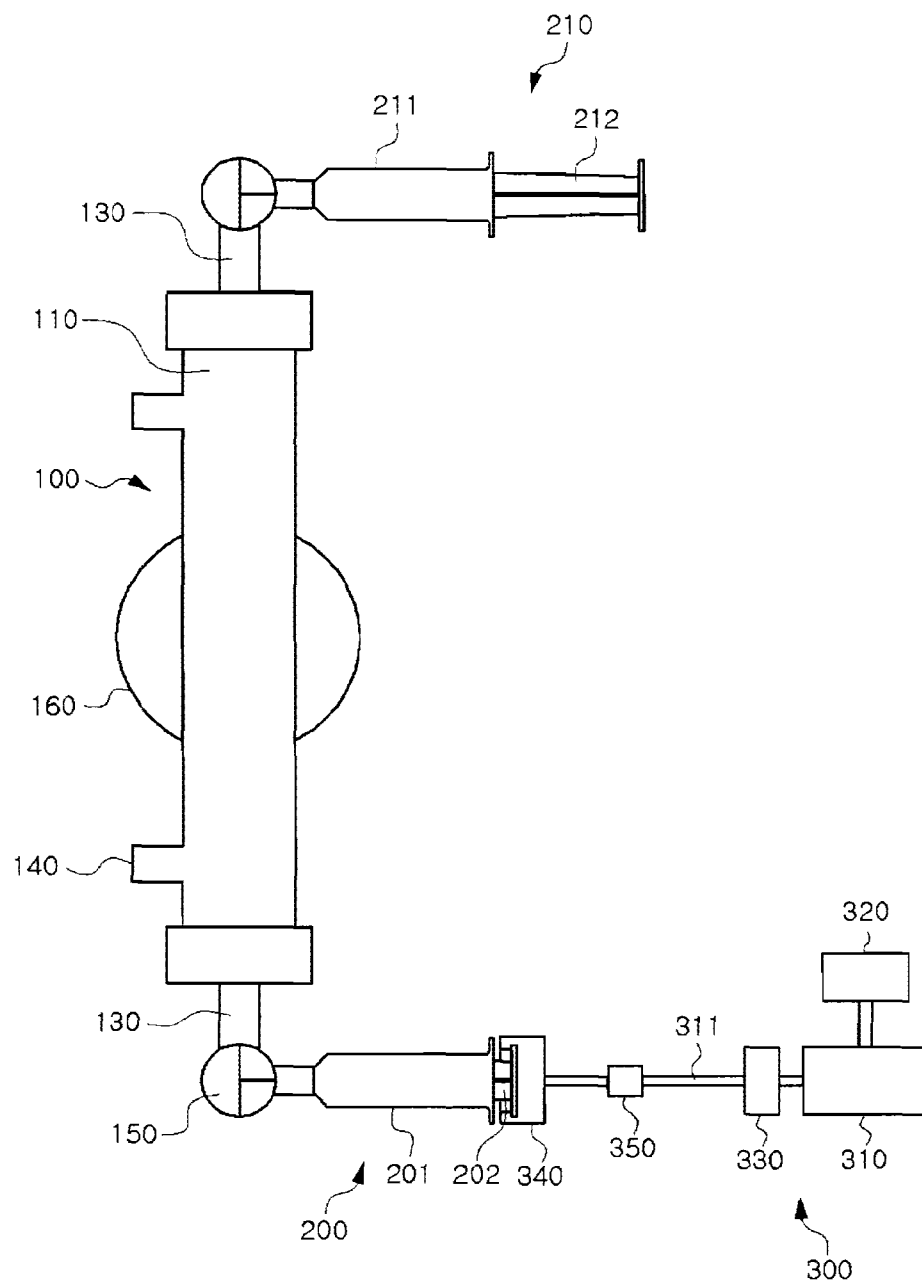


FIG. 4b

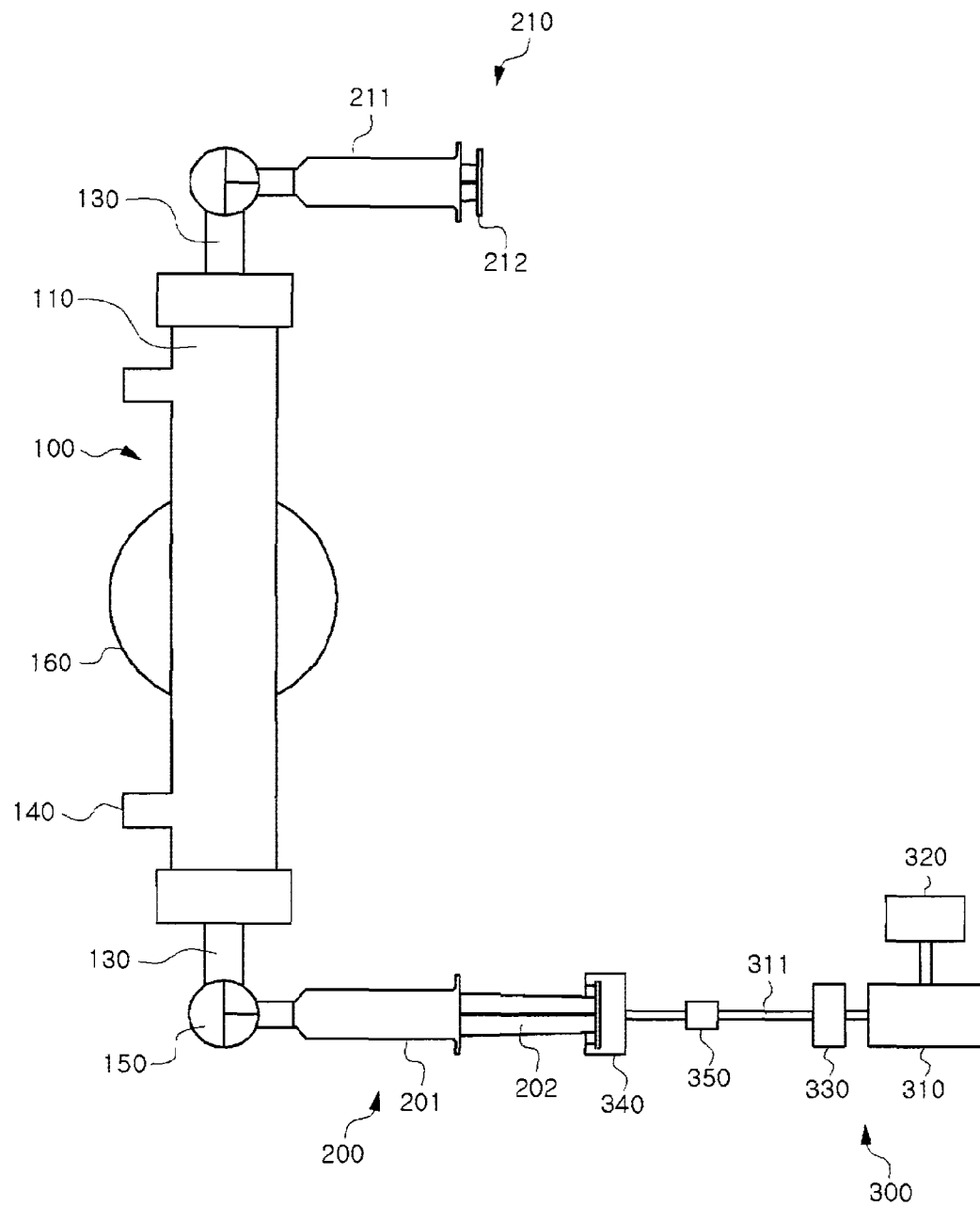


FIG. 4c

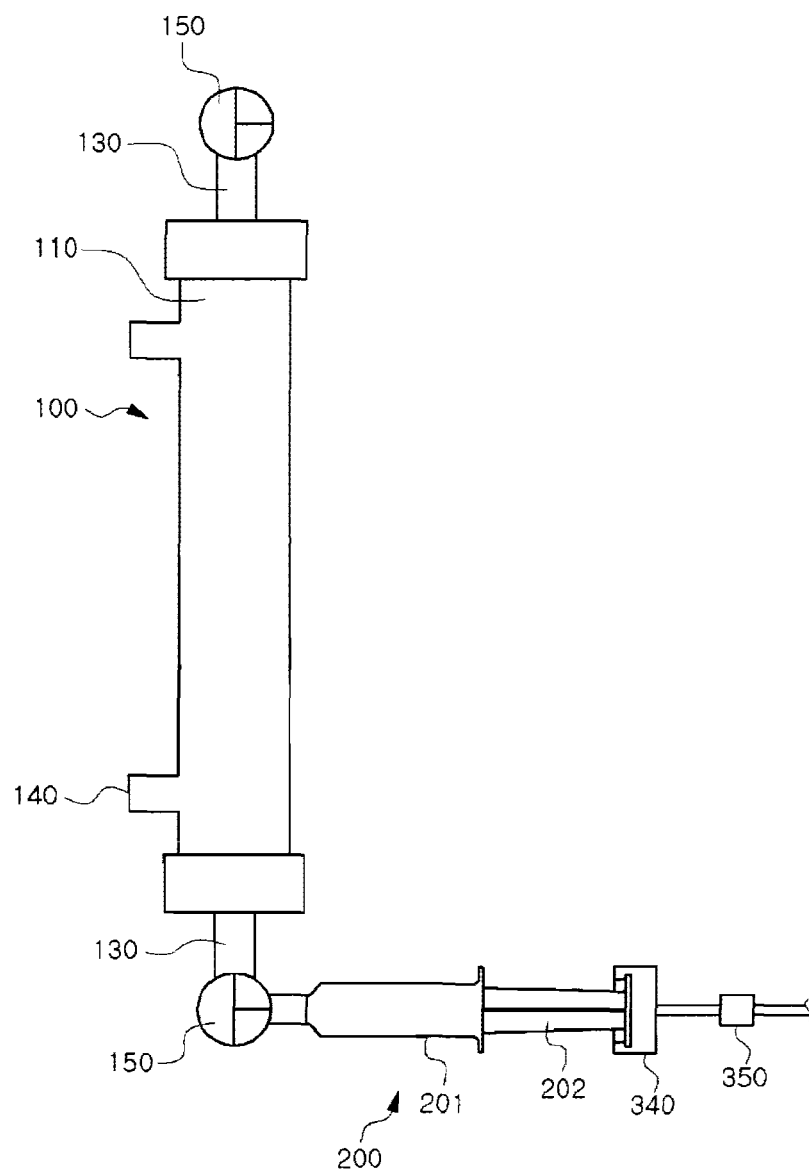


FIG. 5

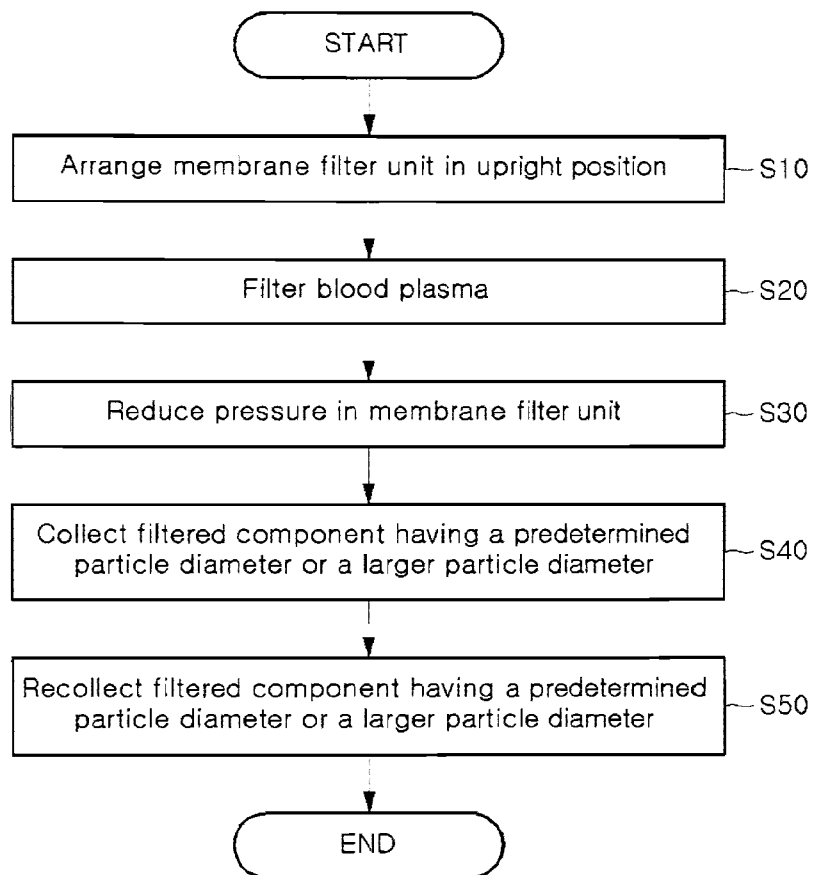
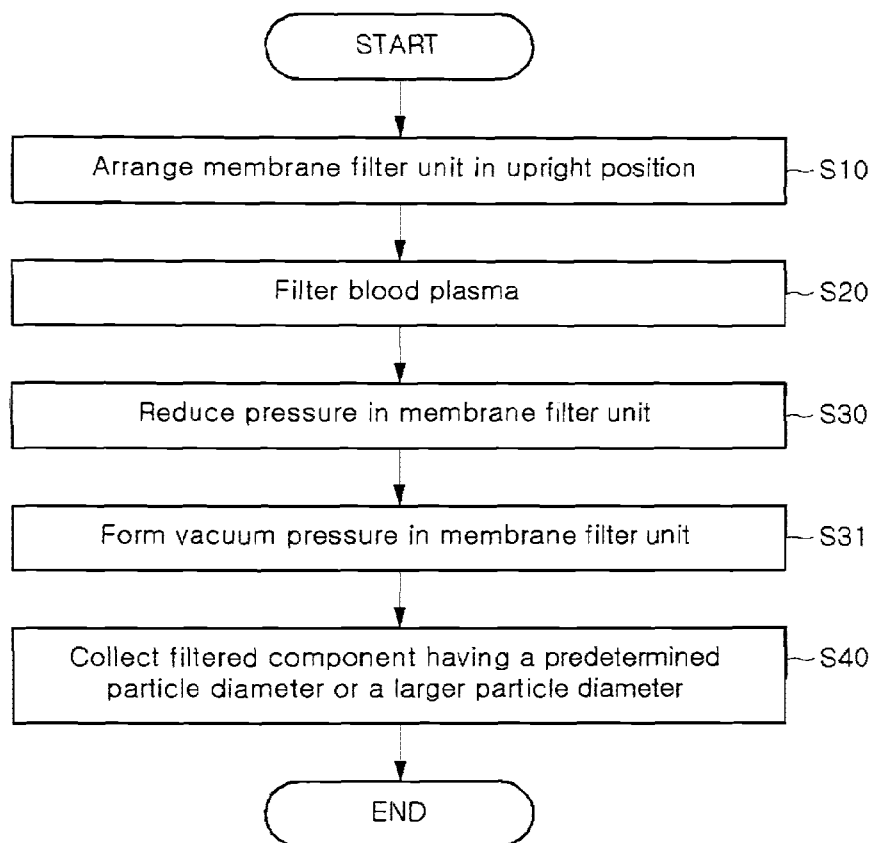


FIG. 6





EUROPEAN SEARCH REPORT

 Application Number
 EP 14 17 6323

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 6 342 157 B1 (HOOD III ANDREW G [US]) 29 January 2002 (2002-01-29) * column 7, line 1 - line 39 * * column 8, line 29 - line 67 * * figure 3 *	1-26	INV. G01N33/49 A61M1/34 B01D61/14
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A	EP 2 407 245 A2 (GLOTECH CO LTD [KR]; IHM KHI PYO [KR]) 18 January 2012 (2012-01-18) * the whole document *	1-26	
			TECHNICAL FIELDS SEARCHED (IPC)
			G01N A61M B01D
The present search report has been drawn up for all claims			
Place of search		Date of completion of the search	Examiner
The Hague		23 September 2015	Baranski, Jörg
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

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**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 14 17 6323

5

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23-09-2015

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

REFERENCES CITED IN THE DESCRIPTION

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- KR 2010011616010 [0008]
- KR 2010004143610 [0008]



ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
18/180,016

RECEIPT DATE / TIME
07/05/2023 10:42:04 AM ET

ATTORNEY DOCKET #
111552.8018.US07

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 # 1816

FILED BY J iYoung Anderson

PATENT CENTER # 62386068

FILING DATE 03/07/2023

CUSTOMER # 25096

FIRST NAMED
INVENTOR Ben Merritt

CORRESPONDENCE
ADDRESS -

AUTHORIZED BY Matthew Williams

Documents

TOTAL DOCUMENTS: 7

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-7-5 IDS SB08 - 111552.8018.US07.PDF	4	Information Disclosure Statement (IDS) Form (SB08)	135 KB
Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
NPL_ISR_PCT_2023-61256- June-7-2023-8-pages.PDF	8	Non Patent Literature	1063 KB
FOR_EP2942624.PDF	24	Foreign Reference	1188 KB
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NPL-Gross-Dump the Pump.PDF	4	Non Patent Literature	870 KB
FOR_WO2006029270.PDF	33	Foreign Reference	1157 KB
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Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-7-5 IDS SB08 - 111552.8018.US07.PDF	2C2F8F99E5E316D4D738D6B7FAAE059F677073A8D5E04EF0A670D20A3CC93BC5E286C76B6F2DA2508CDB86530DF0E45AD154C38C7A4296B3DD91C5147CCE6494
NPL_ISR_PCT_2023-61256-June-7-2023-8-pages.PDF	E29F558402CAA5ECA7B480DBF767FC910107364FF8EB3919C86E39BC20664311EDA23D81B18626667115B85F0FF8707387E626478C646A16AA39EB2CD5DE7AAA
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NPL-ISR PCT-US23-60502-May 25 2023, 9 pages.PDF	AB9E18E8D719D570042421492F6987DD0A13BB5495A02880F62E01BE1CF7C944D083EAFDE8C4E5422B5FFE1CE3AB308FEC A74F813846CF2D5345E92D1EBDA861
NPL-Gross-Dump the Pump.PDF	D44985D30C015BE8DA101967568EDF70598C9DCC517B882F1524CC5F8D5C8C53620135568E11D3A8E76C94DABDD42BADC78DE5603483BF94B00DA3679A300F1D
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FOR_WO2016014955.PDF	DE12ACD76BAE4B0E156B6F9D382CAEBE3E6243ED877F035256811EF33F0A9463A0204B3777321B5207E9E06058DD462E99A3EA229302CDF42B2A63C4E5792EF2

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

PCT

To: Matthew S. Williams
Perkins Coie LLP
P.O. Box 1247
Seattle, WA 98111-1247
United States Of America

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PERKINS COIE LLP

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

(PCT Rule 44.1)

Applicant's or agent's file reference 111552-8035WO00	Date of mailing (day/month/year) <div style="text-align: center; font-size: 1.2em;">JUN 07 2023</div>
International application No. PCT/US23/61256	International filing date (day/month/year) 25 January 2023 (25.01.2023)
Applicant INARI MEDICAL, INC.	

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

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

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

How? Directly to the International Bureau preferably through ePCT, or on paper to:
The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 29, 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 49.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

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

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

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

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

Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1480, Alexandria, Virginia 22313-1480 Facsimile No. 571-273-8300	Authorized officer <div style="text-align: center; font-size: 1.1em;">Shane Thomas</div> Telephone No. PCT Helpdesk: 571-272-4300
---	--

Form PCT/ISA/226 (revised January 2020)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 111552-8035W000		FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US23/61256	International filing date (day/month/year) 25 January 2023 (25.01.2023)	(Earliest) Priority Date (day/month/year) 31 January 2022 (31.01.2022)	
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.

I. Basis of the report

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

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

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

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

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

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

4. With regard to the title,

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

5. With regard to the abstract,

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

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 3A
☒ 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/US23/61256

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61M 1/00 (2023.01)

ADD. A61B 17/22; A61M 25/00 (2023.01)

CPC - INV. A61M 1/04; A61M 25/0043; A61M 25/0045; A61M 25/005

ADD. A61B 2017/22079; A61B 2217/005; A61M 25/0023; A61M 2025/0073; A61M 2206/16; A61M 2206/20

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

See Search History document

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2016/0030706 A1 (ANGIODYNAMICS INC.) 04 February 2016; figures 4, 8b; paragraphs 0006, 0009, 0030, 0036, 0038, 0039; abstract; claim 3	1-13, 15-21 --- 14
X	US 2016/0135829 A1 (ANGIODYNAMICS INC.) 19 May 2016; figures 2a-4c, 7; paragraphs 0037, 0049	22-24
Y	US 2006/0264905 A1 (ESKRIDGE ET AL.) 23 November 2006; paragraphs 0005, 0027	14
A	US 5,244,619 A (BURNHAM) 14 September 1993; entire document	1-24
A	US 2017/0021130 A1 (DYE) 26 January 2017; entire document	1-24

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

* 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 a novel 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

"B" document member of the same patent family

Date of the actual completion of the international search

24 April 2023 (24.04.2023)

Date of mailing of the international search report

JUN 07 2023

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)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: Matthew S. Williams
Perkins Coie LLP
P.O. Box 1247
Seattle, WA 98111-1247
United States Of America

**RECEIVED
PATENT DOCKETING**

JUN 12 2023

PERKINS COIE LLP

Date of mailing
(day/month/year)

JUN 07 2023

Applicant's or agent's file reference
111552-8035WC00

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US23/61256

International filing date (day/month/year)

25 January 2023 (25.01.2023)

Priority date (day/month/year)

31 January 2022 (31.01.2022)

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

IPC - INV. A61M 1/00 (2023.01)

ADD. A61B 17/22; A61M 25/00 (2023.01)

CPC - INV. A61M 1/04; A61M 25/0043; A61M 25/0045; A61M 25/005

ADD. A61B 2017/22079; A61B 2217/005; A61M 25/0023; A61M 2025/0073; A61M 2206/16; A61M 2206/20

Applicant INARI MEDICAL, INC.

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

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

2. **FURTHER ACTION**

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

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

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

Name and mailing address of the ISA/

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300

Date of completion of this opinion

24 April 2023 (24.04.2023)

Authorized officer

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/US23/61258

Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(b)).
3. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. ☐ forming part of the international application as filed.
 - b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13ter.1(a)).
☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.
4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US23/61256

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

1. Statement

Novelty (N)	Claims	14	YES
	Claims	1-13, 15-24	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-24	NO
Industrial applicability (IA)	Claims	1-24	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-3, 7-10, 15, and 17-21 lack novelty under PCT Article 33(2) as being anticipated by AngioDynamics, Inc. US 2016/0030706 A1 (AngioDynamics).

As to claim 1, AngioDynamics teaches an aspiration catheter (30), comprising: a proximal terminus; a distal terminus; and an inner surface defining a lumen (para [0009]), wherein the inner surface includes at least one groove formed therein (channels 33) and that extends from the distal terminus at least partially toward the proximal terminus (fig. 4).

As to claim 2, AngioDynamics teaches the aspiration catheter of claim 1 wherein the at least one groove extends from the distal terminus to the proximal terminus (para [0036]; claim 3).

As to claim 3, AngioDynamics teaches the aspiration catheter of claim 1 wherein the lumen extends along a longitudinal axis, and wherein the at least one groove revolves circumferentially about the longitudinal axis between the proximal terminus and the distal terminus (abstract; para [0009]; para [0030]).

As to claim 7, AngioDynamics teaches the aspiration catheter of claim 1 wherein the at least one groove has a spiral shape (abstract; para [0009]; para [0030]).

As to claim 8, AngioDynamics teaches the aspiration catheter of claim 1 wherein the at least one groove comprises a plurality of grooves (fig. 4; abstract; para [0009]; para [0030]).

As to claim 9, AngioDynamics teaches the aspiration catheter of claim 8 wherein the plurality of grooves are equally spaced apart about a circumference of the inner surface (fig. 4; see cross-section in fig. 8b).

As to claim 10, AngioDynamics teaches the aspiration catheter of claim 8 wherein the lumen extends along a longitudinal axis, and wherein the plurality of grooves revolves circumferentially about the longitudinal axis between the proximal terminus and the distal terminus (para [0036]; claim 3).

As to claim 15, AngioDynamics teaches an aspiration catheter (30), comprising: a proximal terminus; a distal terminus; and an inner surface defining a lumen extending along a longitudinal axis (para [0009]), wherein the inner surface includes a plurality of grooves formed therein (channels 33), wherein the grooves extend at least partially between the distal terminus and the proximal terminus (fig. 4), and wherein the grooves revolve circumferentially about the longitudinal axis between the distal terminus and the proximal terminus (abstract; para [0009]; para [0030]).

As to claim 17, AngioDynamics teaches the aspiration catheter of claim 15 wherein the grooves are equally spaced about a circumference of the inner surface (fig. 4; see cross-section in fig. 8b).

As to claim 18, AngioDynamics teaches the aspiration catheter of claim 15 wherein the grooves extend to the distal terminus (para [0036]; claim 3).

As to claim 19, AngioDynamics teaches the aspiration catheter of claim 15 wherein the grooves extend entirely between the distal terminus and proximal terminus (para [0036]; claim 3).

As to claim 20, AngioDynamics teaches a system for removing material from within a lumen of a human patient, the system comprising: an aspiration catheter (30) configured to be positioned at a treatment site proximate to the material within the lumen, wherein the aspiration catheter comprises a proximal terminus; a distal terminus; and an inner surface defining a lumen (para [0009]), wherein the inner surface includes at least one groove formed therein (channels 33) and that extends from the distal terminus at least partially toward the proximal terminus (fig. 4); a tubing assembly fluidly coupled to the catheter (connected to a port or syringe; para [0036], [0039]) and including a fluid control device (power aspiration para [0008] or syringe 110); and a pressure source fluidly coupled to the tubing assembly and configured to generate negative pressure (power aspiration para [0008] or syringe 110; para [0039]), wherein the fluid control device is movable

Continued in Supplemental Box.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US23/61256

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-

between (a) a first position in which the pressure source is fluidly connected to the aspiration catheter via the tubing assembly and (b) a second position in which the pressure source is fluidly disconnected from the aspiration catheter (the catheter is fully capable of being connected and disconnected from pressure source).

As to claim 21, AngioDynamics teaches the system of claim 20 wherein the lumen extends along a longitudinal axis, wherein the at least one groove includes a plurality of grooves (fig. 4), wherein the grooves are equally spaced about a circumference of the inner surface (fig. 4; see cross-section in fig. 8b), wherein the grooves extend at least partially from the distal terminus to the proximal terminus (fig. 4), and wherein the grooves revolve circumferentially about the longitudinal axis between the proximal terminus and the distal terminus (abstract; para [0009], para [0030]).

Claims 22-24 lack novelty under PCT Article 33(2) as being anticipated by AngioDynamics US 2016/0135629 A1 (AngioDynamics2).

As to claim 22, AngioDynamics2 teaches a method for removing material from within a lumen of a human patient, the method comprising: positioning a distal portion of an aspiration catheter proximate to the material within the lumen (figs. 2a-4c), wherein the aspiration catheter includes an inner surface having at least one groove formed therein (para [0037]), and wherein the at least one groove extends from a distal terminus of the aspiration catheter at least partially toward a proximal terminus of the aspiration catheter (para [0037]); coupling a pressure source to the aspiration catheter via a fluid control device (para [0049]), wherein (a) opening of the fluid control device fluidly connects the pressure source to the aspiration catheter and (b) closing of the fluid control device fluidly disconnects the pressure source from the aspiration catheter; activating the pressure source to generate a vacuum while the fluid control device is closed; and opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the material into the aspiration catheter (it is well known that powering on a vacuum pump will open/activate will connect a vacuum, and powering off the pump will close disconnect a vacuum).

As to claim 23, AngioDynamics2 teaches the method of claim 22 wherein the at least one groove defines a leak path past the clot material when the clot material is aspirated into the aspiration catheter (channels form paths).

As to claim 24, AngioDynamics2 teaches the method of claim 22 wherein the at least one groove generates a helical flow pattern in the lumen when the clot material is aspirated into the aspiration catheter (para [0037], [0039], fig. 7).

Claims 4-6, 11-13, and 16 lack an inventive step under PCT Article 33(3) as being obvious over AngioDynamics.

As to claims 4-6, AngioDynamics teaches the aspiration catheter of claim 3. It should be noted that AngioDynamics fails to specifically teach the at least one groove revolves about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch. AngioDynamics does teach that the pitch of the grooves can be used to optimize flow rate depending of the procedure (para [0035]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the grooves revolves about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made for the grooves of AngioDynamics to revolve about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch depending on the desired effect during a procedure (para [0035]).

As to claims 11-13, AngioDynamics teaches the aspiration catheter of claim 10. It should be noted that AngioDynamics fails to specifically teach the plurality of grooves revolves about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch. AngioDynamics does teach that the pitch of the grooves can be used to optimize flow rate depending of the procedure (para [0035]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the grooves revolves about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made for the grooves of AngioDynamics to revolve about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch depending on the desired effect during a procedure (para [0035]).

As to claims 16, AngioDynamics teaches the aspiration catheter of claim 15. It should be noted that AngioDynamics fails to specifically teach the at least one groove revolves between: about 0.13-0.15 times per inch. AngioDynamics does teach that the pitch of the grooves can be used to optimize flow rate depending of the procedure (para [0035]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the grooves revolves about 0.13-0.15 times per inch, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made for the grooves of AngioDynamics to revolve about 0.13-0.15 times per inch depending on the desired effect during a procedure (para [0035]).

Claim 14 lacks an inventive step under PCT Article 33(3) as being obvious over AngioDynamics in view of Eskridge et al. US 2006/0264905 A1 (Eskridge).

As to claim 14, AngioDynamics teaches the aspiration catheter of claim 1. It should be noted that AngioDynamics fail to teaches wherein the catheter further comprises: an inner liner having the inner surface, wherein the at least one groove is formed in the inner liner; a braid of wires over the inner liner; a wire coiled over the inner liner; and an outer sheath over the braid, the wire, and the inner liner. AngioDynamics does teach the desire to prevent pinching or collapsing of the catheter when negative pressure is applied (para [0007]).

-Continued Within the Next Supplemental Box-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US23/61256

Supplemental Box

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

Continuation of:

-Continued from previous Supplemental Box--

Eskridge teaches multi-layered catheter construction is well known in the art, and it is well known to combinations of liners, coils, and braids to prevent kinks (para {0005}, {0027}). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter of AngioDynamics to include the liner, coil, and braid of Eskridge to prevent pinching or collapsing of the catheter by increasing stiffness while still providing flexibility (para {0005}, {0027}).

Claims 1-24 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.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To: Matthew S. Williams
Perkins Coie LLP
P.O. Box 1247
Seattle, WA 98111-1247
United States Of America

**RECEIVED
PATENT DOCKETING**

JUN 12 2023

PERKINS COIE LLP

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

(PCT Rule 44.1)

Applicant's or agent's file reference 111552-8035WO00	Date of mailing (day/month/year) <div style="text-align: center; font-size: 1.2em;">JUN 07 2023</div>
International application No. PCT/US23/61256	International filing date (day/month/year) 25 January 2023 (25.01.2023)
Applicant INARI MEDICAL, INC.	

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

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

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

How? Directly to the International Bureau preferably through ePCT, or on paper to:

The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland

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

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

3. ☐ With regard to any protest against payment of (an) additional fee(s) under Rule 49.2, the applicant is notified that:

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

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

4. Reminders

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

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

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

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

Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1480, Alexandria, Virginia 22313-1480 Facsimile No. 571-273-8300	Authorized officer <div style="text-align: center; font-size: 1.1em;">Shane Thomas</div> Telephone No. PCT Helpdesk: 571-272-4300
---	--

Form PCT/ISA/226 (revised January 2020)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 111552-8035W000		FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US23/61256	International filing date (day/month/year) 25 January 2023 (25.01.2023)	(Earliest) Priority Date (day/month/year) 31 January 2022 (31.01.2022)	
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 2 sheets.

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

1. Basis of the report

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

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

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

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

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

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

4. With regard to the title,

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

5. With regard to the abstract,

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

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 3A
☒ 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/US23/61256

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61M 1/00 (2023.01)

ADD. A61B 17/22; A61M 25/00 (2023.01)

CPC - INV. A61M 1/04; A61M 25/0043; A61M 25/0045; A61M 25/005

ADD. A61B 2017/22079; A61B 2217/005; A61M 25/0023; A61M 2025/0073; A61M 2206/16; A61M 2206/20

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

See Search History document

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	US 2016/0030706 A1 (ANGIODYNAMICS INC.) 04 February 2016; figures 4, 8b; paragraphs 0006, 0009, 0030, 0036, 0038, 0039; abstract; claim 3	1-13, 15-21 — 14
X	US 2016/0135829 A1 (ANGIODYNAMICS INC.) 19 May 2016; figures 2a-4c, 7; paragraphs 0037, 0049	22-24
Y	US 2006/0264905 A1 (ESKRIDGE ET AL.) 23 November 2006; paragraphs 0005, 0027	14
A	US 5,244,619 A (BURNHAM) 14 September 1993; entire document	1-24
A	US 2017/0021130 A1 (DYE) 26 January 2017; entire document	1-24

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

* 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

"Z" document member of the same patent family

Date of the actual completion of the international search

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Date of mailing of the international search report

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Name and mailing address of the ISA/

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Authorized officer

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

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: Matthew S. Williams
Perkins Coie LLP
P.O. Box 1247
Seattle, WA 98111-1247
United States Of America

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Applicant's or agent's file reference
111552-8035WC00

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US23/61256

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ADD. A61B 2017/22079; A61B 2217/005; A61M 25/0023; A61M 2025/0073; A61M 2206/16; A61M 2206/20

Applicant INARI MEDICAL, INC.

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

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

2. **FURTHER ACTION**

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

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

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

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Date of completion of this opinion

24 April 2023 (24.04.2023)

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US23/61258

Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(b)).
3. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of a sequence listing:
a. ☐ forming part of the international application as filed.
b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13ter.1(a)).
☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.
4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US23/61256

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

1. Statement

Novelty (N)	Claims	14	YES
	Claims	1-13, 15-24	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-24	NO
Industrial applicability (IA)	Claims	1-24	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-3, 7-10, 15, and 17-21 lack novelty under PCT Article 33(2) as being anticipated by AngioDynamics, Inc. US 2016/0030706 A1 (AngioDynamics).

As to claim 1, AngioDynamics teaches an aspiration catheter (30), comprising: a proximal terminus; a distal terminus; and an inner surface defining a lumen (para [0009]), wherein the inner surface includes at least one groove formed therein (channels 33) and that extends from the distal terminus at least partially toward the proximal terminus (fig. 4).

As to claim 2, AngioDynamics teaches the aspiration catheter of claim 1 wherein the at least one groove extends from the distal terminus to the proximal terminus (para [0036]; claim 3).

As to claim 3, AngioDynamics teaches the aspiration catheter of claim 1 wherein the lumen extends along a longitudinal axis, and wherein the at least one groove revolves circumferentially about the longitudinal axis between the proximal terminus and the distal terminus (abstract; para [0009]; para [0030]).

As to claim 7, AngioDynamics teaches the aspiration catheter of claim 1 wherein the at least one groove has a spiral shape (abstract; para [0009]; para [0030]).

As to claim 8, AngioDynamics teaches the aspiration catheter of claim 1 wherein the at least one groove comprises a plurality of grooves (fig. 4; abstract; para [0009]; para [0030]).

As to claim 9, AngioDynamics teaches the aspiration catheter of claim 8 wherein the plurality of grooves are equally spaced apart about a circumference of the inner surface (fig. 4; see cross-section in fig. 8b).

As to claim 10, AngioDynamics teaches the aspiration catheter of claim 8 wherein the lumen extends along a longitudinal axis, and wherein the plurality of grooves revolves circumferentially about the longitudinal axis between the proximal terminus and the distal terminus (para [0036]; claim 3).

As to claim 15, AngioDynamics teaches an aspiration catheter (30), comprising: a proximal terminus; a distal terminus; and an inner surface defining a lumen extending along a longitudinal axis (para [0009]), wherein the inner surface includes a plurality of grooves formed therein (channels 33), wherein the grooves extend at least partially between the distal terminus and the proximal terminus (fig. 4), and wherein the grooves revolve circumferentially about the longitudinal axis between the distal terminus and the proximal terminus (abstract; para [0009]; para [0030]).

As to claim 17, AngioDynamics teaches the aspiration catheter of claim 15 wherein the grooves are equally spaced about a circumference of the inner surface (fig. 4; see cross-section in fig. 8b).

As to claim 18, AngioDynamics teaches the aspiration catheter of claim 15 wherein the grooves extend to the distal terminus (para [0036]; claim 3).

As to claim 19, AngioDynamics teaches the aspiration catheter of claim 15 wherein the grooves extend entirely between the distal terminus and proximal terminus (para [0036]; claim 3).

As to claim 20, AngioDynamics teaches a system for removing material from within a lumen of a human patient, the system comprising: an aspiration catheter (30) configured to be positioned at a treatment site proximate to the material within the lumen, wherein the aspiration catheter comprises a proximal terminus; a distal terminus; and an inner surface defining a lumen (para [0009]), wherein the inner surface includes at least one groove formed therein (channels 33) and that extends from the distal terminus at least partially toward the proximal terminus (fig. 4); a tubing assembly fluidly coupled to the catheter (connected to a port or syringe; para [0036], [0009]) and including a fluid control device (power aspiration para [0008] or syringe 110); and a pressure source fluidly coupled to the tubing assembly and configured to generate negative pressure (power aspiration para [0008] or syringe 110; para [0039]), wherein the fluid control device is movable

Continued in Supplemental Box.

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International application No.

PCT/US23/61256

Supplemental Box

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Continuation of:

-Continued From Box V, 2: Citations and Explanations-

between (a) a first position in which the pressure source is fluidly connected to the aspiration catheter via the tubing assembly and (b) a second position in which the pressure source is fluidly disconnected from the aspiration catheter (the catheter is fully capable of being connected and disconnected from pressure source).

As to claim 21, AngioDynamics teaches the system of claim 20 wherein the lumen extends along a longitudinal axis, wherein the at least one groove includes a plurality of grooves (fig. 4), wherein the grooves are equally spaced about a circumference of the inner surface (fig. 4; see cross-section in fig. 8b), wherein the grooves extend at least partially from the distal terminus to the proximal terminus (fig. 4), and wherein the grooves revolve circumferentially about the longitudinal axis between the proximal terminus and the distal terminus (abstract; para [0009], para [0030]).

Claims 22-24 lack novelty under PCT Article 33(2) as being anticipated by AngioDynamics US 2016/0135629 A1 (AngioDynamics2).

As to claim 22, AngioDynamics2 teaches a method for removing material from within a lumen of a human patient, the method comprising: positioning a distal portion of an aspiration catheter proximate to the material within the lumen (figs. 2a-4c), wherein the aspiration catheter includes an inner surface having at least one groove formed therein (para [0037]), and wherein the at least one groove extends from a distal terminus of the aspiration catheter at least partially toward a proximal terminus of the aspiration catheter (para [0037]); coupling a pressure source to the aspiration catheter via a fluid control device (para [0049]), wherein (a) opening of the fluid control device fluidly connects the pressure source to the aspiration catheter and (b) closing of the fluid control device fluidly disconnects the pressure source from the aspiration catheter; activating the pressure source to generate a vacuum while the fluid control device is closed; and opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the material into the aspiration catheter (it is well known that powering on a vacuum pump will open/activate will connect a vacuum, and powering off the pump will close disconnect a vacuum).

As to claim 23, AngioDynamics2 teaches the method of claim 22 wherein the at least one groove defines a leak path past the clot material when the clot material is aspirated into the aspiration catheter (channels form paths).

As to claim 24, AngioDynamics2 teaches the method of claim 22 wherein the at least one groove generates a helical flow pattern in the lumen when the clot material is aspirated into the aspiration catheter (para [0037], [0039], fig. 7).

Claims 4-6, 11-13, and 16 lack an inventive step under PCT Article 33(3) as being obvious over AngioDynamics.

As to claims 4-6, AngioDynamics teaches the aspiration catheter of claim 3. It should be noted that AngioDynamics fails to specifically teach the at least one groove revolves about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch. AngioDynamics does teach that the pitch of the grooves can be used to optimize flow rate depending of the procedure (para [0035]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the grooves revolves about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made for the grooves of AngioDynamics to revolve about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch depending on the desired effect during a procedure (para [0035]).

As to claims 11-13, AngioDynamics teaches the aspiration catheter of claim 10. It should be noted that AngioDynamics fails to specifically teach the plurality of grooves revolves about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch. AngioDynamics does teach that the pitch of the grooves can be used to optimize flow rate depending of the procedure (para [0035]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the grooves revolves about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made for the grooves of AngioDynamics to revolve about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch depending on the desired effect during a procedure (para [0035]).

As to claims 16, AngioDynamics teaches the aspiration catheter of claim 15. It should be noted that AngioDynamics fails to specifically teach the at least one groove revolves between: about 0.13-0.15 times per inch. AngioDynamics does teach that the pitch of the grooves can be used to optimize flow rate depending of the procedure (para [0035]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the grooves revolves about 0.13-0.15 times per inch, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made for the grooves of AngioDynamics to revolve about 0.13-0.15 times per inch depending on the desired effect during a procedure (para [0035]).

Claim 14 lacks an inventive step under PCT Article 33(3) as being obvious over AngioDynamics in view of Eskridge et al. US 2006/0264905 A1 (Eskridge).

As to claim 14, AngioDynamics teaches the aspiration catheter of claim 1. It should be noted that AngioDynamics fail to teaches wherein the catheter further comprises: an inner liner having the inner surface, wherein the at least one groove is formed in the inner liner; a braid of wires over the inner liner; a wire coiled over the inner liner; and an outer sheath over the braid, the wire, and the inner liner. AngioDynamics does teach the desire to prevent pinching or collapsing of the catheter when negative pressure is applied (para [0007]).

-Continued Within the Next Supplemental Box-

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PCT/US23/61256

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Eskridge teaches multi-layered catheter construction is well known in the art, and it is well known to combinations of liners, coils, and braids to prevent kinks (para {0005}, {0027}). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter of AngioDynamics to include the liner, coil, and braid of Eskridge to prevent pinching or collapsing of the catheter by increasing stiffness while still providing flexibility (para {0005}, {0027}).

Claims 1-24 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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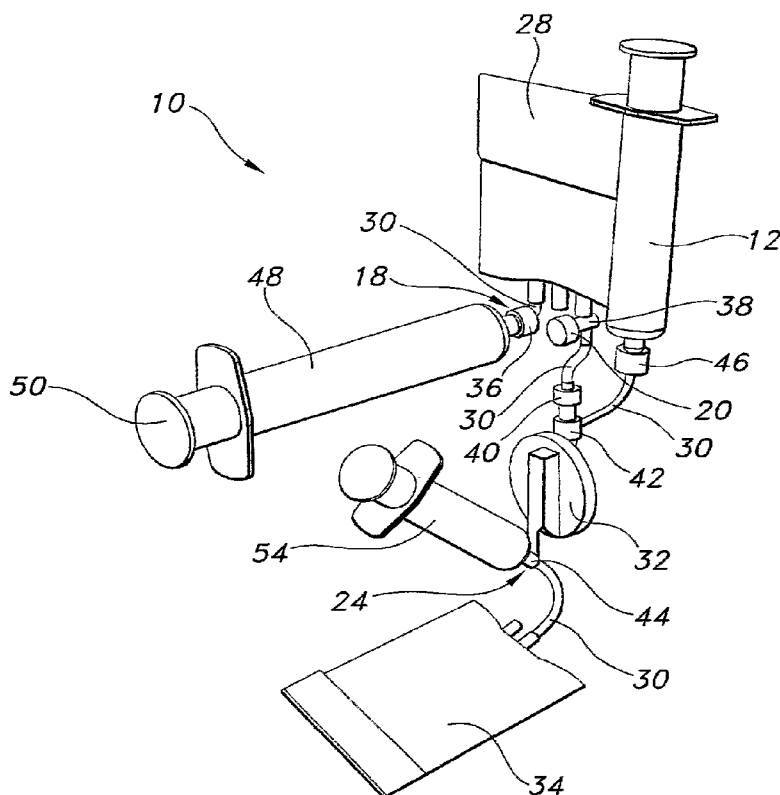
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[Continued on next page]

(54) Title: METHODS AND DEVICES FOR STERILE FIELD TRANSFER



(57) Abstract: Devices and methods for facilitating the transfer of at least a component of a material into a sterile vessel (12). Such devices and methods may utilize a housing (14) at least partially enclosing the sterile vessel to facilitate maintaining the sterility of the vessel before and during the transfer of the at least a component of a material into the sterile vessel.

WO 2006/029270 A1



-
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*
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METHODS AND DEVICES FOR STERILE FIELD TRANSFER

RELATED APPLICATIONS

This application claims the benefit of United States Provisional Patent Application Serial No. 60/607,631, entitled "Sterile Field Transfer Method and Design" filed September 7, 2004, the entire contents of which are hereby incorporated by this reference.

RELATED FIELDS

Embodiments of the present invention relate to methods and devices for transferring at least a component of a material into a sterile vessel for use in a sterile field.

BACKGROUND

It is often necessary to ensure that items used in a sterile field, such as an operating room, research & development facility, or other sterile environment, are themselves sterile. Instruments, devices, containers, implants and other items intended for use in the sterile field may require sterilization and may need to be maintained in a sterile condition. Items that are non-sterile, or that potentially have contacted other non-sterile items or non-sterile persons (such as doctors, technicians or nurses who have come into contact with non-sterile items), may be unacceptable for use in the sterile field. Accordingly, doctors, nurses, technicians and other individuals working in or around sterile fields must follow strict guidelines and procedures for ensuring the sterility of items brought into and/or used in the sterile field. Some of the current sterilization procedures and guidelines, however, are undesirable, burdensome and inefficient.

For example, typical procedures for collecting and transporting blood platelets into a sterile field may be undesirable, as those procedures may require the transfer of the platelets between a number of different containers and devices. Typically, the nurse, technician, doctor or other individual collects a blood sample in a syringe. Next, he or she transfers the blood into a centrifuge. The centrifuge processes the blood to concentrate the blood platelets. Next, the

concentrated blood platelets are collected into another syringe and subsequently transferred into a sterile cup. The sterile cup is finally brought into the sterile field where it can be drawn into a sterile syringe. Such a technique is undesirable, as it requires the blood and blood platelets to be transferred multiple times from vessel to vessel in a manner that is inefficient and subject to spillage or even accidental contamination.

Other procedures, techniques and guidelines for ensuring the sterility of items used in sterile fields may also be undesirable, burdensome and inefficient.

SUMMARY

Embodiments of the present invention provide safe and efficient methods and devices for transferring a material or a component of a material from a non-sterile vessel or potentially non-sterile vessel into a sterile vessel, while maintaining the sterility of the sterile vessel. Embodiments of the present invention may be suitable for transferring a wide variety of materials or material components into a sterile vessel, including, but not limited to, blood, blood components (such as platelets or blood plasma), bone cement, ceramics, allogenic bone, autologous bone, bone marrow, other fluids, polymers, composite materials, nanomaterials, or any other material or material component that is intended for use in a sterile field. Devices according to various embodiments of the present invention may also process the materials or material components introduced into the device prior to or during transfer into the sterile vessel. Exemplary processes include, but are not limited to, filtration to separate larger components of a material from smaller components (e.g, filtering blood to separate the platelets from other blood components), mixing materials together, separating materials, reacting various materials together, instrument fabrication, implant fabrication, sterilization or any other process that may be done to a material or a material component prior to use in a sterile field. In other embodiments, devices of the present invention do not process the materials introduced into them at all, but merely facilitate the material transfer into the sterile vessel without affecting the sterility of the sterile vessel.

Devices of the present invention may include a sterile vessel and a housing at least partially enclosing the sterile vessel. The device housing may enclose the sterile vessel to protect the vessel from direct contact with potentially non-sterile persons and items, which could potentially affect the sterility of the sterile vessel and prevent use of the vessel in the sterile field. In some embodiments, the housing may include a cover that limits access to the sterile vessel until the cover is removed or opened. In other embodiments, such a cover is unnecessary.

Devices according to the present invention may also include a material input accessible from outside the housing. The material input may facilitate the introduction of a material into the device, which eventually may be transferred by the device (or a component of the material may be transferred by the device) into the sterile vessel. In some embodiments, the material input interacts with a non-sterile syringe or other vessel external to the device. In some embodiments, the material input is associated with a conduit within the device that conveys the material to various internal components of the device (such as a filter) and to the sterile vessel. In other embodiments, the conduit is integral with the material input and conveys the material directly into the sterile vessel.

Some embodiments of the present invention may also include internal components, such as filters or other components, for processing the inputted material. In some embodiments, the device may also include additional material inputs and/or internal components for introducing and/or processing additional materials in the device. The additional materials introduced may facilitate various processes of the device and/or may facilitate the movement of other materials (or components thereof) within and between various internal components of the device. In other embodiments, the device does not include such components and merely conveys the material directly into the sterile vessel.

In some embodiments, the device is disposed of after use and is made with relatively inexpensive materials.

STATEMENT OF THE INVENTION

Accordingly, embodiments of the present invention provide for a device for facilitating the transfer of at least a component of a material into a sterile vessel, characterized in that the device comprises: a sterile vessel; a housing at least partially enclosing the sterile vessel; a material input for facilitating the input of a material into the device, the material input accessible from outside the housing; and a conduit for guiding movement of at least a component of the material from the material input to the sterile vessel.

More preferably, embodiments of the present invention provide for a device further characterized in that the housing comprises a cover and wherein moving the cover facilitates accessing the sterile vessel.

Even more preferably, embodiments of the present invention provide for a device further characterized in that the cover is at least temporarily sealed on the device.

Also even more preferably, embodiments of the present invention provide for a device further characterized in that the cover comprises a removable cap or a moveable hatch.

Yet even more preferably, embodiments of the present invention provide for a device further characterized in that the housing comprises an at least semi-transparent window.

Also even more preferably, embodiments of the present invention provide for a device further characterized in that the housing comprises at least one actuator for actuating at least one valve, the at least one valve for at least partially regulating the movement of the at least a component of a material through the conduit.

Also more preferably, embodiments of the present invention provide for a device further characterized in that the device comprises a reservoir associated with the conduit.

Even more preferably, embodiments of the present invention provide for a device further characterized in that the reservoir is associated with the material input and receives material from the material input.

Also more preferably, embodiments of the present invention provide for a device further characterized in that the device comprises a filter for separating the component from a second component of the material.

Even more preferably, embodiments of the present invention provide for a device further characterized in that the conduit directs the component into the sterile vessel.

Yet even more preferably, embodiments of the present invention provide for a device further characterized in that the device comprises a second material input for receiving a second material, wherein introduction of the second material into the device facilitates moving the component from the filter to the sterile vessel.

Also yet even more preferably, embodiments of the present invention provide for a device further characterized in that the device comprises a second reservoir for collecting the second component from the filter.

Other embodiments of the present invention provide for a method for facilitating the transfer of at least a component of a material into a sterile field, characterized in that the method comprises: collecting a material into a vessel; transferring the material from the vessel into a device, characterized in that the device comprises: a sterile vessel; and a housing at least partially enclosing the sterile vessel; transporting the sterile vessel into a sterile field; and removing the sterile vessel from the device.

More preferably, embodiments of the present invention provide for a method further characterized in that the sterile vessel is transported into the sterile field prior to removing the sterile vessel from the device.

Also more preferably, embodiments of the present invention provide for a method further characterized in that the sterile vessel is removed from the device prior to transporting the sterile vessel into the sterile field.

Also more preferably, embodiments of the present invention provide for a method further characterized in that removing the sterile vessel from the device comprises moving a cover of the housing of the device to access the sterile vessel.

Even more preferably, embodiments of the present invention provide for a method further characterized in that moving the cover comprises removing the cover from the device.

Also even more preferably, embodiments of the present invention provide for a method further characterized in that moving the cover comprises opening a hatch.

Also more preferably, embodiments of the present invention provide for a method further characterized in that the method comprises filtering the material to separate the material into a first component and a second component.

Also more preferably, embodiments of the present invention provide for a method further characterized in that the method comprises disposing of the device.

BRIEF DESCRIPTION OF FIGURES

Figure 1 is a schematic of a device according to a first embodiment of the present invention.

Figure 2 is a perspective view of a device according to another embodiment of the present invention, shown without the device's housing.

Figure 3 is a perspective view of a device according to another embodiment of the present invention, shown without the device's housing.

Figure 4 is a perspective view of a device according to another embodiment of the present invention, shown without the device's housing.

Figure 5(a) is a perspective view of the exterior of a device according to another embodiment of the present invention.

Figure 5(b) is a side view of the device of Fig. 5(a).

Figure 6(a) is a perspective view of the exterior of a device according to another embodiment of the present invention.

Figure 6(b) is a side view of the device of Fig. 6(a).

Figure 6(c) is a rear perspective view of the device of Fig. 6(a).

Figure 7(a) is a perspective view of the exterior of a device according to another embodiment of the present invention.

Figure 7(b) is a side view of the device of Fig. 7(a).

Figure 8(a) is a perspective view of the exterior of a device according to another embodiment of the present invention.

Figure 8(b) is a side view of the device of Fig. 8(a).

Figure 9(a) is a perspective view of the exterior of a device according to another embodiment of the present invention.

Figure 9(b) is a side view of the device of Fig. 9(a).

DETAILED DESCRIPTION OF FIGURES

Fig. 1 shows a device 10 in accordance with embodiments of the present invention. In the configuration shown in Fig. 1, device 10 includes a sterile vessel 12, a housing 14 (which includes a cover 16), a material input 18, an actuator 20, a window 22, a second material input 24, a base 26, and a seal 100. In other embodiments, some or all of these features are unnecessary and/or are present in different configurations, positions, orientations, shapes and sizes.

The sterile vessel 12 shown in Fig. 1 is a syringe, however, sterile vessel may be any vessel suitable for receiving materials or components of materials, including test tubes, beakers, vials, IV bags, sample holders, pails, cups, bowls, trays, or gloved hands. Sterile vessel 12 may be sterilized prior to installation in device 10 or sterilized along with the rest of device 10 or components of device 10. Sterile vessel 12 (and other components of device 10 if desired or required) may be sterilized in any suitable procedure or technique, including, but not limited to, gas sterilization or gamma radiation. In other embodiments, it is unnecessary to subject sterile vessel 12 and/or other components of device 10 to a sterilization procedure and/or the sterile vessel may have been maintained in a sterile condition since its manufacture.

The housing 14 shown in Fig. 1 encloses sterile vessel 12. Housing 14 is preferably formed from a plastic, such as polycarbonate, however, housing 14 may be formed from other materials if desired. In some embodiments, it is desirable to form housing 14 (and other components of device 10) from relatively inexpensive materials, as device 10 may be intended to be disposable or intended for "one time use" in some configurations.

Because the housing 14 shown in Fig. 1 encloses sterile vessel 12, the sterility of vessel 12 may be preserved even if device 10 is used in non-sterile fields or comes into contact with non-sterile persons or things. In the embodiment of Fig. 1, the housing 14 (which includes the cover 16 in the configuration shown in Fig. 1) preserves the sterility of vessel 12 until such time as cover 16 is removed or repositioned to allow access to sterile vessel 12 by a sterile nurse, doctor, technician or other individual for use in a sterile field. In some embodiments, a non-sterile individual will remove or reposition the cover 16 and a sterile individual will remove the sterile vessel 12 such that the vessel 12 does not contact non-sterile persons or things and such that the sterile person does not contact the potentially non-sterile housing 14 of device 10. In other embodiments, device 10 may be configured to automatically move the cover 16 or otherwise facilitate access to sterile vessel 12 after the occurrence of one or more events. For instance, in some embodiments, the transfer or completion of transfer of a material into sterile vessel 12 may trigger the device 10 to automatically move the cover 16 or otherwise facilitate accessing vessel 12.

In some embodiments, one person will transport the device 10 into the sterile field and the sterile person will remove the sterile vessel 12. In other embodiments, the sterile person will remove the sterile vessel 12 from the device 10 outside of the sterile field, and then enter the sterile field with the sterile vessel 12.

As shown in Fig. 1, cover 16 is a removable lid. In other embodiments, a cover 16 similar to the one shown in Fig. 1 can be used in conjunction with the devices 10 shown in Figs. 5(a), 5(b), 7(a), 7(b), 8(a), 8(b), 9(a) and 9(b), although the devices 10 shown in these Figures may not necessarily require such a cover in all embodiments. In still other embodiments, such as shown in Fig. 6(c), cover 16 may be a hatch mounted to device 10 in a rotating fashion.

As shown in Fig. 1, cover 16 includes a removable or breakable seal 100 for indicating whether sterile vessel 12 has been previously accessed or tampered with (indicating a potential loss of sterility). A user (in some embodiments, the non-sterile nurse, doctor, technician or other non-sterile individual) may break or remove the seal 100 and remove or reposition the cover

16 to allow access to sterile vessel 12. The seal 100 may be any desired mechanism, structure, device or item for sealing cover 16 onto device 10, including frangible tabs, adhesive tape, gaskets, tamper indicating mechanisms, or any other suitable structure or mechanism for sealing cover 16 prior to removal or repositioning. Fig. 1 shows seal 100 as an adhesive tape at least partially encircling the connection between cover 16 and the rest of housing 14. In still other embodiments, a separate mechanism, structure, device or item is not necessary to seal cover 16 to the rest of housing 14 and the cover is formed integrally with the rest of housing 14. In such embodiments, cover 16 may be punctured, broken or otherwise destroyed once it is desired to access sterile vessel 12. In other embodiments, a seal is unnecessary.

In yet other embodiments, cover 16 is unnecessary. For example, the housing 14 may include an aperture in which sterile vessel 12 is located. Sterile vessel 12 may be positioned deep enough within the housing 14 such that non-sterile persons or things cannot easily contact sterile vessel 12. In such embodiments, device 10 may include a slider or other mechanism for facilitating access to the sterile vessel 12 at the appropriate time. For example, in some embodiments, actuation of the slider may raise sterile vessel 12 into an accessible position. In other embodiments, as the sterile vessel 12 fills with material (described further below), a plunger of the vessel may extend outside of the housing, allowing a sterile nurse, doctor or technician to grasp the end of the plunger and remove sterile vessel 12 from device 10. In some embodiments, the housing 14 may include a plastic film over the aperture or other portions of the housing 14, such that breaking the film allows access to the vessel 12.

The device 10 of Fig. 1 also includes a material input 18. As discussed above, material may be any material that a user desires to transfer into a sterile vessel 12, including blood, blood components (such as platelets or blood plasma), bone cement, ceramics, allogenic bone, autologous bone, bone marrow, other fluids, or any other material. Material input 18 may be configured to receive and convey any desired material into device 10. In one embodiment, material input 18 includes an aperture that corresponds to the size and shape of a syringe tip such that material input 18 receives the tip in a manner that substantially

prevents leakage. In some embodiments, material input 18 is an aperture in housing 14 that allows the syringe or other vessel to interact with internal components such that the syringe can introduce material into device 10. Material input 18 may also include a gasket or other appropriate structures or mechanisms for lessening the chance of leakage. In other embodiments, material input 18 does not interact with a syringe to receive material, but is sized, shaped and positioned for material to be poured directly into material input 18. For example, in some embodiments, material input 18 may be a funnel.

In still other embodiments, material input 18 may comprise other structures or mechanisms for facilitating the input of material into device 10. Additionally, material input 18 may or may not include a check valve or other appropriate structures and mechanisms for preventing material from flowing back out of material input. In some embodiments, material input 18 may include a filter, such as a screen, or other structure for separating impurities or other things from material during input into device 10.

The device 10 shown in Fig. 1 also includes an actuator 20. The actuator 20 may be a slide (such as shown in Figs. 1 and 5(a)), a knob, a button (such as shown in Figs. 6(a), 7(a), 8(a) and 9(a)) or other suitable structure or mechanism for commencing processes or otherwise affecting structures inside device 10, some examples of which are discussed further below. Although Fig. 1 shows device 10 as only including a single actuator 20, devices 10 in accordance with embodiments of this invention may include any number of actuators 20 for controlling or affecting various internal components of device 10. In still other embodiments, an actuator 20 is unnecessary.

The device 10 of Fig. 1 also includes a window 22. In some embodiments, window 22 may be a transparent or semi-transparent window. Window 22 may allow viewing of one or more of the internal components of device 10 and/or the progress of the inputted material through the same. As shown in Figs. 1, 5(a), 6(a), 7(a), 8(a) and 9(a), the size, shape, number and position of windows 22 may be varied to facilitate viewing various interior portions and/or components of device 10. In other embodiments, window 22 is unnecessary and/or other features of device 10 indicate the progress of the inputted material through

device 10. For example, sterile vessel 12 may include a plunger that extends as material fills the vessel 12, which may roughly indicate the amount of material that has moved into the vessel. In some embodiments, device 10 does not include any features or components for indicating the progress of material through device 10.

In the configuration shown in Fig. 1, device 10 includes a second material input 24. Like embodiments of material input 18 described above, second material input 24 may interact with the tip of a syringe 54 (shown in Figs. 2 – 4) to receive and convey a material into device 10 or may include other structures and mechanisms as discussed above for material input 18. Second material input 24 is also discussed further below.

In the configuration shown in Fig. 1, device 10 also includes a base 26. Base 26 may maintain the device 10 in an upright orientation when placed on a surface. Moreover, if desired, a user may push down on base 26 to stabilize device 10 during use. As shown in Figs. 5(a) – 9(b), base 26 may be formed in a wide variety of shapes, sizes and configurations.

The devices 10 shown in Figs. 1 – 9(b) are configured to separate the platelet component of a blood material and transfer those platelets into sterile vessel 12. Devices 10 in accordance with other embodiments of the present invention, however, may be configured to perform a wide variety of processes on a wide variety of materials. Exemplary processes include, but are not limited to, filtering, mixing, separating, reacting, fabrication, or sterilization. In still other embodiments, device 10 does not process the inputted material at all, but merely transfers the material into sterile vessel 12. Exemplary materials useable in conjunction with devices 10 in accordance with the present invention are discussed above.

Figs. 2 - 4 illustrate various configurations of internal components of device 10 for filtering and transferring the blood platelet component of an inputted blood material into sterile vessel 12. As shown in Figs. 2 - 4, the locations and orientations of the internal components can be varied based on the shape and size of housing 14 (e.g., the configuration of Fig. 2 may be suitable for the housings 14 of Figs. 5(a), 5(b), 7(a), 7(b), 8(a) and 8(b), the configuration of Fig.

3 may be suitable for the housing 14 of Figs. 6(a), 6(b) and 6(c), and the configuration of Fig. 4 may be suitable for the housing 14 of Figs. 9(a) and 9(b)). In the configurations shown in Figs. 2 - 4, device 10 includes the following internal components: material reservoir 28, conduits 30, filter 32, waste reservoir 34, and various valves 36, 38, 40, 42, 44 and 46. Device 10 configurations in accordance with other embodiments of the present invention may exclude some or all of these components and/or include other components.

In the configurations of Figs. 2 - 4, introduction of blood material into device 10 via material input 18 (as discussed above) directs the material into material reservoir 28. Syringe 48 interacts with material input 18 to facilitate the introduction of blood material into device 10 in the embodiments of Figs. 2 - 4, however, other vessels, devices or methods can also be used to introduce a material into devices 10 in accordance with the present invention (some examples of which, but not all, are discussed above). In the configurations of Figs. 2 - 4, depressing a plunger 50 associated with the syringe 48 may increase the pressure on blood material within syringe 48, causing it to flow through material input 18 into material reservoir 28.

Figs. 2 - 4 show a conduit 30 for directing material from syringe 48 into material reservoir 28. Other portions of conduit 30 shown in Figs. 2 - 4 direct the movement of materials and components of materials between other components of device 10. In the embodiments shown in Figs. 2 - 4, conduit 30 is a plastic tubing, although in other embodiments, conduit 30 may be any suitable device, structure or mechanism for containing and/or facilitating the movement of material between various components of device 10. In some embodiments, integral portions of material input 18 are a conduit for directing material into material reservoir 28 or other components of device 10.

The devices 10 of Figs. 2 - 4 include a check valve 36 positioned where material is input into material reservoir 28. Check valve 36 may regulate the flow of material such that material can enter material reservoir 28 through check valve 36, but may not exit material reservoir 28 through check valve 36. Check valve 36 may prevent leakage of material from device 10 once the material has entered material reservoir 28. In other embodiments, check valve 36 is unnecessary. For

example, material reservoir 28 may be a sufficient size to contain the material from syringe 48 and/or may include the material input at an upper portion of the reservoir to lessen the chance of undesired leakage.

In still other embodiments, material reservoir 28 is unnecessary and the introduced blood or other material passes directly to other internal components of the device 10 from material input 18 and/or check valve 36.

Figs. 2 – 4 show that material reservoir 28 includes another valve 38 for regulating the movement of material out of the material reservoir 28. Valve 38 may be operatively associated with actuator 20 shown in Fig. 1. Actuation of actuator 20 may open and/or close valve 38. Opening valve 38 may allow material to move from material reservoir 28 to other downstream components of device 10. In the embodiments of Figs. 2 – 4, gravity facilitates moving the material out of material reservoir 28 once valve 38 is opened by actuator 20. In other embodiments, actuator 20 is unnecessary and valve 38 may automatically open once a sufficient amount of material builds up in material reservoir 28. In still other embodiments, valve 38 is unnecessary and material can move directly from material reservoir 28 to down-stream components of device 10.

In the configuration shown in Figs. 2 – 4, once valve 38 opens, material may move from material reservoir 28 into filter 32. In the configurations of Figs. 2 – 4, wherein the material is a blood material, filter 32 may process the blood to separate platelets from other components of the blood. Filter 32 may include a screen having a plurality of apertures that allow smaller components of the blood material to pass through, while retaining the platelets that are too large to pass through the screen. Screens having different sized apertures may be used depending on the size of the components to be retained by filter 32. The components of material that pass through the screen may subsequently be directed by diverter valve 44 (discussed further below) into waste reservoir 34. In other embodiments, filter 32 may include other structures or mechanisms for separating material components from one another.

In other embodiments, the material components that pass through the filter 32 screen may be reserved while the components that are too large to pass through the screen may eventually be directed into a waste reservoir 34 or may

simply remain within the filter 32. In still other embodiments, both the material passing through the filter 32 and the material retained within the filter 32 may be reserved and collected into various vessels. In such embodiments, device 10 may include two sterile vessels to collect both material components.

In the embodiments shown in Figs. 2 – 4, a back-flush procedure may be used to transfer the material components retained in filter 32 into sterile vessel 12. During the back-flush procedure, a back-flush material may be introduced through a second material input 24 and travel through the filter 32 screen in the opposite direction that the blood or other material originally traveled through the filter 32. As the back-flush material travels through the filter 32, it may pick up the platelets or other material components reserved by the filter 32 and carry those reserved components out of the filter 32. The diverter valve 42 (discussed further below) shown in Figs. 2 – 4 may direct the back flush material carrying the reserved component into the sterile vessel. Back-flush material may be any material suitable for carrying the platelets or other material component reserved by filter 32 out of filter 32 and into sterile vessel 12, including, but not limited to, any fluid. Back-flush material may be introduced into device 10 using a syringe 54 or other suitable vessel, device or method. In other embodiments, back-flush procedures and/or back-flush materials are unnecessary.

The diverter valves 42 and 44 shown in Figs. 2 – 4 regulate the direction and sources / destinations of flow through the filter 32. During the filtration process, diverter valve 42 may be positioned to allow material to pass from material reservoir 28 into the filter 32 and diverter valve 44 may be positioned to allow the material components passing through filter 32 to move into waste reservoir 24. During the back-flush procedure, diverter valve 44 may be positioned allow the back-flush material introduced through second material input 24 to pass into filter 32 and diverter valve 42 may be positioned to allow the back-flush material and filtered component to pass into sterile vessel 12. In the embodiments shown in Figs. 2 – 4, device 10 also includes check valve 40, which may prevent back-flush material and the filtered components from entering material reservoir 28.

The diverter valves 42 and 44 shown in Figs. 2 – 4 are configured to automatically switch depending on the direction of flow through the valve body, thereby directing the material or material component to the proper component. In other embodiments, diverter valves 42 and 44 are manually switched using actuators accessible from outside of housing 14. In still other embodiments, diverter valves 42 and 44 and/or check valve 40 may be unnecessary and additional conduit or other structures may be utilized to direct the material flow through the components of device 10 in the proper directions and to the proper destinations.

In the embodiments shown in Figs. 1 and 6(a) – 8(a), device 10 includes indicia 52 for indicating the order of the various steps for processing and/or collecting blood platelets (or other materials or components of materials) into sterile vessel 12.

In some embodiments, device 10 may be disposed of after the removal of sterile vessel 12.

Modifications, additions and deletions may be made to the embodiments described above and shown in the accompanying figures without departing from the scope or spirit of the present invention.

Claims:

1. A device for facilitating the transfer of at least a component of a material into a sterile vessel, characterized in that the device comprises:
 - (a) a sterile vessel;
 - (b) a housing at least partially enclosing the sterile vessel;
 - (c) a material input for facilitating the input of a material into the device, the material input accessible from outside the housing; and
 - (d) a conduit for guiding movement of at least a component of the material from the material input to the sterile vessel.
2. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 1, further characterized in that the housing comprises a cover and wherein moving the cover facilitates accessing the sterile vessel.
3. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 2, further characterized in that the cover is at least temporarily sealed on the device.
4. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 2, further characterized in that the cover comprises a removable cap or a moveable hatch.
5. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 4, further characterized in that the housing comprises an at least semi-transparent window.
6. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 2, further characterized in that the housing comprises at least one actuator for actuating at least one valve, the at least one valve for at least partially regulating the movement of the at least a component of a material through the conduit.

7. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 1, further characterized in that the device comprises a reservoir associated with the conduit.

8. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 7, further characterized in that the reservoir is associated with the material input and receives material from the material input.

9. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 1, further characterized in that the device comprises a filter for separating the component from a second component of the material.

10. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 9, further characterized in that the conduit directs the component into the sterile vessel.

11. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 10, further characterized in that the device comprises a second material input for receiving a second material, wherein introduction of the second material into the device facilitates moving the component from the filter to the sterile vessel.

12. The device for facilitating the transfer of at least a component of a material into a sterile vessel of claim 10, further characterized in that the device comprises a second reservoir for collecting the second component from the filter.

13. A method for facilitating the transfer of at least a component of a material into a sterile field, characterized in that the method comprises:

- (a) collecting a material into a vessel;
- (b) transferring the material from the vessel into a device, characterized in that the device comprises:

- (i) a sterile vessel; and
- (ii) a housing at least partially enclosing the sterile vessel;
- (c) transporting the sterile vessel into a sterile field; and
- (d) removing the sterile vessel from the device.

14. The method for facilitating the transfer of at least a component of a material into a sterile field of claim 13, further characterized in that the sterile vessel is transported into the sterile field prior to removing the sterile vessel from the device.

15. The method for facilitating the transfer of at least a component of a material into a sterile field of claim 13, further characterized in that the sterile vessel is removed from the device prior to transporting the sterile vessel into the sterile field.

16. The method for facilitating the transfer of at least a component of a material into a sterile field of claim 13, further characterized in that removing the sterile vessel from the device comprises moving a cover of the housing of the device to access the sterile vessel.

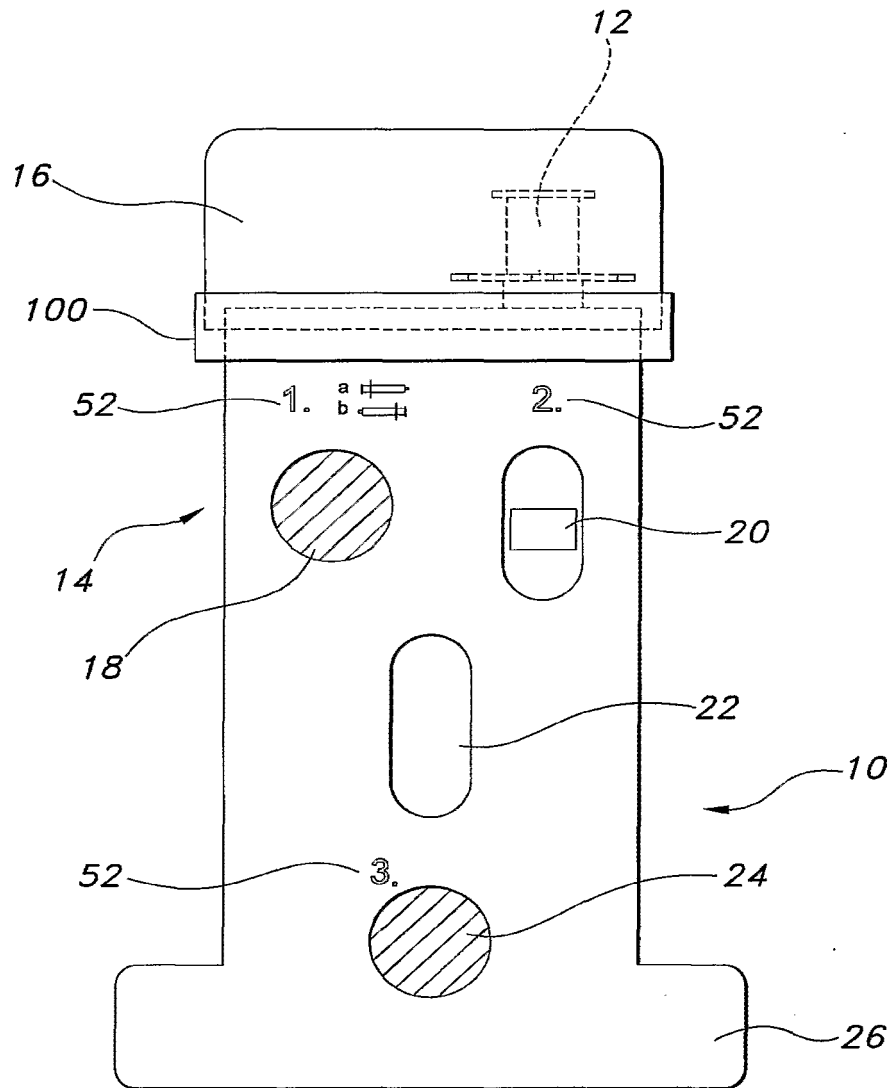
17. The method for facilitating the transfer of at least a component of a material into a sterile field of claim 16, further characterized in that moving the cover comprises removing the cover from the device.

18. The method for facilitating the transfer of at least a component of a material into a sterile field of claim 16, further characterized in that moving the cover comprises opening a hatch.

19. The method for facilitating the transfer of at least a component of a material into a sterile field of claim 13, further characterized in that the method comprises filtering the material to separate the material into a first component and a second component.

20. The method for facilitating the transfer of at least a component of a material into a sterile environment of claim 13, further characterized in that the method comprises disposing of the device.

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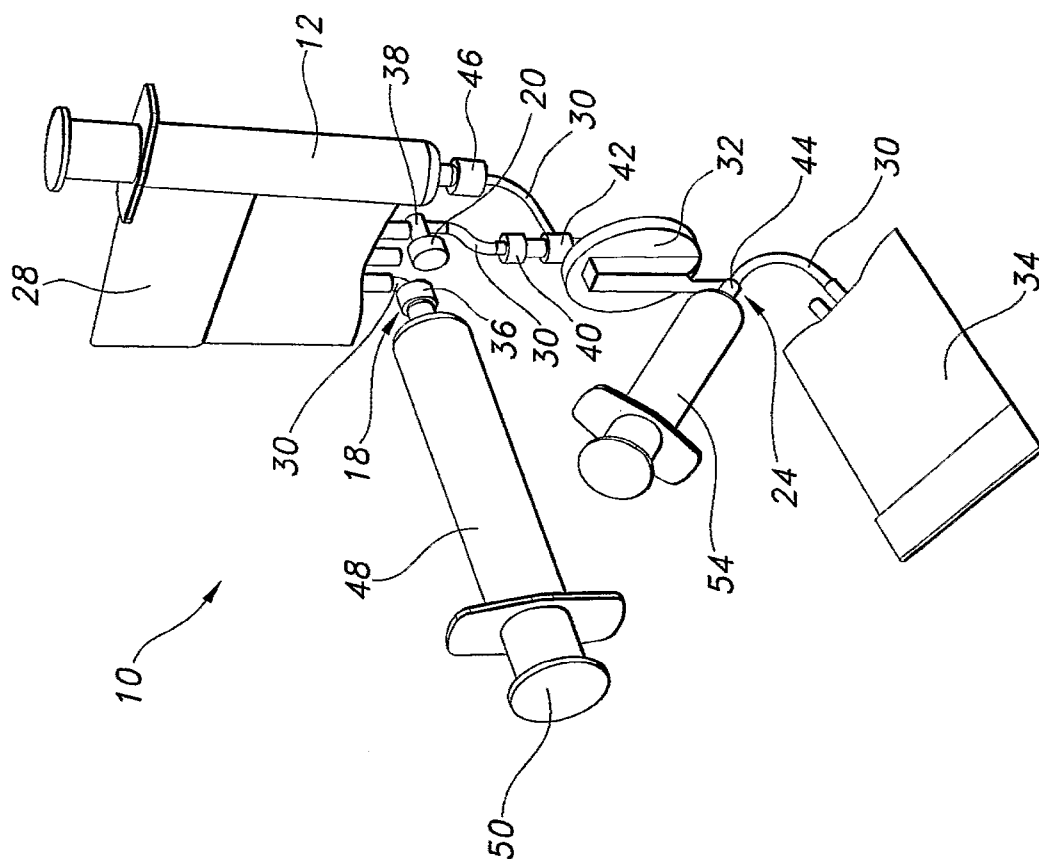
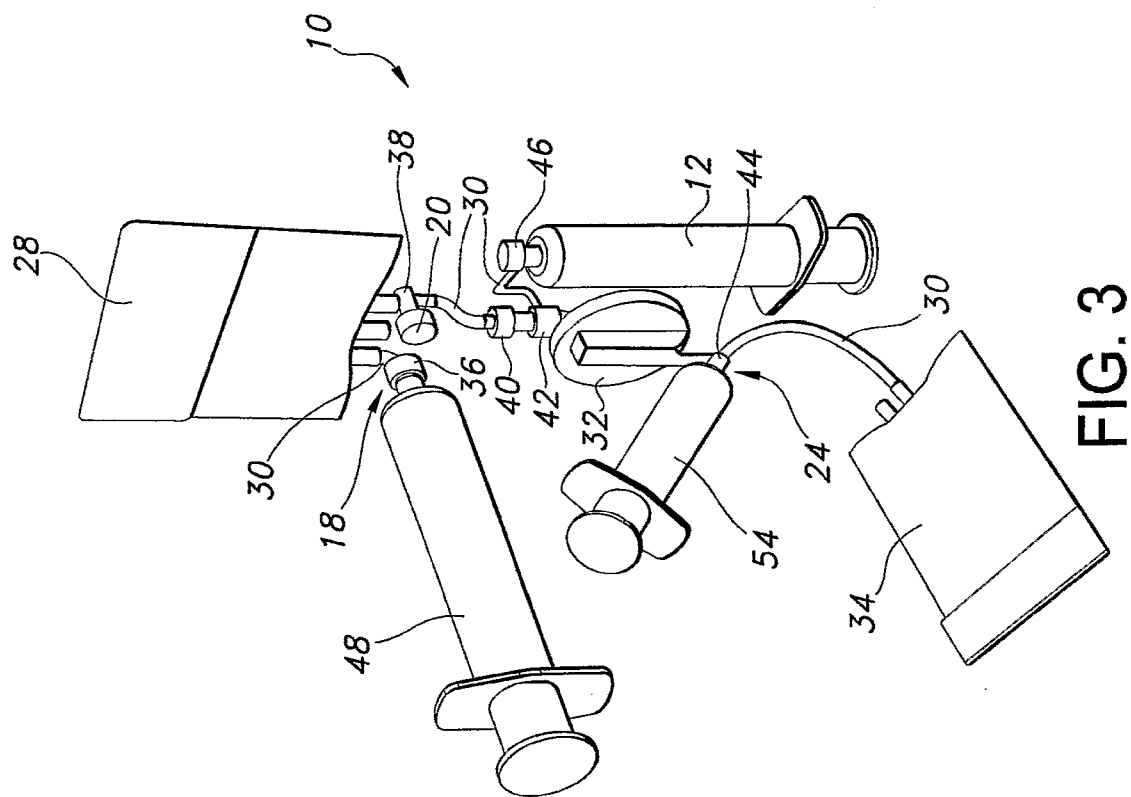


FIG. 2

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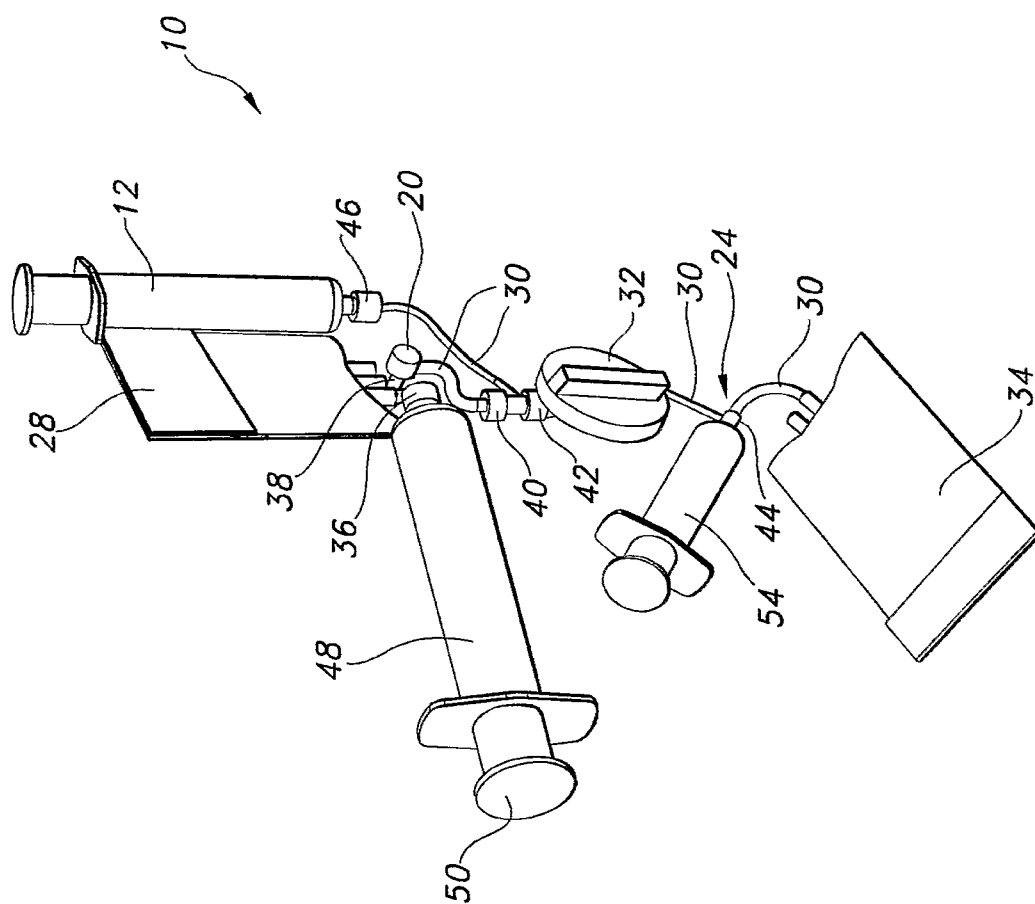


FIG. 4

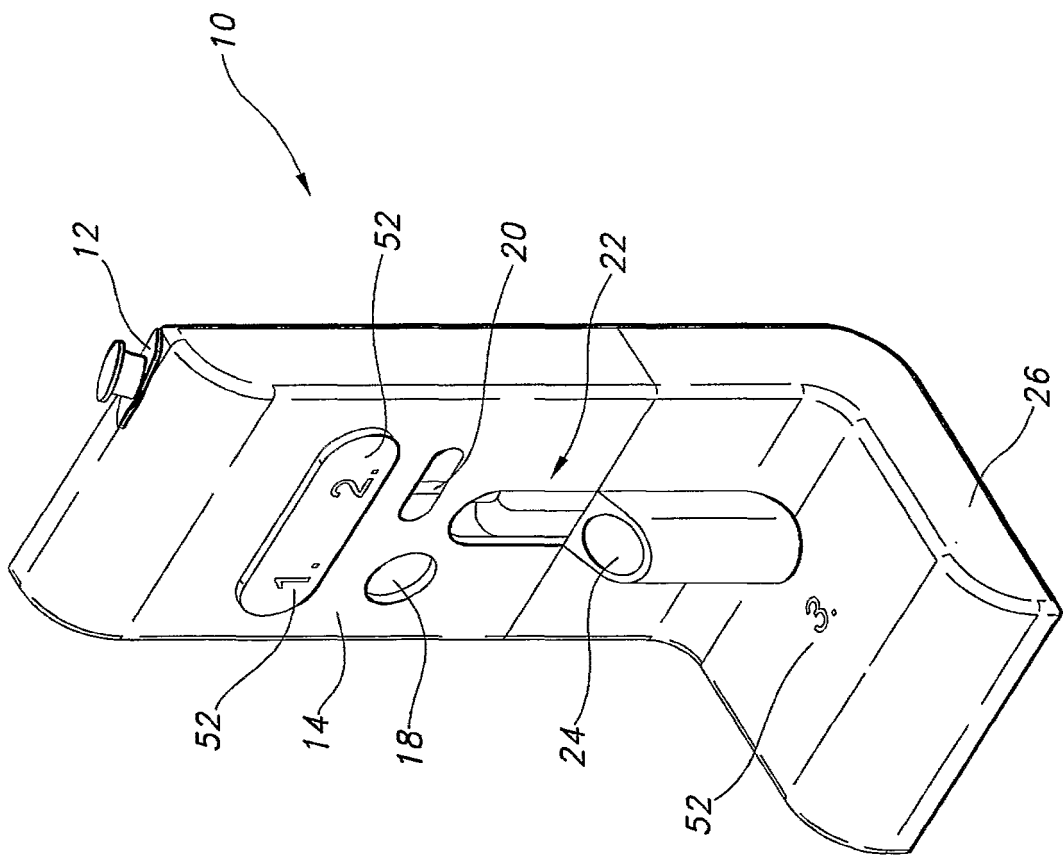


FIG. 5A

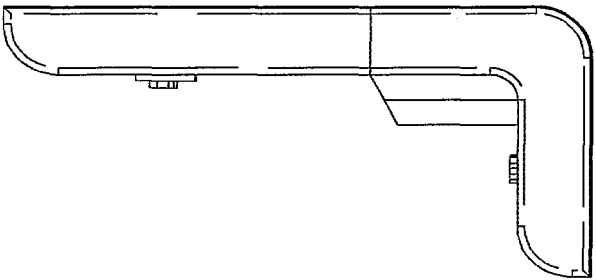


FIG. 5B

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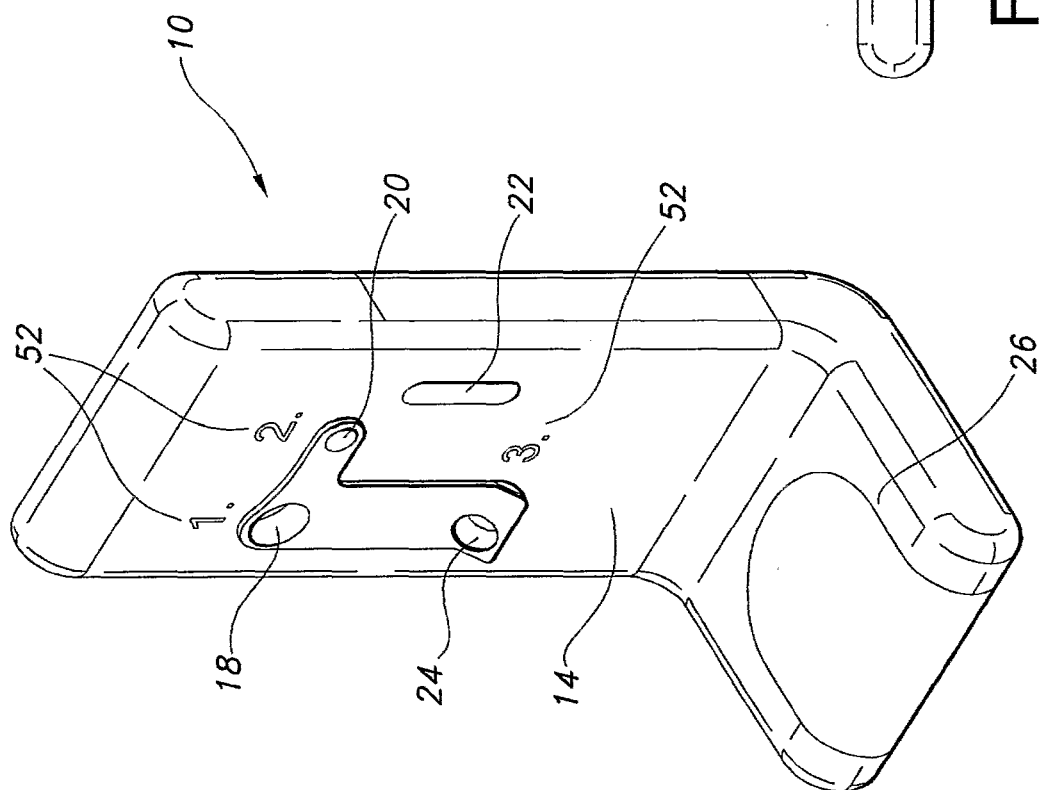


FIG. 6A

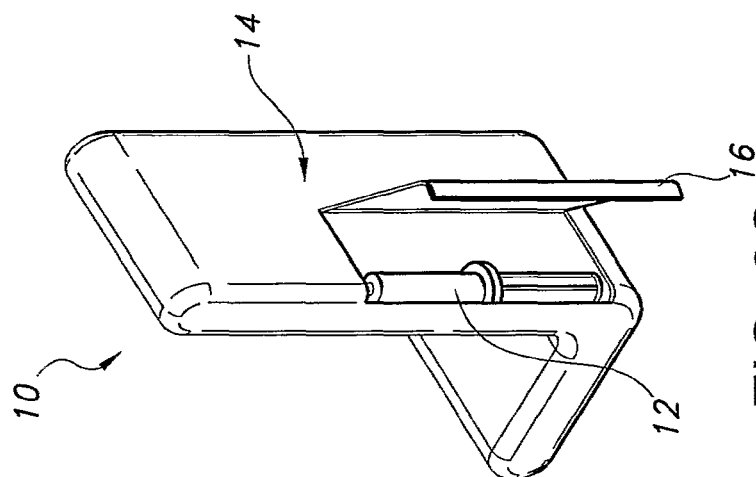


FIG. 6C

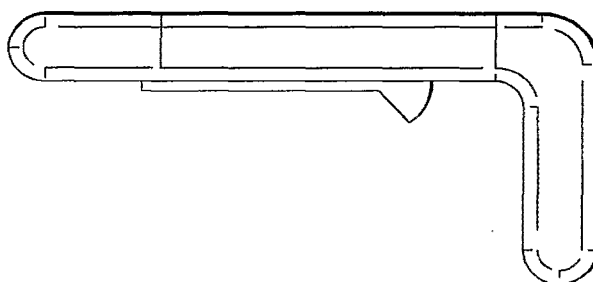


FIG. 6B

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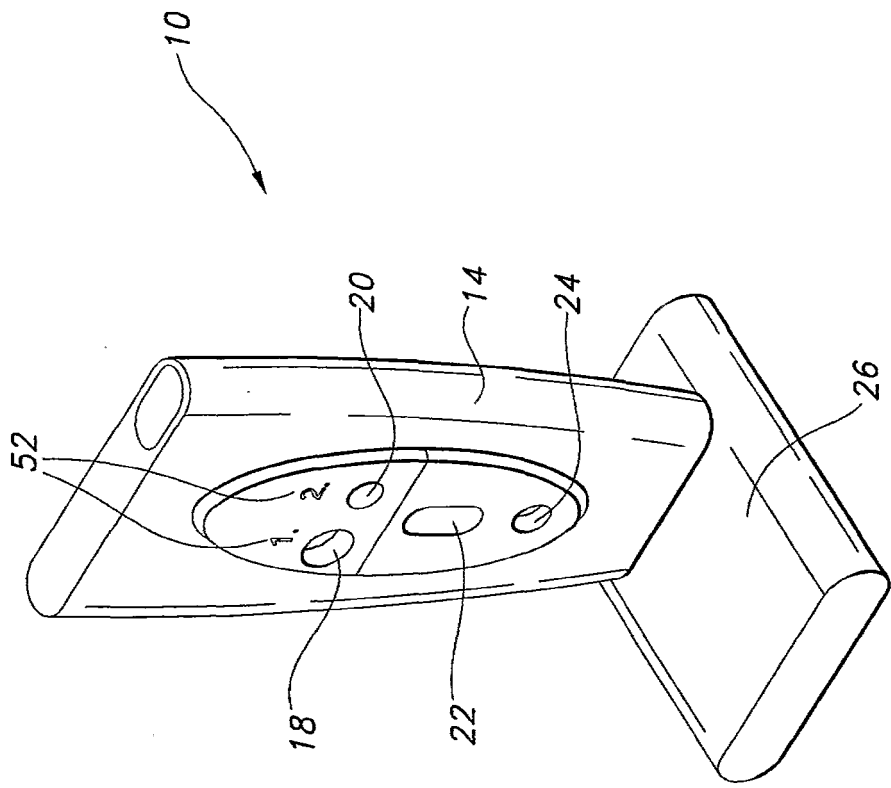


FIG. 7A

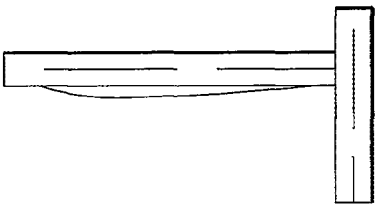


FIG. 7B

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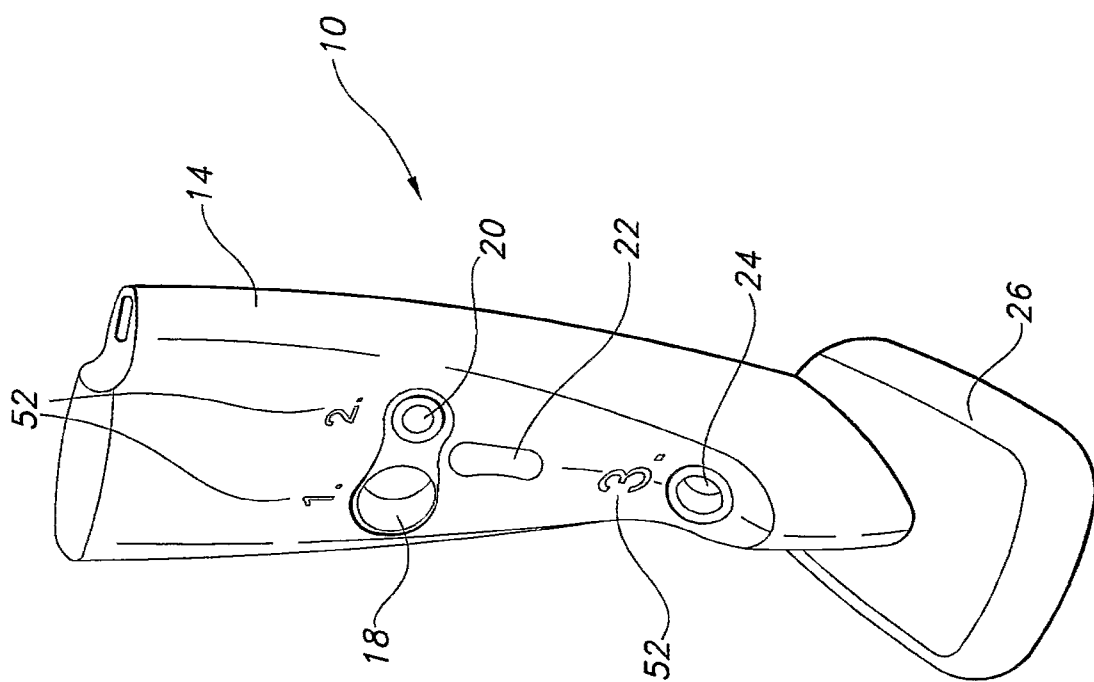


FIG. 8A

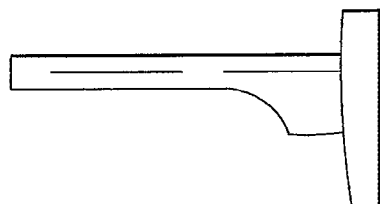


FIG. 8B

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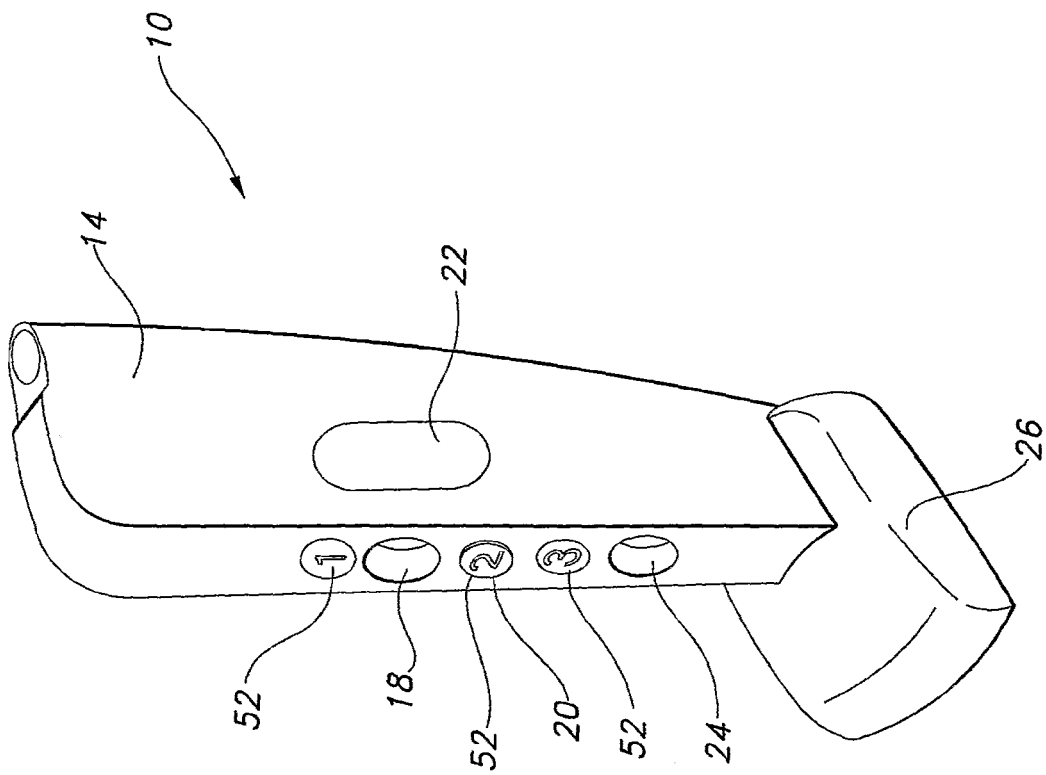


FIG. 9A

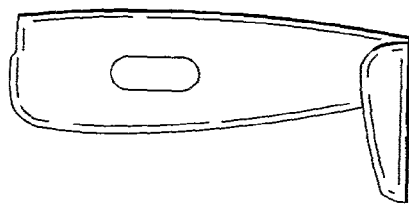


FIG. 9B

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/032006

A. CLASSIFICATION OF SUBJECT MATTER
B65B3/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
B65B A61J

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	US 2003/230521 A1 (SCHICK KARL G) 18 December 2003 (2003-12-18) figures 1-3 paragraph '0027!	1-20
X	US 5 911 252 A (CASSEL ET AL) 15 June 1999 (1999-06-15) column 5, line 11 - line 41 figures 1,1a	1-20
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

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

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- * & * document member of the same patent family

Date of the actual completion of the international search

10 January 2006

Date of mailing of the international search report

19/01/2006

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Damiani, A

INTERNATIONAL SEARCH REPORT

ational Application No
PCT/US2005/032006

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18/180,016 - Conf# 1816
	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US07

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Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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	2.	5030201	07-09-1991	Palestrant	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18/180,016 - Conf# 1816
	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US07

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Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number ³	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
	1.	WO2016014955	01-28-2016	OSTEOMEDIX, INC.		
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NON-PATENT LITERATURE DOCUMENTS					T ⁵
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.			
		International Search Report and Written Opinion for International App. No. PCT/US23/60502; Date of Filing: January 11, 2023, Applicant: Inari Medical, Inc., Date of Mailing: May 25, 2023, 9 pages.			
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18/180,016 - Conf# 1816
	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US07

EXAMINER SIGNATURE	
Examiner Signature	Date Considered
<p>*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.</p> <p>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.</p>	

CERTIFICATION STATEMENT
<p>Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):</p> <p>☐ 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).</p> <p>OR</p> <p>☐ 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).</p> <p>☐ See attached certification statement.</p> <p>☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.</p> <p>☐ None</p> <p>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.</p>
COPIES OF REFERENCES
<p>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).</p>
SIGNATURE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18/180,016 - Conf# 1816
	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt
	Art Unit	3781
	Examiner Name	Eric Rassavong
	Attorney Docket Number	111552-8018.US07

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

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2023-07-05
Name/Print	Matthew S. Williams	Registration Number	77,516

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



ELECTRONIC PAYMENT RECEIPT

APPLICATION #
18/180,016

RECEIPT DATE / TIME
07/05/2023 10:42:04 AM ET

ATTORNEY DOCKET #
111552.8018.US07

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 # 1816

FILED BY J iYoung Anderson

PATENT CENTER # 62386068

AUTHORIZED BY Matthew Williams

CUSTOMER # 25096

FILING DATE 03/07/2023

CORRESPONDENCE ADDRESS -

FIRST NAMED INVENTOR Ben Merritt

Payment Information

PAYMENT METHOD
CARD / 3369

PAYMENT TRANSACTION ID
E202375A43085413

PAYMENT AUTHORIZED BY
J iYoung 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.



ELECTRONIC PAYMENT RECEIPT

APPLICATION #
18/180,016

RECEIPT DATE / TIME
07/03/2023 07:11:50 PM ET

ATTORNEY DOCKET #
111552.8018.US07

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 # 1816

FILED BY J iYoung Anderson

PATENT CENTER # 62383297

AUTHORIZED BY Matthew Williams

CUSTOMER # 25096

FILING DATE 03/07/2023

CORRESPONDENCE ADDRESS -

FIRST NAMED INVENTOR Ben Merritt

Payment Information

PAYMENT METHOD
CARD / 3369

PAYMENT TRANSACTION ID
E202373J 12479006

PAYMENT AUTHORIZED BY
J iYoung Anderson

FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
1202	EACH CLAIM IN EXCESS OF 20	100.00	11	1100.00
TOTAL AMOUNT:				\$1,100.00

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

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
18/180,016

RECEIPT DATE / TIME
07/03/2023 07:11:50 PM ET

ATTORNEY DOCKET #
111552.8018.US07

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 # 1816

FILED BY J iYoung Anderson

PATENT CENTER # 62383297

FILING DATE 03/07/2023

CUSTOMER # 25096

FIRST NAMED
INVENTOR Ben Merritt

CORRESPONDENCE
ADDRESS -

AUTHORIZED BY Matthew Williams

Documents

TOTAL DOCUMENTS: 3

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
2023-7-3 Response to Non-Final OA - 111552.8018US7.PDF		11	-	109 KB
2023-7-3 Response to Non-Final OA - 111552.8018US7-A....pdf	(1-1)	1	Amendment/Request for Reconsideration-After Non-Final Rejection	16 KB
2023-7-3 Response to Non-Final OA - 111552.8018US7-IACS.pdf	(2-8)	7	Amendment Copy Claims/Response to Suggested Claims	36 KB
2023-7-3 Response to Non-Final OA - 111552.8018US7-REM.pdf	(9-11)	3	Applicant Arguments/Remarks Made in an Amendment	69 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-7-3 Response to Non-Final OA - 111552.8018US7.PDF	2D2D5DCA6E16885E19CEA2695681406987C264FF41B4AD7691C0259F5A6DD3E05E539EBE50D41F7C516E9F19E062FAC7E1CED44D9FD6CE2B43CE73DA3A66ACC5
2023-7-3 Response to Non-Final OA - 111552.8018US7-A....pdf	D3738433F4AF23A711A002961E1CF24EC80A151DC4252ED5FB4C301070F4F36DCD0DB10DAF3D01EBC149937051A86C5532AE226D5E4A356A3EC4EAA06E07BB9E
2023-7-3 Response to Non-Final OA - 111552.8018US7-IACS.pdf	A117706628B0C2B4395BF9A484EA090219C849BA111FFC45BDD5DEE2E2606B2B77A595BC192E96330608DE611CBBFF0C048C75450FFC6D3536A0CC7D8F9675D0
2023-7-3 Response to Non-Final OA - 111552.8018US7-REM.pdf	AE6FA427758A12B5541542B8450FCD56E6959B2FBE7A29E98FDDCC14CFC564C4632343B3F9091845A9929D8D6DC77752F9E81A05FDC402C3D90DB27B1BE25043

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New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Ben Merritt et al.

Application No.: 18/180,016

Filed: March 7, 2023

For: SYSTEM FOR TREATING EMBOLISM
AND ASSOCIATED DEVICES AND
METHODS

Conf. No.: 1816

Art Unit: 3781

Examiner: Eric Rassavong

Customer No. 25096

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

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

Dear Commissioner:

In response to the Office Action mailed on June 21, 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 9.

AMENDMENTS TO THE CLAIMS

Please cancel claims 1 and 15, amend claims 2, 6, 10, 11, 14, and 16–20, and add new claims 21–33. Following is a complete listing of the claims pending in the application, as amended:

1. (Canceled)
2. (Currently Amended) The aspiration system of claim ~~4~~10 wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient.
3. (Original) The aspiration system of claim 2 wherein the aspiration catheter has a distal end portion configured to be positioned proximate to clot material within the blood vessel of the patient.
4. (Original) The aspiration system of claim 3 wherein the clot material comprises a pulmonary embolism.
5. (Original) The aspiration system of claim 3 wherein the clot material comprises a deep vein thrombus.
6. (Currently Amended) ~~The~~ An aspiration system ~~of claim 1~~ with accelerated response, further comprising:
an aspiration pump in communication with a first chamber;
a coupled assembly including:
~~the second chamber;~~
~~the~~ an aspiration catheter configured for placement into fluid communication with
the first chamber by way of an aspiration tube; and
a second chamber in between the aspiration pump and the aspiration catheter; and
a hemostasis valve; and

a user-actuatable valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;
wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.

7. (Original) The aspiration system of claim 6 wherein the hemostasis valve is configured to receive a second catheter and direct the second catheter through the aspiration catheter.

8. (Original) The aspiration system of claim 7 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.

9. (Original) The aspiration system of claim 6 wherein the second chamber is removably carried by the assembly.

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

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

a second chamber in between the aspiration pump and the aspiration catheter, wherein the second chamber is removably coupled between the aspiration pump and the aspiration catheter; and
a user-actuatable valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;
wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.

11. (Currently Amended) The aspiration system of claim ~~4~~10, further comprising a filter in the second chamber.

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

13. (Original) The aspiration system of claim 11 wherein the filter is removable from within the second chamber.

14. (Currently Amended) The aspiration system of claim ~~4~~10 wherein the first chamber is fluidically coupled in serial to the second chamber.

15. (Canceled)

16. (Currently Amended) The aspiration system of claim ~~4~~5-18 wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient, wherein the aspiration catheter has a distal end portion configured to be positioned proximate to clot

material within the blood vessel of the patient, and wherein the clot material comprises a pulmonary embolism or a deep vein thrombus.

17. (Currently Amended) ~~The~~ An aspiration system with accelerated response of claim 15, further comprising:

an aspiration pump in communication with a first chamber;

a coupled assembly including:

~~the second chamber;~~

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

a second chamber in between the aspiration pump and the aspiration catheter; and

a hemostasis valve, wherein the hemostasis valve comprises:

a tubular member defining a lumen configured to slidably receive a second catheter and direct the second catheter through the aspiration 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; and

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

wherein upon user actuation to open the valve with negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid decrease in pressure in the aspiration catheter.

18. (Currently Amended) ~~The~~An aspiration system with accelerated response,
comprising: of claim 15

an aspiration pump in communication with a first chamber;

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

a second chamber in between the aspiration pump and the aspiration catheter, wherein the
second chamber is removably coupled between the aspiration pump and the
aspiration catheter; and

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

wherein upon user actuation to open the valve with negative pressure having been
generated in the first and second chambers, fluid flow at least partially from the
second chamber into the first chamber causes rapid decrease in pressure in the
aspiration catheter.

19. (Currently Amended) The aspiration system of claim ~~15~~18, further comprising a
filter in the second chamber, wherein the filter is removable from within the second chamber.

20. (Currently Amended) The aspiration system of claim ~~15-18~~ wherein the first
chamber is fluidically coupled in serial to the second chamber.

21. (New) The aspiration system of claim 6 wherein the aspiration catheter is
configured to be intravascularly positioned within a blood vessel of a patient.

22. (New) The aspiration system of claim 21 wherein the aspiration catheter has a
distal end portion configured to be positioned proximate to clot material within the blood vessel
of the patient.

23. (New) The aspiration system of claim 22 wherein the clot material comprises a pulmonary embolism.

24. (New) The aspiration system 22 wherein the clot material comprises a deep vein thrombus.

25. (New) The aspiration system of claim 6 wherein the second chamber is removably coupled between the aspiration pump and the aspiration catheter.

26. (New) The aspiration system of claim 6, further comprising a filter in the second chamber.

27. (New) The aspiration system of claim 26 wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.

28. (New) The aspiration system of claim 26 wherein the filter is removable from within the second chamber.

29. (New) The aspiration system of claim 6 wherein the first chamber is fluidically coupled in serial to the second chamber.

30. (New) The aspiration system of claim 17 wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient, wherein the aspiration catheter has a distal end portion configured to be positioned proximate to clot material within the blood vessel of the patient, and wherein the clot material comprises a pulmonary embolism or a deep vein thrombus.

31. (New) The aspiration system of claim 17 wherein the second chamber is removably coupled between the aspiration pump and the aspiration catheter.

32. (New) The aspiration system of claim 17 further comprising a filter in the second chamber, wherein the filter is removable from within the second chamber.

33. (New) The aspiration system of claim 17 wherein the first chamber is fluidically coupled in serial to the second chamber.

REMARKS

Claims 1–20 were pending when the present Office Action was mailed on June 21, 2023. In this response, claims 6, 10, 17, and 18 have been rewritten in independent form to put these claims in condition for allowance, and claims 2, 6, 10, 11, 14, and 16–20 have been amended to depend from one of allowable claims 10 or 18. Claims 1 and 15 have been canceled. The foregoing amendments and cancelations are made without commenting on or conceding the merits of the rejections of these claims and without prejudice to or disclaimer of pursuing the subject matter of these claims in a continuation or other related application. New claims 21–33 have been added in this response. Accordingly, claims 2–14 and 16–33 are currently pending.

The status of the application in light of the June 21, 2023, Office Action is as follows:

(A) Claims 1 and 15 were rejected on the ground of nonstatutory double patenting over claims 1–3 of U.S. Patent No. 11,642,209;

(B) Claims 1, 11, 13–15, 19, and 20 were rejected under 35 U.S.C. § 103 over a combination of U.S. Patent No. 8,535,283 to Heaton et al. (“Heaton”) and U.S. Patent Application Publication No. 2005/0004534 to Lockwood et al. (“Lockwood”); and claims 2–5 and 16 were rejected under 35 U.S.C. § 103 over a combination of Heaton, Lockwood, and U.S. Patent Application Publication No. 2015/0352325 to Quick (“Quick”); and

(C) Claims 6–10, 12, 17 and 18 were indicated to be allowable if rewritten in independent form.

A. Response to the Double Patenting Rejection of Claims 1 and 15

Claims 1 and 15 were rejected on the ground of nonstatutory double patenting over claims 1–3 of U.S. Patent No. 11,642,209. Claims 1 and 15 have been canceled in this response and, accordingly, the rejection of these claims is now moot.

B. Response to the Section 103 Rejections of Claims 1–5, 11, 13–16, 19, and 20

Claims 1, 11, 13–15, 19, and 20 were rejected under 35 U.S.C. § 103 over the combination of Heaton and Lockwood. Claims 2–5 and 16 were rejected under 35 U.S.C. § 103 over the combination of Heaton, Lockwood, and Quick.

Without commenting on or conceding the merits of these rejections, claims 1 and 15 have been canceled in this response and, accordingly, the rejections of these claims are now moot. Furthermore, claims 6, 10, 17, and 18 (which were indicated to be allowable) have been rewritten in independent form, and claims 2–5, 11, 13, 14, 16, 19, and 20, as amended, depend from one of allowable claims 10 and 18. Accordingly, the Section 103 rejections of claims 2–5, 11, 13, 14, 16, 19, and 20 should be withdrawn.

C. Indication of Allowable Subject Matter

Claims 6–10, 12, 17 and 18 were indicated to be allowable if rewritten in independent form. Claims 6, 10, 17, and 18 have been rewritten in the stated form and are therefore in condition for allowance.

The Applicant thanks the Examiner for indicating that claims 6–10, 12, 17 and 18 are allowable. Although the undersigned attorney agrees with the Examiner's conclusion that claims 8–20 are allowable, the undersigned attorney notes that these claims may be allowable for reasons other than those identified by the Examiner and does not concede that the Examiner's characterization of the terms of these claims and the prior art are correct.

New Claims 21–33

New claims 21–33 have been added in this response. New claims 21–33 depend from one of allowable independent claims 6 and 17. Accordingly, new claims 21–33 are allowable for at least the same reasons as claims 6 and 17, 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 cited 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.US07 from which the undersigned is authorized to draw.

Respectfully submitted,

Dated: July 3, 2023

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

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Attorney for Applicant

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 18/180,016	Filing Date 03/07/2023	☐ To be Mailed
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ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE (\$)	FEE (\$)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 = *		x \$100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 = *		x \$480 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED - PART II

	(Column 1)		(Column 2)	(Column 3)	RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT	07/03/2023		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	
	Total (37 CFR 1.16(i))	* 31	Minus	** 20	= 11	x \$100 = 1100
	Independent (37 CFR 1.16(h))	* 4	Minus	*** 3	= 1	x \$480 = 480
	☐ Application Size Fee (37 CFR 1.16(s))					
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
TOTAL ADD'L FEE						1580
AMENDMENT			CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	
	Total (37 CFR 1.16(i))	*	Minus	**	=	x \$0 =
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x \$0 =
	☐ Application Size Fee (37 CFR 1.16(s))					
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
TOTAL ADD'L FEE						
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.						PSS
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".						/FIKIRTE A GEREMEW/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".						
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.						

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

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/180,016	03/07/2023	Ben Merritt	111552.8018.US07	1816
25096	7590	06/21/2023	EXAMINER	
PERKINS COIE LLP - SEA General			RASSAVONG, ERIC	
PATENT-SEA			ART UNIT	
P.O. BOX 1247			PAPER NUMBER	
SEATTLE, WA 98111-1247			3781	
			NOTIFICATION DATE	DELIVERY MODE
			06/21/2023	ELECTRONIC

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

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

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

patentprocurement@perkinscoie.com

Office Action Summary	Application No. 18/180,016	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 --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 03/07/2023.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

2a) ☐ This action is **FINAL**.

2b) ☒ This action is non-final.

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

4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☒ Claim(s) 1-20 is/are pending in the application.

5a) Of the above claim(s) ____ is/are withdrawn from consideration.

6) ☐ Claim(s) ____ is/are allowed.

7) ☒ Claim(s) 1-20 is/are rejected.

8) ☒ Claim(s) 6-10, 12 and 17-18 is/are objected to.

9) ☐ Claim(s) ____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10) ☐ The specification is objected to by the Examiner.

11) ☒ The drawing(s) filed on 03/07/2023 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

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

Certified copies:

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

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

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

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

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

3) ☐ Interview Summary (PTO-413)

Paper No(s)/Mail Date ____.

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)

4) ☐ Other: ____.

Paper No(s)/Mail Date ____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

3. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159.

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See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

4. The filing of a terminal disclaimer by itself is not a complete reply to a nonstatutory double patenting (NSDP) rejection. A complete reply requires that the terminal disclaimer be accompanied by a reply requesting reconsideration of the prior Office action. Even where the NSDP rejection is provisional the reply must be complete. See MPEP § 804, subsection I.B.1. For a reply to a non-final Office action, see 37 CFR 1.111(a). For a reply to final Office action, see 37 CFR 1.113(c). A request for reconsideration while not provided for in 37 CFR 1.113(c) may be filed after final for consideration. See MPEP §§ 706.07(e) and 714.13.

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The actual filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/apply/applying-online/eterminal-disclaimer.

5. **Claims 1 and 15** rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 11642209 of Merritt (Merritt 209'). Although the claims at issue are not identical, they are not patentably distinct from each other because Patented claims 1-3 recites more details than the current claim 1 and 15, e.g., a first barrel of a

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first syringe, and wherein the aspiration pump comprises a plunger of the first syringe slidably received in the first barrel.

Claim Rejections - 35 USC § 103

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

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

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

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

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and

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effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C.

102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

10. **Claims 1, 11, 13-15, and 19-20** are rejected under 35 U.S.C. 103 as being unpatentable over Heaton et al. (US 8535283 B2), hereinafter referred to as “Heaton”, in view of Lockwood et al. (US 20050004534 A1), hereinafter referred to as “Lockwood”.

Regarding **claim 1**, Heaton teaches an aspiration system with accelerated response (reduce pressure system (100)), comprising:

an aspiration pump (pump (102)) in communication with a first chamber (in communication with variable volume chamber (110));

an aspiration catheter (connection member (155)) configured for placement into fluid communication with the first chamber by way of an aspiration tube (in fluid communication with variable volume (110) via delivery tube (135), see Figure 1);

a second chamber (fixed volume chamber (115)) in between the aspiration pump and the catheter (located between pump (102) comprising the variable volume (110) and connection member (155)); and

a valve (inlet valve (140)) between the second chamber and the aspiration catheter (in between connection member (155) and fixed volume (115), see Figure 1), wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers (valve (140) can be any type of valve that restricts fluid flow in and out of the fixed chamber (115), see Col. 6 lines 20-27) (a reduce pressure is generated in fixed volume chamber (115) as variable volume chamber (110) expands from the compressed position to the uncompressed

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position, see Col. 9 lines 19-21) (the valve (140) can be closed to generate negative pressure within chamber (115) and bellows (110)), and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers (valve (140) can be open to provide negative pressure to the tissue site, see Col. 6 lines 22-27);

wherein opening the valve with the negative pressure having been generated in the first and second chambers (opening valve (140) with negative pressure in fixed volume (115) and variable volume (110), see Figure 1), fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber (opening valve (140) with negative pressure causes fluid to flow from fixed chamber (115) to rapidly flow into variable chamber (110)).

However, Heaton does not explicitly disclose a aspiration system comprising a user-actuable valve.

Lockwood teaches a wound care bandage system (10) to allow a caregiver to create a negative-pressure above a wound surface, the system (10) further includes a user-actuable valve (stopcock or switch valve (50)) coupled to the single lumen tube (52).

Heaton and Lockwood are analogous art because both deal with a negative pressure aspiration system to collect bodily fluids.

It would have been obvious to a person having ordinary skill in the art before the effective filing date of the invention to modify the valve of the reduce pressure system of Heaton and replace it with the user actuable stopcock or switch valve, as taught by Lockwood. Lockwood teaches the reduce pressure system allows a caregiver to selectively control and/or divert fluid flow therethrough (see Paragraph [0065]).

Regarding **claim 11**, Heaton and Lockwood teaches all of the limitations recited in claim 1 and Heaton further teaches a filter in the second chamber (filter housing (120) be interlocked within the variable volume (110), see Col. 5 lines 59-68) (see Figures 1 and 2).

Regarding **claim 13**, Heaton and Lockwood teaches all of the limitations recited in claim 11 and Heaton further teaches wherein the filter is removable from within the second chamber (filter housing (120) can be coupled to variable volume (110), see Col. 5 lines 59-62) (the filter housing (120) therefore can be releasably coupled to variable volume (110)).

Regarding **claim 14**, Heaton and Lockwood teaches all of the limitations recited in claim 1 and Heaton further teaches wherein the first chamber is fluidically coupled in serial to the second chamber (fixed volume chamber (115) is serial coupled to variable volume chamber (110), see Figure 1).

Regarding **claim 15**, Heaton teaches an aspiration system with accelerated response (reduce pressure system (100)), comprising:

an aspiration pump (pump (102)) in communication with a first chamber (in communication with variable volume chamber (110));

an aspiration catheter (connection member (155)) configured for placement into fluid communication with the first chamber by way of an aspiration tube (in fluid communication with variable volume (110) via delivery tube (135), see Figure 1);

a second chamber (fixed volume chamber (115)) in between the aspiration pump and the catheter (in between connection member (155) and fixed volume (115), see Figure 1); and

a valve (inlet valve (140)) between the second chamber and the aspiration catheter (in between connection member (155) and fixed volume (115), see Figure 1), wherein the valve is

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configured to be closed while negative pressure is generated in the first and second chambers (valve (140) can be any type of valve that restricts fluid flow into and out of the fixed chamber (115), see Col. 6 lines 20-27) (a reduce pressure is generated in fixed volume chamber (115) as variable volume chamber (110) expands from the compressed position to the uncompressed position, see Col. 9 lines 19-21) (the valve (140) can be closed to generate negative pressure within chamber (115), and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers (valve (140) can be open to provide negative pressure to the tissue site, see Col. 6 lines 22-27);

wherein upon opening the valve with negative pressure having been generated in the first and second chambers (opening valve (140) with negative pressure in fixed volume (115) and variable volume (110), see Figure 1), fluid flow at least partially from the second chamber into the first chamber causes rapid decrease in pressure in the aspiration catheter (opening valve (140) with negative pressure causes fluid to flow from fixed chamber (115) to rapidly flow into variable chamber (110)).

However, Heaton does not explicitly disclose a aspiration system comprising a user-actuable valve.

Lockwood teaches a wound care bandage system (10) to allow a caregiver to create a negative-pressure above a wound surface, the system (10) further includes a user-actuable valve (stopcock or switch valve (50)) coupled to the single lumen tube (52).

Heaton and Lockwood are analogous art because both deal with a negative pressure aspiration system to collect bodily fluids.

It would have been obvious to a person having ordinary skill in the art before the effective filing date of the invention to modify the valve of the reduce pressure system of Heaton and replace it with the user actuable stopcock or switch valve, as taught by Lockwood. Lockwood teaches the reduce pressure system allows a caregiver to selectively control and/or divert fluid flow therethrough (see Paragraph [0065]).

Regarding **claim 19**, Heaton and Lockwood teaches all of the limitations recited in claim 15 and Heaton further teaches a filter in the second chamber (filter housing (120) be interlocked within the variable volume (110), see Col. 5 lines 59-68) (see Figures 1 and 2), wherein the filter is removable from within the second chamber (filter housing (120) can be coupled to variable volume (110), see Col. 5 lines 59-62) (the filter housing (120) therefore can be releasably coupled to variable volume (110)).

Regarding **claim 20**, Heaton and Lockwood teaches all of the limitations recited in claim 15 and Heaton further teaches wherein the first chamber is fluidically coupled in serial to the second chamber (fixed volume chamber (115) is serial coupled to variable volume chamber (110), see Figure 1).

11. **Claims 2-5 and 16** are rejected under 35 U.S.C. 103 as being unpatentable over Heaton et al. (US 8535283 B2) and Lockwood et al. (US 20050004534 A1), as applied to claim 1, and in further view of Quick (US 20150352325 A1).

Regarding **claim 2**, Heaton and Lockwood teaches all of the limitations recited in claim 1. However, Heaton and Lockwood fail to teach wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient.

Quick teaches a retraction and aspiration device (100) (see Figure 1) configured to be in use with a catheter system (200, see Paragraph [0048]) (see Figure 5a) to enable intravascular delivery of an interventional device to a treatment site in a blood vessel (see Abstract).

Heaton, Lockwood, and Quick are analogous art because all deals with a negative pressure aspiration device configured to collect bodily fluids.

It would have been obvious to a person having ordinary skill in the art before the effective filing date of the invention to modify the aspiration and catheter system of Heaton and Lockwood and replace it with the catheter system configured to enable intravascular delivery of an interventional device to a treatment site in a blood vessel, as taught by Quick. Quick teaches the catheter system provides a need for an improved embolic extraction device and less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all of the clots (see Paragraph [0009]-[0010]).

Regarding **claim 3**, Modified Heaton and Quick teaches all of the limitations recited in claim 2 and Quick further teaches wherein the aspiration catheter has a distal end portion configured to be positioned proximate to clot material within the blood vessel of the patient (distal portion of catheter system (200) is positioned adjacent an embolism or clot material, see Paragraph [0048]) (see Figure 5).

Regarding **claim 4**, Modified Heaton and Quick teaches all of the limitations recited in claim 2 and Quick further teaches wherein the clot material comprises a pulmonary embolism (clot material can be a pulmonary embolism, see Paragraph [0003]).

Regarding **claim 5**, Modified Heaton and Quick teaches all of the limitations recited in claim 2 and Quick further teaches wherein the clot material comprises a deep vein thrombus (the clot material can be deep venous thrombosis, see Paragraph [0005]).

Regarding **claim 16**, Heaton and Lockwood teaches all of the limitations recited in claim 1. However, Heaton and Lockwood fail to teach wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient, wherein the aspiration catheter has a distal end portion configured to be positioned proximate to clot material within the blood vessel of the patient, and wherein the clot material comprises a pulmonary embolism or a deep vein thrombus.

Quick teaches a retraction and aspiration device (100) (see Figure 1) configured to be in use with a catheter system (200, see Paragraph [0048]) (see Figure 5a) to enable intravascular delivery of an interventional device to a treatment site in a blood vessel (see Abstract); wherein the aspiration catheter (catheter system (200)) is configured to be intravascularly positioned within a blood vessel of a patient (see Figure 5), wherein the aspiration catheter has a distal end portion configured to be positioned proximate to clot material within the blood vessel of the patient (distal portion of catheter system (200) is positioned adjacent an embolism or clot material, see Paragraph [0048]) (see Figure 5), and wherein the clot material comprises a pulmonary embolism or a deep vein thrombus (clot material can be a pulmonary embolism or deep vein thrombosis, see Paragraph [0003] and [0005]).

Heaton, Lockwood, and Quick are analogous art because all deals with a negative pressure aspiration device configured to collect bodily fluids.

It would have been obvious to a person having ordinary skill in the art before the effective filing date of the invention to modify the aspiration and catheter system of Heaton and Lockwood and replace it with the catheter system configured to enable intravascular delivery of an interventional device to a treatment site in a blood vessel, as taught by Quick. Quick teaches the catheter system provides a need for an improved embolic extraction device and less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all of the clots (see Paragraph [0009]-[0010]).

Allowable Subject Matter

12. **Claims 6-10, 12, and 17-18** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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

Claim 6 and 17 would be allowable for reciting, *inter alia*, “a coupled assembly including: the second chamber; the aspiration catheter; and a hemostasis valve”.

Heaton teaches all of the limitations as discussed above in claim 1. However, Heaton fails to teach a coupled assembly including: the second chamber; the aspiration catheter; and a hemostasis valve. The second chamber (variable volume (110)) is not configured to be an additional component apart of another coupled assembly. The second chamber of Heaton is integral to the function of the pump (102) and is configured to be a part of the first chamber (fixed chamber (115)). Therefore having the second chamber be part of another assembly that includes the aspiration catheter and a hemostasis valve would destroy the function of how

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Heaton operates. Also, there is no hemostasis valve mentioned in Heaton. There is no prior art that disclose these limitations. Therefore the combination of limitations on claim 6 would be considered allowable. **Claims 7-9** would be allowable for depending on claim 6.

Claim 10 and 18 would be allowable for reciting, *inter alia*, “wherein the second chamber is removably coupled between the aspiration pump and the catheter”.

Heaton teaches all of the limitations as discussed above in claim 1. However, Heaton fails to teach wherein the second chamber is removably coupled between the aspiration pump and the catheter. The second chamber of Heaton comprises a variable volume such as a bellows that generates negative pressure within the chamber. Therefore it would be impossible for the second chamber, i.e. the bellows pump itself, to be removably coupled between the pump and the catheter. For this reason the limitations of claim 10 would be considered allowable.

Claim 12 would be allowable for reciting, *inter alia*, “wherein the filter permits blood to flow therethrough”.

Heaton teaches all of the limitations as discussed above in claim 1 and Heaton further teaches a filter housing (120) in the second chamber (110). However, Heaton fails to teach wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough. The filter of Heaton is a hydrophobic filter that prevents liquid from entering the at least one variable volume chamber and therefore would not have pores that permit blood to flow therethrough. If fluid were to flow into the variable volume (110) then it would possibly damage the pump and destroy the function of the aspiration device of Heaton. For this reason, claim 12 would be considered allowable.

Conclusion

13. 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.

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/E.R./ (6/14/2023)
Examiner, Art Unit 3781

/SUSAN S SU/
Primary Examiner, Art Unit 3781
14 June 2023

<i>Notice of References Cited</i>	Application/Control No. 18/180,016		Applicant(s)/Patent Under Reexamination Merritt et al.	
	Examiner ERIC RASSAVONG		Art Unit 3781	Page 1 of 1

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*	B	US-20010049486-A1	12-2001	Evans, Michael A.	A61M1/3621	604/35
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*	H	US-20160106353-A1	04-2016	Schuetz; Steffen	A61B5/15003	210/416.1
*	I	US-8535283-B2	09-2013	Heaton; Keith Patrick	A61M1/98	604/319
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NON-PATENT DOCUMENTS

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

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

<i>Index of Claims</i> 	Application/Control No. 18/180,016	Applicant(s)/Patent Under Reexamination Merritt et al.
	Examiner ERIC RASSAVONG	Art Unit 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								
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Search Notes 	Application/Control No. 18/180,016	Applicant(s)/Patent Under Reexamination Merritt et al.
	Examiner ERIC RASSAVONG	Art Unit 3781

CPC - Searched*		
Symbol	Date	Examiner
A61B17/12109, 17/221, 2017/22034, 2017/22079, 2217/005	06/12/2023	/E.R./
A61F2/01	06/12/2023	/E.R./
A61M1/815, 1/84, 1/79, 25/10	06/12/2023	/E.R./

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

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

Search Notes		
Search Notes	Date	Examiner
Inventor Name Search in PALM	06/12/2023	/E.R./
CPC and text searching completed	06/12/2023	/E.R./
Consulted Primary Examiner Susan Su on Prior art	06/12/2023	/E.R./

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	Keyword search in USPAT	06/12/2023	/E.R./

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

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L9	5063	A61B2017/22034.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:02 PM
L10	7706	A61B2017/22079.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:02 PM
L11	29096	A61B2217/005.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:02 PM
L12	4559	A61M1/79.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:02 PM
L13	34247	A61M25/10.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:02 PM
L15	1124	A61F2/01.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU,	OR	ON	ON	2023/06/12 03:32 PM

L16	21	A61M1/815.cpc. AND A61B17/12109.cpc.	SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:32 PM
L17	158	A61M1/84.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:32 PM
L18	1057	A61B17/221.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:33 PM
L19	530	A61B2017/22034.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:33 PM
L20	419	A61B2017/22079.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:33 PM
L21	457	A61B2217/005.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:33 PM
L22	20	A61M1/79.cpc. AND A61B17/12109.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU,	OR	ON	ON	2023/06/12 03:33 PM

L23	1309	A61M25/10.cpc. AND A61B17/12109.cpc.	SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:33 PM
L24	22	A61M1/84.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:33 PM
L25	720	A61B17/221.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:33 PM
L26	219	A61B2017/22034.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:34 PM
L27	103	A61B2017/22079.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:34 PM
L28	103	A61B2217/005.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:34 PM
L29	25	A61M1/79.cpc. AND A61F2/01.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU,	OR	ON	ON	2023/06/12 03:34 PM

L30	120	A61M25/10.cpc. AND A61F2/01.cpc.	SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:34 PM
L31	191	A61M1/84.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:34 PM
L32	20	A61B17/221.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:34 PM
L33	21	A61B2017/22034.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:34 PM
L34	49	A61B2017/22079.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:34 PM
L35	57	A61B2217/005.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:35 PM
L36	89	A61M1/79.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU,	OR	ON	ON	2023/06/12 03:35 PM

L37	20	A61M25/10.cpc. AND A61M1/815.cpc.	SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:35 PM
L38	191	A61M1/84.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:35 PM
L39	20	A61B17/221.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:35 PM
L40	21	A61B2017/22034.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:35 PM
L41	49	A61B2017/22079.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:35 PM
L42	57	A61B2217/005.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:35 PM
L43	89	A61M1/79.cpc. AND A61M1/815.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU,	OR	ON	ON	2023/06/12 03:35 PM

L44	20	A61M25/10.cpc. AND A61M1/815.cpc.	SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:36 PM
L45	400	A61B17/221.cpc. AND A61M1/84.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:37 PM
L46	219	A61B2017/22034.cpc. AND A61M1/84.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:37 PM
L47	625	A61B2017/22079.cpc. AND A61M1/84.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:38 PM
L48	1952	A61B2217/005.cpc. AND A61M1/84.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:38 PM
L49	1952	A61B2217/005.cpc. AND A61M1/84.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:38 PM
L50	620	A61M1/79.cpc. AND A61M1/84.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU,	OR	ON	ON	2023/06/12 03:38 PM

L51	711	A61M25/10.cpc. AND A61M1/84.cpc.	SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:39 PM
L52	3864	A61B2017/22034.cpc. AND A61B17/221.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:39 PM
L53	2443	A61B2017/22079.cpc. AND A61B17/221.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:39 PM
L54	1935	A61B2217/005.cpc. AND A61B17/221.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:39 PM
L55	103	A61M1/79.cpc. AND A61B17/221.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:39 PM
L56	948	A61M25/10.cpc. AND A61B17/221.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:39 PM
L57	982	A61B2017/22079.cpc. AND A61B2017/22034.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU,	OR	ON	ON	2023/06/12 03:51 PM

L58	618	A61B2217/005.cpc. AND A61B2017/22034.cpc.	SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:51 PM
L59	58	A61M1/79.cpc. AND A61B2017/22034.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:51 PM
L60	544	A61M25/10.cpc. AND A61B2017/22034.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:51 PM
L61	3016	A61B2217/005.cpc. AND A61B2017/22079.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:51 PM
L62	238	A61M1/79.cpc. AND A61B2017/22079.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:51 PM
L63	487	A61M25/10.cpc. AND A61B2017/22079.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:51 PM
L64	962	A61M1/79.cpc. AND A61B2217/005.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU,	OR	ON	ON	2023/06/12 03:52 PM

L65	873	A61M25/10.cpc. AND A61B2217/005.cpc.	SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:52 PM
L66	49	A61M25/10.cpc. AND A61M1/79.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 03:52 PM
L67	3	"8535283".pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 05:11 PM
L68	4	"20050004534".pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 05:12 PM
L69	4	"20160106353".pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 02:13 AM
L70	48	((US-20180193042-A1 OR US-20180104404- A1 OR US- 20170196576-A1 OR US-20170143938-A1 OR US-20140155830- A1 OR US- 20180344993-A1 OR US-20180064453-A1 OR US-20170319221- A1 OR US- 20170056032-A1 OR US-20150352325-A1	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 02:42 AM

		OR US-20150327875-A1 OR US-20100094201-A1 OR US-20100152615-A1 OR US-20020035347-A1 OR US-20070060888-A1 OR US-20160220741-A1 OR US-20150133990-A1 OR US-20070010787-A1 OR US-20160270803-A1 OR US-20010049486-A1 OR US-20030069543-A1 OR US-20100106081-A1 OR US-20110196309-A1 OR US-20130281788-A1 OR US-20150173782-A1 OR US-20140296868-A1 OR US-20100217276-A1 OR US-20140257363-A1).did. AND PGPB.dbnm.) OR ((WO-2016126974-A1 OR WO-2018148174-A1 OR WO-2015189354-A1 OR WO-2009082513-A1 OR CN-103501831-A OR WO-2014176121-A1).did. AND FTDB.dbnm.) OR ((WO-9839047-A1).did. AND FPRS.dbnm.) OR ((US-10531883-B1 OR US-6540712-B1 OR US-10478535-B2 OR US-7736355-B2 OR US-7004931-B2 OR US-6960189-B2 OR US-9681882-B2 OR US-6719717-B1 OR US-7223253-B2 OR US-8753322-B2 OR US-8808259-B2).did. AND USPT.dbnm.) OR ((US-20110160762-A1 OR US-20150133990-A1).did. AND DWPI.dbnm.)					
L71	20	A61B17/12109.cpc. AND "deep vein thrombus" AND "pulmonary embolism"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU,	OR	ON	ON	2023/06/13 04:49 PM

L72	0	cathter AND "deep vein thrombus" AND "pulmonary embolism"	SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 04:49 PM
L73	228	catheter AND "deep vein thrombus" AND "pulmonary embolism"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 04:49 PM
L74	1108	A61M1/79.cpc. AND removable	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 06:01 PM
L75	490	A61M1/79.cpc. AND removable	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/13 06:01 PM
L76	373	A61M1/79.cpc. AND pump AND removable	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/13 06:03 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N1	1	(rapid quick fast accelerated speedy).clm. AND (aspiration suction).clm. AND (catheter).clm. AND (syringe).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/14 01:19 PM
N2	29	(rapid quick fast accelerated speedy).clm. AND (aspiration suction).clm. AND (catheter).clm. AND (syringe).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/14 01:20 PM
N3	114	(catheter).clm. AND (syringe).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/14 01:20 PM
N4	29	(rapid quick fast accelerated speedy).clm. AND	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/14 01:20 PM

N5	6	(aspiration suction).clm. AND (catheter).clm. AND (syringe).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/14 01:20 PM
N6	2	(rapid quick fast accelerated speedy).clm. AND (aspiration suction).clm. AND (catheter).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/14 01:20 PM
N7	7	(rapid quick fast accelerated speedy).clm. AND (catheter).clm. AND (syringe).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/14 01:20 PM
N8	2843	(aspiration suction).clm. AND (catheter).clm. AND (syringe).clm. AND (series serial).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/14 01:21 PM

Bibliographic Data

Application No: 18/180,016

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.
03/07/2023	606	3781	111552.8018.US07
RULE			

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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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18/180,016 - Conf# 1816
	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt Eric Rassavong
	Art Unit	Not Yet Assigned 3781
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552.8018.US07

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	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552.8018.US07

U.S. PATENTS AND PUBLICATIONS					
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	Art Unit	Not Yet Assigned
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	Attorney Docket Number	111552.8018.US07

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	First Named Inventor	Ben Merritt
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18/180,016 - Conf# 1816
	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt
	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552.8018.US07

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EXAMINER SIGNATURE		
Examiner Signature	/ERIC RASSAVONG/ (06/12/2023)	06/12/2023
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CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ None

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

COPIES OF REFERENCES

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2). Those documents which are marked with a double asterisk (**) next to the Cite No. in the attached form PTO/SB/08 are not supplied because they were previously cited by or submitted to the Office in prior application number **16/536,185** and filed on **August 8, 2019** and relied upon in this application for an earlier filing date under 35 U.S.C. § 120.

SIGNATURE

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

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2023-04-14
Name/Print	Matthew S. Williams	Registration Number	77,516

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



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/180,016	03/07/2023	Ben Merritt	111552.8018.US07	1816
25096	7590	05/01/2023	EXAMINER	
PERKINS COIE LLP - SEA General PATENT-SEA P.O. BOX 1247 SEATTLE, WA 98111-1247			ART UNIT	PAPER NUMBER
			NOTIFICATION DATE	DELIVERY MODE
			05/01/2023	ELECTRONIC

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

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

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

patentprocurement@perkinscoie.com

<i>Decision Granting Request for Prioritized Examination (Track I)</i>	Application No. 18/180,016	Applicant(s) Merritt et al.	
	Examiner CHERYL P GIBSON BAYLOR	Art Unit OPET	AIA (FITF) Status Yes
<p>1. THE REQUEST FILED <u>07 March 2023</u> IS GRANTED .</p> <p>The above-identified application has met the requirements for prioritized examination</p> <p>A. ☒ for an original nonprovisional application (Track I).</p> <p>B. ☐ for an application undergoing continued examination (RCE).</p> <p>2. The above-identified application will undergo prioritized examination. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:</p> <p>A. filing a <u>petition for extension of time</u> to extend the time period for filing a reply;</p> <p>B. filing an <u>amendment to amend the application to contain more than four independent claims, more than thirty total claims</u>, or a multiple dependent claim;</p> <p>C. filing a <u>request for continued examination</u> ;</p> <p>D. filing a notice of appeal;</p> <p>E. filing a request for suspension of action;</p> <p>F. mailing of a notice of allowance;</p> <p>G. mailing of a final Office action;</p> <p>H. completion of examination as defined in 37 CFR 41.102; or</p> <p>I. abandonment of the application.</p> <p>Telephone inquiries with regard to this decision should be directed to CHERYL GIBSON BAYLOR at (571)272-3213. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.</p>			
/CHERYL GIBSON BAYLOR/ Paralegal Specialist, OPET			

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18/180,016 - Conf# 1816
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	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552.8018.US07

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Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T ⁵
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18/180,016 - Conf# 1816
	Filing Date	March 7, 2023
	First Named Inventor	Ben Merritt
	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
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CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ None

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

COPIES OF REFERENCES

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2). Those documents which are marked with a double asterisk (**) next to the Cite No. in the attached form PTO/SB/08 are not supplied because they were previously cited by or submitted to the Office in prior application number **16/536,185** and filed on **August 8, 2019** and relied upon in this application for an earlier filing date under 35 U.S.C. § 120.

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

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2023-04-14
Name/Print	Matthew S. Williams	Registration Number	77,516

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



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Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
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INVENTOR Ben Merritt

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Documents

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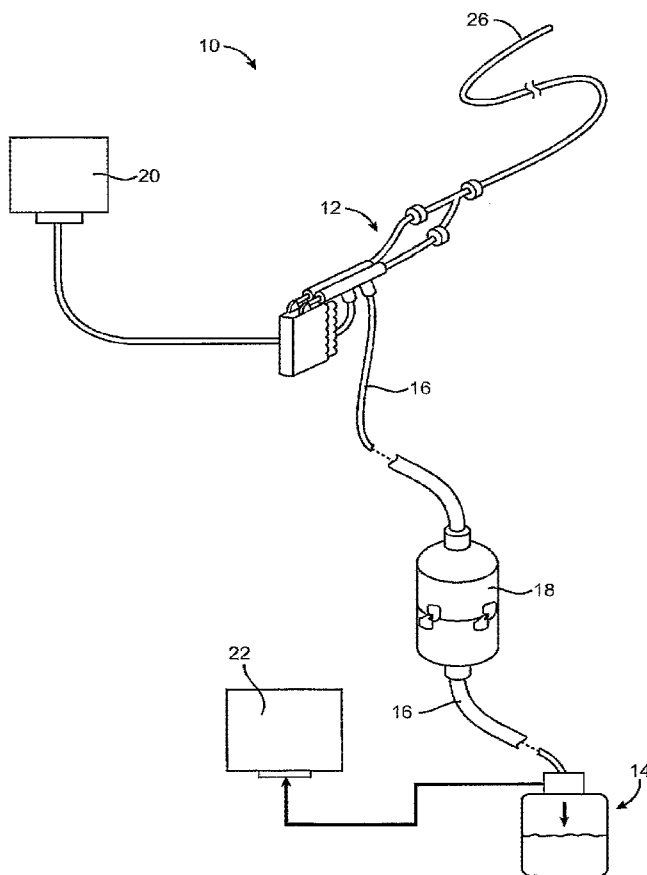
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(54) Title: METHODS AND SYSTEMS FOR FILTERING ASPIRATED MATERIALS



(57) Abstract: Solid materials are separated from hollow body structure aspirates using a filter assembly disposed between an aspiration catheter and an aspirate receptacle. Filter elements having different pore or mesh sizes may be used to size classify the separated solid materials. Multiple filter assemblies may be disposed in parallel or series between the aspiration catheter and aspirate receptacle to provide for different levels of size classification.

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GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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METHODS AND SYSTEMS FOR FILTERING ASPIRATED MATERIALS

BACKGROUND OF THE INVENTION

5 [0001] 1. Field of the Invention. The present invention relates generally to medical apparatus and methods. More particularly, the present invention relates to a method and system for separating and optionally classifying solids removed from a patient in a fluid aspirate.

10 [0002] Aspiration is a part of many surgical procedures performed in various body structures and lumens. Blood and/or other natural body fluids may be aspirated from various hollow body structures, such as blood vessels, cysts, pseudocysts, abscesses, blood vessel grafts, lung passages, bile ducts, ureters, urethras, fallopian tubes, ear canals, the gastrointestinal tract, and the like. In some instances, aspiration is performed on a natural body fluid(s) only, while in many other instances, a liquid irrigant will be introduced which
15 will form at least part of the aspirated fluid. Such irrigants may comprise saline or other biologically inert fluids. Alternatively, such irrigants may comprise biologically active agents, such as thrombolytic agents introduced to occluded blood vessels, antiseptic or antibiotic agents introduced to infected body locations, or the like.

20 [0003] Of particular interest to the present invention, fluids aspirated from any of these hollow body structures will often contain solid materials, such as cellular debris, damaged tissue, thrombus, or the like, which is aspirated together with the fluid. In many instances, such removed solid materials will have diagnostic or other value to a treating physician. For example, during aspiration, it may be desirable to monitor the solid materials which are being removed in order to decide when to terminate or alter or adjust the aspiration protocol.
25 Additionally, the identification of the aspirated material may serve as a diagnostic tool to direct further intervention or other therapies.

[0004] While the collected materials may be observed in the aspirate collection bags which are commonly employed in such procedures, it will usually be difficult to remove the materials while additional aspirate is entering the collection bags and the solids will
30 frequently remain suspended and difficult to separate from the collected materials.

[0005] For these reasons, it would be desirable to provide improved and additional systems and protocols for separating solid materials from liquid and fluid aspirates removed from a hollow body structure. It would be particularly desirable if the methods and protocols permitted direct observation and/or removal of the separated solid materials while an aspiration protocol was continuing. It would be further desirable if the separated solid materials were collected in a form substantially separated from a liquid fraction of the materials removed from the hollow body structure and further that the separated solid materials be in a convenient structure or assembly to permit easy removal and observation. In some instances, it would also be desirable to provide for classification of the solid materials, i.e. separation based on size, while the aspiration protocol was being performed. At least some of these objectives will be met by the inventions described and claimed hereinbelow.

[0006] 2. Description of the Background Art. Patient irrigation and aspiration systems which may employ the separation technology of the present application are described in commonly assigned U.S. Patent Nos. 6,827,701 and 6,878,128, the full disclosures of which are incorporated herein by reference.

BRIEF SUMMARY OF THE INVENTION

[0007] In a first aspect of the present invention, methods are provided for separating materials in fluid aspirates removed from a hollow body structure. The fluid is aspirated from the hollow body structure, where the fluid carries entrained solid materials in the aspirate. The solid materials are filtered from the fluid to produce both a filtrate and a fluid stream. The fluid stream is collected separately from the filtrate. In this way, the filtrate may be easily observed and optionally removed from the aspiration circuit even while the aspiration protocol continues.

[0008] The fluid may be aspirated from a variety of hollow body organs and other structures, including blood vessels, cysts, pseudocysts, abscesses, blood vessel grafts, lung passages, bile ducts, ureters, urethras, fallopian tubes, ear canals, joint capsules, the gastrointestinal tract, and the like. Thus, natural body fluids which may be aspirated according to the present invention include blood, bile, urine, synovial fluid, and the like. In addition to such natural body fluids, the hollow body structures may optionally be irrigated prior to and/or during aspiration. The introduction of irrigation fluid may improve debris capture through the aspiration channel by creating localized mixing / turbulence and possibly

decreasing the viscosity of the aspirant. Thus, the aspirated fluids may comprise or consist of a variety of irrigant fluids introduced to the hollow body structure. Suitable irrigant fluids include saline, lactated ringers, and the like. The irrigant fluids may further comprise active agents intended for therapeutic or diagnostic purposes. For example, in the case of occluded blood vessels, thrombolytic agents may be introduced as part of an irrigant stream. Alternatively, in the case of infected hollow body structures, the irrigant may include antibiotics, antiseptics, or the like.

[0009] Most typically, aspiration will be performed by introducing an aspiration catheter, cannula, or other tubular or needle-like device into the hollow body structure. By applying a vacuum to a proximal end of the aspiration device, the fluid may be withdrawn through a port or ports at or near the distal end of the device which has been placed within an interior region of the hollow body structure. For convenience, as used hereinafter and in the claims, the aspiration structure will be referred to as a "catheter," but it will be appreciated that this term is intended to be broad enough to encompass needles, cannulas, tubular structures, conduits, and other aspiration structures known in the medical art.

[0010] The aspirated fluids will usually be collected in an aspirate receptacle, such as a conventional fluid collection bag. A syringe, vacuum connection, or other conventional vacuum source may be connected at or through the catheter and/or the aspiration receptacle in order to aspirate the fluid from the hollow body structure, through the aspiration catheter, and into the aspirate receptacle. The filter(s) may be positioned before or after the aspiration source.

[0011] In a preferred aspect of the present invention, at least one filter assembly including a filter housing and a removable (and replaceable) filter element is placed between the aspiration catheter and the aspirate receptacle in order to remove solid materials from the aspirate before the remaining liquid phase of the aspirate flows to the aspirate receptacle. The filter element may be any conventional filter element, such as a paper, polymer, a woven filter membrane, a screen, other porous member, or the like. The filter element may have any one of a variety of geometries including cup-shaped, conical and the filter could be inclined or slanted in the filter-housing to spread the filtrate over the filter to permit differentiation of the filtrate material. Additionally, the filter element could be coated or otherwise combined with a chemical, biological, or other indication or marker to facilitate identification of different analytes or markers present in the filtrate, typically using colorimetric indicating

systems. Preferably, the filter element will allow the separated solid materials to collect on an exposed surface so that the solid materials will be easily removed and/or absorbed. The filter element will have a pore size or screen size selected to separate solid particles at a desired particle size cutoff. For example, suitable filter membranes may have a pore size in the range from 1 μm to 1000 μm , usually from 5 μm to 240 μm , and preferably from 20 μm to 120 μm . For separation of larger particles, screens having mesh sizes in the range from 0.1mm to 5mm, and preferably from 0.2mm to 1mm may be used.

[0012] In a specific aspect of the methods of the present invention, at least two filter assemblies may be provided between the aspiration catheter and the aspirate receptacle. The two or more filter assemblies may be disposed in parallel, in series, or in a combination of parallel and series arrangements. Typically, valving will be provided so that the multiple filter assemblies may be isolated from the flowing stream of aspirate so that the filter elements may be removed and the collected solids observed even while the aspiration protocol continues. In some cases, an unfiltered bypass path will be provided with valving so that a single filter assembly or group of filter assemblies may be isolated while the aspirate is directed or shunted to the aspirate receptacle without any filtration.

[0013] In a further specific aspect of the methods of the present invention, two or more filter elements may be employed in series or in parallel in order to size classify the materials being removed. Most simply, two, three, or more filter elements having progressively smaller pore or mesh sizes may be provided in series in a single filter housing. Alternatively, such a series of progressively smaller filtering elements could be provided in separate filter assemblies which are disposed in series between the aspiration catheter and the aspirate receptacle. Alternatively, separate filter assemblies having filter elements with differing particle size cutoffs could be provided in parallel or in a series-parallel arrangement in order to separately collect and classify particles having different sizes. In any of these ways, the solid materials may be filtered and separated into at least two size groups, often at least three size groups, and into virtually any number of different sized collection groups desired.

[0014] In a second aspect of the present invention, systems for aspirating a hollow body structure comprise an aspiration catheter, an aspirate receptacle connectable to receive aspirate from the aspiration catheter, and at least one filter assembly disposed between the aspiration catheter and the aspirate receptacle. Typically, the aspirate receptacle will be a fluid collection bag, although any other conventional medical receptacle would be suitable.

The aspirate receptacle will typically be connected by a flexible tube between the aspiration catheter and the aspirate receptacle. Usually, a syringe, vacuum connector, or other conventional vacuum source will be provided in order to effect the system aspiration.

[0015] The filter assembly usually comprises at least one filter housing having at least one filter element removably disposed in an interior thereof. The filter element, as described above, may comprise a filter membrane, a mesh, link, or the like, having a pore or mesh size selected to collect and separate solids having a target threshold size or sizes. The filter housing and optionally filter element may be at least partially transparent to permit observation of the solid materials as they collect. In an exemplary embodiment, the filter housing has an upper shell and a lower shell which may be taken apart to permit introduction, removal, and replacement of the filter element in the interior of the housing. The housing will further have conventional connectors to permit connection at an upper end to the aspiration catheter and at a lower end to the aspirate receptacle.

[0016] The system may further comprise at least a second filter assembly, a third filter assembly, or even greater number of filter assemblies which may be disposed in parallel or series to the first filter assembly. Additionally, at least one unfiltered flow path may be provided in parallel to the filter assembly(ies), and valving will be provided to permit selective flow through any one or more of the filter assemblies as well as through the unfiltered flow path. The different filter assemblies may each have a filter element with a different pore or mesh size. Alternatively, two or more filter elements may be provided within a single filter assembly, where the individual filter elements within the individual assembly may optionally have different pore or mesh sizes.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Fig. 1 illustrates an exemplary system including an irrigant source, an aspiration and irrigation catheter, a filter assembly, an aspirate receptacle, and a vacuum source, constructed in accordance with the principles of the present invention.

[0018] Fig. 2 illustrates an exemplary filter housing constructed in accordance with the principles of the present invention.

[0019] Figs. 3 and 4 illustrate two exemplary filter assembly connection patterns which may be employed in the apparatus and methods of the present invention.

[0020] Fig. 5 illustrates use of filter elements having different pore or mesh sizes disposed in series for classifying solid materials in accordance with the principles of the present invention.

[0021] Fig. 6 illustrates the use of filter elements having different pore or mesh sizes disposed in parallel for classifying solid material sizes in accordance with the principles of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0022] The present invention provides systems and methods for separating solid materials, typically particulate materials, from aspirated body fluids, including both natural body fluids and introduced fluids. As shown in Fig. 1, an exemplary system 10 comprises catheter 12 (move the arrow for 12 distal to the 2-line section) which is connected to an aspirate receptacle 14 by tubing 16. The catheter 12 is illustrated as an irrigation/aspiration catheter which is connectable to a source of irrigant fluid 20. Exemplary irrigation/aspiration catheters are described in commonly assigned U.S. Patent Nos. 6,827,701 and 6,878,128, both of which have been previously incorporated herein by reference. It will be appreciated, however, that the present invention does not require that the catheters 12 provide for irrigation, but rather only that they provide for aspiration and the ability to discharge a fluid aspirate stream to an aspirate collection receptacle.

[0023] The irrigation/aspiration catheter 12 illustrated in Fig. 1 and described in the copending U.S. patents incorporated above, provides for a pair of syringe elements for both introducing the irrigant fluid from the irrigant source 20 and discharging the aspirate stream to the aspirate receptacle 14. In other cases and for other aspiration catheters, it may be desirable to provide a separate vacuum source 22 which may be connected to or through the catheter 12 and/or aspirate receptacle 14 in order to draw the aspirate stream through the tubing 16 or other discharge connections. The present invention, of course, does not depend on what particular mechanism is provided for generating the aspirate stream or the location of the said mechanism with respect to the filter(s).

[0024] The catheter 12 has a distal end or portion 26 which is introducible into a target hollow body structure in order to withdraw fluid therefrom to produce the aspirate stream. In the preferred example of the irrigation aspiration catheter, described in the previously incorporated commonly owned U.S. patents, the catheter 12 will be intended for introduction

to a blood vessel for introducing a thrombolytic agent in order to disrupt clot. In this exemplary use, the solid material aspirated by the catheter will frequently comprise disrupted clot, thrombus, and/or plaque, which is then discharged through the aspirate line 16 to the aspirate receptacle. It will be appreciated, however, that the present invention is not limited to vascular use, clot disruption, or any other particular treatment protocol, and may instead extend to the different hollow body structures and body fluids described above.

[0025] In the simplest embodiment of the present invention, a single filter housing 18 is disposed between the aspiration catheter 12 and the aspirate receptacle 14, as illustrated in Fig. 1. As shown in Fig. 2, the filter assembly 18 typically comprises an upper shell 30, a lower shell 32, and a filter element 34 which may be disposed within the interior of the shells. The upper shell 30 is removable from the lower shell 32, typically including mating connectors 36 disposed about the open peripheries of each shell. All or a portion of the shells 30 and 32, as well as optionally the filter element 34, may be composed of transparent materials in order to permit observation of the collection of solids within the filter element 34 as the aspiration progresses. While the particular structure of filter assembly 18 shown in Fig. 2) is suitable and presently preferred, a variety of other specific filter assembly constructions could also be used.

[0026] The filter elements 34 may comprise any one of a variety of conventional filtering materials, as generally described above in the Summary of the Invention. The geometries in which the filter elements 34 are arranged will depend in large part on the construction of the remainder of the filter assembly. In the embodiment of Fig. 18, the filter element 34 is constructed so that it nests within the lower shell 32 of the filter assembly. A wide variety of other geometries would also be suitable.

[0027] In many instances, it will be desirable to provide two or more filter assemblies 18 between the aspiration catheter 12 and the aspirate receptacle 14. As illustrated in Fig. 3, a pair of filter assemblies 18 are disposed in parallel to receive the aspirate through an upper portion of tubing 16 and discharge the aspirate through a lower portion of tubing 16. Isolation valves 40 are provided so that either of the filter assemblies 18 may be taken off-line to permit access even while the aspiration continues. Optionally, as shown in broken line, a third filter assembly 18 may also be provided in parallel. It is clear that any number of such filter assemblies may be provided in parallel, although the valving may have to be

modified in order to permit any single one of the assemblies to be isolated while all others remain on line.

[0028] The filter assembly arrangement of Fig. 4 illustrates another arrangement within the scope of the present invention. A first filter assembly 18 may be provided and isolated by valves 40 in parallel with an unfiltered flow path 50 having a valve 52 therein. With this embodiment, all flow could be directed through the filter assembly 18 with valve 52 being closed. Should it be desired to gain access to filter 18, the isolation valves 40 could be closed and the flow path valve 52 open.

[0029] As a still further option, as shown in broken line in Fig. 4, additional filter assemblies 18 could be provided, with individual assemblies 18 being disposed in series, where the two series assemblies may be together placed in parallel with first filter assembly 18. It will be appreciated that a wide variety of different parallel and/or series arrangements of filter assemblies and unfiltered flow paths may be provided within the scope of the present invention.

[0030] Referring now to Figs. 5 and 6, it should also be appreciated that filter elements having different pore or mesh sizes may also be provided in series and/or in parallel in order to permit separation and classification of the particulate solid materials which are being separated from the flowing aspirate. For example, as shown in Fig. 5, three filter elements 70, 72, and 74 may be placed in series, with progressively smaller pore or mesh sizes in the direction of flow. Thus, all particles having a size greater than a first threshold would collect on top of the first filter element 70, while intermediate particle sizes having a smaller threshold size would collect on the second filter element 72. Still smaller particles would collect on the third filter element having the smallest pore or mesh sizes, while still smaller particles would pass into the aspirate receptacle without separation. The three filter elements 70, 72, and 74 could be arranged within a single filter housing or alternately within a series of three filter housings.

[0031] The filter elements 70, 72, and 74 could also be arranged in parallel, as shown in Fig. 6. Each of the screens would collect particles having a size greater than the threshold pore or mesh size of the filter element. Such a parallel arrangement of the different sized filter elements, however, would not result in true size classification, since each of the filters would collect the larger elements and would only allow smaller elements to selectively pass. This configuration would allow the use of indicator media which would be placed in the

filter(s). This indicator(s) could detect the presence of a certain biological or chemical components in the aspirant or filtered solids for the diagnostic purposes.

[0032] The collected elements could be used for a variety of therapeutic purposes. For example, when collecting aspirated thrombus in thrombolytic procedures,

5 [0033] The collected material could be used to diagnose certain disease states or conditions. These diagnostic findings could then be used to direct further interventions and/or treatments.

[0034] While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined
10 by the appended claims.

WHAT IS CLAIMED IS:

- 1 1. A method for separating materials removed from a hollow body
2 structure, said method comprising:
3 aspirating a fluid from the hollow body structure, wherein solid materials from
4 the hollow body structure are entrained in the aspirate;
5 filtering solids from the aspirate to produce a filtrate and a fluid stream; and
6 collecting the fluid stream separately from the filtrate.
- 1 2. A method as in claim 1, wherein aspirating the fluid comprises
2 introducing an aspiration catheter in the hollow body structure.
- 1 3. A method as in claim 1, wherein filtering comprises interposing at least
2 one filter assembly including a filter housing and a removable filter element between the
3 aspiration catheter and an aspirate receptacle.
- 1 4. A method as in claim 3, further comprising removing the filter element
2 from the housing to permit inspection of solids collect by the filter element.
- 1 5. A method as in claim 4, wherein the filter element is removed while
2 aspirate continues to flow from the aspiration catheter to the aspirate receptacle.
- 1 6. A method as in claim 5, wherein the aspirate flow is directed past the
2 filter assembly while the filter element is removed.
- 1 7. A method as in claim 6, wherein the aspirate is directed past the filter
2 assembly through at least a second filter assembly disposed in parallel to the first filter
3 assembly.
- 1 8. A method as in claim 6, wherein the aspirate is directed past the filter
2 assembly through an unfiltered flow path disposed in parallel to the filter assembly.
- 1 9. A method as in claim 1, wherein filtering comprises separating the
2 solids into at least two size groups.
- 1 10. A method as in claim 1, wherein filtering comprises separating the
2 solids into at least three size groups.

1 11. A method as in claim 1, wherein filtering comprises passing the fluid
2 through at least two filter elements, wherein said filter elements have different pore sizes.

1 12. A method as in claim 11, wherein the at least two filter elements are
2 arranged in series.

1 13. A method as in claim 11, wherein the at least two filter elements are
2 arranged in parallel.

1 14. A method as in claim 1, wherein the hollow body structure is selected
2 from the group consisting of blood vessels, cysts, pseudocysts, abscesses, blood vessel grafts,
3 lung passages, bile ducts, ureters, urethras, fallopian tubes, ear canals, and gastrointestinal
4 tracts.

1 15. A method as in claim 14, wherein the hollow body structure is an
2 artery.

1 16. A method as in claim 15, wherein the artery is a coronary artery, a
2 peripheral artery, or a cerebral artery.

1 17. A method as in claim 14, wherein the hollow body structure is a vein.

1 18. A method as in claim 17, wherein the vein is a peripheral vein.

1 19. A method as in claim 1, further comprising introducing an irrigation
2 fluid to the hollow body structure, wherein at least a portion of the aspirated fluid comprises
3 the irrigation fluid.

1 20. A method as in claim 19, wherein aspirating and introducing the
2 irrigation fluid are performed with an irrigation and aspiration catheter positioned in the
3 hollow body structure.

1 21. A method as in claim 19, wherein the irrigation fluid comprises saline.

1 22. A method as in claim 1, wherein the irrigation fluid comprises a
2 biologically active agent.

1 23. A method as in claim 22, wherein the biologically active agent
2 comprises a thrombolytic agent.

1 24. A system for aspirating a hollow body structure, said system
2 comprising:
3 an aspiration catheter;
4 an aspirate receptacle connectable to receive aspirate from the aspiration
5 catheter;
6 at least one filter assembly disposed between the aspiration catheter and the
7 aspirate receptacle.

1 25. A system as in claim 24, wherein the aspirate receptacle is a fluid
2 collection bag.

1 26. A system as in claim 24, further comprising a flexible tube connecting
2 the aspiration catheter to the aspirate receptacle, wherein the filter housing is connected to the
3 flexible tube between the catheter and the receptacle.

1 27. A system as in claim 24, wherein the filter assembly comprises:
2 at least one filter housing; and
3 at least one filter element removably disposed in the filter housing to separate
4 solids from aspirate flowing from the irrigation and aspiration catheter to the aspirate
5 receptacle.

1 28. A system as in claim 26, wherein the filter housing is at least partly
2 transparent to allow observation of the filter contents.

1 29. A system as in claim 26, wherein the filter housing comprises an upper
2 shell and a lower shell, wherein the upper shell and lower shell are separable to provide
3 access to the filter element in an interior of the filter housing.

1 30. A system as in claim 27, further comprising at least a second filter
2 assembly disposed in parallel and/or series to the first filter assembly between the irrigation
3 and aspiration catheter and the aspirate receptacle, and valving to permit selective diversion
4 of aspirate flow through either filter assembly.

1 31. A system as in claim 30, wherein the second filter assembly has a filter
2 element with a pore size different from that of the first filter assembly.

1 32. A system as in claim 27, wherein the filter assembly includes at least
2 two filter elements, wherein at least one of said filter elements has a different pore size than
3 that of another filter element.

1 33. A system as in claim 27, further comprising at least one flow path in
2 parallel to the filter assembly, and valving to permit selective bypass of the filter assembly.

1 34. A system as in claim 24, wherein the aspiration catheter comprises a
2 catheter shaft having at least one irrigation lumen, at least one aspiration lumen, at least one
3 irrigation port near a distal end of the shaft, and at least one aspiration port near said distal
4 end.

1 35. A system as in claim 34, wherein the distal end of the shaft is free from
2 isolation balloons.

1 36. A system as in claim 35, wherein the distal end of the shaft includes at
2 least one isolation balloon disposed proximally of the irrigation and aspiration ports.

1 37. A system as in claim 34, wherein the distal end of the shaft includes at
2 least a second isolation balloon disposed proximally of the irrigation and aspiration ports.

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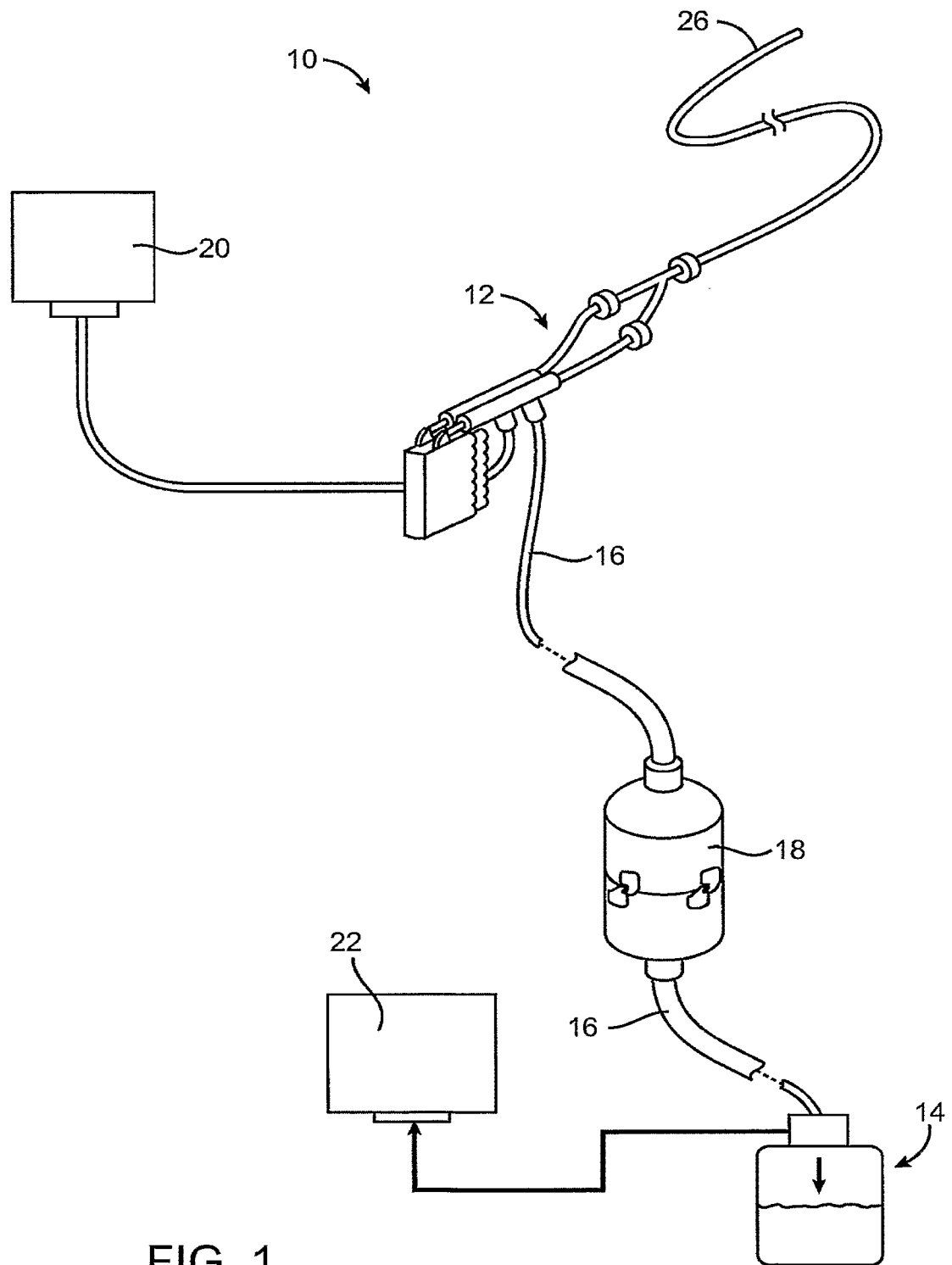
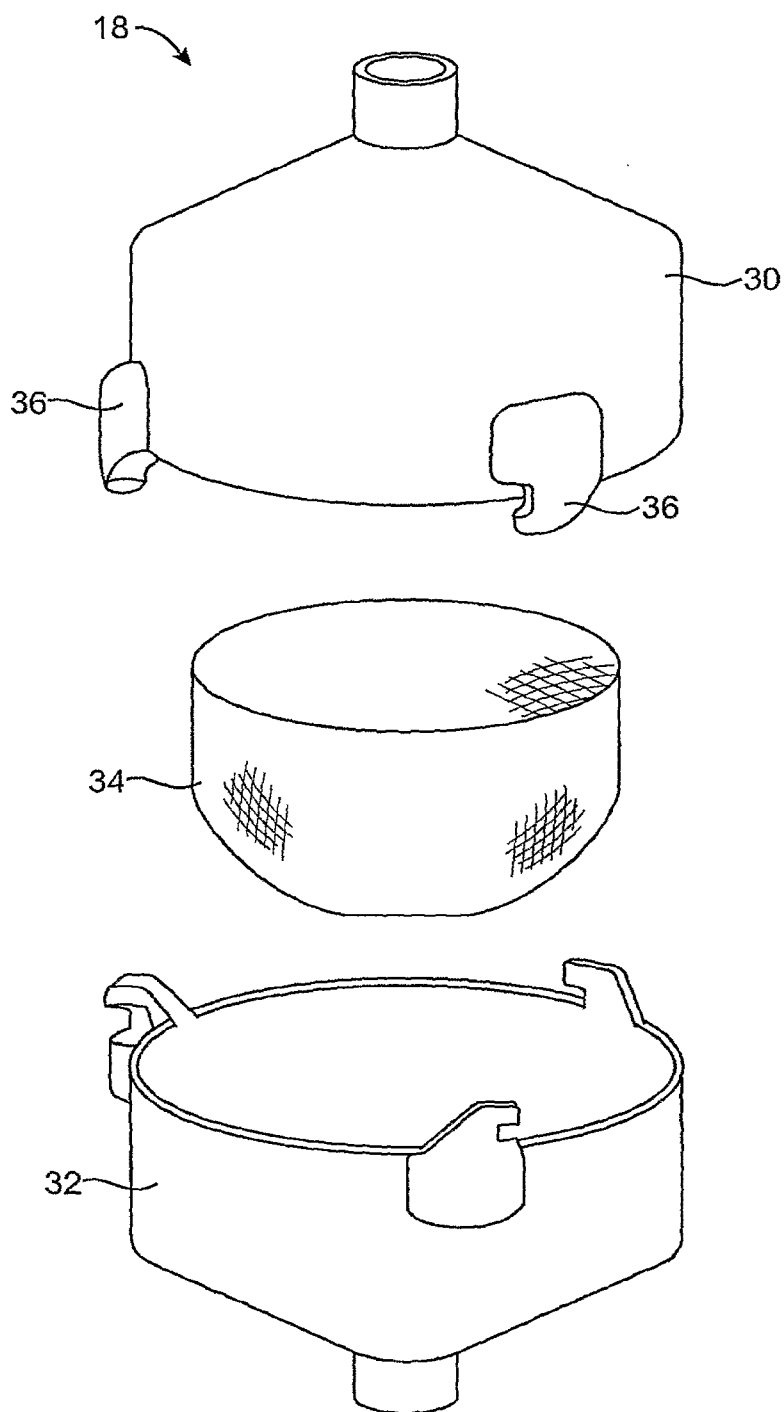


FIG. 1

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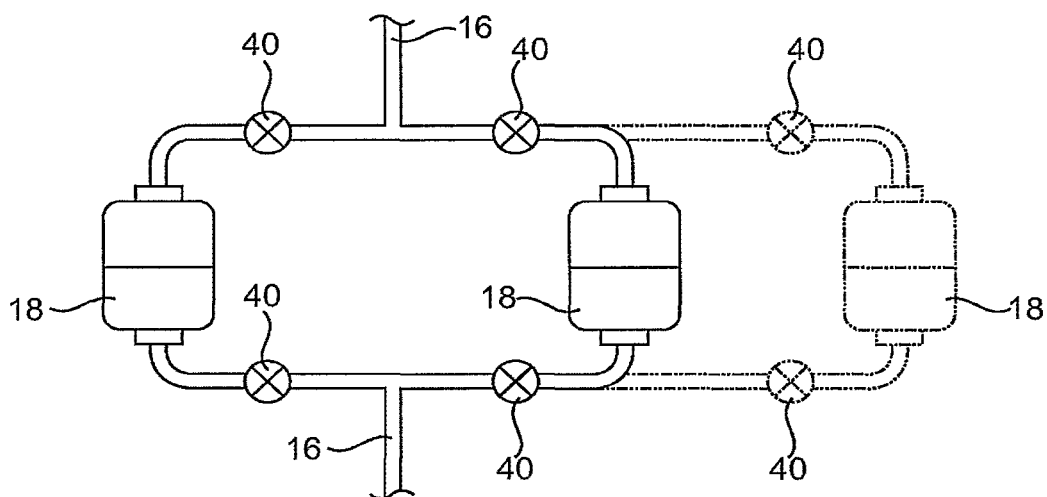


FIG. 3

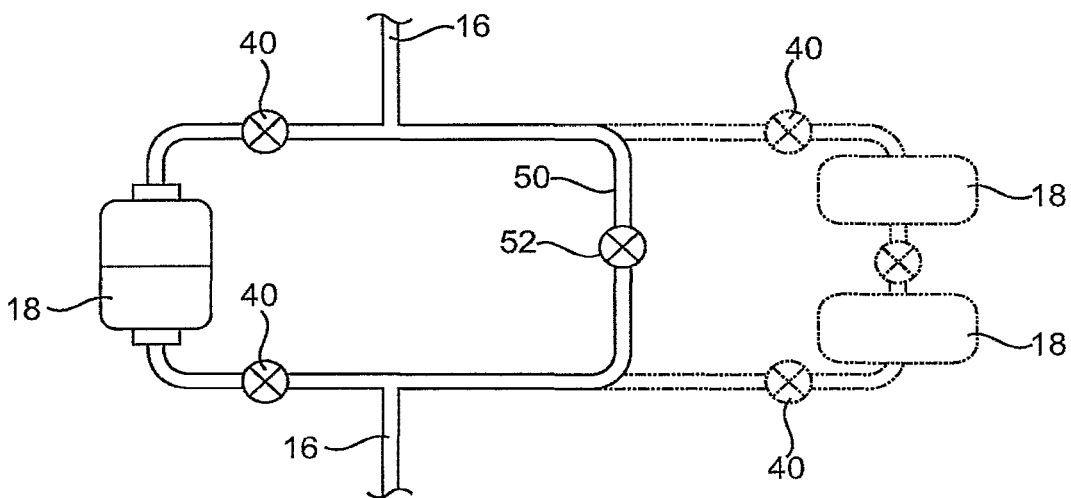
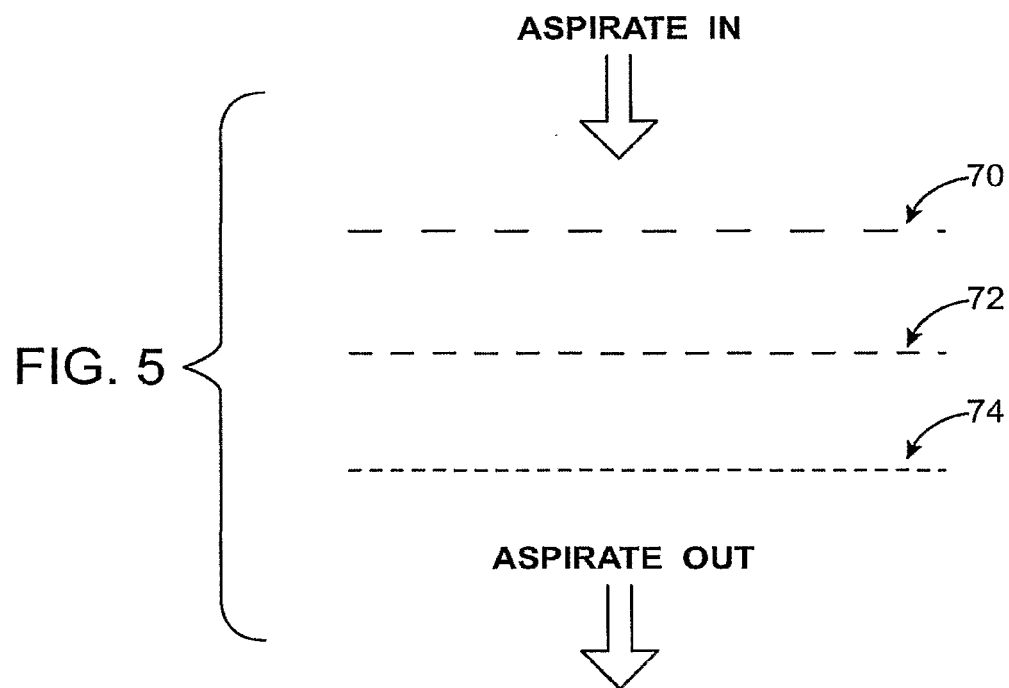
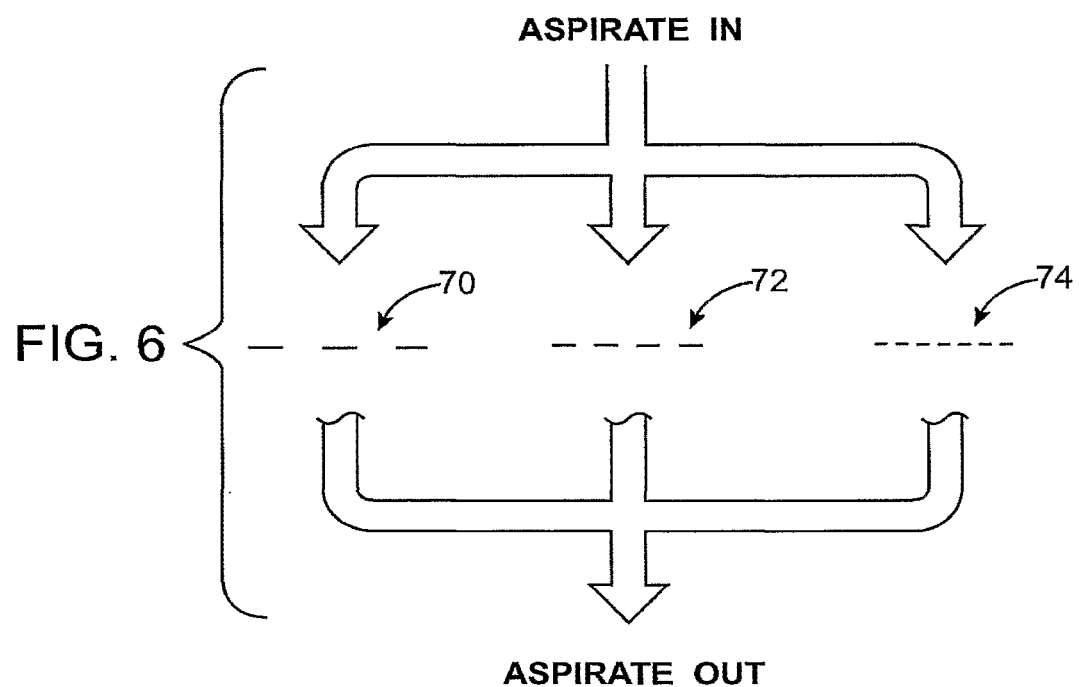


FIG. 4

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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
18/180,016	03/07/2023		1820	111552.8018.US07	20	2

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FILING RECEIPT



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Date Mailed: 04/06/2023

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which is a CON of 17/976,711 10/28/2022
which is a CON of 17/865,315 07/14/2022
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

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If Required, Foreign Filing License Granted: 04/03/2023

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 18/180,016**

Projected Publication Date: 07/13/2023

Non-Publication Request: No

Early Publication Request: No

Title

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Preliminary Class

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

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Substitute for Form PTO-875

Application or Docket Number
18/180,016

APPLICATION AS FILED - PART I

(Column 1)		(Column 2)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	320
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A	700
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	800
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*			OR	x =	0
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*				x =	0
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1820

APPLICATION AS AMENDED - PART II

(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
Total (37 CFR 1.16(i))	*	Minus **	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus ***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))						OR		
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						OR		
				TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
Total (37 CFR 1.16(i))	*	Minus **	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus ***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))						OR		
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						OR		
				TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.



ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
18/180,016

RECEIPT DATE / TIME
03/07/2023 10:03:27 PM ET

ATTORNEY DOCKET #
111552.8018.US07

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 # 1816

FILED BY JiYoung Anderson

PATENT CENTER # 61704960

FILING DATE -

CUSTOMER # 25096

FIRST NAMED
INVENTOR Ben Merritt

CORRESPONDENCE
ADDRESS -

AUTHORIZED BY Matthew Williams

Documents

TOTAL DOCUMENTS: 0

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
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Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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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.



ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
18/180,016

RECEIPT DATE / TIME
03/07/2023 07:03:45 PM ET

ATTORNEY DOCKET #
111552.8018.US07

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 # 1816

FILED BY JiYoung Anderson

PATENT CENTER # 61704296

FILING DATE -

CUSTOMER # 25096

FIRST NAMED
INVENTOR Ben Merritt

CORRESPONDENCE
ADDRESS -

AUTHORIZED BY Matthew Williams

Documents

TOTAL DOCUMENTS: 9

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
General-Fee-Authorization - 111552-8018US7.PDF	2	Authorization for Extension of Time all replies	94 KB
US_POA-signed_2021- Inari.PDF	1	Power of Attorney	106 KB
Signed_Declaration-parent- 111552-8018US7.PDF	4	Oath or Declaration filed	141 KB
POA_Trans-111552- 8018US7.PDF	1	Power of Attorney	625 KB
Track One Request - 111552- 8018US7.PDF	2	Track One Request	856 KB

ADS-111552-8018US7.PDF	10	Application Data Sheet	1781 KB
111552.8018.US07-Drawings-uspto.PDF	38	Drawings-only black and white line drawings	7891 KB
Track One CON Application - 111552-8018.US07-APP.TEXT.DOCX	56	Application body structured text document	105 KB

Warning: Bookmarks were found and have been removed.

CON App 111552-8018US7 - pto.PDF	56	Auxiliary PDF of Application	232 KB
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Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
General-Fee-Authorization - 111552-8018US7.PDF	CC273E5C1C7C1219F0A68F63D22191CDE6A674B9FE94A609BEB2C68B906D9D2D68CBA5C2C805E87982C3F80D3F8689611B52FF4FEEFCE3FB8012278ABD878A3D
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Track One Request - 111552-8018US7.PDF	AE8B27BBFAC82DC3C1A89A8FF39C07E6B7CF56F8EA5CF51FDF815206F6973B757299447002B778E2E14BDAA6497B1C1ACF9200CAD2B9B4A9956878B28D026AE4

ADS-111552-8018US7.PDF	6FA1BD9E0D2151F59CB93ECF251857B358646F133C3E083B0 29CEB147E3184E68FA5F1EA49A9F80BA9D61A1FA3F17F65A4 10184BCFDB055410E5ABAEC4B149D1
111552.8018.US07-Drawings- uspto.PDF	8B36C485D0232508655CD8CA829CB33255E01EDEA2747AB9B 4813E15574C5CFC83B7E8C88820B891EDE1CF6A4F10681F3B CE9DD92666DED276632D1E14F0B283
Track One CON Application - 111552-8018.US07- APP.TEXT.DOCX	C5186F2F36B06241C2E10412926D6939084C46F5FF46426777D 95B7A9C5CCD3A60BB08DF4A786EB544F3852A985B45C9F483 8A1C0FFEF957CEC6289600AFB1BE
CON App 111552-8018US7 - pto.PDF	FAD418468FE7075530784A0654F97AB2DEFB161C3BF18C2A4 46B434DA05FDA51A7BBA2D1F1983867ED882E9F7D8D712CB2 8F6C504B2EE8019B63DCF91BB93646

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

New Applications Under 35 U.S.C. 111

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

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

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New International Application Filed with the USPTO as a Receiving Office

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.

**CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION
UNDER 37 CFR 1.102(e) (Page 1 of 1)**

First Named Inventor:	Ben Merritt	Nonprovisional Application Number (if known):	
Title of Invention:	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently \$0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.
2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.
3. The applicable box is checked below:

I. ☒ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

- i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.
---OR---
(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.
- ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, or the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

- i. A request for continued examination has been filed with, or prior to, this form.
- ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
- iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
- iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
- v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature <u>/Matthew S. Williams/</u>	Date <u>2023-03-07</u>
Name <u>Matthew S. Williams</u> (Print/Typed)	Practitioner Registration Number <u>77,516</u>

Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.*

☒ *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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Ben Merritt et al.

Application No.: Not Yet Assigned

Confirmation No.: N/A

Filed: Concurrently Herewith

Art Unit: Not Yet Assigned

For: SYSTEM FOR TREATING EMBOLISM AND
ASSOCIATED DEVICES AND METHODS

Examiner: Not Yet Assigned

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

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

Dear Commissioner:

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

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

Dated: March 7, 2023

Respectfully submitted,

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

Application No.: UNKNOWN

Docket No.111552-8018.US07

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

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

Attorney for Applicant

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	Not Yet Assigned
Filing Date	Concurrently Herewith
First Named Inventor	Ben Merritt
Title	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	111552.8018.US07

SIGNATURE of Applicant or Patent Practitioner

Signature	/Matthew S. Williams/	Date (Optional)	2023-03-07
Name	Matthew S. Williams	Registration Number	38,264
Title (if Applicant is a juristic entity)	Attorney for Applicant		
Applicant Name (if Applicant is a juristic entity)	Inari Medical, Inc.		

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



*Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

POWER OF ATTORNEY BY APPLICANT

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

Application Number

Filing Date

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



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

25096

OR



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

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



The address associated with the above-mentioned Customer Number

OR



The address associated with Customer Number:

OR



Firm or
Individual Name

Address

City

State

Zip

Country

Telephone

Email

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

Inari Medical, Inc.



Inventor or Joint Inventor (title not required below)



Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)



Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)



Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

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

Signature

Date (Optional)

10 Dec 2021

Name

Brian Strauss

Title

Vice President, Inari Medical, Inc.

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



Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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.US07
		Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS		
<p>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.</p> <p>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.</p>			

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.US07
		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	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	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.US07	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

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	111552.8018.US07
		Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS		

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not be** the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	☒ Customer Number	US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)
Customer Number	25096		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	18/167757	2023-02-10

Application Data Sheet 37 CFR 1.76		Attorney Docket Number		111552.8018.US07	
		Application Number			
Title of Invention		SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS			

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		
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. Add					

Foreign Priority Information:

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

			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.			Add

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	111552.8018.US07
		Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS		

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

<p>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.</p> <p>☐ 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.</p>	
--	--

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	111552.8018.US07
		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.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	111552.8018.US07
		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	Remove
<p>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.</p>		
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:		
<div style="border: 1px solid black; height: 20px; width: 100%;"></div>		
Name of the Deceased or Legally Incapacitated Inventor: <div style="border: 1px solid black; width: 400px; height: 20px;"></div>		
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
Country	US	Postal Code
Phone Number		Fax Number
Email Address		
Additional Applicant Data may be generated within this form by selecting the Add button. Add		

Assignee Information including Non-Applicant Assignee Information:

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

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	111552.8018.US07
		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)	2023-03-07
First Name	Matthew S.	Last Name	Williams	Registration Number
			77,516	

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

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	111552.8018.US07
		Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS		

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

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

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

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

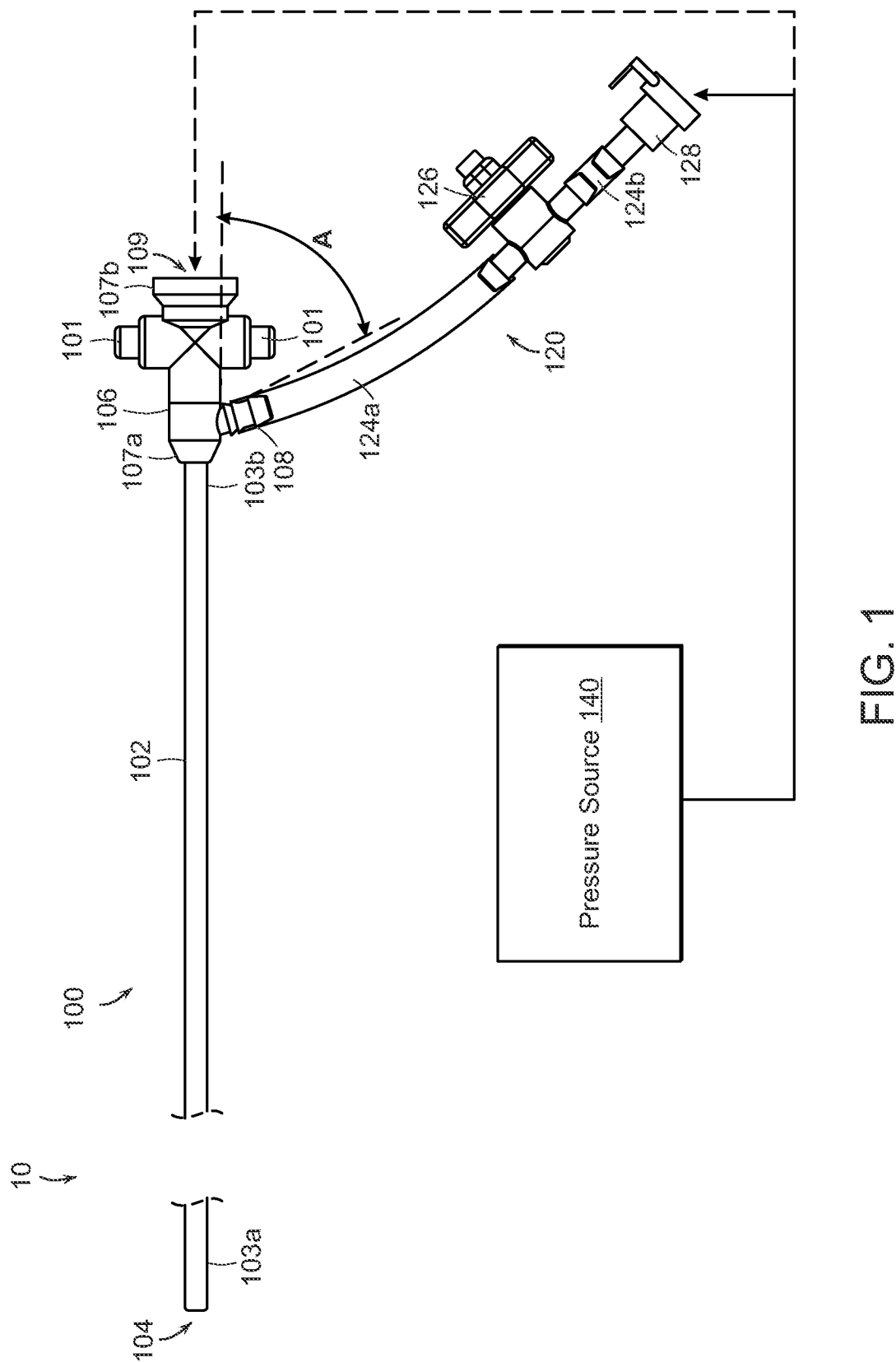


FIG. 1

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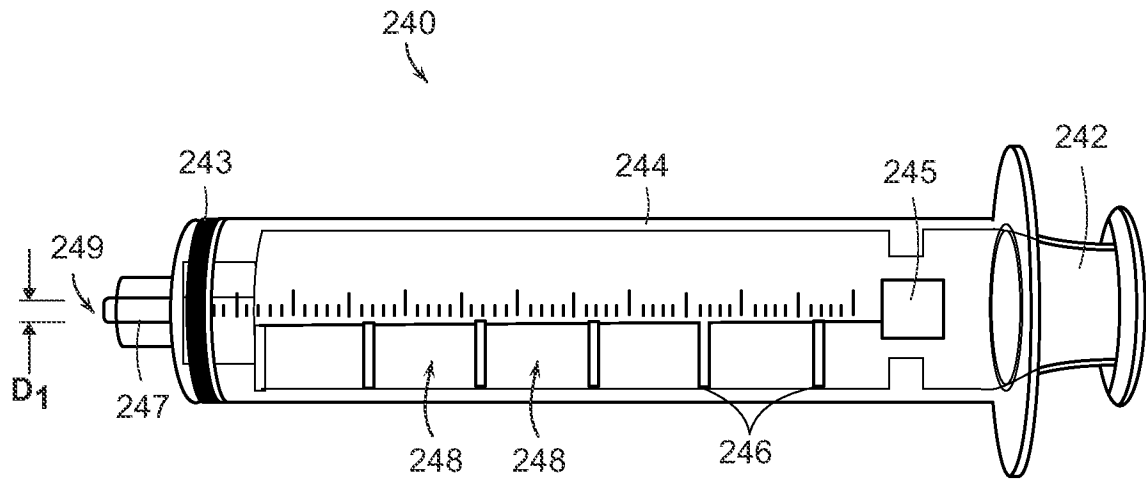


FIG. 2

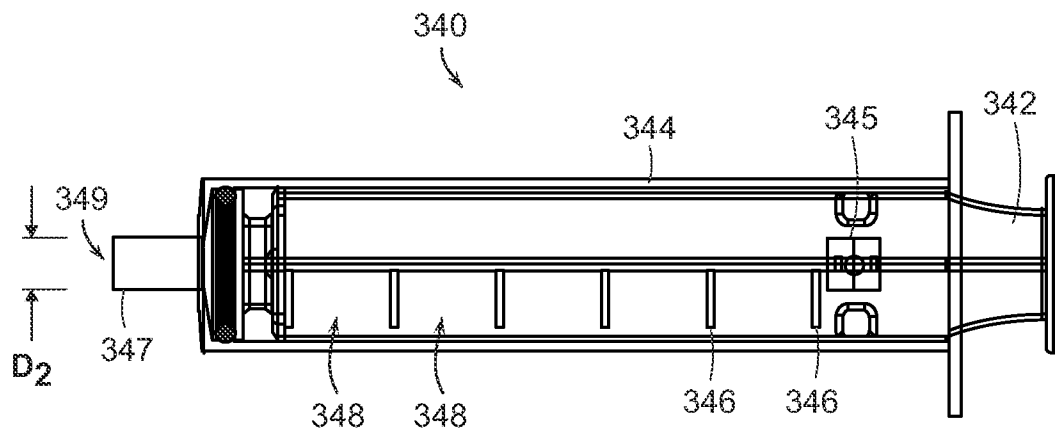


FIG. 3A

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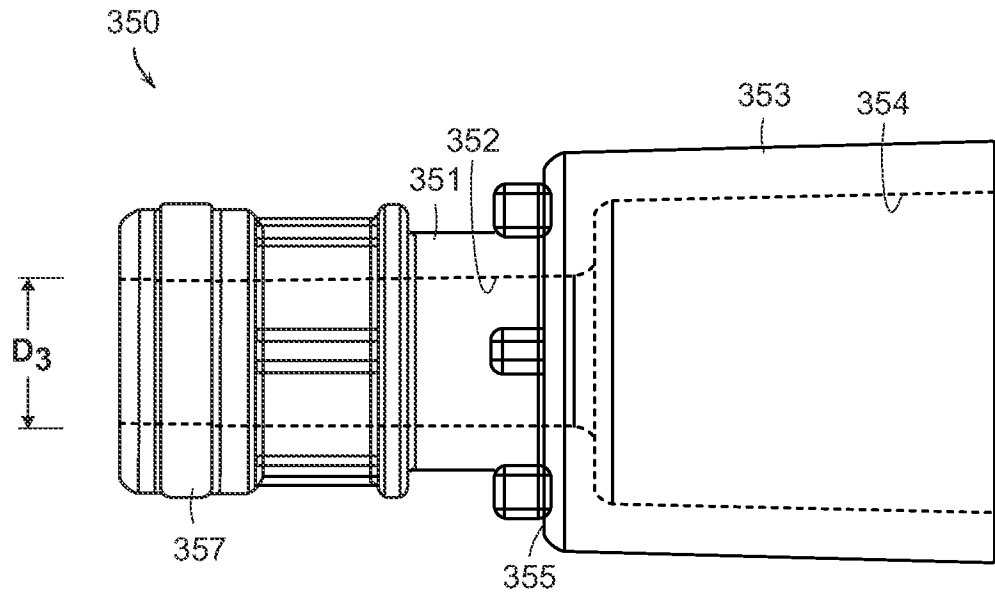


FIG. 3B

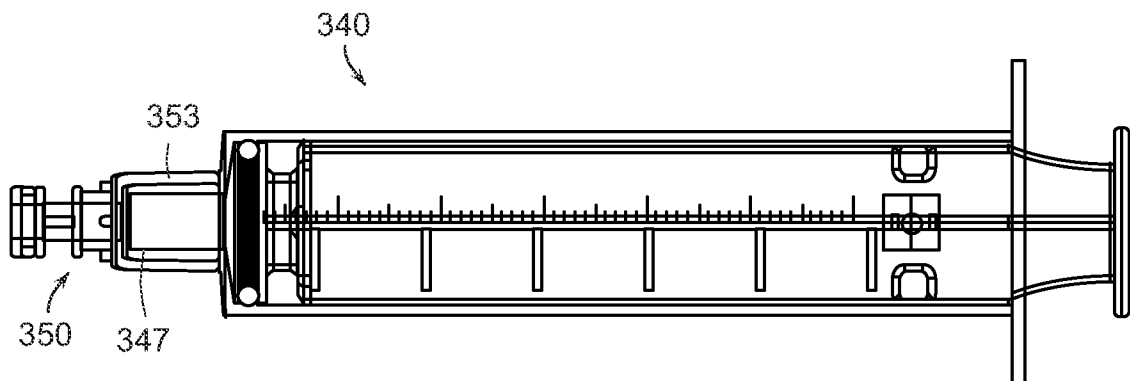
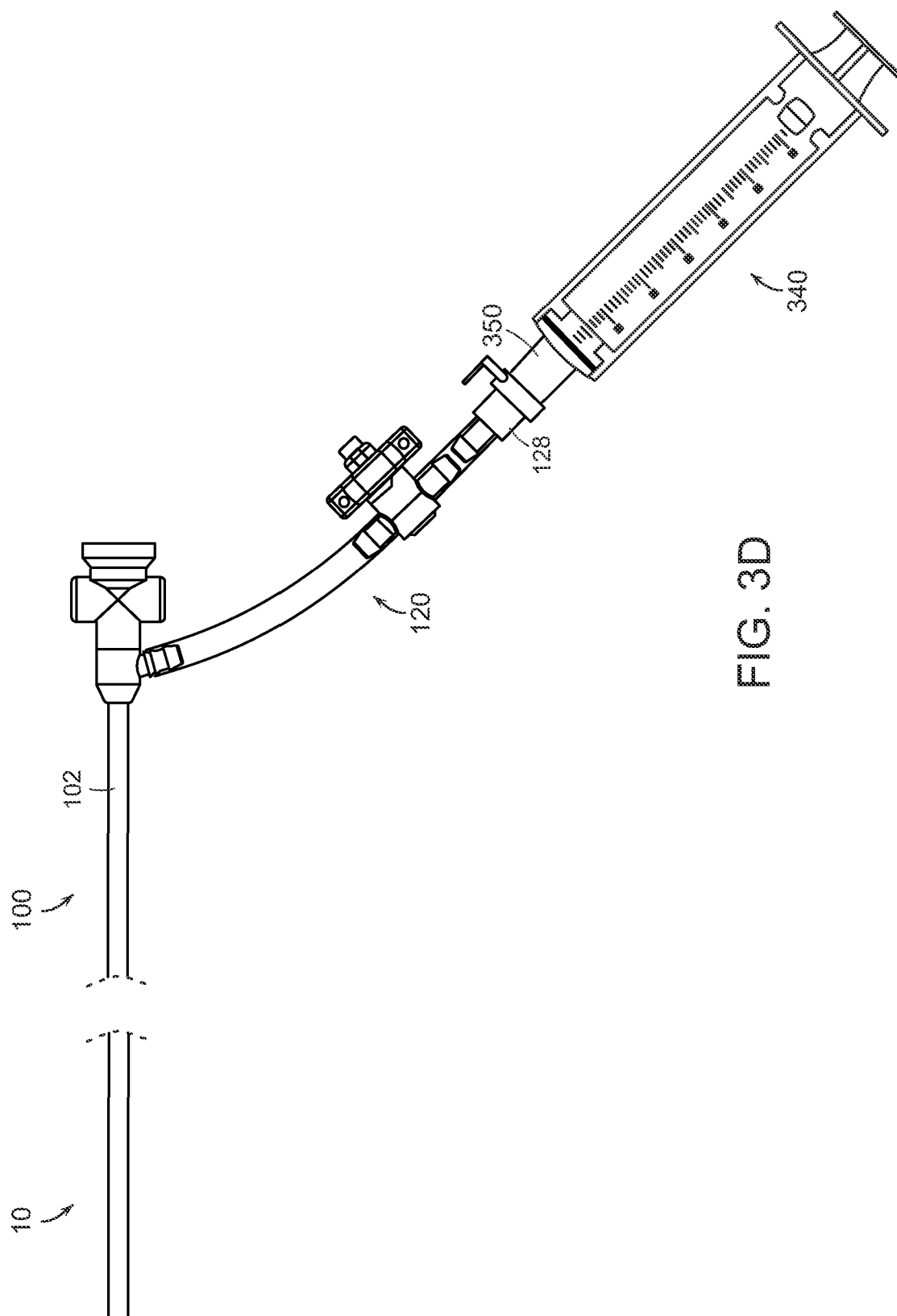


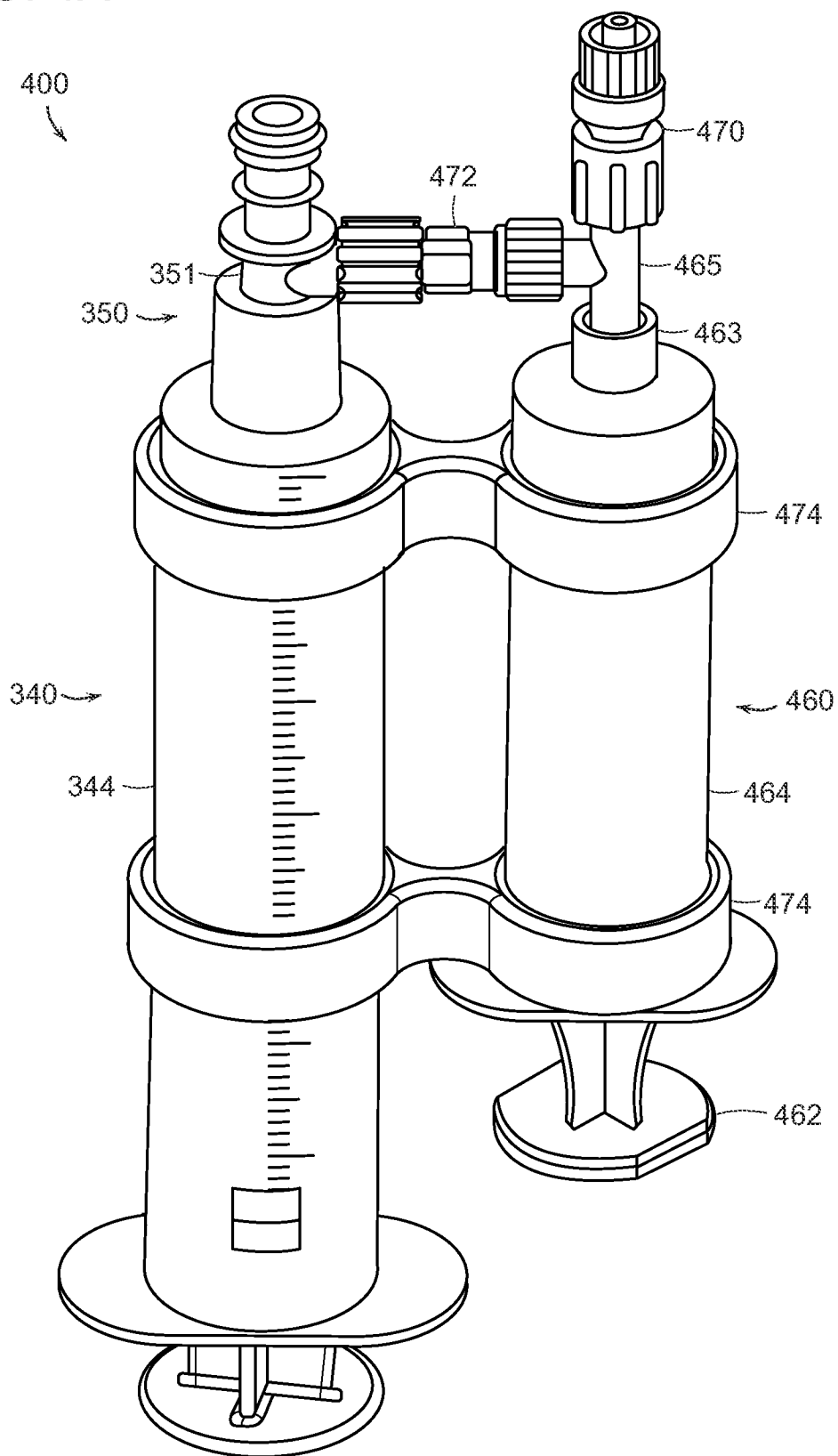
FIG. 3C

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FIG. 4A



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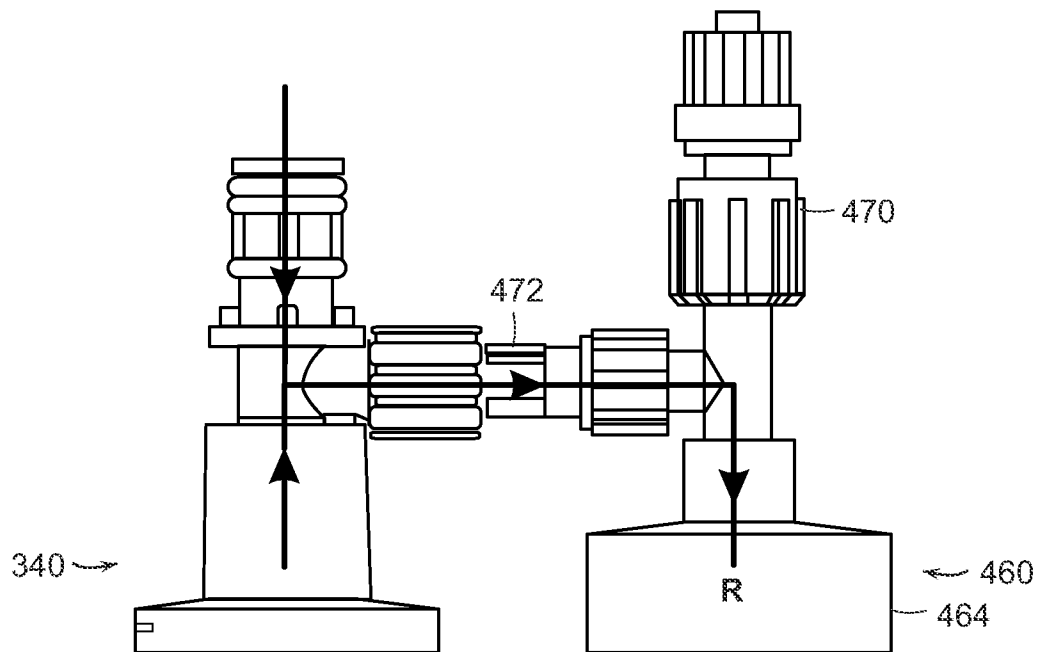


FIG. 4B

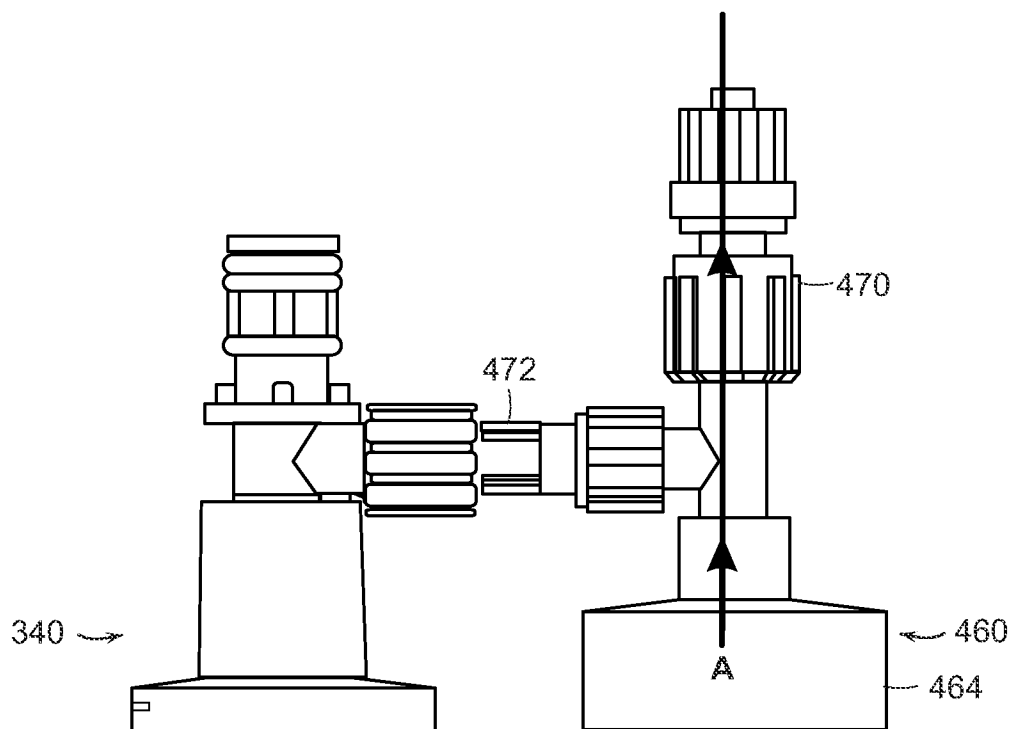
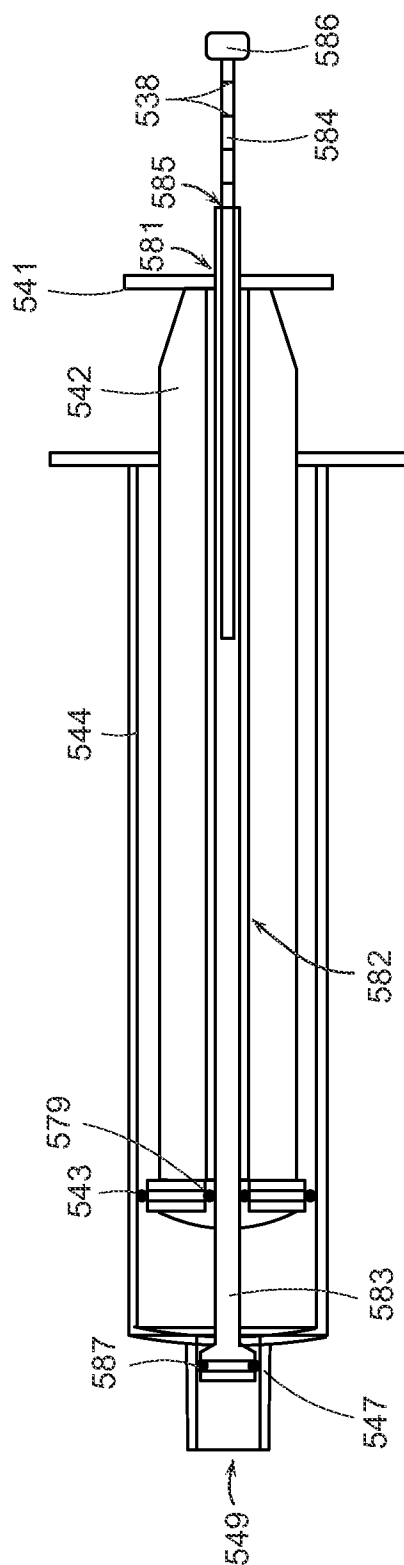


FIG. 4C

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FIG. 6

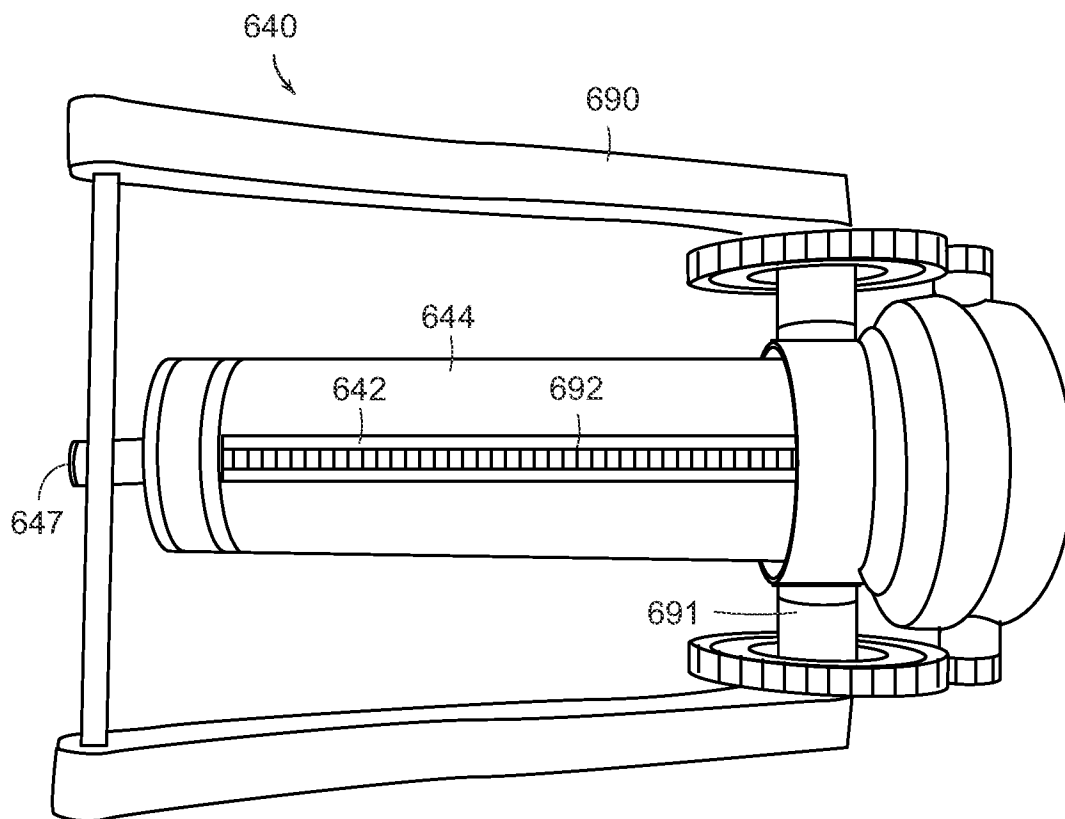
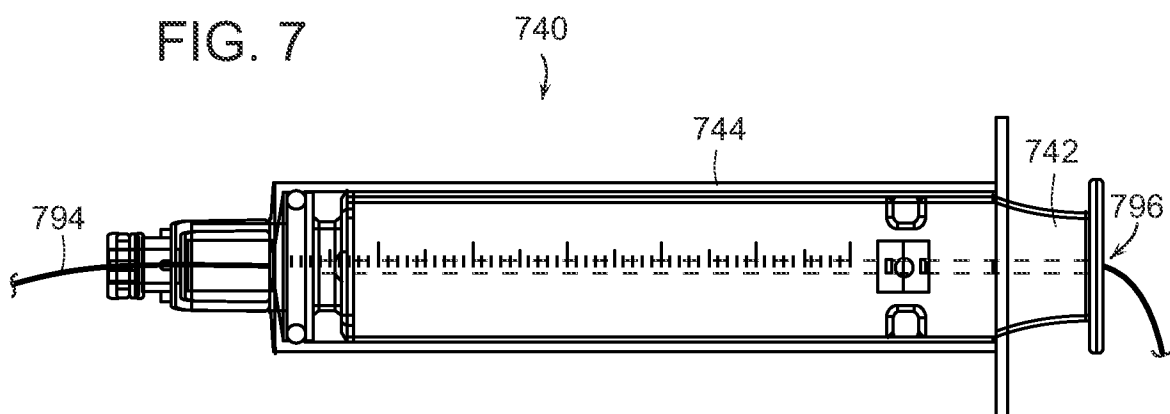


FIG. 7



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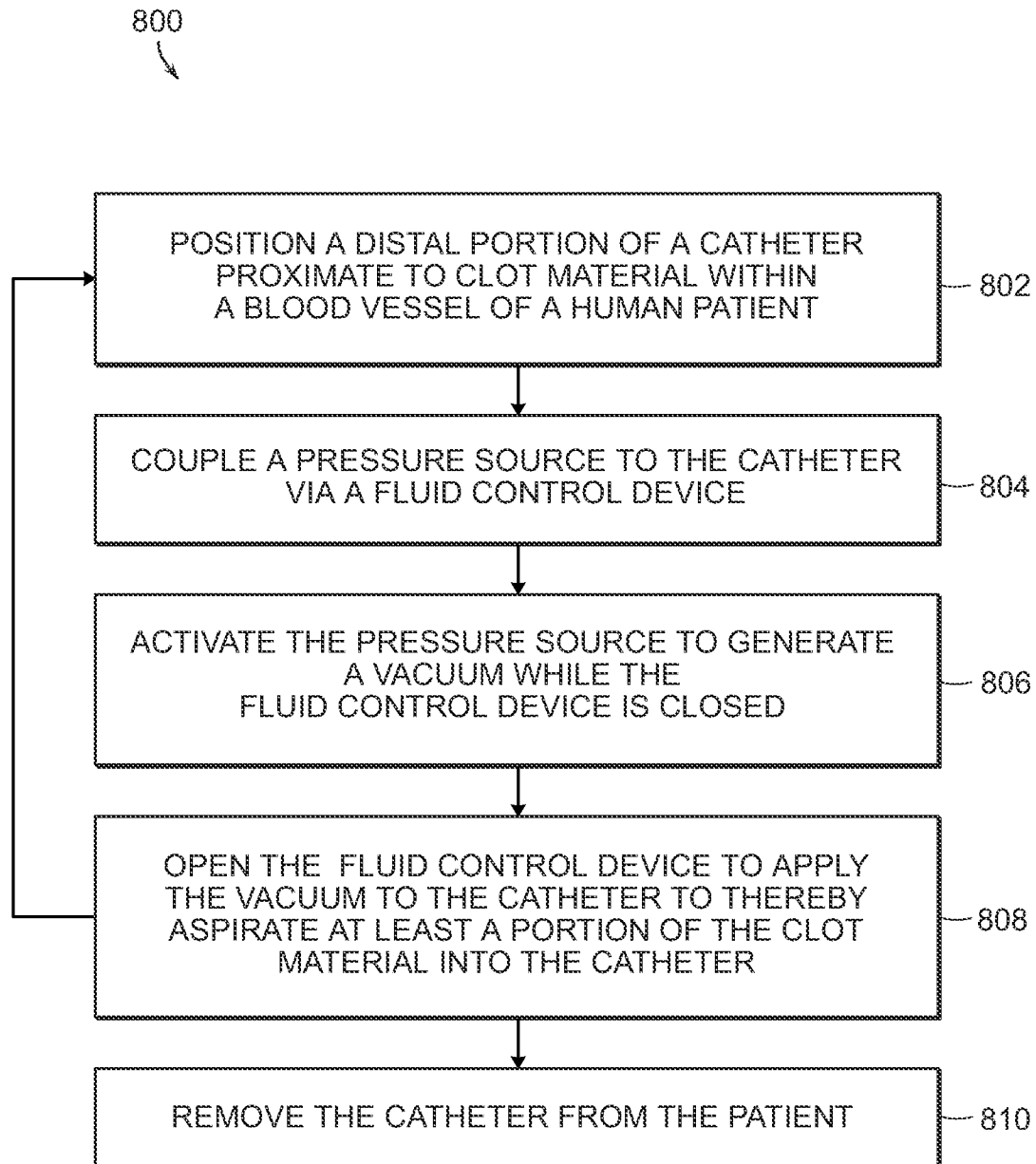
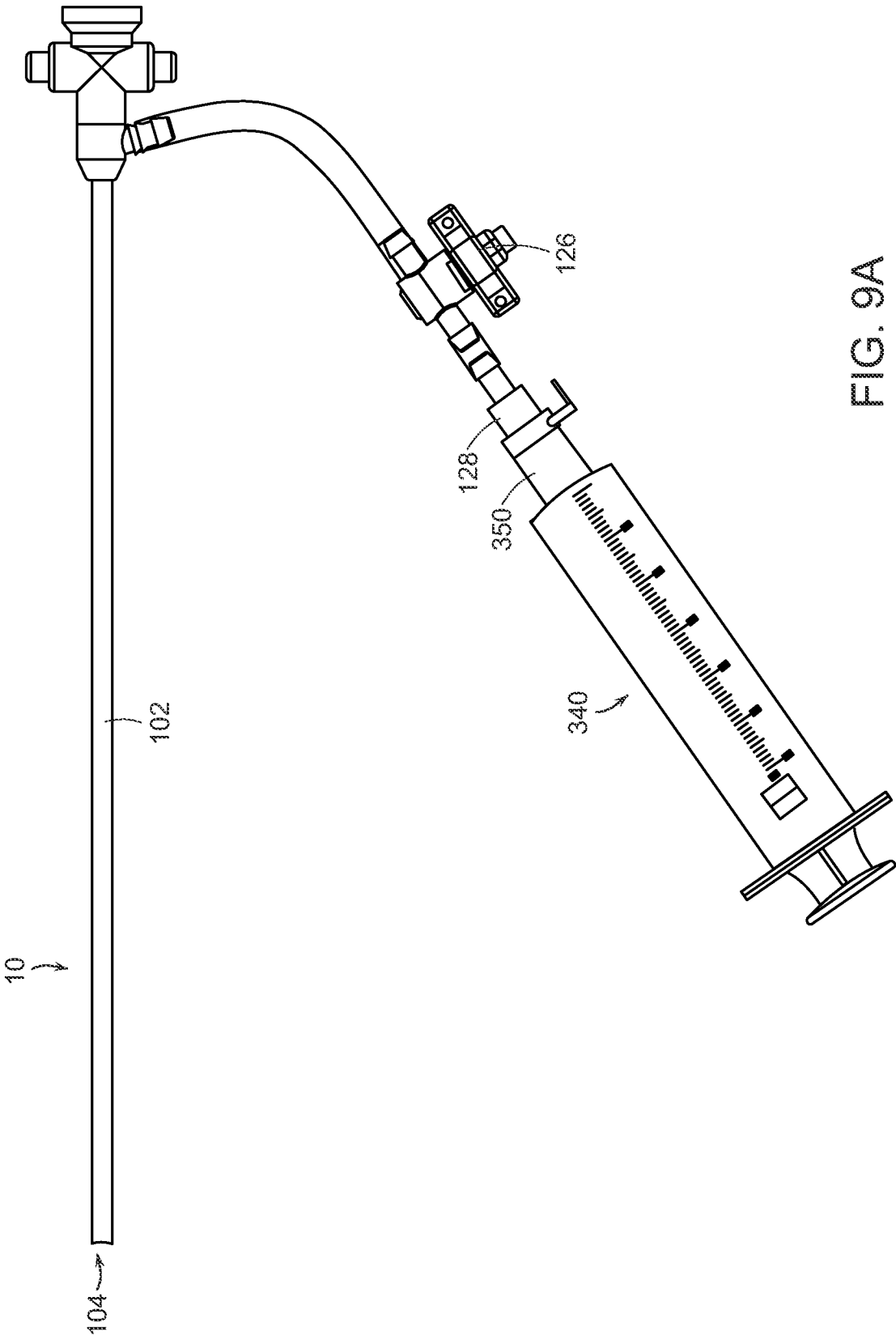
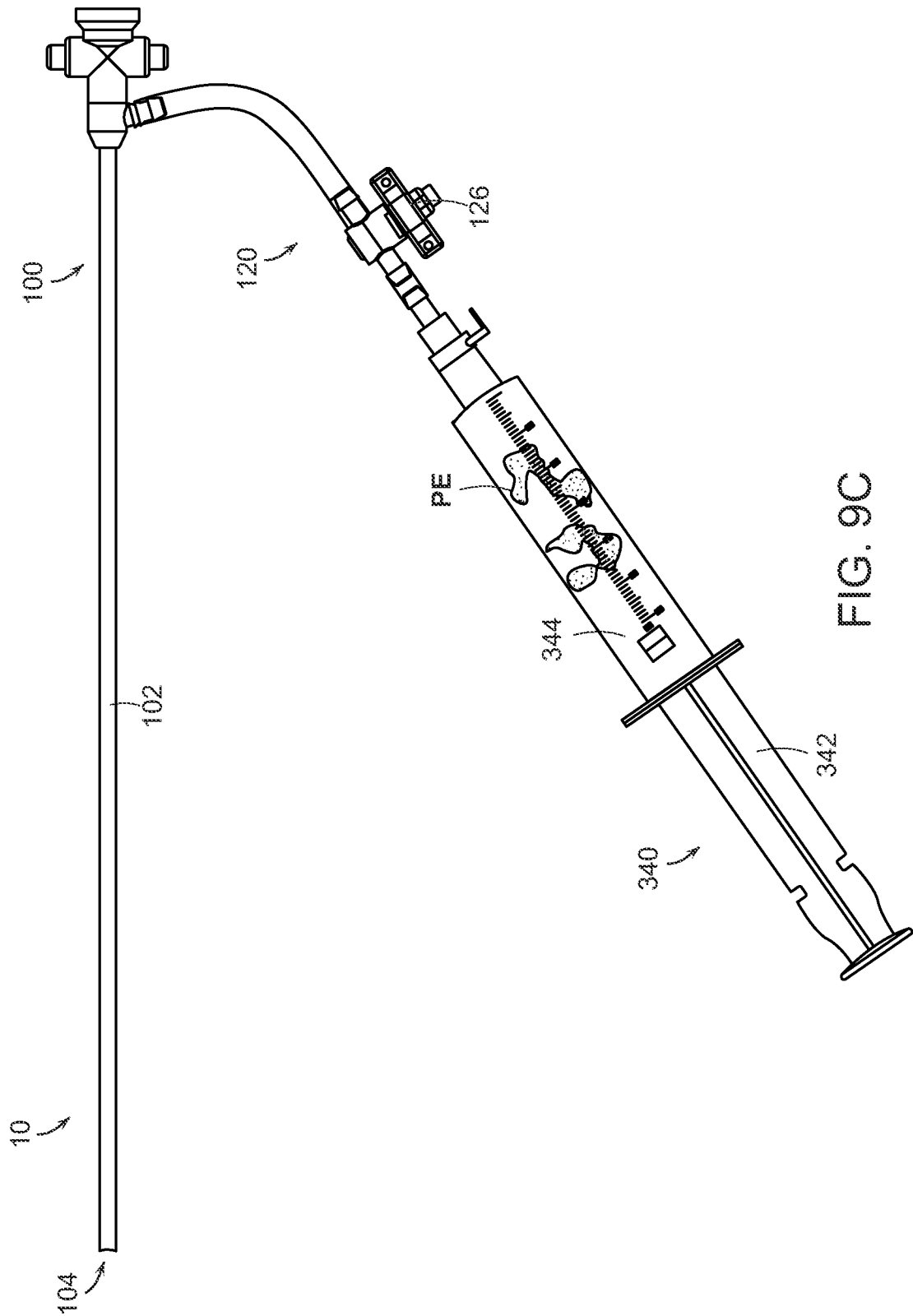


FIG. 8

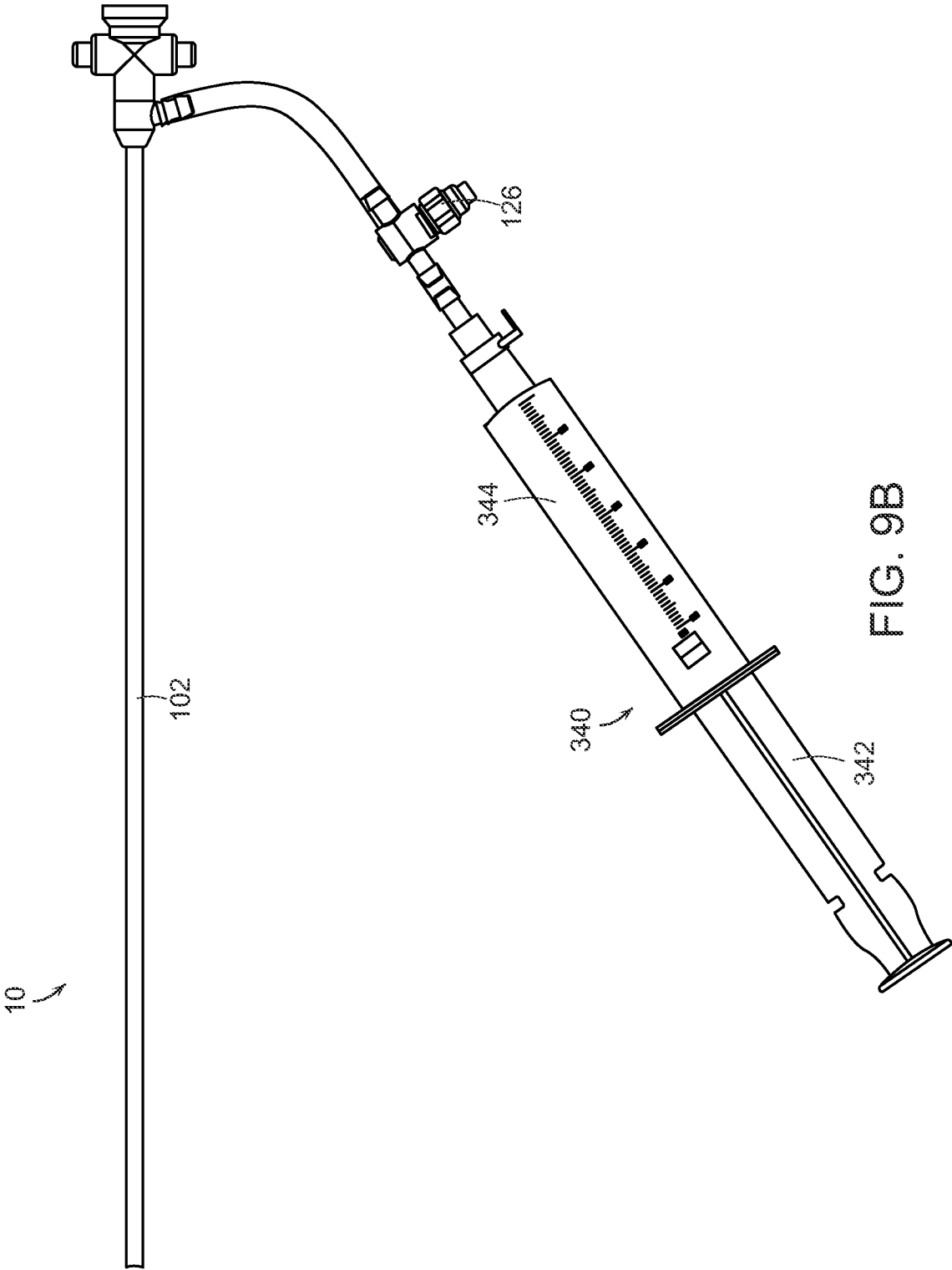
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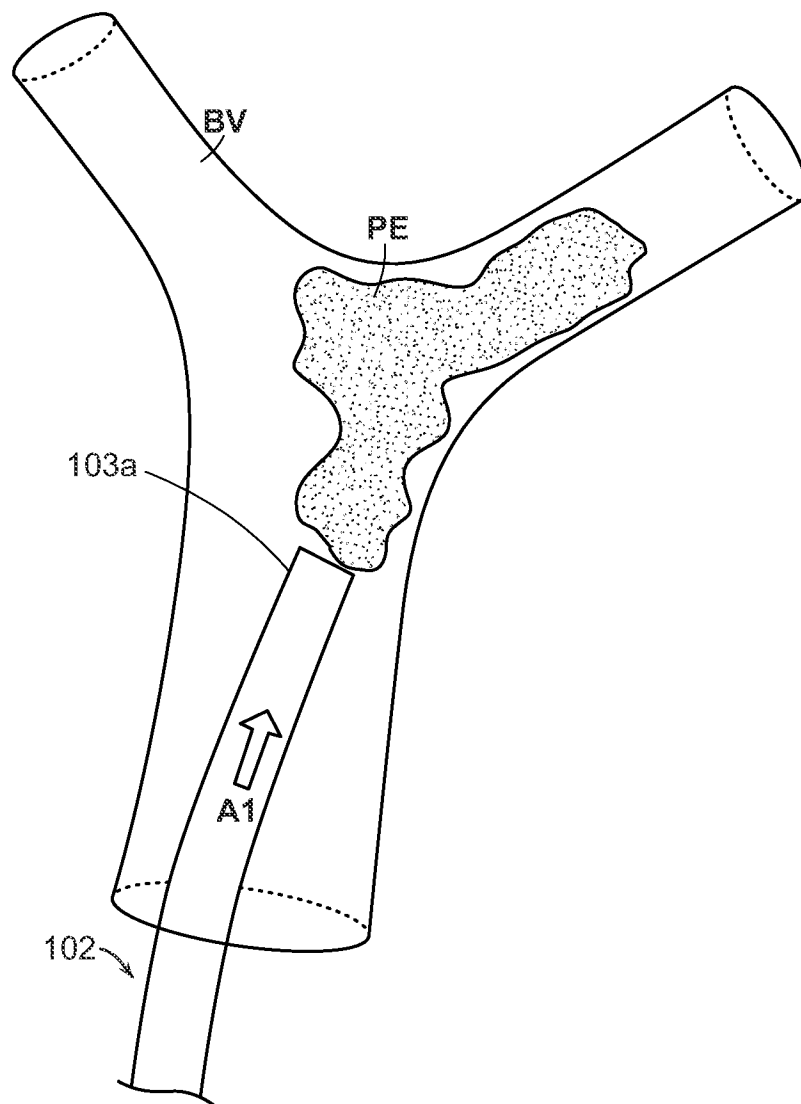
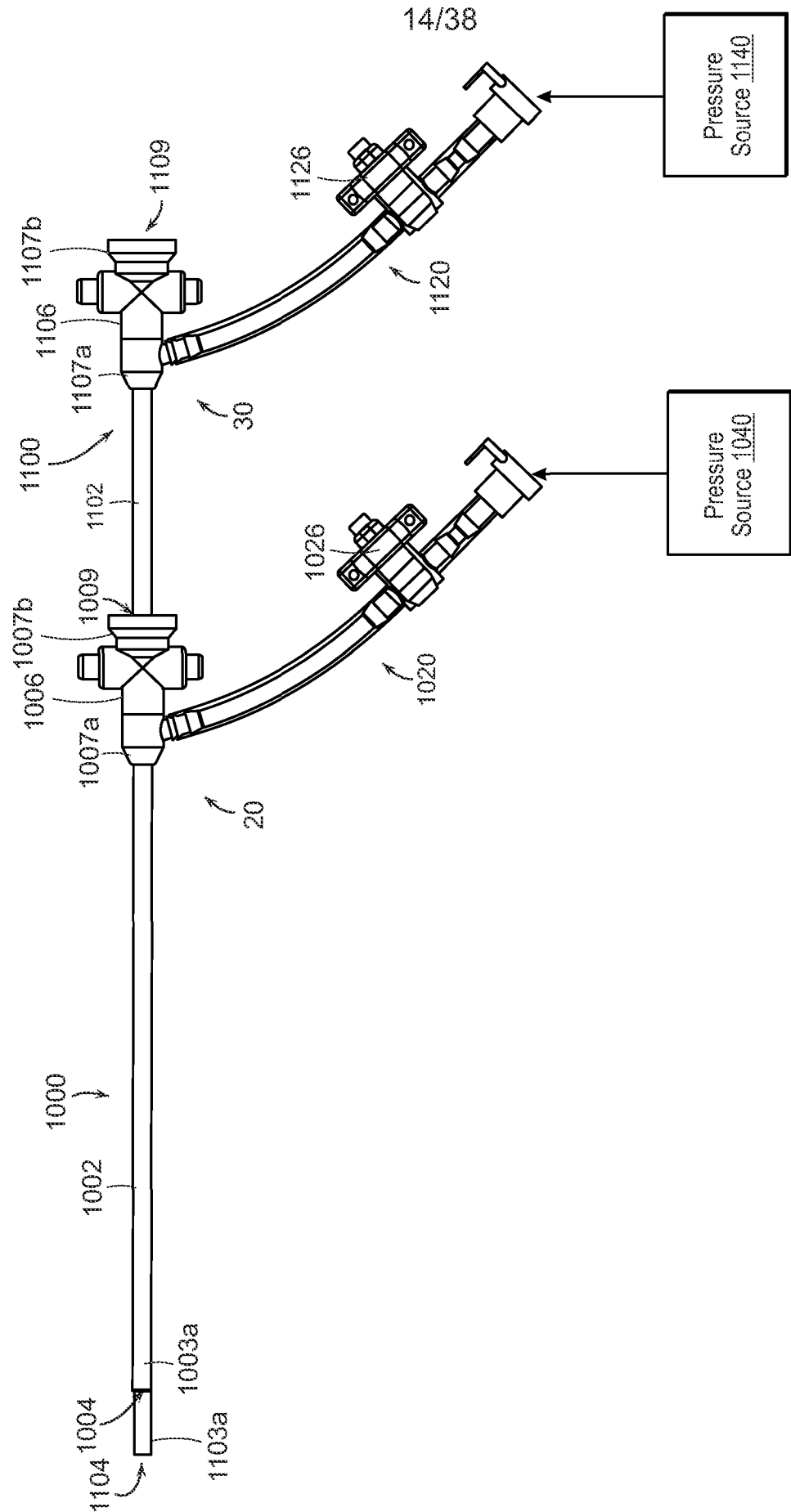


FIG. 10A



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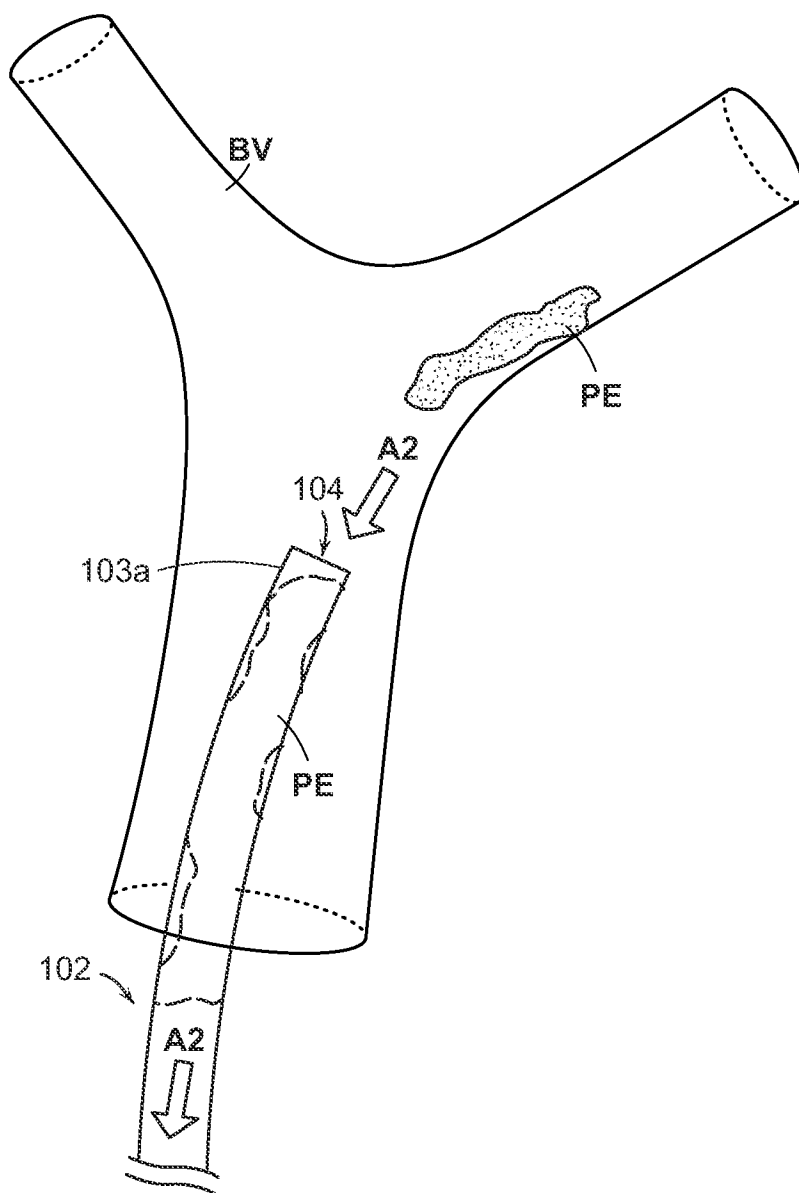


FIG. 10B

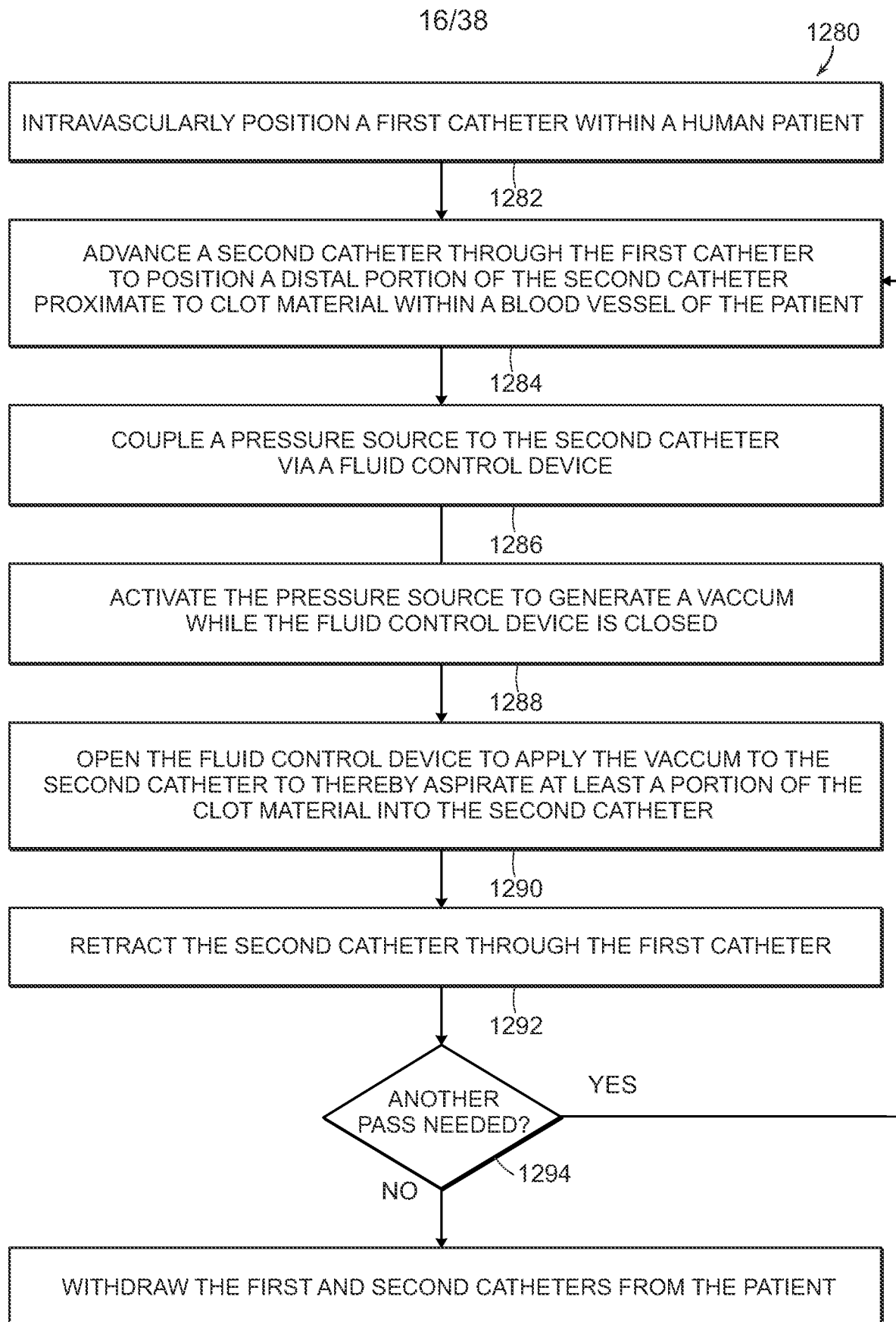


FIG. 12

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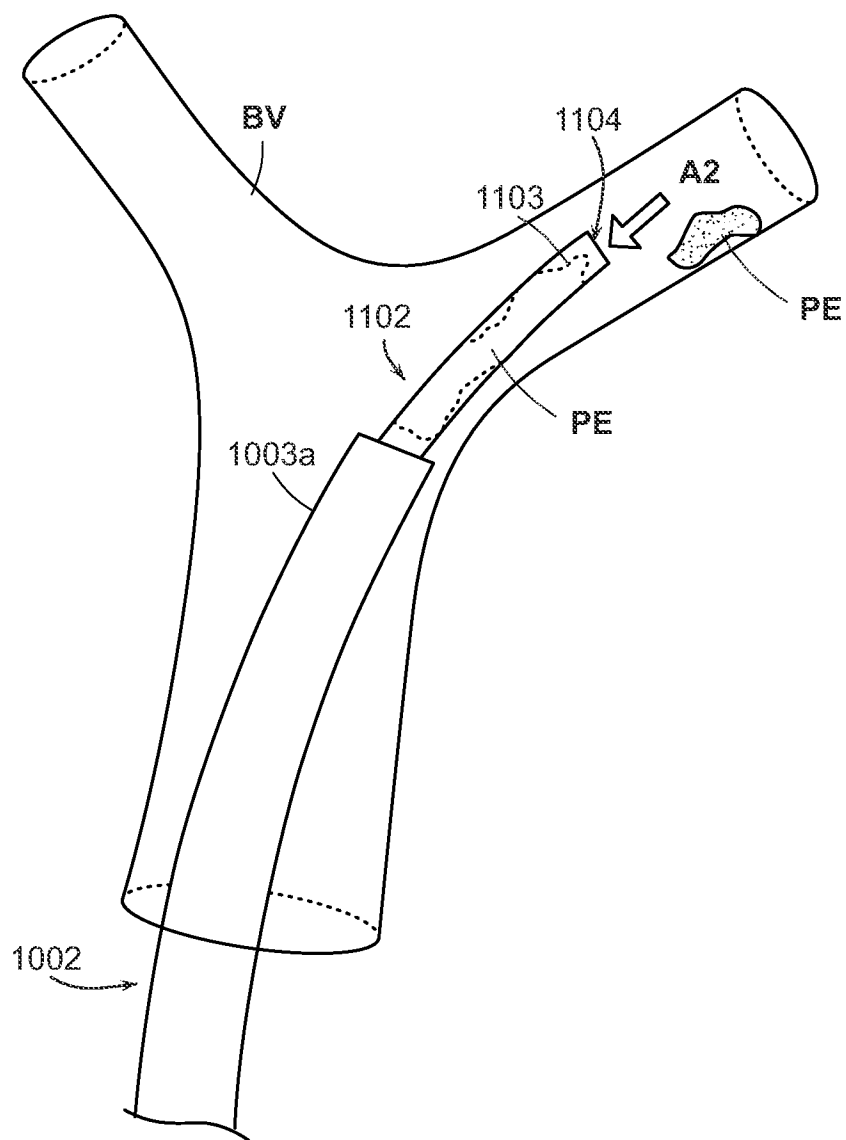


FIG. 13B

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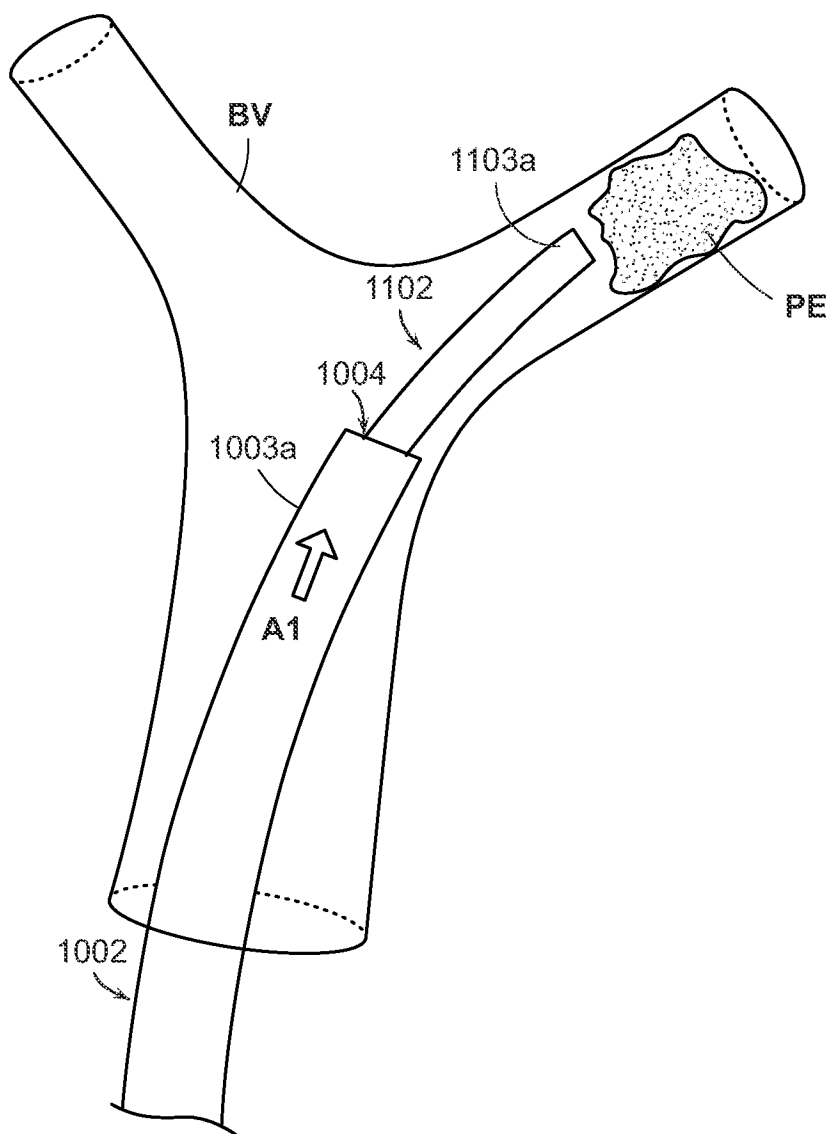


FIG. 13A

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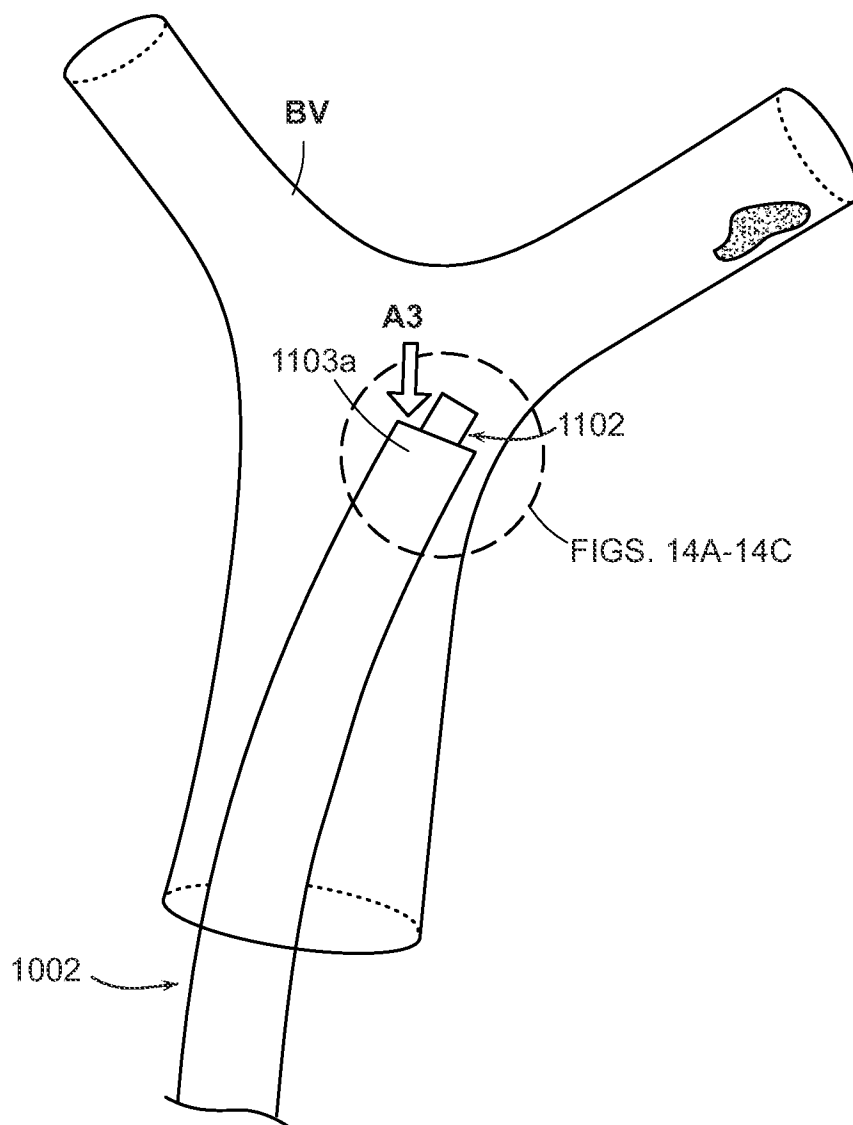


FIG. 13C

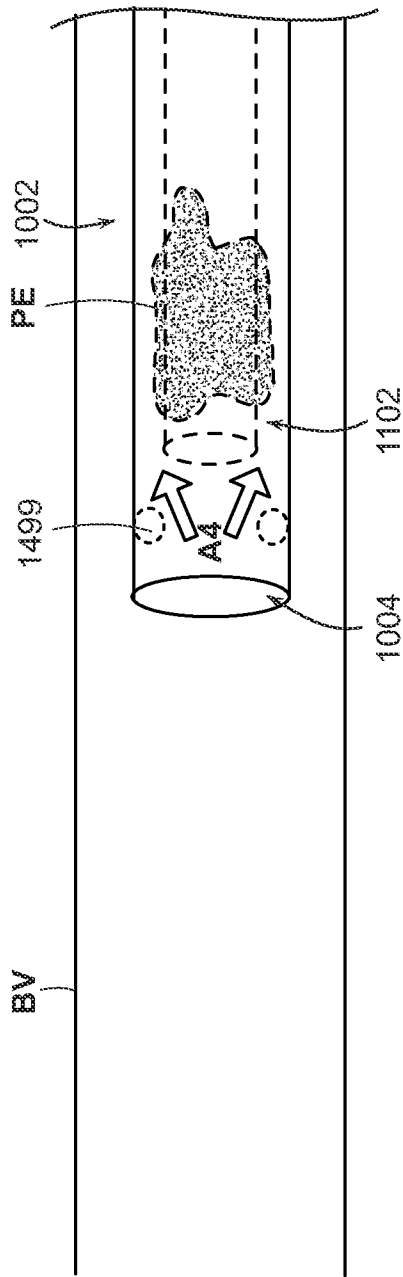


FIG. 14C

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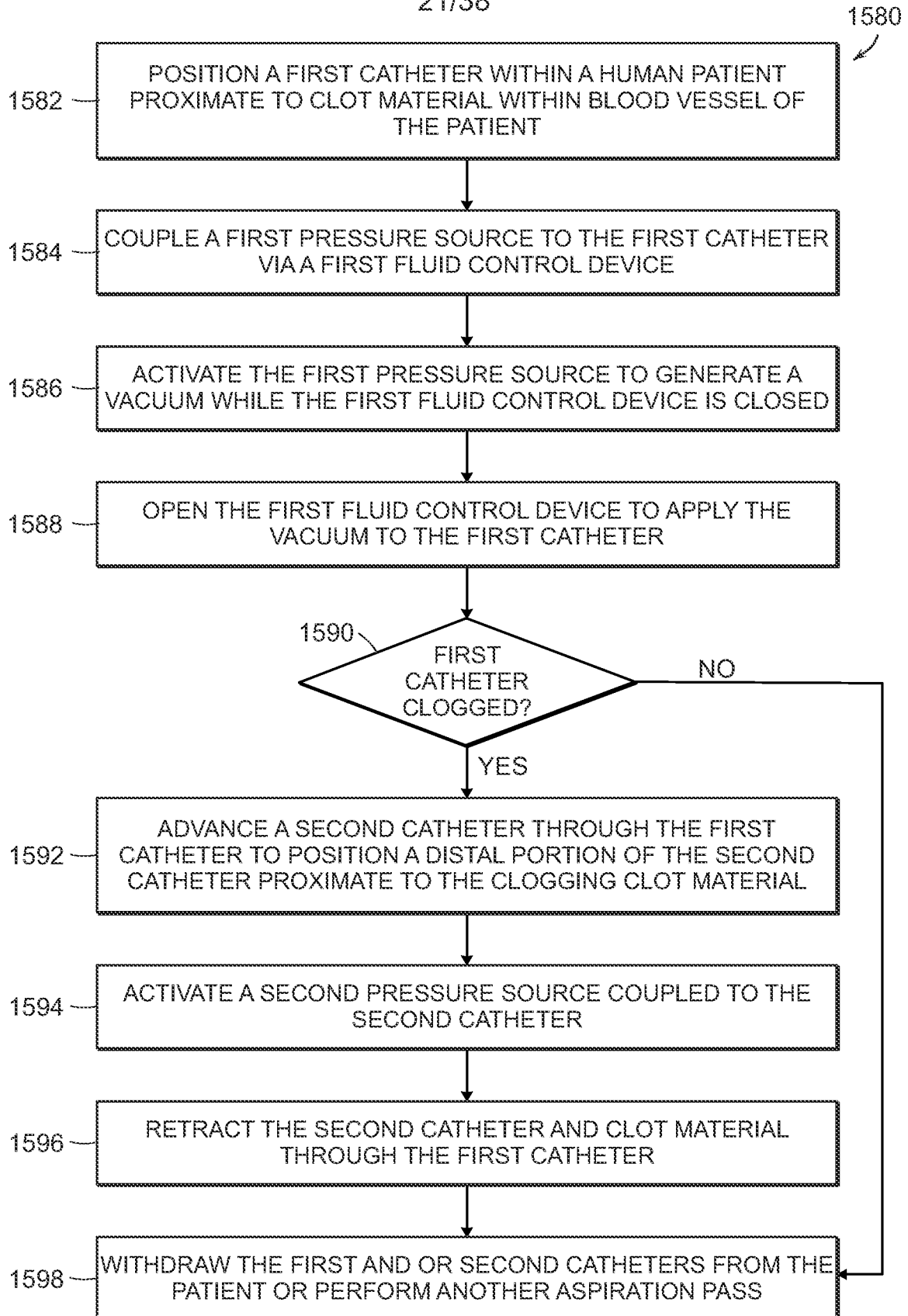
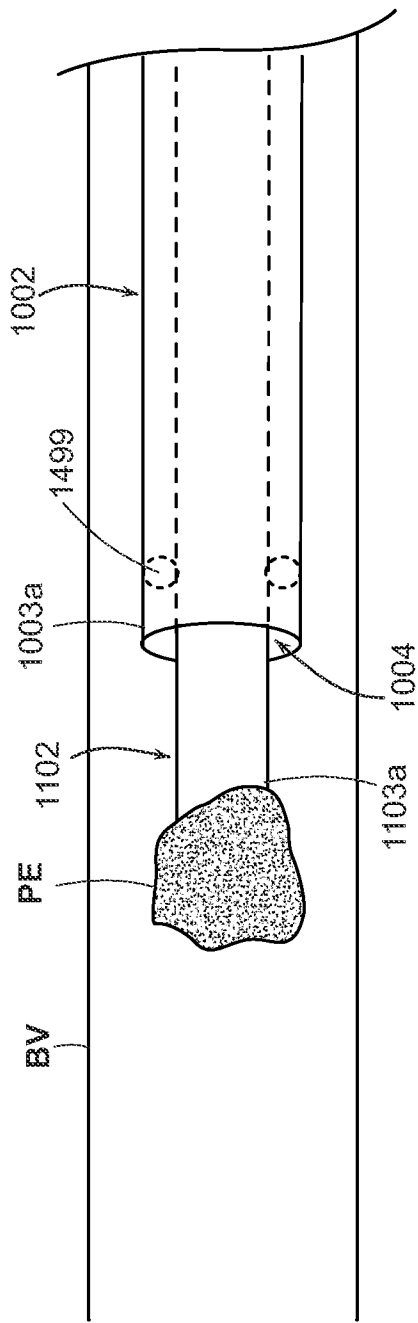
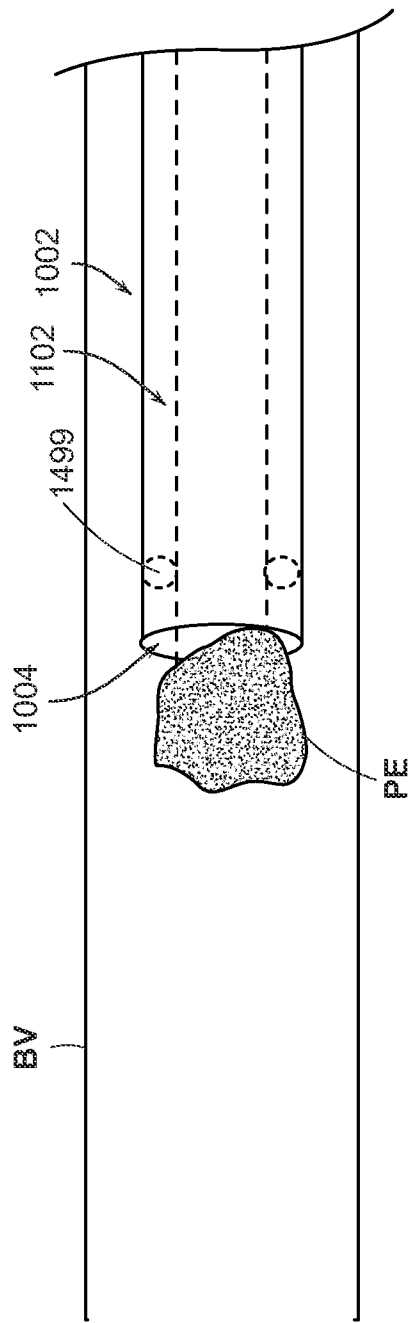


FIG. 15



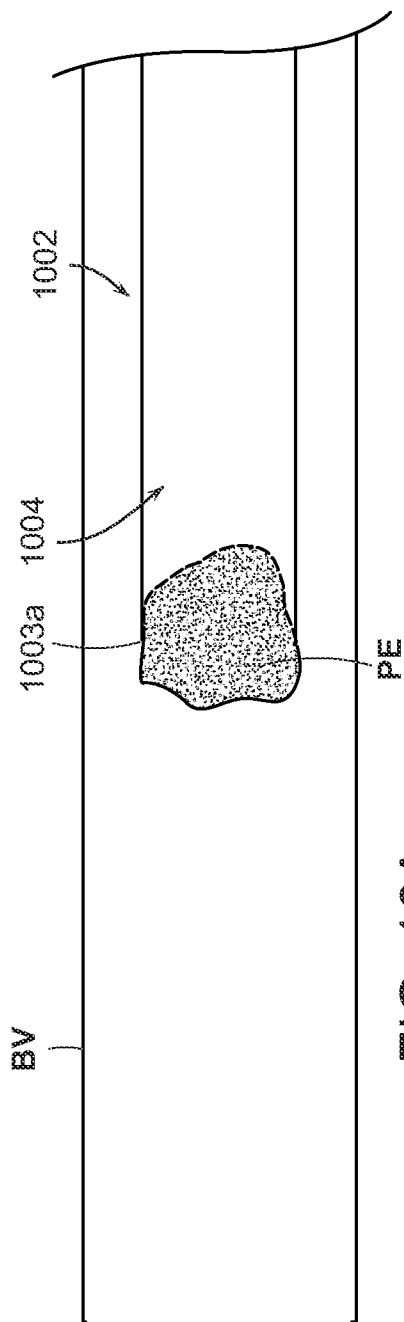


FIG. 16A

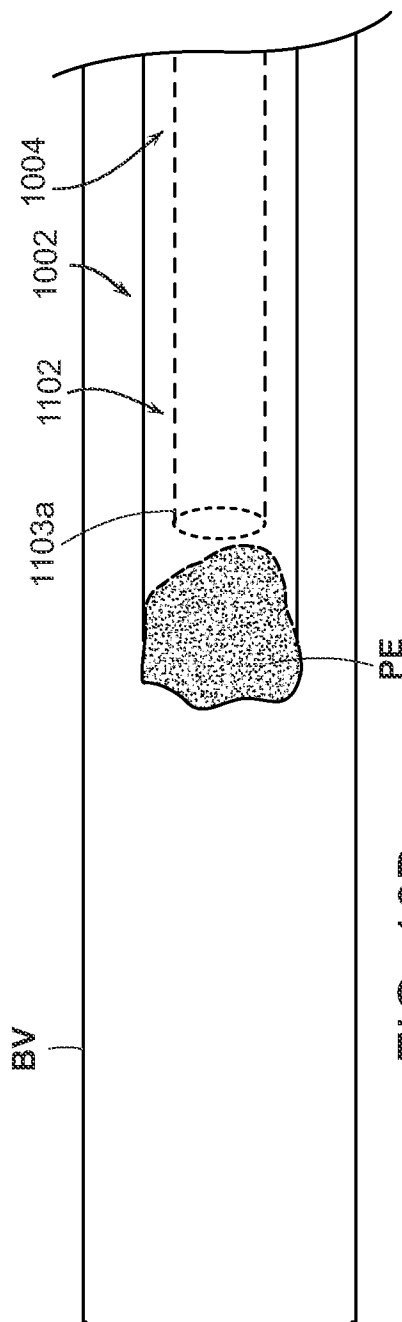
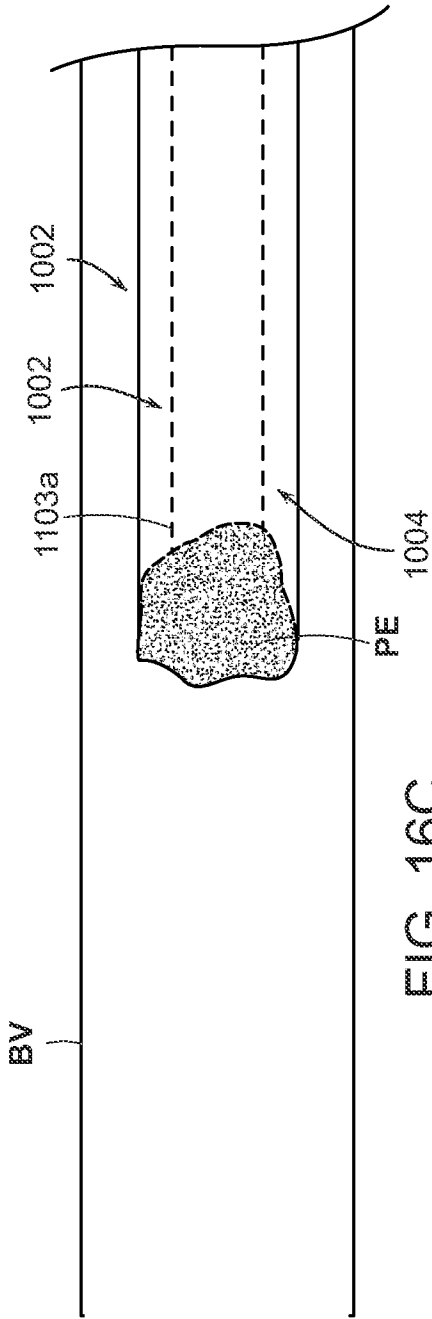
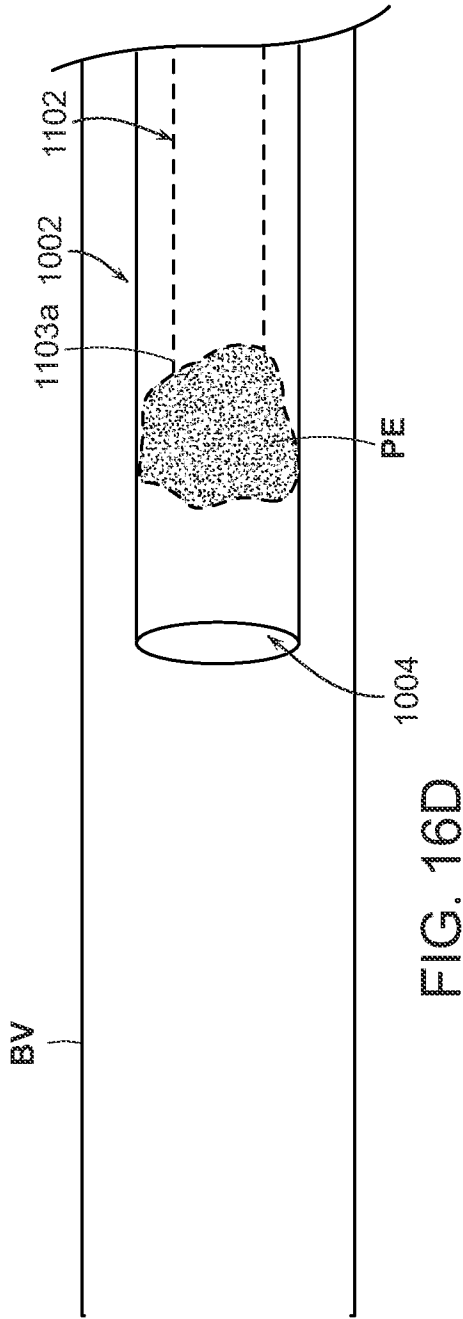


FIG. 16B



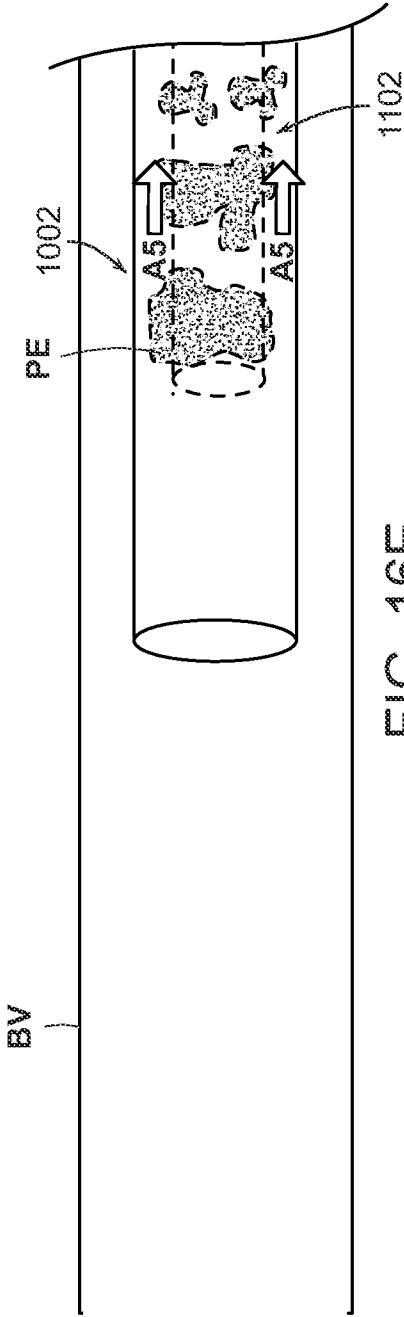
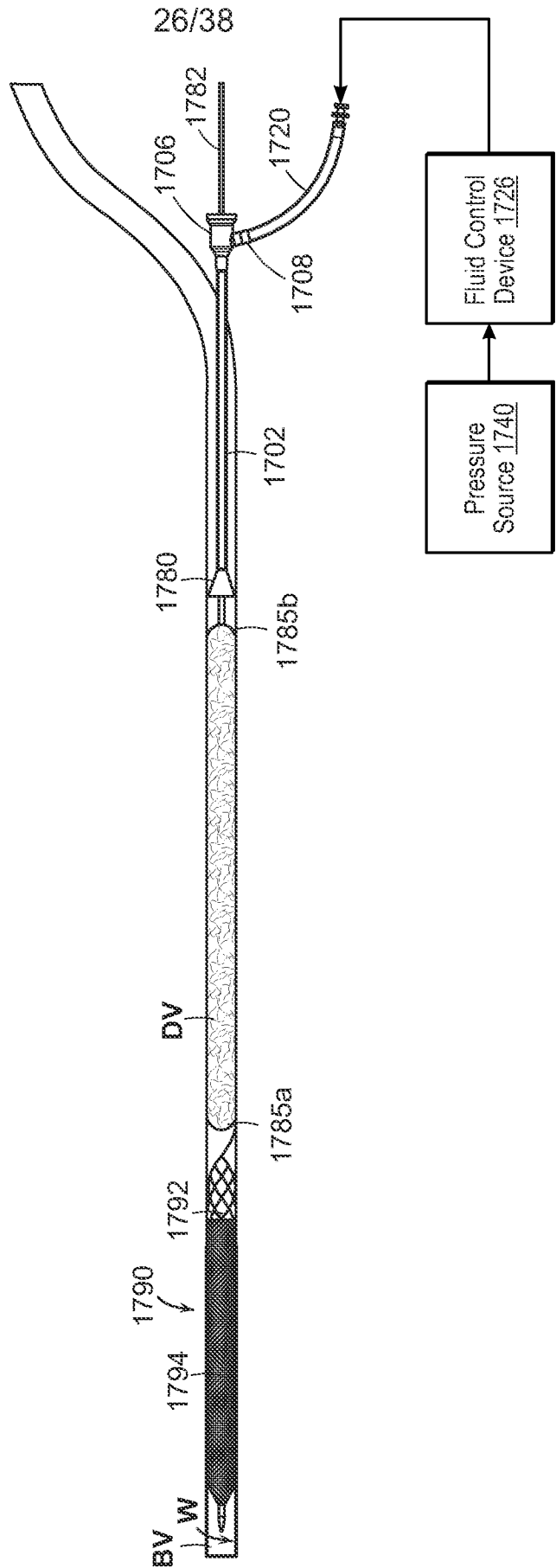


FIG. 16E

FIG. 17

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FIG. 18A

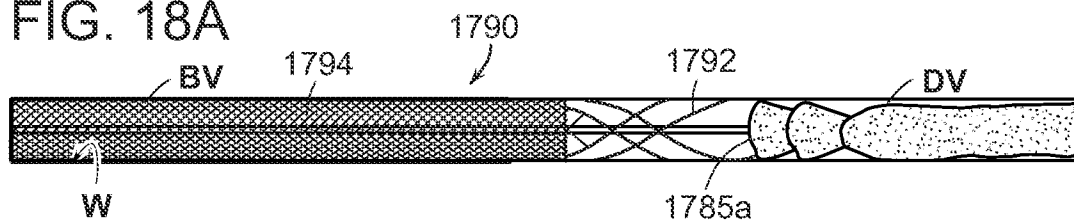


FIG. 18B

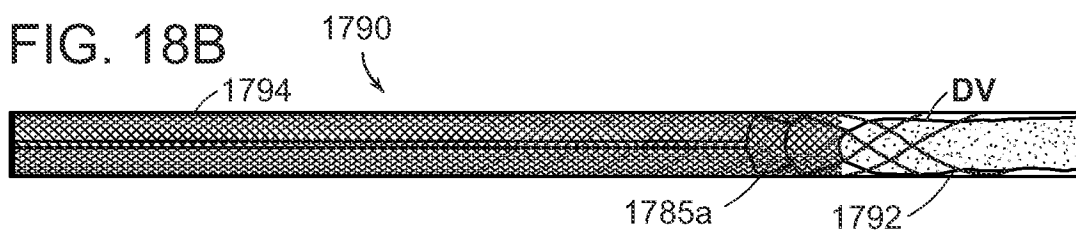


FIG. 18C

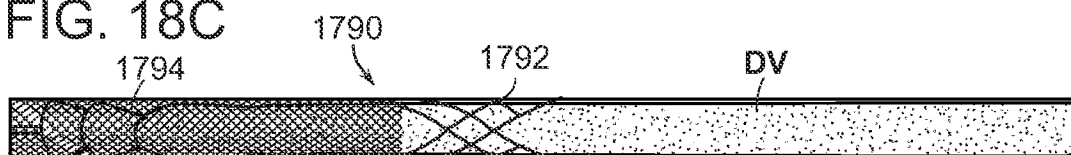


FIG. 18D



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FIG. 18E

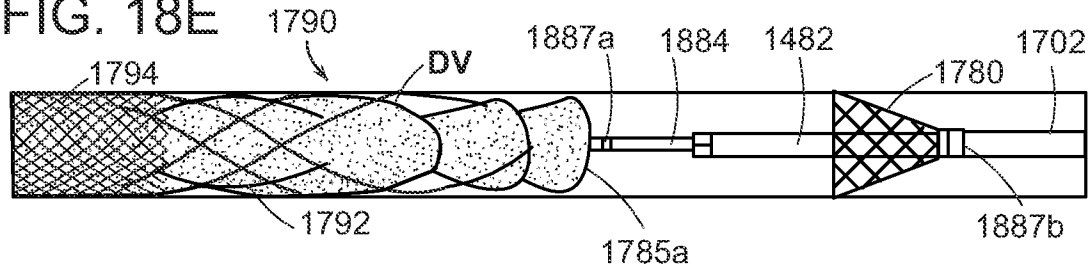


FIG. 18F

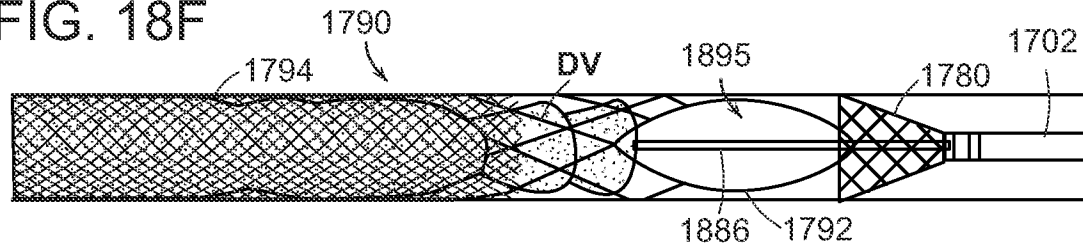


FIG. 18G

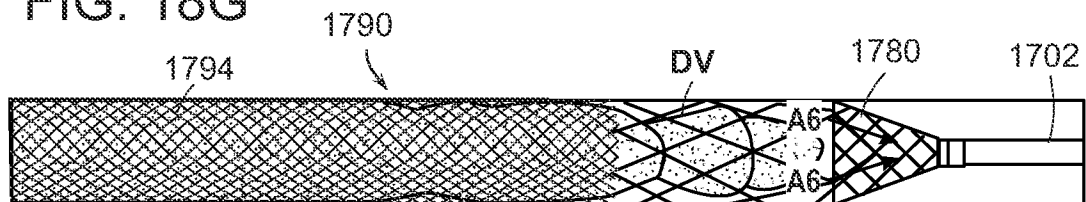
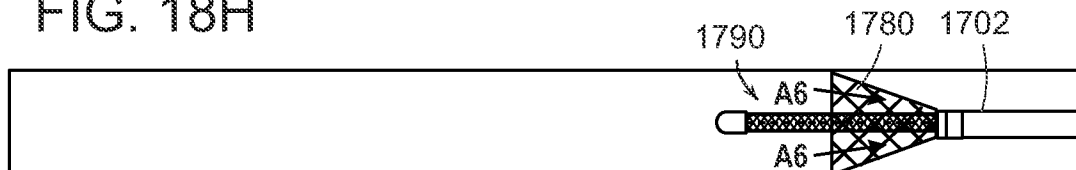


FIG. 18H



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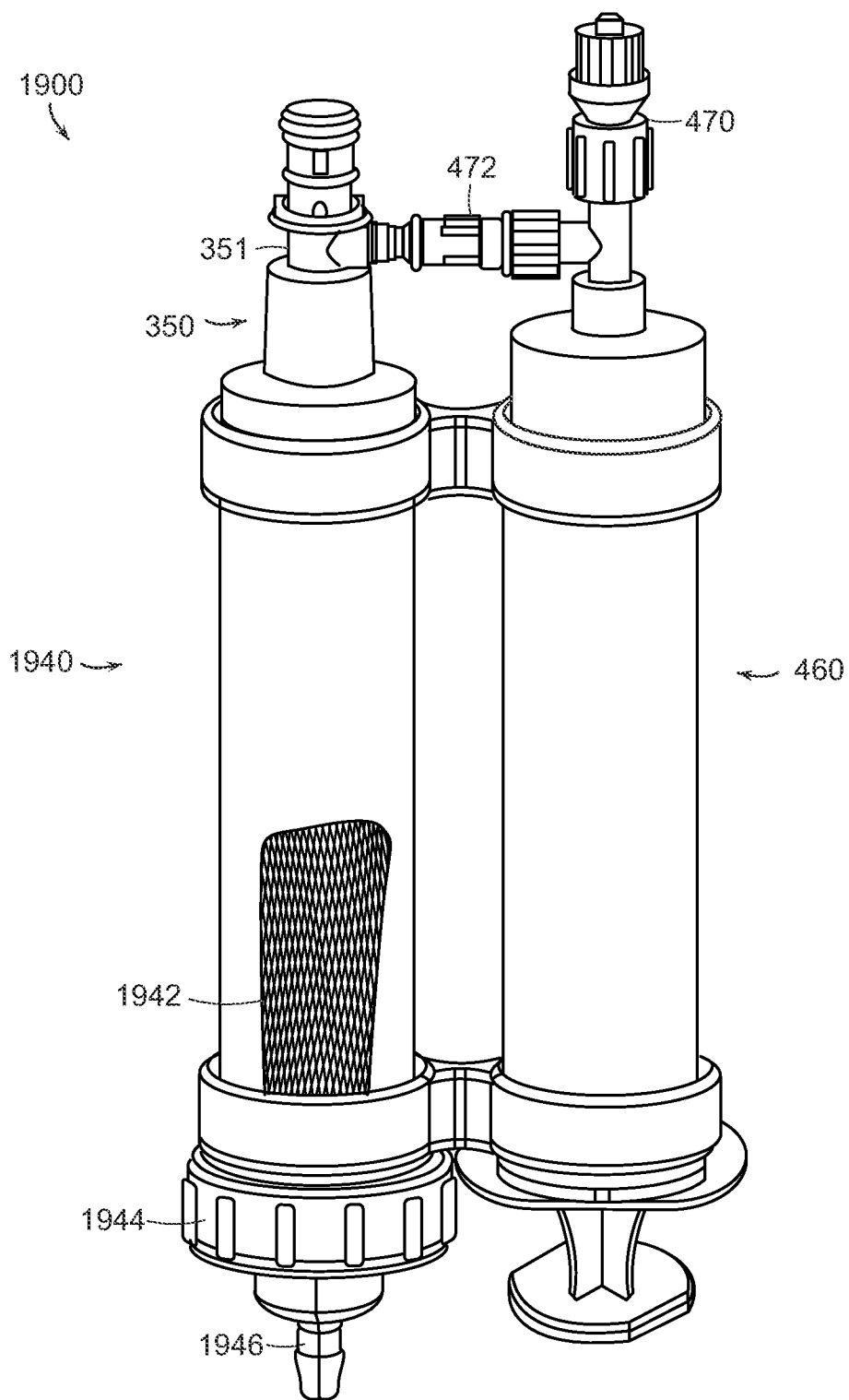
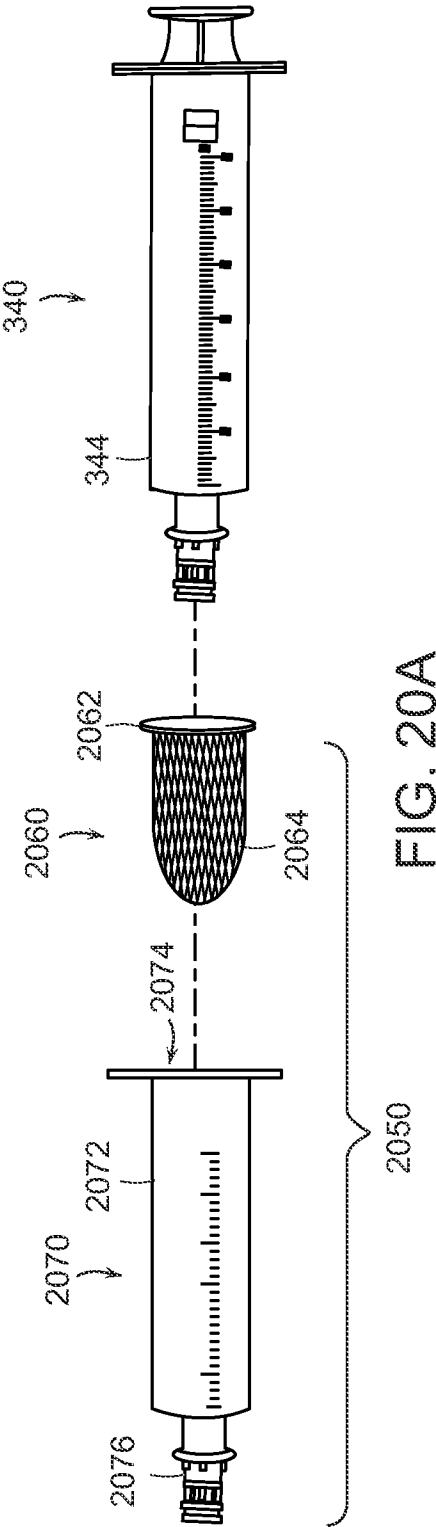
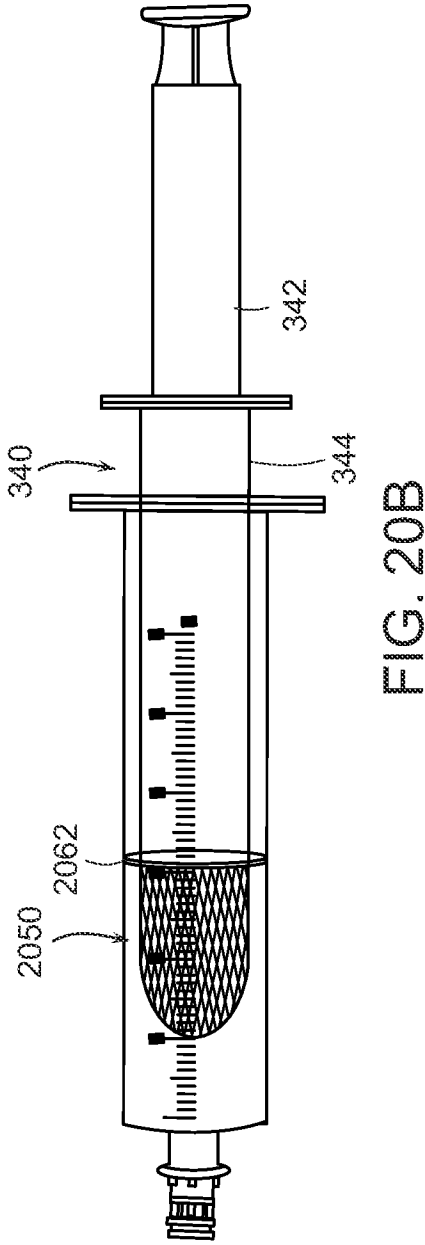


FIG. 19



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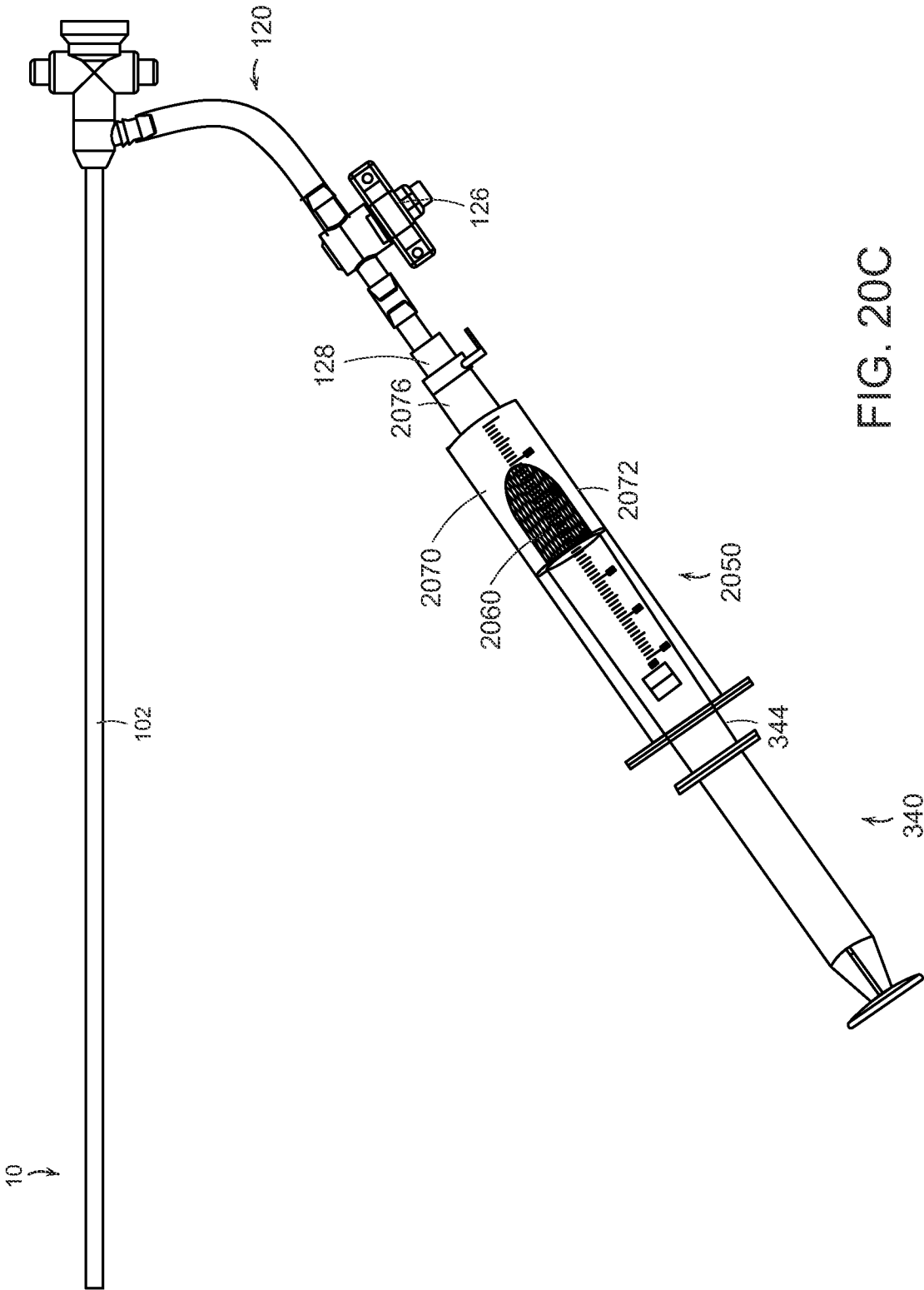


FIG. 20C

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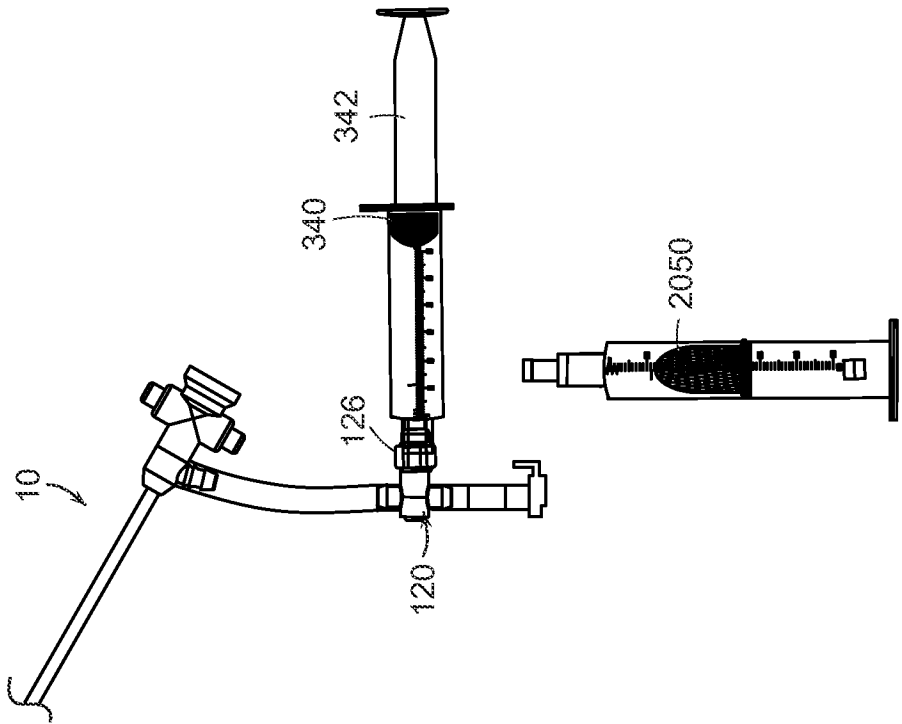


FIG. 20E

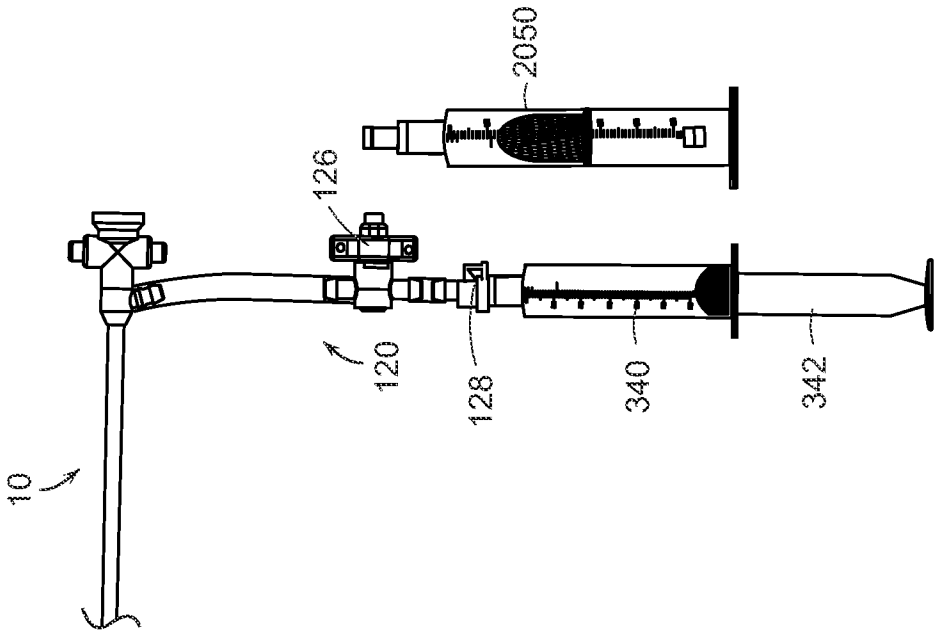


FIG. 20D

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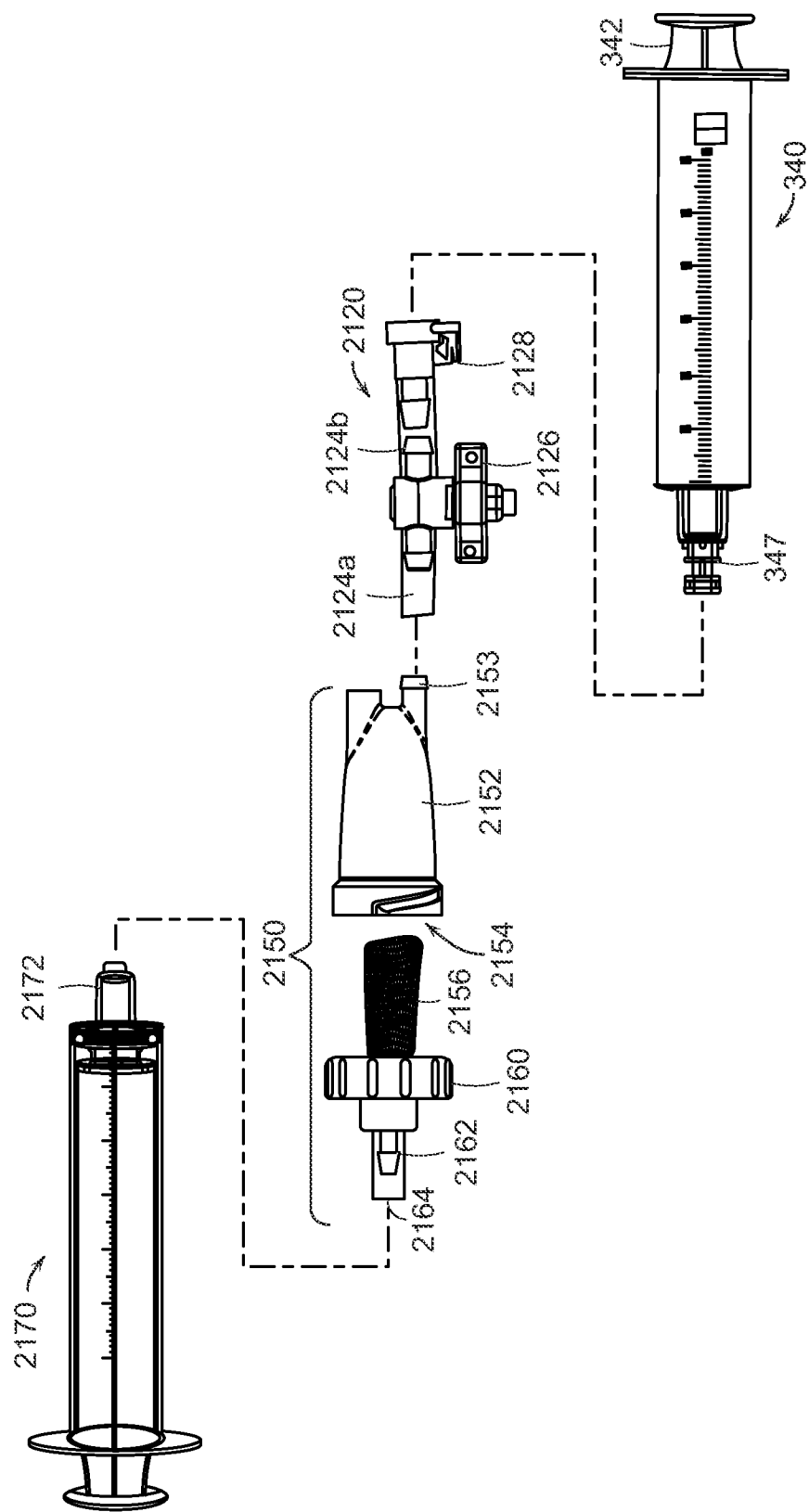


FIG. 21A

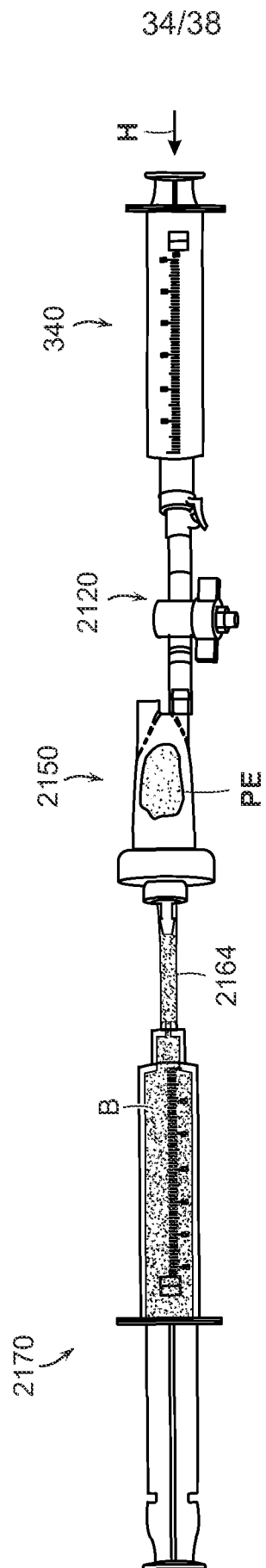


FIG. 21B

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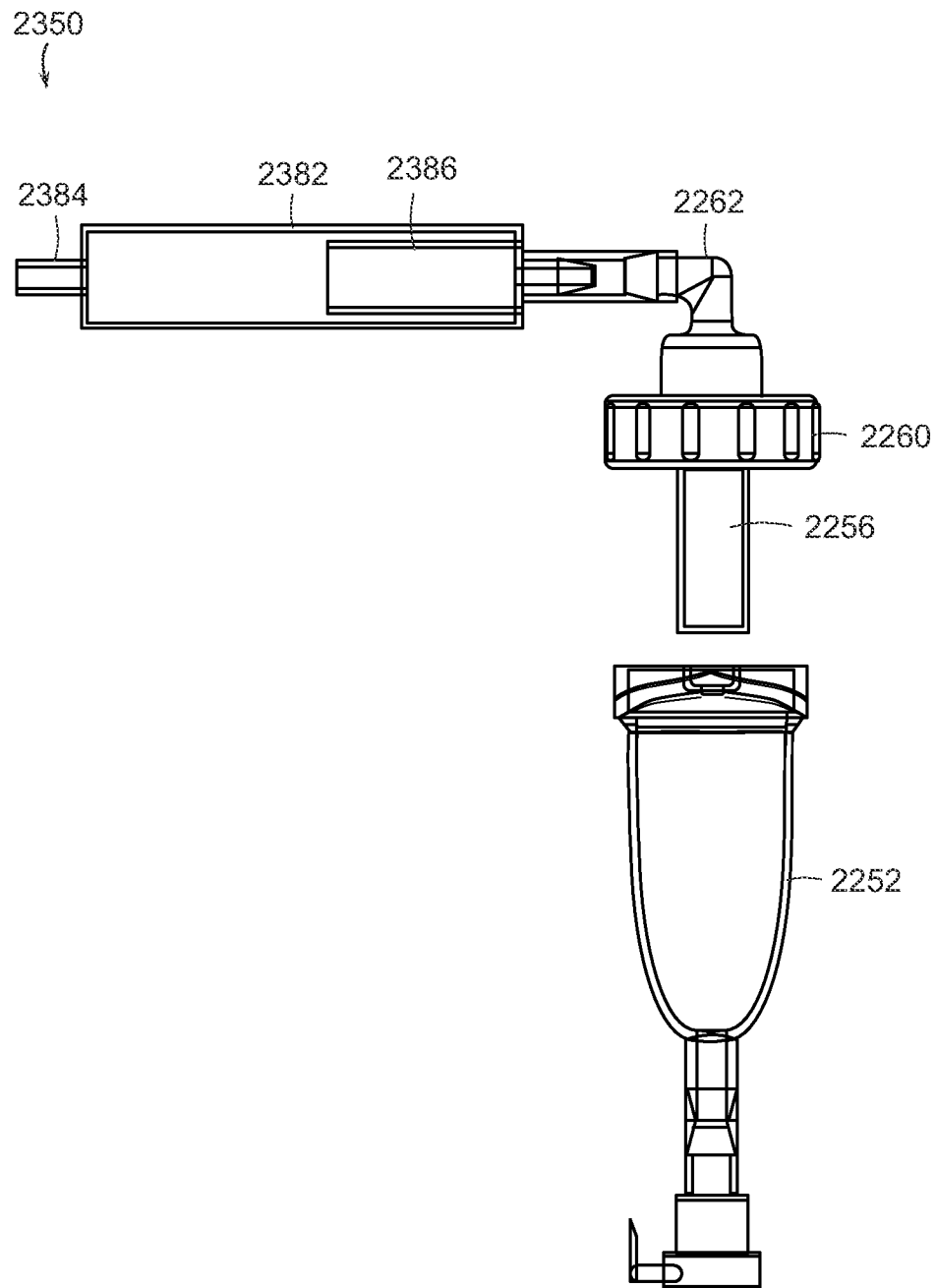
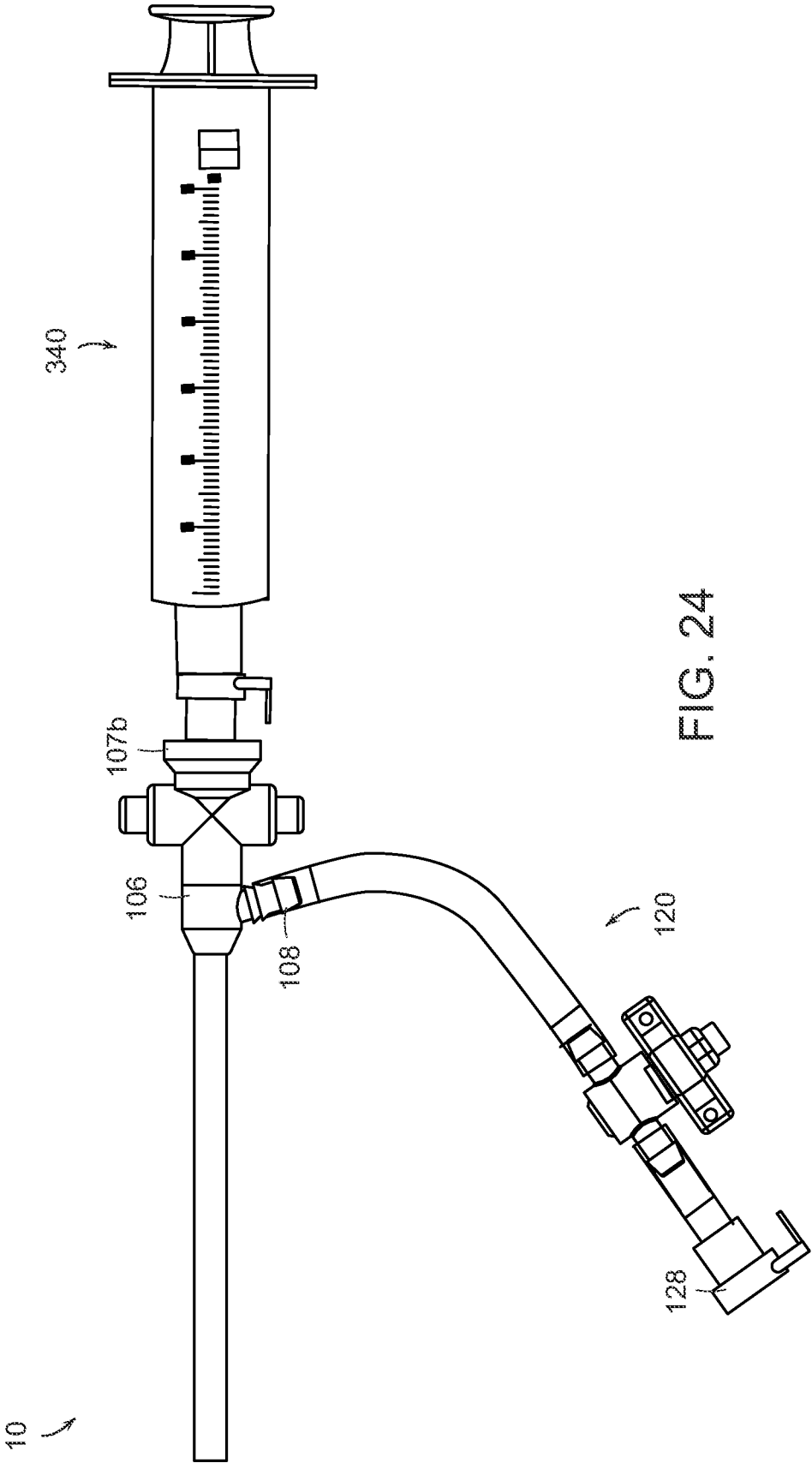


FIG. 23

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First Inventor: Ben Merritt
Title: SYSTEM FOR TREATING EMBOLISM AND
ASSOCIATED DEVICES AND METHODS

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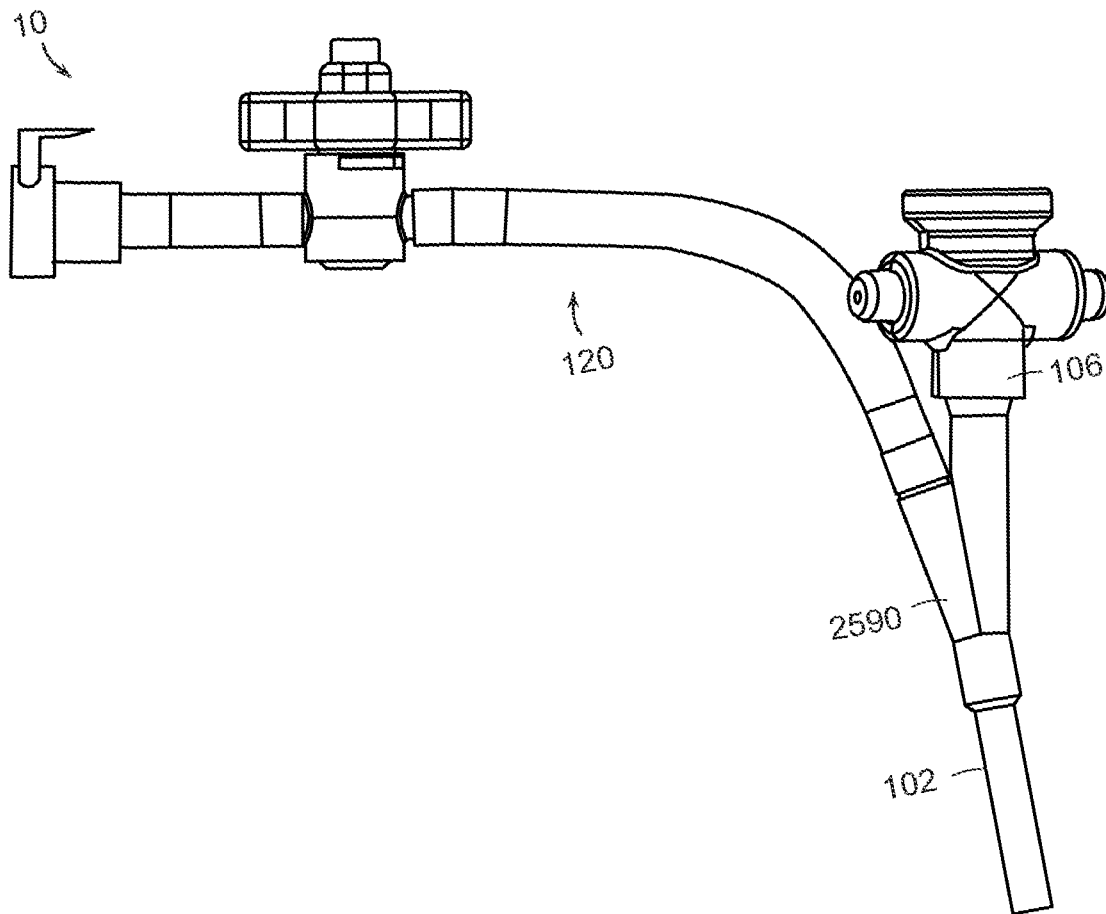


FIG. 25

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. Patent Application No. 18/167,757, filed February 10, 2023, which is a continuation of U.S. Patent Application No. 17/976,711, filed October 28, 2022, which is a continuation of U.S. Patent Application No. 17/865,315, filed July 14, 2022, which is a continuation of U.S. Patent Application No. 16/536,185, filed August 8, 2019, and issued as U.S. Patent No. 11,559,382, which claims the benefit of U.S. Provisional Patent Application No. 62/718,269, filed on August 13, 2018, and U.S. Provisional Patent Application No. 62/718,248, filed on August 13, 2018, each of which is herein incorporated by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology relates generally to systems, methods, and devices for the intravascular treatment of emboli and/or thrombi within a blood vessel of a human patient. In particular, some embodiments of the present technology relate to systems for releasing stored vacuum pressure to aspirate clot material from a blood vessel.

BACKGROUND

[0003] Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

[0004] When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. However, infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can accordingly lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

[0005] In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT commonly occurs where there is a propensity for stagnated blood (e.g., long distance air travel, immobility, 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 (stroke), abdominal organs, and/or extremities.

[0006] In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs, and therefore the entire body. This can result in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting in low blood oxygen and buildup of blood carbon dioxide.

[0007] There are many existing techniques to reestablish blood flow through an occluded vessel. Embolectomies, for example, are a surgical technique involving incising a blood vessel and placing a balloon-tipped device (such as the Fogarty catheter) at the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to withdraw the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Although such surgical techniques have been useful, exposing a patient to surgery may be traumatic and best avoided when possible. Additionally, the use of a Fogarty catheter may be problematic due to the possible risk of damaging the interior lining of the vessel as the catheter is being withdrawn.

[0008] Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating vessel stenosis, but it is generally not effective for treating acute thromboembolisms as none of the occlusive material is removed and restenosis regularly

occurs after dilation. Another percutaneous technique involves placing a catheter near the clot and infusing streptokinase, urokinase, or other thrombolytic agents to dissolve the clot. Unfortunately, thrombolysis typically takes hours to days to be successful. Additionally, thrombolytic agents can cause hemorrhage, and in many patients the thrombolytic agents cannot be used at all.

[0009] Various devices exist for performing a thrombectomy or removing other foreign material. However, such devices have been found to have structures which are either highly complex, cause trauma to the treatment vessel, or lack the ability to be appropriately fixed against the vessel. Furthermore, many of the devices have highly complex structures that lead to manufacturing and quality control difficulties as well as delivery issues when passing through tortuous or small diameter catheters. Less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all of the clot material.

[0010] Thus, there exists a need for improved systems and methods for embolic extraction.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0012] Figure 1 is a partially schematic side view of a clot removal system configured in accordance with the present technology.

[0013] Figure 2 is a side view of a locking syringe configured in accordance with the present technology.

[0014] Figure 3A is a side view of a locking syringe configured in accordance with the present technology.

[0015] Figure 3B is a side view of an adaptor for connecting the locking syringe of Figure 3A to the clot removal system of Figure 1 configured in accordance with the present technology.

[0016] Figure 3C is a side view of the adaptor of Figure 3B coupled to the locking syringe of Figure 3A.

[0017] Figure 3D is a side view of the locking syringe of Figure 3A coupled to the clot removal system of Figure 1 via the adaptor of Figure 3B.

[0018] Figure 4A is a perspective side view of another pressure source configured in accordance with the present technology, and Figures 4B and 4C are enlarged schematic side views of the pressure source of Figure 4A during operation.

[0019] Figure 5 is a cross-sectional side view of an automatic release syringe configured in accordance with the present technology.

[0020] Figure 6 is a perspective top view of a syringe configured in accordance with the present technology.

[0021] Figure 7 is a side view of an over-wire locking syringe configured in accordance with the present technology.

[0022] Figure 8 is a flow diagram of a process or method for operating a clot removal system in accordance with the present technology.

[0023] Figures 9A–9C are side views of a proximal portion of the clot removal system of Figure 1 during a clot removal procedure using the locking syringe of Figure 3 in accordance with the present technology.

[0024] Figures 10A and 10B are schematic illustrations of a distal portion of the clot removal system of Figure 1 during a clot removal procedure in accordance with the present technology.

[0025] Figure 11 is a partially schematic side view of another clot removal system configured in accordance with the present technology.

[0026] Figure 12 is a flow diagram of another process or method for operating a clot removal system in accordance with the present technology.

[0027] Figures 13A–14C are schematic illustrations of a distal portion of the clot removal system of Figure 11 during a clot removal procedure in accordance with the present technology.

[0028] Figure 15 is a flow diagram of another process or method for operating a clot removal system in accordance with the present technology.

[0029] Figures 16A–16E are schematic illustrations of a distal portion of the clot removal system of Figure 11 during a clot removal procedure in accordance with the present technology.

[0030] Figure 17 is a partially schematic side view of another clot removal system configured in accordance with the present technology.

[0031] Figures 18A–18H are side views of a distal portion of the clot removal system shown of Figure 17 during a clot removal procedure in accordance with the present technology.

[0032] Figure 19 is a perspective side view of a pressure source for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology.

[0033] Figure 20A is a partially-exploded side view of a filter device and pressure source configured in accordance with the present technology.

[0034] Figure 20B is a perspective side view of the syringe of Figure 20A coupled to the filter device of the Figure 20A.

[0035] Figure 20C is a side view of the filter device and syringe of Figure 20B coupled to the clot removal system of Figure 1.

[0036] Figures 20D and 20E are side views of the syringe of Figure 20A coupled to the clot removal system of Figure 1 for reintroducing blood to a patient.

[0037] Figure 21A is a partially-exploded side view of a filter device, a pressure source, and a reinfusion syringe configured in accordance with the present technology.

[0038] Figure 21B is a perspective side view of the filter device of Figure 21A coupled to the pressure source and the reinfusion syringe of Figure 21A.

[0039] Figure 22 is a partially-exploded side view of a filter device configured in accordance with the present technology.

[0040] Figure 23 is a partially-exploded side view of a filter device configured in accordance with the present technology.

[0041] Figure 24 is an enlarged isometric view of the clot removal system of Figure 1 configured in accordance with the present technology.

[0042] Figure 25 is an enlarged isometric view of the clot removal system of Figure 1 configured in accordance with the present technology.

DETAILED DESCRIPTION

[0043] The present technology is generally directed to methods and systems for removing clot material from a blood vessel of a human patient. In some embodiments, a catheter can be intravascularly positioned within a blood vessel such that a distal portion (e.g., a distal opening) of the catheter is positioned proximate to clot material within the blood vessel. The catheter can be fluidly coupled to a pressure source via a valve or other fluid control device positioned outside of the patient. With the valve closed, the pressure source can be activated to charge a vacuum chamber of the pressure source with a vacuum. The valve can then be opened to apply the vacuum to the catheter to thereby aspirate at least a portion of the clot material from the blood vessel into the catheter. In some embodiments, an interventional device can be delivered through the catheter and used to engage the clot material before and/or after the vacuum is applied to the catheter.

[0044] In one aspect of the present technology, the pressure source is configured to generate a vacuum and store the vacuum before the pressure source is fluidly connected to the catheter. Therefore, opening the fluid control device can instantaneously or nearly instantaneously apply the stored vacuum pressure to the catheter, thereby generating suction throughout the catheter. In particular, the suction is applied at the distal portion of the catheter proximate to the clot material. Pre-charging or storing the vacuum before applying the vacuum to the catheter can generate greater suction forces (and corresponding fluid flow velocities) at and/or near the distal portion of the catheter compared to, for example, simply activating the pressure source while it is fluidly connected to the catheter. The greater suction forces generated by application of the stored vacuum can be used to aspirate or otherwise remove clot material from within a blood vessel of a human patient.

[0045] Although many of the embodiments are described below with respect to devices, systems, and methods for treating a pulmonary embolism, other applications and other embodiments in addition to those described herein are within the scope of the technology (e.g., intravascular procedures other than the treatment of emboli, intravascular procedures for treating cerebral embolism, intravascular procedures for treating deep vein thrombosis (DVT), etc.).

Additionally, several other embodiments of the technology can have different configurations, states, components, or procedures than those described herein. Moreover, it will be appreciated that specific elements, substructures, advantages, uses, and/or other features of the embodiments described with reference to Figures 1–25 can be suitably interchanged, substituted or otherwise configured with one another in accordance with additional embodiments of the present technology. Furthermore, suitable elements of the embodiments described with reference to Figures 1–25 can be used as standalone and/or self-contained devices. A person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described below with reference to Figures 1–25.

[0046] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," etc. are not meant to limit the referenced component to use in a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

[0047] The headings provided herein are for convenience only and should not be construed as limiting the subject matter disclosed.

I. Selected Embodiments of Clot Removal Systems

[0048] 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 an embodiment of the present technology. In the illustrated embodiment, the assembly 10 includes a catheter subsystem 100, a tubing subsystem 120, and a pressure source 140. 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 subsystem 100 further includes a valve 106 that can be integral with or coupled to the proximal portion 103b of the catheter 102.

[0049] 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. The valve 106 further includes a flow controller (obscured in Figure 1) in the lumen 109. In some embodiments, the valve is a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in the proximal direction through the valve 106 as various components such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters (e.g., as described in detail with reference to Figures 11–16E), 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 a branch or side port 108 positioned distally of the flow controller in the lumen 109 and 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 retraction/aspiration device for aspirating the lumen 104 of the catheter 102 and/or for retracting an interventional device, catheter, delivery sheath, catheter, etc., positioned within the lumen 104. Specific details of such retraction/aspiration devices and associated methods are disclosed in U.S. Patent Application No. 9,526,864, filed June 9, 2015, and titled "RETRACTION AND ASPIRATION DEVICE FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

[0050] The tubing subsystem 120 fluidly couples the catheter subsystem 100 to the pressure source 140. 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 140 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 some embodiments, the fluid control device 126 can define a lumen having a diameter (or other cross-sectional dimension) that is greater than or equal to a diameter of the lumen 104 of the catheter 102, a diameter of the first tubing section 124a, and/or a diameter of the second tubing section 124b.

[0051] 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 140. 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 tubing section 124a and/or the tubing section 124b. In yet other embodiments, the fluid control device 126 can be omitted and its functionality incorporated into the pressure source 140 (e.g., as described in detail below with reference to Figure 5). In some embodiments, the fluid control device 126 can include a quick-release mechanism (e.g., a spring-loaded apparatus) for rapidly opening, unclamping, etc., the fluid control device 126 to (e.g., instantaneously or nearly instantaneously) fluidly connect the pressure source 140 and the catheter 102. In some embodiments, the fluid control device 126 can be opened/closed automatically (e.g., by a motor, switch, etc.). When the pressure source 140 is pre-charged with a vacuum, as described in detail below, such a quick-release fluid control device 126 can reduce the time needed for pressure in the assembly 10 to equalize after opening of the fluid control device 126, and can thereby increase suction forces generated at the distal portion 103a of the catheter 102.

[0052] In some embodiments, the connector 128 is a quick-release connector (e.g., a quick disconnect fitting) that enables rapid coupling/decoupling of the catheter 102 and the fluid control device 126 to/from the pressure source 140. In other embodiments, the tubing subsystem 120 can have more or fewer tubing sections, connectors, and/or fluid control devices, and can have other suitable configurations. In some embodiments, one or more of the components can be permanently connected and/or integrally formed.

[0053] The pressure source 140 is configured to generate (e.g., form, create, charge, build-up, etc.) 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 2–7. During operation of the assembly 10, a

user can first close the fluid control device 126 before activating the pressure source 140 to build up vacuum pressure within the pressure source 140 (e.g., a vacuum chamber of the pressure source 140). 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 140 before the pressure source 140 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 140 to the catheter subsystem 100 and thereby apply or release the vacuum stored in the pressure source 140 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 140 while it is fluidly connected to the catheter 102. As described in detail below, the suction forces generated by application of the stored vacuum can be used to aspirate or otherwise remove clot material from within a blood vessel of a human patient.

II. Selected Embodiments of Pressure Sources for Use with Clot Removal Systems

[0054] As described in detail above with reference to Figure 1, the assembly 10 of the present technology includes a pressure source (e.g., a vacuum source, negative pressure source, etc.) configured to charge a vacuum that can be applied to the catheter subsystem 100 to generate suction forces for aspirating clot material from within a blood vessel. In general, the pressure source can be any suitable source or combination of sources for generating and/or storing negative pressure. In some embodiments, the pressure source can be a pump (e.g., an electric pump coupled to a vacuum chamber) while, in other embodiments, the pressure source can include one or more syringes that can be actuated or otherwise activated by a user of the assembly 10 to generate and store a vacuum therein.

[0055] Figure 2 is a side view of a pressure source 240 comprising a vacuum-pressure locking syringe ("syringe 240") configured in accordance with the present technology. In some

embodiments, the syringe 240 can be of the kind sold under the trademark "VacLok" by Merit Medical System, Inc. In the illustrated embodiment, the syringe 240 includes a plunger 242 slidably and rotatably positioned within a chamber or barrel 244. The barrel 244 is shown as transparent in Figure 2 for the sake of clarity. The plunger 242 includes a seal 243 and a plurality of index members 246 defining slots 248 between adjacent pairs thereof. A tab member 245 projects inwardly from the interior surface of the barrel 244 and is configured to be removably positioned in the slots 248 for locking the plunger 242 in position relative to the barrel 244. In some embodiments, the barrel 244 can be made of a transparent material that permits a user to visualize material (e.g., clot material) within the barrel 244 and to visualize the relative position between the slots 248 and tab member 245 for locking the syringe 240.

[0056] Referring to both Figures 1 and 2 together, the syringe 240 further includes a tip 247 for coupling the syringe 240 to the tubing subsystem 120. In the illustrated embodiment, the tip 247 is a standard luer connector that can be coupled to the connector 128 via one or more suitable adaptors. The tip 247 further defines a lumen or bore 249 having an inner diameter D_1 . In some embodiments, the diameter D_1 is about 0.103", or about 0.080" to about 0.200", or about 0.100" to about 0.150", or about 0.100" to about 0.110". In some embodiments, the inner diameter D_1 is about 14 French.

[0057] During operation of the assembly 10, a user can first close the fluid control device 126 and then grip the plunger 242 and/or the barrel 244 to withdraw (e.g., retract) the plunger 242 at least partially out of the barrel 244 to thereby generate a vacuum in the barrel 244. Once the user has withdrawn the plunger 242 to a sufficient or desired volume, the user can lock the plunger 242 by rotating the plunger 242 relative to the barrel 244 such that the tab member 245 is positioned within a corresponding one of the slots 248. In other embodiments, the syringe 240 may not be a locking syringe, and the user can instead hold the plunger 242 in position relative to the barrel 244. Moreover, the user can control the volume of the vacuum—by withdrawing the plunger 242 more or less—to provide a desired amount or level of suction/aspiration upon opening of the fluid control device 126. In some embodiments, the syringe has a volume of about 60 cc or less than about 60 cc.

[0058] Figure 3A is a side view of a pressure source 340 comprising a vacuum-pressure locking syringe ("syringe 340") configured in accordance with the present technology. The syringe 340 can have some features generally similar to the features of the syringe 240 described above with reference to Figure 2. For example, the syringe 340 includes a plunger 342 slidably and rotatably positioned within a barrel 344, and the plunger 342 includes a plurality of index members 346 defining slots 348 between adjacent pairs thereof. The barrel 344 is shown as transparent in Figure 3A (and Figure 3C) for the sake of clarity. While withdrawing the plunger 342, a user can lock the plunger 342 at a specified volume by rotating the plunger 342 relative to the barrel 344 such that a tab member 345 on the interior surface of the barrel 344 is positioned within a corresponding one of the slots 348. In some embodiments, the syringe 340 has a maximum volume of about 60 cc or greater than 60 cc.

[0059] In the illustrated embodiment, the syringe 340 includes a large-bore tip 347, such as a Toomey tip, defining an inner lumen or bore 349. In some embodiments, the bore 349 can have an inner diameter D_2 that is greater than or equal to the largest inner diameter of the assembly 10 (e.g., of the catheter 102 and tubing subsystem 120). In certain embodiments, the tip 347 can be about 26 French or greater. Accordingly, referring to Figures 2 and 3A together, the diameter D_2 can be greater than the dimension D_1 . For example, the dimension D_2 can be about two, three, four, or more times greater than the diameter D_1 .

[0060] Figure 3B is a side view of an adaptor 350 for connecting the syringe 340 to the catheter subsystem 100 configured in accordance with the present technology. Figure 3C is a side view of the adaptor 350 coupled to the syringe 340, and Figure 3D is a side view of the syringe 340 coupled to the tubing subsystem 120 via the adaptor 350. The adaptor 350 is shown as partially transparent in Figure 3C for the sake of illustration. Referring to Figure 3B, the adaptor 350 includes (i) a first portion 351 defining a first lumen or bore 352 having an inner diameter D_3 , (ii) a second portion 353 defining a second lumen or bore 354, and (iii) a stepped surface or interface 355 between the first and second portions 351, 353. The first portion 351 can further include a seal 357 such as an O-Ring around an exterior surface thereof.

[0061] Referring to Figures 3A–3D together, the second bore 354 of the adaptor 350 is configured to removably receive the tip 347 of the syringe 340 therein. In some embodiments, the

tip 347 can be snugly received in the second bore 354 via an interference fit. In some embodiments, a seal (e.g., an O-ring) can be positioned between an exterior surface of the tip 347 and an interior surface of the second bore 354. In other embodiments, the syringe 340 can be permanently coupled or integrally formed with the adaptor 350. The first portion 351 of the adaptor 350 is configured to be removably positioned within the connector 128 of the tubing subsystem 120 to fluidly couple the syringe 340 to the tubing subsystem 120. In some embodiments, the first portion 351 of the adaptor 350 can be pushed into the connector 128 until the interface 355 abuts the connector 128. When the first portion 351 of the adaptor 350 is positioned within the connector 128, the seal 357 seals the interface between the connector 128 and the adaptor 350.

[0062] The diameter D_3 of the first bore 352 of the adaptor 350 can be selected to be about the same as or greater than the greatest inner diameter of the assembly 10 (e.g., of the catheter 102 and the tubing subsystem 120). For example, the catheter 102 can be about 9 French or greater, and the diameter D_3 can be selected to be larger than the size of the catheter 102. Accordingly, when the fluid control device 126 is open, the continuous lumen between the catheter 102 and the syringe 340 can have a generally constant diameter and/or does not contain any narrowing at the interface between the syringe 340 and the tubing subsystem 120. That is, the adaptor 350 can connect the syringe 340 and the tubing subsystem 120 without any restriction or narrowing of the fluid path. In contrast, a standard luer connector (e.g., the syringe 240) can only provide a continuous lumen for catheters of about 8 French or smaller. Any narrowing of the fluid pathway between the catheter 102 and the syringe 340 can reduce the volumetric flow rate (e.g., suction forces and fluid velocities) that can be generated when a vacuum stored in the syringe 340 is applied to the catheter 102.

[0063] In general, the syringe 340 and the adaptor 350 can reduce the fluid resistance in the assembly 10 and therefore facilitate a more rapid pressure equalization in the assembly 10 when the fluid control device 126 is opened to apply the charged vacuum to the catheter 102. In some embodiments, for example, when the syringe 240 (Figure 2) is charged with a 60 cc vacuum and the fluid control device 126 is opened, the pressure in the assembly 10 can take about 1–2 seconds to equalize. In contrast, when the syringe 340 is charged with a 60 cc vacuum and the fluid control device 126 is opened, the pressure in the assembly 10 can take less than about 1 second (e.g.,

about 0.5 seconds) to equalize. More specifically, Table 1 illustrates representative pressure equalization times and associated flow rates when the syringe 240 is coupled to a 20 French catheter (i.e., the catheter 102). Table 2 illustrates representative pressure equalization times and associated flow rates when the syringe 340 and the adaptor 350 are coupled to a 20 French catheter (i.e., the catheter 102).

Table 1

<u>Pressure Equalization Time (seconds)</u>	<u>Flow Rate (cc/sec)</u>
2.0	30.0
1.9	31.6
1.8	33.3
1.7	35.3
1.6	37.5
1.5	40.0
1.4	42.9
1.3	46.2

Table 2

<u>Pressure Equalization Time (seconds)</u>	<u>Flow Rate (cc/sec)</u>
0.9	66.7
0.8	75.0
0.7	85.7
0.6	100.0
0.5	120.0
0.4	150.0
0.3	200.0

0.2	300.0
0.1	600.0

[0064] In each instance, the syringe 340 provides for relatively faster equalization times and correspondingly greater flow rates. It is expected that the more rapid pressure equalization and flow rates provided by the syringe 340 will provide correspondingly greater suction forces at the distal portion 103a of the catheter 102. That is, in general, it is expected that increasing the bore size of a syringe used to provide vacuum pressure will provide greater suction forces over a smaller period of time (e.g., will provide a larger vacuum impulse). In some embodiments, the greater suction forces can facilitate the removal of clot material from a blood vessel of a patient even where the clot material is strongly lodged or attached within the blood vessel (e.g., a chronic clot).

[0065] Moreover, as shown in Figure 3D, the adaptor 350 can couple the syringe 340 to the connector 128 without the need for any intervening tubing sections or additional adaptors. This arrangement can minimize the total length, volume, etc., of the components fluidly coupling the catheter 102 to the syringe 340. It is expected that the magnitude of suction forces generated at the distal portion 103a of the catheter 102—e.g., when a vacuum charged in the syringe 340 is applied to the catheter 102 by opening of the fluid control device 126—is proportional to the length of the fluid path between the pressure source 340 and catheter 102. Thus, operation of the assembly 10 with the syringe 340 and adaptor 350 is expected to increase the suction forces generated at the distal portion 103a of the catheter 102. In some embodiments, the greater suction forces can facilitate the removal of clot material from a blood vessel of a patient even where the clot material is strongly lodged or attached within the blood vessel (e.g., a chronic clot).

[0066] Figure 4A is a side perspective view a pressure source 400 including the syringe 340 ("primary syringe 340") shown in Figures 3A–3D and a secondary syringe 460 configured in accordance with the present technology. The secondary syringe 460 can include a plunger 462 slidably positioned within a chamber or barrel 464. The primary and secondary syringes 340, 460 can have the same volume or different volumes. In the illustrated embodiment, a tip 463 of the secondary syringe 460 is coupled to a first one-way valve (e.g., a check valve) 470 via a coupling

member 465, such as a tube. The first one-way valve 470 is configured to fluidly connect the secondary syringe 460 to the ambient environment or another device coupled to the first one-way valve 470. A second one-way valve (e.g., a check valve) 472 spans between and is configured to fluidly connect the primary syringe 340 to the secondary syringe 460. More specially, in the illustrated embodiment the second one-way valve 472 is connected between the first portion 351 of the adaptor 350 and the coupling member 465. In other embodiments, the second one-way valve 472 can couple the primary and secondary syringes 340, 460 in different manners. For example, the second one-way valve 472 can span between and directly connect the barrels 344, 464. The primary and secondary syringes 340, 460 can be coupled or fastened together via one or more connectors 474 that fix the positions of the barrel 344, 464 relative to one another.

[0067] In some embodiments, the second one-way valve 472 is a normally-open check valve configured to (i) permit fluid (e.g., air) flow from the primary syringe 340 and the adaptor 350 to the secondary syringe 460 and (ii) inhibit fluid flow in the opposite direction from the secondary syringe 460 into the primary syringe 340. In some embodiments, the second one-way valve 472 has a cracking (e.g., opening) pressure of about 0 psi. In one aspect of the present technology, this arrangement maximizes the magnitude of the vacuum that can be charged within the primary syringe 340. That is, the cracking pressure of the second one-way valve 472 does not reduce the effective vacuum within the primary syringe 340. In other embodiments a normally-closed or other type of valve could be used for the second one-way valve 472. However, in such embodiments the vacuum efficiency of the pressure source 400 would be reduced by the cracking pressure of the second one-way valve 472. Similarly, the first one-way valve 470 can be a check valve configured to (i) permit fluid flow from the secondary syringe 460 to the ambient environment (or other device) and (ii) inhibit fluid flow in the opposite direction from the ambient environment into the secondary syringe 460.

[0068] Figures 4B and 4C are enlarged schematic side views of the pressure source 400 during operation. More specifically, Figures 4B and 4C illustrate fluid flow paths through the first and second one-way valves 470, 472 during retraction and advancement, respectively, of the plunger 462 through the barrel 464 of the secondary syringe 460. Referring first to Figures 4A and 4B together, during retraction/withdrawal of the plunger 462, (i) the first one-way valve 470 is closed to inhibit fluid from flowing into the secondary syringe 460 while (ii) the second one-

way valve is open 472 to permit fluid to flow from the primary syringe 340, the catheter subsystem 100 (Figure 1), and/or the tubing subsystem 120 (Figure 1) into the secondary syringe 460. This flow path is indicated by the arrows R in Figure 4B. Referring to Figures 4A and 4C together, during advancement of the plunger 462, (i) the first one-way valve 470 is open to permit fluid flow (e.g., fluid expulsion) from the secondary syringe 460 to the ambient environment (or other device) while (ii) the second one-way valve 472 is closed to inhibit fluid flow from the secondary syringe 460 into (e.g., back into) the primary syringe 360, the catheter subsystem 100, and/or the tubing subsystem 120. This flow path is indicated by the arrows A in Figure 4C.

[0069] Referring to Figures 1 and 3A–4C together, the pressure source 400 can be coupled to the tubing subsystem 120 by coupling the primary syringe 340 to the connector 128 (e.g., as shown in Figure 3D). When the pressure source is coupled to the tubing subsystem 120, retraction of the plunger 462 of the secondary syringe 460 evacuates an evacuable volume of the assembly 10. For example, when the fluid control device 126 is closed, retraction of the plunger 462 of the secondary syringe 460 evacuates fluid, through the second one-way valve 472, from (i) the primary syringe 340 (e.g., from the barrel 344, the tip 347, and/or the adaptor 350) and (ii) the portion of the tubing subsystem 120 between the fluid control device 126 and the primary syringe 340. This can enable a greater charged/stored vacuum to be generated for subsequent application to the catheter subsystem 100 for aspirating clot material. In some embodiments, the plunger 462 of the secondary syringe 460 can be withdrawn/advanced (e.g., "cycled") one or more times before withdrawing the plunger 342 of the primary syringe 340 to evacuate air from (i) the tip 347 of the primary syringe 340 and/or (ii) the portion of the tubing subsystem 120 between the fluid control device 126 and the tip 347. In other embodiments, the plunger 462 of the secondary syringe 460 can alternatively or additionally be withdrawn after withdrawing the plunger 342 of the primary syringe 340 to further evacuate the barrel 344 of the primary syringe 340. In some embodiments, the plunger 462 can be cycled when the fluid control device 126 is open to, for example, facilitate the removal of clot material stuck or clogged within the catheter subsystem 100. That is, cycling the secondary syringe 460 when the fluid control device 126 is open can generate vacuum pressure and suction in the catheter 102 to aid in the aspiration/removal of clot material.

[0070] In some embodiments, the volumes of the primary and secondary syringes 340, 460 can be selected based on one or more desired characteristics of a clot removal procedure using the

pressure source 400. For example, the secondary syringe 460 can have a larger volume than the primary syringe 340 to permit a high vacuum to be charged within the primary syringe 340 while also limiting blood loss from the patient.

[0071] In one aspect of the present technology, the pressure source 340 permits a greater vacuum to be generated without increasing the volume of the primary syringe 340. For example, the vacuum generated by the primary syringe 340 alone is directly proportional to the volume of the primary syringe 340. Thus, to generate a greater vacuum using the primary syringe 340 alone, the volume of the primary syringe 340 must be increased. In contrast, inclusion of the secondary syringe 460 in the pressure source 400 and the configuration of the first and second one-way valves 470, 472 allows the (e.g., maximum) generated vacuum to be independent of the volume of the primary syringe 340. Therefore, for example, the generated vacuum can be increased without correspondingly increasing the volume of blood withdrawn from the patient when applying the vacuum to the catheter subsystem 100.

[0072] In some embodiments, (e.g., as described in greater detail below with reference to Figure 19), the primary syringe 340 of the pressure source 400 can be replaced with a simple pressure vessel or other volume, such as a canister, barrel, tube, etc. In such embodiments, a vacuum can be generated in the canister simply by cycling the secondary syringe 460 one or more times. In some embodiments, the secondary syringe 460 can comprise a pump or vacuum source other than a syringe. Likewise, the secondary syringe 460 or other vacuum source can be fluidly coupled to the primary syringe 340 in other manners (e.g., via a different arrangement of check valves) to produce the same or similar flow patterns as shown in Figures 4B and 4C. Moreover, in some embodiments the first and second one-way valves 470, 472 can be other types of flow control devices that are mechanically activated/deactivated (e.g., opened and closed) rather than passively operated via pressure differentials within the pressure source 400. For example, the flow control devices 470, 472 can be mechanically coupled to the plunger 462 of the secondary syringe 460 such that cycling the plunger 462 activates/deactivates the flow control devices 470, 472 to operate the pressure source 400 in the manner illustrated in Figures 4B and 4C.

[0073] Figure 5 is a side cross-sectional view of a pressure source 540 comprising an automatic release syringe ("syringe 540") configured in accordance with the present technology.

In general, the syringe 540 is configured to automatically apply a charged vacuum of a selected volume to the catheter subsystem 100 without requiring the actuation of an intervening fluid control device, such as the fluid control device 126 shown in Figure 1. The syringe 540 can have some features generally similar to the features of the syringes 240, 340 described in detail above with reference to Figures 2 and 3A–3D. For example, the syringe 540 includes a first plunger 542 slidably positioned within a chamber or barrel 544. The first plunger 542 further includes a first seal 543 that engages an interior surface of the barrel 544 such that a vacuum is formed within the barrel 544 as the first plunger 542 is withdrawn through the barrel 544. Likewise, referring to both Figures 1 and 5 together, the syringe 540 includes a tip 547 (e.g., a Toomey tip) for coupling the syringe 540 to the tubing subsystem 120 (e.g., via a Toomey tip adaptor) and defining a bore 549. In some embodiments, the bore 549 has a relatively large diameter selected to provide rapid pressure equalization in the assembly 10 after a vacuum stored in the syringe 540 is released.

[0074] The first plunger 542 can further include (i) a grip portion 541 configured to be engaged by a user for retracting the first plunger 542 and (ii) a lumen 581 extending lengthwise therethrough. In the illustrated embodiment, a plunger assembly 582 is slidably positioned within and extends through the lumen 581 of the first plunger 542. The plunger assembly 582 includes (i) a second plunger 583 and (ii) a release member 584 slidably and/or rotatably positioned within a lumen 585 of the second plunger 583. The release member 584 includes an engagement member 586 configured to engage the grip portion 541 of the first plunger 542 when the first plunger 542 is withdrawn from the barrel 544. The second plunger 583 includes a second seal 587 configured to engage and seal an interior surface of the bore 549 of the syringe 540 to enable a vacuum to be formed in the barrel 544 as the first plunger 542 is withdrawn through the barrel 544. That is, the second seal 587 can seal (e.g., fluidly disconnect) the barrel 544 of the syringe from the tubing subsystem 120 and the catheter subsystem 100. In some embodiments, the syringe 540 can further include an O-ring 579 or other suitable component for sealing an interface between the first and second plungers 542, 582 to maintain the vacuum formed within the barrel 544, while also permitting the first plunger 542 to move (e.g., translate) relative to the second plunger 583.

[0075] The plunger assembly 582 further includes a locking mechanism (not shown) configured to permit/inhibit the release member 584 from moving longitudinally relative to the second plunger 583. In some embodiments, for example, rotation of the release member 584 in a

first direction relative to the second plunger 583 can lock the two components in position, while rotation of the release member 584 in a second direction relative to the second plunger 583 can unlock the two components so that the release member 584 can be withdrawn or pushed into the lumen 585 of the second plunger 583. In other embodiments, the release member 584 and the second plunger 583 can be integrally formed or permanently locked together.

[0076] The plunger assembly 582 enables (i) a user of the syringe 540 to select a desired volume for a vacuum to be formed in the syringe 540 and (ii) the automatic release or application of a generated vacuum via opening (e.g., unplugging) of the bore 549. Specifically, during operation of the syringe 540, a user can first unlock the release member 584 and slide the release member 584 to a position corresponding to a desired vacuum volume. For example, the release member 584 can have tick marks 588 or other indicia along its length that correspond to a volume of the syringe 540 (e.g., a vacuum chamber volume). After selecting a desired volume, the user can lock the release member 584 relative to the second plunger 583 (e.g., by rotating the release member 584) to inhibit relative movement of the two components. After locking the release member 584, the user can grasp the grip portion 541 to retract the first plunger 542 relative to the barrel 544 and the plunger assembly 582 to generate a vacuum within the barrel 544 between the first and second seals 543, 587. When the first plunger 542 has been retracted to the desired volume, the grip portion 541 engages the engagement member 586 of the release member 584 such that further retraction of the first plunger 542 simultaneously retracts the plunger assembly 582. As the plunger assembly 582 is retracted, the second seal 587 of the second plunger 583 is pulled out of the bore 549, thereby releasing the vacuum stored in the barrel 544. In this manner, the syringe 540 provides for the automatic release of charged vacuum pressure at a specified volume and with a single retraction of the first plunger 542. Put differently, the syringe 540 has a built-in fluid control device and thus eliminates the need for a separate fluid control device 126 and/or an additional step for opening the fluid control device 126.

[0077] Figure 6 is a top perspective view of a pressure source 640 comprising a syringe ("syringe 640") configured in accordance with the present technology. The syringe 640 can include some features generally similar to the features of the syringes 240, 340, and 540 described in detail above with reference to Figures 2–3D and 5. For example, the syringe 640 includes a plunger 642 slidably positioned within a barrel 644, and a tip 647 (e.g., a large-bore tip). In the

illustrated embodiment, the syringe 640 further includes a lever or handle 690 operably coupled to the plunger 642. The handle 690 provides mechanical leverage for withdrawing the plunger 642 to create a vacuum within the barrel 644. More specifically, the handle 690 can be coupled to a crossbar 691 that rotates relative to the plunger 642 via actuation (e.g., rotation) of the handle 690. The crossbar 691 can be coupled to a gear (obscured in Figure 6) configured to engage a track 692 on the plunger 642. Accordingly, rotation of the handle 690 in a first direction retracts the plunger 642 relative to the barrel 644 to charge a vacuum in the barrel 644. And, rotation of the handle 690 in a second (e.g., opposite) direction advances the plunger 642 into the barrel 644 to, for example, expel fluid, material, etc., from the barrel 644.

[0078] In one aspect of the present technology, the handle 690 provides additional mechanical leverage relative to a standard syringe, and can thus reduce the force (e.g., strain, energy, etc.) required by a user of the syringe 640 to form a vacuum in the syringe 640. Therefore, use of the syringe 640 can reduce the time needed to remove clot material with the assembly 10. In some embodiments, the syringe 640 can have a volume greater than 60 cc (e.g., greater than 80 cc, greater than 100 cc, greater than 120 cc, greater than 140 cc, etc.). In a particular embodiment, for example, the syringe 640 can have a volume of about 140 cc. With such large volumes, it may be difficult for some users to manually retract the plunger 642 without the additional mechanical leverage provided by the handle 690. Thus, the syringe 640 can enable the use of larger volume syringes that can generate correspondingly greater suction forces in the catheter subsystem 100.

[0079] Referring again to Figure 1, it is expected that less tortuous (e.g., more linear) fluid paths between the pressure source 140 and the catheter subsystem 100 will produce greater suction forces and corresponding fluid velocities at the distal portion 103a of the catheter 102 when stored vacuum pressure is applied to the catheter subsystem 100. Accordingly, in some embodiments the side port 108 of the valve 106 can be formed to have an angle A that is less than about 90°, less than about 75°, less than about 60°, less than about 45°, less than about 30°, less than about 15° etc. Reducing the relative angle between the side port 108 and the lumen 109 of the valve 106 (and thus the lumen 104 of the catheter 102) reduces the tortuosity of the fluid path between the pressure source 140 and the catheter 102. Moreover, in some embodiments, the pressure source 140 can be coupled to the proximal portion 107b of the valve 106 instead of or in addition to the side port 108 to provide a more linear fluid path between the pressure source 140 and the catheter

102. For example, Figure 24 is an enlarged isometric view of the assembly 10 showing the pressure source 340 coupled directly to the proximal portion 107b of the valve rather than to the connector 128 of the tubing subsystem 120 and the side port 108 of the valve 106. Although the pressure source 340 is illustrated in Figure 24, any of the pressure sources described in detail above with reference to Figures 2–6 can be configured to be coupled to the proximal portion 107b of the valve 106 rather than the side port 108. In other embodiments, the side port 108 can be omitted and the valve 106 and the tubing subsystem 120 can be coupled to the catheter 102 via a Y-connector. For example, Figure 25 is an enlarged isometric view of the assembly 10 showing the valve 106 and the tubing subsystem 120 coupled to the catheter 102 via a Y-connector 2590. In yet other embodiments, the tubing system 120 is linearly coupled to the catheter 102, and the valve 106 protrudes at an angle from the catheter 102.

[0080] In some embodiments, however, a guidewire or other component is positioned within the valve 106 during the duration of a clot removal procedure (e.g., for delivering interventional devices to a treatment site within a patient). Accordingly, in some embodiments, to facilitate coupling of the pressure source 140 to the proximal portion 107b of the valve 106—even when a guidewire is inserted therethrough—the pressure source 140 can be a syringe configured for over-wire delivery. For example, Figure 7 is a side view of a pressure source 740 comprising a vacuum-pressure locking syringe ("syringe 740") configured in accordance with the present technology for delivery and operation over a guidewire 794. The syringe 740 can have some features generally similar to the features of the syringe 340 described in detail above with reference to Figure 3. For example, the syringe 740 includes a plunger 742 slidably and rotatably positioned within a barrel 744. The barrel 744 is shown as transparent in Figure 7 for the sake of clarity. In the illustrated embodiment, the plunger 742 includes a lumen 796 (shown in broken lines) extending longitudinally therethrough. The guidewire 794 can be inserted through the lumen 796 of the plunger 742 such that the syringe 740 can be advanced over the guidewire 794 for attachment to the proximal portion 107b of the valve 106. The syringe 740 can further include one or more sealing components (e.g., valves, O-rings, etc.; not shown) for maintaining a seal between the guidewire 794 and the plunger 742 to permit build-up and storage of a vacuum in the barrel 744.

[0081] In general, one skilled in the art will understand that the various embodiments of pressure sources disclosed herein may be combined to, for example, include multiple pressure

sources or pressure sources having different components or combinations of components. For example, in some embodiments the secondary syringe 460 (Figures 4A–4C) can be coupled via one or more one-way valves to the syringes 240, 540, 640 or 740 (Figures 2 and 5–7, respectively) to generate additional vacuum. In some embodiments, multiple pressure sources can be coupled to the catheter 102 via the tubing subsystem 120 and/or via the valve 106. Moreover, the individual pressure sources can be the same or different, and can be coupled to the catheter subsystem 100 via a single fluid control device, such as the fluid control device 126, or can be coupled to the catheter subsystem 100 via separate fluid control devices. Therefore, the profile of the vacuum applied to the catheter 102 can be selected or adjusted by using multiple different pressure sources. For example, a specific vacuum profile can depend at least on (i) the individual characteristics of the multiple pressure sources (e.g., volume, bore-size, etc.), (ii) the manner in which the pressure sources are coupled to the catheter subsystem 100 (e.g., via individual valves, via the same valve, etc.), and (iii) the timing of the application or release of the vacuum of each pressure source to the catheter subsystem 100 (e.g., staggered release, simultaneous release, etc.). As one example, in some embodiments, the syringe 240 (Figure 2) and the syringe 340 (Figure 3) can both be coupled to the tubing subsystem 120 via, for example, a Y-connector. After charging both syringes 240, 340 with vacuum pressure, opening the fluid control device 126 can simultaneously apply the combined vacuum to the catheter 102. The larger-bored syringe 340 can provide a short but powerful impulse of vacuum pressure, while the smaller-bored syringe 240 can provide a longer and more sustained vacuum pull. This combination can apply a large, fast-acting suction force to dislodge and capture clot material in the catheter 102, and simultaneously apply a more sustained suction force to capture more clot material.

III. Selected Embodiments of Methods of Clot Removal

[0082] Figure 8 is a flow diagram of a process or method 800 for operating a clot removal system including the assembly 10 to remove clot material from within a blood vessel (e.g., a pulmonary blood vessel) of a human patient in accordance with the present technology. Figures 9A–9C are side views of a proximal portion of the assembly 10, and Figures 10A and 10B are schematic illustrations of a distal portion of the assembly 10, during a clot removal procedure in accordance with embodiments of the present technology. In particular, Figures 9A–9C are side

views of the assembly 10 including the syringe 340 and adaptor 350 (Figures 3A–3D), and Figures 10A and 10B are side views of the catheter 102 with the distal portion 103a of the catheter 102 positioned proximate to an embolism or clot material PE within a blood vessel BV (e.g., a pulmonary blood vessel). Although some features of the method 800 are described in the context of the embodiments shown in Figures 1, 3A–3D, and 9A–10B for the sake of illustration, one skilled in the art will readily understand that the method 800 can be carried out using other suitable systems and/or devices described herein. In particular, although described in the context of the syringe 340, the method 800 can be carried out using any one or combination of the pressure sources described in detail above with reference to Figures 2–7.

[0083] At block 802, the method 800 includes positioning the distal portion 103a of the catheter 102 proximate to clot material within a blood vessel of a human patient (e.g., at a treatment site). For example, in the embodiment illustrated in Figure 10A, a distal terminus of the distal portion 103a of the catheter 102 is positioned proximate to a proximal portion of the clot material PE. It is expected that reducing the distance between the distal terminus of the catheter 102 and the proximal portion of the clot material PE—without contacting the clot material PE with the catheter 102—will maximize the suction forces on the clot material PE when the fluid control device 126 is opened. It is also expected that reducing the distance (e.g., clearance) between the inner diameter of the blood vessel BV and the outer diameter of the catheter will maximize the suction forces on the clot material PE. However, in other embodiments, the distal terminus of the catheter 102 can be positioned at least partially within the clot material PE, or the distal terminus of the catheter 102 can be positioned distal of the clot material PE.

[0084] Access to the pulmonary vessels can be achieved through the patient's vasculature, for example, via the femoral vein. In some embodiments, the catheter subsystem 100 can include an introducer (e.g., a Y-connector with a hemostasis valve; not shown) that can be partially inserted into the femoral vein. A guidewire (not shown) can be guided into the femoral vein through the introducer and navigated through the right atrium, the tricuspid valve, the right ventricle, the pulmonary valve, and into the main pulmonary artery. Depending on the location of the embolism, the guidewire can be guided to one or more of the branches of the right pulmonary artery and/or the left pulmonary artery. In some embodiments, the guidewire can be extended entirely or partially through the clot material PE. In other embodiments, the guidewire can be extended to a

location just proximal of the clot material PE. After positioning the guidewire, the catheter 102 can be placed over the guidewire and advanced (e.g., as indicated by arrow A1) to a position proximate to the clot material PE as illustrated in Figure 10A.

[0085] In some embodiments, to confirm the position of the distal portion 103a of the catheter 102, a contrast agent can be injected through the catheter 102 and viewed using fluoroscopic imaging techniques, as is known in the art. In some embodiments, the valve 106 can be opened to determine the position of the distal portion 103a of the catheter 102 relative to the clot material PE. For example, the activation buttons 101 can be depressed to open the lumen 109 of the valve 106. If there is substantially no back-bleeding through the valve 106, the operator can determine that the distal portion 103a of the catheter 102 is fully engaged with the clot material PE. Conversely, if there is some back-bleeding through the valve 106, the operator can determine that the distal portion 103a of the catheter is not fully engaged with the clot material PE. Accordingly, to locate the distal portion 103a of the catheter 102 just proximal of the clot material PE, the operator can (i) first determine that distal portion 103a of the catheter is fully engaged with the clot material PE by activating the valve 106 and detecting no back-bleeding and (ii) then reposition the catheter 102 (e.g., by withdrawing the catheter 102 proximally) and activate the valve 106 until back-bleeding is detected—thereby confirming that the distal portion 103a of the catheter 102 is positioned proximal of the clot material PE. In some embodiments, the valve 106 can be opened during retraction of the catheter 102 until back-bleeding is detected. In other embodiments, the valve 106 can be closed during retraction of the catheter 102, and the catheter 106 can be retracted a set (e.g., predetermined) distance before the valve 106 is opened again. In one aspect of the present technology, determining the position of the distal portion 103a of the catheter 102 via activation of the valve 106 can be used when it is difficult to determine the position of the catheter 102 via radiographic techniques. In contrast, many conventional hemostasis valves cannot be activated in this manner.

[0086] In some embodiments, the guidewire can then be withdrawn while, in other embodiments, the guidewire can remain and can be used to guide other catheters (e.g., delivery catheters, additional aspiration catheters, etc.), interventional devices, etc., to the treatment site. It will be understood, however, that other access locations into the venous circulatory system of a patient are possible and consistent with the present technology. For example, the user can gain

access through the jugular vein, the subclavian vein, the brachial vein, or any other vein that connects or eventually leads to the superior vena cava. Use of other vessels that are closer to the right atrium of the patient's heart can also be advantageous as it reduces the length of the instruments needed to reach the pulmonary embolism.

[0087] At block 804, the method 800 includes coupling a pressure source (e.g., the syringe 340) to the catheter 102 via the fluid control device 126. For example, in the embodiment illustrated in Figure 9A, the tip 347 (shown in Figures 3A and 3C but obscured in Figure 9A) of the syringe 340 can be coupled to the connector 128 via the adaptor 350. Once the syringe 340 is coupled to the catheter 102, (i) opening the fluid control device 126 fluidly connects the syringe 340 to the lumen 104 of the catheter 102, and (ii) closing the fluid control device 126 fluidly disconnects the syringe 340 from the lumen 104 of the catheter 102. The fluid control device 126 is in an open position in Figure 9A.

[0088] At block 806, the method 800 includes activating the syringe 340 to generate a vacuum while the fluid control device 126 is closed. For example, as shown in Figure 9B, the user can first actuate the fluid control device 126 to close the fluid control device 126, and then retract the plunger 342 to generate a vacuum in the barrel 344 of the syringe 340. The user can subsequently lock the plunger 342 relative to the barrel 344, as described in detail above, to store or maintain a vacuum of known volume in the syringe 340. In this manner, the syringe 340 can be pre-charged with a vacuum before the vacuum is applied to the catheter 102. In contrast, many conventional aspiration techniques include activating a negative pressure source (e.g., a pump, a syringe, etc.) while the pressure source is fluidly connected to a lumen to be aspirated. In some embodiments, when the pressure source 400 with the secondary syringe 460 (Figures 4A–4C) is used with the primary syringe 340; the secondary syringe 460 can be cycled one or more times before or after retracting the plunger 342 to increase the vacuum pressure.

[0089] At block 808, the method 800 includes opening the fluid control device 126 to apply the vacuum to the lumen 104 of the catheter 102. For example, with reference to Figure 9C, the user can actuate (e.g., twist a handle of) the fluid control device 126 to open the fluid control device 126 and apply the vacuum stored in the syringe 340 to the catheter subsystem 100. As shown in Figure 10B, application of the vacuum causes suction at the distal tip 103a of the catheter 102

(e.g., as indicated by arrow A2) that aspirates at least a portion of the clot material PE from the blood vessel BV and into the lumen 104 of the catheter 102. In some embodiments, opening the fluid control device 126 instantaneously or nearly instantaneously generates suction at the distal portion 103a of the catheter 102. In certain embodiments, application of the vacuum can generate suction for less than about 1 second (e.g., about 0.5 second), substantially less than about 1 second (e.g., about 0.3 second, about 0.1 second, etc.) less than about 2 seconds, or greater than about 2 seconds—until the pressure in the assembly 10 equalizes. In some embodiments, depending on the volume of the vacuum chamber formed in the syringe 340 and the dimensions of the catheter subsystem 100 and the tubing subsystem 120 (e.g., where the syringe 340 has a volume that is greater than or about equal to a volume of the catheter subsystem 100), at least some of the clot material PE can be aspirated entirely through the lumen 104 of the catheter 102 and into the barrel 344 of the syringe 340. In some such embodiments, the user can determine whether subsequent steps for treating the clot material PE are necessary or desirable by visualizing the amount of clot material collected in the syringe 340. Figure 9C, for example, illustrates the syringe 340 and the tubing subsystem 120 after the fluid control device 126 has been opened to apply the vacuum stored in the syringe 340 to the catheter 102. In the illustrated embodiment, some of the clot material PE is visible in the syringe 340.

[0090] In some embodiments, the fluid control device 126 or another fluid control device can be intermittently operated to provide discrete bursts of suction. For example, the fluid control device 126 can be quickly opened and closed to provide a first burst of suction (e.g., vacuum release) without fully equalizing the pressure in the assembly 10. The fluid control device 126 can then be opened again to provide a second burst of suction, or opened and closed repeatedly to provide a desired suction pattern. In some embodiments, the assembly 10 can be specifically configured to facilitate the application of multiple bursts of suction. For example, (i) the fluid control device 126 can be spring-loaded, electronically controlled, etc., to rapidly open and close the valve, and/or (ii) the pressure source 140 can have a large vacuum chamber and/or small bore size to increase the time required for pressure in the assembly 10 to equalize (e.g., to increase a discharge time of the pressure source 140).

[0091] Sometimes, as shown in Figure 10B, discharging the vacuum stored in the pressure source to aspirate the lumen 104 of the catheter 102 may not remove all of the clot material PE (or

a desired amount of the clot material PE) from the blood vessel BV. That is, a single aspiration may not adequately remove the clot material PE from the blood vessel BV. In such instances, the user of the assembly 10 may wish to again apply vacuum pressure (conduct an "aspiration pass") to remove all or a portion of the remaining clot material PE in the blood vessel BV. In such instances, the pressure source can be disconnected from the tubing subsystem 120 and drained (e.g., aspirated clot removal removed) before the method 800 returns to block 802. For example, the adaptor 350 and the syringe 340 can be decoupled from the connector 128, and the plunger 342 can be pushed into the barrel 344 to expel the clot material PE and associated fluid from the barrel 344 via the tip 347. With the distal portion of the catheter 102 positioned proximate to the remaining clot material PE (e.g., unmoved relative the last aspiration pass), the pressure source can then be re-coupled to the connector 128 (block 804), primed again (block 806), and the vacuum pressure discharged (block 808) to aspirate all or a portion of the remaining clot material PE.

[0092] Blocks 802–808 can be repeated until a desired amount of clot material is removed from the patient or until the catheter 102 becomes clogged. In some embodiments, to check for clogging of the catheter 102, the fluid control device 126 and/or the valve 106 can be opened to check for back bleeding. A lack of back bleeding can indicate that the catheter 102 is likely clogged. Similarly, if the barrel 344 of the syringe 340 contains mostly air and relatively little blood and clot material (e.g., less than 5–10 cc) after aspiration of the catheter 102 (block 808), it can indicate that the catheter 102 is likely clogged. When the catheter 102 is clogged or a sufficient amount of clot material PE has been removed from the patient, the method 800 can proceed to block 810 and the catheter 102 can be removed from the patient. When the catheter 102 is clogged, the catheter 102 can be flushed and cleared prior to reentry into the patient (block 802). In other embodiments, a different (e.g., new, unused, etc.) catheter can be inserted into the patient and positioned to remove the remaining clot material PE from the patient.

[0093] In some embodiments, rather than removing the catheter 102 from the patient if the catheter 102 is clogged, the syringe 340 can be recharged and used to apply one or more subsequent vacuum pulses to the catheter 102. More specifically, the fluid control device 126 can be closed and the syringe 340 can be removed from the connector 128 and evacuated to remove the clot material and blood therein. Then, blocks 804–808 can be repeated to apply another pulse of vacuum to the catheter 102. That is, rather than removing the catheter 102 after a clog is detected,

the syringe 340 can be "cycled" until the vacuum force on the clot material PE overcomes the forces between the clot material PE and the catheter 102 and sucks the clot material PE into the syringe 340. In some embodiments, when the pressure source 400 with the secondary syringe 460 (Figures 4A–4C) is used with the primary syringe 340, the secondary syringe 460 can be cycled one or more times to increase the vacuum in the assembly 10 (e.g., in the catheter 102) and thus increase the suction force exerted against the clot material PE. That is, rather than removing the catheter 102 after a clog is detected, the secondary syringe 460 can be cycled until the vacuum force on the clot material PE overcomes the forces between the clot material PE and the catheter 102 and sucks the clot material PE into the syringe 340. In some embodiments, as described in detail below with reference to Figures 15–16E, a second clot removal assembly can be telescoped through the first assembly 10 to facilitate removal of the clogged clot material PE.

[0094] In some embodiments, an interventional device such as a clot removal and/or clot treatment device can be delivered to the treatment site through the catheter 102 for engaging and facilitating clot removal before and/or after application of a stored vacuum to the catheter 102. Suitable interventional devices and associated methods are disclosed in U.S. Patent Application No. 9,526,864, filed June 9, 2015, and titled "RETRACTION AND ASPIRATION DEVICE FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," and U.S. Patent Application No. 8,784,434, filed March 15, 2013, and titled "METHODS AND APPARATUS FOR TREATING EMBOLISM," both of which are incorporated herein by reference in their entireties. In some embodiments, for example, the user can first advance an interventional device to the treatment site and at least partially engage the clot material PE with the interventional device to loosen (e.g., scour) the clot material PE. Such loosening of the clot material PE can facilitate the removal of the clot material PE upon a subsequent aspiration pass. Likewise, in some embodiments, the user can use an interventional device to engage residual clot material PE (Figure 10B) after a first aspiration pass.

IV. Selected Embodiments of Telescoping Clot Removal Systems and Associated Methods of Clot Removal

[0095] Figure 11 is a partially schematic side view of another clot treatment or clot removal system configured in accordance with the present technology. In the illustrated embodiment, the

clot removal system includes a first aspiration assembly 20 and a second aspiration assembly 30. The first and second aspiration assemblies 20, 30 ("assemblies 20, 30") can include some features generally similar to the features of the aspiration assembly 10 described in detail above with reference to Figures 1–10B. For example, the first aspiration assembly 20 includes (i) a first catheter subsystem 1000 having a first catheter 1002 and a first valve 1006, (ii) a first tubing subsystem 1020 having a first fluid control device 1026 (e.g., a stopcock), and (iii) a first pressure source 1040 that can be fluidly coupled to the first catheter subsystem 1000 via the first tubing subsystem 1020. Likewise, the second aspiration assembly 30 includes (i) a second catheter subsystem 1100 having a second catheter 1102 and a second valve 1106, (ii) a second tubing subsystem 1120 having a second fluid control device 1126 (e.g., a stopcock), and (iii) a second pressure source 1140 that can be fluidly coupled to the second catheter subsystem 1100 via the second tubing subsystem 1120.

[0096] The first and second catheters 1002, 1102 each comprise an elongated shaft defining a lumen 1004, 1104 and having a distal portion 1003a, 1103a, respectively. The first and second valves 1006, 1106 each include (i) a distal portion 1007a, 1107a, (ii) a proximal portion 1007b, 1107b, (iii) a lumen 1009, 1109 extending therethrough, and (iv) a flow controller (obscured in Figure 10) in the lumen 1009, 1109, respectively. The first fluid control device 1026 is operable to regulate or control fluid flow between (e.g., fluidly connect or disconnect) the first pressure source 1040 and the first catheter subsystem 1000. The second fluid control device 1126 is operable to regulate or control fluid flow between (e.g., fluidly connect or disconnect) the second pressure source 1140 and the second catheter subsystem 1100.

[0097] In the illustrated embodiment, the second catheter 1102 has a smaller cross-sectional dimension (e.g., diameter) than the first catheter 1002 so that the second catheter 1102 can be inserted through the first valve 1006 and into the lumen 1004 of the first catheter 1002. In some embodiments, the second catheter 1102 can be telescoped through the lumen 1004 of the first catheter 1002 until the distal portion 1103a of the second catheter 1102 extends beyond a distal terminus of the first catheter 1002. Accordingly, the second catheter 1102 can be longer than the first catheter 1002. In some embodiments, the second catheter 1102 can have a size of 16 French or smaller and the first catheter 1002 can have a size of 20 French or greater. The first valve 1006 can provide a hemostatic seal that inhibits fluid flow (e.g., blood flow) through the first valve 1006

and from the first catheter subsystem 1000 when the second catheter 1102 is positioned within the first catheter 1002. In some embodiments (e.g., as described in detail below with reference to Figures 14A–14C), a sealing member 1499 can be positioned between the first catheter 1002 and the second catheter 1102 for sealing the lumen 1004 of the first catheter 1002 when the second catheter 1102 is advanced distally past the sealing member.

[0098] In some embodiments, the first and second pressure sources 1040, 1140 ("pressure sources 1040, 1140") are separate sources each configured to generate and store a vacuum for subsequent application to the first and second catheter subsystems 1000, 1100, respectively, as described in detail above with reference to Figures 1–10B. In other embodiments, one or both of the pressure sources 1040, 1140 can be configured to provide sustained negative pressure rather than a charge or burst of stored vacuum pressure. In yet other embodiments, one of the pressure sources 1040, 1140 can be omitted, or the pressure sources 1040, 1140 can be fluidly coupled and/or integrally formed.

[0099] Figure 12 is a flow diagram of a process or method 1280 for operating a clot removal system including the assemblies 20 and 30 to remove clot material from within a blood vessel (e.g., a pulmonary blood vessel) of a human patient in accordance with the present technology. Figures 13A–13C are schematic illustrations of a distal portion of the assemblies 20, 30 during a clot removal procedure in accordance with the present technology. Figures 14A–14C are schematic side views of a distal portion of the assemblies 20, 30 during a clot removal procedure and including an optional sealing member in accordance with the present technology. Although some features of the method 1280 are described in the context of the embodiments shown in Figures 11 and 13A–14C for the sake of illustration, one skilled in the art will readily understand that the method 1280 can be carried out using other suitable systems and/or devices.

[0100] At block 1282, the method 1280 includes intravascularly positioning the first catheter 1002 within a human patient. Figure 13A, for example, illustrates the first catheter 1002 after it has been advanced (e.g., as indicated by arrow A1) to a position within a blood vessel BV (e.g., a pulmonary blood vessel). More specifically, the first catheter 1002 can be advanced within the blood vessel BV until the distal portion 1003a of the first catheter 1002 is positioned proximal to clot material PE within the blood vessel BV. In some embodiments, the position of the distal

portion 1003a of the first catheter 1002 relative to the clot material PE can be determined by activating the first valve 1006 and determining whether there is back-bleeding through the first valve 1006, as described in detail above. In the illustrated embodiment, the clot material PE is located within a branch (e.g., a reduced diameter portion) of the blood vessel BV. In some embodiments, access to the blood vessel BV can be achieved using an introducer and guidewire as described in detail above with reference to Figure 8.

[0101] At block 1284, the method 1280 includes advancing the second catheter 1102 through the first catheter 1002 until the distal portion 1103a of the second catheter 1102 is positioned proximate to the clot material PE within the blood vessel BV (e.g., at a treatment site). To advance the second catheter 1102 through the first catheter 1002, the user can first insert the distal portion 1103a of the second catheter 1102 through the first valve 1006 before advancing the second catheter 1102 (e.g., as indicated by the arrow A1) through the lumen 1004 of the first catheter 1002. In some embodiments, the first valve 1006 can be actuated (e.g., by depressing one or more buttons) to open the lumen 1009 of the first valve 1006 so that the second catheter 1102 can be inserted therethrough. In some embodiments, the position of the distal portion 1103a of the second catheter 1102 relative to the clot material PE can be determined by activating the second valve 1106 and determining whether there is back-bleeding through the second valve 1106, as described in detail above. In other embodiments, the (smaller) second catheter 1102 can be intravascularly positioned proximate to the clot material PE before intravascularly positioning the (larger) first catheter 1002. In such embodiments, the second catheter 1102 can act as a guide or rail for guiding the advancement of the first catheter 1002 to the treatment site.

[0102] Figure 13A illustrates the second catheter 1102 after it has been advanced through the first catheter 1002 and past a distal terminus of the first catheter 1002 to position a distal terminus of the second catheter 1102 proximate to a proximal portion of the clot material PE. In other embodiments, the distal terminus of the second catheter 1102 can be positioned at least partially within the clot material PE, or the distal terminus of the second catheter 1102 can be positioned distal of the clot material PE. In one aspect of the present technology, because the second catheter 1102 has a smaller cross-sectional dimension than the first catheter 1002, the second catheter 1102 can be advanced to narrower (e.g., more distal) treatment sites within the blood vessel BV. In the embodiment illustrated in Figure 13A, for example, the first catheter 1002

may be too large to be positioned within the branch of the blood vessel BV, while the second catheter 1102 can be positioned within the branch proximate to or within the clot material PE.

[0103] At block 1286, the method 1280 includes coupling the second pressure source 1140 to the second catheter 1102 via the second fluid control device 1126. For example, any one or combination of the pressure sources described in detail above with reference to Figures 2–7 can be coupled to the second catheter 1102 via the second tubing subsystem 1120. Once the second pressure source 1140 is coupled to the second catheter 1102, (i) opening of the second fluid control device 1126 fluidly connects the second pressure source 1140 to the lumen 1104 of the second catheter 1102, and (ii) closing of the second fluid control device 1126 fluidly disconnects the second pressure source 1140 from the lumen 1104 of the second catheter 1102. In some embodiments, the method 1280 can further include coupling the first pressure source 1040 to the first catheter 1002 (e.g., via the first tubing subsystem 1020).

[0104] At block 1288, the method 1280 includes activating the second pressure source 1140 to generate a vacuum while the second fluid control device 1126 is closed. In particular, the second pressure source 1140 can be activated to build-up or pre-charge a vacuum for subsequent application to the second catheter 1102. In some embodiments, the first pressure source 1040 can also be activated to generate and store a vacuum for subsequent application to the first catheter 1002.

[0105] At block 1290, the method 1280 includes opening the second fluid control device 1126 to apply the vacuum stored in second pressure source 1140 to the lumen 1104 of the second catheter 1102. As shown in Figure 13B, application of the vacuum causes suction (e.g., as indicated by arrow A2) that aspirates at least a portion of the clot material PE from the blood vessel BV and into the lumen 1104 of the second catheter 1102. In some embodiments, opening the second fluid control device 1126 instantaneously or nearly instantaneously generates suction at the distal portion 1103a of the second catheter 1102. In one aspect of the present technology, pre-charging or storing the vacuum before applying the vacuum to the lumen 1104 of the second catheter 1102 is expected to generate greater suction forces (and corresponding fluid flow velocities) at and/or near the distal portion 1103a of the second catheter 1102 compared to simply

activating the second pressure source 1140 while it is fluidly connected to the second catheter 1102.

[0106] In some embodiments, where the first pressure source 1040 is also activated to generate and store a vacuum (e.g., at block 1288), the method 1280 can further comprise opening the first fluid control device 1026 to generate suction at the distal portion 1003a of the first catheter 1002. One skilled in the art will understand that the suction profile in the blood vessel BV can be selected or modified based on the characteristics of the pressure sources 1040, 1140 (e.g., volume, bore size, etc.) and the timing of the opening of the first and second fluid control devices 1026, 1126. For example, the first fluid control device 1026 can be opened at the same time as the second fluid control device 1126 to generate a combined and relatively large suction force in the blood vessel BV. In other embodiments, the first fluid control device 1026 can be opened after the second fluid control device 1126 to generate staggered or stepped suction forces in the blood vessel BV. For example, the first fluid control device 1026 can be opened after the second fluid control device 1126 to aspirate any of the clot material PE (i) remaining in the blood vessel BV after aspiration of the second catheter 1102 and/or (ii) stuck to or extending from the second catheter 1102. In other embodiments, the first pressure source 1040 can be a pump or other source for providing sustained negative pressure—rather than a built-up charge of negative pressure—and thus can generate sustained (e.g., constant) suction at the distal portion 1003a of the first catheter 1002. In some such embodiments, the first fluid control device 1026 can remain open during the clot removal procedure to provide sustained suction throughout the procedure.

[0107] In some embodiments, an interventional device can be delivered through the second catheter 1102 and used to engage the clot material PE before and/or after the vacuum is applied to the second catheter 1102. Specific details of suitable interventional devices and associated methods of use are disclosed in, for example, provisional U.S. Patent Application No. 16/258,344, filed January 25, 2019, and titled "SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

[0108] At block 1292, the method 1280 includes retracting the second catheter 1102 proximally through the first catheter 1002. In some embodiments, multiple aspiration passes can

be performed with the second catheter 1102 before retracting the second catheter 1102. In some embodiments, as shown in Figure 13C, the first pressure source 1040 or another pressure source coupled to the first catheter 1002 can be activated to generate suction (e.g., as indicated by arrow A3) at the distal portion 1003a of the first catheter 1002 during retraction of the second catheter 1102. The suction can be constant or provided in one or more bursts, as described in detail above. In some embodiments, the second catheter 1102 can be fully withdrawn from the patient and disposed of or cleaned (e.g., flushed with a sterile liquid) for reuse.

[0109] Sometimes, the clot material PE is not fully pulled into the second catheter 1102 when the vacuum is applied to the second catheter 1102 (block 1290) and can therefore stick to or dangle from the distal portion 1103a of the second catheter 1102. Figure 14A, for example, is an enlarged view of the distal portion of the assemblies 20, 30 shown in Figure 13C and illustrating a portion of the clot material PE stuck to or dangling from the distal portion 1103a of the second catheter 1102. In the illustrated embodiment, an optional seal 1499 is disposed between the first and second catheters 1002, 1102 to facilitate the removal of such dangling clot material PE. More specifically, the seal 1499 (shown in cross-section) can be disposed between an outer surface of the second catheter 1102 and an inner surface of the first catheter 1002. The seal 1499 can be an O-ring, grommet, or other suitable component that fluidly disconnects the lumen 1004 of the first catheter 1002 from the blood vessel BV when the second catheter 1102 is positioned therethrough (e.g., when the distal terminus of the second catheter 1102 is positioned distally of the seal 1499).

[0110] Figures 14B and 14C are enlarged views of the distal portion of the assemblies 20, 30 and illustrating further retraction of the second catheter 1102 (and the dangling clot material PE) into the lumen 1004 of the first catheter 1002. In some embodiments, the first pressure source 1040 can be activated to charge a vacuum in the lumen 1004 of the first catheter 1002. For example, after the second catheter 1102 is advanced through the first catheter 1002 and past the seal 1499 (e.g., block 1284)—thereby sealing the lumen 1004 of the first catheter 1002—the operator can open the first fluid control device 1026 and activate the first pressure source 1040 to build up the vacuum in the lumen 1004 of the first catheter 1002. Referring to Figure 14C, when the distal terminus of the second catheter 1102 is retracted proximally past the seal 1499, the lumen 1004 of the first catheter 1002 becomes fluidly connected to the blood vessel BV and the vacuum is instantaneously or nearly instantaneously released to generate suction (e.g., as indicated by

arrows A4). In the illustrated embodiment, the suction acts to separate or otherwise dislodge the clot material PE from the second catheter 1102 and pull the clot material PE proximally through the lumen 1004 of the first catheter 1002. In this manner, a second burst of suction is automatically applied via the first catheter 1002 during retraction of the second catheter 1102. In one aspect of the present technology, the user does not need to take any additional step to release the vacuum stored in the first catheter 1002—as release is automatically triggered by retraction of the second catheter 1102.

[0111] At block 1294, the user can determine whether it is necessary or desirable to redeploy the second catheter 1102 or another catheter through the first catheter 1002 in order to remove any residual clot material PE that was not removed during the first aspiration pass and/or any clot material located elsewhere in the blood vessel BV (e.g., to initiate a second aspiration pass). In some embodiments, the operator can visualize the amount of clot material PE collected in the first pressure source 1040 and/or the second pressure source 1140 to at least partially determine whether another aspiration pass is needed. In other embodiments, the operator can rely on imaging (e.g., fluoroscopic imaging) of the blood vessel BV or other techniques known in the art to determine whether an additional aspiration pass is necessary or desirable.

[0112] If another pass is not needed (e.g., the clot material PE was adequately removed), the user can elect to fully withdraw the assemblies 20, 30 from the patient at block 1296. If clot material PE remains in the vessel, the method can return to block 1284. In particular, the same second catheter 1102 can be cleaned (e.g., flushed with saline) and advanced again through the first catheter 1002 until the distal portion 1103a of the second catheter 1102 is positioned proximate to the remaining clot material PE within the blood vessel BV. In some embodiments, a new second catheter 1102 can be used for each pass to reduce the likelihood of contamination (e.g., reintroduction of clot material PE). In some embodiments, the first catheter 1002 can be aspirated (e.g., via the first pressure source 1040) prior to redeployment of the second catheter 1102 to, for example, remove any clot material PE that may be in the first catheter 1002 to inhibit its reintroduction into the blood vessel BV as the second catheter 1102 is advanced therethrough during another pass. Once the desired amount of clot material PE has been removed from the patient, the assemblies 20, 30 may be fully withdrawn from the patient (block 1294).

[0113] In one aspect of the present technology, the method 1280 provides for an aspiration catheter to be deployed multiple times without requiring that the first catheter 1002 be removed after each deployment. Accordingly, the present technology allows for only a single insertion of a guide catheter during a procedure including multiple passes to remove clot material—increasing the speed of the procedure and reducing trauma to the patient since the guide catheter does not need to be reintroduced (e.g., advanced through the vasculature and past the heart) before each pass. Moreover, in certain embodiments, the present technology can enable the first catheter 1002 to be relocated to an alternate treatment site within the patient without removing the first catheter 1002 from the patient and, therefore, without reintroducing the first catheter 1002 through the heart. For example, the first catheter 1002 can be relocated to another treatment site within the lungs including a treatment site in the opposite lung. More specifically, (i) a dilator can be reintroduced into the first catheter 1002, (ii) the first catheter 1002 can be withdrawn into the main pulmonary artery, (iii) a guidewire can be redirected to the new treatment site, (iv) the first catheter 1002 can be advanced over the guidewire to the new treatment site, and (v) the dilator can be removed.

[0114] Figure 15 is a flow diagram of another process or method 1580 for operating a clot removal system including the assemblies 20, 30 (Figure 1) to remove clot material from within a blood vessel (e.g., a pulmonary blood vessel) of a human patient in accordance with the present technology. Figure 16A is an enlarged side view of a distal portion of the first assembly 20, and Figures 16B–16E are side views of a distal portion of the assemblies 20, 30 during a clot removal procedure in which clot material clogs the first assembly 20 in accordance with the present technology. Although some features of the method 1580 are described in the context of the embodiments shown in Figures 11 and 16A–16E for the sake of illustration, one skilled in the art will readily understand that the method 1580 can be carried out using other suitable systems and/or devices.

[0115] Some features of the method 1580 are generally similar to those of the methods 880 and/or 1280 described in detail above with reference to Figures 8 and 12, respectively. For example, at block 1582 the method includes intravascularly positioning the first catheter 1002 of the first assembly 20 within a human patient. At block 1584, the method 1580 includes coupling the first pressure source 1040 to the first catheter 1002 via the first fluid control device 1026. For

example, any one or combination of the pressure sources described in detail above with reference to Figures 2–7 can be coupled to the second catheter 1002 via the first tubing subsystem 1020. At block 1586, the method 1580 includes activating the first pressure source 1040 to generate a vacuum while the first fluid control device 1026 is closed. In particular, the first pressure source 1040 can be activated to build-up or pre-charge a vacuum for subsequent application to the first catheter 1002. At block 1588, the method 1580 includes opening the first fluid control device 1026 to apply the vacuum stored in the first pressure source 1040 to the lumen 1004 of the first catheter 1002. As described in detail above, opening the first fluid control device 1026 instantaneously or nearly instantaneously generates suction at the distal portion 1003a of the first catheter 1002.

[0116] Sometimes, however, clot material is not fully pulled into the first catheter 1002 and/or clogs the first catheter 1002 when the vacuum is applied to the first catheter 1002 (block 1588). Figure 16A, for example, is an enlarged view of the distal portion of the first assembly 20 illustrating a portion of clot material PE that extends beyond from the distal portion 1003a of the first catheter 1002 and blocks/clogs the lumen 1004 of the first catheter 1002. As such, a portion of the clot material PE is not within the first catheter 1002. Accordingly, at block 1590, the method 1580 can include determining whether the first catheter 1002 is clogged. In some embodiments, the operator can determine that the first catheter 1002 is clogged based on the vacuum chamber of the first pressure source 1040 containing little to no clot material PE and blood. For example, since the clot material PE clogs the first catheter 1002, the vacuum chamber of the first pressure source 1040 cavitates when the first fluid control device 1026 is opened. If the first catheter 1002 is not clogged, the method 1580 can proceed to block 1598 and the first catheter 1002 can be withdrawn from the patient or the operator can perform another aspiration pass (e.g., as described in detail above with reference to blocks 808 and 810 of the method 800 shown in Figure 8).

[0117] If the first catheter 1002 is clogged, the method 1580 can proceed to block 1592 which includes advancing the second catheter 1102 through the first catheter 1002 until the distal portion 1103a of the second catheter 1102 is positioned in or proximate to the clogging clot material PE. For example, Figure 16B illustrates the second catheter 1102 after it has been advanced to a position within the first catheter 1002 in which the distal terminus of the second catheter 1102 is at or proximate to the clogging clot material PE. To advance the second catheter

1102 through the first catheter 1002, the user can first insert the distal portion 1103a of the second catheter 1102 through the first valve 1006 (Figure 11) before advancing the second catheter 1102 through the lumen 1004 of the first catheter 1002.

[0118] At block 1594, the method 1580 includes activating the second pressure source 1140 (Figure 11) coupled to the second catheter 1102. More specifically, the second pressure source 1140 (e.g., any one or combination of the pressure sources described in detail above with reference to Figures 2–7) can be coupled to the second catheter 1102 via the second fluid control device 1126 (Figure 11), and the second pressure source 1140 can be activated to build-up or pre-charge a vacuum while the second fluid control device 1126 is closed. The second fluid control device 1126 can then be actuated to apply the vacuum stored in the second pressure source 1140 to the lumen 1104 of the second catheter 1102. In other embodiments, the second pressure source 1140 can simply provide a sustained vacuum rather than an instantaneous release of vacuum. That is, in some embodiments the second pressure source 1140 is not pre-charged with a vacuum.

[0119] Applying the vacuum to second catheter 1102 can aspirate at least a portion of the clogging clot material PE into the second catheter 1102 and/or suck the clot material PE against the distal terminus of the second catheter 1102. Figure 16C, for example, illustrates a portion of the clot material PE stuck to or extending from the distal portion 1103a of the second catheter 1102 after aspirating the second catheter 1102. In the embodiment illustrated in Figure 16C, the added vacuum pressure generated through the second catheter 1102 is still not enough to break apart the clot material PE such that it can be fully aspirated through the first and/or second catheters 1002, 1102. That is, the clot material PE clogs the lumen 1004 of the first catheter 1002. In other embodiments, the added vacuum pressure from the second pressure source 1140 is sufficient to break apart the clot material PE such that it is aspirated into, for example, the vacuum chambers of the first and/or second pressure sources 1040, 1140.

[0120] At block 1596, the method can include retracting the second catheter 1102 and the clot material PE through the lumen 1004 of the first catheter 1002. For example, Figure 16D illustrates retracting the second catheter 1102, which in turn retracts the attached clot material PE, through the lumen 1004 of the first catheter 1002. In some embodiments, the second catheter 1102 and clot material PE can be fully withdrawn through the first catheter 1002. In other embodiments,

retracting the clot material PE through the first catheter 1002 causes the clot material PE to break apart and be aspirated into the vacuum chambers of the first and/or second pressure sources 1040, 1140. Figure 16E, for example, illustrates the clot material PE breaking apart as the vacuum of the first and/or second pressure sources 1040, 1140 is instantaneously or nearly instantaneously released to suck the clot material PE proximally (e.g., as indicated by arrows A5).

[0121] At block 1598, the first and second catheters 1002, 1102 can be withdrawn from the patient or the operator can perform another aspiration pass using one or both of the first and second catheters 1002, 1102.

[0122] In one aspect of the present technology, the method 1580 removes clot material even when a first aspiration pass clogs the first catheter 1002. More particularly, the second catheter 1102 can be used to remove clogged clot material PE without requiring the first catheter 1002 and the clogged clot material PE to be withdrawn through the blood vessel BV.

V. Additional Selected Embodiments of Clot Removal Systems and Associated Methods of Clot Removal

[0123] From the foregoing, it will be appreciated that specific embodiments of the present technology have been described herein for purposes of illustration, but that various modifications may be made without deviating from the scope of the present technology. For example, in many of the embodiments described above, stored vacuum pressure can be used to aspirate or suck clot material from a blood vessel and into a catheter without the need to engage an interventional device with the clot material. However, one skilled in the art will understand that the aspiration devices and techniques disclosed herein can be used in conjunction with any suitable interventional device and/or during a clot removal procedure utilizing an interventional device. In some embodiments, for example, a clot removal system can be configured to apply stored vacuum pressure to a guide catheter to generate a burst of suction while an interventional device is retracted into and/or through the guide catheter.

[0124] Figure 17, for example, is a partially schematic view of a clot removal system 1700 ("system 1700") configured in accordance with the present technology. The system 1700 includes some features generally similar to the features of the clot removal system described in detail above with reference to Figure 1. For example, the system 1700 includes a catheter or sheath 1702

comprising an elongated shaft, and a valve 1706 coupled to a proximal portion of the sheath 1702. The valve 1706 has a side port 1708 that fluidly couples a lumen of the sheath 1702 to a tubing subsystem 1720 and a pressure source 1740 (shown schematically). A fluid control device 1726 (e.g., a stopcock or clamp; shown schematically) is operable to fluidly disconnect or connect the pressure source 1740 from/to the lumen of the sheath 1702. The pressure source 1740 can be any suitable pressure source for generating and storing vacuum pressure, as described in detail above.

[0125] In the illustrated embodiment, the system 1700 further includes (i) a self-expanding (e.g., mesh) funnel 1780 coupled to a proximal portion of the sheath 1702 and (ii) an interventional device (e.g., a thrombus extraction device) 1790. In the illustrated embodiment, the interventional device 1790 includes an expandable coring element (e.g., a first portion) 1792 coupled to an expandable cylindrical element (e.g., a second portion) 1794. In some embodiments, the interventional device 1790 is configured to self-expand from a compressed delivery state to an expanded deployed state. The interventional device 1790 is shown in the deployed state in Figure 17. An elongated shaft 1782 and/or one or more shafts positioned within the elongated shaft 1782 (e.g., an intermediate shaft 1884 and an inner shaft 1886 as shown in Figures 18E and 18F, respectively) are coupled to the interventional device 1790 and configured to retract, advance, and/or manipulate (e.g., move between the delivery and deployed states) the interventional device 1790. In some embodiments, the system 1700 can be generally the same as or similar to any of the clot removal systems disclosed in U.S. Patent Application Publication No. 2018/0193043, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," which is incorporated herein by reference in its entirety.

[0126] In the illustrated embodiment, the system 1700 is shown intravascularly positioned within a blood vessel BV of a human patient and proximate to clot material DV (e.g., a deep vein thrombus) within the blood vessel BV. Specifically, Figure 17 shows the system 1700 after (i) advancing the sheath 1702 to a position proximate to a proximal portion 1785b of the clot material DV, (ii) deploying the funnel 1780, (iii) deploying the interventional device 1790 from the sheath 1702 (e.g., by advancing the interventional device 1790 through the valve 1706 and the sheath 1702 to a position distal of a distal portion 1785a of the clot material DV), and (iv) expanding the interventional device 1790 from the compressed delivery state to the deployed state.

[0127] Figures 18A–18H are enlarged views of a distal portion of the system 1700 during a clot removal procedure in accordance with the present technology. In general, Figures 18A–18H illustrate the proximal retraction of the interventional device 1790 through the clot material DV to capture at least a portion of the clot material DV, and the subsequent joint retraction of the interventional device 1790 and the captured clot material DV into the funnel 1780 and the sheath 1702. In one aspect of the present technology, charged vacuum pressure generated in the vacuum source 1740 can be applied to the sheath 1702 at one or more times during the illustrated process to generate suction for aspirating the captured clot material DV through the sheath 1702 and/or to inhibit clogging of the sheath 1702.

[0128] Referring first to Figure 18A, proximal retraction of the interventional device 1790 causes the coring element 1792 to separate and/or core the distal end portion 1785a of the clot material DV from the walls W of the blood vessel BV. As shown in Figure 18B, continued proximal retraction of the interventional device 1790 through the clot material DV causes the cylindrical element 1794 to capture the distal end portion 1785a of the clot material therein. Figures 18C–18E illustrate further proximal retraction of the interventional device 1790 which causes further separation, coring, and/or capture of the clot material DV. As seen in Figure 18E, the proximal end portion 1785b of the clot material DV is cored and captured as the interventional device 1790 is proximally retracted toward the funnel 1780 and the sheath 1702. As further shown in Figure 18E, a first radiopaque marker 1887a can be positioned on a distal end portion of the inner shaft 1884 and a second radiopaque marker 1887b can be positioned on a distal end portion of the sheath 1702.

[0129] In some embodiments, as shown in Figure 18F, the interventional device 1790 can be proximally retracted until a portion of the coring element 1792 is contained (e.g., positioned) within the funnel 1780. More specifically, the interventional device 1790 can be proximally retracted until a mouth 1895 of the coring element 1792 is contained within the funnel 1780. In some embodiments, the containment of the mouth 1895 within the funnel 1780 can be fluoroscopically verified by visualization of the radiopaque markers 1887 (Figure 18E). In some embodiments, for example, the mouth 1895 can be determined as wholly contained within the funnel 1780 via fluoroscopic monitoring based on the alignment of the distal end portion of the inner shaft 1884 (e.g., the first radiopaque marker 1885a) relative to the distal end portion of the

sheath 1702 (e.g., the second radiopaque marker 1885b). In some embodiments, when the mouth 1895 of the coring element 1792 is positioned within the funnel 1780, the interventional device 1790 can be moved or transformed from the expanded deployed state to the compressed delivery state to compress and secure the clot material DV captured by the interventional device 1790. In some embodiments, for example, the intermediate shaft 1884 can be unlocked and/or decoupled from the inner shaft 1886 (e.g., via user actuation of a plunger or other device) such that the inner shaft 1886 can be advanced distally relative to the intermediate shaft 1884 to collapse or compress the interventional device 1790.

[0130] After the interventional device 1790 has been collapsed, the interventional device 1790 can be proximally retracted through the funnel 1780 and into the sheath 1702 as depicted in Figure 18G. As shown in Figure 18H, the interventional device 1790 can continue to be proximally retracted until the interventional device 1790 and the captured clot material DV are fully contained within the sheath 1702. In some embodiments, the interventional device 1790 and the captured clot material DV can then be withdrawn through the sheath 1702 and the valve 1706 (Figure 17), and from the patient's body.

[0131] In some embodiments, the collapse of the interventional device 1790 and/or the retraction of the interventional device 1790 into the funnel 1780 and/or the sheath 1702 can result in one or more portions of the clot material DV breaking away from the clot material DV contained in the interventional device 1790. For example, all or a portion of the captured clot material DV can be extruded through pores of the (e.g., mesh) cylindrical element 1794 as the interventional device 1790 collapses. In some embodiments, any such clot material can be captured by the funnel 1780. Referring to Figure 17, in some embodiments, the pressure source 1740 can be activated to charge a vacuum, and the fluid control device 1726 can subsequently be opened to apply the charged vacuum to the sheath 1702 (as described in detail above). The vacuum can be applied to the sheath 1702 at any point during retraction of the interventional device 1790. As shown in Figures 18G and 18H, application of the vacuum can generate instantaneous or nearly instantaneous suction (e.g., as indicated by arrows A6) at the distal end portion the sheath 1702 that can aspirate the extruded portions and/or other portions of the clot material DV into and/or through the sheath 1702. In particular, the generated suction can aspirate some or all of the clot material DV captured by the funnel 1780. Moreover, in some embodiments, application of a

vacuum from the pressure source 1740 can facilitate smooth retraction of the captured clot material DV through the sheath 1702. For example, a burst of suction generated by application of the vacuum can help inhibit clogging of the sheath 1702, and/or help resolve (e.g., break apart) a clog formed in the sheath 1702 during retraction.

VI. Selected Embodiments of Clot Removal Systems Having Filters and Associated Methods of Clot Removal

[0132] The systems and methods for clot removal described herein can include applying a pre-charged vacuum to generate suction for aspirating clot removal from the blood vessel of a patient. In one aspect of the present technology, aspiration of the clot material also aspirates blood from the patient. It can be advantageous to reintroduce the aspirated blood to the patient to lessen the trauma to the patient—especially where the removal procedure may comprise multiple aspiration passes that can together withdraw a significant amount of blood. However, the aspirated blood is often mixed with clot material and is therefore not suitable for reintroduction into the patient. Figures 19–20E illustrate various devices for filtering aspirated blood from removed clot material to reintroduce the aspirated blood into the patient without reintroducing a significant amount of clot material.

[0133] For example, Figure 19 is a perspective side view of a pressure source 1900 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The pressure source 1900 is generally similar to the pressure source 400 described in detail above with reference to Figures 4A–4C. For example, the pressure source 1900 includes the secondary syringe 460 ("syringe 460") and the first and second one-way valves 470 and 472. However, the secondary syringe 460 is coupled to a canister 1940 rather than the primary syringe 340 (Figures 4A–4C). The canister 1940 includes a tip (obscured) coupled to the adaptor 350 and is configured to be removably positioned within the connector 128 of the tubing subsystem 120 (Figure 1) to fluidly couple the canister 1940 to the tubing subsystem 120. Because the canister 1940 does not include a plunger or other component for changing a volume thereof, the syringe 460 is the only vacuum source for evacuating the canister 1940 (e.g., via repeated cycling of the secondary syringe 460).

[0134] In the illustrated embodiment, the canister 1940 further includes a filter 1942. The canister 1940 is shown as transparent in Figure 19 for the sake of clarity. The filter 1942 is coupled to and/or covers a removable end cap 1944 having a blood separation port 1946. In operation, when blood and clot material are aspirated into the canister 1940 (e.g., via any of the methods described in detail above), the filter 1942 separates the blood from the clot material within the canister 1940. The filtered blood can be removed via the blood separation port 1946. For example, a syringe (not shown) or other device can be fluidly coupled to the blood separation port 1946 and used to draw the blood through the filter 1942 and out of the canister 1940. The filtered blood can then be reintroduced to the patient via, for example, the fluid control device 126 and/or the connector 128 of the tubing subsystem 120. Once the blood is removed from the canister 1940, the end cap 1944 can be removed from the canister 1940 (e.g., by unscrewing the end cap 1944 from the body of the canister 1940) for removing the captured clot material. In some embodiments, the filter 1942 is attached to the end cap 1944 such that removing the end cap 1944 removes the filter 1942 and permits clot material to be dumped, scooped, or otherwise removed from the canister 1940.

[0135] Figures 20A–20E illustrate a filter device 2050 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The filter device 2050 is configured as an in-line filter for use with, for example, one or more of the pressure sources described in detail above with reference to Figures 2–7. For example, Figure 20A is a partially-exploded side view of the filter device 2050 and the pressure source 340 (Figures 3A–3D). In the illustrated embodiment, the filter device 2050 comprises a filter portion 2060 that is removably positionable within a barrel portion 2070. In the illustrated embodiment, the barrel portion 2070 includes a barrel 2072 that defines a chamber 2074, and a large bore tip 2076 configured to fluidly couple the chamber 2074 to external components, such as the tubing subsystem 120 (e.g., as shown in Figure 20C). The filter portion 2060 includes a seal 2062 configured to engage (i) an interior surface of the barrel 2072 when the filter portion 2060 is positioned within the chamber 2074 of the barrel portion 2070 and (ii) an exterior surface of the syringe 340 (e.g., an exterior surface of the barrel 344) when the syringe 340 is inserted into the filter device 2050. In other embodiments, the filter portion 2060 can be permanently attached to or integrally formed with the barrel portion 2070. The filter portion 2060 further includes a filter

(e.g., a mesh) 2064 configured (e.g., sized and shaped) to inhibit clot material from passing therethrough. In some embodiments, the filter 2064 can be configured to inhibit clots larger than about 100 μm (e.g., larger than about 110 μm) from passing therethrough.

[0136] Figure 20B is a perspective side view of the syringe 340 coupled to the filter device 2050. The barrel 2072 of the barrel portion 2070 is shown as transparent in Figure 20B (and Figures 20C–20E) for the sake of clarity. In the illustrated embodiment, the seal 2062 is positioned between the exterior surface of the barrel 344 of the syringe 340 and the interior surface of the barrel 2072 of the barrel portion 2070. The filter 2064 is positioned around (e.g., covers) the tip 347 of the syringe 340 to inhibit clot material from entering the barrel 344 of the syringe 340 during operation.

[0137] Figure 20C is a side view of the filter device 2050 and syringe 340 coupled to the tubing subsystem 120 of the assembly 10. More specifically, the tip 2076 can be inserted into the connector 128 of the tubing subsystem 120 as described in detail above. When the filter device 2050 and the syringe 340 are coupled to the tubing subsystem 120, the filter device 2050 is positioned in-line (e.g., in series) with the syringe 340. In the embodiment illustrated in Figure 20C, the plunger 342 of the syringe 340 has been withdrawn to generate negative pressure in the combined volume of the barrels 2072 and 344. As described in detail above, opening the fluid control device 126 nearly instantaneously applies the negative pressure to the catheter 102 to generate suction therein. When clot material and blood are aspirated through the catheter 102 and the tubing subsystem 120, the filter portion 2060 inhibits the clot material from entering the barrel 344 of the syringe 340. Thus, aspirated blood is collected in the barrel 344 of the syringe 340 while the aspirated clot material is collected in the barrel 2072 of the barrel portion 2070 of the filter device 2050. In this manner, clot material and blood can be separated during aspiration.

[0138] In one aspect of the present technology, separating the blood from the clot material such that the blood is within the syringe 340 permits the blood to be easily reintroduced to the patient. For example, Figures 20D and 20E are side views of the syringe 340 coupled to the tubing subsystem 120 of the assembly 10 for reintroducing blood to a patient. In some embodiments, as shown in Figure 20D, the syringe 340 can be decoupled from the filter device 2050 and directly coupled to the connector 128. With the fluid control device 126 in an open position, the blood can

then be reintroduced to the patient through the assembly 10 by depressing the plunger 342 of the syringe 340. In some embodiments, as shown in Figure 20E, the syringe 340 can be decoupled from the filter device 2050 and directly coupled to a port on the fluid control device 126. With the fluid control device 126 in a closed position, the blood can then be reintroduced to the patient through the assembly 10 by depressing the plunger 342 of the syringe 340. Referring to Figures 20A–20E together, after or before reintroducing filtered blood to the patient, the filter portion 2060 of the filter device 2050 can be removed from the barrel portion 2070 so that the collected clot material can be removed and the filter device 2050 cleaned. In some embodiments, the filter device 2050 and a coupled pressure source can be used to filter blood from clot material after—as opposed to during—an aspiration pass. For example, the filter device 2050 and coupled pressure source could be used to withdraw blood and clot material collected in the canister 1940 of the pressure source 1900 (e.g., where the canister 1940 does not include the filter 1942).

[0139] Figures 21A and 21B illustrate a filter device 2150 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The filter device 2150 is configured for use with, for example, one or more of the pressure sources described in detail above with reference to Figures 2–7. For example, Figure 21A is a partially-exploded side view of the filter device 2150 and the pressure source 340 (Figures 3A–3D). In the illustrated embodiment, the filter device 2150 includes a housing 2152 defining a chamber 2154, a filter 2156 configured to be positioned within the housing 2152, and a cap assembly 2160 configured to be releasably coupled to the housing 2152 (e.g., via a threaded connection, snap-fit connection, etc.). In some embodiments, the filter 2156 can have a porosity of between about 50–200 microns.

[0140] The housing 2152 can include a port 2153 configured to be removably, fluidly coupled to the pressure source 340 via a tubing subsystem 2120. In the illustrated embodiment, the tubing subsystem 2120 includes tubing sections 2124 (individually labeled as a first tubing section 2124a and a second tubing section 2124b), a fluid control device 2126 (e.g., a valve, stop cock, clamp, etc.), and a connector 2128 (e.g., a large bore connector) for fluidly coupling the tubing subsystem 2120 to the pressure source 340. In the illustrated embodiment, the cap assembly 2160 includes a fluid connector 2162 (e.g., a standard Luer or large bore connector) configured to be connected to a receiving/reinfusion syringe 2170 via, for example, a tubing section 2164. In

some embodiments, the cap assembly 2160 can include a valve (e.g., a one-way valve, a check valve, etc.) that provides for one-way fluid flow through filter assembly 2150.

[0141] In operation, during a clot removal procedure, the pressure source 340 can be decoupled from the connector 128 (Figure 1) after an aspiration pass and when the pressure source 340 is full of blood and clot material. After connecting the filter device 2150 to the receiving syringe 2170, the pressure source 340 can be coupled to the filter device 2150. For example, Figure 21B is a perspective side view of the filter device 2150 coupled to (i) the pressure source 340 via the tubing subsystem 2120 and (ii) the reinfusion syringe 2170 via the tubing section 2164. More specifically, referring to Figures 21A and 21B together, the tip 347 of the pressure source 340 can be coupled to the connector 2128 of the tubing subsystem 2120, and a tip 2172 of the reinfusion syringe 2170 can be coupled to the tubing section 2164. In other embodiments, the filter device 2150 can be coupled to the pressure source 340 and/or the reinfusion syringe 2170 in other manners (e.g., directly such that the all or part of the tubing subsystem 120 is omitted). Alternatively, the filter device 2150 can be directly attached to the side port 108 (Figure 1), an IV line (not shown), or another suitable connection point for reintroducing blood to the patient,

[0142] After coupling the pressure source 340 to the filter device 2150, the fluid control device 2128 can be opened to fluidly connect the pressure source 340 to the filter device 2150. Then, the operator can depress the plunger 342 of the pressure source 340 to drive the blood and clot material from the pressure source 340 into and/or through the filter device 2150. The filter 2156 of the filter device 2150 filters the blood from the clot material such that the blood flows into the reinfusion syringe 2170 and the clot material remains in the chamber 2154 of the filter device 2150. For example, as shown in Figure 21B, blood B fills the reinfusion syringe 2170 and clot material PE remains within the chamber 2154 of the filter device 2150 after depressing the plunger 342 of the pressure source 340 in the direction indicated by the arrow H.

[0143] Next, the reinfusion syringe 2170 can be decoupled from the filter device 2150 so that the blood B can be reintroduced to the patient. For example, the reinfusion syringe 2170 could be directly coupled to a port on the fluid control device 126 (Figure 1). The cap assembly 2160 can be decoupled from the housing 2152 of the filter device 2150 to, for example, permit an

operator to remove the clot material PE collected in the housing 2152 and thereby clean and prepare the filter device 2150 for another use.

[0144] Figure 22 is a partially-exploded side view of a filter device 2250 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The filter device 2250 is configured for use with, for example, one or more of the pressure sources described in detail above with reference to Figures 2–7. In general, the filter device 2250 is generally similar to the filter device 2150 described in detail with reference to Figures 21A and 21B. For example, the filter device 2250 includes a housing 2252 defining a chamber 2254, a filter 2256 configured to be positioned within the housing 2252, and a cap assembly 2260 configured to be releasably coupled to the housing 2252. However, in the illustrated embodiment the filter device 2250 includes a port 2253 that is directly connected to a connector 2228 configured to be coupled to a pressure source (e.g., the pressure source 340 shown in Figures 3A–3D). The cap assembly 2260 includes a fluid connector 2162 (e.g., a standard Luer or large bore connector) configured to be connected to a reinfusion syringe, a sheath, an IV line, etc., (not shown). In some embodiments, the fluid connector 2262 is angled relative to the filter 2260 and/or the housing 2252. For example, the fluid connector 2262 is formed to have an approximately right angle in Figure 22. In one aspect of the present technology, this arrangement makes the filter device more ergonomic during use.

[0145] Figure 23 is a partially-exploded side view of a filter device 2350 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The filter device 2350 is configured for use with, for example, one or more of the pressure sources described in detail above with reference to Figures 2–7. The filter device 2350 is generally identical to the filter device 2250 described in detail with reference to Figure 22—including, for example, the housing 2252 ("a first housing 2252"), the filter 2256 ("a first filter 2256"), and the cap assembly 2260 including the fluid connector 2262 ("a first fluid connector 2262"). However, in the illustrated embodiment a second housing 2382 and a second filter 2386 are fluidly connected to the fluid connector 2262. The second housing 2382 includes a second fluid connector 2384 that can be fluidly connected to a reinfusion syringe, a sheath, an IV line, etc., (not shown). The second filter 2386 is configured to provide a second stage of filtration. For example, in some embodiments the first filter 2256 has a larger porosity than the second filter

2386. For example, the first filter 2256 can have a porosity of between about 50–200 microns and the second filter 2386 can have a porosity of between about 50–170 microns.

[0146] In general, one skilled in the art will understand that the various embodiments of filter devices disclosed herein may have different components or combinations of components. For example, the filter devices 2050, 2150, 2250, and/or 2350 ("the filter devices") could be utilized with any of several different pressure sources other than the syringe 340 (e.g., those shown in Figures 2 and 4–7). In some embodiments, the filter devices can be formed as a component of the tubing subsystem 120 (Figure 1). Moreover, the filter devices can include any number of filters and/or housings to provide any number of filtration stages.

Conclusion

[0147] 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.

[0148] 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.

[0149] 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.

ABSTRACT OF THE DISCLOSURE

Systems and methods for the intravascular treatment of clot material within a blood vessel of a human patient are disclosed herein. A method in accordance with embodiments of the present technology can include, for example, positioning a distal portion of a catheter proximate to the clot material within the blood vessel. The method can further include coupling a pressure source to the catheter via a tubing subsystem including a valve or other fluid control device and, while the valve is closed, activating the pressure source to charge a vacuum. The valve can then be opened to apply the vacuum to the catheter to thereby aspirate at least a portion of the clot material from the blood vessel and into the catheter.

CLAIMS

I/We claim:

1. An aspiration system with accelerated response, comprising:
an aspiration pump in communication with a first chamber;
an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;
a second chamber in between the aspiration pump and the catheter; and
a user-actuatable valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;
wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.
2. The aspiration system of claim 1 wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient.
3. The aspiration system of claim 2 wherein the aspiration catheter has a distal end portion configured to be positioned proximate to clot material within the blood vessel of the patient.
4. The aspiration system of claim 3 wherein the clot material comprises a pulmonary embolism.

5. The aspiration system of claim 3 wherein the clot material comprises a deep vein thrombus.
6. The aspiration system of claim 1, further comprising a coupled assembly including:
the second chamber;
the aspiration catheter; and
a hemostasis valve.
7. The aspiration system of claim 6 wherein the hemostasis valve is configured to receive a second catheter and direct the second catheter through the aspiration catheter.
8. The aspiration system of claim 7 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.
9. The aspiration system of claim 6 wherein the second chamber is removably carried by the assembly.
10. The aspiration system of claim 1 wherein the second chamber is removably coupled between the aspiration pump and the catheter.
11. The aspiration system of claim 1, further comprising a filter in the second chamber.
12. The aspiration system of claim 11 wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.

13. The aspiration system of claim 11 wherein the filter is removable from within the second chamber.

14. The aspiration system of claim 1 wherein the first chamber is fluidically coupled in serial to the second chamber.

15. An aspiration system with accelerated response, comprising:
an aspiration pump in communication with a first chamber;
an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;
a second chamber in between the aspiration pump and the catheter; and
a user-actuatable valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;
wherein upon user actuation to open the valve with negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid decrease in pressure in the aspiration catheter.

16. The aspiration system of claim 15 wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient, wherein the aspiration catheter has a distal end portion configured to be positioned proximate to clot material within the blood vessel of the patient, and wherein the clot material comprises a pulmonary embolism or a deep vein thrombus.

17. The aspiration system of claim 15, further comprising a coupled assembly including:
the second chamber;
the aspiration catheter; and

a hemostasis valve, wherein the hemostasis valve comprises:

- a tubular member defining a lumen configured to slidably receive a second catheter and direct the second catheter through the aspiration 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.

18. The aspiration system of claim 15 wherein the second chamber is removably coupled between the aspiration pump and the catheter.

19. The aspiration system of claim 15, further comprising a filter in the second chamber, wherein the filter is removable from within the second chamber.

20. The aspiration system of claim 15 wherein the first chamber is fluidically coupled in serial to the second chamber.



ELECTRONIC PAYMENT RECEIPT

APPLICATION #
18/180,016

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Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
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FIRST NAMED
INVENTOR Ben Merritt

Payment Information

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PAYMENT TRANSACTION ID
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PAYMENT AUTHORIZED BY
JiYoung Anderson

FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
1817	REQUEST FOR PRIORITIZED EXAMINATION	4200.00	1	4200.00
1111	UTILITY PATENT APPL. SEARCH FEE	700.00	1	700.00
1011	BASIC FILING FEE - UTILITY (PAPER FILING ALSO REQUIRES NON-ELECTRONIC FILING FEE UNDER 1.16(T))	320.00	1	320.00
1311	PATENT APPL. EXAMINATION FEE	800.00	1	800.00
1830	PROCESSING FEE, EXCEPT IN PROVISIONAL APPLICATIONS	140.00	1	140.00

TOTAL	\$6,160.00
AMOUNT:	

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

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

New International Application Filed with the USPTO as a Receiving Office

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

**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 ☐ The attached application, or
is directed to:

☒ United States application or PCT international application number 16/536,185
filed on August 8, 2019

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

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

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

I hereby state that I have reviewed and understand the contents of the above identified application, including the claims,
as amended by any amendment.

I acknowledge the duty to disclose information material to patentability as defined in 37 C.F.R. 1.56 including for
continuation-in-part applications, material information which became available between the filing date of the prior
application and the national or PCT international filing date of the continuation-in-part application.

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LEGAL NAME OF INVENTOR

Inventor: Thomas Tu

Date: Mar 23, 2020

Signature: 

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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 ☐ The attached application, or
is directed to:

☒ United States application or PCT international application number 16/536,185
filed on August 8, 2019.

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

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

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

I hereby state that I have reviewed and understand the contents of the above identified application, including the claims, as amended by any amendment.

I acknowledge the duty to disclose information material to patentability as defined in 37 C.F.R. 1.56 including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

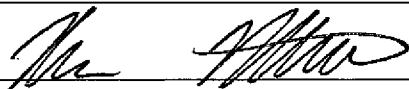
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LEGAL NAME OF INVENTOR

Inventor: Ben Merritt

Date: 2/5/2020

Signature: 

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LEGAL NAME OF INVENTOR

Inventor: Jacqueline Macias

Date: 02/06/2020

Signature: Jacqueline Macias

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**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
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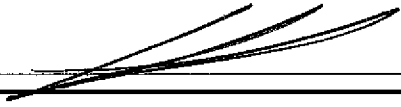
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LEGAL NAME OF INVENTOR

Inventor: Brian Michael Strauss

Date: 06 Feb 2020

Signature: 

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SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. Patent Application No. 18/167,757, filed February 10, 2023, which is a continuation of U.S. Patent Application No. 17/976,711, filed October 28, 2022, which is a continuation of U.S. Patent Application No. 17/865,315, filed July 14, 2022, which is a continuation of U.S. Patent Application No. 16/536,185, filed August 8, 2019, and issued as U.S. Patent No. 11,559,382, which claims the benefit of U.S. Provisional Patent Application No. 62/718,269, filed on August 13, 2018, and U.S. Provisional Patent Application No. 62/718,248, filed on August 13, 2018, each of which is herein incorporated by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology relates generally to systems, methods, and devices for the intravascular treatment of emboli and/or thrombi within a blood vessel of a human patient. In particular, some embodiments of the present technology relate to systems for releasing stored vacuum pressure to aspirate clot material from a blood vessel.

BACKGROUND

[0003] Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

[0004] When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. However, infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can accordingly lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

[0005] In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT commonly occurs where there is a propensity for stagnated blood (e.g., long distance air travel, immobility, 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 (stroke), abdominal organs, and/or extremities.

[0006] In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs, and therefore the entire body. This can result in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting in low blood oxygen and buildup of blood carbon dioxide.

[0007] There are many existing techniques to reestablish blood flow through an occluded vessel. Embolectomies, for example, are a surgical technique involving incising a blood vessel and placing a balloon-tipped device (such as the Fogarty catheter) at the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to withdraw the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Although such surgical techniques have been useful, exposing a patient to surgery may be traumatic and best avoided when possible. Additionally, the use of a Fogarty catheter may be problematic due to the possible risk of damaging the interior lining of the vessel as the catheter is being withdrawn.

[0008] Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating vessel stenosis, but it is generally not effective for treating acute thromboembolisms as none of the occlusive material is removed and restenosis regularly

occurs after dilation. Another percutaneous technique involves placing a catheter near the clot and infusing streptokinase, urokinase, or other thrombolytic agents to dissolve the clot. Unfortunately, thrombolysis typically takes hours to days to be successful. Additionally, thrombolytic agents can cause hemorrhage, and in many patients the thrombolytic agents cannot be used at all.

[0009] Various devices exist for performing a thrombectomy or removing other foreign material. However, such devices have been found to have structures which are either highly complex, cause trauma to the treatment vessel, or lack the ability to be appropriately fixed against the vessel. Furthermore, many of the devices have highly complex structures that lead to manufacturing and quality control difficulties as well as delivery issues when passing through tortuous or small diameter catheters. Less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all of the clot material.

[0010] Thus, there exists a need for improved systems and methods for embolic extraction.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0012] Figure 1 is a partially schematic side view of a clot removal system configured in accordance with the present technology.

[0013] Figure 2 is a side view of a locking syringe configured in accordance with the present technology.

[0014] Figure 3A is a side view of a locking syringe configured in accordance with the present technology.

[0015] Figure 3B is a side view of an adaptor for connecting the locking syringe of Figure 3A to the clot removal system of Figure 1 configured in accordance with the present technology.

[0016] Figure 3C is a side view of the adaptor of Figure 3B coupled to the locking syringe of Figure 3A.

[0017] Figure 3D is a side view of the locking syringe of Figure 3A coupled to the clot removal system of Figure 1 via the adaptor of Figure 3B.

[0018] Figure 4A is a perspective side view of another pressure source configured in accordance with the present technology, and Figures 4B and 4C are enlarged schematic side views of the pressure source of Figure 4A during operation.

[0019] Figure 5 is a cross-sectional side view of an automatic release syringe configured in accordance with the present technology.

[0020] Figure 6 is a perspective top view of a syringe configured in accordance with the present technology.

[0021] Figure 7 is a side view of an over-wire locking syringe configured in accordance with the present technology.

[0022] Figure 8 is a flow diagram of a process or method for operating a clot removal system in accordance with the present technology.

[0023] Figures 9A–9C are side views of a proximal portion of the clot removal system of Figure 1 during a clot removal procedure using the locking syringe of Figure 3 in accordance with the present technology.

[0024] Figures 10A and 10B are schematic illustrations of a distal portion of the clot removal system of Figure 1 during a clot removal procedure in accordance with the present technology.

[0025] Figure 11 is a partially schematic side view of another clot removal system configured in accordance with the present technology.

[0026] Figure 12 is a flow diagram of another process or method for operating a clot removal system in accordance with the present technology.

[0027] Figures 13A–14C are schematic illustrations of a distal portion of the clot removal system of Figure 11 during a clot removal procedure in accordance with the present technology.

[0028] Figure 15 is a flow diagram of another process or method for operating a clot removal system in accordance with the present technology.

[0029] Figures 16A–16E are schematic illustrations of a distal portion of the clot removal system of Figure 11 during a clot removal procedure in accordance with the present technology.

[0030] Figure 17 is a partially schematic side view of another clot removal system configured in accordance with the present technology.

[0031] Figures 18A–18H are side views of a distal portion of the clot removal system shown of Figure 17 during a clot removal procedure in accordance with the present technology.

[0032] Figure 19 is a perspective side view of a pressure source for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology.

[0033] Figure 20A is a partially-exploded side view of a filter device and pressure source configured in accordance with the present technology.

[0034] Figure 20B is a perspective side view of the syringe of Figure 20A coupled to the filter device of the Figure 20A.

[0035] Figure 20C is a side view of the filter device and syringe of Figure 20B coupled to the clot removal system of Figure 1.

[0036] Figures 20D and 20E are side views of the syringe of Figure 20A coupled to the clot removal system of Figure 1 for reintroducing blood to a patient.

[0037] Figure 21A is a partially-exploded side view of a filter device, a pressure source, and a reinfusion syringe configured in accordance with the present technology.

[0038] Figure 21B is a perspective side view of the filter device of Figure 21A coupled to the pressure source and the reinfusion syringe of Figure 21A.

[0039] Figure 22 is a partially-exploded side view of a filter device configured in accordance with the present technology.

[0040] Figure 23 is a partially-exploded side view of a filter device configured in accordance with the present technology.

[0041] Figure 24 is an enlarged isometric view of the clot removal system of Figure 1 configured in accordance with the present technology.

[0042] Figure 25 is an enlarged isometric view of the clot removal system of Figure 1 configured in accordance with the present technology.

DETAILED DESCRIPTION

[0043] The present technology is generally directed to methods and systems for removing clot material from a blood vessel of a human patient. In some embodiments, a catheter can be intravascularly positioned within a blood vessel such that a distal portion (e.g., a distal opening) of the catheter is positioned proximate to clot material within the blood vessel. The catheter can be fluidly coupled to a pressure source via a valve or other fluid control device positioned outside of the patient. With the valve closed, the pressure source can be activated to charge a vacuum chamber of the pressure source with a vacuum. The valve can then be opened to apply the vacuum to the catheter to thereby aspirate at least a portion of the clot material from the blood vessel into the catheter. In some embodiments, an interventional device can be delivered through the catheter and used to engage the clot material before and/or after the vacuum is applied to the catheter.

[0044] In one aspect of the present technology, the pressure source is configured to generate a vacuum and store the vacuum before the pressure source is fluidly connected to the catheter. Therefore, opening the fluid control device can instantaneously or nearly instantaneously apply the stored vacuum pressure to the catheter, thereby generating suction throughout the catheter. In particular, the suction is applied at the distal portion of the catheter proximate to the clot material. Pre-charging or storing the vacuum before applying the vacuum to the catheter can generate greater suction forces (and corresponding fluid flow velocities) at and/or near the distal portion of the catheter compared to, for example, simply activating the pressure source while it is fluidly connected to the catheter. The greater suction forces generated by application of the stored vacuum can be used to aspirate or otherwise remove clot material from within a blood vessel of a human patient.

[0045] Although many of the embodiments are described below with respect to devices, systems, and methods for treating a pulmonary embolism, other applications and other embodiments in addition to those described herein are within the scope of the technology (e.g., intravascular procedures other than the treatment of emboli, intravascular procedures for treating cerebral embolism, intravascular procedures for treating deep vein thrombosis (DVT), etc.).

Additionally, several other embodiments of the technology can have different configurations, states, components, or procedures than those described herein. Moreover, it will be appreciated that specific elements, substructures, advantages, uses, and/or other features of the embodiments described with reference to Figures 1–25 can be suitably interchanged, substituted or otherwise configured with one another in accordance with additional embodiments of the present technology. Furthermore, suitable elements of the embodiments described with reference to Figures 1–25 can be used as standalone and/or self-contained devices. A person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described below with reference to Figures 1–25.

[0046] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," etc. are not meant to limit the referenced component to use in a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

[0047] The headings provided herein are for convenience only and should not be construed as limiting the subject matter disclosed.

I. Selected Embodiments of Clot Removal Systems

[0048] 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 an embodiment of the present technology. In the illustrated embodiment, the assembly 10 includes a catheter subsystem 100, a tubing subsystem 120, and a pressure source 140. 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 subsystem 100 further includes a valve 106 that can be integral with or coupled to the proximal portion 103b of the catheter 102.

[0049] 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. The valve 106 further includes a flow controller (obscured in Figure 1) in the lumen 109. In some embodiments, the valve is a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in the proximal direction through the valve 106 as various components such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters (e.g., as described in detail with reference to Figures 11–16E), 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 a branch or side port 108 positioned distally of the flow controller in the lumen 109 and 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 retraction/aspiration device for aspirating the lumen 104 of the catheter 102 and/or for retracting an interventional device, catheter, delivery sheath, catheter, etc., positioned within the lumen 104. Specific details of such retraction/aspiration devices and associated methods are disclosed in U.S. Patent Application No. 9,526,864, filed June 9, 2015, and titled "RETRACTION AND ASPIRATION DEVICE FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

[0050] The tubing subsystem 120 fluidly couples the catheter subsystem 100 to the pressure source 140. 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 140 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 some embodiments, the fluid control device 126 can define a lumen having a diameter (or other cross-sectional dimension) that is greater than or equal to a diameter of the lumen 104 of the catheter 102, a diameter of the first tubing section 124a, and/or a diameter of the second tubing section 124b.

[0051] 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 140. 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 tubing section 124a and/or the tubing section 124b. In yet other embodiments, the fluid control device 126 can be omitted and its functionality incorporated into the pressure source 140 (e.g., as described in detail below with reference to Figure 5). In some embodiments, the fluid control device 126 can include a quick-release mechanism (e.g., a spring-loaded apparatus) for rapidly opening, unclamping, etc., the fluid control device 126 to (e.g., instantaneously or nearly instantaneously) fluidly connect the pressure source 140 and the catheter 102. In some embodiments, the fluid control device 126 can be opened/closed automatically (e.g., by a motor, switch, etc.). When the pressure source 140 is pre-charged with a vacuum, as described in detail below, such a quick-release fluid control device 126 can reduce the time needed for pressure in the assembly 10 to equalize after opening of the fluid control device 126, and can thereby increase suction forces generated at the distal portion 103a of the catheter 102.

[0052] In some embodiments, the connector 128 is a quick-release connector (e.g., a quick disconnect fitting) that enables rapid coupling/decoupling of the catheter 102 and the fluid control device 126 to/from the pressure source 140. In other embodiments, the tubing subsystem 120 can have more or fewer tubing sections, connectors, and/or fluid control devices, and can have other suitable configurations. In some embodiments, one or more of the components can be permanently connected and/or integrally formed.

[0053] The pressure source 140 is configured to generate (e.g., form, create, charge, build-up, etc.) 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 2–7. During operation of the assembly 10, a

user can first close the fluid control device 126 before activating the pressure source 140 to build up vacuum pressure within the pressure source 140 (e.g., a vacuum chamber of the pressure source 140). 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 140 before the pressure source 140 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 140 to the catheter subsystem 100 and thereby apply or release the vacuum stored in the pressure source 140 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 140 while it is fluidly connected to the catheter 102. As described in detail below, the suction forces generated by application of the stored vacuum can be used to aspirate or otherwise remove clot material from within a blood vessel of a human patient.

II. Selected Embodiments of Pressure Sources for Use with Clot Removal Systems

[0054] As described in detail above with reference to Figure 1, the assembly 10 of the present technology includes a pressure source (e.g., a vacuum source, negative pressure source, etc.) configured to charge a vacuum that can be applied to the catheter subsystem 100 to generate suction forces for aspirating clot material from within a blood vessel. In general, the pressure source can be any suitable source or combination of sources for generating and/or storing negative pressure. In some embodiments, the pressure source can be a pump (e.g., an electric pump coupled to a vacuum chamber) while, in other embodiments, the pressure source can include one or more syringes that can be actuated or otherwise activated by a user of the assembly 10 to generate and store a vacuum therein.

[0055] Figure 2 is a side view of a pressure source 240 comprising a vacuum-pressure locking syringe ("syringe 240") configured in accordance with the present technology. In some

embodiments, the syringe 240 can be of the kind sold under the trademark "VacLok" by Merit Medical System, Inc. In the illustrated embodiment, the syringe 240 includes a plunger 242 slidably and rotatably positioned within a chamber or barrel 244. The barrel 244 is shown as transparent in Figure 2 for the sake of clarity. The plunger 242 includes a seal 243 and a plurality of index members 246 defining slots 248 between adjacent pairs thereof. A tab member 245 projects inwardly from the interior surface of the barrel 244 and is configured to be removably positioned in the slots 248 for locking the plunger 242 in position relative to the barrel 244. In some embodiments, the barrel 244 can be made of a transparent material that permits a user to visualize material (e.g., clot material) within the barrel 244 and to visualize the relative position between the slots 248 and tab member 245 for locking the syringe 240.

[0056] Referring to both Figures 1 and 2 together, the syringe 240 further includes a tip 247 for coupling the syringe 240 to the tubing subsystem 120. In the illustrated embodiment, the tip 247 is a standard luer connector that can be coupled to the connector 128 via one or more suitable adaptors. The tip 247 further defines a lumen or bore 249 having an inner diameter D_1 . In some embodiments, the diameter D_1 is about 0.103", or about 0.080" to about 0.200", or about 0.100" to about 0.150", or about 0.100" to about 0.110". In some embodiments, the inner diameter D_1 is about 14 French.

[0057] During operation of the assembly 10, a user can first close the fluid control device 126 and then grip the plunger 242 and/or the barrel 244 to withdraw (e.g., retract) the plunger 242 at least partially out of the barrel 244 to thereby generate a vacuum in the barrel 244. Once the user has withdrawn the plunger 242 to a sufficient or desired volume, the user can lock the plunger 242 by rotating the plunger 242 relative to the barrel 244 such that the tab member 245 is positioned within a corresponding one of the slots 248. In other embodiments, the syringe 240 may not be a locking syringe, and the user can instead hold the plunger 242 in position relative to the barrel 244. Moreover, the user can control the volume of the vacuum—by withdrawing the plunger 242 more or less—to provide a desired amount or level of suction/aspiration upon opening of the fluid control device 126. In some embodiments, the syringe has a volume of about 60 cc or less than about 60 cc.

[0058] Figure 3A is a side view of a pressure source 340 comprising a vacuum-pressure locking syringe ("syringe 340") configured in accordance with the present technology. The syringe 340 can have some features generally similar to the features of the syringe 240 described above with reference to Figure 2. For example, the syringe 340 includes a plunger 342 slidably and rotatably positioned within a barrel 344, and the plunger 342 includes a plurality of index members 346 defining slots 348 between adjacent pairs thereof. The barrel 344 is shown as transparent in Figure 3A (and Figure 3C) for the sake of clarity. While withdrawing the plunger 342, a user can lock the plunger 342 at a specified volume by rotating the plunger 342 relative to the barrel 344 such that a tab member 345 on the interior surface of the barrel 344 is positioned within a corresponding one of the slots 348. In some embodiments, the syringe 340 has a maximum volume of about 60 cc or greater than 60 cc.

[0059] In the illustrated embodiment, the syringe 340 includes a large-bore tip 347, such as a Toomey tip, defining an inner lumen or bore 349. In some embodiments, the bore 349 can have an inner diameter D_2 that is greater than or equal to the largest inner diameter of the assembly 10 (e.g., of the catheter 102 and tubing subsystem 120). In certain embodiments, the tip 347 can be about 26 French or greater. Accordingly, referring to Figures 2 and 3A together, the diameter D_2 can be greater than the dimension D_1 . For example, the dimension D_2 can be about two, three, four, or more times greater than the diameter D_1 .

[0060] Figure 3B is a side view of an adaptor 350 for connecting the syringe 340 to the catheter subsystem 100 configured in accordance with the present technology. Figure 3C is a side view of the adaptor 350 coupled to the syringe 340, and Figure 3D is a side view of the syringe 340 coupled to the tubing subsystem 120 via the adaptor 350. The adaptor 350 is shown as partially transparent in Figure 3C for the sake of illustration. Referring to Figure 3B, the adaptor 350 includes (i) a first portion 351 defining a first lumen or bore 352 having an inner diameter D_3 , (ii) a second portion 353 defining a second lumen or bore 354, and (iii) a stepped surface or interface 355 between the first and second portions 351, 353. The first portion 351 can further include a seal 357 such as an O-Ring around an exterior surface thereof.

[0061] Referring to Figures 3A–3D together, the second bore 354 of the adaptor 350 is configured to removably receive the tip 347 of the syringe 340 therein. In some embodiments, the

tip 347 can be snugly received in the second bore 354 via an interference fit. In some embodiments, a seal (e.g., an O-ring) can be positioned between an exterior surface of the tip 347 and an interior surface of the second bore 354. In other embodiments, the syringe 340 can be permanently coupled or integrally formed with the adaptor 350. The first portion 351 of the adaptor 350 is configured to be removably positioned within the connector 128 of the tubing subsystem 120 to fluidly couple the syringe 340 to the tubing subsystem 120. In some embodiments, the first portion 351 of the adaptor 350 can be pushed into the connector 128 until the interface 355 abuts the connector 128. When the first portion 351 of the adaptor 350 is positioned within the connector 128, the seal 357 seals the interface between the connector 128 and the adaptor 350.

[0062] The diameter D_3 of the first bore 352 of the adaptor 350 can be selected to be about the same as or greater than the greatest inner diameter of the assembly 10 (e.g., of the catheter 102 and the tubing subsystem 120). For example, the catheter 102 can be about 9 French or greater, and the diameter D_3 can be selected to be larger than the size of the catheter 102. Accordingly, when the fluid control device 126 is open, the continuous lumen between the catheter 102 and the syringe 340 can have a generally constant diameter and/or does not contain any narrowing at the interface between the syringe 340 and the tubing subsystem 120. That is, the adaptor 350 can connect the syringe 340 and the tubing subsystem 120 without any restriction or narrowing of the fluid path. In contrast, a standard luer connector (e.g., the syringe 240) can only provide a continuous lumen for catheters of about 8 French or smaller. Any narrowing of the fluid pathway between the catheter 102 and the syringe 340 can reduce the volumetric flow rate (e.g., suction forces and fluid velocities) that can be generated when a vacuum stored in the syringe 340 is applied to the catheter 102.

[0063] In general, the syringe 340 and the adaptor 350 can reduce the fluid resistance in the assembly 10 and therefore facilitate a more rapid pressure equalization in the assembly 10 when the fluid control device 126 is opened to apply the charged vacuum to the catheter 102. In some embodiments, for example, when the syringe 240 (Figure 2) is charged with a 60 cc vacuum and the fluid control device 126 is opened, the pressure in the assembly 10 can take about 1–2 seconds to equalize. In contrast, when the syringe 340 is charged with a 60 cc vacuum and the fluid control device 126 is opened, the pressure in the assembly 10 can take less than about 1 second (e.g.,

about 0.5 seconds) to equalize. More specifically, Table 1 illustrates representative pressure equalization times and associated flow rates when the syringe 240 is coupled to a 20 French catheter (i.e., the catheter 102). Table 2 illustrates representative pressure equalization times and associated flow rates when the syringe 340 and the adaptor 350 are coupled to a 20 French catheter (i.e., the catheter 102).

Table 1

<u>Pressure Equalization Time (seconds)</u>	<u>Flow Rate (cc/sec)</u>
2.0	30.0
1.9	31.6
1.8	33.3
1.7	35.3
1.6	37.5
1.5	40.0
1.4	42.9
1.3	46.2

Table 2

<u>Pressure Equalization Time (seconds)</u>	<u>Flow Rate (cc/sec)</u>
0.9	66.7
0.8	75.0
0.7	85.7
0.6	100.0
0.5	120.0
0.4	150.0
0.3	200.0

0.2	300.0
0.1	600.0

[0064] In each instance, the syringe 340 provides for relatively faster equalization times and correspondingly greater flow rates. It is expected that the more rapid pressure equalization and flow rates provided by the syringe 340 will provide correspondingly greater suction forces at the distal portion 103a of the catheter 102. That is, in general, it is expected that increasing the bore size of a syringe used to provide vacuum pressure will provide greater suction forces over a smaller period of time (e.g., will provide a larger vacuum impulse). In some embodiments, the greater suction forces can facilitate the removal of clot material from a blood vessel of a patient even where the clot material is strongly lodged or attached within the blood vessel (e.g., a chronic clot).

[0065] Moreover, as shown in Figure 3D, the adaptor 350 can couple the syringe 340 to the connector 128 without the need for any intervening tubing sections or additional adaptors. This arrangement can minimize the total length, volume, etc., of the components fluidly coupling the catheter 102 to the syringe 340. It is expected that the magnitude of suction forces generated at the distal portion 103a of the catheter 102—e.g., when a vacuum charged in the syringe 340 is applied to the catheter 102 by opening of the fluid control device 126—is proportional to the length of the fluid path between the pressure source 340 and catheter 102. Thus, operation of the assembly 10 with the syringe 340 and adaptor 350 is expected to increase the suction forces generated at the distal portion 103a of the catheter 102. In some embodiments, the greater suction forces can facilitate the removal of clot material from a blood vessel of a patient even where the clot material is strongly lodged or attached within the blood vessel (e.g., a chronic clot).

[0066] Figure 4A is a side perspective view a pressure source 400 including the syringe 340 ("primary syringe 340") shown in Figures 3A–3D and a secondary syringe 460 configured in accordance with the present technology. The secondary syringe 460 can include a plunger 462 slidably positioned within a chamber or barrel 464. The primary and secondary syringes 340, 460 can have the same volume or different volumes. In the illustrated embodiment, a tip 463 of the secondary syringe 460 is coupled to a first one-way valve (e.g., a check valve) 470 via a coupling

member 465, such as a tube. The first one-way valve 470 is configured to fluidly connect the secondary syringe 460 to the ambient environment or another device coupled to the first one-way valve 470. A second one-way valve (e.g., a check valve) 472 spans between and is configured to fluidly connect the primary syringe 340 to the secondary syringe 460. More specially, in the illustrated embodiment the second one-way valve 472 is connected between the first portion 351 of the adaptor 350 and the coupling member 465. In other embodiments, the second one-way valve 472 can couple the primary and secondary syringes 340, 460 in different manners. For example, the second one-way valve 472 can span between and directly connect the barrels 344, 464. The primary and secondary syringes 340, 460 can be coupled or fastened together via one or more connectors 474 that fix the positions of the barrel 344, 464 relative to one another.

[0067] In some embodiments, the second one-way valve 472 is a normally-open check valve configured to (i) permit fluid (e.g., air) flow from the primary syringe 340 and the adaptor 350 to the secondary syringe 460 and (ii) inhibit fluid flow in the opposite direction from the secondary syringe 460 into the primary syringe 340. In some embodiments, the second one-way valve 472 has a cracking (e.g., opening) pressure of about 0 psi. In one aspect of the present technology, this arrangement maximizes the magnitude of the vacuum that can be charged within the primary syringe 340. That is, the cracking pressure of the second one-way valve 472 does not reduce the effective vacuum within the primary syringe 340. In other embodiments a normally-closed or other type of valve could be used for the second one-way valve 472. However, in such embodiments the vacuum efficiency of the pressure source 400 would be reduced by the cracking pressure of the second one-way valve 472. Similarly, the first one-way valve 470 can be a check valve configured to (i) permit fluid flow from the secondary syringe 460 to the ambient environment (or other device) and (ii) inhibit fluid flow in the opposite direction from the ambient environment into the secondary syringe 460.

[0068] Figures 4B and 4C are enlarged schematic side views of the pressure source 400 during operation. More specifically, Figures 4B and 4C illustrate fluid flow paths through the first and second one-way valves 470, 472 during retraction and advancement, respectively, of the plunger 462 through the barrel 464 of the secondary syringe 460. Referring first to Figures 4A and 4B together, during retraction/withdrawal of the plunger 462, (i) the first one-way valve 470 is closed to inhibit fluid from flowing into the secondary syringe 460 while (ii) the second one-

way valve is open 472 to permit fluid to flow from the primary syringe 340, the catheter subsystem 100 (Figure 1), and/or the tubing subsystem 120 (Figure 1) into the secondary syringe 460. This flow path is indicated by the arrows R in Figure 4B. Referring to Figures 4A and 4C together, during advancement of the plunger 462, (i) the first one-way valve 470 is open to permit fluid flow (e.g., fluid expulsion) from the secondary syringe 460 to the ambient environment (or other device) while (ii) the second one-way valve 472 is closed to inhibit fluid flow from the secondary syringe 460 into (e.g., back into) the primary syringe 360, the catheter subsystem 100, and/or the tubing subsystem 120. This flow path is indicated by the arrows A in Figure 4C.

[0069] Referring to Figures 1 and 3A–4C together, the pressure source 400 can be coupled to the tubing subsystem 120 by coupling the primary syringe 340 to the connector 128 (e.g., as shown in Figure 3D). When the pressure source is coupled to the tubing subsystem 120, retraction of the plunger 462 of the secondary syringe 460 evacuates an evacuable volume of the assembly 10. For example, when the fluid control device 126 is closed, retraction of the plunger 462 of the secondary syringe 460 evacuates fluid, through the second one-way valve 472, from (i) the primary syringe 340 (e.g., from the barrel 344, the tip 347, and/or the adaptor 350) and (ii) the portion of the tubing subsystem 120 between the fluid control device 126 and the primary syringe 340. This can enable a greater charged/stored vacuum to be generated for subsequent application to the catheter subsystem 100 for aspirating clot material. In some embodiments, the plunger 462 of the secondary syringe 460 can be withdrawn/advanced (e.g., "cycled") one or more times before withdrawing the plunger 342 of the primary syringe 340 to evacuate air from (i) the tip 347 of the primary syringe 340 and/or (ii) the portion of the tubing subsystem 120 between the fluid control device 126 and the tip 347. In other embodiments, the plunger 462 of the secondary syringe 460 can alternatively or additionally be withdrawn after withdrawing the plunger 342 of the primary syringe 340 to further evacuate the barrel 344 of the primary syringe 340. In some embodiments, the plunger 462 can be cycled when the fluid control device 126 is open to, for example, facilitate the removal of clot material stuck or clogged within the catheter subsystem 100. That is, cycling the secondary syringe 460 when the fluid control device 126 is open can generate vacuum pressure and suction in the catheter 102 to aid in the aspiration/removal of clot material.

[0070] In some embodiments, the volumes of the primary and secondary syringes 340, 460 can be selected based on one or more desired characteristics of a clot removal procedure using the

pressure source 400. For example, the secondary syringe 460 can have a larger volume than the primary syringe 340 to permit a high vacuum to be charged within the primary syringe 340 while also limiting blood loss from the patient.

[0071] In one aspect of the present technology, the pressure source 340 permits a greater vacuum to be generated without increasing the volume of the primary syringe 340. For example, the vacuum generated by the primary syringe 340 alone is directly proportional to the volume of the primary syringe 340. Thus, to generate a greater vacuum using the primary syringe 340 alone, the volume of the primary syringe 340 must be increased. In contrast, inclusion of the secondary syringe 460 in the pressure source 400 and the configuration of the first and second one-way valves 470, 472 allows the (e.g., maximum) generated vacuum to be independent of the volume of the primary syringe 340. Therefore, for example, the generated vacuum can be increased without correspondingly increasing the volume of blood withdrawn from the patient when applying the vacuum to the catheter subsystem 100.

[0072] In some embodiments, (e.g., as described in greater detail below with reference to Figure 19), the primary syringe 340 of the pressure source 400 can be replaced with a simple pressure vessel or other volume, such as a canister, barrel, tube, etc. In such embodiments, a vacuum can be generated in the canister simply by cycling the secondary syringe 460 one or more times. In some embodiments, the secondary syringe 460 can comprise a pump or vacuum source other than a syringe. Likewise, the secondary syringe 460 or other vacuum source can be fluidly coupled to the primary syringe 340 in other manners (e.g., via a different arrangement of check valves) to produce the same or similar flow patterns as shown in Figures 4B and 4C. Moreover, in some embodiments the first and second one-way valves 470, 472 can be other types of flow control devices that are mechanically activated/deactivated (e.g., opened and closed) rather than passively operated via pressure differentials within the pressure source 400. For example, the flow control devices 470, 472 can be mechanically coupled to the plunger 462 of the secondary syringe 460 such that cycling the plunger 462 activates/deactivates the flow control devices 470, 472 to operate the pressure source 400 in the manner illustrated in Figures 4B and 4C.

[0073] Figure 5 is a side cross-sectional view of a pressure source 540 comprising an automatic release syringe ("syringe 540") configured in accordance with the present technology.

In general, the syringe 540 is configured to automatically apply a charged vacuum of a selected volume to the catheter subsystem 100 without requiring the actuation of an intervening fluid control device, such as the fluid control device 126 shown in Figure 1. The syringe 540 can have some features generally similar to the features of the syringes 240, 340 described in detail above with reference to Figures 2 and 3A–3D. For example, the syringe 540 includes a first plunger 542 slidably positioned within a chamber or barrel 544. The first plunger 542 further includes a first seal 543 that engages an interior surface of the barrel 544 such that a vacuum is formed within the barrel 544 as the first plunger 542 is withdrawn through the barrel 544. Likewise, referring to both Figures 1 and 5 together, the syringe 540 includes a tip 547 (e.g., a Toomey tip) for coupling the syringe 540 to the tubing subsystem 120 (e.g., via a Toomey tip adaptor) and defining a bore 549. In some embodiments, the bore 549 has a relatively large diameter selected to provide rapid pressure equalization in the assembly 10 after a vacuum stored in the syringe 540 is released.

[0074] The first plunger 542 can further include (i) a grip portion 541 configured to be engaged by a user for retracting the first plunger 542 and (ii) a lumen 581 extending lengthwise therethrough. In the illustrated embodiment, a plunger assembly 582 is slidably positioned within and extends through the lumen 581 of the first plunger 542. The plunger assembly 582 includes (i) a second plunger 583 and (ii) a release member 584 slidably and/or rotatably positioned within a lumen 585 of the second plunger 583. The release member 584 includes an engagement member 586 configured to engage the grip portion 541 of the first plunger 542 when the first plunger 542 is withdrawn from the barrel 544. The second plunger 583 includes a second seal 587 configured to engage and seal an interior surface of the bore 549 of the syringe 540 to enable a vacuum to be formed in the barrel 544 as the first plunger 542 is withdrawn through the barrel 544. That is, the second seal 587 can seal (e.g., fluidly disconnect) the barrel 544 of the syringe from the tubing subsystem 120 and the catheter subsystem 100. In some embodiments, the syringe 540 can further include an O-ring 579 or other suitable component for sealing an interface between the first and second plungers 542, 582 to maintain the vacuum formed within the barrel 544, while also permitting the first plunger 542 to move (e.g., translate) relative to the second plunger 583.

[0075] The plunger assembly 582 further includes a locking mechanism (not shown) configured to permit/inhibit the release member 584 from moving longitudinally relative to the second plunger 583. In some embodiments, for example, rotation of the release member 584 in a

first direction relative to the second plunger 583 can lock the two components in position, while rotation of the release member 584 in a second direction relative to the second plunger 583 can unlock the two components so that the release member 584 can be withdrawn or pushed into the lumen 585 of the second plunger 583. In other embodiments, the release member 584 and the second plunger 583 can be integrally formed or permanently locked together.

[0076] The plunger assembly 582 enables (i) a user of the syringe 540 to select a desired volume for a vacuum to be formed in the syringe 540 and (ii) the automatic release or application of a generated vacuum via opening (e.g., unplugging) of the bore 549. Specifically, during operation of the syringe 540, a user can first unlock the release member 584 and slide the release member 584 to a position corresponding to a desired vacuum volume. For example, the release member 584 can have tick marks 588 or other indicia along its length that correspond to a volume of the syringe 540 (e.g., a vacuum chamber volume). After selecting a desired volume, the user can lock the release member 584 relative to the second plunger 583 (e.g., by rotating the release member 584) to inhibit relative movement of the two components. After locking the release member 584, the user can grasp the grip portion 541 to retract the first plunger 542 relative to the barrel 544 and the plunger assembly 582 to generate a vacuum within the barrel 544 between the first and second seals 543, 587. When the first plunger 542 has been retracted to the desired volume, the grip portion 541 engages the engagement member 586 of the release member 584 such that further retraction of the first plunger 542 simultaneously retracts the plunger assembly 582. As the plunger assembly 582 is retracted, the second seal 587 of the second plunger 583 is pulled out of the bore 549, thereby releasing the vacuum stored in the barrel 544. In this manner, the syringe 540 provides for the automatic release of charged vacuum pressure at a specified volume and with a single retraction of the first plunger 542. Put differently, the syringe 540 has a built-in fluid control device and thus eliminates the need for a separate fluid control device 126 and/or an additional step for opening the fluid control device 126.

[0077] Figure 6 is a top perspective view of a pressure source 640 comprising a syringe ("syringe 640") configured in accordance with the present technology. The syringe 640 can include some features generally similar to the features of the syringes 240, 340, and 540 described in detail above with reference to Figures 2–3D and 5. For example, the syringe 640 includes a plunger 642 slidably positioned within a barrel 644, and a tip 647 (e.g., a large-bore tip). In the

illustrated embodiment, the syringe 640 further includes a lever or handle 690 operably coupled to the plunger 642. The handle 690 provides mechanical leverage for withdrawing the plunger 642 to create a vacuum within the barrel 644. More specifically, the handle 690 can be coupled to a crossbar 691 that rotates relative to the plunger 642 via actuation (e.g., rotation) of the handle 690. The crossbar 691 can be coupled to a gear (obscured in Figure 6) configured to engage a track 692 on the plunger 642. Accordingly, rotation of the handle 690 in a first direction retracts the plunger 642 relative to the barrel 644 to charge a vacuum in the barrel 644. And, rotation of the handle 690 in a second (e.g., opposite) direction advances the plunger 642 into the barrel 644 to, for example, expel fluid, material, etc., from the barrel 644.

[0078] In one aspect of the present technology, the handle 690 provides additional mechanical leverage relative to a standard syringe, and can thus reduce the force (e.g., strain, energy, etc.) required by a user of the syringe 640 to form a vacuum in the syringe 640. Therefore, use of the syringe 640 can reduce the time needed to remove clot material with the assembly 10. In some embodiments, the syringe 640 can have a volume greater than 60 cc (e.g., greater than 80 cc, greater than 100 cc, greater than 120 cc, greater than 140 cc, etc.). In a particular embodiment, for example, the syringe 640 can have a volume of about 140 cc. With such large volumes, it may be difficult for some users to manually retract the plunger 642 without the additional mechanical leverage provided by the handle 690. Thus, the syringe 640 can enable the use of larger volume syringes that can generate correspondingly greater suction forces in the catheter subsystem 100.

[0079] Referring again to Figure 1, it is expected that less tortuous (e.g., more linear) fluid paths between the pressure source 140 and the catheter subsystem 100 will produce greater suction forces and corresponding fluid velocities at the distal portion 103a of the catheter 102 when stored vacuum pressure is applied to the catheter subsystem 100. Accordingly, in some embodiments the side port 108 of the valve 106 can be formed to have an angle A that is less than about 90°, less than about 75°, less than about 60°, less than about 45°, less than about 30°, less than about 15° etc. Reducing the relative angle between the side port 108 and the lumen 109 of the valve 106 (and thus the lumen 104 of the catheter 102) reduces the tortuosity of the fluid path between the pressure source 140 and the catheter 102. Moreover, in some embodiments, the pressure source 140 can be coupled to the proximal portion 107b of the valve 106 instead of or in addition to the side port 108 to provide a more linear fluid path between the pressure source 140 and the catheter

102. For example, Figure 24 is an enlarged isometric view of the assembly 10 showing the pressure source 340 coupled directly to the proximal portion 107b of the valve rather than to the connector 128 of the tubing subsystem 120 and the side port 108 of the valve 106. Although the pressure source 340 is illustrated in Figure 24, any of the pressure sources described in detail above with reference to Figures 2–6 can be configured to be coupled to the proximal portion 107b of the valve 106 rather than the side port 108. In other embodiments, the side port 108 can be omitted and the valve 106 and the tubing subsystem 120 can be coupled to the catheter 102 via a Y-connector. For example, Figure 25 is an enlarged isometric view of the assembly 10 showing the valve 106 and the tubing subsystem 120 coupled to the catheter 102 via a Y-connector 2590. In yet other embodiments, the tubing system 120 is linearly coupled to the catheter 102, and the valve 106 protrudes at an angle from the catheter 102.

[0080] In some embodiments, however, a guidewire or other component is positioned within the valve 106 during the duration of a clot removal procedure (e.g., for delivering interventional devices to a treatment site within a patient). Accordingly, in some embodiments, to facilitate coupling of the pressure source 140 to the proximal portion 107b of the valve 106—even when a guidewire is inserted therethrough—the pressure source 140 can be a syringe configured for over-wire delivery. For example, Figure 7 is a side view of a pressure source 740 comprising a vacuum-pressure locking syringe ("syringe 740") configured in accordance with the present technology for delivery and operation over a guidewire 794. The syringe 740 can have some features generally similar to the features of the syringe 340 described in detail above with reference to Figure 3. For example, the syringe 740 includes a plunger 742 slidably and rotatably positioned within a barrel 744. The barrel 744 is shown as transparent in Figure 7 for the sake of clarity. In the illustrated embodiment, the plunger 742 includes a lumen 796 (shown in broken lines) extending longitudinally therethrough. The guidewire 794 can be inserted through the lumen 796 of the plunger 742 such that the syringe 740 can be advanced over the guidewire 794 for attachment to the proximal portion 107b of the valve 106. The syringe 740 can further include one or more sealing components (e.g., valves, O-rings, etc.; not shown) for maintaining a seal between the guidewire 794 and the plunger 742 to permit build-up and storage of a vacuum in the barrel 744.

[0081] In general, one skilled in the art will understand that the various embodiments of pressure sources disclosed herein may be combined to, for example, include multiple pressure

sources or pressure sources having different components or combinations of components. For example, in some embodiments the secondary syringe 460 (Figures 4A–4C) can be coupled via one or more one-way valves to the syringes 240, 540, 640 or 740 (Figures 2 and 5–7, respectively) to generate additional vacuum. In some embodiments, multiple pressure sources can be coupled to the catheter 102 via the tubing subsystem 120 and/or via the valve 106. Moreover, the individual pressure sources can be the same or different, and can be coupled to the catheter subsystem 100 via a single fluid control device, such as the fluid control device 126, or can be coupled to the catheter subsystem 100 via separate fluid control devices. Therefore, the profile of the vacuum applied to the catheter 102 can be selected or adjusted by using multiple different pressure sources. For example, a specific vacuum profile can depend at least on (i) the individual characteristics of the multiple pressure sources (e.g., volume, bore-size, etc.), (ii) the manner in which the pressure sources are coupled to the catheter subsystem 100 (e.g., via individual valves, via the same valve, etc.), and (iii) the timing of the application or release of the vacuum of each pressure source to the catheter subsystem 100 (e.g., staggered release, simultaneous release, etc.). As one example, in some embodiments, the syringe 240 (Figure 2) and the syringe 340 (Figure 3) can both be coupled to the tubing subsystem 120 via, for example, a Y-connector. After charging both syringes 240, 340 with vacuum pressure, opening the fluid control device 126 can simultaneously apply the combined vacuum to the catheter 102. The larger-bored syringe 340 can provide a short but powerful impulse of vacuum pressure, while the smaller-bored syringe 240 can provide a longer and more sustained vacuum pull. This combination can apply a large, fast-acting suction force to dislodge and capture clot material in the catheter 102, and simultaneously apply a more sustained suction force to capture more clot material.

III. Selected Embodiments of Methods of Clot Removal

[0082] Figure 8 is a flow diagram of a process or method 800 for operating a clot removal system including the assembly 10 to remove clot material from within a blood vessel (e.g., a pulmonary blood vessel) of a human patient in accordance with the present technology. Figures 9A–9C are side views of a proximal portion of the assembly 10, and Figures 10A and 10B are schematic illustrations of a distal portion of the assembly 10, during a clot removal procedure in accordance with embodiments of the present technology. In particular, Figures 9A–9C are side

views of the assembly 10 including the syringe 340 and adaptor 350 (Figures 3A–3D), and Figures 10A and 10B are side views of the catheter 102 with the distal portion 103a of the catheter 102 positioned proximate to an embolism or clot material PE within a blood vessel BV (e.g., a pulmonary blood vessel). Although some features of the method 800 are described in the context of the embodiments shown in Figures 1, 3A–3D, and 9A–10B for the sake of illustration, one skilled in the art will readily understand that the method 800 can be carried out using other suitable systems and/or devices described herein. In particular, although described in the context of the syringe 340, the method 800 can be carried out using any one or combination of the pressure sources described in detail above with reference to Figures 2–7.

[0083] At block 802, the method 800 includes positioning the distal portion 103a of the catheter 102 proximate to clot material within a blood vessel of a human patient (e.g., at a treatment site). For example, in the embodiment illustrated in Figure 10A, a distal terminus of the distal portion 103a of the catheter 102 is positioned proximate to a proximal portion of the clot material PE. It is expected that reducing the distance between the distal terminus of the catheter 102 and the proximal portion of the clot material PE—without contacting the clot material PE with the catheter 102—will maximize the suction forces on the clot material PE when the fluid control device 126 is opened. It is also expected that reducing the distance (e.g., clearance) between the inner diameter of the blood vessel BV and the outer diameter of the catheter will maximize the suction forces on the clot material PE. However, in other embodiments, the distal terminus of the catheter 102 can be positioned at least partially within the clot material PE, or the distal terminus of the catheter 102 can be positioned distal of the clot material PE.

[0084] Access to the pulmonary vessels can be achieved through the patient's vasculature, for example, via the femoral vein. In some embodiments, the catheter subsystem 100 can include an introducer (e.g., a Y-connector with a hemostasis valve; not shown) that can be partially inserted into the femoral vein. A guidewire (not shown) can be guided into the femoral vein through the introducer and navigated through the right atrium, the tricuspid valve, the right ventricle, the pulmonary valve, and into the main pulmonary artery. Depending on the location of the embolism, the guidewire can be guided to one or more of the branches of the right pulmonary artery and/or the left pulmonary artery. In some embodiments, the guidewire can be extended entirely or partially through the clot material PE. In other embodiments, the guidewire can be extended to a

location just proximal of the clot material PE. After positioning the guidewire, the catheter 102 can be placed over the guidewire and advanced (e.g., as indicated by arrow A1) to a position proximate to the clot material PE as illustrated in Figure 10A.

[0085] In some embodiments, to confirm the position of the distal portion 103a of the catheter 102, a contrast agent can be injected through the catheter 102 and viewed using fluoroscopic imaging techniques, as is known in the art. In some embodiments, the valve 106 can be opened to determine the position of the distal portion 103a of the catheter 102 relative to the clot material PE. For example, the activation buttons 101 can be depressed to open the lumen 109 of the valve 106. If there is substantially no back-bleeding through the valve 106, the operator can determine that the distal portion 103a of the catheter 102 is fully engaged with the clot material PE. Conversely, if there is some back-bleeding through the valve 106, the operator can determine that the distal portion 103a of the catheter is not fully engaged with the clot material PE. Accordingly, to locate the distal portion 103a of the catheter 102 just proximal of the clot material PE, the operator can (i) first determine that distal portion 103a of the catheter is fully engaged with the clot material PE by activating the valve 106 and detecting no back-bleeding and (ii) then reposition the catheter 102 (e.g., by withdrawing the catheter 102 proximally) and activate the valve 106 until back-bleeding is detected—thereby confirming that the distal portion 103a of the catheter 102 is positioned proximal of the clot material PE. In some embodiments, the valve 106 can be opened during retraction of the catheter 102 until back-bleeding is detected. In other embodiments, the valve 106 can be closed during retraction of the catheter 102, and the catheter 106 can be retracted a set (e.g., predetermined) distance before the valve 106 is opened again. In one aspect of the present technology, determining the position of the distal portion 103a of the catheter 102 via activation of the valve 106 can be used when it is difficult to determine the position of the catheter 102 via radiographic techniques. In contrast, many conventional hemostasis valves cannot be activated in this manner.

[0086] In some embodiments, the guidewire can then be withdrawn while, in other embodiments, the guidewire can remain and can be used to guide other catheters (e.g., delivery catheters, additional aspiration catheters, etc.), interventional devices, etc., to the treatment site. It will be understood, however, that other access locations into the venous circulatory system of a patient are possible and consistent with the present technology. For example, the user can gain

access through the jugular vein, the subclavian vein, the brachial vein, or any other vein that connects or eventually leads to the superior vena cava. Use of other vessels that are closer to the right atrium of the patient's heart can also be advantageous as it reduces the length of the instruments needed to reach the pulmonary embolism.

[0087] At block 804, the method 800 includes coupling a pressure source (e.g., the syringe 340) to the catheter 102 via the fluid control device 126. For example, in the embodiment illustrated in Figure 9A, the tip 347 (shown in Figures 3A and 3C but obscured in Figure 9A) of the syringe 340 can be coupled to the connector 128 via the adaptor 350. Once the syringe 340 is coupled to the catheter 102, (i) opening the fluid control device 126 fluidly connects the syringe 340 to the lumen 104 of the catheter 102, and (ii) closing the fluid control device 126 fluidly disconnects the syringe 340 from the lumen 104 of the catheter 102. The fluid control device 126 is in an open position in Figure 9A.

[0088] At block 806, the method 800 includes activating the syringe 340 to generate a vacuum while the fluid control device 126 is closed. For example, as shown in Figure 9B, the user can first actuate the fluid control device 126 to close the fluid control device 126, and then retract the plunger 342 to generate a vacuum in the barrel 344 of the syringe 340. The user can subsequently lock the plunger 342 relative to the barrel 344, as described in detail above, to store or maintain a vacuum of known volume in the syringe 340. In this manner, the syringe 340 can be pre-charged with a vacuum before the vacuum is applied to the catheter 102. In contrast, many conventional aspiration techniques include activating a negative pressure source (e.g., a pump, a syringe, etc.) while the pressure source is fluidly connected to a lumen to be aspirated. In some embodiments, when the pressure source 400 with the secondary syringe 460 (Figures 4A–4C) is used with the primary syringe 340; the secondary syringe 460 can be cycled one or more times before or after retracting the plunger 342 to increase the vacuum pressure.

[0089] At block 808, the method 800 includes opening the fluid control device 126 to apply the vacuum to the lumen 104 of the catheter 102. For example, with reference to Figure 9C, the user can actuate (e.g., twist a handle of) the fluid control device 126 to open the fluid control device 126 and apply the vacuum stored in the syringe 340 to the catheter subsystem 100. As shown in Figure 10B, application of the vacuum causes suction at the distal tip 103a of the catheter 102

(e.g., as indicated by arrow A2) that aspirates at least a portion of the clot material PE from the blood vessel BV and into the lumen 104 of the catheter 102. In some embodiments, opening the fluid control device 126 instantaneously or nearly instantaneously generates suction at the distal portion 103a of the catheter 102. In certain embodiments, application of the vacuum can generate suction for less than about 1 second (e.g., about 0.5 second), substantially less than about 1 second (e.g., about 0.3 second, about 0.1 second, etc.) less than about 2 seconds, or greater than about 2 seconds—until the pressure in the assembly 10 equalizes. In some embodiments, depending on the volume of the vacuum chamber formed in the syringe 340 and the dimensions of the catheter subsystem 100 and the tubing subsystem 120 (e.g., where the syringe 340 has a volume that is greater than or about equal to a volume of the catheter subsystem 100), at least some of the clot material PE can be aspirated entirely through the lumen 104 of the catheter 102 and into the barrel 344 of the syringe 340. In some such embodiments, the user can determine whether subsequent steps for treating the clot material PE are necessary or desirable by visualizing the amount of clot material collected in the syringe 340. Figure 9C, for example, illustrates the syringe 340 and the tubing subsystem 120 after the fluid control device 126 has been opened to apply the vacuum stored in the syringe 340 to the catheter 102. In the illustrated embodiment, some of the clot material PE is visible in the syringe 340.

[0090] In some embodiments, the fluid control device 126 or another fluid control device can be intermittently operated to provide discrete bursts of suction. For example, the fluid control device 126 can be quickly opened and closed to provide a first burst of suction (e.g., vacuum release) without fully equalizing the pressure in the assembly 10. The fluid control device 126 can then be opened again to provide a second burst of suction, or opened and closed repeatedly to provide a desired suction pattern. In some embodiments, the assembly 10 can be specifically configured to facilitate the application of multiple bursts of suction. For example, (i) the fluid control device 126 can be spring-loaded, electronically controlled, etc., to rapidly open and close the valve, and/or (ii) the pressure source 140 can have a large vacuum chamber and/or small bore size to increase the time required for pressure in the assembly 10 to equalize (e.g., to increase a discharge time of the pressure source 140).

[0091] Sometimes, as shown in Figure 10B, discharging the vacuum stored in the pressure source to aspirate the lumen 104 of the catheter 102 may not remove all of the clot material PE (or

a desired amount of the clot material PE) from the blood vessel BV. That is, a single aspiration may not adequately remove the clot material PE from the blood vessel BV. In such instances, the user of the assembly 10 may wish to again apply vacuum pressure (conduct an "aspiration pass") to remove all or a portion of the remaining clot material PE in the blood vessel BV. In such instances, the pressure source can be disconnected from the tubing subsystem 120 and drained (e.g., aspirated clot removal removed) before the method 800 returns to block 802. For example, the adaptor 350 and the syringe 340 can be decoupled from the connector 128, and the plunger 342 can be pushed into the barrel 344 to expel the clot material PE and associated fluid from the barrel 344 via the tip 347. With the distal portion of the catheter 102 positioned proximate to the remaining clot material PE (e.g., unmoved relative the last aspiration pass), the pressure source can then be re-coupled to the connector 128 (block 804), primed again (block 806), and the vacuum pressure discharged (block 808) to aspirate all or a portion of the remaining clot material PE.

[0092] Blocks 802–808 can be repeated until a desired amount of clot material is removed from the patient or until the catheter 102 becomes clogged. In some embodiments, to check for clogging of the catheter 102, the fluid control device 126 and/or the valve 106 can be opened to check for back bleeding. A lack of back bleeding can indicate that the catheter 102 is likely clogged. Similarly, if the barrel 344 of the syringe 340 contains mostly air and relatively little blood and clot material (e.g., less than 5–10 cc) after aspiration of the catheter 102 (block 808), it can indicate that the catheter 102 is likely clogged. When the catheter 102 is clogged or a sufficient amount of clot material PE has been removed from the patient, the method 800 can proceed to block 810 and the catheter 102 can be removed from the patient. When the catheter 102 is clogged, the catheter 102 can be flushed and cleared prior to reentry into the patient (block 802). In other embodiments, a different (e.g., new, unused, etc.) catheter can be inserted into the patient and positioned to remove the remaining clot material PE from the patient.

[0093] In some embodiments, rather than removing the catheter 102 from the patient if the catheter 102 is clogged, the syringe 340 can be recharged and used to apply one or more subsequent vacuum pulses to the catheter 102. More specifically, the fluid control device 126 can be closed and the syringe 340 can be removed from the connector 128 and evacuated to remove the clot material and blood therein. Then, blocks 804–808 can be repeated to apply another pulse of vacuum to the catheter 102. That is, rather than removing the catheter 102 after a clog is detected,

the syringe 340 can be "cycled" until the vacuum force on the clot material PE overcomes the forces between the clot material PE and the catheter 102 and sucks the clot material PE into the syringe 340. In some embodiments, when the pressure source 400 with the secondary syringe 460 (Figures 4A–4C) is used with the primary syringe 340, the secondary syringe 460 can be cycled one or more times to increase the vacuum in the assembly 10 (e.g., in the catheter 102) and thus increase the suction force exerted against the clot material PE. That is, rather than removing the catheter 102 after a clog is detected, the secondary syringe 460 can be cycled until the vacuum force on the clot material PE overcomes the forces between the clot material PE and the catheter 102 and sucks the clot material PE into the syringe 340. In some embodiments, as described in detail below with reference to Figures 15–16E, a second clot removal assembly can be telescoped through the first assembly 10 to facilitate removal of the clogged clot material PE.

[0094] In some embodiments, an interventional device such as a clot removal and/or clot treatment device can be delivered to the treatment site through the catheter 102 for engaging and facilitating clot removal before and/or after application of a stored vacuum to the catheter 102. Suitable interventional devices and associated methods are disclosed in U.S. Patent Application No. 9,526,864, filed June 9, 2015, and titled "RETRACTION AND ASPIRATION DEVICE FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," and U.S. Patent Application No. 8,784,434, filed March 15, 2013, and titled "METHODS AND APPARATUS FOR TREATING EMBOLISM," both of which are incorporated herein by reference in their entireties. In some embodiments, for example, the user can first advance an interventional device to the treatment site and at least partially engage the clot material PE with the interventional device to loosen (e.g., scour) the clot material PE. Such loosening of the clot material PE can facilitate the removal of the clot material PE upon a subsequent aspiration pass. Likewise, in some embodiments, the user can use an interventional device to engage residual clot material PE (Figure 10B) after a first aspiration pass.

IV. Selected Embodiments of Telescoping Clot Removal Systems and Associated Methods of Clot Removal

[0095] Figure 11 is a partially schematic side view of another clot treatment or clot removal system configured in accordance with the present technology. In the illustrated embodiment, the

clot removal system includes a first aspiration assembly 20 and a second aspiration assembly 30. The first and second aspiration assemblies 20, 30 ("assemblies 20, 30") can include some features generally similar to the features of the aspiration assembly 10 described in detail above with reference to Figures 1–10B. For example, the first aspiration assembly 20 includes (i) a first catheter subsystem 1000 having a first catheter 1002 and a first valve 1006, (ii) a first tubing subsystem 1020 having a first fluid control device 1026 (e.g., a stopcock), and (iii) a first pressure source 1040 that can be fluidly coupled to the first catheter subsystem 1000 via the first tubing subsystem 1020. Likewise, the second aspiration assembly 30 includes (i) a second catheter subsystem 1100 having a second catheter 1102 and a second valve 1106, (ii) a second tubing subsystem 1120 having a second fluid control device 1126 (e.g., a stopcock), and (iii) a second pressure source 1140 that can be fluidly coupled to the second catheter subsystem 1100 via the second tubing subsystem 1120.

[0096] The first and second catheters 1002, 1102 each comprise an elongated shaft defining a lumen 1004, 1104 and having a distal portion 1003a, 1103a, respectively. The first and second valves 1006, 1106 each include (i) a distal portion 1007a, 1107a, (ii) a proximal portion 1007b, 1107b, (iii) a lumen 1009, 1109 extending therethrough, and (iv) a flow controller (obscured in Figure 10) in the lumen 1009, 1109, respectively. The first fluid control device 1026 is operable to regulate or control fluid flow between (e.g., fluidly connect or disconnect) the first pressure source 1040 and the first catheter subsystem 1000. The second fluid control device 1126 is operable to regulate or control fluid flow between (e.g., fluidly connect or disconnect) the second pressure source 1140 and the second catheter subsystem 1100.

[0097] In the illustrated embodiment, the second catheter 1102 has a smaller cross-sectional dimension (e.g., diameter) than the first catheter 1002 so that the second catheter 1102 can be inserted through the first valve 1006 and into the lumen 1004 of the first catheter 1002. In some embodiments, the second catheter 1102 can be telescoped through the lumen 1004 of the first catheter 1002 until the distal portion 1103a of the second catheter 1102 extends beyond a distal terminus of the first catheter 1002. Accordingly, the second catheter 1102 can be longer than the first catheter 1002. In some embodiments, the second catheter 1102 can have a size of 16 French or smaller and the first catheter 1002 can have a size of 20 French or greater. The first valve 1006 can provide a hemostatic seal that inhibits fluid flow (e.g., blood flow) through the first valve 1006

and from the first catheter subsystem 1000 when the second catheter 1102 is positioned within the first catheter 1002. In some embodiments (e.g., as described in detail below with reference to Figures 14A–14C), a sealing member 1499 can be positioned between the first catheter 1002 and the second catheter 1102 for sealing the lumen 1004 of the first catheter 1002 when the second catheter 1102 is advanced distally past the sealing member.

[0098] In some embodiments, the first and second pressure sources 1040, 1140 ("pressure sources 1040, 1140") are separate sources each configured to generate and store a vacuum for subsequent application to the first and second catheter subsystems 1000, 1100, respectively, as described in detail above with reference to Figures 1–10B. In other embodiments, one or both of the pressure sources 1040, 1140 can be configured to provide sustained negative pressure rather than a charge or burst of stored vacuum pressure. In yet other embodiments, one of the pressure sources 1040, 1140 can be omitted, or the pressure sources 1040, 1140 can be fluidly coupled and/or integrally formed.

[0099] Figure 12 is a flow diagram of a process or method 1280 for operating a clot removal system including the assemblies 20 and 30 to remove clot material from within a blood vessel (e.g., a pulmonary blood vessel) of a human patient in accordance with the present technology. Figures 13A–13C are schematic illustrations of a distal portion of the assemblies 20, 30 during a clot removal procedure in accordance with the present technology. Figures 14A–14C are schematic side views of a distal portion of the assemblies 20, 30 during a clot removal procedure and including an optional sealing member in accordance with the present technology. Although some features of the method 1280 are described in the context of the embodiments shown in Figures 11 and 13A–14C for the sake of illustration, one skilled in the art will readily understand that the method 1280 can be carried out using other suitable systems and/or devices.

[0100] At block 1282, the method 1280 includes intravascularly positioning the first catheter 1002 within a human patient. Figure 13A, for example, illustrates the first catheter 1002 after it has been advanced (e.g., as indicated by arrow A1) to a position within a blood vessel BV (e.g., a pulmonary blood vessel). More specifically, the first catheter 1002 can be advanced within the blood vessel BV until the distal portion 1003a of the first catheter 1002 is positioned proximal to clot material PE within the blood vessel BV. In some embodiments, the position of the distal

portion 1003a of the first catheter 1002 relative to the clot material PE can be determined by activating the first valve 1006 and determining whether there is back-bleeding through the first valve 1006, as described in detail above. In the illustrated embodiment, the clot material PE is located within a branch (e.g., a reduced diameter portion) of the blood vessel BV. In some embodiments, access to the blood vessel BV can be achieved using an introducer and guidewire as described in detail above with reference to Figure 8.

[0101] At block 1284, the method 1280 includes advancing the second catheter 1102 through the first catheter 1002 until the distal portion 1103a of the second catheter 1102 is positioned proximate to the clot material PE within the blood vessel BV (e.g., at a treatment site). To advance the second catheter 1102 through the first catheter 1002, the user can first insert the distal portion 1103a of the second catheter 1102 through the first valve 1006 before advancing the second catheter 1102 (e.g., as indicated by the arrow A1) through the lumen 1004 of the first catheter 1002. In some embodiments, the first valve 1006 can be actuated (e.g., by depressing one or more buttons) to open the lumen 1009 of the first valve 1006 so that the second catheter 1102 can be inserted therethrough. In some embodiments, the position of the distal portion 1103a of the second catheter 1102 relative to the clot material PE can be determined by activating the second valve 1106 and determining whether there is back-bleeding through the second valve 1106, as described in detail above. In other embodiments, the (smaller) second catheter 1102 can be intravascularly positioned proximate to the clot material PE before intravascularly positioning the (larger) first catheter 1002. In such embodiments, the second catheter 1102 can act as a guide or rail for guiding the advancement of the first catheter 1002 to the treatment site.

[0102] Figure 13A illustrates the second catheter 1102 after it has been advanced through the first catheter 1002 and past a distal terminus of the first catheter 1002 to position a distal terminus of the second catheter 1102 proximate to a proximal portion of the clot material PE. In other embodiments, the distal terminus of the second catheter 1102 can be positioned at least partially within the clot material PE, or the distal terminus of the second catheter 1102 can be positioned distal of the clot material PE. In one aspect of the present technology, because the second catheter 1102 has a smaller cross-sectional dimension than the first catheter 1002, the second catheter 1102 can be advanced to narrower (e.g., more distal) treatment sites within the blood vessel BV. In the embodiment illustrated in Figure 13A, for example, the first catheter 1002

may be too large to be positioned within the branch of the blood vessel BV, while the second catheter 1102 can be positioned within the branch proximate to or within the clot material PE.

[0103] At block 1286, the method 1280 includes coupling the second pressure source 1140 to the second catheter 1102 via the second fluid control device 1126. For example, any one or combination of the pressure sources described in detail above with reference to Figures 2–7 can be coupled to the second catheter 1102 via the second tubing subsystem 1120. Once the second pressure source 1140 is coupled to the second catheter 1102, (i) opening of the second fluid control device 1126 fluidly connects the second pressure source 1140 to the lumen 1104 of the second catheter 1102, and (ii) closing of the second fluid control device 1126 fluidly disconnects the second pressure source 1140 from the lumen 1104 of the second catheter 1102. In some embodiments, the method 1280 can further include coupling the first pressure source 1040 to the first catheter 1002 (e.g., via the first tubing subsystem 1020).

[0104] At block 1288, the method 1280 includes activating the second pressure source 1140 to generate a vacuum while the second fluid control device 1126 is closed. In particular, the second pressure source 1140 can be activated to build-up or pre-charge a vacuum for subsequent application to the second catheter 1102. In some embodiments, the first pressure source 1040 can also be activated to generate and store a vacuum for subsequent application to the first catheter 1002.

[0105] At block 1290, the method 1280 includes opening the second fluid control device 1126 to apply the vacuum stored in second pressure source 1140 to the lumen 1104 of the second catheter 1102. As shown in Figure 13B, application of the vacuum causes suction (e.g., as indicated by arrow A2) that aspirates at least a portion of the clot material PE from the blood vessel BV and into the lumen 1104 of the second catheter 1102. In some embodiments, opening the second fluid control device 1126 instantaneously or nearly instantaneously generates suction at the distal portion 1103a of the second catheter 1102. In one aspect of the present technology, pre-charging or storing the vacuum before applying the vacuum to the lumen 1104 of the second catheter 1102 is expected to generate greater suction forces (and corresponding fluid flow velocities) at and/or near the distal portion 1103a of the second catheter 1102 compared to simply

activating the second pressure source 1140 while it is fluidly connected to the second catheter 1102.

[0106] In some embodiments, where the first pressure source 1040 is also activated to generate and store a vacuum (e.g., at block 1288), the method 1280 can further comprise opening the first fluid control device 1026 to generate suction at the distal portion 1003a of the first catheter 1002. One skilled in the art will understand that the suction profile in the blood vessel BV can be selected or modified based on the characteristics of the pressure sources 1040, 1140 (e.g., volume, bore size, etc.) and the timing of the opening of the first and second fluid control devices 1026, 1126. For example, the first fluid control device 1026 can be opened at the same time as the second fluid control device 1126 to generate a combined and relatively large suction force in the blood vessel BV. In other embodiments, the first fluid control device 1026 can be opened after the second fluid control device 1126 to generate staggered or stepped suction forces in the blood vessel BV. For example, the first fluid control device 1026 can be opened after the second fluid control device 1126 to aspirate any of the clot material PE (i) remaining in the blood vessel BV after aspiration of the second catheter 1102 and/or (ii) stuck to or extending from the second catheter 1102. In other embodiments, the first pressure source 1040 can be a pump or other source for providing sustained negative pressure—rather than a built-up charge of negative pressure—and thus can generate sustained (e.g., constant) suction at the distal portion 1003a of the first catheter 1002. In some such embodiments, the first fluid control device 1026 can remain open during the clot removal procedure to provide sustained suction throughout the procedure.

[0107] In some embodiments, an interventional device can be delivered through the second catheter 1102 and used to engage the clot material PE before and/or after the vacuum is applied to the second catheter 1102. Specific details of suitable interventional devices and associated methods of use are disclosed in, for example, provisional U.S. Patent Application No. 16/258,344, filed January 25, 2019, and titled "SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

[0108] At block 1292, the method 1280 includes retracting the second catheter 1102 proximally through the first catheter 1002. In some embodiments, multiple aspiration passes can

be performed with the second catheter 1102 before retracting the second catheter 1102. In some embodiments, as shown in Figure 13C, the first pressure source 1040 or another pressure source coupled to the first catheter 1002 can be activated to generate suction (e.g., as indicated by arrow A3) at the distal portion 1003a of the first catheter 1002 during retraction of the second catheter 1102. The suction can be constant or provided in one or more bursts, as described in detail above. In some embodiments, the second catheter 1102 can be fully withdrawn from the patient and disposed of or cleaned (e.g., flushed with a sterile liquid) for reuse.

[0109] Sometimes, the clot material PE is not fully pulled into the second catheter 1102 when the vacuum is applied to the second catheter 1102 (block 1290) and can therefore stick to or dangle from the distal portion 1103a of the second catheter 1102. Figure 14A, for example, is an enlarged view of the distal portion of the assemblies 20, 30 shown in Figure 13C and illustrating a portion of the clot material PE stuck to or dangling from the distal portion 1103a of the second catheter 1102. In the illustrated embodiment, an optional seal 1499 is disposed between the first and second catheters 1002, 1102 to facilitate the removal of such dangling clot material PE. More specifically, the seal 1499 (shown in cross-section) can be disposed between an outer surface of the second catheter 1102 and an inner surface of the first catheter 1002. The seal 1499 can be an O-ring, grommet, or other suitable component that fluidly disconnects the lumen 1004 of the first catheter 1002 from the blood vessel BV when the second catheter 1102 is positioned therethrough (e.g., when the distal terminus of the second catheter 1102 is positioned distally of the seal 1499).

[0110] Figures 14B and 14C are enlarged views of the distal portion of the assemblies 20, 30 and illustrating further retraction of the second catheter 1102 (and the dangling clot material PE) into the lumen 1004 of the first catheter 1002. In some embodiments, the first pressure source 1040 can be activated to charge a vacuum in the lumen 1004 of the first catheter 1002. For example, after the second catheter 1102 is advanced through the first catheter 1002 and past the seal 1499 (e.g., block 1284)—thereby sealing the lumen 1004 of the first catheter 1002—the operator can open the first fluid control device 1026 and activate the first pressure source 1040 to build up the vacuum in the lumen 1004 of the first catheter 1002. Referring to Figure 14C, when the distal terminus of the second catheter 1102 is retracted proximally past the seal 1499, the lumen 1004 of the first catheter 1002 becomes fluidly connected to the blood vessel BV and the vacuum is instantaneously or nearly instantaneously released to generate suction (e.g., as indicated by

arrows A4). In the illustrated embodiment, the suction acts to separate or otherwise dislodge the clot material PE from the second catheter 1102 and pull the clot material PE proximally through the lumen 1004 of the first catheter 1002. In this manner, a second burst of suction is automatically applied via the first catheter 1002 during retraction of the second catheter 1102. In one aspect of the present technology, the user does not need to take any additional step to release the vacuum stored in the first catheter 1002—as release is automatically triggered by retraction of the second catheter 1102.

[0111] At block 1294, the user can determine whether it is necessary or desirable to redeploy the second catheter 1102 or another catheter through the first catheter 1002 in order to remove any residual clot material PE that was not removed during the first aspiration pass and/or any clot material located elsewhere in the blood vessel BV (e.g., to initiate a second aspiration pass). In some embodiments, the operator can visualize the amount of clot material PE collected in the first pressure source 1040 and/or the second pressure source 1140 to at least partially determine whether another aspiration pass is needed. In other embodiments, the operator can rely on imaging (e.g., fluoroscopic imaging) of the blood vessel BV or other techniques known in the art to determine whether an additional aspiration pass is necessary or desirable.

[0112] If another pass is not needed (e.g., the clot material PE was adequately removed), the user can elect to fully withdraw the assemblies 20, 30 from the patient at block 1296. If clot material PE remains in the vessel, the method can return to block 1284. In particular, the same second catheter 1102 can be cleaned (e.g., flushed with saline) and advanced again through the first catheter 1002 until the distal portion 1103a of the second catheter 1102 is positioned proximate to the remaining clot material PE within the blood vessel BV. In some embodiments, a new second catheter 1102 can be used for each pass to reduce the likelihood of contamination (e.g., reintroduction of clot material PE). In some embodiments, the first catheter 1002 can be aspirated (e.g., via the first pressure source 1040) prior to redeployment of the second catheter 1102 to, for example, remove any clot material PE that may be in the first catheter 1002 to inhibit its reintroduction into the blood vessel BV as the second catheter 1102 is advanced therethrough during another pass. Once the desired amount of clot material PE has been removed from the patient, the assemblies 20, 30 may be fully withdrawn from the patient (block 1294).

[0113] In one aspect of the present technology, the method 1280 provides for an aspiration catheter to be deployed multiple times without requiring that the first catheter 1002 be removed after each deployment. Accordingly, the present technology allows for only a single insertion of a guide catheter during a procedure including multiple passes to remove clot material—increasing the speed of the procedure and reducing trauma to the patient since the guide catheter does not need to be reintroduced (e.g., advanced through the vasculature and past the heart) before each pass. Moreover, in certain embodiments, the present technology can enable the first catheter 1002 to be relocated to an alternate treatment site within the patient without removing the first catheter 1002 from the patient and, therefore, without reintroducing the first catheter 1002 through the heart. For example, the first catheter 1002 can be relocated to another treatment site within the lungs including a treatment site in the opposite lung. More specifically, (i) a dilator can be reintroduced into the first catheter 1002, (ii) the first catheter 1002 can be withdrawn into the main pulmonary artery, (iii) a guidewire can be redirected to the new treatment site, (iv) the first catheter 1002 can be advanced over the guidewire to the new treatment site, and (v) the dilator can be removed.

[0114] Figure 15 is a flow diagram of another process or method 1580 for operating a clot removal system including the assemblies 20, 30 (Figure 1) to remove clot material from within a blood vessel (e.g., a pulmonary blood vessel) of a human patient in accordance with the present technology. Figure 16A is an enlarged side view of a distal portion of the first assembly 20, and Figures 16B–16E are side views of a distal portion of the assemblies 20, 30 during a clot removal procedure in which clot material clogs the first assembly 20 in accordance with the present technology. Although some features of the method 1580 are described in the context of the embodiments shown in Figures 11 and 16A–16E for the sake of illustration, one skilled in the art will readily understand that the method 1580 can be carried out using other suitable systems and/or devices.

[0115] Some features of the method 1580 are generally similar to those of the methods 880 and/or 1280 described in detail above with reference to Figures 8 and 12, respectively. For example, at block 1582 the method includes intravascularly positioning the first catheter 1002 of the first assembly 20 within a human patient. At block 1584, the method 1580 includes coupling the first pressure source 1040 to the first catheter 1002 via the first fluid control device 1026. For

example, any one or combination of the pressure sources described in detail above with reference to Figures 2–7 can be coupled to the second catheter 1002 via the first tubing subsystem 1020. At block 1586, the method 1580 includes activating the first pressure source 1040 to generate a vacuum while the first fluid control device 1026 is closed. In particular, the first pressure source 1040 can be activated to build-up or pre-charge a vacuum for subsequent application to the first catheter 1002. At block 1588, the method 1580 includes opening the first fluid control device 1026 to apply the vacuum stored in the first pressure source 1040 to the lumen 1004 of the first catheter 1002. As described in detail above, opening the first fluid control device 1026 instantaneously or nearly instantaneously generates suction at the distal portion 1003a of the first catheter 1002.

[0116] Sometimes, however, clot material is not fully pulled into the first catheter 1002 and/or clogs the first catheter 1002 when the vacuum is applied to the first catheter 1002 (block 1588). Figure 16A, for example, is an enlarged view of the distal portion of the first assembly 20 illustrating a portion of clot material PE that extends beyond from the distal portion 1003a of the first catheter 1002 and blocks/clogs the lumen 1004 of the first catheter 1002. As such, a portion of the clot material PE is not within the first catheter 1002. Accordingly, at block 1590, the method 1580 can include determining whether the first catheter 1002 is clogged. In some embodiments, the operator can determine that the first catheter 1002 is clogged based on the vacuum chamber of the first pressure source 1040 containing little to no clot material PE and blood. For example, since the clot material PE clogs the first catheter 1002, the vacuum chamber of the first pressure source 1040 cavitates when the first fluid control device 1026 is opened. If the first catheter 1002 is not clogged, the method 1580 can proceed to block 1598 and the first catheter 1002 can be withdrawn from the patient or the operator can perform another aspiration pass (e.g., as described in detail above with reference to blocks 808 and 810 of the method 800 shown in Figure 8).

[0117] If the first catheter 1002 is clogged, the method 1580 can proceed to block 1592 which includes advancing the second catheter 1102 through the first catheter 1002 until the distal portion 1103a of the second catheter 1102 is positioned in or proximate to the clogging clot material PE. For example, Figure 16B illustrates the second catheter 1102 after it has been advanced to a position within the first catheter 1002 in which the distal terminus of the second catheter 1102 is at or proximate to the clogging clot material PE. To advance the second catheter

1102 through the first catheter 1002, the user can first insert the distal portion 1103a of the second catheter 1102 through the first valve 1006 (Figure 11) before advancing the second catheter 1102 through the lumen 1004 of the first catheter 1002.

[0118] At block 1594, the method 1580 includes activating the second pressure source 1140 (Figure 11) coupled to the second catheter 1102. More specifically, the second pressure source 1140 (e.g., any one or combination of the pressure sources described in detail above with reference to Figures 2–7) can be coupled to the second catheter 1102 via the second fluid control device 1126 (Figure 11), and the second pressure source 1140 can be activated to build-up or pre-charge a vacuum while the second fluid control device 1126 is closed. The second fluid control device 1126 can then be actuated to apply the vacuum stored in the second pressure source 1140 to the lumen 1104 of the second catheter 1102. In other embodiments, the second pressure source 1140 can simply provide a sustained vacuum rather than an instantaneous release of vacuum. That is, in some embodiments the second pressure source 1140 is not pre-charged with a vacuum.

[0119] Applying the vacuum to second catheter 1102 can aspirate at least a portion of the clogging clot material PE into the second catheter 1102 and/or suck the clot material PE against the distal terminus of the second catheter 1102. Figure 16C, for example, illustrates a portion of the clot material PE stuck to or extending from the distal portion 1103a of the second catheter 1102 after aspirating the second catheter 1102. In the embodiment illustrated in Figure 16C, the added vacuum pressure generated through the second catheter 1102 is still not enough to break apart the clot material PE such that it can be fully aspirated through the first and/or second catheters 1002, 1102. That is, the clot material PE clogs the lumen 1004 of the first catheter 1002. In other embodiments, the added vacuum pressure from the second pressure source 1140 is sufficient to break apart the clot material PE such that it is aspirated into, for example, the vacuum chambers of the first and/or second pressure sources 1040, 1140.

[0120] At block 1596, the method can include retracting the second catheter 1102 and the clot material PE through the lumen 1004 of the first catheter 1002. For example, Figure 16D illustrates retracting the second catheter 1102, which in turn retracts the attached clot material PE, through the lumen 1004 of the first catheter 1002. In some embodiments, the second catheter 1102 and clot material PE can be fully withdrawn through the first catheter 1002. In other embodiments,

retracting the clot material PE through the first catheter 1002 causes the clot material PE to break apart and be aspirated into the vacuum chambers of the first and/or second pressure sources 1040, 1140. Figure 16E, for example, illustrates the clot material PE breaking apart as the vacuum of the first and/or second pressure sources 1040, 1140 is instantaneously or nearly instantaneously released to suck the clot material PE proximally (e.g., as indicated by arrows A5).

[0121] At block 1598, the first and second catheters 1002, 1102 can be withdrawn from the patient or the operator can perform another aspiration pass using one or both of the first and second catheters 1002, 1102.

[0122] In one aspect of the present technology, the method 1580 removes clot material even when a first aspiration pass clogs the first catheter 1002. More particularly, the second catheter 1102 can be used to remove clogged clot material PE without requiring the first catheter 1002 and the clogged clot material PE to be withdrawn through the blood vessel BV.

V. Additional Selected Embodiments of Clot Removal Systems and Associated Methods of Clot Removal

[0123] From the foregoing, it will be appreciated that specific embodiments of the present technology have been described herein for purposes of illustration, but that various modifications may be made without deviating from the scope of the present technology. For example, in many of the embodiments described above, stored vacuum pressure can be used to aspirate or suck clot material from a blood vessel and into a catheter without the need to engage an interventional device with the clot material. However, one skilled in the art will understand that the aspiration devices and techniques disclosed herein can be used in conjunction with any suitable interventional device and/or during a clot removal procedure utilizing an interventional device. In some embodiments, for example, a clot removal system can be configured to apply stored vacuum pressure to a guide catheter to generate a burst of suction while an interventional device is retracted into and/or through the guide catheter.

[0124] Figure 17, for example, is a partially schematic view of a clot removal system 1700 ("system 1700") configured in accordance with the present technology. The system 1700 includes some features generally similar to the features of the clot removal system described in detail above with reference to Figure 1. For example, the system 1700 includes a catheter or sheath 1702

comprising an elongated shaft, and a valve 1706 coupled to a proximal portion of the sheath 1702. The valve 1706 has a side port 1708 that fluidly couples a lumen of the sheath 1702 to a tubing subsystem 1720 and a pressure source 1740 (shown schematically). A fluid control device 1726 (e.g., a stopcock or clamp; shown schematically) is operable to fluidly disconnect or connect the pressure source 1740 from/to the lumen of the sheath 1702. The pressure source 1740 can be any suitable pressure source for generating and storing vacuum pressure, as described in detail above.

[0125] In the illustrated embodiment, the system 1700 further includes (i) a self-expanding (e.g., mesh) funnel 1780 coupled to a proximal portion of the sheath 1702 and (ii) an interventional device (e.g., a thrombus extraction device) 1790. In the illustrated embodiment, the interventional device 1790 includes an expandable coring element (e.g., a first portion) 1792 coupled to an expandable cylindrical element (e.g., a second portion) 1794. In some embodiments, the interventional device 1790 is configured to self-expand from a compressed delivery state to an expanded deployed state. The interventional device 1790 is shown in the deployed state in Figure 17. An elongated shaft 1782 and/or one or more shafts positioned within the elongated shaft 1782 (e.g., an intermediate shaft 1884 and an inner shaft 1886 as shown in Figures 18E and 18F, respectively) are coupled to the interventional device 1790 and configured to retract, advance, and/or manipulate (e.g., move between the delivery and deployed states) the interventional device 1790. In some embodiments, the system 1700 can be generally the same as or similar to any of the clot removal systems disclosed in U.S. Patent Application Publication No. 2018/0193043, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," which is incorporated herein by reference in its entirety.

[0126] In the illustrated embodiment, the system 1700 is shown intravascularly positioned within a blood vessel BV of a human patient and proximate to clot material DV (e.g., a deep vein thrombus) within the blood vessel BV. Specifically, Figure 17 shows the system 1700 after (i) advancing the sheath 1702 to a position proximate to a proximal portion 1785b of the clot material DV, (ii) deploying the funnel 1780, (iii) deploying the interventional device 1790 from the sheath 1702 (e.g., by advancing the interventional device 1790 through the valve 1706 and the sheath 1702 to a position distal of a distal portion 1785a of the clot material DV), and (iv) expanding the interventional device 1790 from the compressed delivery state to the deployed state.

[0127] Figures 18A–18H are enlarged views of a distal portion of the system 1700 during a clot removal procedure in accordance with the present technology. In general, Figures 18A–18H illustrate the proximal retraction of the interventional device 1790 through the clot material DV to capture at least a portion of the clot material DV, and the subsequent joint retraction of the interventional device 1790 and the captured clot material DV into the funnel 1780 and the sheath 1702. In one aspect of the present technology, charged vacuum pressure generated in the vacuum source 1740 can be applied to the sheath 1702 at one or more times during the illustrated process to generate suction for aspirating the captured clot material DV through the sheath 1702 and/or to inhibit clogging of the sheath 1702.

[0128] Referring first to Figure 18A, proximal retraction of the interventional device 1790 causes the coring element 1792 to separate and/or core the distal end portion 1785a of the clot material DV from the walls W of the blood vessel BV. As shown in Figure 18B, continued proximal retraction of the interventional device 1790 through the clot material DV causes the cylindrical element 1794 to capture the distal end portion 1785a of the clot material therein. Figures 18C–18E illustrate further proximal retraction of the interventional device 1790 which causes further separation, coring, and/or capture of the clot material DV. As seen in Figure 18E, the proximal end portion 1785b of the clot material DV is cored and captured as the interventional device 1790 is proximally retracted toward the funnel 1780 and the sheath 1702. As further shown in Figure 18E, a first radiopaque marker 1887a can be positioned on a distal end portion of the inner shaft 1884 and a second radiopaque marker 1887b can be positioned on a distal end portion of the sheath 1702.

[0129] In some embodiments, as shown in Figure 18F, the interventional device 1790 can be proximally retracted until a portion of the coring element 1792 is contained (e.g., positioned) within the funnel 1780. More specifically, the interventional device 1790 can be proximally retracted until a mouth 1895 of the coring element 1792 is contained within the funnel 1780. In some embodiments, the containment of the mouth 1895 within the funnel 1780 can be fluoroscopically verified by visualization of the radiopaque markers 1887 (Figure 18E). In some embodiments, for example, the mouth 1895 can be determined as wholly contained within the funnel 1780 via fluoroscopic monitoring based on the alignment of the distal end portion of the inner shaft 1884 (e.g., the first radiopaque marker 1885a) relative to the distal end portion of the

sheath 1702 (e.g., the second radiopaque marker 1885b). In some embodiments, when the mouth 1895 of the coring element 1792 is positioned within the funnel 1780, the interventional device 1790 can be moved or transformed from the expanded deployed state to the compressed delivery state to compress and secure the clot material DV captured by the interventional device 1790. In some embodiments, for example, the intermediate shaft 1884 can be unlocked and/or decoupled from the inner shaft 1886 (e.g., via user actuation of a plunger or other device) such that the inner shaft 1886 can be advanced distally relative to the intermediate shaft 1884 to collapse or compress the interventional device 1790.

[0130] After the interventional device 1790 has been collapsed, the interventional device 1790 can be proximally retracted through the funnel 1780 and into the sheath 1702 as depicted in Figure 18G. As shown in Figure 18H, the interventional device 1790 can continue to be proximally retracted until the interventional device 1790 and the captured clot material DV are fully contained within the sheath 1702. In some embodiments, the interventional device 1790 and the captured clot material DV can then be withdrawn through the sheath 1702 and the valve 1706 (Figure 17), and from the patient's body.

[0131] In some embodiments, the collapse of the interventional device 1790 and/or the retraction of the interventional device 1790 into the funnel 1780 and/or the sheath 1702 can result in one or more portions of the clot material DV breaking away from the clot material DV contained in the interventional device 1790. For example, all or a portion of the captured clot material DV can be extruded through pores of the (e.g., mesh) cylindrical element 1794 as the interventional device 1790 collapses. In some embodiments, any such clot material can be captured by the funnel 1780. Referring to Figure 17, in some embodiments, the pressure source 1740 can be activated to charge a vacuum, and the fluid control device 1726 can subsequently be opened to apply the charged vacuum to the sheath 1702 (as described in detail above). The vacuum can be applied to the sheath 1702 at any point during retraction of the interventional device 1790. As shown in Figures 18G and 18H, application of the vacuum can generate instantaneous or nearly instantaneous suction (e.g., as indicated by arrows A6) at the distal end portion the sheath 1702 that can aspirate the extruded portions and/or other portions of the clot material DV into and/or through the sheath 1702. In particular, the generated suction can aspirate some or all of the clot material DV captured by the funnel 1780. Moreover, in some embodiments, application of a

vacuum from the pressure source 1740 can facilitate smooth retraction of the captured clot material DV through the sheath 1702. For example, a burst of suction generated by application of the vacuum can help inhibit clogging of the sheath 1702, and/or help resolve (e.g., break apart) a clog formed in the sheath 1702 during retraction.

VI. Selected Embodiments of Clot Removal Systems Having Filters and Associated Methods of Clot Removal

[0132] The systems and methods for clot removal described herein can include applying a pre-charged vacuum to generate suction for aspirating clot removal from the blood vessel of a patient. In one aspect of the present technology, aspiration of the clot material also aspirates blood from the patient. It can be advantageous to reintroduce the aspirated blood to the patient to lessen the trauma to the patient—especially where the removal procedure may comprise multiple aspiration passes that can together withdraw a significant amount of blood. However, the aspirated blood is often mixed with clot material and is therefore not suitable for reintroduction into the patient. Figures 19–20E illustrate various devices for filtering aspirated blood from removed clot material to reintroduce the aspirated blood into the patient without reintroducing a significant amount of clot material.

[0133] For example, Figure 19 is a perspective side view of a pressure source 1900 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The pressure source 1900 is generally similar to the pressure source 400 described in detail above with reference to Figures 4A–4C. For example, the pressure source 1900 includes the secondary syringe 460 ("syringe 460") and the first and second one-way valves 470 and 472. However, the secondary syringe 460 is coupled to a canister 1940 rather than the primary syringe 340 (Figures 4A–4C). The canister 1940 includes a tip (obscured) coupled to the adaptor 350 and is configured to be removably positioned within the connector 128 of the tubing subsystem 120 (Figure 1) to fluidly couple the canister 1940 to the tubing subsystem 120. Because the canister 1940 does not include a plunger or other component for changing a volume thereof, the syringe 460 is the only vacuum source for evacuating the canister 1940 (e.g., via repeated cycling of the secondary syringe 460).

[0134] In the illustrated embodiment, the canister 1940 further includes a filter 1942. The canister 1940 is shown as transparent in Figure 19 for the sake of clarity. The filter 1942 is coupled to and/or covers a removable end cap 1944 having a blood separation port 1946. In operation, when blood and clot material are aspirated into the canister 1940 (e.g., via any of the methods described in detail above), the filter 1942 separates the blood from the clot material within the canister 1940. The filtered blood can be removed via the blood separation port 1946. For example, a syringe (not shown) or other device can be fluidly coupled to the blood separation port 1946 and used to draw the blood through the filter 1942 and out of the canister 1940. The filtered blood can then be reintroduced to the patient via, for example, the fluid control device 126 and/or the connector 128 of the tubing subsystem 120. Once the blood is removed from the canister 1940, the end cap 1944 can be removed from the canister 1940 (e.g., by unscrewing the end cap 1944 from the body of the canister 1940) for removing the captured clot material. In some embodiments, the filter 1942 is attached to the end cap 1944 such that removing the end cap 1944 removes the filter 1942 and permits clot material to be dumped, scooped, or otherwise removed from the canister 1940.

[0135] Figures 20A–20E illustrate a filter device 2050 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The filter device 2050 is configured as an in-line filter for use with, for example, one or more of the pressure sources described in detail above with reference to Figures 2–7. For example, Figure 20A is a partially-exploded side view of the filter device 2050 and the pressure source 340 (Figures 3A–3D). In the illustrated embodiment, the filter device 2050 comprises a filter portion 2060 that is removably positionable within a barrel portion 2070. In the illustrated embodiment, the barrel portion 2070 includes a barrel 2072 that defines a chamber 2074, and a large bore tip 2076 configured to fluidly couple the chamber 2074 to external components, such as the tubing subsystem 120 (e.g., as shown in Figure 20C). The filter portion 2060 includes a seal 2062 configured to engage (i) an interior surface of the barrel 2072 when the filter portion 2060 is positioned within the chamber 2074 of the barrel portion 2070 and (ii) an exterior surface of the syringe 340 (e.g., an exterior surface of the barrel 344) when the syringe 340 is inserted into the filter device 2050. In other embodiments, the filter portion 2060 can be permanently attached to or integrally formed with the barrel portion 2070. The filter portion 2060 further includes a filter

(e.g., a mesh) 2064 configured (e.g., sized and shaped) to inhibit clot material from passing therethrough. In some embodiments, the filter 2064 can be configured to inhibit clots larger than about 100 μm (e.g., larger than about 110 μm) from passing therethrough.

[0136] Figure 20B is a perspective side view of the syringe 340 coupled to the filter device 2050. The barrel 2072 of the barrel portion 2070 is shown as transparent in Figure 20B (and Figures 20C–20E) for the sake of clarity. In the illustrated embodiment, the seal 2062 is positioned between the exterior surface of the barrel 344 of the syringe 340 and the interior surface of the barrel 2072 of the barrel portion 2070. The filter 2064 is positioned around (e.g., covers) the tip 347 of the syringe 340 to inhibit clot material from entering the barrel 344 of the syringe 340 during operation.

[0137] Figure 20C is a side view of the filter device 2050 and syringe 340 coupled to the tubing subsystem 120 of the assembly 10. More specifically, the tip 2076 can be inserted into the connector 128 of the tubing subsystem 120 as described in detail above. When the filter device 2050 and the syringe 340 are coupled to the tubing subsystem 120, the filter device 2050 is positioned in-line (e.g., in series) with the syringe 340. In the embodiment illustrated in Figure 20C, the plunger 342 of the syringe 340 has been withdrawn to generate negative pressure in the combined volume of the barrels 2072 and 344. As described in detail above, opening the fluid control device 126 nearly instantaneously applies the negative pressure to the catheter 102 to generate suction therein. When clot material and blood are aspirated through the catheter 102 and the tubing subsystem 120, the filter portion 2060 inhibits the clot material from entering the barrel 344 of the syringe 340. Thus, aspirated blood is collected in the barrel 344 of the syringe 340 while the aspirated clot material is collected in the barrel 2072 of the barrel portion 2070 of the filter device 2050. In this manner, clot material and blood can be separated during aspiration.

[0138] In one aspect of the present technology, separating the blood from the clot material such that the blood is within the syringe 340 permits the blood to be easily reintroduced to the patient. For example, Figures 20D and 20E are side views of the syringe 340 coupled to the tubing subsystem 120 of the assembly 10 for reintroducing blood to a patient. In some embodiments, as shown in Figure 20D, the syringe 340 can be decoupled from the filter device 2050 and directly coupled to the connector 128. With the fluid control device 126 in an open position, the blood can

then be reintroduced to the patient through the assembly 10 by depressing the plunger 342 of the syringe 340. In some embodiments, as shown in Figure 20E, the syringe 340 can be decoupled from the filter device 2050 and directly coupled to a port on the fluid control device 126. With the fluid control device 126 in a closed position, the blood can then be reintroduced to the patient through the assembly 10 by depressing the plunger 342 of the syringe 340. Referring to Figures 20A–20E together, after or before reintroducing filtered blood to the patient, the filter portion 2060 of the filter device 2050 can be removed from the barrel portion 2070 so that the collected clot material can be removed and the filter device 2050 cleaned. In some embodiments, the filter device 2050 and a coupled pressure source can be used to filter blood from clot material after—as opposed to during—an aspiration pass. For example, the filter device 2050 and coupled pressure source could be used to withdraw blood and clot material collected in the canister 1940 of the pressure source 1900 (e.g., where the canister 1940 does not include the filter 1942).

[0139] Figures 21A and 21B illustrate a filter device 2150 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The filter device 2150 is configured for use with, for example, one or more of the pressure sources described in detail above with reference to Figures 2–7. For example, Figure 21A is a partially-exploded side view of the filter device 2150 and the pressure source 340 (Figures 3A–3D). In the illustrated embodiment, the filter device 2150 includes a housing 2152 defining a chamber 2154, a filter 2156 configured to be positioned within the housing 2152, and a cap assembly 2160 configured to be releasably coupled to the housing 2152 (e.g., via a threaded connection, snap-fit connection, etc.). In some embodiments, the filter 2156 can have a porosity of between about 50–200 microns.

[0140] The housing 2152 can include a port 2153 configured to be removably, fluidly coupled to the pressure source 340 via a tubing subsystem 2120. In the illustrated embodiment, the tubing subsystem 2120 includes tubing sections 2124 (individually labeled as a first tubing section 2124a and a second tubing section 2124b), a fluid control device 2126 (e.g., a valve, stop cock, clamp, etc.), and a connector 2128 (e.g., a large bore connector) for fluidly coupling the tubing subsystem 2120 to the pressure source 340. In the illustrated embodiment, the cap assembly 2160 includes a fluid connector 2162 (e.g., a standard Luer or large bore connector) configured to be connected to a receiving/reinfusion syringe 2170 via, for example, a tubing section 2164. In

some embodiments, the cap assembly 2160 can include a valve (e.g., a one-way valve, a check valve, etc.) that provides for one-way fluid flow through filter assembly 2150.

[0141] In operation, during a clot removal procedure, the pressure source 340 can be decoupled from the connector 128 (Figure 1) after an aspiration pass and when the pressure source 340 is full of blood and clot material. After connecting the filter device 2150 to the receiving syringe 2170, the pressure source 340 can be coupled to the filter device 2150. For example, Figure 21B is a perspective side view of the filter device 2150 coupled to (i) the pressure source 340 via the tubing subsystem 2120 and (ii) the reinfusion syringe 2170 via the tubing section 2164. More specifically, referring to Figures 21A and 21B together, the tip 347 of the pressure source 340 can be coupled to the connector 2128 of the tubing subsystem 2120, and a tip 2172 of the reinfusion syringe 2170 can be coupled to the tubing section 2164. In other embodiments, the filter device 2150 can be coupled to the pressure source 340 and/or the reinfusion syringe 2170 in other manners (e.g., directly such that the all or part of the tubing subsystem 120 is omitted). Alternatively, the filter device 2150 can be directly attached to the side port 108 (Figure 1), an IV line (not shown), or another suitable connection point for reintroducing blood to the patient,

[0142] After coupling the pressure source 340 to the filter device 2150, the fluid control device 2128 can be opened to fluidly connect the pressure source 340 to the filter device 2150. Then, the operator can depress the plunger 342 of the pressure source 340 to drive the blood and clot material from the pressure source 340 into and/or through the filter device 2150. The filter 2156 of the filter device 2150 filters the blood from the clot material such that the blood flows into the reinfusion syringe 2170 and the clot material remains in the chamber 2154 of the filter device 2150. For example, as shown in Figure 21B, blood B fills the reinfusion syringe 2170 and clot material PE remains within the chamber 2154 of the filter device 2150 after depressing the plunger 342 of the pressure source 340 in the direction indicated by the arrow H.

[0143] Next, the reinfusion syringe 2170 can be decoupled from the filter device 2150 so that the blood B can be reintroduced to the patient. For example, the reinfusion syringe 2170 could be directly coupled to a port on the fluid control device 126 (Figure 1). The cap assembly 2160 can be decoupled from the housing 2152 of the filter device 2150 to, for example, permit an

operator to remove the clot material PE collected in the housing 2152 and thereby clean and prepare the filter device 2150 for another use.

[0144] Figure 22 is a partially-exploded side view of a filter device 2250 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The filter device 2250 is configured for use with, for example, one or more of the pressure sources described in detail above with reference to Figures 2–7. In general, the filter device 2250 is generally similar to the filter device 2150 described in detail with reference to Figures 21A and 21B. For example, the filter device 2250 includes a housing 2252 defining a chamber 2254, a filter 2256 configured to be positioned within the housing 2252, and a cap assembly 2260 configured to be releasably coupled to the housing 2252. However, in the illustrated embodiment the filter device 2250 includes a port 2253 that is directly connected to a connector 2228 configured to be coupled to a pressure source (e.g., the pressure source 340 shown in Figures 3A–3D). The cap assembly 2260 includes a fluid connector 2162 (e.g., a standard Luer or large bore connector) configured to be connected to a reinfusion syringe, a sheath, an IV line, etc., (not shown). In some embodiments, the fluid connector 2262 is angled relative to the filter 2260 and/or the housing 2252. For example, the fluid connector 2262 is formed to have an approximately right angle in Figure 22. In one aspect of the present technology, this arrangement makes the filter device more ergonomic during use.

[0145] Figure 23 is a partially-exploded side view of a filter device 2350 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The filter device 2350 is configured for use with, for example, one or more of the pressure sources described in detail above with reference to Figures 2–7. The filter device 2350 is generally identical to the filter device 2250 described in detail with reference to Figure 22—including, for example, the housing 2252 ("a first housing 2252"), the filter 2256 ("a first filter 2256"), and the cap assembly 2260 including the fluid connector 2262 ("a first fluid connector 2262"). However, in the illustrated embodiment a second housing 2382 and a second filter 2386 are fluidly connected to the fluid connector 2262. The second housing 2382 includes a second fluid connector 2384 that can be fluidly connected to a reinfusion syringe, a sheath, an IV line, etc., (not shown). The second filter 2386 is configured to provide a second stage of filtration. For example, in some embodiments the first filter 2256 has a larger porosity than the second filter

2386. For example, the first filter 2256 can have a porosity of between about 50–200 microns and the second filter 2386 can have a porosity of between about 50–170 microns.

[0146] In general, one skilled in the art will understand that the various embodiments of filter devices disclosed herein may have different components or combinations of components. For example, the filter devices 2050, 2150, 2250, and/or 2350 ("the filter devices") could be utilized with any of several different pressure sources other than the syringe 340 (e.g., those shown in Figures 2 and 4–7). In some embodiments, the filter devices can be formed as a component of the tubing subsystem 120 (Figure 1). Moreover, the filter devices can include any number of filters and/or housings to provide any number of filtration stages.

Conclusion

[0147] 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.

[0148] 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.

[0149] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various

modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. An aspiration system with accelerated response, comprising:
an aspiration pump in communication with a first chamber;
an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;
a second chamber in between the aspiration pump and the catheter; and
a user-actuable valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;
wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.
2. The aspiration system of claim 1 wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient.
3. The aspiration system of claim 2 wherein the aspiration catheter has a distal end portion configured to be positioned proximate to clot material within the blood vessel of the patient.
4. The aspiration system of claim 3 wherein the clot material comprises a pulmonary embolism.

5. The aspiration system of claim 3 wherein the clot material comprises a deep vein thrombus.
6. The aspiration system of claim 1, further comprising a coupled assembly including:
the second chamber;
the aspiration catheter; and
a hemostasis valve.
7. The aspiration system of claim 6 wherein the hemostasis valve is configured to receive a second catheter and direct the second catheter through the aspiration catheter.
8. The aspiration system of claim 7 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.
9. The aspiration system of claim 6 wherein the second chamber is removably carried by the assembly.
10. The aspiration system of claim 1 wherein the second chamber is removably coupled between the aspiration pump and the catheter.
11. The aspiration system of claim 1, further comprising a filter in the second chamber.
12. The aspiration system of claim 11 wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.

13. The aspiration system of claim 11 wherein the filter is removable from within the second chamber.

14. The aspiration system of claim 1 wherein the first chamber is fluidically coupled in serial to the second chamber.

15. An aspiration system with accelerated response, comprising:
an aspiration pump in communication with a first chamber;
an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;
a second chamber in between the aspiration pump and the catheter; and
a user-actuable valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;
wherein upon user actuation to open the valve with negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid decrease in pressure in the aspiration catheter.

16. The aspiration system of claim 15 wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient, wherein the aspiration catheter has a distal end portion configured to be positioned proximate to clot material within the blood vessel of the patient, and wherein the clot material comprises a pulmonary embolism or a deep vein thrombus.

17. The aspiration system of claim 15, further comprising a coupled assembly including:
the second chamber;
the aspiration catheter; and

a hemostasis valve, wherein the hemostasis valve comprises:

- a tubular member defining a lumen configured to slidably receive a second catheter and direct the second catheter through the aspiration 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.

18. The aspiration system of claim 15 wherein the second chamber is removably coupled between the aspiration pump and the catheter.

19. The aspiration system of claim 15, further comprising a filter in the second chamber, wherein the filter is removable from within the second chamber.

20. The aspiration system of claim 15 wherein the first chamber is fluidically coupled in serial to the second chamber.

ABSTRACT OF THE DISCLOSURE

Systems and methods for the intravascular treatment of clot material within a blood vessel of a human patient are disclosed herein. A method in accordance with embodiments of the present technology can include, for example, positioning a distal portion of a catheter proximate to the clot material within the blood vessel. The method can further include coupling a pressure source to the catheter via a tubing subsystem including a valve or other fluid control device and, while the valve is closed, activating the pressure source to charge a vacuum. The valve can then be opened to apply the vacuum to the catheter to thereby aspirate at least a portion of the clot material from the blood vessel and into the catheter.